



National Gene  
Technology  
Scheme

An Australian, State and Territory  
Governments Collaboration

The Third  
Review of the

# National Gene Technology Scheme

October 2018

**FINAL REPORT**



## **The Third Review of the National Gene Technology Scheme**

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# Foreword

## Legislative and Governance Forum on Gene Technology

On behalf of the Legislative and Governance Forum on Gene Technology (the Forum), I am pleased to present the Final Report on the Third Review of the National Gene Technology Scheme (the Scheme).

The Scheme has now been in place for almost two decades. In the face of rapid technological change and evolving societal values and expectations, advances in and extensions of gene technology continue to present new challenges to the regulatory framework. As such, this Review was a timely opportunity to examine the Scheme in depth, to consider updates that will ensure it remains effective and fit for purpose into the future.

I would also like to acknowledge and thank all who have contributed to the Review. Over the period July 2017 to May 2018, more than 320 stakeholder submissions were considered, across three phases of consultation. This ensured the views of all interested parties were heard, including research, industry, community and government sectors.

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Minister for Aboriginal Affairs, Minister for Primary Industry and Resources, and Arafura Games (NT)

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Minister for Health and Wellbeing (SA)

**The Hon. Alannah MacTiernan MLC**

Minister for Regional Development, Agriculture and Food, and Minister assisting the Minister for State Development, Jobs and Trade (WA)



Forum Ministers (left to right), Minister Stephen Wade (SA), Minister Meegan Fitzharris (ACT), Minister Bridget McKenzie (Chair, Commonwealth), Minister Allannah MacTiernan (WA), Minister Jill Hennessey (VIC), and Minister Michael Ferguson (proxy for TAS)

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# Acknowledgement

The Third Review of the National Gene Technology Scheme (the Review) has been an extensive undertaking by all Australian Governments. The assistance of all parties and contributors is appreciated and acknowledged, in particular the contributions from:

- Stakeholders – who have participated in consultations and provided submissions leading to identification of issues and proposed policy solutions;
- Reviewers – the Gene Technology Standing Committee, the Gene Technology Standing Committee Working Group, the Review Expert Advisory Panel, the Review Support Team hosted within Commonwealth Department of Health, and their jurisdictional counterparts; and
- The Gene Technology Regulator and the Office of the Gene Technology Regulator – for the availability and provision of technical advice.

## Release of this Report

Overall, many sources have provided input for the Review to consider. This input, supported by related reports, reviews and adjunct research, has led to the development of 27 recommendations presented herein.

These recommendations address the 33 Findings in response to the Review Terms of Reference, published in the Third Review of the Gene Technology Scheme: *Preliminary Report* (March 2018). The *Preliminary Report* informed the third and final phase of consultation for the Review. It reflected the views and suggestions made by stakeholders about the Scheme, the issues for investigation and potential solutions to address them.

This Final Review Report is the culmination of analysis of all materials, views and proposed solutions, and the prevailing government settings. The resulting suite of recommendations is for all Australian Governments to progress, led through the Legislative and Governance Forum on Gene Technology.

## How to use this document

This Review Report is the final part of a suite of materials supporting and completing the Review.

For further context to the development of this Review Report, it should be read in conjunction with the companion pieces:

- Third Review of the Gene Technology Scheme, *Preliminary Report*<sup>1</sup>
- Review of the National Gene Technology Scheme 2017, Phase 2 *Consultation Paper*<sup>2</sup>
- Legislative and Governance Forum on Gene Technology communique announcing the third review of the National Gene Technology Regulatory Scheme<sup>3</sup> and
- Third Review *Background Paper*.<sup>4</sup>

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1 Third Review of the Gene Technology Scheme – *Preliminary Report*, Retrieved August 10, 2018, from <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-technology-review>

2 Review of the National Gene Technology Scheme 2017, Phase 2, *Consultation Paper*, Retrieved August 10, 2018, from <https://consultations.health.gov.au/best-practice-regulation/review-of-national-gene-technology-scheme/>

3 Legislative and Governance Forum on Gene Technology communique announcing the third review of the National Gene Technology Regulatory Scheme, Retrieved August 10, 2018, from <http://www.health.gov.au/internet/main/publishing.nsf/Content/mr-yr17-gene-technology>

4 Third Review *Background Paper*, Retrieved August 10 2018, from <https://consultations.health.gov.au/health-systems-policy-division/genetechreview2017/>



# Acronyms

Acronym	Term
ACOLA	Australian Council of Learned Academies
APVMA	Australian Pesticides and Veterinary Medicines Authority
CBD	Convention on Biological Diversity
CCI	Confidential Commercial Information
CRISPR	Clustered Regularly-Interspaced Short Palindromic Repeats
DAWR	Australian Government Department of Agriculture and Water Resources
DIR	Dealing involving Intentional Release
DNA	Deoxyribonucleic acid
DNIR	Dealings Not involving an Intentional Release
EDD	Emergency Dealing Determination
FSANZ	Food Standards Australia New Zealand
GM	Genetically modified
GMO	Genetically modified organism
GT	Gene technology
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
LLP	Low Level Presence
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
PC	Physical containment
R&D	Research and development
RAF	Risk Analysis Framework
RARMP	Risk assessment and risk management plan
RNA	Ribonucleic acid
TALEN	Transcription activator-like effector nucleases
TGA	Therapeutic Goods Administration
WTO	World Trade Organization
ZFN	Zinc Finger Nuclease

# Executive summary

Gene technology makes changes to genetic material, including genes or parts of genes. Using gene technology techniques, scientists can modify organisms by inserting, removing, or altering the activity of one or more genes, or parts of a gene, so that an organism gains, loses or changes specific characteristics. Living things which have been modified by gene technology are known as genetically modified organisms (GMOs).

Australia's National Gene Technology Scheme (the Scheme) is highly regarded, both domestically and internationally. The Scheme is designed to protect the health and safety of people, and the environment, from the risks associated with gene technology. It has continued to demonstrate its ability to achieve this objective since inception.

The Scheme is a national cooperative of all state, territory and Commonwealth governments, set out in the intergovernmental Gene Technology Agreement 2001 (the Agreement). The Scheme comprises the Agreement, the *Gene Technology Act 2000* (Cth) (the Act),<sup>5</sup> the Gene Technology Regulations 2001 (Cth) (the Regulations),<sup>6</sup> and corresponding state and territory legislation. These Commonwealth and state laws provide national coverage for the regulation of GMOs. The Scheme also works in conjunction with, and complements, other regulatory frameworks that deal with genetically modified (GM) products.<sup>7</sup>

The object of the Act, the primary piece of legislation regulating GMOs, 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 Scheme regulates gene technology using a risk-based approach<sup>8</sup>, where higher risk activities involving GMOs are subject to greater regulatory oversight. Further information about the current operation of the Scheme can be found in [Chapter Two: What is the Gene Technology Scheme and how does it work?](#)

All stakeholders with an interest in the Australian Scheme expect a regulatory framework that achieves the object set out above. To be truly effective, this framework must be reviewed and delivered at a national level, with all interested stakeholders playing their part. To support this aim, the intergovernmental Agreement establishes a collaborative mechanism across all jurisdictions – states, territories and the Commonwealth – to oversight regulation of gene technology across Australia.

Multi-jurisdictional arrangements can be difficult and challenging. Australia's gene technology scheme is purposefully designed to create a consistent, predictable and transparent approach to the regulation of GMOs across the country. However, within this framework, our constitution supports jurisdictions advocating for their own interests. The Agreement provides a formal national framework to achieve the shared objectives of the Scheme, as well as a mechanism to work through any differing views.

The Legislative and Governance Forum on Gene Technology (the Forum) is the ministerial body charged, through the Agreement, with responsibility for ensuring the national consistency of the Scheme. All jurisdictions have equal membership on the Forum. The Review has identified 27 recommendations, some of which call for further investigation, to be progressed via a work program overseen by the Forum. Recommendation 1 specifically recognises the role of the Forum, and the importance of continuing collaboration to implement the recommendations.

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5 *Gene Technology Act 2000* (Cth) (Austl.). Retrieved July 10, 2018, from <https://www.legislation.gov.au/Details/C2016C00792>

6 Gene Technology Regulations 2001 (Cth). Retrieved July 18, 2018 from <https://www.legislation.gov.au/Details/F2016C00615>

7 A genetically modified product (GM product) means a thing (other than a GMO) derived or produced from a GMO (section 10 of the *Gene Technology Act 2000*). For example, Food Standards Australia New Zealand is responsible for the safety assessment of genetically modified foods, and the use of GM products as human therapeutics is regulated by the Therapeutic Goods Administration.

8 Office of the Gene Technology Regulator. (2013). *Risk Analysis Framework*. Retrieved July 10, 2018, from [www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raffinal5-toc/\\$FILE/raffinal5\\_2.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raffinal5-toc/$FILE/raffinal5_2.pdf)

# Third Review of the Scheme

Regular reviews of the Scheme are required under the Agreement. Since the Scheme commenced in 2001, two reviews have been conducted (in 2006 and 2011). They focused on the operation of the Scheme and whether the policy objectives were being achieved. While there was some attention given to technical considerations, these reviews were predominately retrospective in nature, reviewing how well the Scheme had been meeting its purpose.

The Third Review of the Scheme (the Review) has continued to focus on the ongoing achievement of the policy objectives of the Scheme. This is in a global environment where governments and citizens are discussing appropriate regulatory approaches to manage future advances in gene technology, and biotechnology more broadly. The Review's Terms of Reference emphasise the need to assess and support the Scheme with a view to the future, taking into account the rapidly developing and innovative area of gene technology. Additionally, the Review considered how best to progress any outcomes of previous reviews that require further attention. Terms of Reference for the Review can be found in the [Introduction](#).

Separate to the reviews of the Scheme, the Gene Technology Regulator (the Regulator) may also conduct technical reviews of the Regulations. While they have no scope to amend policy settings, technical reviews can consider enhancements to the operation of the Scheme, and may also lead to Regulation amendments. As the timing of the Regulator's most recent technical review overlapped with the Third Review of the Scheme, consultation approaches aimed to minimise confusion and duplication of effort for stakeholders.

Governance of the Review reflects the Scheme's national governance structure. Day to day operational oversight was provided through the Gene Technology Standing Committee (the Standing Committee) – senior officials from all jurisdictions, who report to the Forum. The Review was designed to harness the spectrum of views of government and non-government stakeholders across Australia. Consultation was supported by research and expert technical advice, which helped to address the complex scientific and regulatory nature of gene technology.

## Consultation approach

All Australian Governments have understood the importance of thorough consultation to inform and address the Review Terms of Reference. The consultation process involved three key phases:

- Phase 1: identifying key issues for consideration.
- Phase 2: collaboratively exploring policy solutions to these issues.
- Phase 3: providing an opportunity to comment on the findings.

Phase 1 and 2 consultations included almost 160 written and online submissions, 11 face-to-face consultation workshops, two online webinar sessions, and numerous bilateral meetings with specific stakeholders. A *Preliminary Report* was subsequently published, outlining 33 findings.

Phase 3 consultation included the opportunity to comment on these findings. Across all phases, over 320 submissions ultimately informed the recommendations outlined in this final report.

Additional information about the conduct of the Review can be found in [Chapter Three: The Third Review of the Gene Technology Scheme](#).

## Review findings and recommendations

A diverse range of views were heard through the public consultation processes. These views were further informed by discussions with the Gene Technology Regulator, other experts and relevant bodies. This input, in combination with information from related reports, reviews and adjunct research, supported 33 initial findings arising from the Terms of Reference, and the subsequent development of 27 recommendations. The recommendations acknowledge and address:

- the aspects of the Scheme that have operated successfully since its establishment and which should be maintained; and
- areas within the Scheme where changes may assist to future-proof and modernise the Scheme and help ensure efficiency and timeliness in this context.

The Review outcomes are presented in Chapter 1, which details the rationale supporting each recommendation. A high-level summary, grouped under the following themes, is provided below:

- Overarching issues
- Technical issues
- Regulatory issues
- Governance issues
- Social and ethical issues

### Overarching issues

The legislative framework, and the Agreement that establishes the national Scheme, remain central to the successful operation of the regulatory framework. Equally important is the legislative and governance oversight provided by the Forum. The Review's first recommendation acknowledges this sound foundation and the expectation that it should continue, while also recognising the need for updates and enhancements as the Scheme evolves.

It became apparent early on in consultations that the complexity and scope of the Scheme mean that it is not always well understood by all sectors. However, the majority of stakeholders agreed that the Scheme effectively provides for, and should continue to provide for, the health and safety of people and the protection of the environment, from the risks posed by or as a result of gene technology.

The Scheme benefits both the public and industry at this broad level, and there was no call to alter the object of the Act. The Review also found that the Agreement is working well to support a national collaborative arrangement between jurisdictions and across relevant portfolios, and recognised the importance of maintaining this to ensure the Scheme continues to work into the future.

## Review theme one: Technical issues

The foundations of the Scheme, now almost two decades old, are still providing a solid regulatory framework. This is a strong testament to a well-designed Scheme. Many of the issues that have arisen over recent years do not relate to the base construct of the Scheme, but to its ability to keep pace with the technology.

The Review considered several issues relating to technical aspects of the Scheme. This included exploring the degree to which the legislative definitions are able to appropriately classify a range of advances in technology. There is debate occurring at both national and international levels that may impact these definitions, with other key reviews and activities still ongoing. The Review also noted significant differences in stakeholder opinion as to how, or even whether, definitions should be amended. These matters are central to the Review outcomes, particularly given the scope to 'future-proof' the Scheme. Any further work to resolve the definitions should consider this context.

The Review also investigated issues relating to extensions or advancements of modern technology, including synthetic biology, human gene therapy, GMOs released into the broader environment and gene drive organisms. The Review discussed the ongoing regulation of these applications, and options to manage possible risks associated with their application.

## Review theme two: Regulatory issues

The Review considered contemporary approaches to regulation, including current best-practice and risk-based approaches. This is in an environment where understanding about the science and any inherent risks is evolving. Opportunities to improve the flexibility and agility of the Scheme, while maintaining the appropriate oversight measures, were key areas of focus.

Like many other systems for the regulation of gene technology around the world, Australia currently employs what is known as a 'process-based trigger'. This means that any organism developed using a gene technology process is subject, at least initially, to regulatory requirements. The Review explored an option where risk assessments focus instead on the end-use or 'product'.

Despite much discussion, stakeholders generally agreed that maintaining the current 'regulatory trigger' would be the most sensible outcome at this point. This position recognises that other regulatory schemes (i.e. food, medicines, etc.) would also need to be reviewed and amended for any change to be effective.

The application of different levels, or 'tiers', of regulation within the Scheme was discussed, with a view to finding ways to ensure that regulatory requirements are proportionate to risk. This included exploring mechanisms to determine additional regulatory tiers for organisms with a history of safe use, as well as appropriate regulatory pathways and requirements for these organisms.

Thought has also been given to whether additional mechanisms should be available, or existing mechanisms can be leveraged, to help future-proof the Scheme's ability to address technological advances. These include improving the utility of the GMO register, incorporating a principles-based approach to some aspects of regulation, and utilising the Gene Technology Standing Committee to progress updates to the Scheme, where possible.

The Review includes recommendations for streamlining the Scheme's regulatory requirements, and for ensuring the Scheme is suitably equipped to regulate work with GMOs undertaken outside of universities, research institutions or large companies. The Review also considered how the Scheme impacts market access and international trade, and the role for the Australian Government in this area.

In summary, the Review determined that the ability to capture a broader scope of activities within the Scheme, via the process trigger, should be maintained. However, better alignment of regulation to the level of risk would enhance this fundamental strength, and support contemporary best practice.



## Review theme three: Governance issues

The Review discussed the credibility, integrity and legitimacy of the Scheme, its legislative and governance provisions, as well as the independence of the Regulator. Supporting the overarching view that the core of the Scheme is sound and should be preserved, the Review concluded the current governance mechanisms should be upheld.

Matters relating to national consistency were also considered. This included the mechanism for applying corresponding legislation across the country, and the benefits of states and territories ensuring that their gene technology Acts continue to facilitate a nationally consistent Scheme.

The Review found that stakeholders continue to hold conflicting views regarding the advantages and disadvantages of moratoria legislation (whereby states and territories may ban the commercialisation of genetically modified crops for marketing purposes). This issue was explored in detail, with a recommendation calling for states and territories to give ongoing consideration to the economic effects, value and scope of their moratoria legislation. Other recommendations recognise the role of the Forum in pursuing national consistency of the Scheme, and addressing practical issues that may arise from moratoria legislation (such as transport).

Australia's regulatory scheme for gene technology is based upon scientific evaluation, and any potential benefits arising from a GMO are not currently considered in regulatory decision making. Whether this remains appropriate was examined by the Review. It was concluded that the objectives of the Scheme – protecting the health and safety of people, and the environment – are best achieved through a focus on gene technology risks and their management. Evaluation of potential benefits should not form part of regulatory decision making at this time. However, the Review also determined that the Scheme should ensure that no unnecessary regulatory burdens are imposed that might prevent potential economic, health or welfare benefits from being realised.

The Review explored whether specific topic areas would benefit from additional policy direction (for example, the release of gene drives into the environment). Significantly, the Review recommended that the Forum should lead an Action Plan for the implementation of the Review recommendations. This may include mechanisms to clarify policy positions on key matters.

Further, the Review considered, and made recommendations on, the interface between the Office of the Gene Technology Regulator, other regulators and legislation, the level of funding required for the sustainable operation of the Scheme, and the most appropriate funding mechanism to achieve this.

## Review theme four: Social and ethical issues

The Review's discussion on social and ethical issues explored public attitudes and understanding of genetic modification, and the impacts for Australia. Consultation was supported by market research<sup>9</sup>, which identified a number of misperceptions and knowledge gaps. These highlighted the need for better communication with the public (including the most appropriate body, or bodies, to undertake such communication activities). Increased understanding of the regulatory process and what is and isn't covered by it, is particularly needed, as is better information on risk assessment and the existing transparency measures for communicating regulatory data. To further build public understanding and confidence in the Scheme, the Review recommends the development of additional targeted communication mechanisms. Recommendations also address ongoing concerns within some sectors of the community about the safety of GMOs, and the ability of the Regulator to monitor commercialised GMOs for long-term impacts.

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<sup>9</sup> Market research undertaken to inform the Review employed a mixed-methodology research approach, including both qualitative research and quantitative evaluation (carried out in line with the Market Research International Standard, AS ISO 20252). Twelve focus groups across Australia, split across various educational/occupational levels, explored broad consumer understanding of the issues, with deep dives into particular areas. Quantitative evaluation was administered via an online survey of 1,500 consumers, structured as a nationally representative sample. Further detail is in [Appendix 10](#).

## International context

When reviewing Australia's domestic regulation of gene technology, it is also important to be aware of how it is regulated in other countries. The international context is complex, and there is currently no agreed international regulatory framework for gene technology regulation, with countries taking a variety of different approaches. Unlike some countries, Australia currently has a 'one size fits all' approach, which means that regulatory changes that may be considered justifiable by some sectors, may have unintended consequences not only nationally, but internationally. Additional information about gene technology regulation in the international context can be found in [Chapter Two: What is the Gene Technology Scheme and how does it work?](#).

## Scope of the Review

The Review acknowledges that some applications of gene technology raise concerns for some stakeholder groups. While those that are within scope of the Review have been addressed, some of the concerns raised are beyond the scope of the Review to consider, and these topic areas are highlighted on [page 16](#) and in [Appendix 2: Matters out of scope of the Review](#).

## Next steps and implementation considerations

The Review acknowledges that the scope of work arising from the Review recommendations is considerable, wide-reaching and will require cross-jurisdictional and cross-portfolio coordination to achieve. Some outcomes may be delivered in the short term, while others may require a medium or longer term for implementation.

The Review recommends that an action plan be agreed by the Forum, to outline and demonstrate governments' commitment to delivering the national priorities of the Forum. Part of this action plan will include consideration of the Review recommendations and how and when they may be implemented. As such, Ministers, via the Forum, will have further decision-making opportunities to determine priorities, responsibilities and funding impacts. Consideration will also need to be given to any administrative, legal and financial implications, prior to implementation of recommendations.

The Scheme is legislatively complex, comprising corresponding Commonwealth, state and territory legislation. It operates in conjunction with other jurisdictional regulatory schemes relevant to GMOs and genetically modified products. Any recommendations that are implemented through legislative amendments will need to be thoroughly tested and enacted through all applicable legislation, noting the Review cannot recommend changes to legislation outside the remit of the Scheme.

Where possible, it would be sensible to implement recommendations via administrative changes rather than legislative amendments. The Standing Committee could be tasked with managing the operational aspects of implementation through the Forum's action plan, which would include development of a comprehensive Implementation Plan. Working in collaboration with stakeholders could also support implementation of recommendations in a timely, appropriate and cost-effective manner.

The Review was undertaken by all governments through the Forum, using a comprehensive consultation process that included government (and non-government) stakeholders. As such, the recommendations represent the views of all governments. Through the Forum, all governments will collectively decide how best to progress the recommendations, through an agreed action plan.

# List of Recommendations

## Recommendation

### Overarching Recommendations

**Recommendation 1:** To build upon and futureproof the Scheme, which is highly regarded, the Review recommends:

- a) the Forum progress options to update and enhance the operations of the Scheme; and
- b) these options be implemented in short, medium and long-term tranches, according to an action plan to be developed by the Forum.

**Recommendation 2:** The Review recommends that the object of the *Gene Technology Act 2000* be maintained.

**Recommendation 3:** The Review recommends that the Gene Technology Agreement be maintained.

### Review Theme One: Technical Issues

**Recommendation 4:** The Review recommends updating, where required, the existing definitions in the *Gene Technology Act 2000* (Cth), to clarify the scope of regulation in light of ongoing technical advances. Any changes to definitions should take into account concurrent work, including relevant domestic reviews and ongoing work internationally.

**Recommendation 5:** The Review recommends that:

- a) extensions and advancements of gene technology, such as synthetic biology, continue to remain within the scope of the Scheme; and
- b) a watching brief on synthetic biology should be maintained, to ensure the appropriate level of regulation is applied to future applications of synthetic biology.

**Recommendation 6:** The Review recommends:

- a) the definition of a genetically modified organism under the *Gene Technology Act 2000* (Cth) be amended to clarify that humans are not [considered to be] GMOs; and that
- b) subject to consideration, the COAG (Council of Australian Governments) Health Council might also consider whether additional regulatory oversight is needed for humans who may receive or inherit germline therapies (or other somatic therapies not within the remit of the Scheme). The COAG Health Council should also consider which regulatory (or other) body would be most appropriate to undertake such oversight.

**Recommendation 7:** The Review recommends clarifying, and where necessary strengthening, the mechanisms for regulating the:

- a) broader environmental release of genetically modified organisms; and
- b) environmental release of GM gene drive organisms (as well as any additional requirements for contained work).

## Recommendation

### Review Theme Two: Regulatory Issues

**Recommendation 8:** The Review recommends that a process-based trigger be maintained as the entry point for the Scheme at the present, to allow for any potential risks associated with new technologies to be initially considered within the scope of the Scheme.

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**Recommendation 9:** The Review recommends the introduction of additional risk tiering into the Scheme, to facilitate flexibility of the regulatory Scheme and ensure:

- a) the level of regulation remains proportionate to risk, and protects against under regulation and over-regulation; and
  - b) where appropriate, there is flexibility to move organisms between categories, based on identification of new risks, a history of safe use, or other relevant factors.
- 

**Recommendation 10:** The Review recommends reducing regulatory burden through streamlining processes and current regulatory requirements where appropriate. For example, this may include streamlining facility certifications and application processes.

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**Recommendation 11:** The Review recommends that changes be made to enable the GMO Register to be more effectively utilised within the Scheme.

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**Recommendation 12:** The Review recommends that, to ensure the Scheme's current monitoring and enforcement activities remain adequate:

- a) regular reviews of these activities are undertaken;
  - b) regulatory requirements for working with gene technologies are widely communicated and known; and
  - c) the scope and associated risks of 'DIY biology' activity continue to be monitored.
- 

**Recommendation 13:** The Review recommends that to better respond to changes in scientific understanding and understandings of risk, consideration should be given to:

- a) enabling the Gene Technology Regulator to make decisions on the applicability of regulation to any technological developments, until such time as a policy approach has been agreed; and
  - b) introducing elements of principles-based regulation to some parts of the Scheme, focusing on areas of the Scheme with a history of safe use.
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**Recommendation 14:** The Review recommends reaffirming and clarifying governance arrangements to increase the agility of the Scheme, including more effective use of mechanisms for:

- a) the Gene Technology Standing Committee to consider and recommend changes to the legislation for the Legislative and Governance Forum on Gene Technology endorsement; and
  - b) delegating certain activities and work programs of the Legislative and Governance Forum on Gene Technology to the Gene Technology Standing Committee.
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**Recommendation 15:** The Review recommends that the Australian Government, including the Gene Technology Regulator on regulatory matters, continues to:

- a) engage with appropriate international fora on matters relevant to market access and international trade; and
  - b) ensure that any relevant international obligations continue to be met.
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**Recommendation****Review Theme Three: Governance Issues**

**Recommendation 16:** The Review recommends maintaining current governance mechanisms to ensure that the Scheme's current levels of credibility, integrity and legitimacy are upheld.

This includes maintaining:

- a) high level governance oversight provided by all states and territories through a Legislative and Governance Forum on Gene Technology;
- b) the independence and credibility of the Gene Technology Regulator; and
- c) robust governance processes providing oversight of advisory structures and appointments.

**Recommendation 17:** The Review recommends that states and territories continue to ensure that their gene technology Acts remain corresponding and that appropriate mechanisms are in place to update corresponding state and territory legislation following amendment of the *Gene Technology Act 2000* (Cth).

**Recommendation 18:** The Review recommends that states and territories give ongoing consideration to the economic effects, value and scope of moratoria.

**Recommendation 19:** The Review recommends that consideration of benefits (e.g. potential economic, environmental and health benefits) should not be introduced as an element of regulatory decision making at this time.

**Recommendation 20:** The Review recommends that the Scheme ensures regulation remains commensurate with the level of risk posed by a dealing (see [Recommendations 9 and 10](#)) so that no unnecessary regulatory burdens are imposed.

**Recommendation 21:** The Review recommends clarifying the intersection between the Gene Technology Regulator, other regulators and legislation, which may include:

- a) identifying opportunities to enhance communication mechanisms and linkages;
- b) identifying any emerging areas where legislative or administrative changes can be made, to reduce any unnecessary duplication; and
- c) adopting relevant effective mechanisms from other schemes (for example, the *Therapeutic Goods Act 1989* Special Access Scheme) where they may strengthen the Scheme.

**Recommendation 22:** The Review recommends that further consideration be given to the most appropriate funding mechanisms to support the ongoing operation of the Scheme, and to appropriate funding levels for the Gene Technology Regulator's activities, taking into account any changes to the Scheme.



## Recommendation

### Review Theme Four: Social and Ethical Issues

**Recommendation 23:** The Review recommends that targeted communications be developed to aid public understanding and confidence in the Gene Technology Scheme and identify the most appropriate body/bodies to deliver communications materials.

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**Recommendation 24:** The Review recommends that the Gene Technology Regulator continue to lead communication activities on topics related to the assessment of risk associated with gene technology.

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**Recommendation 25:** The Review recommends that the Gene Technology Regulator continue to identify and manage the risks posed by, or as a result of, gene technology, and to increase transparency and understanding.

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**Recommendation 26:** The Review recommends a science-based review of monitoring arrangements to ensure that any post release risks continue to be appropriately managed.

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**Recommendation 27:** The Review recommends that the Gene Technology Regulator continue to make relevant information publicly available, to maintain a high level of transparency within the Scheme.

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# Introduction

The Report for the Third Review (the Review) of the National Gene Technology Regulatory Scheme (the Scheme) provides the findings and recommendations to address the Review Terms of Reference, together with background information about the governance and operations of the Scheme and the conduct of the Review. The Report reflects the views of stakeholders provided during consultation, noting that perspectives varied considerably across the range of issues explored.

The Report presents 27 Review recommendations and also outlines potential implementation considerations. The progress and outcomes of concurrent reviews and inquiries have also informed these recommendations (refer [Chapter Three: The Third Review of the Gene Technology Scheme, Other reviews and inquiries](#)).

## Terms of Reference

The Review Terms of Reference seek to investigate the 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 includes, but is not 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.

# Principles underpinning the Review

In undertaking the Review, there were a number of principles that underpinned the Review and the Scheme. These included:

1. *We must maintain the key elements of the Scheme* – the broad focus on protecting the health and safety of people and protecting the environment.
2. *We must maintain and enhance the key strengths of the Scheme* – public confidence and trust in the Scheme, particularly through:
  - a) A high degree of transparency.
  - b) Independence of the Gene Technology Regulator.
  - c) Focus on science-based risk assessment.
3. *We work within a Commonwealth jurisdictional framework* – strong state and territory support for the Scheme provides national consistency, which avoids many challenges faced by other regulators.
4. *We need efficient and effective regulation* – consideration needs to be given to where the risks are, and an appropriate/proportionate level of regulation applied.
5. *We should design for the future* – given the rapid evolution of gene technology and the potential applications across a range of sectors, the scheme needs to be future-proofed as much as possible, so it will continue to be effective.
6. *We recognise a range of perspectives* – gene technology, its applications and products elicit strong reactions across a spectrum of viewpoints; it is important to understand these views in order to appropriately address concerns.
7. *We need to be respectful and constructive* as we collaboratively develop options to deal with identified issues.

# Organisation of this Report

**Chapter 1** provides the Review's findings and recommendations, with the sections structured to align with the themes identified in the Phase 2 Consultation Paper. The Report chapters are structured as follows:

- **Chapter 1.1:** Overarching Issues – the object of the *Gene Technology Act 2000* (the Act) and the operation of the Gene Technology Agreement 2001 (the Agreement).
- **Chapter 1.2:** Review Theme One: Technical Issues – classification of new technologies, emerging applications and intentional environmental releases.
- **Chapter 1.3:** Review Theme Two: Regulatory Issues – regulatory triggers, risk tiering, streamlining regulation, DIY biology, future-proofing regulation, and market access and international trade.
- **Chapter 1.4:** Review Theme Three: Governance Issues – credibility, integrity and legitimacy of the Scheme, corresponding legislation, moratoria legislation, consideration of benefits, regulatory burden, the policy direction, interface between regulators and funding model.
- **Chapter 1.5:** Review Theme Four: Social and Ethical Issues – communication with the public, safety concerns and Scheme transparency.

**Chapter 2** provides background on the current Scheme, its legislative and governance arrangements, and its position within the broader Australian and international setting. It also provides information on the operations and powers of the Gene Technology Regulator (the Regulator). This information has been included to provide essential background and context to the Review. This is particularly relevant given the indicative level of awareness or misunderstanding of the regulatory system reflected in some stakeholder's views.

**Chapter 3** provides an overview of the Review process, describing the consultation processes and outcomes that led to the development of the findings and recommendations. The consultation approach for this Review has been purposefully extensive and robust. It encouraged transparency, inclusion and ownership of outcomes, regardless of whether stakeholder views and expectations are divided.

This report has been designed with chapters of standalone information, acknowledging that the broad stakeholder readership may have a focus on particular, many or all chapters. By necessity, there is some repetition throughout the document to ensure clarity, which will result in some duplication for readers of the entire document.

Descriptions of key terms used throughout this Report (refer [Appendix 1: Glossary](#)), as well as additional background information, are provided in the [Appendices](#).

## Out of scope

The Terms of Reference for the Review were intentionally cast broad to permit a complete and wide-ranging review of the Scheme.

While the Review has maintained this broad approach, there were several topics raised by stakeholders that are beyond the scope of this Review. These topics instead fall under the remit of other regulatory schemes, laws or regulatory forums. Key examples of out of scope topics raised include food labelling, and the regulation of herbicide and pesticide use.

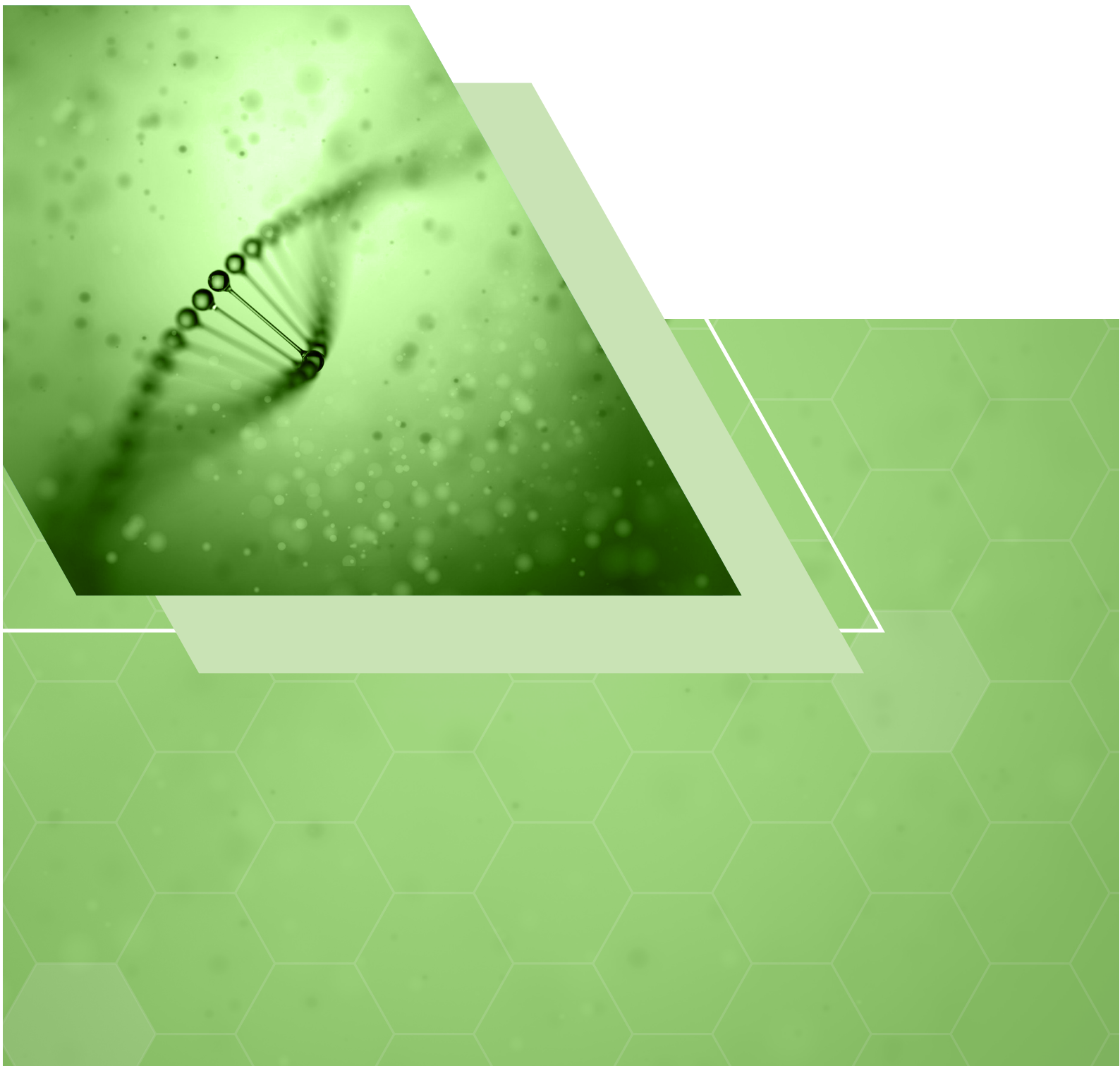
Labelling of food products is the remit of Food Standards Australia New Zealand (FSANZ), and the Food Standards Code is the legislative instrument outlining these labelling requirements in both Australia and New Zealand. The safety and efficacy of glyphosate, as well as the guidelines for safe use, is the remit of the Australian Pesticides and Veterinary Medicines Authority (APVMA). Further information has been provided at [Appendix 2: Matters out of scope of the Review](#).

Building on other research undertaken to explore consumer views, market research commissioned by the Review investigated public attitudes, knowledge and beliefs about GMOs. Results highlighted that public perceptions often relate to issues that are out of scope of the Scheme and the Review, such as food safety and labelling (refer to [Appendix 10: Outcomes of Market Research](#)).

Where issues raised during the Review were identified as being pertinent to other schemes, reviews, or inquiries occurring in parallel, this information has been shared with the appropriate scheme, regulator or agency. Information was shared in accordance with appropriate permissions and privacy obligations, applicable to the materials.



# Review outcomes



## CHAPTER 1.1

# The National Gene Technology Scheme

This section presents recommendations that address the findings of the Third Review of the Gene Technology Scheme (the Review) on the suitability of the **object of the Act** and **the Agreement**.

The Gene Technology Scheme (the Scheme) came into effect on 21 June 2001, under the *Gene Technology Act 2000* (the Act). This Scheme replaced the previous voluntary system of oversight. The object of the 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 genetically modified organisms (GMOs).

The Scheme is underpinned by the Gene Technology Agreement 2001 (the Agreement) – an inter-governmental agreement which sets out the understanding between Commonwealth, state and territory governments regarding the establishment of a nationally consistent regulatory system for gene technology.

The Legislative and Governance Forum on Gene Technology (the Forum) is the ministerial body responsible for overseeing the Scheme and ensuring that national consistency is achieved through the Agreement. The Review has identified 27 recommendations to support this mandate, many of which provide for further investigation to be progressed via a Forum endorsed work program.

The Review acknowledges that a few recommendations from previous reviews of the Scheme have not yet been progressed to administrative or legislative amendment. In some cases, recommendations may not have been implemented for practical reasons (for example, implementation was overtaken by subsequent events). However, where previously raised issues remain a concern for stakeholders, these were considered by the current Review.

## National Policy Consistency

The Agreement was signed by the Commonwealth, states and territories in 2001, and was reaffirmed in 2008. It formalises the rights and responsibilities of all parties to cooperate in the management of the Scheme, and underpins the intent of all parties to establish an efficient and effective regulatory system for the application of gene technologies.

Additionally, stakeholders value the **national legislative** and **policy consistency** aims of the Scheme. As such, the Forum is the appropriate mechanism to continue the policy debate and work towards achieving and maintaining that consistency, through their ongoing work program.

While there may be competing policy perspectives across jurisdictions, governments and stakeholders generally acknowledge that the Agreement drives the strategic development of national policy for gene technology. National policy balances the value of a specific jurisdiction-based policy agenda, against the value to the Australian community (in terms of cost, effectiveness and predictability) of having a consistent national regulatory Scheme.

*The Review recognised that the foundation of the Scheme is sound, but that there are opportunities for enhancements to update and modernise it. The role of the Forum is also recognised, as is the importance of continuing national collaboration to implement the recommendations from the Review. This might be best progressed via an action plan, to be developed by the Forum.*

*Future work may include identifying areas where the Forum could issue Policy Principles, Policy Guidelines and Codes of Practice to provide or clarify policy positions on key matters, noting the responsibility of the Forum to consult and collaborate with other relevant government forums in the conduct of its business.*

*In operationalising an action plan, the Forum might consider opportunities to leverage the role of the Gene Technology Standing Committee.*

**Recommendation 1:** To build upon and futureproof the Scheme, which is highly regarded, the Review recommends:

- a) the Forum progress options to update and enhance the operations of the Scheme; and
- b) these options be implemented in short, medium and long-term tranches, according to an action plan to be developed by the Forum.

## Object of the *Gene Technology Act 2000*

Stakeholders uniformly agreed that the object of the Act remains entirely appropriate. This is consistent with findings from both the 2006 and 2011 reviews of the Scheme.

The vast majority of stakeholders who contributed to the Review agreed that, since its inception, the Scheme has operated successfully, in assessing and managing the risks to human health and safety and the environment. Consistent with this viewpoint, the Review noted that no adverse events, and high levels of stakeholder compliance, are consistently reported in annual reports of the Office of the Gene Technology Regulator (OGTR).<sup>10</sup>

Some stakeholders did express ongoing concerns about the safety of GMOs; however these concerns did not suggest that the object of the Act should be changed. Safety concerns and post-market review mechanisms are discussed further in [Chapter 1.5](#).

While what is sometimes referred to as a ‘precautionary approach’<sup>11</sup> was seen as a central tenet by some, other stakeholders argued that the Scheme is overly precautionary. It was suggested that the potential for products of gene technology to protect human health or the environment may not be fully realised if potential ‘benefits’ of gene technology are not brought into the equation. It was argued, for example, that an overly precautionary Scheme may restrict the availability of health solutions. See [Chapter 1.4](#) for additional discussion on the consideration of ‘benefits’ in regulatory decision making.

*Stakeholders recognised that the Scheme benefits both the public and industry in providing strong legislative protections and a basis for regulatory certainty. The Review found that, overall, the Scheme is demonstrating the ability to manage any health and environmental issues with GMOs.*

*The Review did not encounter any calls to amend the Object of the Act and therefore considers that the Object of the Act remains appropriate and should be maintained.*

**Recommendation 2:** The Review recommends that the object of the *Gene Technology Act 2000* be maintained.

10 Office of the Gene Technology Regulator, *Annual and Quarterly Reports under the Gene Technology Act 2000*. Retrieved July 10, 2018, from [www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1#2017](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1#2017)

11 Section 4 of the Act provides that “the object of [the 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”.

## The Gene Technology Agreement 2001

The Agreement, signed by Heads of Government of the Commonwealth, states and territories, was established 17 years ago and was reaffirmed by them in 2008. The Review found that, overall, the Agreement is still working well and should be maintained. By formalising the cooperative arrangements that underpin the Scheme, the Agreement continues to support the operation of the Scheme by facilitating national collaboration on gene technology.

The Agreement originally established a Ministerial Council under the Council of Australian Governments (COAG) structure, to govern the operation of the Scheme. In 2013 this group became a COAG Legislative and Governance Forum on Gene Technology (the Forum). Following further streamlining of COAG councils between 2015 and 2017, the Forum became independent of the COAG work program and oversight. The Forum membership includes ministers with responsibility for gene technology from each state, territory and the Commonwealth, and currently reflects a range of portfolio interests including health, environment and primary industries. The Forum is supported by the Gene Technology Standing Committee (the Standing Committee), which is made up of senior officials whose role is to support their responsible Forum representative.<sup>12</sup>

The Review found that the Standing Committee plays a fundamental role in fostering collegiality and effective collaboration between jurisdictions, as well as between ministers and relevant policy areas within each jurisdiction. The Review acknowledges the impact of this role and recognises the importance of continuing to utilise the strength and effectiveness of the Standing Committee. There are also opportunities for the role of the Standing Committee to be strengthened (see [Chapter 1.3](#)).

Some stakeholders suggested that the Commonwealth and state and territory governments should formulate additional Policy Principles, as authorised under the Agreement. However, no changes to the current form of the Agreement would be required to enable this to occur if, and when, additional Policy Principles are warranted (see [Chapter 1.4](#)).

*The Review notes the importance of the Agreement in providing a commonly agreed basis for the regulation of gene technology nationally. The Review did not encounter any calls to amend the Gene Technology Agreement (2001) and agrees that the Agreement is working well and continues to facilitate effective national cooperation on gene technology. As such, the Agreement should be maintained.*

**Recommendation 3:** The Review recommends that the Gene Technology Agreement be maintained.

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<sup>12</sup> For more information on the role of the Standing Committee, see Department of Health, *Gene Technology Standing Committee*. Retrieved July 10, 2018, from <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-gtstandingcommittee.htm>

## CHAPTER 1.2

# Review Theme One – Technical Issues

The Third Review (the Review) of the Gene Technology Scheme (the Scheme) was designed to be forward-looking, and to consider appropriate policy settings in an environment of rapidly developing technology.

This section includes discussion of existing **definitions in the Gene Technology Act 2000 (the Act) and the Gene Technology Regulations 2001 (the Regulations)**, and their ability to appropriately classify a range of advances in technology. Specifically, the Review considered whether there is scientific justification for organisms developed through the application of these technologies to be regulated as genetically modified organisms (GMOs), noting the object of the Act.

**Synthetic biology** has been defined in various ways, and while there is no formally agreed definition of synthetic biology,<sup>13</sup> the Review has adopted a provisional working definition to enable discussion on the topic. The provisional working definition includes techniques for producing novel nucleic acid or protein sequences, or combinations thereof. The Scheme's coverage of this application is discussed in this section.

The Scheme was not designed to regulate humans. In fact, when the Scheme was first established the intent was to avoid the situation whereby a person who has undergone gene therapy becomes a GMO. Whether **human gene therapy** could result in humans being inadvertently caught within the definition of a GMO under the Act, is discussed in this section.

Finally, the regulation of **GMOs released into the broader environment** (for example, biological control agents) is discussed, including how to best address possible risks associated with this kind of environmental release. One mechanism to develop genetically modified (GM) biological control agents is through the application of gene drive technology. Consideration of **GM gene drive organisms** (released either as biological control agents or for other purposes), and whether they require an additional level of regulatory oversight, is developed in this section.

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13 See [Appendix 1: Glossary](#)

## CASE STUDY 1:

### An Australia-Africa partnership for better childhood nutrition

The Centre for Tropical Crops and Biocommodities at the Queensland University of Technology (QUT) is a world leader in using genetic technology to fight childhood malnutrition. Together with Uganda's National Agricultural Research Organisation, and with the support of the Bill and Melinda Gates Foundation, QUT is spearheading the Banana 21 Initiative.<sup>14</sup> The Initiative is intended to improve childhood health outcomes in East Africa by developing bananas with higher levels of iron and vitamin A.

Throughout much of tropical Africa, bananas are a staple food. As a perennial fruit that is relatively resistant to climate change, they are well suited to the region. However, despite their advantages, the East African Highland Banana (EAHB) favoured by most farmers is low in vitamin A. As a result, children with banana-based diets can suffer from night-blindness and compromised immune systems.

The Banana 21 initiative is tackling this problem by using gene technology to modify the EAHB using DNA from another variety of banana that is much higher in vitamin A, the Asupina. A native of the Southwest Pacific, the Asupina is not suitable for cultivation by African farmers due to its small fruit yield. After identifying the gene responsible for the high vitamin content of the Asupina in 2011, Australian and African scientists working together have successfully incorporated it into the EAHB. The result has been the successful creation of a fruit which combines the best characteristics of the EAHB with the nutrition of the Asupina. It will likely provide a vital source of nutrition for children throughout East Africa and beyond.

While farmers have used natural hybridization to improve their crops for millennia, this has always been a long and somewhat imprecise process. Bananas in particular are known for being difficult to cross-breed. The Banana 21 initiative is essentially using gene technology to increase the speed and precision of this ancient agricultural technique.

Banana 21 Initiative related research is ongoing in Uganda, Australia and the United States. It is hoped that a strain of EAHB with higher levels of vitamin A will be ready for the consideration of regulatory authorities by 2021, and that farmers will be able to access the plants soon afterwards.

Given the challenges posed by climate change and population growth, the need for research that supports farmers in raising nutritious, sustainable crops has never been more important. The Banana 21 Initiative shows the role gene technology has to play in this endeavour, and what can be achieved when Australian researchers collaborate with their colleagues in developing countries.

## Classification of new technologies

The Review found that the Australian population is generally not very clear on what is meant by genetic modification. A majority of those questioned during market research to inform the Review identified that it involves DNA modification, and many understand that foods, plants or crops will have been changed from their natural state. However, many consumers mistake a broad range of non-GM modifications (such as selective breeding) for what would be classified as gene technology.

When the Act and Regulations were originally drafted, gene technology was primarily used to move genes from one species to another. Ensuing scientific progress has delivered a broad and diverse set of techniques with the capacity to change the genomes of living organisms. It has also opened up many new applications that do

14 Further information is available at <http://www.banana21.org/about.html>. Retrieved 9 July, 2018.

not involve the introduction of DNA from another species. Further, it is becoming commonplace to use gene technology with the sole intent of making changes that are within the bounds of normal genetic variation.

The Review found that there may be a lack of clarity regarding:

- whether organisms developed through the application of these technologies are within the current scope of the Scheme, based on the language of current definitions; and
- whether there is scientific justification for organisms developed through the application of these technologies to be regulated as GMOs.

Currently, for an organism to be regulated under the Scheme it must first meet the definition of a GMO under the Act. The definition of a **GMO** includes ‘*an organism that has been modified by **gene technology***’. Further, the Regulations exclude a range of organisms from the definition of GMO, including ‘*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 number of stakeholders raised concerns about these definitions and their applicability to advances in technology; for example, whether applications of cisgenesis or intragenesis<sup>15</sup> constitute the introduction of any ‘foreign nucleic acid’.<sup>16</sup> Stakeholders also identified other advances in gene technology (including but not limited to CRISPR, ZFNs and TALEN<sup>17</sup>) that will need to be considered when assessing the definition of techniques that produce a GMO (or if appropriate, the exclusions from this definition).

## CRISPR: an advancement in gene technology

CRISPR is the term used to refer to a novel tool that allows the editing of genes with a high degree of accuracy. It takes its name (‘clustered regularly interspaced short palindromic repeats’) from part of a mechanism used by bacteria to defend themselves from attacking viruses by cutting their DNA. In 2013 researchers discovered it was possible to repurpose this mechanism for the precise cutting of an organism’s DNA.

While methods for modifying DNA existed previously, CRISPR is widely considered a breakthrough because it allows researchers to edit genes with an accuracy and efficiency that was not previously possible. Using CRISPR and its associated techniques, it is possible to modify genetic material with a degree of specificity that greatly increases its range of uses in medicine, agriculture, environmental conservation, and industry. Although research is ongoing, there is broad agreement that in the future this tool may give rise to treatments for previously untreatable conditions such as haemophilia, cystic fibrosis, and Duchenne muscular dystrophy.

Along with these opportunities, CRISPR enables a method known as a ‘gene drive’ (See ‘[Gene drives](#)’, [page 31](#)).

The adaptability of CRISPR also poses a regulatory challenge. While the technique can be used to insert foreign DNA into an organism, creating a GMO, it can also be used to produce organisms that feature no introduced DNA. This technique can produce organisms that are genetically identical to organisms that could arise naturally, or from conventional breeding techniques not subject to regulation.

15 These techniques involve the introduction of DNA obtained from the same, or a cross-compatible species, into the genome of an organism.

16 Schedule 1 to the Regulations (where the term ‘foreign nucleic acid’ is used) is currently being considered by the Regulator’s Technical Review. At the time this Report was completed, the outcomes of the Technical Review were still not finalised. While final decisions have yet to be made, the Review notes that the outcomes of the Technical Review will be relevant to ongoing work regarding the classification of advanced technologies.

17 (CRISPR) Clustered Regularly Interspaced Short Palindromic Repeat, (ZFN) Zinc Finger Nuclease, (TALEN) Transcription Activator-like Effector Nucleases. CRISPR, ZFN and TALEN systems are all examples of site-directed nucleases (SDNs). These are methods for cutting DNA at a specific nucleotide sequence. Once the DNA has been cut, there are two main pathways by which the cut can be repaired, both of which involve natural repair mechanisms: Non-homologous end-joining ...[or] Homology-directed repair’. See Office of the Gene Technology Regulator. (2016). *Technical Review of the Gene Technology Regulations 2001 – Discussion Paper*, pp. 26–7. Retrieved July 10, 2018, from [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/977EF3D4FDD4552ECA2580B10014663C/\\$File/Discussion%20Paper%20-%20Review%20of%20the%20Gene%20Technology%20Regulations%20.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/977EF3D4FDD4552ECA2580B10014663C/$File/Discussion%20Paper%20-%20Review%20of%20the%20Gene%20Technology%20Regulations%20.pdf)



The question of if and how such uses of CRISPR, and other similar vectors,<sup>18</sup> should be regulated is a key consideration of this review.

The Review acknowledges that the development of tools such as CRISPR demands a careful consideration of what falls under the remit of gene technology, and how it should be regulated. In the future this is intended to foster an environment where safe and high quality genetic research allows Australians to receive the maximum possible benefit from these scientific advances.

It is clear that the language in some of the core definitions in the Act has not kept up to date with technological advances, and that the resulting lack of clarity should be remedied. However, there is a lack of consensus among stakeholders as to how these definitions should be amended to achieve this clarity. In particular, debate surrounds how the definition of 'gene technology' should capture techniques that range from effecting changes to the genetic sequence of an organism, to other changes to genetic material that may or may not be heritable (e.g. RNA interference and various transient modifications).

Some stakeholders suggest that advances in technology (including ODM, SDN-1 and SDN-2, which have developed rapidly in recent years),<sup>19</sup> should be excluded from the scope of the Scheme as they pose no additional risks compared to conventional breeding. It has been argued these techniques produce changes that can be identical to those that are, or could be, produced in nature (i.e. naturally) and can be indistinguishable from conventional or other techniques that have been excluded from the Scheme (due to a history of safe use). There is also complexity in determining the reference point for what is 'natural', given it is not a static state.

Conversely, some stakeholders contend that the existing definition of gene technology was drafted intentionally broad in order to capture all forms of modification of genetic material. Moreover, that it does, and should, continue to capture all advances in technology within the scope of the Scheme. These stakeholders emphasised the risks associated with potential unknown off-target effects. The Review recognises that some stakeholders are concerned about off-target effects. However, an alternative perspective highlights a growing body of literature<sup>20</sup> suggesting that, for gene editing applications where no 'foreign nucleic acid' is introduced, any changes in the edited genome may be equivalent to those that could have arisen during conventional breeding. This would be the case even if there were any unintended off-target changes, as conventional breeding also produces changes in addition to those that were intended.

During conventional plant breeding, large numbers of gene variants are introduced by outcrossing or mutagenesis. This results in undesired traits being inherited together with the trait of interest. Plant breeders then undertake many generations of selective breeding to remove undesirable traits before they finally produce a new commercial variety of the crop with the desired trait. The same selective breeding process is undertaken with GM crops to ensure that any undesired traits resulting from off target modifications are removed, prior to the new crop being produced for commercial growing.

A number of recent analyses have looked at the off-target effects of gene editing in different organisms. This includes studies that have quantified the frequency of off-target effects and found them to be less frequent

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18 See footnote above for descriptions of similar vectors (i.e. ZFN, and TALEN technologies).

19 Oligo-directed mutagenesis (ODM) 'is a process for making small, precise changes to a genomic DNA sequence using a short piece of single stranded synthetic nucleic acid (DNA or RNA) called an oligonucleotide (oligo) as a template'. OGTR (2016). Technical Review of the Gene Technology Regulations 2001, Discussion Paper, pp. 26. Site-directed nuclease techniques, however, may take three distinct forms: SDN 1, SDN 2, and SDN 3. SDN 1 refers to the 'unguided repair of a targeted double-strand break (i.e. no template is used)'. SDN 2 'involves template-guided repair of a targeted double-strand break, using an oligonucleotide to guide small sequence changes'. SDN 3 is the use of a 'template-guided repair of a targeted double-strand break, using a long template to insert new sequences'. See Office of the Gene Technology Regulator. (2016). *Technical Review of the Gene Technology Regulations 2001 – Discussion Paper*, pp. 26–7. Retrieved 10 August, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewdiscussionpaper-htm>

20 Nicolia, A., Manzo, A., Veronesi, F. & Rosellini D. (2014) *An overview of the last 10 years of genetically engineered crop safety research*, *Critical Reviews in Biotechnology*, 34:1, 77–88, DOI: <http://dx.doi.org/10.3109/07388551.2013.823595>



compared with those found after random mutagenesis or conventional breeding.<sup>21</sup> It has also been noted that the off-target effects are no different than those which occur in nature.<sup>22</sup>

Gene editing advances are regarded by many as a technological breakthrough with great potential. Evidence is still accumulating, however, on the prevalence of any off-target effect of such techniques employed during the research phase (as opposed to the commercialisation phase, where the effects can be bred out through conventional breeding). To help clarify the issue of off-target effects, a comprehensive set of assays for measuring gene editing outcomes could be further considered. To this end, there are continual advances in the ability to 'conduct comprehensive genome-wide characterisation for the detection of off-target sites'.<sup>23</sup>

However, additional work is required before a conclusion can be reached on how the relevant definitions in the Act and the Regulations should be amended, with this additional work needing to seek viewpoints from a wide range of stakeholders.

When the Scheme was first developed, gene technology activity mainly occurred in the agricultural sector. The language of the legislation underpinning the Scheme is plant centric as an artefact of that time period. However, the Scheme is designed to regulate gene technology in all sectors, and definitions must accommodate the different characteristics of, and implications for, all organisms. Any amendments to definitions would therefore require thorough testing to avoid any unintended interpretations or consequences (for example, for dealings with GMOs in the medical sector). This issue should also be informed by the evolving international research and regulatory environments.

The regulatory status of gene editing techniques is being considered around the world. The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) issued a statement on how it intends to regulate plants produced through innovative new breeding techniques, which include gene editing. The statement outlined the USDA "does not regulate or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are not plant pests or developed using plant pests".<sup>24</sup>

The Court of Justice of the European Union has recently (June 2018) provided judgement on organisms obtained by mutagenesis.<sup>25</sup> The judgement found that organisms created using mutagenic techniques 'fall within the scope of the GMO Directive and are subject to the obligations laid down by that directive'. However, the judgement also stipulates that organisms obtained from mutagenesis techniques with a history of wide use, and a long safety record, are exempted from the requirements of the GMO Directive. EU member states, however, retain the right to legislate with regard to organisms created using exempted mutagenic techniques.

*The Review found that there are existing definitions in the Gene Technology Act 2000 and Gene Technology Regulations 2001 that may not appropriately classify a range of advances in technology. For example, the definitions of 'gene technology' and 'genetically modified organism', including use of the terms 'other genetic material' and 'foreign', could be reviewed to ensure they are still fit for purpose.*

*In both the Australian and international context, the value of having consistent definitions is well understood, as is recognition that definitions have a primary role in the classification of technologies and subsequent regulatory requirements. Any examination of definitions should therefore take into account concurrent work, including the current Technical Review of the Gene Technology Regulations 2001, as well as ongoing work internationally.*

21 Zhao, H. & Wolt, J. D. (2017). *Risk associated with off-target plant genome editing and methods for its limitation*, Emerging Topics in Life Sciences Nov 10, 2017, 1 (2) 231–240, DOI: <http://dx.doi.org/10.1042/ETLS20170037>

22 Conko, G., Kershen, D.L., Miller, H. & Parrott, W.A. (2016). *A risk-based approach to the regulation of genetically engineered organisms*, Nature Biotechnology 34(5)493–503, DOI: <http://dx.doi.org/10.1038/nbt.3568>

23 Zhao, H. & Wolt, J. D. (2017). *Risk associated with off-target plant genome editing and methods for its limitation*, Emerging Topics in Life Sciences Nov 10, 2017, 1 (2) 231–240, DOI: <http://dx.doi.org/10.1042/ETLS20170037>

24 United States Department of Agriculture, Secretary Perdue Issues USDA Statement on Plant Breeding Innovation. Retrieved October 9, 2018, from <https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation>

25 Court of Justice of the European Union, Press Release No 111/18 (25 July 2018). Retrieved October 11, 2018 from <https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf>

*In progressing this work, the Review notes that primary consideration should be given to ensuring:*

- *definitional amendments do not change the objective of the Scheme (to protect the health and safety of people and to protect the environment); and*
- *a rigorous science-based analysis of all concerns raised.*

*The Reviews notes the following secondary considerations:*

- *whether it will be possible to detect modifications resulting from advanced technologies to definitively distinguish them from naturally occurring variations, and the impact this may have on monitoring and enforceability;*
- *examining advances in gene technology to determine whether they should be included or excluded from regulation;*
- *the definition of 'other genetic material'; and*
- *the potential implications for trade and market access from any proposed amendments to definitions (noting that some stakeholders consider that more inclusive definitions are more conducive to international trade, while others consider that defining small changes to the genome as GMOs is a barrier to trade).*

**Recommendation 4:** The Review recommends updating, where required, the existing definitions in the *Gene Technology Act 2000* (Cth), to clarify the scope of regulation in light of ongoing technical advances. Any changes to definitions should take into account concurrent work, including relevant domestic reviews and ongoing work internationally.

## Emerging applications: Synthetic biology

To future proof the Scheme, extensions and advancements in modern biology need to be assessed to determine whether they fall within the scope of the Scheme. An example is synthetic biology, covering a broad range of techniques, applications and products that are not qualitatively different from modern biotechnology. While there is no legally accepted definition of synthetic biology,<sup>26</sup> there is wide agreement that the term includes techniques for producing novel nucleic acid or protein sequences, or combinations thereof. The end results have the potential to create entirely new and unique organisms.

Throughout the Review process, a high degree of support for the continued regulation of what might fall under the term synthetic biology was demonstrated.

Stakeholders recognised that the Act covers **current** synthetic biology applications, and many agreed that current risk assessment and containment methodologies are adequate to account for all current applications. This is consistent with a 2015 report from the Secretariat of the Convention on Biological Diversity (CBD),<sup>27</sup> and the Australian Council of Learned Academies' (ACOLA) forthcoming horizon scanning report on Synthetic Biology in Australia.<sup>28</sup>

The CBD report suggested that in the international context, existing biosafety risk assessment frameworks are likely to be sufficient to assess the risks of current and near-term applications of synthetic biology. The ACOLA report concurs with this finding, stating "the majority of existing regulation applicable to the assessment and management of risks presented by gene technology and GMOs will also be relevant to synthetic biology."<sup>29</sup> Australia's Scheme

<sup>26</sup> See [Appendix 1: Glossary](#)

<sup>27</sup> Secretariat of the Convention on Biological Diversity, (2015). *Synthetic Biology: Technical Series No. 82*. Retrieved March 20, 2018, from <http://www.cbd.int/ts/cbd-ts-82-en.pdf>

<sup>28</sup> The ACOLA report is expected to be formally released in the second half of 2018.

<sup>29</sup> Gray, P., Meek, S., Griffiths, P., Trapani, J., Small, I., Vickers, C., Waldby, C., and Wood, R. (2018). *Synthetic Biology in Australia: An Outlook to 2030*. Report for the Australian Council of Learned Academies, [www.acola.org.au](http://www.acola.org.au), (forthcoming), p. 85.

utilises a case-by-case, science-based assessment of environmental releases, in line with the Office of the Gene Technology Regulator's (OGTR) Risk Analysis Framework 2013.<sup>30</sup>

There was also agreement among stakeholders that **future** extensions and advancements in biotechnology should continue to be closely monitored by the Scheme, to ensure regulation remains appropriate to address any emerging risks. The Australian Chief Scientist and the Commonwealth Science Council, through ACOLA, are examining the opportunities and issues synthetic biology may present in Australia in the coming decade.

The ACOLA report lists potential applications that, while not currently available, may warrant further consideration if they evolve and are likely to be used.<sup>31</sup> Such applications, however, were generally considered to be 'future possibilities', and no evidence was presented to the Review of any applications that did not involve the genetic modification of an existing organism. Some stakeholders expressed concern that some organisms developed through synthetic biology in the future may have no clear non-GM parent for comparison, and identified that this may be an area requiring additional consideration, especially as the technology progresses.

Another area that has been used to distinguish the field of Synthetic Biology from traditional gene technology or modern biotechnology is its use of engineering principles<sup>32</sup>. While modern biotechnology has arguably always utilised engineering principles, a defining feature of synthetic biology is the increased capacity to customise living organisms with relative speed and cost efficiency. The ACOLA report acknowledges that in the medium term it is that synthetic biology will likely facilitate a range of new industrial, agricultural and therapeutic applications<sup>33</sup>.

While it is conceivable that synthetic biology will progress from its current developmental stage to being widely applied in the future, the existing risk assessment frameworks are appropriate to manage the risks posed. However, the increased volume of synthetic biology work may present challenges to existing regulatory resources.

*As previously stated, synthetic biology is currently within the scope of the Scheme, and there is a high degree of support for this to continue. Moreover, there is a high degree of support for the current case-by-case assessment of risk performed by the OGTR for any release of a GMO into the environment.*

*The Review notes that work is currently underway to further inform this issue going forward. This may include considering the best mechanism(s) to ensure the appropriate levels of regulation are applied to synthetic biology. To this end, the Review recommends a 'watching brief' apply to future developments in synthetic biology, and that current applications continue to remain within the remit of the Gene Technology Act 2000 (Cth).*

**Recommendation 5:** The Review recommends that:

- a)** extensions and advancements of gene technology, such as synthetic biology, continue to remain within the scope of the Scheme; and
- b)** a watching brief on synthetic biology should be maintained, to ensure the appropriate level of regulation is applied to future applications of synthetic biology.

30 Office of the Gene Technology Regulator. (2013). *Risk Management Framework*. Retrieved March 19, 2018, from [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raffinal5-toc/\\$FILE/raffinal5\\_2.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raffinal5-toc/$FILE/raffinal5_2.pdf)

31 Two examples of note include the possibility of building a live and viable organism, rather than modifying an existing organism, from molecular building blocks (from the ground up so to speak). A second example is the potential for a future organism to lack an existing comparator in nature or otherwise. These examples are considered a 'future possibility' only at this point in time. Gray, P., Meek, S., Griffiths, P., Trapani, J., Small, I., Vickers, C., Waldby, C., and Wood, R. (2018). *Synthetic Biology in Australia: An Outlook to 2030*. Report for the Australian Council of Learned Academies, [www.acola.org.au](http://www.acola.org.au), (forthcoming), p. 85.

32 Gray, P., Meek, S., Griffiths, P., Trapani, J., Small, I., Vickers, C., Waldby, C., and Wood, R. (2018). *Synthetic Biology in Australia: An Outlook to 2030*. Report for the Australian Council of Learned Academies, [www.acola.org.au](http://www.acola.org.au), (forthcoming), p. 18

33 "Our ability to engineer biology to do useful things underpins the Fourth Industrial Revolution – the intersection of biotechnology, information technology, manufacturing, and automation. Synthetic biology builds upon earlier techniques for genetic modification to generate toolboxes with which we can advance this revolution, and as such is driving the bioeconomy". Gray, P., Meek, S., Griffiths, P., Trapani, J., Small, I., Vickers, C., Waldby, C., and Wood, R. (2018). *Synthetic Biology in Australia: An Outlook to 2030*. Report for the Australian Council of Learned Academies, [www.acola.org.au](http://www.acola.org.au), (forthcoming), pp. 17,97–100 .

## Emerging applications: Human gene therapy

This Review was designed to be forward-looking and to consider appropriate policy settings in an environment of rapidly developing technology. One such area is the field of human gene therapy. There are two general types of gene therapy: germline therapy and somatic cell therapy.

Germline gene therapy modifies reproductive cells, with changes being passed onto the patient's offspring and subsequent generations. This is different to somatic cell gene therapy, which makes changes to a patient's non-reproductive cells, which are therefore not passed on to their offspring.

Currently in Australia, making heritable changes to the human embryonic genome is prohibited by the *Prohibition of Human Cloning for Reproduction Act 2002*,<sup>34</sup> although some research may be authorised under the *Research Involving Human Embryos Act 2002*.<sup>35</sup> In order to ensure there are no regulatory gaps, and to future-proof the Scheme should any of the current prohibitions be lifted, the Review investigated whether the Scheme should play a role in regulating this area.

There are three issues to consider in assessing advancements in gene technology [on humans]:

- Social and ethical issues;
- Implications on the definition of a GMO; and
- Any regulatory gaps that may arise from amendments.

### Social and ethical issues

Some stakeholders considered that germline therapies, particularly those involving humans, should be more heavily regulated than other applications of gene technology, due to the social and ethical issues associated with them. However, others suggested that the social and ethical issues relevant to human gene therapies (for example, the distinction between genetic diseases and genetically undesirable traits) are beyond the scope of the Scheme.

The prohibition (or otherwise) of making heritable changes to the human embryonic genome falls within the remit of the National Health and Medical Research Council (NHMRC) and its legislation. Many stakeholders suggested a ban on human germline therapies for any purpose should be maintained until a society-wide consideration of the issue.

### Definition of GMO

The definition of a GMO in the Act<sup>36</sup> includes, '(a) an organism that has been modified by gene technology' but excludes 'a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy'. Exclusions to this definition are provided in the Regulations in Schedule 1 – Organisms that are not genetically modified organisms.<sup>37</sup>

Any patient who receives treatment which modifies their germline<sup>38</sup> (reproductive) cells rather than their somatic<sup>39</sup> (non-reproductive) cells would appear to be captured within the scope of the Act. This raises the potential of these people inadvertently being caught within the definition of a GMO under the Act.

Questions then arise regarding the appropriateness of this scenario and any flow-on implications. GMOs are subject to a range of requirements such as licensing, physical containment and transport restrictions that are clearly not appropriate to apply to human beings.

34 *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) (Austl.). Retrieved July 10, 2018, from <http://www.legislation.gov.au/Details/C2017C00306>

35 *Research Involving Human Embryos Act 2002* (Cth) (Austl.). Retrieved July 10, 2018, from <http://www.legislation.gov.au/Details/C2016C00968>

36 *Gene Technology Act 2000* (Cth) (Austl.). Retrieved July 10, 2018, from <http://www.legislation.gov.au/Details/C2016C00792>

37 *Gene Technology Regulations 2001* (Cth) (Austl.). Retrieved July 10, 2018, from <http://www.legislation.gov.au/Details/F2016C00615>

38 See [Appendix 1: Glossary](#).

39 See [Appendix 1: Glossary](#).

The Scheme was not designed to regulate humans.<sup>40</sup> This was in part because the existing regulator at the time the Scheme began, the NHMRC, had the policy remit for gene therapies. As the Explanatory Guide to the Commonwealth Gene Technology Bill 2000 states, ‘the intent was to avoid the situation whereby a person who has undergone gene therapy becomes a GMO’.<sup>41</sup>

While human germline therapies are currently prohibited in Australia, having definitional clarity will be important in the future to ensure that people who undergo human germline therapy in other countries, and then enter Australia, fall outside the definition of a GMO. It will also be important for the Regulations to continue to be updated to ensure that humans who have received somatic cell gene therapies (for example, immune therapies) continue to be excluded from the definition of a GMO. This includes therapies that were not envisaged when the Act and the Regulations were drafted, and so may not fit clearly within the language of this legislation.

## A potential regulatory gap

Some stakeholders identified a potential gap in regulation pertaining to the modification of humans. For example, the regulation of clinical trials under the *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990 are limited to the use of therapeutic goods. As such, there may be a need to ensure research conducted on disease-causing mutations in living adults and children are covered by either the regulatory scheme for gene technology, or therapeutic goods.

The Scheme was not designed to regulate humans, including those who may receive or inherit germline therapies (or somatic therapies). Containment requirements for GMOs are not appropriate for humans and the Scheme is also not best placed to consider or address any ethical, legal or social issues raised by such therapies.

Any consideration of whether additional regulatory oversight is needed in this area will benefit from national collaboration across all jurisdictions and the health sector, to identify the most appropriate body, or bodies, to undertake this work.

*The Review proposes that the definition of a GMO be amended to exclude ‘a human being’ entirely from the definition, by removing the text that currently restricts this exclusion only to humans who have received somatic cell gene therapy.*

*The Review notes that this amendment may result in the need for another existing, or new, regulatory body to expand its scope of regulatory activity, to ensure that appropriate regulatory oversight is provided in this area.*

### **Recommendation 6:** The Review recommends:

- a) the definition of a genetically modified organism under the *Gene Technology Act 2000* (Cth) be amended to clarify that humans are not [considered to be] GMOs, and that
- b) subject to consideration, the COAG (Council of Australian Governments) Health Council might also consider whether additional regulatory oversight is needed for humans who may receive or inherit germline therapies (or other somatic therapies not within the remit of the Scheme). The COAG Health Council should also consider which regulatory (or other) body would be most appropriate to undertake such oversight.

40 Interim Office of the Gene Technology Regulator. (1999). *Proposed national regulatory system of genetically modified organisms. How it should work (Discussion Paper)*.

41 Interim Office of the Gene Technology Regulator. (2000). *Explanatory Guide to the Gene Technology Bill 2000*, p. 24. Retrieved July 10, 2018, from [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gtbill-3/\\$FILE/expguidebill.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gtbill-3/$FILE/expguidebill.pdf)

## Intentional environmental release: Biological control agents (including gene drive organisms)

The Review sought to ensure the Scheme can accommodate continued technological development. In doing so it addressed the potential risks associated with intentional environmental releases, for example treating threatened species so they become more resistant to disease. Another area of interest was the consideration of GM gene drive organisms, specifically organisms engineered to contain a gene drive element.<sup>42</sup>

Any organism containing a gene drive, or created using gene technology, would be classified as a GMO and regulated under the Act. Regulatory requirements would depend on whether the organism is contained or released into the environment (see [Gene drives](#)).

At the time of this Report, the appropriate level of regulation for GM gene drive organisms in containment<sup>43</sup> was being considered as part of the Regulator's Technical Review. The Technical Review proposed that contained dealings with GMOs that have functional gene drives hold a Dealings Not involving Intentional Release (DNIR) licence. This would ensure case-by-case evaluation of risks and tailored risk management of activities with these organisms.

As part of this evaluation and risk management, the Regulator could consider control measures including:

- segregation of gene drive organisms within containment (including transportation);
- molecular, sexual, and ecological confinement measures;
- measures against accidental release;
- punitive measures against unauthorised intentional release;
- safeguard and control measures, including reversibility of the impact;
- communications tools (in the case of both containment and release); and
- any trans-boundary issues (in the Australian context).

At the time of finalising this report, no application for a GM gene drive organism has been received by the Regulator. Should an application to release a functional GM gene drive organism into the environment be submitted, it would be appropriate for the dealing to require a Dealing involving Intentional Release (DIR) licence.<sup>44</sup> This would ensure a case-by-case evaluation of risks and tailored risk management of activities, as well as a range of consultation requirements, including formal consultation with the Minister for the Environment.<sup>45</sup> In considering this topic, the Review has explored whether this level of regulation is appropriate.

Some stakeholders have raised the potential for GM gene drives to be intentionally spread throughout the environment as a shift in focus for GMO releases, pointing to provisions in the current Act that are focused on limiting the spread of GM elements. Because of this, various perspectives on how to most appropriately regulate gene drive GMOs were put forward, including that:

- a new licensing category for intentional environmental releases should be introduced;
- as GM gene drive organisms are already GMOs, standard risk and containment measures are sufficient to manage any risk associated with such organisms;
- consideration be given to developing new Policy Principles, Guidelines or Codes of Practice;

42 The development of GM biological control agents could be achieved through both the application of gene drive technology, or through other gene technology applications

43 'Containment' in this sense refers to the physical containment of live and viable GMOs in facilities such as laboratories, without release of GMOs into the environment.

44 The notion of 'use' of a GMO may also need to be considered for amendment. The notion of 'dealing' may need to be expanded to include 'use' for intentional environmental releases of GM organisms.

45 See section 50(3)(d) of the Act. Noting the Environment Minister oversees the *Environment Protection and Biodiversity Conservation Act 1999* (Cth). (EPBC Act)



- a moratorium be placed on all GM gene drive research (both contained dealings and those involving environmental release) because of their potential to spread through the environment; or
- given the purpose of a gene drive is to spread beneficial traits in the environment, as well as the lack of an accumulated body of evidence around the safety of GM gene drives, they may require additional biosafety considerations beyond those for conventional transgenes (including specific post-release monitoring requirements).

## Gene drives

Gene drives are 'genetic elements that are favoured for inheritance, and which can therefore spread through populations at a greater rate than genes with standard Mendelian inheritance'. Put simply, gene drives increase the rate at which certain genes are inherited by offspring of a sexually reproducing organism, spreading the genes or traits through the population of a species faster than would occur normally. (See [Figure 1](#))

There is a developing interest in the potential for gene drive systems to control invasive species, in ways that avoid the indiscriminate 'off-target' effects associated with conventional control methods. Introduced invasive species can breed quickly and devastate native flora and fauna. However, existing control methods (such as poisons, trapping or shooting) used to control invasive species are prone to unintended or undesired consequences, which could potentially be avoided through the use of gene drives as a control mechanism.

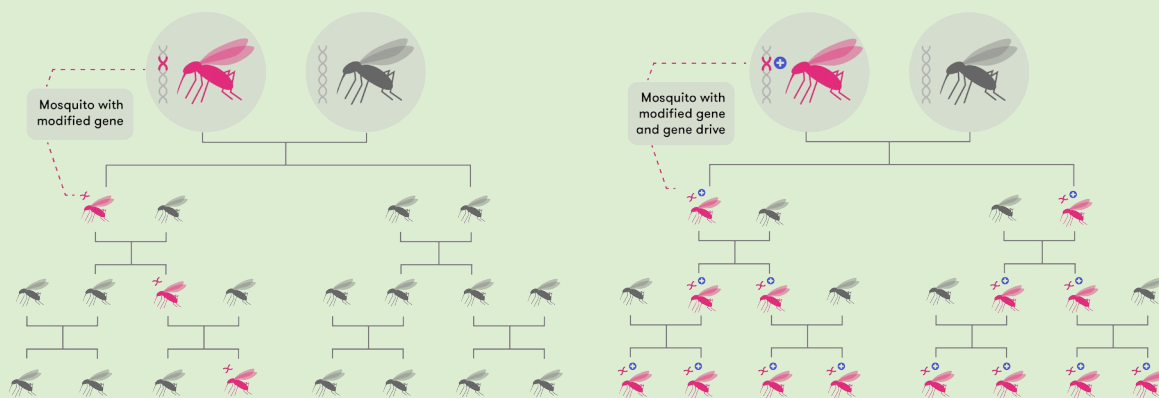
The current focus of gene drive research involves attempting to: control mice to protect biodiversity on islands; control weeds to protect biodiversity in forests and parklands; or use mosquitoes to manage the spread of diseases such as dengue, zika, or malaria.

In the case of malaria, the potential benefits of gene drive technology are promising. Malaria is caused by a parasite spread by the *anopheles* mosquito. In 2017, the World Health Organization reported an estimated 219,000,000 new cases of the disease had occurred and more than 400,000 deaths had resulted from disease, many of them children.

Scientists have recently begun to explore the possibility of using gene drive technology to either remove the ability of mosquitos to carry the malaria parasite, or to reduce the numbers of malaria carrying mosquitos.

**FIGURE 1**

Mendelian Inheritance of standard GM (left) versus Gene Drive Inheritance (right)



Source: Australian Academy of Science (May 2017) Discussion Paper – Synthetic Gene Drives in Australia: Implications of Emerging Technologies, <https://www.science.org.au/support/analysis/reports/synthetic-gene-drives-australia-implications-emerging-technologies>

Gene drives are transgenic organisms and would be subject to regulation under the *Gene Technology Act 2000*.

While contained work, as well as any future environmental releases of genetically modified organisms (including gene drives) should be clearly within the scope of the Scheme, there would be benefit in further work being undertaken to determine the most appropriate approach for regulating any intentional environmental release of such organisms (as well as any additional requirements for contained work).

Through formal submissions and other consultation mechanisms, the following options were raised:

- a new licensing category;
- additional mechanisms within risk management plans;
- consideration of the intersection between the Scheme and the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act) and related state and territory laws;
- utilising Policy Principles, Guidelines or Codes of Practice; and
- post-release monitoring.

## A new licence category

Currently the Act provides for two primary licensing categories: Dealings involving Intentional Release into the environment (DIR), and Dealings Not involving Intentional Release into the environment (DNIR).<sup>46</sup> DNIR licensed activity takes place under containment – most commonly in certified facilities, while DIR licensed activity takes place outside contained facilities and has been used for controlled field trials or wider commercial releases (such as agricultural crops or vaccines).

As noted in the 2011 Review of the Scheme, these licensing categories are predicated on field trials and commercial applications. It is foreseeable that future applications of gene technology may occur outside these traditional areas. For example, there are a number of invasive species in Australia that could be the subject of research on biological control agents developed using gene technology. This research could potentially lead to environmental releases outside of field trial or commercial farming settings.

It may be appropriate for the release of biological control agents, created through gene technology, to be regulated via a DIR licence (which involves the preparation of a risk assessment and risk management plan (RARMP)<sup>47</sup> and 'case-by-case' assessments and public consultation). However, legislative amendments may be required for this to be possible. Specifically, consideration would have to be given to the definition of 'dealings' in the Act and whether it would capture the release of a GM biological control agent.<sup>48</sup> Alternatively, a new licence category (with specific requirements relevant to biological control agents) could be considered.

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46 A third licence category also exists under the Act – for inadvertent dealings – However this licence category can only be used in circumstances when the Regulator is satisfied that a person came into commission of a GMO inadvertently (refer section 40A of the Act). It is therefore not relevant to considerations regarding the intentional release into the environment of GM biological control agents.

47 The RARMP are conducted prior to a licensing decision for the Regulator, and include 'details of the GMO, the proposed activities, including any proposed controls, limits or containment measures'. See Office of the Gene Technology Regulator. (2013). Risk Management Framework. Retrieved July 10, 2018, from [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raffinal5-toc/\\$FILE/raffinal5\\_2.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raffinal5-toc/$FILE/raffinal5_2.pdf)

48 As was discussed in the Final Report of the 2011 Review of the *Gene Technology Act 2000*, the Act regulates 'GMO dealings' (including conducting experiments with and propagating GMOs). This does not cover the 'use' of a GMO unless the use occurs for the purpose of a dealing. It is currently unclear whether the environmental release of a GM biological control agent would be captured by the Act in the same way that GM plants and other dealings are. See Department of Health, *2011 Review of the Gene Technology Act 2000*, Retrieved July 10, 2018, from <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-techact-review>



## Risk management plans

Some stakeholders have highlighted that the potential exists for additional mechanisms to be used within RARMP procedures to assess more complex environmental releases; for example, the use of probability modelling for complex environmental releases in addition to other quantitative modelling, particularly for gain-of-function GMOs.

This may be of particular interest if a trait had the potential to expand a species' environmental niche, or produce high impacts within a niche. If this approach were to be progressed, it would be important to balance the benefits of including quantitative modelling within RARMPs with associated costs, and consider whether such an approach would be better applied on a case-by-case basis dependent on the circumstances.

Information required for intentional release applications is currently specified in the relevant application forms. Any special information that may be required for more complex environmental releases, such as biological control agents, could be captured in new or amended application forms. Furthermore, the Review also notes that (under section 42 of the Act) the Regulator has the capacity to request additional information in relation to an application at any time before making a decision, including before beginning to consider the application.

Whether the release of a biological control agent entails greater complexity than previous commercialised releases and therefore requires extended timeframes (for application assessment and the preparation of RARMPs) is also an area of consideration. Such assessments could lead to additional matters that require attention.

## Environmental protection legislation

The intersection between the Scheme and existing environmental protection legislation could be investigated further, to determine how such releases should be regulated. Relevant environmental protection legislation includes the EPBC Act. Potential legislative impacts on environmental and agricultural sectors could also be considered, including impacts on the Scheme set up by the *Biological Control Act 1984*, and related state and territory laws.

Internationally, the importation of any gene drive organism would trigger the *Biosecurity Act 2015*, as well as provisions pertaining to the Live Import List.<sup>49</sup>

Stakeholders also highlighted the increasing need for the provision of appropriate advice to the Gene Technology Regulator (the Regulator) (for example, advice from environmental scientists). The Review acknowledges the benefit of environmental science, as well as evolutionary modelling,<sup>50</sup> in the decisions regarding intentional environmental releases (including invasive pest controls). It should be noted that skills or expertise in ecology is an existing identified skills area for Gene Technology Technical Advisory Committee (GTTAC) appointment, and that the current GTTAC includes a member with ecological expertise.

There is an existing power under section 102 of the Act for the Minister to appoint one or more persons to give expert advice to GTTAC. Such individuals can be appointed on a continuing or an ad hoc basis. The Review considers that the increased use of this provision may be beneficial if GTTAC expertise is not sufficient to consider matters related to the release of genetically modified biological control agents.

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49 The Department of Agriculture and Water Resources administers the Biosecurity Act, while the Live Import List is maintained by the Department of the Environment and Energy. See Department of Agriculture and Water Resources, *The Biosecurity Act 2015*. Retrieved July 10, 2018, from <http://www.agriculture.gov.au/biosecurity/legislation/biosecurity-legislation> and Department of the Environment and Energy, *Live Import List*. Retrieved July 10, 2018, from <http://www.environment.gov.au/biodiversity/wildlife-trade/live/import-list>

50 Australian Academy of Science. (2017). *Synthetic Gene Drives in Australia*. Retrieved March 20, 2018, from <http://www.science.org.au/support/analysis/reports/synthetic-gene-drives-australia-implications-emerging-technologies>

## Policy Principles, Guidelines or Codes of Practice

Within the existing provisions of the Act, unrestricted environmental releases could be subject to a DIR authorisation, with applicable Policy Principles or Guidelines provided by the Legislative and Governance Forum on Gene Technology (the Forum). Several stakeholders raised the potential for existing, yet under-utilised, provisions of the Scheme – such as Policy Principles, Guidelines or Codes of Practice issued by the Forum – to solve some of the emerging issues the Scheme is facing. This may include the issuing of a Principle, Guideline or Code relevant to the release of genetically modified biological control agents (including gene drives).

Some stakeholders suggested the post-release monitoring should be applicable for intentional environmental releases (i.e. not restricted to farm boundaries), or that they should be subject to periodic post-release review.

To this end, some stakeholders have suggested the use of genetic markers may provide additional assistance in post-release detection, monitoring and containment.<sup>51</sup>

## Additional work

It is anticipated that an action plan will progress the above options, noting that a solution may utilise a combination of approaches and complexity, and need for considered examination, particularly in creating a new licensing category or when these releases may contain a gene drive.

*The Review notes that there is benefit in undertaking further work to determine the most appropriate approach for regulating the broader environmental release of genetically modified organisms (including gene drives). Subject to administrative and legal considerations, this could include:*

- *a new licence category with additional requirements specifically relevant to genetically modified biological control agents;*
- *the application of current risk assessment and risk management approaches and information requirements;*
- *consideration of the role of the Environment Protection and Biodiversity Conservation Act 1999, the scheme set up by the Biological Control Act 1984 and related state and territory laws, and the intersection of these laws with the Gene Technology Act 2000;*
- *a new Policy Principle, set of guidelines or code issued by the Legislative and Governance Forum on Gene Technology; and*
- *other appropriate approaches that may be suggested to achieve the desired outcome (for example, post-release monitoring).*

**Recommendation 7:** The Review recommends clarifying, and where necessary strengthening, the mechanisms for regulating the:

- a) broader environmental release of genetically modified organisms; and
- b) environmental release of GM gene drive organisms (as well as any additional requirements for contained work).

<sup>51</sup> A well-chosen marker may assist with traceability and aid post release identification. However, certain markers carry additional implications, including resource implications, and the question of whether they would need to be assessed for any potential risks themselves. As such the purpose for requiring genetic markers would need to be carefully considered, and standards developed. Such measures should only be considered where any identified additional risk would warrant their use. Also see Organisation for Economic Co-operation and Development. (1986). *Recombinant DNA Safety Considerations*. Retrieved July 10, 2018, from <http://www.oecd.org/sti/biotech/40986855.pdf>

## CHAPTER 1.3

# Review Theme Two – Regulatory Issues

This section explores the most appropriate way for a best-practice, risk-based approach to regulation to be applied to the Gene Technology Scheme (the Scheme), in an environment where understanding about the science and the inherent risks is evolving. A best-practice, risk-based approach to regulation calls for a regulatory scheme to focus on harm prevention and achieving outcomes. Regulatory effort should be placed on the highest levels of risk and be designed to encourage innovation and reduce regulatory burden.

The first step in ensuring that a regulatory scheme imposes regulatory requirements that are commensurate with risk is to have an appropriate **'regulatory trigger'**. This determines what falls inside and outside the scope of regulation. An appropriate trigger is one that is broad enough to capture the activities that require regulatory oversight, but not so broad as to capture activities that are regulated by other regulatory schemes, or activities that do not require government regulation.

A second step in imposing an appropriate level of regulation for a range of activities is to **'tier' regulatory requirements**. Different activities with genetically modified organisms (GMOs) will have varying levels of risk associated with them. As such, once it has been determined that work with a GMO is captured by the Scheme (as determined by the 'regulatory trigger'), the specific regulatory requirements, commensurate with the level of risk of specific types of activities, need to be determined. This can be done by assigning different types of work with GMOs, to different authorisation categories. This section of the Report explores whether existing authorisation categories (or 'tiers') are appropriate.

This section also explores whether there are any opportunities to **streamline regulatory requirements** of the Scheme. This may include investigating IT solutions for application processes and whether any opportunities exist to make processes timelier for regulated stakeholders.

The Third Review of the Gene Technology Scheme (the Review) has also considered whether the Scheme is suitably equipped to regulate work with GMOs undertaken outside of universities, research institutions and large companies. This includes consideration of any specific requirements for the regulation of work done by 'community-based citizen scientists' or **'DIY biologists'**.

Technological advances are a constant, as is the likelihood of future developments in gene technology. Scientific techniques are being developed faster than the Scheme is currently being reviewed and changes legislated. Recognising these facts, this section considers whether there are additional mechanisms available to help **future-proof** the Scheme.

Finally, this section considers how the Scheme impacts **market access and international trade**, and the role for the Australian Government in this space. Additional information on the regulation of gene technology in other countries is included in [Chapter Two](#).

## CASE STUDY 2:

### Moving towards a cure for haemophilia

The recent success of Australian researchers working to cure haemophilia is a dramatic example of how gene therapy is changing the way we think about diseases once considered incurable.

Haemophilia is a rare, inherited blood condition that affects around 2800 people in Australia. People who suffer from the disease are limited in their ability to produce blood clotting factor, making them susceptible to often painful internal 'bleeds'. Those with this condition find it difficult to participate in physical activity, and over time are likely to develop difficulties with mobility.

Up until last year, the condition was considered a chronic one. It was managed by avoiding activities likely to cause bleeding and providing transfusions of specially prepared blood plasma containing the missing clotting factor. While its cause has been known for decades (a defect in the gene that should prompt the production of clotting factor), until recently the technology to address it did not exist.

In December 2017, a research team at Sydney's Royal Prince Alfred Hospital announced a breakthrough in their efforts to use gene therapy treatment for haemophilia.

Building on recent advances in gene therapy, a virus engineered to carry a specially engineered replacement gene was injected into patients in the hope it would embed itself in their system and enable them to do away with blood transfusions by producing a clotting factor of their own. The findings, published in the *New England Journal of Medicine*, were exceptionally positive: Nine of the ten participants reporting no haemophilia-related bleeding in the year following their treatment.

One of the first hereditary diseases described by medical literature in the early 1800s, for centuries haemophilia has vexed doctors as a chronic and painful condition that disproportionately affects children. Australian genetic researchers have now reached the point that credible sources are talking about a cure being within reach. This can be taken as demonstrative of the significant potential of this technology to address and alleviate human suffering, and the importance of Australian Governments providing a regulatory environment in which this life saving work can take place.

## Regulatory triggers

Different regulatory schemes use different methods for determining what falls inside and outside the scope of regulation. A common approach is to use 'triggers'; that is, to specify which factors will 'trigger' or make the law apply.

Australia's Scheme currently operates initially via a process trigger, which means that any organism that has been developed using a gene technology process is subject to the regulatory requirements of the Scheme. Once the process trigger has determined whether an organism is within the scope of the Scheme, product factors determine whether certain organisms (products) are considered exempt, low risk dealings or licensable dealings. Because of this, the Scheme is considered by some to be a 'hybrid' of process and product trigger systems.

The majority of gene technology regulatory schemes across the world similarly operate via a process trigger. However, some have a scheme with a product trigger. For example, the Canadian approach considers the novelty of a product, rather than its method of production, as the trigger for regulatory review. A product may be considered novel and thus captured by the regulatory scheme if it has one or more new or changed traits, or a new use, regardless of whether it has been developed through the application of gene technology or another process.<sup>52</sup>

52 Canadian Food Inspection Agency, (2007). *Regulation of Agricultural Biotechnology in Canada*, Retrieved July 10, 2018, from [http://www.publications.gc.ca/collections/collection\\_2007/cfia-acia/A104-24-2007E.pdf](http://www.publications.gc.ca/collections/collection_2007/cfia-acia/A104-24-2007E.pdf)

A primary concern for most stakeholders is to ensure regulation remains commensurate with risk. That is, regulation should be proportionate to the identified risk and should not impose unnecessary requirements. Throughout the Review process, a number of stakeholders have suggested that a product trigger is better able to achieve this balance.

Arguments that were put forward in favour of a product trigger included:

- Risk resides in a modified organism, not the process used to produce that organism. For example, the same technology could be used to produce both a harmful or safe product. Whether or not the outcome of a modification is safe or harmful can only be found by looking at the organism itself.
- It is possible for GMOs to be genetically identical to, and thus indistinguishable from, an organism developed using non-genetically modified (GM) methods. This poses both detectability and equity issues,<sup>53</sup> which some stakeholders believe could be avoided by a product trigger.
- A process trigger can be seen as too broad, capturing some activity that poses little or no risk.

However, others submitted that a process trigger is more appropriate and proportionate to risk. Arguments that were put forward in favour of maintaining a process trigger included:

- Given the rapid advance of technology, continuing to regulate on the basis of a process trigger (which captures a broader scope of activities within the scope of the Scheme) allows products that do not yet have a history of safe use to be monitored.
- Community sentiment supports a precautionary approach to regulation, which is arguably better achieved with a regulatory scheme with a broad scope.
- The majority of gene technology regulatory schemes internationally, including many of our trading partners, utilise a process trigger. Maintaining a process trigger will facilitate trade, as the traceability of products is arguably enhanced by a scheme that broadly captures gene technology activity.
- Process-based regulation has served Australia well since the commencement of the Scheme and continues to be well understood.

These stakeholders also pointed out that changing the trigger would involve considerable complexity and extended timeframes, particularly given the interface between the Scheme and other product regulatory systems. Therefore, they argued that the Review should instead focus on improving the existing process-based legislative framework by reducing the level of regulatory oversight of proven modifications with a history of safe use. This could be supported by an approach that enables the system to continuously respond to emerging technical developments and, consequently, any emerging risks.

Some stakeholders emphasised the merit in further considering the potential for designated exit points to the Scheme, based on the eventual product.

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<sup>53</sup> Detectability issues relate to whether gene technology legislation can be enforced if you cannot tell whether an organism was the product of gene technology or a natural process. Equity issues relate to why the Scheme would regulate a GMO if it is identical to a natural variation.

## Exclusions to the definitions of gene technology and GMO

The definitions of 'genetically modified organism' and 'gene technology' in the *Gene Technology Act 2000* (the Act) were intentionally cast broad, to capture all current and any new methods of genetic modification that are developed. This was intended to help future-proof the Scheme.

However, to avoid capturing things not intended to be regulated by the Scheme, organisms and technologies excluded from these definitions are listed in Schedules 1A and 1 in the *Gene Technology Regulations 2001* (the Regulations).<sup>54</sup> As the Explanatory Statement to the Regulations states, the organisms excluded from the Regulations are those types of organisms that:

- have been exempt or excluded from controls on GMOs for many years (some since the late 1970s);
- exchange genetic material in nature, and as such do not pose any unique biosafety risks to the environment or human health and safety;
- are commonly used in biological research; and/or
- have a very long history of usage in Australia and overseas.<sup>55</sup>

These lists of exclusions help clarify what is not regulated under the Act and ensure the process-based trigger system can operate effectively. Also, the ability to qualify or reduce the scope of the definitions in the Act, through the use of these Schedules provides flexibility, which is a strength of the existing Scheme.

*On balance, the Review concurred with the arguments supporting maintenance of a process-based regulatory approach (i.e. a broad range of technologies, including new technologies, are within the scope of the Scheme), noting that a product trigger could be considered again in the future as the Scheme progresses. Given the gene technology system in Australia consists of multiple product-based regulators as well as the Gene Technology Regulator, and the system has shown to be effective in identifying and managing risk, it might be counter-productive, time consuming and expensive, at this stage, to review the entire, intersecting system.*

*However, the Review identified the potential to reduce unnecessary regulation by removing regulatory requirements that are not commensurate with the level of risk posed by the GMO, and which provide no additional protections for the health and safety of people and the environment. This could be achieved by introducing more 'risk tiering' into the Scheme (refer Recommendation 9), streamlining regulatory requirements (refer Recommendation 10) and addressing any identified regulatory duplication (refer Recommendation 21).*

*The Review noted that the continuing successful operation of the Scheme's process trigger is dependent on appropriate definitions of 'genetically modified organism' and 'gene technology'.*

**Recommendation 8:** The Review recommends that a process-based trigger be maintained as the entry point for the Scheme at the present, to allow for any potential risks associated with new technologies to be initially considered within the scope of the Scheme.

54 See 'Schedule 1A – Techniques that are not gene technology' and 'Schedule 1 – Organisms that are not genetically modified organisms' in the Regulations. See *Gene Technology Regulations 2001* (Cth) (Austl.). Retrieved July 10, 2018, from <http://www.legislation.gov.au/Details/F2016C00615>

55 *Gene Technology Regulations 2001* (Cth), *Explanatory Statement*. Retrieved July 10, 2018, from <http://www.legislation.gov.au/Details/F2001B00162/Explanatory Statement/Text>

## Risk tiering and appropriate regulation of environmental releases

Regulators and stakeholders across the board agree that regulation needs to be commensurate with risk. Risk tiering is one method that can be used to try to achieve this. In the context of gene technology, risk tiering is a system in which GMO dealings are assigned to different groups or 'tiers' based on their level of risk. Each risk group is then subject to different levels of regulation, as appropriate to the level of risk they pose and the amount of regulation required to adequately manage that risk.

In conjunction with the maintenance of a process-based trigger as an entry point for the Scheme (see [Recommendation 8](#)), the introduction of additional risk tiering is also a mechanism to update and facilitate flexibility of the regulatory Scheme.

There are a number of advantages to a risk tiering system. It can reduce unnecessary regulatory burden for safer products assigned to lower risk groups, and increase efficiencies in regulatory functions. This allows for prioritisation of regulatory resources and efforts, with greater oversight given where the risks are higher, difficult to quantify or less well characterised, and less to those cases that are known to be low risk. Risk tiering can also avoid inconsistent outcomes, ensuring that GMO dealings with the same level of risk are subject to the same level of regulation. If implemented effectively, a risk tiering approach means regulation is more targeted and efficiently applied, while still ensuring that appropriate levels of protection and oversight for all GMOs are maintained.

Elements of risk tiering are already used within the current Scheme. Each of the current authorisation categories within the Scheme, including DIR<sup>56</sup> and DNIR<sup>57</sup> licences, NLRDs<sup>58</sup> and exempt dealings,<sup>59</sup> have different regulatory requirements assigned to them. These have been determined based on the level of risk posed by the organisms in that category. This provides opportunity for further risk tiering.

### Opportunities for further risk tiering within the Scheme

The Review found that there are opportunities to incorporate further risk tiering into the Scheme, in addition to the use of the authorisation categories discussed above. Further investigation is required to determine the most appropriate tiers for different applications of gene technology. Future work in this area should consider the following:

- The application/technology that has been used, including:
  - how long the application/technology has been in use;
  - whether an established application/technology has a history of safe use; and
  - the inherent risk of a particular application/technology (for example, taking into account whether any foreign DNA is introduced or if edits are only made to the existing genome).

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56 Dealings involving an Intentional Release (DIR) of GMOs into the Australian environment are dealings with GMOs which take place outside of containment facilities. The majority of DIR licences issued to date have been for experimental field trials (limited and controlled releases) or general/commercial releases of GM plants. A small number of DIR licences have also been issued for GM vaccines for human or veterinary use, either for trial (limited and controlled release) or general/commercial release. The release of GM animals would also require a DIR licence. See Office of the Gene Technology Regulator, *What are Dealings involving an Intentional Release (DIR) of a GMO Into the environment?* Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dirclass-2>

57 Dealings NOT involving an Intentional Release (DNIR) of GMOs into the environment are dealings with GMOs in contained facilities which do not meet the criteria for classification as exempt dealings or Notifiable Low Risk Dealings (NLRDs). Dealings with a GMO licensed as a DNIR must not involve release into the environment. See Office of the Gene Technology Regulator, *What are Dealings NOT involving an Intentional Release (DNIR) of a GMO Into the environment?* Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dnirclass-2>

58 Notifiable Low Risk Dealings (NLRDs) are activities with GMOs undertaken in containment (i.e. not released into the environment) that have been assessed as posing low risk to the health and safety of people and the environment, provided certain risk management conditions are met. The types of GMOs and activities classified as NLRDs are specified in the Regulations. See Office of the Gene Technology Regulator, *What are Notifiable Low Risk Dealings (NLRDs)?*, Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/nldrclass-2>

59 Exempt dealings are a category of dealings with GMOs that have been assessed over time as posing a very low risk (i.e. contained research involving very well understood organisms and processes for creating and studying GMOs). The only legislative requirement for exempt dealings is that they must not involve an intentional release of a GMO into the environment.



- Previous assessment of similar organisms and species/trait combinations, including:
  - how similar a GMO is to a previously assessed GMO; and
  - if the similar GMO has a history of safe use in particular combinations (species plus traits).
- The type of genes introduced into or removed from an organism and the modified trait(s) that result (for example, low risk traits versus higher risk traits).
- The characteristics of the final organism (i.e. the end product).
- The role of principles-based regulation in developing a risk tiering system.
- The type of organism to which the modification has been made (for example, plant, animal, human, microbe). This option is discussed further below.

## Risk tiering on the basis of organism type

The idea of risk tiering based on the type of organism (for example, plants, animals, humans and microbes) was discussed extensively by stakeholders during the Review. Overall, tiering on the basis of the type of organism was not broadly supported.

Whilst it was acknowledged there may be different risks associated with different classes of organisms, it was also suggested that this approach could lead to potential inconsistencies in regulation and unnecessary complexity within the Scheme.

For example, some stakeholders suggested that the risks associated with GM plants are significantly less than other classes of organisms, such as microorganisms (noting that plant mobility and susceptibility to climatic conditions provide inherent containment measures). As such, these should have fewer regulatory requirements. Others, however, noted that some plants could potentially contain risk elements (such as allergenicity or toxicity) while some microorganisms may be benign. In this context, regulating all microorganisms higher than plants would not provide a level of regulation commensurate with risk.

## Streamlining the regulatory pathway for lower risk GMO dealings

A second key point raised by stakeholders in relation to risk tiering was the idea of streamlining regulation for lower risk categories. Many stakeholders strongly supported implementing a more simplified or 'streamlined' regulatory pathway for organisms that have a demonstrably low level of risk, organisms that have a history of safe use, organisms where no foreign DNA has been introduced, and where highly characterised organisms have been used.

A number of potential mechanisms to streamline lower-risk regulatory pathways were suggested by stakeholders, which could be considered once a method for assigning risk tiers is developed. This includes:

- reducing data set requirements for lower-risk regulatory categories;
- using notifications to the Office of the Gene Technology Regulator (OGTR) and/or approvals granted by accredited Institutional Biosafety Committees (IBC) rather than full licence assessments for lower-risk categories;
- simplifying approvals processes for small scale testing; and
- progressing toward a product-trigger, which would consider the characteristics of the GM product, rather than how it was developed.

Some stakeholders further suggested that less regulation and greater streamlining in these lower-risk categories could be accompanied by a system of regular or random audits, to ensure the Scheme continues to provide responsible and risk-proportionate regulation.



## Further issues to be considered in risk tiering

A number of other factors will need to be taken into account when considering changes to risk tiering within the Scheme. While supporters of risk tiering affirmed its ability to provide responsive, responsible, and risk-proportionate regulation, others highlighted it has the potential to create regulatory 'grey areas' (i.e. gaps or loopholes in regulatory coverage). Some stakeholders also suggested that some forms of risk tiering may increase complexity leading to increased regulatory burden for the Regulator and increased compliance costs for applicants. It could also present potential challenges to maintaining public confidence. It would be important for these concerns to be taken into account in the development of any new risk tiering approaches.

The Review also identified the need for risk tiers within the Scheme to be sufficiently flexible to accommodate new information. Stakeholders noted that, should information about new risks become known, the Scheme needs to be flexible enough to impose additional regulatory requirements quickly. Conversely, where a body of evidence is accumulated that shows that existing regulatory requirements are no longer needed, the Scheme should be able to quickly remove requirements that are no longer evidence-based (for example, by moving the dealing into the exempt dealing category).

*In order to 'future proof' the Scheme, the Review found that a body of work should be undertaken to review existing risk tiering approaches, with the view to developing a contemporary risk proportionate approach. This would identify the most appropriate risk tiers and the types of regulatory treatment applied to each tier.*

*This then provides a way to move towards future proofing the Scheme, by implementing policy decisions and mechanisms to allow the Regulator to more appropriately regulate well understood activities (by not imposing unnecessary regulatory burdens when this is not justified on a risk basis), and likewise ensure that any newly identified risks are regulated to an appropriate level.*

*Where appropriate, flexibility to move organisms between categories, based on a history of safe use, or the identification of new risks or other relevant factors, should be considered. Any changes should aim to ensure the level of regulation remains proportionate with risk and protects against both under-regulation or over-regulation.*

**Recommendation 9:** The Review recommends the introduction of additional risk tiering into the Scheme, to facilitate flexibility of the regulatory Scheme, and ensure:

- a) the level of regulation remains proportionate to risk, and protects against underregulation and over-regulation; and
- b) where appropriate, there is flexibility to move organisms between categories, based on identification of new risks, a history of safe use, or other relevant factors.

## Streamlining regulation

The Scheme aims to regulate in a manner that is commensurate with the level of risk posed by the activity being undertaken. This includes potential risks associated with where, how and what work is undertaken. The Scheme imposes regulatory requirements in the following broad areas:

- **Organisation accreditation** – assessment of organisations undertaking licensed dealings, to evaluate resources and internal processes to effectively oversee work with GMOs.
- **Facility certification** – certain work with GMOs must only be undertaken in facilities that are certified by the Gene Technology Regulator (the Regulator).
- **Level of regulatory oversight** – every dealing with a GMO needs to have an appropriate authorisation: for example, a licence, a Notifiable Low Risk Dealing (NLRD)<sup>60</sup> risk assessment by an IBC<sup>61</sup> or it needs to meet the definition of an exempt dealing, each of which correspondingly impose different requirements (including containment levels and transport requirements).
- **Monitoring and inspection** – facilities and field trial sites are subject to OGTR monitoring activities.

Throughout the Review process, stakeholders identified a range of areas where current regulatory requirements could be streamlined, especially in the areas of facility certification and level of regulatory oversight.

Some stakeholders expressed concerns that some streamlining activities could equate to reduced protections or an unacceptable level of deregulation. However, the Review notes that streamlining of current requirements would need to be risk based and be supported by an appropriate body of evidence.

The OGTR is well placed to consider the streamlining suggestions received from stakeholders during the Review (detailed below), and to provide advice to Australian Governments as to whether they are appropriate and feasible.<sup>62</sup> In doing so, it will be important to consider whether the proposed changes are commensurate with risk, whether there are any compliance implications, and the capacity of IBCs to take on additional roles.

In assessing the proposals, consideration should be given to whether any of the benefits sought could be achieved through other elements of this Review. For example, if additional risk tiering is introduced into the Scheme, some of the subsequent application processes may be streamlined, leading to reduced application assessment timeframes. Another overarching measure, which may be able to address many of the streamlining proposals received, could be the introduction of an IT solution for application submission and assessment.

### IT solutions

The physical application process (both for facility certification applications and licence applications) was identified as a key area of the Scheme that would benefit from streamlining. A number of stakeholders have suggested that application processes could be improved through the use of an electronic submission and real-time tracking process.

An electronic submission process could also be used to facilitate reporting requirements and the sharing of information between regulatory agencies (so that the same information or data packages need not be provided multiple times to different agencies).

In order to implement digital application management and data capture, resources (including funding, staffing and infrastructure) would need to be made available to the OGTR for this purpose.

60 NLRDs are activities with GMOs undertaken in containment (i.e. not released into the environment) that have been assessed as posing low risk to the health and safety of people and the environment, provided certain risk management conditions are met. The types of GMOs and activities classified as NLRDs are specified in the Regulations.

61 An IBC is the committee established in accordance with written guidelines issued by the Regulator under section 98 of the Act. IBCs assist organisations working with GMOs by advising on the identification and management of the risks associated with dealings with GMOs undertaken by the organisation, including the containment of the GMO and providing an interface with the OGTR.

62 As per section 27 (g) (ii) of the Act, a function of the Regulator is to provide advice to the Forum about the effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation.

## Stakeholder streamlining proposals

Proposals received from stakeholders for streamlining (which may or may not be addressed through the above discussed mechanisms) are outlined in Table 1:

**Table 1: Stakeholder streamlining proposals**

Category	Stakeholder streamlining proposals
Facility certifications	<ul style="list-style-type: none"> <li>Enabling IBCs to grant conditional approval for PC1 and PC2<sup>63</sup> facilities prior to formal certification by the OGTR, or devolving PC1 and PC2 facility certifications to IBCs.</li> <li>Accrediting individuals to undertake certification inspections and provide provisional facility certifications.</li> <li>Recognising pre-existing quality systems as a surrogate for certifications.</li> </ul>
Facility certification extensions	<ul style="list-style-type: none"> <li>Introducing an automated process for facility certification extensions.</li> <li>The OGTR providing provisional approval (short assessment timeframe) for PC1 and PC2 facility certification extensions, or introducing greater responsibility for IBCs to manage suspension and reinstatement of facility certifications.</li> <li>Enabling facility certification to be provided following an organisational statement of which conditions have been met.</li> </ul>
Notifiable Low Risk Dealings (NLRD)	<ul style="list-style-type: none"> <li>Allowing IBCs to extend NLRDs where there is no change in risk level.</li> <li>Removing the requirement for new NLRD numbers to be issued when NLRDs are varied.</li> <li>Amending NLRD reporting requirements so that organisations report to their IBC, rather than the OGTR.</li> </ul>
Dealings Not involving Intentional Release (DNIR)	<ul style="list-style-type: none"> <li>Introducing an automatic approval system for DNIR extensions where there are no changes to the licence conditions.</li> <li>Reviewing the DNIR assessment timeframes (particularly for extensions).</li> <li>Devolving DNIR authorisations to IBCs.</li> <li>Extending the maximum length of dealing approval.</li> </ul>
Dealings involving Intentional Release (DIR)	<ul style="list-style-type: none"> <li>Redesigning the DIR application form for clinical trial applications.</li> <li>Devolving some DIR authorisations (small scale field releases of well-studied crops) to IBCs.</li> </ul>
Classification levels	<ul style="list-style-type: none"> <li>Reviewing the current classification levels for a number of organisms.</li> </ul>
Harmonisation	<ul style="list-style-type: none"> <li>Harmonising OGTR dealing (DNIR and DIR) inspections and certified facility inspections.</li> <li>Harmonising OGTR and Department of Agriculture and Water Resources facility certification inspections.</li> <li>Adopting the Australian/New Zealand Standards as a benchmark for certifying facilities.</li> <li>Standardising OGTR, Therapeutic Goods Administration (TGA), National Health and Medical Research Council (NHMRC) and International Air Transport Association transport (labelling) requirements.</li> </ul>

63 PC1 and PC2 are levels of physical containment (PC). There are four levels of physical containment applied to facilities certified by the Regulator. These are arranged in order of ascending stringency of containment requirements, which reflect the level of risk involved in the dealings that can be undertaken at each level. The four levels are PC1, PC2, PC3 and PC4.

## Confidential Commercial Information

In addition to the opportunities for streamlining identified by stakeholders, the Review has also identified an opportunity for current Confidential Commercial Information (CCI)<sup>64</sup> provisions within the Act to be streamlined.

Currently, the time-consuming assessment of applications for the protection of CCI does not have its own statutory timeframe (or stop-clock mechanism until the point of decision-making), which risks the statutory timeframe for a licence application assessment not being met. CCI declarations have no expiry date, meaning that information that has been previously declared as CCI may retain the need to be protected (and retain the corresponding high penalties for disclosure), even if this level of protection is no longer justified. This has the potential to introduce inefficiencies into the Scheme.

The Review considers that there would be merit in the OGTR undertaking a body of work to identify the most appropriate mechanism to ensure that CCI applications do not risk the efficient and effective assessment of licence applications, or unnecessarily risk inadvertent disclosure of CCI. This work could include consideration of amendments to the Act to:

- allow for additional assessment time for applications that include CCI (for example, up to an additional 30 days); or
- introduce a stop-clock which would pause the statutory timeframe for licence application assessments while CCI matters were being clarified with the applicant; or
- require applications for CCI to meet certain requirements before the Regulator commences assessing a licence application; or
- introduce an expiry for CCI declarations if there is no further need for information to have CCI protections.

*The Review agreed that there are a number of opportunities to streamline current regulatory requirements, such as through the introduction of IT and other solutions across a range of areas, including facility certifications, application processes, classification levels, harmonisation of requirements and Confidential Commercial Information assessment timeframes.*

*This will help to introduce operational efficiencies for the Regulator, reduce unnecessary regulatory burden for stakeholders, and help to improve the operation of the Scheme and legislation.*

*The Review notes that streamlining of current requirements would need to be risk based, supported by an appropriate body of evidence, assess whether there are any compliance implications, and assess the capacity of any identified organisations (e.g. IBCs) to take on additional roles.*

**Recommendation 10:** The Review recommends reducing regulatory burden through streamlining processes and current regulatory requirements where appropriate. For example this may include streamlining facility certifications and application processes.

64 Confidential Commercial Information (CCI) means information declared by the Regulator to be CCI under section 185 of the Act. A person who supplies information to the Regulator as part of a licence application (or other application, notification or submission) may apply to the Regulator for a declaration that certain information is CCI. If the Regulator declares information to be CCI it must not be released publicly.

## Operation of the GMO Register

In Australia, all dealings with GMOs are prohibited unless they are appropriately authorised. Authorisation may be given by the granting of a licence, the classification of a dealing as an NLRD or Exempt Dealing,<sup>65</sup> or through other categories introduced into the Scheme as discussed in [Recommendation 9](#).

The GMO Register (the Register) is a list of dealings that the Regulator has determined poses minimal risk to the health and safety of people or the environment. It provides an alternative mechanism for dealings with certain GMOs to be authorised. Dealings with organisms listed on the Register are not required to be covered by a licence.<sup>66</sup> Because the Register only includes organisms assessed as being very low risk (e.g. a change of colour in flowers), it provides a mechanism within the regulatory Scheme to regulate certain GMOs, while not requiring any specific authorisation for their dealings. This may enable the Regulator to dedicate resources to events with higher levels of uncertainty, or higher risk organisms.

As of August 2018, there was only one dealing included on the Register (the commercial scale release of four lines of colour modified GM carnations) despite the Register being in operation since the inception of the Scheme. The Review noted a number of potential impediments to entering GMOs on the Register that may prevent the Register from being used effectively within the Scheme.

### Requirement for a dealing to have been authorised by a licence before being included on the Register

Dealings must generally have first been authorised by a licence before being eligible for inclusion on the Register.<sup>67</sup> For a licence to be granted there needs to be a licence applicant, and thus the Regulator is unable to enter a dealing on the Register where there is no licence applicant. This requirement may be an impediment to entering GMOs on the Register in cases where it may be beneficial.

For example, a situation could arise in which specific colour modified GM carnations are listed on the Register and the developer produces a new GM carnation with the same inserted genes. Under the current system, this new variety would need to be licensed before it can be added to the Register, even though the risks of the GM inserted genes have been assessed previously.

A possible solution could be to give the Regulator the power to undertake a risk assessment of the new GMO prior to entering it on the Register, without requiring this to be part of a licence application. If the new GMO was assessed as having no (or manageable) risks to human health and safety and the environment, the Regulator could add the new GMO to the Register, legalising dealings of the new GMO. Introducing mandatory public consultation prior to entry on the Register as part of this process could also be considered.

The Review noted that if the OGTR was to move to a cost recovery model (see [Recommendation 22](#)), consideration would need to be given to how such risk assessments (i.e. Regulator initiated risk assessments not linked to a licence application) would be funded.

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65 Authorisations can also be granted through the making of an Emergency Dealing Determination, which gives the responsible Minister the power to expedite an approval of dealings with a GMO in an emergency (refer to sections 72A-72E of the Act). However, this type of authorisation can only be used in limited circumstances.

66 Section 78 of the Act provides for the Regulator to determine that a dealing with a GMO may, by legislative instrument, be included on the Register. The effect of a GMO dealing being included on the Register is that anyone can conduct the dealing, as authorised by the Register, without requiring a licence or other authorisation under the Act.

67 Note that there are some circumstances in which a dealing with certain GM products may be added to the Register without first being authorised by a licence, as outlined in section 78(1)(b) of the Act. However, this alternative pathway to add a dealing to the Register has never been used.

## Requirement for the Regulator to make a legislative instrument to include a GMO on the Register

The Review identified there is benefit in considering whether the current mechanism for entering a dealing on the Register is an impediment to effective use of the Register, and how this process might be improved. Currently, to add a GMO to the Register, the Regulator must make a legislative instrument which is tabled in Parliament and subject to disallowance.

There are a number of factors related to this requirement which may not necessarily be commensurate with risk, including that:

- this is an administratively onerous process, requiring a long implementation timeframe, which reduces the agility and responsiveness of the Register processes;
- adding GMOs to the Register becomes dependent on the Parliament having the time to table and potentially debate the legislative instrument; and
- this introduces the risk of factors other than human health and safety and the environment coming into play.

With these factors in mind, the Review found that consideration should be given to removing the requirement for the Regulator to make a legislative instrument to add a GMO to the Register. An alternate process could be implemented by which the Regulator may add GMOs to the Register on their own undertaking. There are already other checks and balances in place to ensure GMOs are added to the Register appropriately, including that:

- under the Act, the Regulator may only add GMOs to the Register if the risks they pose are minimal and can be adequately managed;
- when assessing whether the risks posed are minimal and can be adequately managed, the Act requires the Regulator to consider a range of information including any data about adverse effects and other risk information;
- any GMO proposed to be added to the Register will have been through the OGTR's accountable and robust risk assessment processes, prior to dealings with the GMO being authorised by a licence or other mechanism; and
- any decision made by the Regulator is subject to merit and judicial review rights.

If the requirement to make a legislative instrument was removed, further internal transparency and accountability mechanisms could also be introduced to the process for adding GMOs to the Register, if deemed necessary.

This could include requiring the Regulator to consult with states and territories and the public when proposing to include a new GMO on the Register.

Improving the process by which the Regulator can add GMOs to the Register would also be beneficial in cases in which a licence is surrendered. A situation could arise where a GMO persists in the environment long after it ceases to be commercially sold. The licence holder may no longer wish to sell the GMO commercially, so applies to surrender the licence. However, this would result in any dealings with the GMOs already existing in the environment becoming illegal, without any risk basis for this change.

A GMO dealing becoming illegal may give rise to the perception that there is a new risk to human health and safety and the environment, which is not supported by fact. Giving the Regulator access to a more efficient mechanism to enter the dealing on the Register (if appropriate from a risk perspective) could remove this misconception, increase public confidence and prevent unnecessarily rendering a dealing illegal.

*In conclusion, the Review noted the GMO Register provides an alternative mechanism for authorising dealings with certain GMOs that the Regulator has determined pose minimal risk. Being low risk, GMOs listed on the Register do not require a licence. As such, the GMO Register can reduce the regulatory burden for the lowest risk organisms, and/or organisms with a safe history of use, and enable the Regulator to concentrate resourcing on higher risk organisms.*

*However, it can be difficult to add organisms to the Register. For example, additions currently require legislative instruments to be passed through Federal Parliament and ultimately gain royal assent. The high*

*level of regulatory effort and scrutiny is not commensurate with the level of risk posed by an organism that is deemed to be of the lowest level of risk.*

*Where a licence is surrendered on an organism with a safe history of use, the organism could also be added to the Register as a way of managing low risk organisms without a resource intensive licensing requirement.*

*The Review heard that changes could be made to enable the GMO Register to be more effectively utilised within the Scheme. In progressing any changes, consideration could be given to whether:*

- *the requirement for a dealing to have been authorised by a licence before being included on the GMO Register should be removed; and*
- *an alternative mechanism for adding dealings to the GMO Register should be introduced that is more time and resource efficient, and better reflects the level of risk than the current system requiring a disallowable legislative instrument.*

*The Review found a number of possible changes that will improve the functionality of the GMO Register and serve to enhance the Scheme. The most effective options to deliver this outcome can be further examined as part of the action plan.*

**Recommendation 11:** The Review recommends that changes be made to enable the GMO Register to be more effectively utilised within the Scheme.

## Accessibility and managing new potential harms

Gene technology is undergoing a period of rapid development at present. New genetic modification tools are more precise, targeted, and easy to use. The entry costs for undertaking genetic modification research have also lowered considerably. These factors have raised concerns for some stakeholders regarding safety and potential misuse. Gene technology has shifted from being solely the remit of universities, research institutions and large companies, to now being accessible to ‘community-based citizen scientists’.<sup>68</sup>

For example, at the time of the Review’s consideration several ‘DIY biology’ kits were available for purchase via the internet.

Stakeholders raised concerns that the accessibility of genetic modification tools to the general public increases the likelihood of unlicensed experimentation, and with this, safety concerns arise regarding accidental or intentional misuse.

The use of gene technology is prohibited unless authorised under the Act, or specifically exempted by the Regulations. Even lower risk experimentation has requirements to be undertaken within a certified containment facility. There are criminal penalties within the Act for breaches of these requirements. These requirements apply to everyone working with GMOs, including ‘DIY-biologists’.

However, the democratisation of science and the movement of gene technology from traditional academic institutions to the public is something the Scheme was not initially designed to regulate.<sup>69</sup> The Review found it would be beneficial for the Regulator to ensure that gene technology regulatory requirements are widely known, ensure good risk

68 Citizen Science involves the democratisation of science research and the public in scientific research – whether community-driven research or global investigations. For examples of this movement see Citizen Science’s website. Retrieved July 10, 2018, from <http://www.citizenscience.org/>. Also see Biofoundry’s website. Retrieved July 10, 2018, from <http://www.foundry.bio/>

69 This issue is not unique to Australia, with the ubiquity of the technology posing issues for governments around the world. See Kuiken, T. (2016). *Governance: Learn from DIY biologists*, Nature 531, pp. 167–168. Retrieved July 10, 2018, from <http://www.nature.com/news/governance-learn-from-diy-biologists-1.19507>; National Academies of Sciences, Engineering, and Medicine. (2017). *Dual Use Research of Concern in the Life Sciences: Current Issues and Controversies*, Washington, DC: The National Academies Press, p. 24, <http://dx.doi.org/10.17226/24761>



management practices are followed, and to provide guidance to the DIY biology community on responsible research. Effective and targeted public communication to aid public understanding, discussed further in [Recommendations 23 and 24](#), is crucial to ensuring all people using gene technology are doing so safely and responsibly.

The Review found there is benefit to quantifying the scope of activity of the DIY biology community and working with that group to facilitate transparency, information flow, and encourage the development of community Codes of Practice and IBCs. Moreover, the Regulator should be appropriately resourced to ensure community-based use of gene technology can be adequately monitored and compliance and enforcement activity can take place as required.

*The Review identified opportunities for further work to be undertaken to quantify the scope of ‘DIY biology’ activity, ensure that regulatory requirements are widely known, and to further investigate whether current monitoring and enforcement activities are appropriate for all sectors of the Scheme.*

*The entry of more entities, of all sizes, into the gene technology research sector should be welcomed, as this might be expected to spur innovation and help to build scientific, technical and medical research capability. However, the incidence of any non-complying gene technology research would be likely to have a damaging impact on public confidence in the Scheme.*

**Recommendation 12:** The Review recommends that, to ensure the Scheme’s current monitoring and enforcement activities remain adequate:

- a) regular reviews of these activities are undertaken;
- b) regulatory requirements for working with gene technologies are widely communicated and known; and
- c) the scope and associated risks of ‘DIY biology’ activity continue to be monitored.

## Future-proofing regulation and principles based regulation

Many stakeholders acknowledged the advantage of the existing legislative and governance arrangements for the Scheme, in providing full regulatory coverage of gene technology across Australia. These arrangements, however, while appropriately rigorous, lack the agility needed to keep pace with the advances in technology.

Stakeholders agreed technological advances are a constant, and that future developments in gene technology are likely. Scientific techniques are being developed faster than the Scheme is reviewed and changes legislated.

Regulation needs to provide guidance and certainty to researchers working with rapidly changing technology, especially when their work is not referenced in legislation.<sup>70</sup> A number of stakeholders cited the inability to rapidly amend the scope of regulation as an impediment to the Scheme’s ability to flexibly adapt to technological advances. They requested mechanisms to increase the responsiveness of regulation.

Stakeholders provided two general solutions to this problem:

- more frequent reviews, scoped to specifically target changes in technology; and
- increased provision for principles-based regulation.

### More frequent technical reviews

It was acknowledged that five yearly intervals are appropriate for major reviews. However, the pace of changes in gene technology over the last few years has been exceptional. The Review found that more regular technical reviews of the regulatory scope (including regular reviews of exemptions) could be conducted. However, review frequency would need to be balanced with resourcing implications.

<sup>70</sup> For example, when a researcher’s work is not explicitly referenced within Schedule 1 and 1A of the Regulations.



There was varying opinion over the scope, governance and timeframes for such reviews. Some stakeholders expressed the view that:

- appropriate intervals for targeted technical reviews were between one and three years, with many settling for biennial reviews;
- the Regulator could be responsible for initiating and conducting such reviews;
- the Gene Technology Technical Advisory Committee (GTTAC) could be enabled to do an assessment of emerging technologies and empowered to trigger a review of the Regulations; or
- certain decisions could be delegated from the Legislative and Governance Forum on Gene Technology (the Forum) to the Gene Technology Standing Committee (the Standing Committee).

Section 27 of the Act enables the Regulator to provide advice to the Forum about 'the effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation'. It also enables the Regulator to commission research into the biosafety of GMOs. Section 101 of the Act provides for GTTAC to provide scientific and technical advice on GMOs, gene technology or the biosafety aspects of gene technology.

Arguably these provisions include the ability to instigate and conduct periodic review of advances in gene technology (noting the funding implications of more frequent reviews – see [Recommendation 22](#)). However, existing provisions do not address stakeholder concerns regarding the timeframes for implementation. The 2011 Review found that the Regulations enable the inclusion or exclusion of technologies in the Scheme through Schedules 1 and 1A.<sup>71</sup> However, the process for amending the Regulations is complex and not time efficient. In practice it can take up to eighteen months to implement.

One solution would be for such amendments to be excised from the Regulations and given the status of operational policy. This could enable timely amendments to the Regulations, but removes national oversight. While it may be appropriate for the Regulator to instigate and potentially conduct a review of any technological advances, the federated nature of the Scheme, and need for national coverage, mean it may be preferable for parties to the Agreement to maintain responsibility for any binding decisions.

Another approach that would introduce greater agility to the Scheme, future proof it, and streamline processes to make the Scheme sufficiently flexible, could be to enable the Regulator to make interim decisions to clarify the applicability of existing regulation to any technological developments. These decisions could be reflected in the Regulations, until such times that they are included in legislation (for example following a major policy cycle review or an interim technical review). This solution provides certainty of scope to regulated entities in a time appropriate manner, while still maintaining appropriate governance and oversight. As an example, where the definitions in the Act do not cover a future development, the Regulator may make a decision that the definition does apply, until there has been proper consideration and consultation to determine if legislative amendment is required.

## Principles-based regulation

Some stakeholders expressed the view that advances in technology are outpacing any rules-based legislative system's ability to respond in a timely manner. Principles-based regulation is an option to be considered to address this situation. Principles-based regulation sets out more general, higher-level rules and principles for entities to observe, focusing more on outcomes than specifying the process of how outcomes should be achieved.<sup>72</sup> It is less detailed and prescriptive than a rules-based regulation approach, and thus can potentially enable greater regulatory flexibility and future-proofing.<sup>73</sup>

71 Schedules 1 and 1A of the Regulations specify organisms that are not considered GMOs and techniques that are not considered to be gene technology under the legislation.

72 Black, J., (2007). 'Principles based regulation: risks, challenges and opportunities', in *Principles Based Regulation*, Sydney, Australia; Sparrow, M., (2008). *The Character of Harms: Operational Challenges in Control*, Cambridge University Press: Cambridge.

73 According to the OECD: 'principle based legislation is likely to be the most appropriate way of meeting policy objectives in complex or rapidly changing fields'. Organisation for Economic Cooperation and Development. (2012). *Best Practice Principles for the Governance of Regulators, Chapter 1: Role Clarity*, p. 31. Retrieved July 10, 2018, from <http://www.oecd.org/gov/regulatory-policy/governance-regulators.htm>

Principles-based regulation has the potential to allow for more outcomes-based regulation and flexibility; for example, general principles could be applied to advances in gene technology. However, it is also important for regulated entities to have clarity and certainty and for the public to have confidence in the Scheme. Therefore, some degree of rules-based regulation is often preferred.

While some stakeholders showed an interest in principles-based regulation, only a few suggested concrete areas in which it could be utilised within the Scheme. Some stakeholders suggested that application of principles-based regulation would not provide certainty for the public, describing it as a ‘trust me’ form of regulation that is more likely than rules-based regulation to require court adjudication of different interpretations.

Any implementation of this approach would require active guidance and standard setting in the early stages, as stakeholders adjust. Some stakeholders expressed some concern over the ability of the Scheme to accommodate a principles-based approach. Others expressed a preference for such an approach to be trialled in applicable areas of the Scheme (such as plants with a safe history of use).

The Review found there may be scope to introduce elements of a principles-based approach to some parts of the Scheme. The Review found that this would be most appropriately applied, in the first instance, to mature areas of the Scheme with significant evidence to demonstrate a history of safe use.

## Reaffirmation of the Gene Technology Standing Committee

The Gene Technology Standing Committee (the Standing Committee) is an advisory committee of senior officials from state and territory portfolio departments, reporting to Legislative and Governance Forum on Gene Technology (the Forum) Ministers. The Standing Committee supports the Forum in fulfilling its functions and facilitating the implementation of its decisions. The Standing Committee is not currently a formally recognised committee under the Act.

Given the desire to both increase the agility of the Scheme and maintain appropriate oversight structures, the Review found there may be benefit in reaffirming and leveraging the role of the Standing Committee. The Standing Committee was established under the authority of the ministerial body around the time the Scheme began.

The Review notes that the Standing Committee supports the Forum by providing high level policy and technical support (see [Recommendation 14](#)). While the Standing Committee is not formally recognised in the Act, Regulations, or Agreement, the Forum may delegate administrative, operational and policy development functions to this group. These arrangements could be formalised by developing a Standing Committee work program in consultation with jurisdictions, through the Forum.

The Standing Committee endorsement of certain activities would maintain appropriate national governance oversight structures, whilst increasing the agility of the Scheme to respond to changes in its environment.

*The Review considered that there is a need for increased flexibility within the Scheme, to enable it to appropriately respond to changes in the scientific understanding of gene technology (notably including its definitions), and an understanding of its risks.*

*Options to increase this flexibility include delegating to the Standing Committee, the ability to progress inconsequential amendments to the Act; or for the Regulator to undertake more frequent reviews, scoped to target specific changes in technology. Such regulations should be investigated further, and be subject to administrative and legal considerations. The Review considers that in this way there is scope to increase the agility of the Scheme, while maintaining appropriate oversight measures.*

*Enhancing the response capacity of the Scheme may deliver greater scope for the Regulator to meet the needs of industry and the community in a more adept and timely manner, while being consistent with the principles of best practice regulation.*

**Recommendation 13:** The Review recommends that to better respond to changes in scientific understanding and understandings of risk, consideration should be given to:

- a) enabling the Gene Technology Regulator to make decisions on the applicability of regulation to any technological developments, until such time as a policy approach has been agreed; and
- b) introducing elements of principles-based regulation to some parts of the Scheme, focusing on areas of the Scheme with a history of safe use.

**Recommendation 14:** The Review recommends reaffirming and clarifying governance arrangements to increase the agility of the Scheme, including more effective use of mechanisms for:

- a) the Gene Technology Standing Committee to consider and recommend changes to the legislation for the Legislative and Governance Forum on Gene Technology endorsement; and
- b) delegating certain activities and work programs of the Legislative and Governance Forum on Gene Technology to the Gene Technology Standing Committee.

## Market access and international trade

The Review noted the importance of market access for producers and exporters of Australian products, including GMOs. Stakeholders representing the producers and exporters of grain and oilseeds highlighted the fact that the Australian industry relies on overseas markets for their prosperity. Agricultural advocates expressed support for the right of the individual farm businesses to use the production system of their choice, be that organic, conventional, or the integration of GM crop or pasture varieties.

Stakeholders identified the key factors affecting market access and international trade of GMOs:

- asynchronous GMO authorisations;
- importing countries maintaining 'zero tolerance' policies for GMOs not approved in that country;
- segregation of GM, conventional and organic products; and
- time and resources required to navigate the regulatory approval process.

### Asynchronous approvals

An importing country will generally not accept a GMO or a product derived from a GMO unless the GM trait has been approved by regulators in that jurisdiction. Some stakeholders to the Review are involved in regulatory approval processes in a number of overseas jurisdictions. They provided evidence of the delays and difficulties that can arise when seeking multiple approvals of a GM trait, in different countries.

It was suggested that some developers of GM traits in crop plants do not release these new varieties for commercial propagation until they have achieved regulatory approval in key importing countries. This presents a particular hurdle for small scale enterprise and publicly funded research organisations. Stakeholders proposed that harmonising approvals of GM traits with international trade partners would minimise legal uncertainty and serve to minimise the chance of trade disruptions.

## Low Level Presence and ‘zero tolerance’ policies

Low Level Presence (LLP), or adventitious presence, refers to trace amounts of an approved GMO (for example, a GM grain variety), becoming accidentally mixed with a non-GM grain variety. The Primary Industries Ministerial Council (PIMC), an intergovernmental body, specified adventitious presence thresholds for Gene Technology Regulator approved GM canola of 0.9 per cent in non-GM canola grain and 0.5 per cent in non-GM canola seed-for-sowing.<sup>74</sup> These thresholds for canola seed and grain were adopted in 2005 by Australian states and territories.<sup>75</sup> These thresholds are also agreed nationally by the Australian seed and grain industries.

Stakeholders also identified the related issue of countries maintaining a zero tolerance<sup>76</sup> for LLP of GMOs unapproved in the importing country (sometimes occurring because of asynchronous approval timetables).<sup>77</sup> The Review acknowledged that analytical testing of a strictly ‘zero-presence’ level is not always possible as detection will always be limited by the sensitivity of the test methods used, by the number of samples taken and the number of seeds analysed per sample.

Stakeholders noted that peak body representatives of the grain industry are active internationally, seeking to coordinate policy and trade standards with traders and importers of bulk grain to address this issue. The Review also noted ongoing Australian Government involvement, including the Gene Technology Regulator on regulatory matters, in this area.<sup>78</sup> LLP is discussed further in [Recommendation 15](#).

## Product segregation

A number of stakeholders involved in the supply of organic food and food products cited concerns regarding the potential impact on organic production or supply chains, due to the commercialisation of GM crops. Conversely, grain handling companies informed the Review that their business models involve the delivery of grain storage and handling services that provide segregated grain, including GM, non-GM or organic. They maintained that they are capable of delivering segregated product to overseas markets.

The Review notes that this matter was considered in the *Productivity Commission Inquiry Report: Regulation of Australian Agriculture* (2017),<sup>79</sup> which found that ‘the successful coexistence of GM and non-GM crops is possible and has been demonstrated both in Australia and overseas.’ The Productivity Commission also found that industry codes of practice and stewardship programs that included crop buffer zones and best practice could deliver co-existence. The Review noted, however, that product segregation is a contentious issue and that the Productivity Commission’s findings were not supported by some stakeholder groups.

In considering the above issues, the Review found strong support for the Australian Government remaining active in appropriate government level policy and regulatory fora, including the World Trade Organization (WTO) and the Global Initiative on Low Level Presence. Wherever possible, the coordination and harmonisation of policy positions and regulatory approval processes should be sought.

74 National Measurement Institute. (2008). *Maintaining product integrity in the Australian seed and grain supply chain – the role of sampling and testing for GM events*, Retrieved July 10, 2018, from [http://www.agriculture.gov.au/SiteCollectionDocuments/ag-food/biotech/for\\_printing\\_gm\\_sampling\\_and\\_testing.pdf](http://www.agriculture.gov.au/SiteCollectionDocuments/ag-food/biotech/for_printing_gm_sampling_and_testing.pdf)

75 Excepting Queensland, Tasmania and the Northern Territory.

76 Australia maintains a zero tolerance for non-approved LLP in imported product.

77 Asynchronous approval timetables refer to the different approval timeframes of different countries to assess and approve a GMO to be released into the environment.

78 The Review notes the following Australian government activities in this area: International Statement on Low Level Presence and Joint statement on innovative agricultural production technologies, particularly plant biotechnologies. See Department of Agriculture and Water Resources, *International Statement on Low Level Presence*. Retrieved July 10, 2018, from <http://www.agriculture.gov.au/ag-farm-food/biotechnology/international-statement-low-level-presence> and Department of Agriculture and Water Resources, *Joint statement on innovative agricultural production technologies, particularly plant biotechnologies*. Retrieved July 10, 2018, from <http://www.agriculture.gov.au/ag-farm-food/biotechnology/ag-production-technologies>. The Review also notes Codex guidance in relation to ‘Food safety assessment in situations of low-level presence of Recombinant-DNA plant material in food’ (Annex 3 to the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants 2008). See Codex Alimentarius. (2008). *Food safety assessment in situations of low-level presence of Recombinant-DNA plant material in food’ guidelines*. Retrieved July 10, 2018, from [http://www.fao.org/input/download/standards/10021/CXG\\_045e.pdf](http://www.fao.org/input/download/standards/10021/CXG_045e.pdf)

79 Productivity Commission. (2016). *Regulation of Agriculture*. Retrieved July 10, 2018, from <https://www.pc.gov.au/inquiries/completed/agriculture/report>

## Regulatory approval process

Some stakeholders stated that small-scale, niche researchers, or Australian owned plant breeding companies, cannot afford to take a product through the regulatory approval process due to the timeframe and budget required to do so. Further, it was put to the Review that researchers of this scale have been placed in the position of having to sell or licence their intellectual property to an entity with the financial capacity to commercialise the GMO.

It is well established across many industries that Australia is regarded as a small market on a global scale, and some stakeholders to the Review provided examples of GM products safely used in other jurisdictions, but not introduced to Australia for commercialisation. The time and resources required to navigate the regulatory approval process was cited as providing poor incentive to do so, when there is little prospect of a commercial rate of financial return.

The Review recognised the need for appropriate levels of well-targeted regulation for these stakeholders, that does not impose unnecessary burdens. Refer to [Chapter 1.3](#) for additional discussion on risk tiering and the appropriate level of regulation for environmental releases.

## Cartagena Protocol on Biosafety

The Review additionally found some stakeholder support for Australia to ratify and be compliant with the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The Review noted that ratification of appropriate international agreements is an ongoing body of work for the Australian Government. Consideration of Australia's position with respect to the Cartagena Protocol on Biosafety will be determined as part of usual governmental processes.

## World Trade Organization agreements

Australia has a number of international obligations it must maintain. In particular, Australia has several WTO commitments. A key means for ensuring Australia maintains consistency with these obligations is to ensure any regulatory changes are consistent with international standards, and – if or where these differ – to be able to justify this difference.

For example, two key agreements relevant to international trade are the WTO's Sanitary and Phytosanitary Measures<sup>80</sup> and the Technical Barriers to Trade agreement.<sup>81</sup> While a focus of the current Review is to support innovation, it remains important to balance market access and trade considerations with the need to ensure new GMOs meet Australia's obligations more broadly.

*The Review heard that the Australian Government has an important role in coordinating internationally on matters relevant to market access and international trade. The unimpeded flow of information, and coordinated actions by government agencies and industry, are essential to identifying emerging opportunities for, or potential barriers to, trade, and resolving associated problems for Australian exporters.*

*One of the roles of government is to represent the interests of Australian primary producers and exporters in trade and market access processes. This is a particularly complex issue, with potential gains in productivity existing alongside the risk of foreign regulators creating barriers to the importation of GMO products, or foreign consumers rejecting them because of safety or ethical concerns.*

**Recommendation 15:** The Review recommends that the Australian Government, including the Gene Technology Regulator on regulatory matters, continues to:

- a) engage with appropriate international fora on matters relevant to market access and international trade; and
- b) ensure that any relevant international obligations continue to be met.

80 The SPS agreement is designed to ensure that human and animal life are not endangered by international trade activities, including that a country's consumers are being supplied with food that is safe to eat. See World Trade Organisation, *Sanitary and phytosanitary measures*. Retrieved July 10, 2018, from [www.wto.org/english/tratop\\_e/spse/spse\\_e.htm](http://www.wto.org/english/tratop_e/spse/spse_e.htm)

81 The purpose of the TBT agreement is to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade. See World Trade Organisation, *Technical barriers to trade*. Retrieved July 10, 2018, from [http://www.wto.org/english/tratop\\_e/tbt\\_e/tbt\\_e.htm](http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm)

## CHAPTER 1.4

# Review Theme Three – Governance Issues

The Gene Technology Scheme (the Scheme) was established to align and work with existing regulatory schemes, to address the rapidly developing area of gene technology.

Responsibility for governance oversight, and determining the policy setting of the Scheme, is vested with Ministers in the Commonwealth, state and territory governments (the Legislative and Governance Forum on Gene Technology, known as the Forum). The Gene Technology Regulator (the Regulator) is an independent statutory office holder, who is responsible for administering the *Gene Technology Act 2000* (Cth) (the Act) and corresponding state and territory laws.

The Third Review of the Scheme (the Review) explored the **credibility, integrity and legitimacy of the Scheme** including current legislative and governance oversight, the independence of the Regulator and the operation of the Scheme's advisory committees. Matters related to national consistency across the Scheme were also considered. These include both the mechanisms for applying **corresponding legislation** across the country, and state and territory **moratoria legislation**.

Regulation of gene technology in Australia focuses on potential risks posed by, or as a result of, gene technology and how these risks may be mitigated. Any **potential benefits** which may flow from a GMO are not currently considered in regulatory decision making. The Review considered whether this remains appropriate in a modernised Scheme.

The Review also considered 'benefit' in terms of opportunity cost. That is, whether the current Scheme imposes any **unnecessary regulatory burdens** that may prevent economic and health benefits of gene technology from being realised.

As described above, the Forum is responsible for providing governance oversight and determining the policy setting of the Scheme. The Review considered whether specific topic areas (for example, the release of gene drives into the environment and mechanisms for managing the low level presence (LLP) of GMOs) would benefit from **Forum consideration and policy direction**.

As was also described above, the Scheme was established within the context of existing regulatory schemes, including Food Standards Australia New Zealand (FSANZ), the Therapeutic Goods Administration (TGA), the Australian Pesticides and Veterinary Medicines Authority (APVMA), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Department of Agriculture and Water Resources for Biosecurity Matters. The Review looked at the **interface between the Office of the Gene Technology Regulator (OGTR) and these other regulators**.

Finally, the Review examined the **level of funding** required for the sustainable operation of the Scheme and the most appropriate **funding model to provide this**.

## Credibility, integrity and legitimacy of the Scheme

There is a high level of stakeholder support for the Scheme. The majority of stakeholders see it as well-designed and consider that it remains, at heart, fit for purpose. Many stakeholders expressed confidence in the operation of the Scheme, its governance structures, and the checks and balances in place to ensure the Scheme's integrity.

Notwithstanding the effective design, some stakeholders raised the concern that a number of existing features of the Act and governance structures are underutilised. They contend that these should be used more effectively to capitalise on the full potential of the Scheme.

The Review also recognised that some stakeholders have concerns about the credibility and integrity of the Scheme's governance structures. These stakeholders expressed dissatisfaction with aspects of the Scheme's operation. Some stakeholders stated that they do not have confidence in the independence of the Regulator, or the advice received by the Regulator from advisory committees.



## Legislative and governance oversight

Legislative and governance oversight of the Scheme is achieved through the Forum, which comprises of Ministers with portfolio responsibility for gene technology in their respective jurisdiction (refer [Table 2: Members of the Legislative and Governance Forum on Gene Technology](#)). The core functions of the Forum include:

- issuing Policy Principles, Policy Guidelines and Codes of Practice to govern the activities of the Regulator and the operation of the Scheme;
- approving proposed regulations (with specific exceptions) for the purpose of the Scheme;
- overseeing the implementation of the Scheme; and
- initiating reviews of the Scheme.

**Table 2: Members of the Legislative and Governance Forum on Gene Technology as at August 2018**

Jurisdiction	Minister	Portfolio
Cth	Senator the Hon Bridget McKenzie MP	Minister for Regional Services [including Rural Health and Regional Communications], Sport, Local Government and Decentralisation
QLD	The Hon LEEANNE ENOCH MP	Minister for Environment and the Great Barrier Reef, Science, and the Arts
NSW	The Hon Niall Blair MLC	Minister for Primary Industries, Regional Water, and Trade and Industry
ACT	The Hon Meegan Fitzharris MLA	Minister for Health and Wellbeing, Transport and City Services, and Higher Education, Training and Research
VIC	The Hon Jill Hennessy MP	Minister for Health and Ambulance Services
TAS	The Hon Sarah Courtney MP	Minister for Primary Industries and Water and Minister for Racing
NT	The Hon Ken Vowles MLA	Minister for Aboriginal Affairs, Minister for Primary Industry and Resources, and Minister for Arafura Games
SA	The Hon Stephen Wade MLC	Minister for Health and Wellbeing
WA	The Hon Alannah MacTiernan MLC	Minister for Regional Development, Agriculture and Food, and Minister assisting the Minister for State Development, Jobs and Trade

There is a lack of visibility for some stakeholders about the work program for the Forum, and some stakeholders have contended that the Forum has not always effectively or efficiently discharged some of its duties. This includes the unresolved status of a small number recommendations from previous reviews of the Scheme. These include those that require administrative or legislative amendment to address the national consistency of the Scheme, and the streamlining of some legislative amendment processes

The Review noted that, in some cases, recommendations were not implemented for practical reasons, such as the need for further consideration of resourcing or funding issues, or where subsequent events impacted prioritisation.

Where previously raised issues were identified as still being of concern for stakeholders, these matters, including the reasons why they were not progressed, were considered as part of this current review.

To increase transparency about the 'business as usual' work program, priority activities of the Forum, and their commitment to delivering them, some stakeholders suggested formalising the functions and activities of the Forum through an agreed action plan (refer [Recommendation 1](#)). This would also provide stakeholders with some visibility of expected timeframes to implement any identified reforms, and could highlight where implementation of some reforms were dependent on other work being achieved. Allocating priorities, timeframes, and responsibilities for jurisdictional governments, are therefore seen as important mechanisms for addressing stakeholder concerns.

## Gene Technology Regulator

The Gene Technology Regulator (the Regulator) is an independent statutory role, appointed by the Governor General with the agreement of the majority of all jurisdictions, subject to public and parliamentary scrutiny. The Act clearly defines the functions, powers, independence as well as mandatory consultation arrangements regarding regulatory decision making for the Regulator.

The Regulator is responsible for administering the national regulatory system for gene technology, as set out in the Act and corresponding state and territory legislation. This arrangement balances the appropriate constitutional reach of governments in the structure of legislative arrangements.

The Regulator and the OGTR must comply with all relevant legislation, including the *Public Governance, Performance and Accountability Act 2013*,<sup>82</sup> the *Privacy Act 1988*,<sup>83</sup> the *Freedom of Information Act 1982*,<sup>84</sup> the *Work Health and Safety Act 2011*<sup>85</sup> and the *Public Service Act 1999*.<sup>86</sup>

## Advisory committees

The Act also establishes two advisory committees; the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics and Community Consultative Committee (GTECCC). Committee members are appointed on the basis of their knowledge, skills and experience. As the field of gene technology is a highly specialised area of science, GTTAC and GTECCC members need to have up-to-date expertise relevant to gene technology, and the work of the committees, to perform their roles effectively. This may include having committee members that are currently involved in the diverse research and development fields related to gene technology, including research into, or the development of, GMOs and GM-derived products and applications.

The governance, advisory and consultation structures for the Scheme are depicted in Figure 2: National Gene Technology Regulatory Scheme governance, advisory and consultation structures.

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82 *Public Governance, Performance and Accountability Act 2013* (Cth) (Austl.). Retrieved July 10, 2018 from <http://www.legislation.gov.au/Details/C2017C00269>

83 *Privacy Act 1988* (Cth) (Austl.). Retrieved July 13, 2018 from <http://www.legislation.gov.au/Details/C2018C00034>

84 *Freedom of Information Act 1982* (Cth) (Austl.). Retrieved July 13, 2018 from <http://www.legislation.gov.au/Details/C2018C00016>

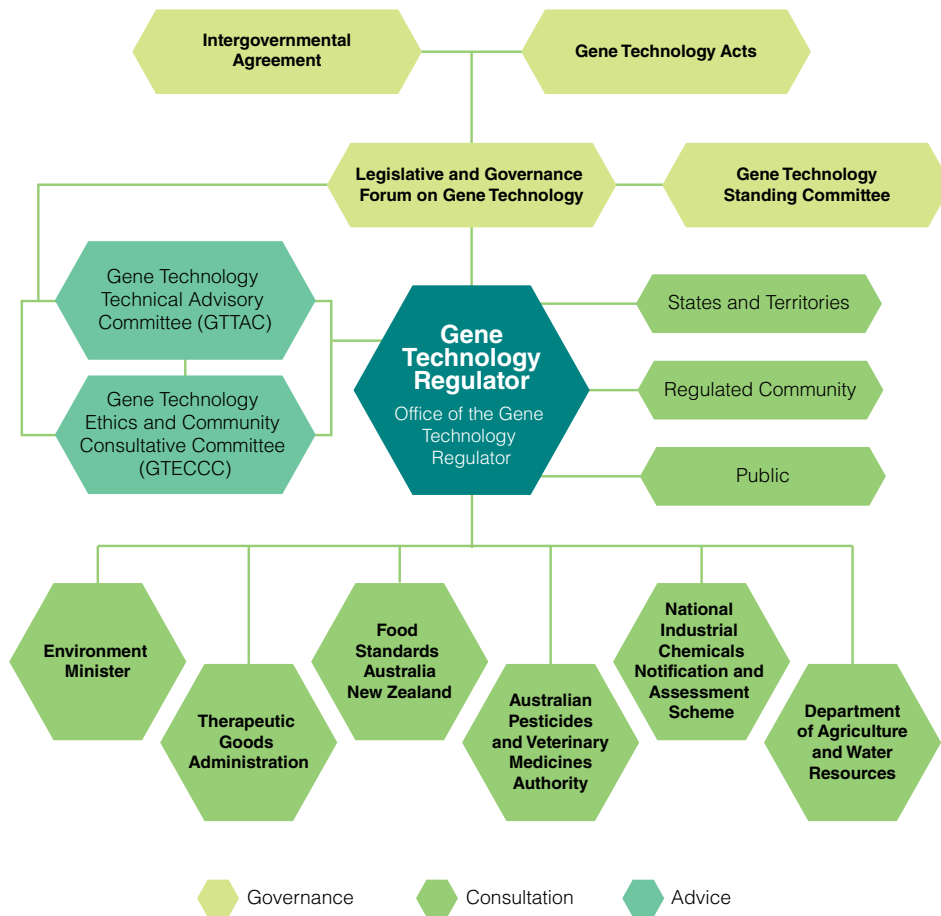
85 *Work Health and Safety Act 2011* (Cth) (Austl.). Retrieved July 13, 2018 from <http://www.legislation.gov.au/Details/C2017C00305>

86 *Public Service Act 1999* (Cth) (Austl.). Retrieved July 13, 2018 from <http://www.legislation.gov.au/Details/C2017C00270>



**FIGURE 2**

National Gene Technology Regulatory Scheme governance, advisory and consultation structures



(Source: OGTR)

Some stakeholders perceived that potential conflicts of interest applying to members on the advisory committees undermines the integrity and credibility of the Scheme and its advisory structures. However, the Review noted that there are appropriate mechanisms in place to manage any potential conflicts of interest. Consistent with best practice governance, clear procedures to deal with potential or real conflicts of interest are specified in The Gene Technology Regulations 2001 (the Regulations). This includes requiring all GTTAC and GTECCC members to declare and disclose the nature of any interests that could be perceived as a possible conflict of interest, on any matter to be considered prior to being appointed. During their appointment, if any conflicts of interest arise, they may be managed by ensuring the member: is not present during discussions; or does not take part in any decisions about that matter.

Further discussion on the transparency and accountability of the Scheme can be found in [Recommendation 27](#).

*The Review found that the operation of the Scheme has been shown to be credible, and that the Scheme operates with integrity and legitimacy. This is evidenced by high level governance oversight provided by all states and territories through the Legislative and Governance Forum on Gene Technology, and the independence and credibility of the Gene Technology Regulator. It is further evidenced by the robust governance processes providing oversight of advisory structures and appointments.*

*The stability and agility of the Scheme is tied to these governance arrangements and the Review concluded that they remain effective and will support the future operation of the Scheme.*

*These arrangements can be optimised and made transparent through a Forum action plan (Recommendation 1), that clearly establishes the government priorities for the Scheme, and demonstrates commitment to maintaining the credible and robust oversight of the Scheme.*

**Recommendation 16:** The Review recommends maintaining current governance mechanisms to ensure that the Scheme's current levels of credibility, integrity and legitimacy are upheld.

This includes maintaining:

- a) high level governance oversight provided by all states and territories through a Legislative and Governance Forum on Gene Technology;
- b) the independence and credibility of the Gene Technology Regulator; and
- c) robust governance processes providing oversight of advisory structures and appointments.

## National consistency of the Scheme: Governance

The constitutional power to regulate gene technology is shared between the Australian Government and state and territory governments. As such, the Gene Technology Agreement 2001 (the Agreement) outlines the provisions and expectations for a nationally consistent Scheme. The Act forms a component of this nationally consistent Scheme, together with the state and territory legislation. This arrangement balances the appropriate constitutional reach of governments and ensures full regulatory coverage for gene technology across Australia.

Legislative consistency benefits government and non-government stakeholders. It forms the basis of the predictability and transparency of decision making and regulatory outcomes across all jurisdictions, and facilitates stakeholders' ability to comply with regulatory requirements. It provides assurances to the public that regulatory protections, through national regulatory coverage, manage risk in the same way across all jurisdictions.

### Corresponding legislation

State and territory gene technology legislation applies to dealings with GMOs by individuals and organisations that are not otherwise covered by the Commonwealth Act, due to limitations of constitutional reach. Once state or territory legislation has been declared corresponding to the Commonwealth Act, the functions and powers of the state or territory legislation are conferred on the Regulator. It is important that state and territory legislation is formally declared to be corresponding, to enable the Regulator to administer this legislation.

### Lock-step or mirroring

Given the existence of multiple pieces of gene technology legislation, stakeholders noted that it is important that they remain consistent. This is especially relevant when the Commonwealth Act is updated. Inconsistency can result in confusion and uncertainty for regulated organisations in terms of which provisions apply. It can also create potential compliance issues for organisations and the Regulator, and may potentially undermine risk management. Legislative inconsistency can also mean that two organisations undertaking similar work with GMOs, within a given jurisdiction, would be subject to different regulatory requirements, depending on which legislation applied to them.

Some jurisdictions (New South Wales, Northern Territory, Queensland, and Tasmania) have adopted the applied laws approach, where amendments to the Commonwealth Act are applied through an automatic procedure. This is referred to as 'lock-step'. A 'lock-step' approach avoids any periods of inconsistency before amendments to the Commonwealth legislation are incorporated into state or territory legislation.

Other jurisdictions (Victoria, South Australia and the Australian Capital Territory) have adopted a mirror approach. This is where the state or territory amends their legislation to mirror the changes that have been made to the Commonwealth legislation.

For this to occur, an amendment is introduced into the state or territory Parliament, allowing the Parliament to consider and debate any changes and decide on how to implement them. In practice, this manual amendment process is resource intensive, with statutory consultation requirements, and tabling of legislation dependent on jurisdiction parliamentary priorities. As such, the mirroring approach can also lead to a temporary lapse in national consistency during the period between the Commonwealth Act being updated and the corresponding state or territory amendment legislation being passed. The unintentional non-consistency creates risk related to regulatory coverage.

*The Review heard that ensuring national consistency of the Scheme is valued, and that maintaining consistency between all state and territory Acts and the Gene Technology Act 2000 helps provide certainty for stakeholders in relation to current regulatory requirements.*

*In addition to the governance arrangements (Recommendation 16), the stability and agility of the Scheme is also tied to the effectiveness of the legislative framework. As such, the Review concluded that the sharing of legislative responsibility across jurisdictions remains effective and appropriate, and continuing to do so will support the future operation of the Scheme and provide clarity for stakeholders.*

**Recommendation 17:** The Review recommends that states and territories continue to ensure that their gene technology Acts remain corresponding and that appropriate mechanisms are in place to update corresponding state and territory legislation following amendment of the *Gene Technology Act 2000 (Cth)*.

## Adaptability, flexibility and national consistency of the Scheme: Moratoria legislation

The Act provides that the Forum may, by legislative instrument, issue Policy Principles in relation to a number of topic areas including ‘recognising areas, if any, designated under state law for the purpose of preserving the identity of one or both of the following: (i) GM crops; (ii) non-GM crops; for marketing purposes’.

### Recognition of Designated Areas Principle

In 2003 the *Gene Technology (Recognition of Designated Areas) Principle 2003* (the Principle) was issued to reduce the potential for inconsistencies between state, territory and Commonwealth laws to arise. The Principle gave effect to the recognition that any jurisdiction may legislate to preserve the identity of crops for marketing purposes (moratoria legislation).

Moratoria legislation was passed by all states and territories, with the exception of Queensland and the Northern Territory. Today, South Australia, Tasmania and the Australian Capital Territory have active moratoria legislation. Other jurisdictions have either rescinded their legislation, or retained it without any active prohibitions relating to Australia’s commercially approved GMOs.

The Review considered some stakeholder suggestions that revoking the Principle would be an appropriate mechanism to allow an authorisation under the Act to override the effect of state and territory moratoria legislation. However, the removal of this Principle would not necessarily have this effect if the states and territories were to maintain their current legislation.

The Review noted that laws enabling moratoria on GM crops are a policy decision for jurisdictions. Removal of the Principle could therefore create uncertainty regarding how the gene technology legislation (with a health and safety focus), and moratoria legislation (with a marketing focus) would coexist, and which would prevail. Further, removal of the Principle would not change outcomes for agricultural producers. For example, the removal of the Principle does not remove a state or territory moratoria, and so the prohibition on GM crops would persist.

The existence of moratoria legislation has been, and continues to be, a controversial issue.<sup>87</sup> While market research highlighted that only a small proportion of the general public appear to be aware of any moratorium on GM crops in Australia, many stakeholders expressed strong feelings about the impact of moratoria (positive or negative). These opposing views are summarised below.

## Concern about the existence of moratoria legislation

Throughout the Review process, a large number of stakeholders expressed concern that because of the existence of jurisdictional moratoria legislation:

- Australia's regulatory burden is not commensurate with the risks posed by the products of biotechnology;
- access to the technology was able to be denied at the state level, which was seen to reduce the effectiveness of the Scheme;
- 'non-GM' branding may contribute to public confusion, as 'non-GM' is equated with 'safer and greener';
- innovation and growth of agricultural, environmental and industrial biotechnology industries in Australia are hampered, due to a restricted path-to-market for a range of technologies;
- there is uncertainty about the future of crop biotechnology in Australia, and Australia will continue to fall behind in the development and adoption of biotechnology innovations, in relation to its export competitor countries;
- there are unrealistic restrictions (e.g. banning the transport of GM seed across state borders), compliance practices and management costs being imposed; and
- there is investment uncertainty for applicants who are potentially unable to commercialise their products in key markets.

These stakeholders reasoned that the marketing purposes which form the basis of the moratoria legislation have been shown to have little foundation, arguing that no business case for GM-free crop status has been established. One analysis provided to the Review (notably from 2005) estimated that an economic loss to Australia's canola growers could amount to \$3 billion, over the period 2005 to 2015, due to the state and territory moratoria on the commercial cultivation of GM canola.<sup>88</sup>

These stakeholders also argued that there is no evidence to support claims of trade or market advantages provided by moratoria legislation. A 2017 analysis was referenced, which claimed that data does not demonstrate that South Australia has achieved a premium for its non-GM canola crop because of the moratorium on GM technology.<sup>89</sup>

Examples were also presented showing that non-GM price premiums could be higher in jurisdictions without moratoria, than in jurisdictions with active moratoria legislation. For example, some market data provided to the Review showed that in WA, over the three years to January 2018, non-GM canola has delivered regular price premiums of between 4% and 10%, compared with GM canola (noting that daily canola prices can be volatile).<sup>90</sup> In addition, analysis of canola values in Victoria over the same period have shown regular premiums for non-GM canola of between 5% and 10%.<sup>91</sup>

Stakeholders to the Review also submitted that this premium, forgone by GM canola growers, may be surpassed by higher yield from the GM variety, improved in-crop weed control, a lower weed burden the following year and greater flexibility over sowing time. GM varieties now comprise 30% of the WA canola crop.<sup>92</sup>

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87 Productivity Commission. (2016). *Regulation of Agriculture*. Retrieved July 10, 2018, from <http://www.pc.gov.au/inquiries/completed/agriculture/report>

88 Apted, S., McDonald, D., and Rodgers, H. (2005). *Transgenic Crops: Welfare Implications for Australia*, Australian Commodities: Forecasts and Issues, Vol. 12, No. 3.: 532–542.

89 Whitelaw, A. (2017). *Controversial canola. Mecardo Expert Analysis*. Retrieved July 10, 2018, from <http://www.mecardo.com.au/commodities/analysis/controversial-canola.aspx>

90 Unpublished information provided by Co-operative Bulk Handling Group, (January 2018) indicates that the observed market premium over that period for non-GM canola in WA has varied between 0% and 11%.

91 Unpublished information provided by Lachstock Consulting, (January 2018) indicates that the observed premium for non-GM canola in Victoria over that period has varied from 0% to 13%.

92 Government of Western Australia, Department of Primary Industries and Regional Development, *Genetically modified crops in Western Australia*. Retrieved July 10, 2018, from <http://www.agric.wa.gov.au/genetic-modification/genetically-modified-crops-western-australia>

The Review noted that agricultural commodity markets are complex, with numerous domestic and international factors affecting prices at any given time. Observed price premiums can differ across years and States, and data can be interpreted by different stakeholders in different ways.

One consideration is whether 'GMO free' marketing advantage can be achieved via mechanisms other than state and territory moratoria legislation. This may include industry run certification schemes such as those that apply to organic products, and leveraging existing GM crop stewardship programs. Whilst there is merit in stakeholders further considering these alternatives, such mechanisms would operate independently of the Act, and are out of scope for the Scheme, and hence the Review's remit.

Many of these arguments were also presented to the *Productivity Commission's Inquiry Report: Regulation of Australian Agriculture* (2017)<sup>93</sup> and the House of Representatives Standing Committee on Agriculture and Industry's *Smart Farming – Inquiry into Agricultural Innovation* report (2016).<sup>94</sup> Both inquiries identified removal of state and territory moratoria on genetically modified crops as a matter for government consideration.

## Support for moratoria legislation

The existence of moratoria legislation is a highly contested topic for some stakeholders (including some jurisdictions). Strong arguments were heard for this legislation to be retained, on the basis that moratoria legislation:

- can position a jurisdiction in the global marketplace as a producer of food that is unambiguously free from genetic modification;
- protects a 'clean and green' brand for some jurisdictions, without which both markets and individual businesses would be affected and future opportunities lost;
- enables all agricultural producers, food and beverage manufacturers and the tourism sector (in jurisdictions with active moratoria) to have access to brand differentiation; and
- addresses concerns about the future commercialisation of GM wheat. Some stakeholders argued that there are market signals from international and domestic customers that reservations exist concerning GM wheat.<sup>95</sup>

Supportive stakeholders also argued that the economic benefits of having moratoria legislation outweigh the costs of retaining or extending the timeframes of existing moratoria.<sup>96</sup> These arguments focused on broader economic benefits associated with the ability to use 'non-GM' branding. That is, in jurisdictions with active moratoria, 'non-GM' or 'GM free' marketing can be applied by all producers in that state or territory, rather than focusing solely on the only two commercially GM crops currently grown in Australia; cotton and canola.<sup>97</sup>

The argument was also raised that state and territory moratoria legislation are not part of the Scheme itself, and therefore are out of scope for the Review. However, given many stakeholders consider that the moratoria have an impact on the national consistency of the Scheme, it falls within scope for the Review; particularly in the context of Australian Governments working towards a nationally consistent policy basis for the Scheme (discussed at [Recommendation 17](#)).

In addition to the arguments for or against the continuation of moratoria legislation, concerns were also raised about whether some pieces of moratoria legislation extend (potentially unintentionally) beyond the 'marketing purposes' described in section 21 of the Act (for example, transport restrictions).

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93 Productivity Commission. (2016). *Regulation of Agriculture*. Retrieved July 10, 2018, from <https://www.pc.gov.au/inquiries/completed/agriculture/report>

94 House of Representatives Standing Committee on Agriculture and Industry. (2016). *Smart farming – inquiry into agricultural innovation*. Retrieved July 10, 2018, from [http://www.aph.gov.au/Parliamentary\\_Business/Committees/House/Agriculture\\_and\\_Industry/Agricultural\\_innovation/Report](http://www.aph.gov.au/Parliamentary_Business/Committees/House/Agriculture_and_Industry/Agricultural_innovation/Report)

95 WA Legislative Council (2006). *Hansard*, p. 2453, Wednesday, 10 May 2006.

96 Government of Tasmania, *Genetically Modified Organisms Control Act Amendment Bill 2014: Decision Regulatory Impact Statement Summary*. Retrieved July 10, 2018, from <https://dipipwe.tas.gov.au/agriculture/tasmanian-gene-technology-policy-2014-2019>

97 A licence authorising the commercial release of safflower, genetically modified for high oleic acid composition, was announced 27 June 2018. The release of GM safflower may enter general commerce, for use in industrial oil production and animal feed. There is no intention to use the GM safflower in human food. Retrieved July 10, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir158>

As described above, there are conflicting views among stakeholders regarding the economic effect (advantages and disadvantages) of state and territory moratoria legislation, and the evidence supporting views on economic impacts for non-GM crops is not conclusive. This is partly because different factors are considered relevant to these calculations by different stakeholder groups. This is also a complex and context-specific area, with commodity premiums that are not stable, complicated by other economic considerations that are sometimes difficult to quantify.

The Review recognised that, ultimately, the decision to retain or repeal this legislation is a matter for states and territories to determine. However, the Review also recognised the role of the Forum in considering issues that impact the national consistency of the Scheme, including practical challenges such as transport restrictions. Some stakeholders suggested that any existing and ongoing work undertaken by states and territories to review their moratoria legislation could be combined and made publicly available, to consolidate an evidence base to support further consideration being given to this matter by the relevant jurisdictions.

## What do consumers think?

The Scheme recognises the constitutional right of states and territories to 'preserve the identity' of either GM or non-GM crops 'for marketing purposes'. The term 'marketing purposes' may be interpreted in different ways, but is generally taken to mean any impact on the marketability of a specific product or its entrance into the marketplace.

Most Australians, when questioned, have never heard of moratoria legislation. However, it is reasonable to assume that presumed consumer views play a part in what is considered to be marketable. Market research to inform the Review has highlighted a high degree of public confusion around the availability of GM products in Australia – particularly with respect to crops and food. While this research indicates a level of concern that GM food products may not be safe to consume, almost three quarters of Australians surveyed believe that genetic modification of crops is permitted, and two thirds believe that GM fruits and vegetables are permitted. In fact the majority of market research participants incorrectly assumed that many of the grains, fruits and vegetables they consume were likely to be GM. For example, GM status was often incorrectly ascribed to foods due to their qualities (e.g. seedless, low GI), their abundance (e.g. avocados, bananas) or their tastelessness as a compromise for shelf-life (tomatoes).

When given a choice, almost half of Australians who participated in market research indicated a preference for non-GM food (noting that being chemical-free or organic may be confused with being non-GM). However, an almost equal proportion acknowledged that there are other factors at play when choosing food. Indeed, when price is brought into the equation, the preference for purchasing non-GM foods over cheaper GM foods significantly decreases.

That said, the majority of Australians surveyed believe that genetic modification can potentially provide farmers with crops that are disease or drought resistant. The market research highlighted a degree of confusion and disagreement within the general community as to whether GM farming practices are worse for the environment than traditional farming. However, views on whether GM crops are worse for the environment than naturally occurring crops are fairly evenly balanced between those who agree and those who don't (noting that there is a significant proportion of the community that simply do not know). There also appears to be support for GM giving farmers more control over their crops. However, it should also be noted that just over half of Australians, when questioned, feel that there are more important things to worry about than GM.

This exploration of consumer views highlights the need to provide the public with more information – about GM foods in particular. This issue is further discussed in [Chapter 1.5 Review Theme Four – Social and Ethical Issues](#), and in [Appendix 10: Outcomes of Market Research](#).

The Australian public generally acknowledge that GM is expensive and time consuming, and that therefore only large companies and well-funded research institutes have the ability to develop GM technologies and products. While some consumers conclude that being irresponsible in developing GM applications would not be in an organisation's long-term interests, there appears to be a prevalent community view that big companies are profit driven, and that without adequate regulation this may result in compromises which are not in the public interest.



## Compensation schemes

Related to considerations of the right to grow GM crops in particular jurisdictions, is the concern expressed by some stakeholders about the impact of GM plant material coming into contact with non-GM crops. Some stakeholders suggested that strict liability legislation should be passed in all jurisdictions to ensure that GMO developers are liable for any adverse economic effects caused by their GM products.

As is the case for moratoria legislation, economic considerations are outside the scope of the Scheme, which covers human health and safety and environmental considerations. As such, the introduction of compensation schemes for economic loss is a matter for jurisdictional governments to consider. The Review noted, for example, the *Inquiry into mechanisms for compensation for economic loss to farmers in Western Australia caused by contamination by genetically modified material*, currently being considered by the WA Standing Committee on Environment and Public Affairs.<sup>98</sup>

The recent update to the *Guideline for responding to contamination by prohibited substances or materials in the organic export supply chain*<sup>99</sup> was also of interest to the Review. This Guideline is used in conjunction with the *Export Control (Organic Produce Certification) Orders*,<sup>100</sup> and the update was issued by the Department of Agriculture and Water Resources following consultation with stakeholders. This Guideline provides pathways for primary producers to rectify and resolve the unnecessary intentional use, negligent introduction and accidental introduction or necessary intentional use of prohibited substances (including GMOs) into an organic or biodynamic production system.<sup>101</sup>

The Review additionally noted that the agility of the Scheme is broader than just a consideration of moratoria legislation. Additional discussion on the frequency with which the Scheme's policy settings are reviewed, and the rate at which reforms are progressed, is included in Recommendations 13 and 14.

*In conclusion, the Review found that there are conflicting views among stakeholders regarding the advantages and disadvantages of state and territory moratoria legislation. Further, there is inconsistent evidence regarding this matter, particularly on the economic effect of moratoria legislation, as economic calculations are context-specific and complex (often based on non-stable factors).*

*The Review also found that some stakeholders believe that the focus of some moratoria legislation extends beyond marketing purposes, and there may be benefit in further consideration of whether all restrictions (for example, transport restrictions) are appropriate to meet this objective.*

In line with these findings, the Review acknowledged that whilst decisions on moratoria legislation are the remit of states and territories, some stakeholders suggested that regular policy reviews, and ensuring public access to the information that informs jurisdictions' government decisions, are an important aspect of effective regulatory policy. This includes assurance that moratoria are only for marketing purposes, and that they can not detract from the Scheme achieving the object of the Act (safety and protections).

Further, in line with **Recommendation 17**, the high level of commitment by Australian Governments for the Forum to work towards a national, consistent policy basis for the Scheme, should underpin states' and territories' ongoing considerations on the use of moratoria for marketing purposes. Ongoing policy discussions about the results of jurisdiction's moratoria evaluations, and their impacts on the national policy on gene technology, should form an important element in a Forum action plan.

**Recommendation 18:** The Review recommends that states and territories give ongoing consideration to the economic effects, value and scope of moratoria.

98 Legislative Council, Western Australia, *Inquiry into mechanisms for compensation for economic loss to farmers in Western Australia caused by contamination by genetically modified material*. Retrieved July 10, 2018, from [http://www.parliament.wa.gov.au/parliament/commit.nsf/\(\\$all\)/CA81A38C140AF895482581EE0081A3CC?opendocument](http://www.parliament.wa.gov.au/parliament/commit.nsf/($all)/CA81A38C140AF895482581EE0081A3CC?opendocument)

99 Department of Agriculture and Water Resources. (2018). *Guideline for responding to contamination by prohibited substances or materials in the organic export supply chain – (2018-01)*. Retrieved July 10, 2018, from <http://www.agriculture.gov.au/export/controlled-goods/organic-bio-dynamic/organic-notices/2018/2018-01>

100 *Export Control (Organic Produce Certification) Orders* (Cth) (Austl.). Retrieved July 13, 2018 from <http://www.legislation.gov.au/Details/F2005C00434>

101 Note that this Guideline is not specified in legislation.

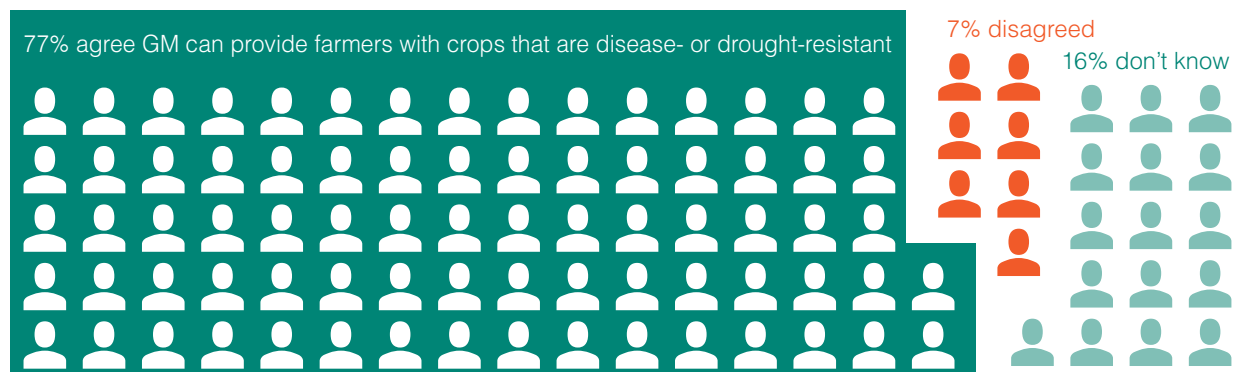
## Harnessing the economic and health benefits of gene technology: Benefit consideration

The regulation of gene technology in Australia currently focuses on considering potential risks posed by, or as a result of, gene technology, and how these risks may be mitigated through regulating certain dealings with GMOs. Currently, when deciding whether to issue a licence to deal with a GMO, the Regulator cannot consider any potential benefits which may flow from that GMO.

The majority of Australians surveyed during market research to inform the Review see at least some need for GM, and are more likely than not to acknowledge that there is a place for GM in today's world. They acknowledged that it can produce breakthroughs in medicine and may play a part in ensuring the growing world population can be fed. Market research also indicated that the most commonly understood application of genetic modification is that it can benefit farmers (and therefore potentially the population and the economy) with crops that are disease or drought resistant. The general public also appear to recognise that GM can provide hope for eradicating genetically inherited diseases. However, beyond this, there is a great deal of confusion and lack of knowledge within the general population regarding the potential uses and impacts of GM. The research highlights that the general public do not appear to have been broadly exposed to the arguments for and against GM, and have little understanding regarding any potential benefits.

### FIGURE 3

#### Market research – Impacts of genetic modification



Some stakeholders proposed that, in making decisions, the Regulator should have the ability to take into account benefits such as any potential health, environmental or economic benefits of the GMO. A theoretical example might be to assess the overall 'benefit' of using a GMO to reduce the impact of an invasive pest or save an endangered species. Stakeholders' interpretations of the term 'benefit' differed, and some stakeholders contended that there are no broader benefits of GMOs other than to the businesses producing them (particularly in the agricultural space).

A number of stakeholders suggested that the consideration of potential benefits could compromise the rigorous science-based nature of the Scheme, undermine confidence in its ability to achieve the objective of protecting the health and safety of people and the environment, and result in a loss of public trust. These stakeholders also argued that consideration of benefits is more appropriately a matter of evaluating efficacy and comparative value, which falls within the purview of product regulators (such as FSANZ and the TGA).

A number of stakeholders additionally claimed that there is a lack of, or inability to establish, recognised methodologies for assessing benefit. In the absence of such methodologies, any assessments undertaken would rely on assumptions and may provide weak and speculative data, with limited application.

The Review found that for a potential benefit of a GMO to be a consideration in the future, a state and territory position (perhaps issued through the Forum) would be required, rather than the Regulator alone considering these factors (see [Recommendation 1](#)).



*As such, the Review found that consideration of benefits (e.g. potential economic, environmental and health benefits) could risk the effective operation of the Scheme, although it was noted that this may be an area of ongoing focus in future reviews if further justification becomes apparent.*

*The Review concluded that, to achieve the objectives of the Scheme, continuing to focus on gene technology risks and their management remains appropriate, as benefits are sufficiently addressed through other parts of the regulatory ecosystem (eg. through the product regulators). This conclusion aligns with Recommendation 2, which confirms that the object of the Act should not be expanded.*

**Recommendation 19:** The Review recommends that consideration of benefits (e.g. potential economic, environmental and health benefits) should not be introduced as an element of regulatory decision making at this time.

## Harnessing the economic and health benefits of gene technology: Regulatory burden

The *Consultation Paper*, stakeholder feedback and *Preliminary Report* all presented views that the failure of the Scheme to keep pace with technological advances could stifle innovation in gene technology. This might also prevent the potential economic and health benefits of these technologies from being harnessed by the community.

There was widespread support from stakeholders for reforms to the Scheme to ensure that it is fit for purpose and appropriate for the level of risk posed by the technology. Ensuring the OGTR is focused on higher risk activity will allow it to better utilise available resources, and lower risk activity can proceed with appropriate regulatory compliance (see [Recommendation 9](#)). Some stakeholders identified areas where current regulatory requirements may impact on innovation or act as a barrier to harnessing the benefits of gene technology, currently or in the future. These included:

- Concerns that timeframes and requirements of the current regulatory approval system are a disincentive to pharmaceutical clinical trials being carried out in Australia. As a result, some new therapies may not be available to the medical system in this country.
- Concerns about imposing unnecessary barriers to the adoption of new applications of gene technology in agriculture.
- Support from research organisations for streamlining regulatory requirements for facility certification and approval processes, in a manner that reduces costs and timeframes, while delivering the objects of the Scheme.
- Examples of GM vaccines with a history of safe use for companion animals and commercial livestock, that are used overseas, not being registered for use in Australia due to regulatory overheads. These vaccines can deliver effective protection from diseases that would alternatively require treatment with antibiotics.

*The Review heard that in order for the potential economic and health benefits of gene technology to be harnessed now and into the future, the Scheme should not impose unnecessary regulatory burdens. The Review found that this may be achieved through regulation that is commensurate with the level of risk posed by a dealing (see Recommendations 9 and 10).*

*The Review also heard from stakeholders who emphasised that appropriate levels of oversight must continue to be applied to innovative areas of gene technology until safety has been established.*

*The Review determined that retaining the risk based approach to regulation is still valid for the Scheme now, and to manage risks posed by dealings into the future.*

**Recommendation 20:** The Review recommends that the Scheme ensures regulation remains commensurate with the level of risk posed by a dealing (see Recommendations 9 and 10) so that no unnecessary regulatory burdens are imposed.

## Clarity on policy considerations of the Scheme

Policy clarity provides certainty to industry and the community about the purpose and intent of regulatory systems, and greater transparency for all regarding decision making. Greater clarity in turn assists with choice, including for research and development investments, regulatory compliance actions, marketing strategies, and spending. Throughout the Review process, stakeholders maintained that a nationally consistent policy focus was important to support a clear policy approach. In addition, stakeholders raised a number of topics that they considered would benefit from improved regulatory and policy clarity.

One mechanism to provide this clarity would be for the Forum to exercise their authority, as empowered under Section 21 of the Act, to perform a number of functions. These include issuing Policy Principles, Policy Guidelines and Codes of Practice to govern the activities of the Regulator and the operation of the Scheme. These mechanisms allow the Forum to provide policy clarity in relation to a number of matters:

- ethical issues;
- designated areas under State law; and
- matters related to dealings with GMOs prescribed by the Regulations).

Specific topic areas identified by stakeholders as matters that would benefit from policy clarity include (but are not limited to):

- operational policy clarity on considerations relevant to stacked traits;
- guidance on the regulation of GMOs released into the broader environment (for example, GM biological control agents) – see [Recommendation 7](#);
- guidance on regulation for releasing gene drives into the environment – see [Recommendation 7](#);
- consideration of benefits for some gene technology applications – see [Recommendation 19](#);
- investigation of the regulation of non-transgenic applications of synthetic biology under the Scheme; and
- establishing Codes of Conduct for DIY-biologists – see [Recommendation 12](#).

The Review has also identified that the following action items could be delivered, with policy clarity set by the Forum:

- the development of criteria for a simplified process to consider non-material or consequential changes to legislation (noting that some stakeholders have suggested that all proposed changes should undergo full Forum consideration, and full consideration by state and territory Parliaments);
- enhanced Forum liaison with other ministerial forums, to align frameworks; and
- identification of bodies of work that a formalised Regulators' Forum could undertake.

For operational matters, policy clarity could be achieved through the development or updating of OGTR operational policies. Some stakeholders also suggested maintaining continued engagement of the various regulators (including the OGTR, APVMA and FSANZ) through forums which progress matters relevant to multiple agencies.<sup>102</sup>

Some stakeholders advised that the Scheme would benefit from policy clarity with regard to low level presence (LLP). LLP refers to trace amounts of an approved GMO, for example a GM grain variety, accidentally becoming mixed with a non-GM grain variety and then exported to a country where the GMO is not approved.

As technological advancements allow for more and more traits to be introduced onto an organism, the question arises as to how far this could appropriately extend. An example might be a crop plant with tolerances to multiple herbicides. Under current regulations, a licence for dealings with the organism must be granted if a case-by-case assessment finds that the GM organism does not pose a risk to the health and safety of humans or to the environment. However, if for agronomic purposes there might be a justifiable reason to limit the number or type of such stacked traits in an organism, the decision making process may benefit from the Forum providing policy guidance or advice on appropriate thresholds or circumstances.

<sup>102</sup> The Review notes that the OGTR continues to be engaged in the Australian Government's Regulatory Science Network, a platform encouraging the sharing of information between Regulators.

Work to provide policy clarity in these areas could be progressed by the Forum through the development of an action plan, leveraging the Standing Committee or other appropriate organisations as required.

The Review also noted that the OGTR has an existing Unintended Presence Strategy<sup>103</sup> and that Australia was one of 13 countries to endorse an International Statement on Low Level Presence<sup>104</sup> in 2012.

In addition, the Scheme already has a number of mechanisms that can be flexibly applied on a case-by-case basis to address cases of LLP. These include:

- Notifiable Low Risk Dealings (NLRDs) which can be proactively granted to manage any unintended presence of unapproved GMOs, as long as they are dealt with in PC2<sup>105</sup> Plant Houses; and
- inadvertent dealings licences, which can be granted to enable disposal of an unapproved GMO.

The Review concluded that these existing mechanisms are likely to be sufficient to deal with cases of LLP. However, there is benefit in Australia remaining active in international fora such as the World Trade Organization, the Global Initiative on Low Level Presence, and the Asia-Pacific Economic Cooperation (APEC) (see [Recommendation 15](#)), which consider appropriate approaches dependent on national circumstances. Consideration could also be given to utilising the GMO Register (see [Recommendation 11](#)) as an additional mechanism to address cases of LLP.

*The Review found that there is an opportunity for the Legislative and Governance Forum on Gene Technology (the Forum) to lead an action plan to consider a range of matters. The action plan may increase the Forum's effectiveness by providing a practical and measurable mechanism to implement the recommendations. This may include identifying areas where the Forum could issue Policy Principles, Policy Guidelines and Codes of Practice to provide or clarify policy positions on key matters, noting the responsibility of the Forum to consult and collaborate with other relevant government forums in the conduct of its business. In operationalising an action plan, the Forum might consider opportunities to leverage the role of the Gene Technology Standing Committee.*

*The Review also found that consideration could be given to using the current provisions of section 21 of the Gene Technology Act 2000, to enable Policy Principles to be issued on a wider range of topics.*

In line with [Recommendation 1](#), a Forum agreed, national forward action plan provides clarity to government and non-government stakeholders about the national policy priorities for the Scheme, their expected timing and the allocation of responsibility.

Further, determining the priority for the development of policy principles provides reassurance to stakeholders of the ongoing policy oversight, and predictability of regulatory outcomes.

However, while there may be additional areas where policy principles could be issued to strengthen the Scheme, there are limitations on the topics on which policy principles can be issued. There are also other limitations on their scope, given they must align with the overarching objective of maintaining the protections afforded by the Act. Notwithstanding, the Review considers that there is merit in further examining the scope of Section 21, including whether there is potential to amend the legislation to enable Policy Principles to be issued on a wider range of topics.

This approach aligns with the objective of the Gene Technology Agreement; to ensure rigorous science-based decision making by an independent regulator, whose decisions are consistent with policy principles issued by the Forum, to capture social, cultural, ethical and other non-scientific matters (that must not detract from the health and safety of people or the environment).<sup>106</sup>

103 Office of the Gene Technology Regulator, *Unintended Presence Strategy (Unapproved GMOs in seed for sowing)*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mon-unintended-1>

104 Department of Agriculture and Water Resources, *International Statement on Low Level Presence*. Retrieved July 10, 2018, from <http://www.agriculture.gov.au/ag-farm-food/biotechnology/international-statement-low-level-presence>

105 PC2 refers to levels of physical containment (PC). There are four levels of physical containment applied to facilities certified by the Regulator. These are arranged in order of ascending stringency of containment requirements, which reflect the level of risk involved in the dealings that can be undertaken at each level. The four levels are PC1, PC2, PC3 and PC4.

106 Gene Technology Agreement 2001 – Recitals B(d)

## Coordination with other regulators

The gene technology Scheme was developed to work alongside the regulatory schemes for human food, human therapeutics, veterinary medicines, agricultural and industrial chemicals and biosecurity matters, with the OGTR managing risks associated with live and viable GMOs. However, it is acknowledged that the numerous intersecting pieces of legislation that apply may add to the complexity of gene technology regulation.

In considering the interface between the OGTR and GM product regulators (for example, the TGA, APVMA and FSANZ), the Review has identified that most stakeholder concerns fall into two key areas:

- a perceived lack of delineation between the different regulatory schemes; and
- areas of potential duplication, or differing requirements, between regulators.

The Review has also identified that there are mechanisms available in other schemes which may be beneficial to the regulation of gene technology. These are explored further below.

### Clarity regarding regulator roles

Some stakeholders stated that identifying the different responsibilities of different regulators is not always easy. These stakeholders suggested that there is a need for a single regulatory entry point (such as a web portal) to all regulators who have responsibility for overseeing work which relates to gene technology or GMOs (including the OGTR).

Stakeholders suggested that a web portal would assist developers or importers to easily determine the regulatory requirements applicable to them. Separately, other stakeholders have suggested that a central web portal could provide access for members of the public to request the various regulators' risk assessment documentation.

The Review noted that should this proposal be taken forward, there would need to be clear identification of which organisation is responsible for building and maintaining the portal, and the allocation of appropriate resources for its development and maintenance. Refer to [Recommendation 10](#) for additional discussion on options to streamline the Scheme, including the development of a web portal.

### Potential duplication between regulators

Some stakeholders identified duplication between regulators as a key area of concern, potentially increasing costs for applicants, with no associated benefit. These stakeholders identified the following examples of potential duplication between:

- the OGTR and APVMA with regard to the regulation of pesticide incorporating plants;
- the OGTR and APVMA with regard to the regulation of GM veterinary medicines;
- the OGTR and TGA with regard to the regulation of human therapeutics; and
- the OGTR and TGA with regard to the requirement to report adverse events associated with GM pharmaceutical products (and inconsistencies between timeframes for reporting to each agency).

In addition, some stakeholders called for an audit to determine points of duplication between regulators, or a review of the roles of the respective agencies. Some potential solutions proposed by stakeholders to address these areas of perceived duplication include:

- enabling one regulator to accept the risk assessment of another regulator as part of their overall assessment;
- removing regulatory oversight from one regulator so that it is solely the responsibility of another (noting that different regulators have different objectives, so may take different factors into account in their assessments);
- addressing adverse event reporting duplication through: only reporting (this information) to the TGA; provisions for sharing of reports between regulators; or through the introduction of a shared portal for the reporting of adverse events; and
- the establishment of a formal inter-agency regulators' forum to discuss matters related to the interface between regulators.

With regard to the potential solutions identified above, the Review noted that some areas of duplication previously experienced by stakeholders have already been addressed administratively. For example, where appropriate, a regulator's report can be made available to another government agency to form part of the assessment process.

In considering which regulator is best placed to assume responsibilities for regulatory oversight of particular dealings, stakeholders have made the following proposals:

- pesticide incorporating plants should be regulated by the OGTR and not the APVMA;
- the APVMA should assume sole responsibility for the registration and compliance of all veterinary medicines, including GM veterinary medicines; and
- ethics committees and the TGA should have sole responsibility for risk managing clinical trials in Australia where they involve gene or cell therapies (using conventional means that have a history of safe use with respect to persons handling the GMO and the environment).

The Review noted that some areas of perceived duplication may serve a specific purpose and there is therefore a justifiable risk basis for continuing. However, the Review also recognised that there may be areas of potential duplication which are unnecessarily burdensome for stakeholders and which provide no additional protections for the health and safety of people and the environment. It is therefore proposed that further work be undertaken to investigate possible solutions.

## ‘Super-regulator’ or ‘one stop shop’

Some stakeholders also suggested that the OGTR (or a separate, newly formed organisation) should be the lead regulator for all dealings that involve GMOs, acting as a ‘super agency’ with lead responsibility for all work with both GMOs and GM products. This proposal was not widely supported however, with other stakeholders suggesting that such an approach would not help with the issues of delay and inconsistency. Instead, the OGTR is seen as requiring more resources. It was also noted that each regulator has their own regulatory focus and area of expertise, which could be lost through the creation of a ‘super agency’.

The Review noted that the establishment of a ‘super-regulator’ or ‘one stop shop’ was considered in the Gene Technology Bill 2000 when the Scheme was first established. A key disadvantage identified with this approach at the time was the risks associated with assessing GM products entirely separately from their non-GM counterparts, even when the effect of the genetic modification was minimal (leading to significant discrepancies in costs of compliance).

Separate to discussions relating to duplication between the OGTR and GM product regulators, some stakeholders also raised concerns regarding a lack of harmonisation between the OGTR and Department of Agriculture and Water Resources (DAWR) facility certification requirements.<sup>107</sup> This is discussed further in [Recommendation 10](#).

Stakeholders also raised concerns about a lack of consistency between the definitions used by the OGTR and FSANZ, with many stakeholders arguing that alignment would improve regulatory efficiency, make the regulatory system more predictable and reduce costs for government and non-government stakeholders. The Review also notes the progress of the 2018 FSANZ review of how the Food Standards Code applies to food derived using new breeding techniques (including considering the definitions for ‘food produced using gene technology’ and ‘gene technology’).<sup>108</sup> FSANZ aims to conclude the review in early 2019, at which time they will consider whether to prepare a proposal to amend the Code. More information on the status of this review is in [Chapter Three](#), at [Food Standards Australia New Zealand \(FSANZ\) Review](#).

<sup>107</sup> *Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016* made under subsection 174(1) of the *Biosecurity Act 2015* (Cth) (Austl.). Retrieved July 10, from <http://www.legislation.gov.au/Details/F2018C00130>

<sup>108</sup> Food Standards Australia New Zealand, *Food derived using new breeding techniques – review*. Retrieved August 09, 2018, from <http://www.foodstandards.gov.au/consumer/gmfood/Pages/Review-of-new-breeding-technologies-.aspx>

## Mechanisms available in other schemes that could be adopted

The Review also identified the following areas as possibly requiring additional investigation:

- Whether the mechanism available under the *Therapeutic Goods Act 1989* Special Access Scheme could be investigated for application to the Gene Technology Scheme. Under the Special Access Scheme, an unapproved therapeutic good can be imported and/or supplied for a single patient in certain (urgent) circumstances. Currently, however, GM therapeutic goods would not be able to be provided as quickly as intended by the Special Access Scheme because the Act does not have equivalent provisions. This means that the GM therapeutic would have to be assessed through standard licence application processes (with associated extended timeframes).
- Whether there are sufficient communication mechanisms between the Gene Technology Regulator and state and territory environmental protection agencies. It has been noted that the sharing of data on downstream environmental and health effects of GMOs may inform the Regulator's future decision making, or post-market review actions.

*In conclusion, the Review heard that:*

- *there is a lack of clarity for some stakeholders regarding the roles of the Office of the Gene Technology Regulator and regulators of genetically modified products, which might be addressed through mechanisms such as the development of a dedicated gene technology regulation web portal.*
- *there may be areas of overlapping regulatory oversight between the Gene Technology Regulator and some product regulators, and that work could be undertaken to investigate potential solutions and any required administrative or legislative changes.*
- *there are potential mechanisms in other schemes (for example, the Therapeutic Goods Act 1989 Special Access Scheme) that could be adopted to strengthen the Scheme, and there may be benefit in additional investigation being undertaken.*

As such, opportunities exist to improve public understanding of the regulatory scheme, the regulatory boundaries between the OGTR and other regulators, and the governance structures that are in place across the regulatory continuum for GMOs and GM products. This includes promoting existing communication activities and developing other targeted communications to stakeholders (see [Recommendation 23](#)).

There are other opportunities for improving the business transaction experiences of stakeholders crossing these regulatory boundaries. These could be implemented in the shorter term through administrative and stakeholder engagement changes, or in the medium-longer term through legislative amendments. This may be done by leveraging existing effective (and relevant) mechanisms from other schemes.

There is merit in further consideration of potential e-business solutions, which could include the viability of a dedicated gene technology regulation web portal, to help clarify the role of different regulators. This would complement potential IT enhancements to streamline applications and data sharing between regulators (refer to [Recommendation 10](#)). However, a scoping study is recommended as an initial step, as it may become apparent that certain solutions (such as a web portal) would not be an efficient, effective or financially viable way to achieve the desired outcome.

**Recommendation 21:** The Review recommends clarifying the intersection between the Gene Technology Regulator, other regulators and legislation, which may include:

- identifying opportunities to enhance targeted communication mechanisms and linkages;
- identifying any emerging areas where legislative or administrative changes can be made, to reduce any unnecessary duplication; and
- adopting relevant effective mechanisms from other schemes (for example, the *Therapeutic Goods Act 1989* Special Access Scheme) where they may strengthen the Scheme.



## Funding model

The Review's fourth Term of Reference directs the Review to consider funding arrangements to ensure sustainable funding levels and mechanisms are aligned with the level and depth of activity to support the Scheme. This requires examination of both the:

- **level of funding** required for the sustainable operation of the Scheme; and
- most appropriate **mechanism to source this funding**.

Since its establishment in 2001, the operations of the OGTR have been fully funded by the Australian Government. To date, the OGTR has not charged for any of its regulatory services. There has also been an increase in the complexity of the applications being considered by the OGTR in recent years; funding however, has remained relatively constant – equating to a decrease in real terms.

In considering the most appropriate funding arrangements to ensure sustainable funding levels and mechanisms for the Scheme, stakeholders confirmed their support for the OGTR to be resourced adequately in order to avoid regulatory failure and provide for applications to be processed in a timely manner.

Some stakeholders suggested that current resourcing of the OGTR does not appear to be adequate to meet the needs of stakeholders. In particular, stakeholders have called for appropriate funding to support timely assessment of the number of facility certification applications received, for monitoring and compliance teams, and for licences to be reviewed in a timely manner.

Some stakeholders also highlighted the need for appropriate funding to address new gene technology applications, for example gene drive licensing, which may require new and additional considerations.

Stakeholders also pointed out the need to ensure that the funding mechanism does not hinder innovation or access to technology, and strongly supported the government continuing to be the source of funding for the Scheme.

However, recognising that current funding arrangements may not be sustainable long-term, stakeholders provided input on alternative funding options, primarily the introduction of a cost recovery funding model. Stakeholders put forward arguments – both supportive of, and strongly opposed to – the introduction of a cost recovery model. The vast majority of stakeholders opposed such a funding model on the basis that a user-pays model could:

- stifle innovation (discouraging research and investment in Australia and inhibiting the commercialisation of GM products);
- impact international competitiveness (including in global markets where most grain production is sold) by preventing Australian organisations from gaining access to competitive technologies available in other countries, or discouraging international commercial investment;
- restrict work with gene technology (especially bringing new products to market) to large multi-national organisations;
- erode the community's trust in the independence of the Regulator;
- erode regulated stakeholders' trust in the OGTR if there is a perception (or reality) of over-servicing users who are charged per site/facility inspection;
- increase inefficiencies through the introduction of a cost-shifting exercise between government funded agencies undertaking research and development, and the OGTR;
- drive counterproductive behaviour (aggregation of multiple proposals into one application); and
- impose unreasonable financial burden on research organisations that may not be sustainable in the medium to long term, noting the financial commitments that organisations already incur by funding Institutional Biosafety Committees (IBCs) and ensuring other regulatory obligations are met (as well as fees payable to APVMA and FSANZ).

Stakeholders who are supportive of the introduction of a cost recovery model have put forward the following arguments for its introduction:

- a partial user-pays model (for facility certifications) would allow organisations which require expedited approval to pay a fee; and
- a user-pays approach could assist with OGTR resourcing and reduce assessment timeframes.

This is not the first time that the introduction of cost recovery has been considered. The Review noted that in addition to the 2006 and 2011 reviews of the Scheme, which considered the introduction of a cost recovery mechanism among other matters, three focused cost recovery investigations have also been undertaken.

Previous reviews did not recommend the introduction of a cost recovery mechanism. The Review noted that the Commonwealth Department of Health has also undertaken subsequent work looking at funding arrangements for the Scheme (including a 2013 investigation of potential cost recovery arrangements for the services of the OGTR). A final decision on this work was postponed until this Review of the Scheme.

Appropriate funding for the Regulator to deliver the object of the Act is not in question. However, in recognising that current funding arrangements may not be sustainable long-term, together with the strong arguments against the introduction of a full cost recovery funding model, the Review identified that additional consideration of this topic by the Australian Government and state and territory governments is required. This will need to determine the most suitable appropriation or cost-sharing arrangements to support the ongoing sustainable operation of the Scheme. This could include consideration of avenues to supplement government funding, or alternative sources of government funding.

Relevant to the funding consideration is the Australian Government Charging Framework (the Charging Framework) introduced by Government in 2015<sup>109</sup>. This was designed to improve consistency of charging activities and help determine when it is appropriate to charge for a government activity. The Charging Framework covers activities where the government charges the non-government sector for a specific government activity, such as regulation, goods, services, or access to resources or infrastructure.

*The Review heard that full cost recovery has the potential to detrimentally affect the sector (for example, by stifling innovation, impacting international competitiveness and eroding trust). This should be taken into account in any work to determine appropriate funding mechanisms to support the ongoing operation of the Scheme.*

*The Review also found that current funding levels provided for the Gene Technology Regulator's operational activities may not be sufficient to support future regulatory activities. However, there is scope for additional work to be undertaken to determine appropriate funding levels going forward.*

*The Review notes that other recommendations within this report (if accepted by governments) have the potential to change the current regulatory framework in a manner that would affect resource allocation (for example, see Recommendations 9 and 10). It is therefore suggested that it would be prudent for further consideration of the most appropriate funding arrangements for the Scheme to be progressed following the Forum's decisions on the other relevant recommendations.*

Additional work has commenced to investigate funding mechanisms that will also inform governments' consideration on the multiple possible approaches for sustainable funding of the regulatory elements of the Scheme. Funding of the administrative elements of the Scheme (such as any future Reviews, support for governance committees, or implementation of Review recommendations) is a separate issue, which also need to be considered by all Governments.

**Recommendation 22:** The Review recommends that further consideration be given to the most appropriate funding mechanisms to support the ongoing operation of the Scheme, and to appropriate funding levels for the Gene Technology Regulator's activities, taking into account any changes to the Scheme.

109 Australian Government, Department of Finance, *Australian Government Charging Framework*. Retrieved March 20, 2018, available from <http://www.finance.gov.au/resource-management/charging-framework/>



## CHAPTER 1.5

# Review Theme Four – Social and Ethical Issues

Informed decision-making about gene technology requires a level of understanding of the nature of the technology, and the benefits and risks of using it. A number of reviews have highlighted the need to communicate appropriately with the public about gene technology, its applications and end products.

This chapter explores **communication with the public** (including which is the most appropriate body to undertake such communication activities) to ensure that social and ethical concerns are properly addressed.

Despite current regulatory arrangements, there remain ongoing concerns within some sectors of the community about the **safety of genetically modified organisms (GMOs)** and the ability of the Gene Technology Regulator (the Regulator) to monitor commercialised GMOs for long-term impacts. These matters are discussed further in this section. Being an important mechanism to support public confidence in the appropriate regulation of GMOs, the various **transparency measures** built into the Scheme are also discussed.

## Public understanding and confidence in the Gene Technology Scheme

Community support and the views of the general public are central to the successful operation of the Gene Technology Scheme (the Scheme), with some stakeholders arguing that a limiting factor for the use of gene technology in Australia is community acceptance. Many stakeholders note that this is best addressed through ongoing public communication and informed debate.

Noting a significant body of existing information on community attitudes to gene technology,<sup>110</sup> the Review further explored public perceptions about GMOs and GM products. This helped to gain a better understanding of what is an important and often emotive issue for some sectors of the community.

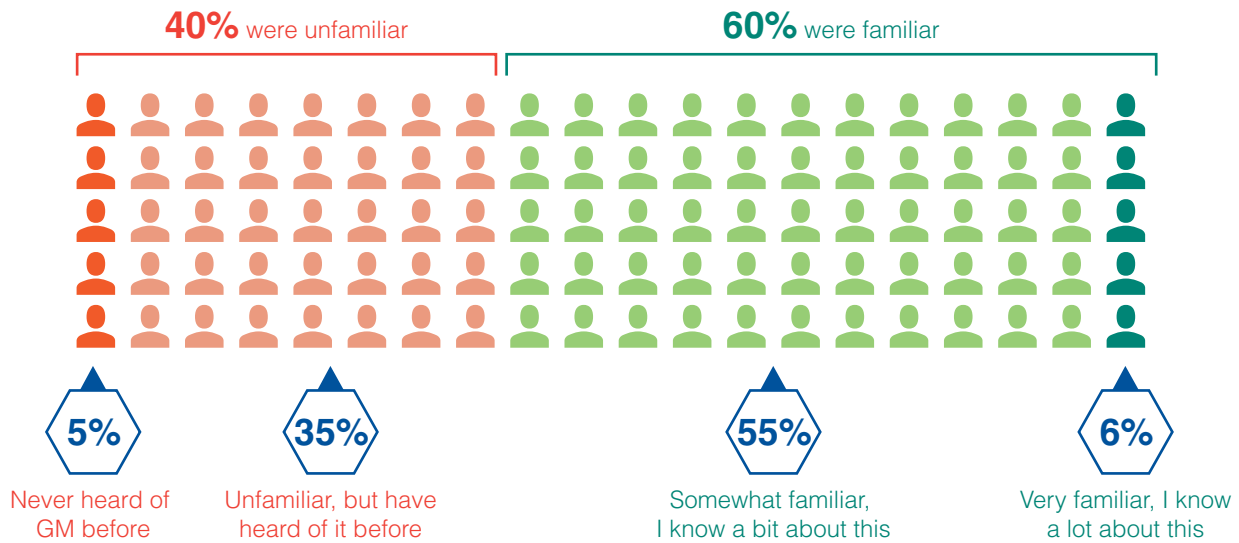
It is clear that public familiarity with the concept of genetic modification varies considerably. While around half of the population is somewhat familiar with the term, only around one in 20 believe they know a lot about GM. Significantly, even in this latter group, many misunderstandings exist.

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110 See the OGTR website for reports on community attitudes to gene technology (accessed August 9, 2018): <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-other>

**FIGURE 4**

Market research – Self-classified level of familiarity with the term ‘genetic modification (GM)’

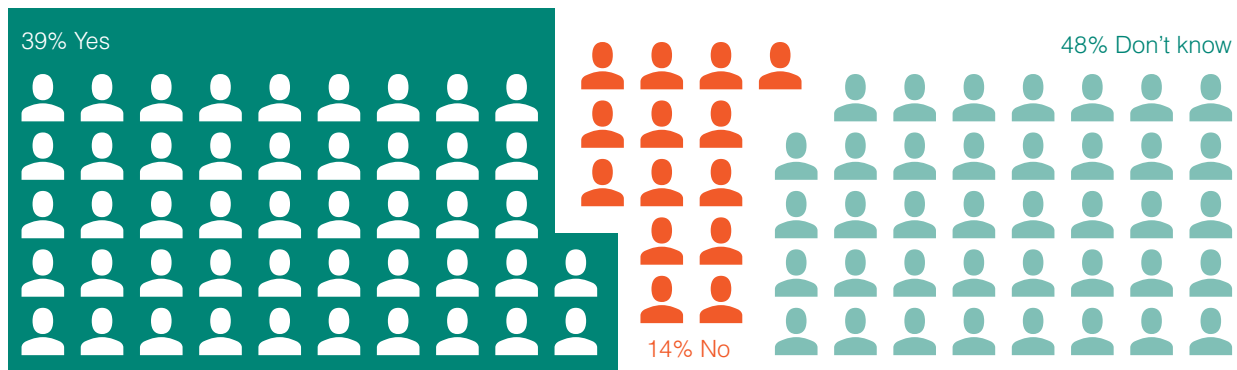


Awareness of GM in those surveyed through market research was found to be primarily limited to crop applications, with GM medications and other industrial applications being less known. The majority of those questioned considered that there isn't enough information available about the pros and cons of GM and almost half didn't know whether gene technology is regulated.

**FIGURE 5**

Market research – Understanding of GM regulation in Australia

**Do you think GM is currently regulated in Australia?**



Although there may have been an underlying assumption that gene technologies are regulated, the majority of Australians surveyed were unclear about how that may look in practice. One of the strongest concerns expressed was in relation to GM products being imported into Australia from countries with little or no regulation. This highlights a considerable lack of knowledge about how the Australian regulatory system works. However, when members of the general public were provided with information about the Scheme, they were generally impressed by the thoroughness of the process. Market research also highlighted an opportunity to draw a comparison with the better known regulatory process for medicines, as this has been shown to often result in a more favourable public attitude towards the regulation of gene technologies.

While governments are seen to have a role as a centralised decision-maker and enforcer of regulation, the importance of bringing in a range of expertise and alternative insights was also recognised. Despite being among the less trusted entities in relation to information about GM, a significant proportion of those participating in market research considered that companies producing GM products should have a role in informing regulation, given they

are potentially the most technically knowledgeable and certainly among the most directly affected by legislation. However, an equal proportion also disagreed with this sentiment. A majority of Australians surveyed consider it inappropriate for food retailers and activists/lobby groups to have a role in regulation of GM.

Overall, the general public do not appear to feel well informed about GM. Market research to inform the Review has identified the need to further explore the following topics:

- address the public misconception that 'many things that we eat are GM, whether we like it or not';
- communicate the regulatory process for gene technology in a way which resonates with consumers; and
- address public understanding of the boundaries of what isn't GM.

Stakeholders have suggested that public communication approaches should:

- provide a common understanding for the community about gene technology and the wider context in which it is, or could be, used;
- provide information about Australia's regulatory requirements for GMOs, and the governance elements of the Scheme (for example, the independence of the Regulator);
- inform the public on both established and more recent forms of gene technology (for example, transgenic modifications and gene editing applications) and the differences between them; and
- provide information on the history of GMOs in Australia.

The *Productivity Commission Inquiry Report: Regulation of Australian Agriculture* also considered whether more effective communication is needed to address community concerns. The Productivity Commission recommended that legislative change 'should be accompanied by coordinated communication strategies designed to increase public knowledge about the benefits and risks to the Australian community from genetic modification technologies'.<sup>111</sup>

The Third Review notes that some of the above communication topics may be beyond the scope of the Regulator's remit (being the health and safety of people and the environment) if the need for information extends to exploring benefits of gene technology (discussed at [Recommendation 19](#)). There is a recognised advantage in not expanding this remit so as not to jeopardise existing trust in the Regulator, as it has the potential to create inconsistency between what the Regulator considers when administering the *Gene Technology Act 2000* (the Act), and the Regulator's communication activities. While it would not be appropriate for the Regulator to undertake communication activities regarding the benefits of gene technology, there is merit in the Australian Government considering alternative communication approaches.

Some stakeholders have also proposed that additional, more detailed information about public understanding and opinion on gene technology be gathered. However, the Review notes that a body of information on public perceptions already exists. For example, successive reports on community attitudes to gene technology<sup>112,113</sup> have investigated the level of awareness and support for gene technologies in Australia.

Market research undertaken by the Review has shown that there is an opportunity for targeted communication activities to increase the level of awareness and understanding of the extent of gene technology, any risks, and how they are managed through regulation. It highlighted the complexity of actively engaging with the public, because different stakeholders have varying levels of trust in the information, and in the originator and promoter of that information.

The vast majority of Australians surveyed have highlighted the need to better educate the public about GM in Australia.

111 Productivity Commission. (2016). *Regulation of Agriculture*, p. 40. Retrieved July 10, 2018, from <http://www.pc.gov.au/inquiries/completed/agriculture/report>

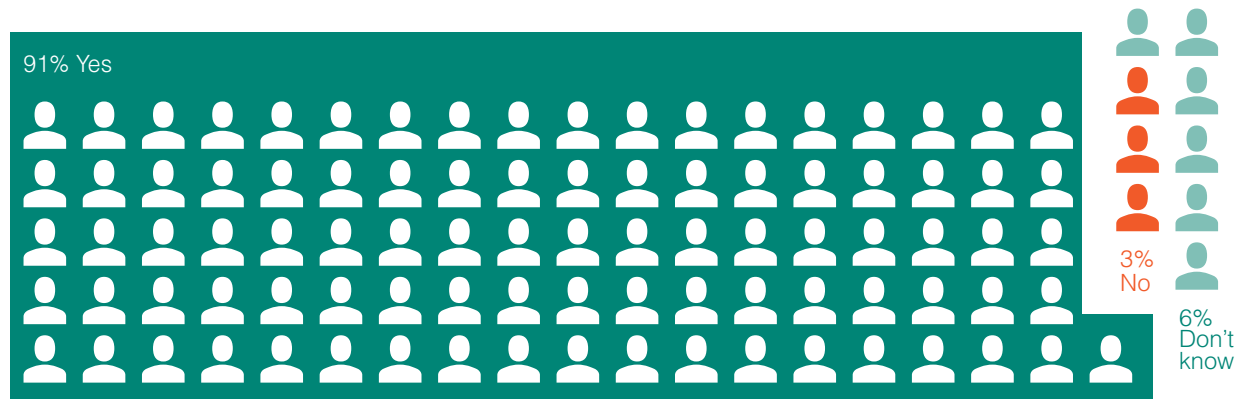
112 Instinct and Reason. (2017). *Community attitudes to gene technology*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-other>

113 Instinct and Reason (2015). *Community attitudes to gene technology*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-other>

**FIGURE 6**

Market research – Education about gene technology

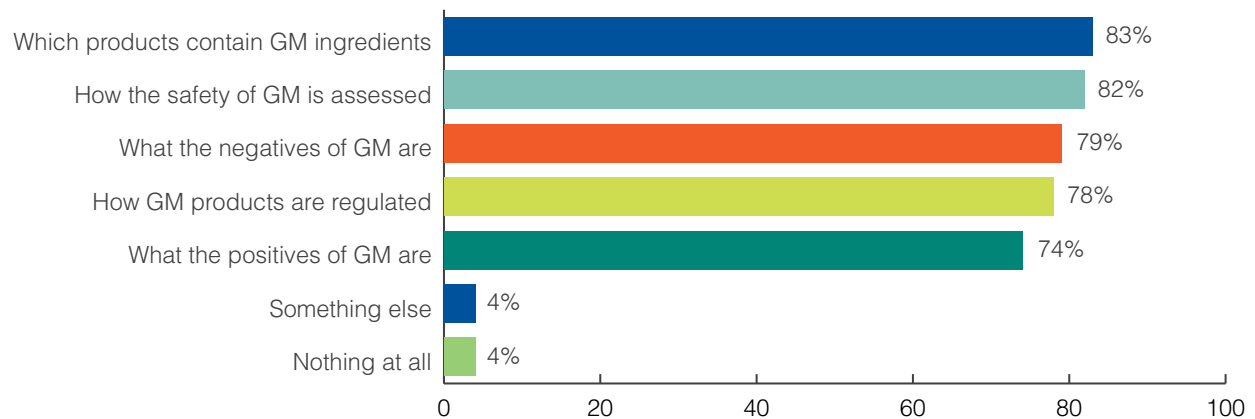
**Do you think there is a need to provide the public with more information about GM foods?**



Market research sought to understand what the general public wants to know about in relation to GM and gene technology. The majority of those surveyed expressed interest in a broad range of information, as outlined below:

**FIGURE 7**

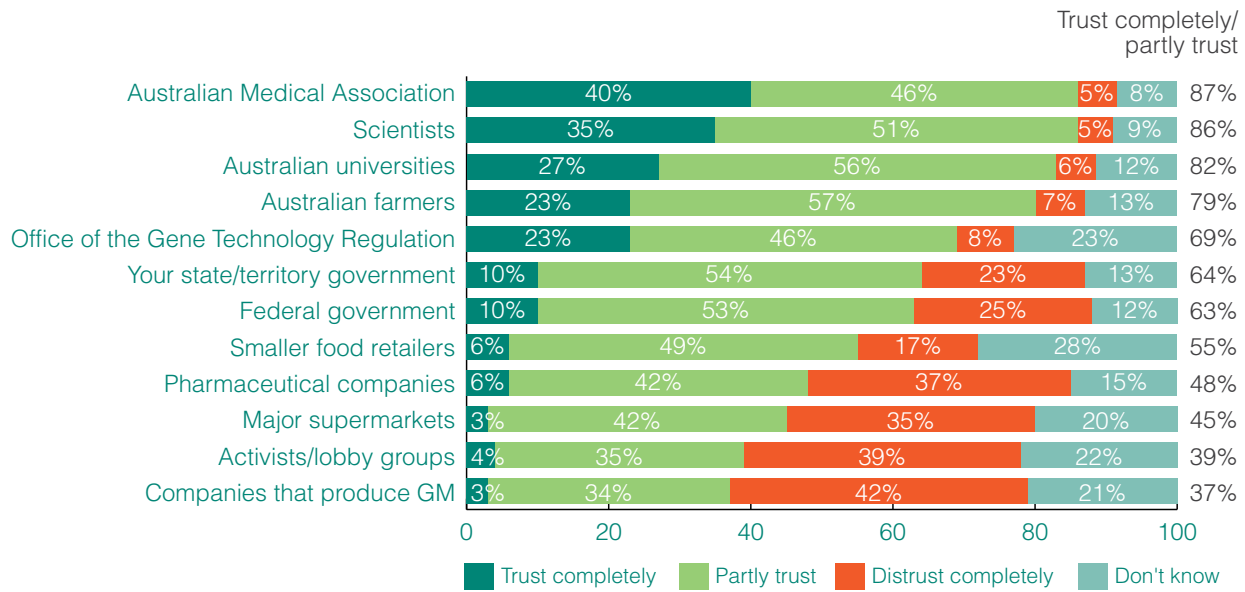
Market research – Type of information the public needs



Given that public trust in the regulatory Scheme and the agencies involved is a crucial element of best practice regulation, the research also provided insight into agencies that would be trusted to deliver the information required. Market research identified that Australians currently report getting most of their information about gene technology from a wide variety of sources, most commonly via TV (e.g. documentaries, current affairs). However, they believe that the Australian Medical Association, scientists and universities are the most trusted sources for providing unbiased and regulated response to the public. See Figure 8 and [Appendix 10: Outcomes of Market Research](#) for more detail.

**FIGURE 8**

Market research – Trusted sources for reputable information



Stakeholders acknowledged the challenge associated with implementing the proposed public information and communication campaign, given the complexity and technical nature of gene technology. Some highlighted the need for designated funding to develop and deliver such a campaign.

*In Summary, the Review heard that public understanding and confidence in the Scheme may be aided by additional communication mechanisms (building on existing bodies of work), delivered by an appropriate body, and appropriately funded.*

*Additionally, the Review recognised that any new information and communication work would need to consider:*

- *specific topics to target communication activities appropriately;*
- *the type of communication mechanism that will build confidence in the Scheme;*
- *previously undertaken communication activities, so as not to duplicate work unnecessarily;*
- *the best way to capture particular groups, so that it will assist them to understand the regulatory requirements and facilitate compliance (such as in the 'DIY biology' sector, Recommendation 12); and*
- *that the success of any communication activities will depend on appropriately directed delivery, by an appropriate person/organisation.*

**Recommendation 23:** The Review recommends that targeted communications be developed to aid public understanding and confidence in the Gene Technology Scheme and identify the most appropriate body/bodies to deliver communications materials.

*The Review concluded that it is appropriate for the Gene Technology Regulator to continue to lead communication activities on topics related to their legislated responsibilities.*

**Recommendation 24:** The Review recommends that the Gene Technology Regulator continue to lead communication activities on topics related to the assessment of risk associated with gene technology.

# Public understanding and confidence in the Gene Technology Scheme: Safety concerns and post market review

The acceptance of a regulatory scheme is dependent on public trust that it is well designed and managed, and that the rules are being followed. How to achieve this public trust and enable the community to best understand the benefits and risks of a complex, science-based technology is discussed below, as well as in [Recommendation 27](#).

Stakeholders generally expressed a high level of support for the Scheme, and trust in the Regulator to protect people and the environment from any risks associated with gene technology. However, a number of stakeholders expressed concerns regarding the safety of GMOs, and in particular the safety of genetically modified (GM) foods. This includes concerns about the inherent safety of GMOs, about information and knowledge gaps, the safety of herbicide or pesticide used on some GM crops, and the ability of the Regulator to monitor commercialised GMOs for long-term impacts.

## Concerns about the inherent safety of GMOs

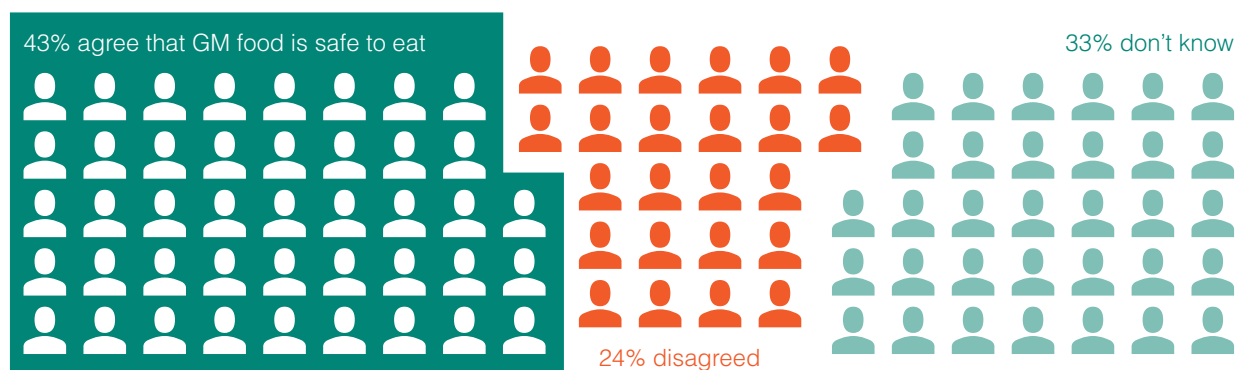
There is significant research to support the view that sentiment towards GM in Australia is highly polarised. Some stakeholders have described a lack of public confidence in the long-term safety of GMOs in the environment and in the human diet. These stakeholders point to studies and articles which suggest potential safety concerns about GMOs. Conversely, other stakeholders have referenced large bodies of work on the history of safe use of GMOs, both in Australia and internationally.

Despite considerable regulatory controls and research to the contrary, some sections of the community continue to have ongoing concerns about the safety of GMOs, specifically in relation to genetically modified crops. Concerns relate to potential harm to the health and safety of humans or to the environment, such as an unintended trait introduced into a GMO, or an unintended or unpredicted consequence based on the traits of the GMO. These risks may be more acceptable for some GMOs than others, depending on the context of the GMO's use and environment. To address this, the Regulator's comparative risk assessment takes into account the risk of the GMO and the environment where it will be present.

While many Australians, when questioned, contend that they have far more important and immediate issues to deal with than GM, safety of GMOs is an area of confusion for many. Overall, while almost half of those surveyed in market research agree that GM food is safe to eat, a quarter of represented Australians disagreed – and one third just didn't know. Despite general acknowledgement that there have been no health scares or widely reported controversies over GM in Australia, some consumers still suspect that health and safety concerns around consuming genetically modified foods have not been completely disproven.

**FIGURE 9**

Market research – Is genetically modified food safe to eat?



With respect to the safety of GM medicines, it is interesting to note that while many Australians surveyed consider that GM medicine may not be safe, they are still likely to take it if prescribed by their doctor. This view is influenced by the general assumption that there is some sort of regulation in effect in Australia – and that GM medicines will be tested to ensure the benefits outweigh the risks.

The Review notes that evidence concerning the safety of particular GMOs is considered by the Regulator, and forms the basis of risk assessment and risk management activities. Further, the level of risk is evaluated according to the degree of seriousness and chance of harm that can be attributed to gene technology. The Office of the Gene Technology Regulator *Risk Analysis Framework* details the comparative risk assessment approach, which takes into account the risk of the GMO and the environment where the GMO will be present.<sup>114</sup>

The Review also noted that Food Standards Australia New Zealand (FSANZ) publishes responses to studies cited as evidence of adverse effects from GM foods.<sup>115</sup> However, despite the mechanisms currently in place, concerns continue to be raised by some stakeholders, with calls to broaden the scope of research considered by the Scheme.

A detailed scientific analysis of this matter is outside the scope of the current Review. However, the Review has undertaken a preliminary investigation of some of the published evidence that supports the safety concerns raised by some stakeholders. The Review also noted recent peer reviewed scientific publications and a number of case studies.<sup>116,117</sup> The Review's view to date is that the weight of recent scientific, peer reviewed evidence supports the underlying safety of GMO's released into the environment in Australia. There does not appear to be evidence of harms to human health or the environment at this point in time. Existing regulatory controls contribute to this outcome, given Australian licences are only granted should GMOs be assessed as safe in the context to which they will be used.

To ensure this remains the case, the existing monitoring and surveillance activities of the Regulator include consideration of recent scientific publications, and the Regulator also continues to monitor and act on any new evidence that may come to light. This may include a decision to commission specific research to assess the safety of a GMO to inform regulatory decisions (discussed below).

The Review concluded that there was no need to undertake further detailed analysis into this matter at this time. Consideration of safety aspects is fundamental to the Regulators' assessment and is an ongoing policy objective of the Scheme. Further, consideration of safety aspects will be integral to activities undertaken by the Forum in its forward action plan to implement recommendations from the Review.

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114 Office of the Gene Technology Regulator, Risk Analysis Framework, Retrieved 9 August 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/risk-analysis-framework>

115 Food Standards Australia New Zealand, *Response to studies cited as evidence of adverse effects of GM food*, Retrieved July 10, 2018, from <http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx>

116 National Academies of Sciences E, Medicine. *Genetically Engineered Crops: Experiences and Prospects*. Washington, DC: The National Academies Press; 2016

117 See Appendix 11 for a list of other materials considered by the Review. While the list is not exhaustive, further references are listed in footnotes throughout this document.

## Concerns about information and knowledge gaps

Some stakeholders also expressed concern that Office of the Gene Technology Regulator (OGTR) assessments are reliant solely on the data provided by applicants. To clarify, the OGTR assessments are informed by data provided in the application, as well as analysis of domestic and international published literature, and consultation with the Gene Technology Technical Advisory Committee (GTTAC) and other prescribed agencies (see section 52 of the Act).

In addition, some stakeholders have expressed concern that in situations where applications to the OGTR identify information gaps, these gaps are subsequently filled with 'best guesses'. These stakeholders have suggested that the Regulator should have the power to commission research to fill regulatory requirements or information gaps. Again, this function already exists in section 27 of the Act, which provides that a function of the Regulator is 'to undertake or commission research in relation to risk assessment and the biosafety of GMOs'. The Review notes that additional research is undertaken or commissioned on an 'as needs' basis.

Some stakeholders also called for GM foods to undergo additional (animal and human) testing, and for mandatory labelling requirements to apply. However, under the current Scheme the Regulator has no authority to impose food labelling requirements. Mandatory labelling requirements for GM foods are set out in the Food Standards Code, which FSANZ administers. These requirements reflect the policy decisions agreed to by food ministers when the Standard came into effect in December 2000. These were reaffirmed in 2011.

A number of stakeholders raised topics related to public access to regulatory material and the transparency of the scheme. This is discussed further in [Recommendation 27](#).

## Concerns about the safety of herbicides and pesticides used on GM crops

Throughout the Review consultation phases, concern has been expressed by some stakeholders regarding potential health and environmental impacts of herbicides or pesticides, such as glyphosate, used on some GM crops. The Review notes that while specifically useful for GM crops that have been modified to be glyphosate resistant, glyphosate is a commonly used herbicide that is also used to treat weeds and grasses that compete with non-GM crops, as well as to treat weeds in home gardens. Therefore, these concerns relate to the regulation of agricultural and veterinary products which is beyond the powers of the Act and is administered by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

## Concerns about the ability of the Regulator to monitor commercialised GMOs for long-term impacts

A number of stakeholders have expressed concerns about the potential unintended effects of GMOs in the environment. They support the establishment of a surveillance system in Australia.

Post-market review activities are already possible under the existing Scheme, as described in the OGTR's Risk Analysis Framework 2013<sup>118</sup> (RAF). Chapter 5 of the RAF describes the ability of the Regulator to impose licence conditions (as per Part 5, Division 6 of the Act) that require the licence holder to supply, or enable the Regulator to collect, specific information on the release. Potential 'triggers' for this component of post-release review are where the risk estimate is greater than negligible, or where there is relevant uncertainty (e.g. lack of consensus among expert advisors).

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118 Office of the Gene Technology Regulator. (2013). *Risk Management Framework*. Retrieved July 10, 2018, from [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raffinal5-toc/\\$FILE/raffinal5\\_2.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raffinal5-toc/$FILE/raffinal5_2.pdf)



The RAF also describes an additional two components of post-release review. These are:

- the collection of information on possible adverse effects of released GMOs on human health and the environment, which could form the basis of further investigation; and
- the review of Risk Assessment and Risk Management Plans (RARMPs) at any time after a licence is issued, to take into account any relevant new information.

The Regulator also has a series of contact points, as well as an information checklist, with which to report any allegations of non-compliance.<sup>119</sup>

The existing post-release review mechanisms, described above, provide substantial ability for the Regulator to identify any unintended effects of GMOs in the environment. However, given ongoing concern from some stakeholders, there may be benefit in additional engagement activities being undertaken to communicate with the public about these existing mechanisms. Additionally, consideration could be given to whether these mechanisms are sufficient going forward, or whether the Regulator requires additional powers. Any new post-release review mechanisms must not undermine science-based risk assessments and must only be utilised on the basis of credible evidence.

Some stakeholders have also expressed support for such a surveillance system to also monitor the effects of GMOs in the food supply. However, as described above, the approval of GM foods is a matter for FSANZ.

*Recognising the broad spectrum of views across stakeholder sectors, the Review found that despite current regulatory arrangements, there remain ongoing concerns – or for some an acknowledged lack of understanding – within some sectors of the community about the safety of genetically modified organisms, and in particular the safety of genetically modified foods.*

*Furthermore, the Review recognises that there are arrangements currently in place that identify and address stakeholder concerns regarding GMOs, and in particular the safety of GMOs.*

**Recommendation 25:** The Review recommends that the Gene Technology Regulator continue to identify and manage the risks posed by, or as a result of, gene technology, and to increase transparency and understanding.

*The Review heard that there may be benefit in additional consideration being given to whether current post-release review mechanisms are sufficient, whether additional public communication of activities undertaken is required to increase transparency, and whether mechanisms and resourcing for the Gene Technology Regulator to undertake additional surveillance activities are required.*

*The Review heard that some stakeholders have concerns about current post-release review mechanisms, recognising also that there are multiple possible approaches for addressing these concerns (i.e. additional mechanisms, additional communication, no action required).*

**Recommendation 26:** The Review recommends a science-based review of monitoring arrangements to ensure that any post release risks continue to be appropriately managed.

<sup>119</sup> Office of the Gene Technology Regulator, *Allegations of non-compliance*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/non-compliance-1>

## Transparency and access to information for the Australian public

The Review found that ensuring transparency of regulatory decision making, public access to information, and effective communication are crucial to the operation of the Scheme. These factors are important in alleviating community concerns regarding gene technology, facilitating choice and building the public trust and confidence necessary for effective regulation.

### Labelling of GM foods

A large number of submissions stated that the labelling of GM foods was a primary object of concern. The Review noted that food labelling is not within the remit of the Regulator, and that *the Australia New Zealand Food Standards Code – Standard 1.5.2 – Food produced using gene technology (Standard 1.5.2)*<sup>120</sup> is currently being reviewed.

However, while food labelling requirements are outside the scope of this Review, and it is not the remit of this Review to comment on food labelling (this is properly the remit of FSANZ), the Review noted there are only two commercially available crops currently grown in Australia: GM Canola, and GM cotton.<sup>121</sup>

Standard 1.5.2 requires food to be labelled as 'genetically modified' when the food consists of, or has as an ingredient, food that is a GM food. The mandatory labelling statement also applies when GM food has an altered characteristic, for example when the GM food has an altered composition or nutritional profile compared to its non-GM counterpart. There is an important exemption in this definition: when the refining process removes the novel DNA or novel protein, no label is required.<sup>122</sup> In other words, when the refining process removes all of the material that would make a plant a GMO in the first place, no label is required. As an example, this would be the case for GM canola where the oil refining process removes any novel DNA or novel protein. However, if the GM canola oil had a different fatty acid profile as a result of genetic modification, the mandatory labelling statement would still apply, irrespective of whether novel DNA or novel protein is present or absent.

The Review noted stakeholder views expressing dissatisfaction with GM food labelling. In line with Standard 1.5.2 discussed above, the Review understands that 'limited labelling of GM foods on supermarket shelves' may not indicate a flaw in the labelling system, but instead may be representative of the actual amount of GM foods available in Australia. Longitudinal surveys into community attitudes of gene technology would support this view. One such survey indicates Australians readily overestimate the amount of GM food in their environment.<sup>123</sup>

This is also borne out in market research undertaken by the Review to explore the type of information about gene technology, the risks and how they are managed through regulation, that the public would find valuable, as well as the sources that could be trusted to provide that information. Market research showed that most Australians believed there was a need to provide the public with more information about GM food. When asked whether GM foods should be labelled, the majority of people surveyed said yes. Refer to [Appendix 10: Outcomes of Market Research](#).

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120 *Australia New Zealand Food Standards Code – Standard 1.5.2 – Food produced using gene technology* (Cth) (Austl.). Retrieved July 10, from [http://www.foodstandards.gov.au/code/Documents/1.5.2 GM foods v157.pdf](http://www.foodstandards.gov.au/code/Documents/1.5.2%20GM%20foods%20v157.pdf)

121 A licence authorising the commercial release of safflower genetically modified for high oleic acid composition was announced 27 June 2018. The release of GM safflower may enter general commerce, for use in industrial oil production and animal feed. There is no intention to use the GM safflower in human food. See <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir158>

122 Importantly, where no genetic material remains, there is no physical means to directly distinguish the substance from that derived from a non-GMO source.

123 Instinct and Reason. (2017). Community attitudes to gene technology. Retrieved July 10, 2018, from [www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-other](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-other)

## Transparency

The Review found that there are a number of measures that contribute to high levels of openness, transparency and public access to information within the Scheme. These include:

- The 'Fact sheets' information page,<sup>124</sup> which includes information about how the public can get involved in the assessment process for release of genetically modified organisms;
- GMO Record (described below);<sup>125</sup>
- Field Trial Interactive Mapping;<sup>126</sup>
- Operational policy publications;<sup>127</sup>
- Publicly available scientific documents (i.e. science strategy, risk analysis framework, biology documents, and fact sheets);<sup>128</sup>
- Guidelines for working with GMOs;<sup>129</sup>
- Monitoring and Compliance protocols;<sup>130</sup> and
- Annual Reports tabled in Parliament.<sup>131</sup>

The GMO Record is a notable transparency provision of the Scheme. It is a comprehensive record available to the public and is designed to provide open access to information about GMOs released in Australia. It includes notifications of licence decisions,<sup>132</sup> full RARMPs,<sup>133</sup> and post-release licence conditions.<sup>134</sup>

In Australia, all Dealings involving Intentional Releases into the environment (DIR) involve a full public consultation process,<sup>135</sup> as well as consultation with all state and territory governments, other prescribed Commonwealth entities,<sup>136</sup> and the Scheme's technical advisory committee prior to each DIR licensing decision.

124 Office of the Gene Technology Regulator, Public participation in assessing gene technology. Retrieved July 30, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/factsheets>

125 Office of the Gene Technology Regulator, *Record of GMO Dealings*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmorec-index-1>

126 This interactive map shows locations of field trial sites, and includes both current field trial sites as well as post-harvest monitoring sites. See Office of the Gene Technology Regulator, *Genetically Modified Organisms – Field Trial Sites*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/map>

127 Office of the Gene Technology Regulator, *Operational Policies*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/policies-1>

128 See Office of the Gene Technology Regulator's website, Retrieved July 10, 2018, from [www.ogtr.gov.au](http://www.ogtr.gov.au)

129 Office of the Gene Technology Regulator, *Accreditation process*. Retrieved July, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/accreditation-process>

130 Office of the Gene Technology Regulator, *Monitoring and Compliance*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mc-index-1>

131 Office of the Gene Technology Regulator, *Annual and Quarterly Reports under the Gene Technology Act 2000*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1>

132 Notification of licence decisions outlines the Regulator's decision to issue a licence following the assessment of an application. The Review considers that the transparency of the licence application process is a strength underpinning the decision-making processes in the Scheme. The detail specific to a licence application (that is generally publicly available on the OGTR website) includes the entity applying for a licence, the organism involved, the introduced gene and modified trait, the length of the proposed licence, the location and size of any field trials.

133 Full RARMPs explain the risk assessment context, provide an assessment of risks posed by the GMO(s) and detail whether any of those risks require management. They also included a summary of submissions received during the public consultation process.

134 Licence conditions explain the licence conditions imposed by the Regulator. They provide details of the licence holder's obligations, including both general conditions required in all licences, and specific conditions for individual licences, as well as reporting requirements.

135 The DIR public consultation process invites written submissions from the public on the RARMP (consultation version) prepared by the Regulator as part of the assessment of the application. It explains how the public can access or obtain the consultation documents and the due date for submissions.

136 The prescribed agencies include,  
a) Food Standards Australia New Zealand,  
b) Department of Agriculture (Biosecurity),  
c) National Industrial Chemical Notification and Assessment Scheme,  
d) Australian Pesticides and Veterinary Medicines Authority,  
e) Therapeutic Goods Administration.

Some stakeholders have registered criticisms of the licence application process, citing concerns about commercially confidential information (CCI) relevant to licence applications, which is not available to third parties. The Review notes, however, that section 185(2) of the Act already enables the Regulator to refuse to declare information as CCI if the Regulator is satisfied that the public interest in disclosure outweighs the prejudice that the disclosure would cause to any person. This helps ensure the Scheme is appropriately transparent and that its underpinning objective of protecting human health and the environment remains the primary concern.

## Communication

Making relevant information publicly available, and catering to different public information needs (communicating effectively at a broader level, as well as having more detailed information publicly available), plays an important role in transparency. A significant number of stakeholders stated that 'freedom of information' was important to them, as information promotes accountability and informed choice in relation to use of gene technology.

The Review also notes the need to balance transparency with the potential for confusion and 'information overload' for audiences that are not familiar with gene technology and molecular biology.

## Accountability

The public has the opportunity to be involved in the process for granting a GMO dealing licence. Upon receipt of an application to release a GMO into the environment, the Regulator is required to prepare a RARMP. For a minimum period of 30 days, any interested party has the opportunity to provide comment on this public document. The Regulator will assess input on the RARMP in order to finalise the document and deliberate on whether to issue the licence.

Some stakeholders have suggested that members of the general public should be able to appeal regulatory decisions. Currently, the process for the review of a decision is specified in part 12 of the Act, which defines an 'eligible person' (and includes, for example, licence applicants and licence holders, but not members of the public) who may apply to the Regulator for the review of a decision. This approach is consistent with other regulatory schemes, such as the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which specifies the parties that are eligible to seek the review of decisions. Balancing any additional accountability achieved against the practical implications and additional burdens on other stakeholders, the Review does not consider that changing the current procedure in this area is warranted.

Market research conducted for the Review indicated that there was a prevalent expectation that big companies are profit driven and that, without adequate regulation, this may result in compromises which are not in the public interest. This perception highlights the need to balance a reasonable expectation of confidentiality to protect significant financial investments, with potential distrust in the regulatory scheme arising from what might be seen as a lack of transparency.

**FIGURE 10**  
Market research – Big organisations and genetic modification

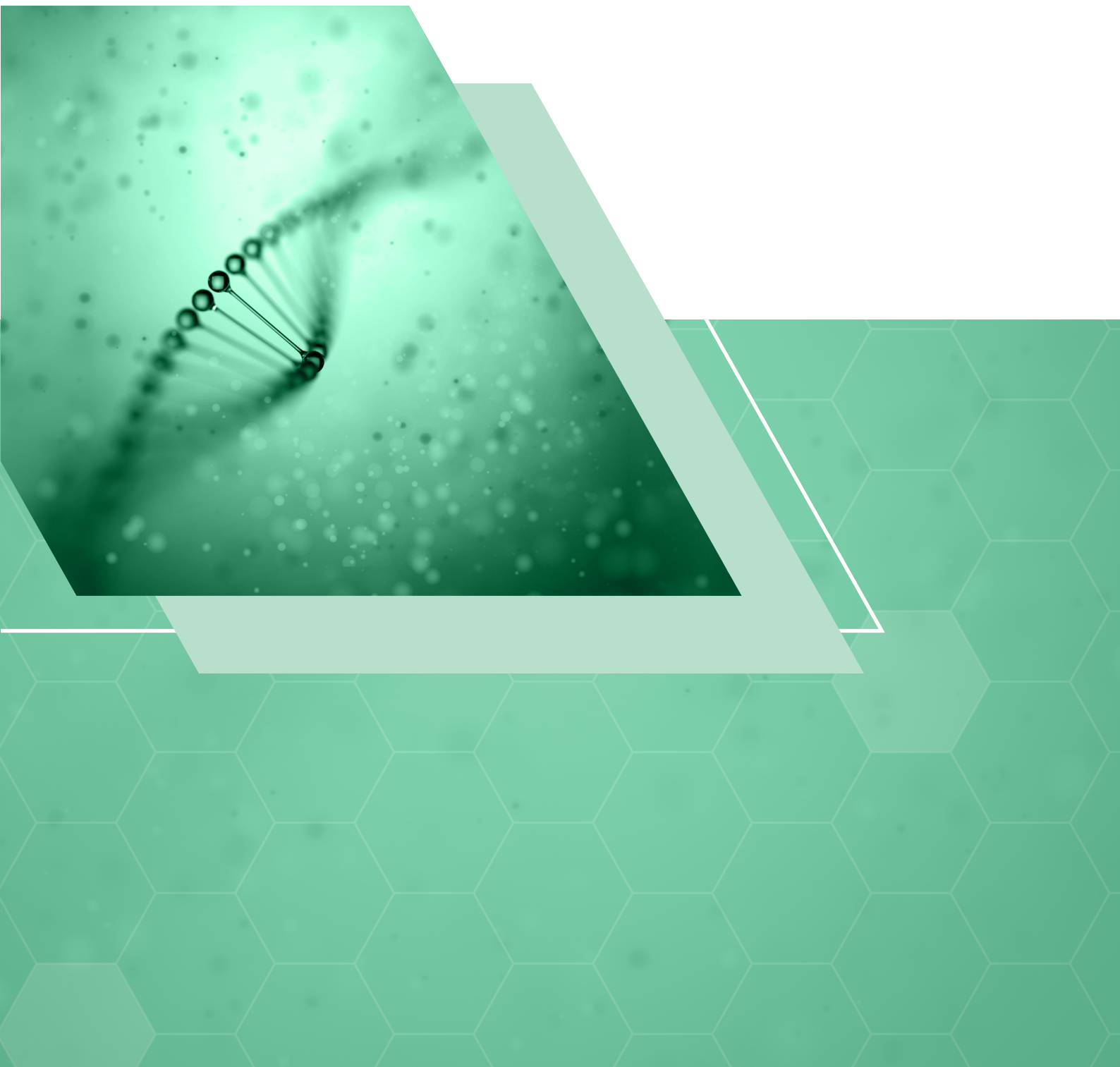


*The Review found that a high level of transparency and public access to information can be achieved through the Gene Technology Regulator continuing to make relevant information publicly available, and through increased communication with the public.*

*Ensuring transparency of regulatory decision making (in line with best practice regulation), public access to information, and effective communication, is vital to the operation of the Scheme. These factors play an important role in alleviating community concerns, facilitating choice and promoting the public confidence necessary for effective regulation.*

**Recommendation 27:** The Review recommends that the Gene Technology Regulator continue to make relevant information publicly available, to maintain a high level of transparency within the Scheme.

# What is the Gene Technology Scheme and how does it work?



# The Scheme

**Australia's National Gene Technology Scheme (the Scheme) regulates live and viable genetically modified organisms (GMOs). The Scheme regulates gene technology using a risk-based approach, where higher risk work with GMOs is subject to greater regulatory oversight. The Scheme came into effect on 21 June 2001, replacing the previous voluntary system of oversight.**

The complex regulatory landscape is represented in Figure 11: Overview of the Gene Technology Landscape in Australia.

## FIGURE 11

### Overview of the Gene Technology Landscape in Australia

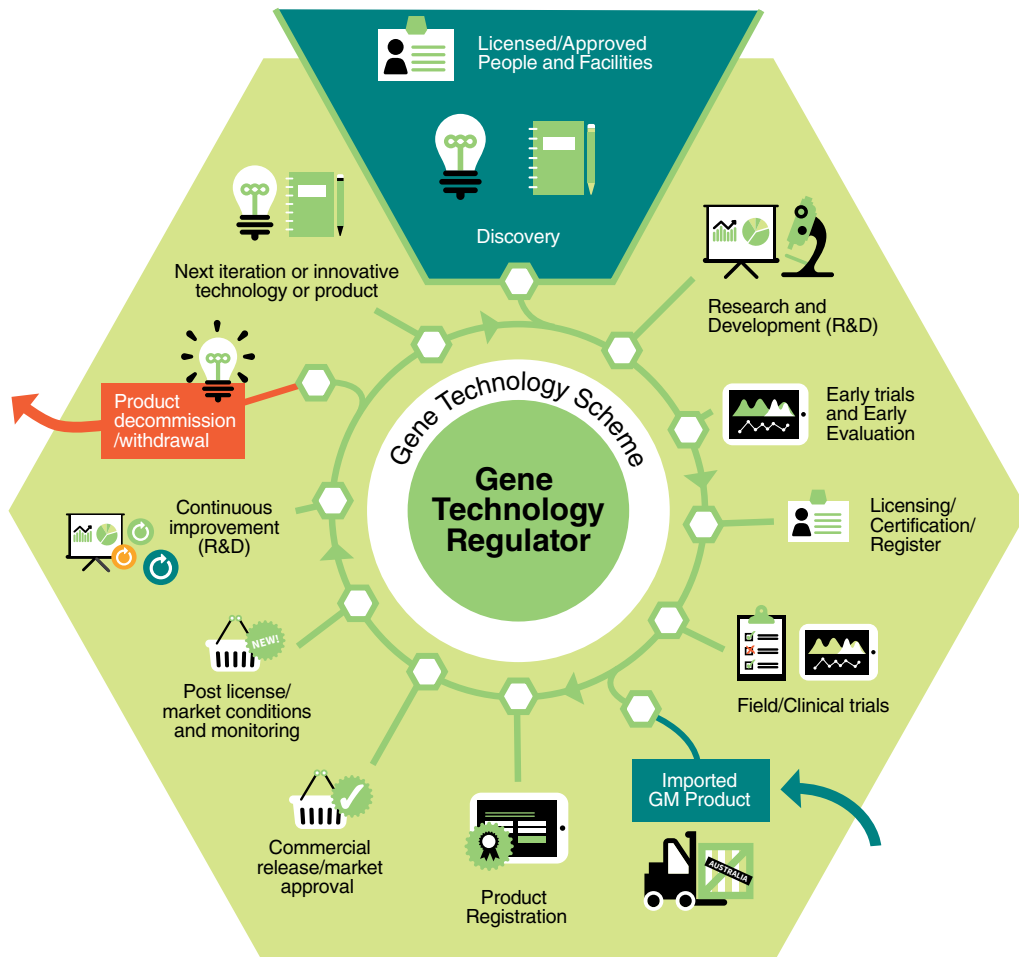
The activities, influences and controls that gene technology encounters in Australia are dependent on the technology used, the organism or the product.

#### Influences:

- environment
- research
- health
- industry
- transport
- trade
- science
- Intellectual property
- biosecurity
- food
- medicine
- consumers
- economy
- government
- international
- agreements

#### Controls:

- TGA (human therapeutics products)
- FSANZ (safe food supply products)
- APVMA (pesticides and animal therapeutics products)
- NICNAS (industrial chemicals products)
- DAWR (pest and disease control, conservation and biosecurity)
- State and Territory regulators
- National Health and Medical Research Council
- Institutional Biosafety Committees
- Ethics Committees
- Local governments
- Australian Competition and Consumer Commission
- IP Australia





The Scheme arose from the need to provide regulatory coverage for GMOs and genetically modified (GM) products not subject to existing regulatory schemes. The history leading to the development of the Scheme is in [Figure 12: Chronology of Gene Technology regulation in Australia](#). The Scheme operates in conjunction with other Australian regulatory schemes relevant to GMOs and GM products.

These include agencies regulating:

- food (Food Standards Australia New Zealand (FSANZ));
  - human therapeutic goods (Therapeutic Goods Administration (TGA));
  - agricultural and veterinary chemicals (Australian Pesticides and Veterinary Medicines Authority (APVMA));
  - industrial chemicals (National Industrial Chemical Notification and Assessment Scheme (NICNAS));
  - biosecurity (Department of Agriculture and Water Resources (DAWR)); and
  - protection of the environment (Department of the Environment and Energy (DoEE)).
- These relationships are represented in [Figure 14: Gene Technology Scheme interface with other Commonwealth regulatory schemes](#).

The *Gene Technology Act 2000* (the Act)<sup>137</sup> is the primary piece of legislation applying to gene technology. The Act and the *Gene Technology Regulations 2001* (the Regulations),<sup>138</sup> in conjunction with state and territory legislation, provides the legislative basis for the Scheme.

***The object of the Act and the Scheme 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 'dealings' (see below) with GMOs.***

An organism is regulated under the Scheme if it meets the definition of a GMO under the Act: 'an organism that has been modified by gene technology', with gene technology being 'any technique for the modification of genes or other genetic material'.<sup>139</sup> The scope of the Scheme and the definitions in the Act are intentionally broad. This ensures the Scheme captures current gene technology, as well as future extensions and advances in gene technology not otherwise regulated by the existing product regulators. This arrangement recognises that any organism created using a technological process that changes the genome should be examined to determine whether any potential harm to humans or the environment may arise.

This broad scope is balanced by the Regulations, which exclude certain organisms from the definition so that organisms and techniques with a long history of safe use are not unnecessarily regulated.

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137 *Gene Technology Act 2000* (Cth) (Austl.). Retrieved July 10, 2018 from <http://www.legislation.gov.au/Details/C2016C00792>

138 *Gene Technology Regulations 2001* (Cth) (Austl.). Retrieved July 10, 2018 from <http://www.legislation.gov.au/Details/F2016C00615>

139 See section 10(1) of the Act for complete definitions of these terms.

The scope of the Scheme is limited to 'dealings' with GMOs that are not captured by other regulator's existing legislation. To 'deal with' a GMO means to:

- conduct experiments with the GMO;
- make, develop, produce or manufacture the GMO;
- breed the GMO;
- propagate the GMO;
- use the GMO in the course of manufacture of a thing that is not the GMO;
- grow, raise or culture the GMO;
- import the GMO;
- transport the GMO;
- dispose of the GMO; or
- possess, supply or use the GMO for the purpose of any of the activities listed above.

Notably, this definition means that the Scheme does not cover the 'use' of a GMO, unless the use occurs for the purpose of a dealing. This, in part, recognises the role of existing schemes in regulating the use of the GMO or GM product, for example as a therapeutic, food or veterinary product.

Collectively, these interconnected regulatory schemes address the safety of the process to develop the GMO, as well as the safety of the subsequent product. This results in an integrated regulatory pathway through the lifecycle of a GM product. For example, in the case of a GM food product, the OGTR regulates the research and development, field trial and commercialisation phases of a GM crop. When a crop delivers a food product, its commercial use is regulated by FSANZ.

In Australia, all dealings with GMOs, whether conducted by a research facility or a member of the community, are prohibited by the Act unless they are appropriately authorised.

## The Gene Technology Agreement 2001

The Scheme is underpinned by the Gene Technology Agreement 2001 (the Agreement),<sup>140</sup> which exists between the Commonwealth and state and territory governments. Its aim is to support a nationally consistent regulatory system for gene technology. The Agreement acknowledges the need for a cooperative national legislative scheme, which collaborates with relevant, existing product regulators, and is consistent with international obligations.

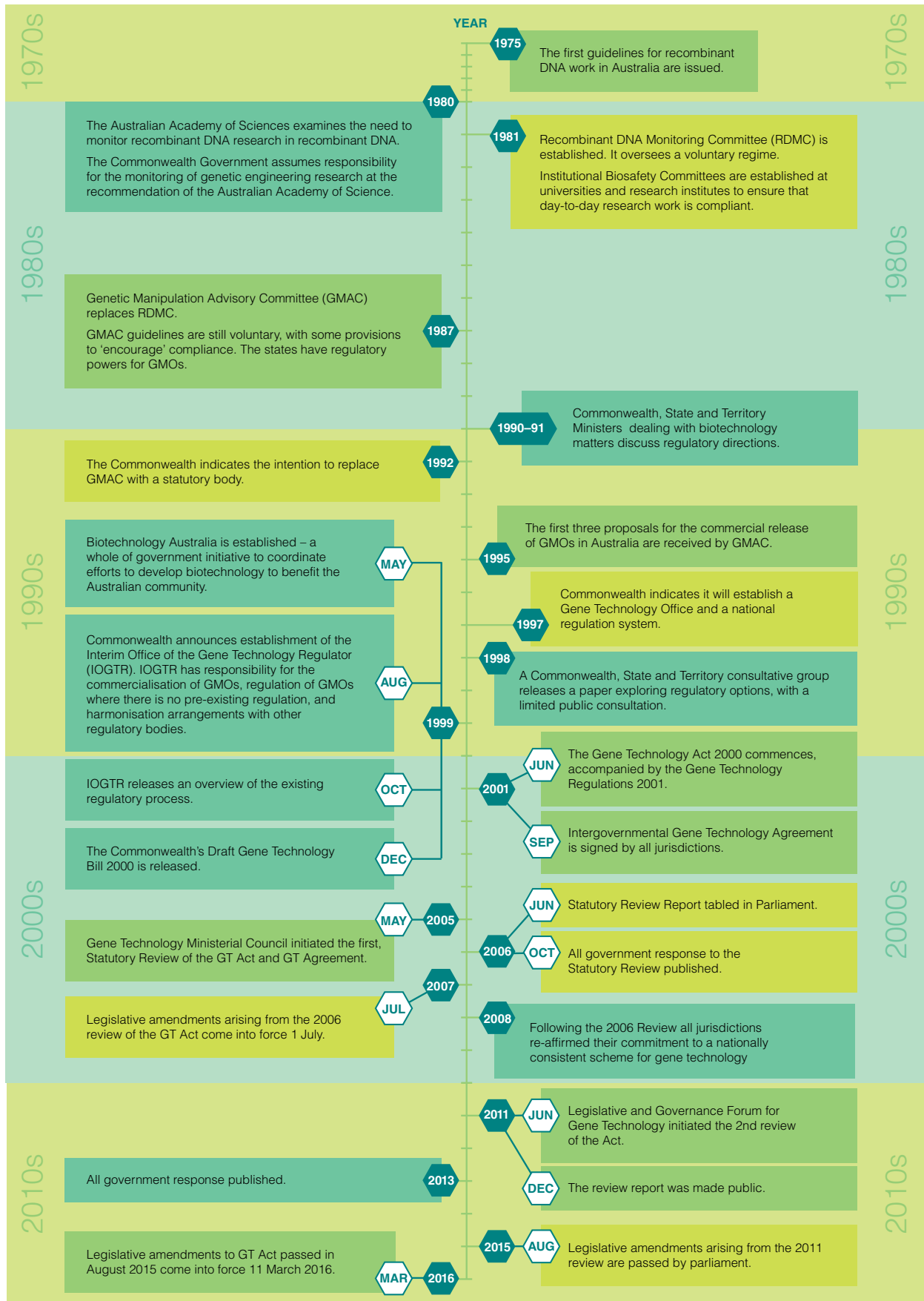
## The role of states and territories in the Scheme

The Scheme is a cooperative arrangement between the Commonwealth, states and territories. In addition to the Act and the Regulations at the Commonwealth level, each state and territory has its own legislation on gene technology. To allow for nationally consistent regulation, states and territories may request that the Commonwealth Minister declare their legislation to be corresponding to the Act. This gives the Gene Technology Regulator (the Regulator) powers to administer the gene technology legislation within that state or territory jurisdiction. Such an approach helps avoid possible inconsistencies in regulation, enforcement and compliance of GMO dealings across jurisdictions, as all gene technology legislation is administered by a single independent regulator. It also enables national coverage for all licence holders using gene technology.

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140 Department of Health, *The Gene Technology Agreement*. Retrieved July 10, 2018, from [www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-agreement](http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-agreement)

**FIGURE 12**  
Chronology of Gene Technology regulation in Australia



## The Legislative and Governance Forum on Gene Technology

The Agreement establishes a Ministerial Council, now known as the Legislative and Governance Forum on Gene Technology (the Forum), to govern the operation of the Scheme and the activities of the Regulator. The Forum is comprised of Ministers with responsibility for gene technology from every state and territory and the Commonwealth.<sup>141</sup> Members represent all portfolios with an interest in gene technology within their jurisdiction, ensuring the national Scheme is robust and representative of multiple policy and stakeholder perspectives.

The Forum has the power to issue Policy Principles, Policy Guidelines and Codes of Practice (as defined in the Act). These govern the activities of the Regulator and the operation of the Scheme. The Forum may issue Policy Principles or Policy Guidelines that relate to matters other than human health and safety and the environment, such as social, cultural and ethical considerations. The Regulator cannot issue a GMO dealing licence that is inconsistent with these Principles, and must have regard to any relevant Policy Guidelines.

## The Gene Technology Standing Committee

The Forum is supported by the Gene Technology Standing Committee (the Standing Committee), comprising senior officials from all jurisdictions (supporting their responsible Forum Minister). Members provide their jurisdiction's views, as a whole, on the matters considered by the committee.

The Standing Committee coordinates policy advice to the Forum and promotes a consultative national approach to gene technology policy development and implementation. It also supports the Forum in developing and issuing Policy Principles, Policy Guidelines and Codes of Practice.

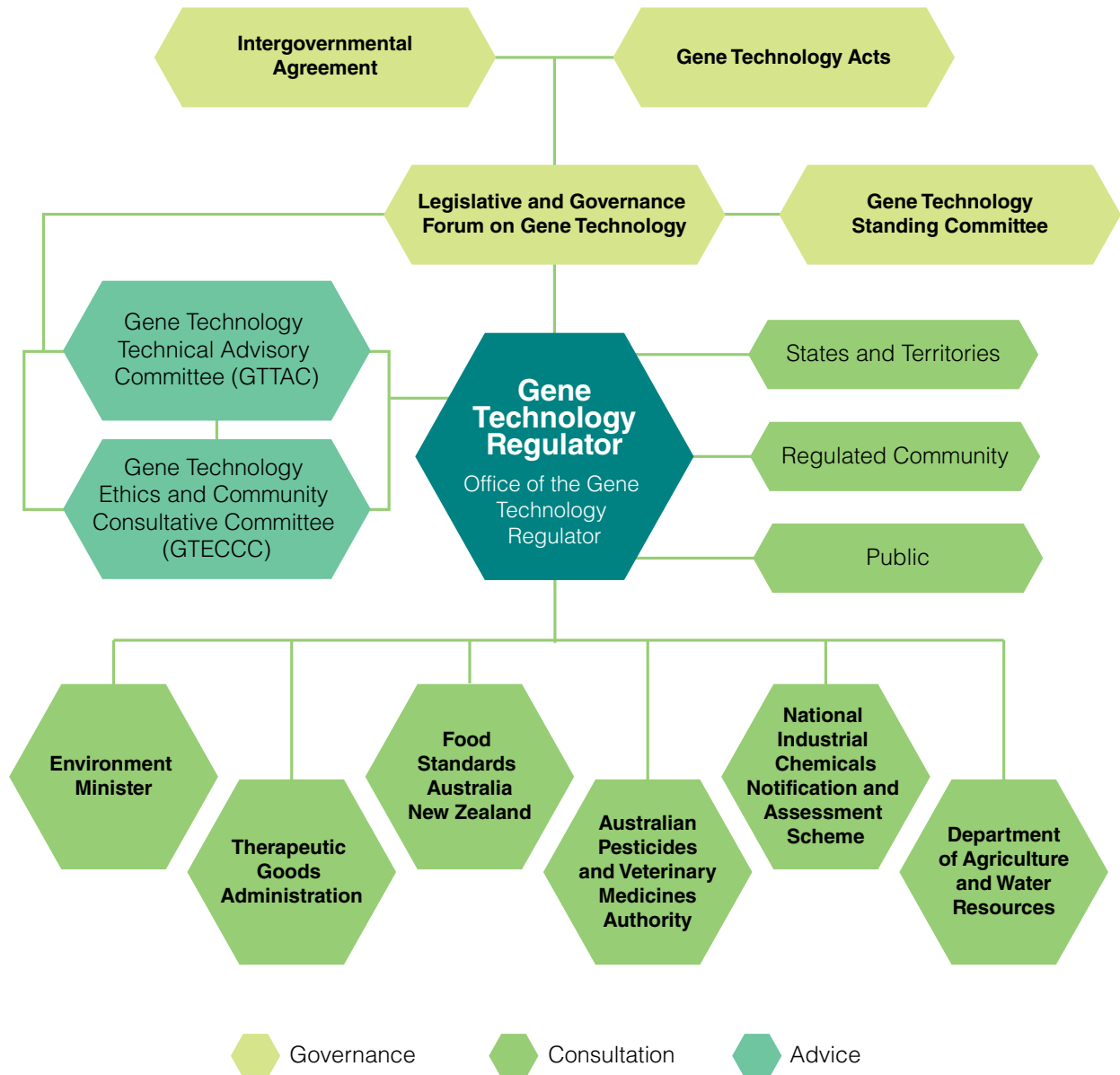
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<sup>141</sup> Department of Health, *Legislative and Governance Forum on Gene Technology*. Retrieved July 10, 2018, from [www.health.gov.au/internet/main/publishing.nsf/Content/gene-gtmc.htm](http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-gtmc.htm)

## Governance of the Scheme

The Act, corresponding state and territory law, and the Agreement together provide governance mechanisms to administer the Scheme. The governance, advisory and consultation structures for the Scheme are depicted in **Figure 13: National Gene Technology Regulatory Scheme governance, advisory and consultation structures:**

**FIGURE 13**  
National Gene Technology Regulatory Scheme governance, advisory and consultation structures<sup>142</sup>



<sup>142</sup> Sourced from Office of the Gene Technology Regulator, *Governance Arrangements for the Gene Technology Regulator*. Retrieved July 13, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/governance-1>

## The Gene Technology Technical Advisory Committee

The Gene Technology Technical Advisory Committee (GTTAC), established under the Act, provides scientific and technical advice on the request of the Forum or the Regulator, including advice on applications to deal with GMOs made under the Act.

GTTAC members are appointed by the Commonwealth Minister responsible for gene technology, following consultation with the Regulator, state and territory Ministers, and relevant scientific, community, health, environmental and industry organisations. Members are appointed based on their relevant knowledge and experience, and include experts in relevant scientific fields including risk assessment, public health and ecology, as well as a layperson. GTTAC must also include a person who is a member of the Gene Technology Ethics and Community Consultative Committee (see below).

## The Gene Technology Ethics and Community Consultative Committee

The Act also establishes the Gene Technology Ethics and Community Consultative Committee (GTECCC), which provides advice on the request of the Forum, or the Regulator, on ethical issues and matters of concern to the community in relation to GMOs.

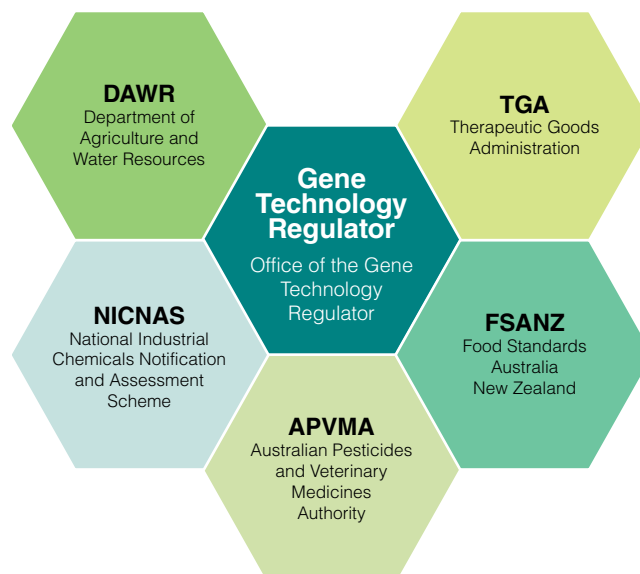
The GTECCC comprises members appointed by the Commonwealth Minister responsible for gene technology, following the same consultation process as for the appointment of GTTAC members. Members are appointed based on their skills and experience in relevant fields including community consultation, risk communication, ethics, law and environmental issues. The GTECCC must include a member of the GTTAC and a member of the Australian Health Ethics Committee.

## Interface with other legislation

As described above, the Scheme arose from the need to provide regulatory coverage for GMOs and GM products not regulated under existing regulatory schemes – for example, growing GM crops, or activity in the research sector. The Scheme’s interface with other regulatory schemes is represented below in [Figure 14: Gene Technology Scheme interface with other Commonwealth regulatory schemes](#).

**FIGURE 14**

Gene Technology Scheme interface with other Commonwealth regulatory schemes



The model provides for expertise on gene technology and GMOs to be centralised with the Regulator, ensuring safety advice on any risks posed by the technology are adequately addressed. It is also designed to minimise duplication between regulators.

Over time there has been an increase in health-related applications reaching commercialisation, delivering health outcomes in the therapeutic product and clinical sectors. Accordingly, in line with the increasing volume of regulatory activity in this space, the intersections and interactions with health related agencies and regulators are increasing.

A number of Commonwealth, state and territory governments and agencies have intersections and influence within the policy setting for the Scheme. As such, there are links to environment, transport, economic, trade, primary industry, international and health policy domains.

## Designated Areas Principle

The focus of the Scheme is to protect the health and safety of people and the environment, not to deal with marketing issues related to GMOs. These are matters for state and territory governments. This separation of responsibilities is acknowledged in the Act, which allows the Forum to issue Policy Principles<sup>143</sup> in relation to a number of topic areas, including:

*'recognising areas, if any, designated under state law for the purpose of preserving the identity of one or both of the following:*

*(i) GM crops;*

*(ii) non-GM crops;*

*for marketing purposes'.<sup>144</sup>*

Accordingly, in 2003 the Gene Technology (Recognition of Designated Areas) Principle 2003 was issued.

This Policy Principle recognises that a state or territory has the power to designate (under its own laws) areas to be 'GM crop areas' or 'non-GM crop areas'. These state and territory laws are known as 'moratoria legislation' and provide a means for preserving the identity of these crops for marketing purposes.<sup>145</sup>

This Policy Principle was intended to provide clarity and reduce the potential for inconsistencies to arise between state and territory laws and the Commonwealth Act. It prevents the Regulator from issuing a licence allowing GM crops to be grown in areas which have been designated as GM-free under state or territory law.

Moratoria legislation was subsequently passed by all states and territories, with the exception of Queensland and the Northern Territory. However, as at May 2018, South Australia, Tasmania and the Australian Capital Territory are the only states that still have active moratoria legislation. Other jurisdictions have rescinded their legislation, or have retained moratoria legislation but have no active prohibitions in place which relate to Australia's commercially approved GMOs.

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143 Policy Principles are legislative instruments

144 See section 21(1)(aa) of the *Gene Technology Act 2000* (Cth) (Austl.). Retrieved July 10, 2018 from <http://www.legislation.gov.au/Details/C2016C00792>

145 'Marketing purposes' is taken broadly to mean impacts on the marketability of a specific product or its entrance into the marketplace, but is not defined in the Act and may be interpreted in different ways.



# Who is the Regulator and what do they do?

## Gene Technology Regulator

The Act<sup>146</sup> establishes the statutory office holder,<sup>147</sup> the independent Gene Technology Regulator (the Regulator), to administer the Act and corresponding state and territory legislation. The Regulator is appointed by the Governor-General, following agreement by a majority of jurisdictions, for a term of between three to five years.

The functions of the Regulator are outlined in the Act<sup>148</sup> and include the performance of functions in relation to GMO licences, and the provision of advice on the effectiveness of the legislative framework. A full list of the Regulator's functions is included at [Appendix 3](#).

## Office of the Gene Technology Regulator

The Department of Health provides staff who support the Regulator in the performance of their functions, by providing scientific and technical advice and undertaking risk analyses of dealings with GMOs. These staff form the Office of the Gene Technology Regulator (OGTR) and have expertise in scientific, legal, policy and administrative functions.<sup>149</sup> The Regulator may also choose to utilise staff from other Commonwealth or state and territory agencies.

The functions of the Regulator are currently funded through an annual Commonwealth appropriation to the Gene Technology Special Account, established by the Act.<sup>150</sup>

## Regulatory mechanisms

The Regulator's administration of the Act, and corresponding state and territory legislation, involves a wide range of regulatory activities. Additional information on some of the key regulatory activities of the Regulator is provided below.

## GMO authorisations

All dealings with GMOs are prohibited unless they are authorised by the Regulator under the Act.<sup>151</sup> The Act requires that dealings with GMOs are authorised as:

- an exempt dealing;
- a Notifiable Low Risk Dealing (NLRD);
- a licensed dealing;
- a dealing included on the GMO Register; or
- specified in an emergency dealing determination.

Australia has a risk-based regulatory scheme for GMOs. Each of the above authorisation categories (or 'tiers') impose different regulatory requirements depending on the level of risk posed by the GMOs in that particular category. For example, some categories impose specific containment requirements, while others require case-by-case assessment. The Regulations specify which dealings are suitable to be conducted under the authorisation categories.

See [Appendix 4](#) for additional information on GMO authorisation categories.

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146 Section 26 of the of the *Gene Technology Act 2000* (Cth) (Austl.). Retrieved July 10, 2018 from <http://www.legislation.gov.au/Details/C2016C00792>

147 A statutory office holder is an individual appointed to a position established through legislation for a public purpose.

148 Section 27 of the of the *Gene Technology Act 2000* (Cth) (Austl.). Retrieved July 10, 2018 from <http://www.legislation.gov.au/Details/C2016C00792>

149 Office of the Gene Technology Regulator, *Operations of the Gene Technology Regulator Annual Report 2016–17*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1>

150 Department of Health, *Annual Reports*. Retrieved July 10, 2018, from <http://www.health.gov.au/internet/main/publishing.nsf/Content/Annual+Reports-3>

151 Section 31 of the of the *Gene Technology Act 2000* (Cth) (Austl.). Retrieved July 10, 2018 from <http://www.legislation.gov.au/Details/C2016C00792>

## Facility certification and organisation accreditation

All dealings with a GMO that are not authorised for an intentional release into the environment must be carried out in a certified facility. The Act allows the Regulator to certify physical containment (PC) facilities to ensure that appropriate standards are met for containment of GMOs, including that only trained and competent staff work with GMOs.

The Regulator has issued guidelines under the Act specifying requirements for various facility types (for example, laboratory, plant and animal), which must be met prior to certification.<sup>152</sup> Certification requirements address both the physical and behavioural aspects of containment.

The Act also allows for the accreditation of organisations. The process of accreditation enables the Regulator to assess if the organisation has the resources and the internal processes in place to enable it to effectively oversee work with GMOs.<sup>153</sup>

## Monitoring and compliance

The OGTR undertakes a range of monitoring and compliance activities, including monitoring, audits, inspections and investigations. Monitoring and compliance activities also comprise risk assessment and management, reviews of an organisation's activities and reporting.<sup>154</sup>

See [Appendix 5](#) for additional information on OGTR monitoring and compliance activities.

## Public communication

One of the functions of the Regulator is to provide “*information and advice to the public about the regulation of GMOs*”. This information is primarily provided via the OGTR website and includes:

- The GMO Record – a comprehensive record available to the general community, providing open access to information about GMOs released in Australia. It includes notifications of environmental release licence decisions, risk assessments, and post-release licence conditions;
- Field Trial Interactive Mapping;
- Operational policy publications;
- Scientific documents including science strategies, risk analysis frameworks and fact sheets;
- Guidelines for working with GMOs;
- Monitoring and Compliance protocols; and
- Annual Reports tabled in Parliament.

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152 Office of the Gene Technology Regulator, *Application to certify facilities*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/certifications-1>

153 Office of the Gene Technology Regulator, *Accreditation process*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/accreditation-process>

154 Office of the Gene Technology Regulator, *Monitoring and Compliance*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mc-index-1>

## Technical Review

Another core function of the Regulator is to provide advice to the Forum about 'the effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation'.<sup>155</sup> The Regulator is currently undertaking a technical review of the Regulations (the Technical Review) to provide clarity about whether organisms developed using a range of new technologies are subject to regulation as GMOs, and to ensure that new technologies are regulated in a manner commensurate with the risks they pose.<sup>156</sup> The Technical Review is intended to provide an interim solution while broader policy considerations associated with new technologies are being progressed through the Review of the Scheme.

## How and why is gene technology used in Australia?

Since the establishment of the Scheme in 2001, the application of gene technology in Australia has changed. There has been an expansion in the types of GM traits being trialled, the range of crop species being modified has expanded, and human and animal therapeutics have advanced from testing and clinical trial stages to commercialisation.

In the future, it is very likely that there will continue to be rapid changes in the types of gene technology applications seen in Australia. Some of the main applications of gene technology in Australia currently include the following.

### Medical and veterinary applications

The production of pharmaceuticals derived from GMOs has been proceeding for a number of years, with gene technology utilised to produce vaccines and therapeutics for both humans and animals. Authorisations have been granted by the Regulator for the commercialisation of a GM dengue vaccine, a GM influenza vaccine and for the commercial supply of a tumour-selective GM virus for cancer therapy.<sup>157</sup>

### Agricultural applications

The current commercially released GM crops in Australia, cotton and canola<sup>158</sup>, have been modified to introduce insect resistance and/or herbicide resistance. Today, the majority of cotton grown in Australia is GM, while approximately twenty percent of canola grown in Australia is GM.<sup>159</sup>

More recently, GM crop varieties are being trialled which have been developed to include disease resistance, growth vigour or tolerance of moisture stress. There are also a number of other products under development that include traits designed to benefit the community, such as production of omega 3 oils in canola, rye grass with low allergenic properties, and oilseeds and cereals with improved food characteristics.<sup>160</sup>

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155 Section 27 of the *Gene Technology Act 2000* (Cth) (Austl.). Retrieved July 10, 2018 from <http://www.legislation.gov.au/Details/C2016C00792>

156 For more information on the Technical Review, see Office of the Gene Technology Regulator, *Technical Review of the Gene Technology Regulations 2001*. Retrieved July 10, 2018 from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewregulations-1>

157 Office of the Gene Technology Regulator, *Table of authorisations for commercial therapeutic GMOs (subset list of licences involving Intentional Release)*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gm-1>

158 A licence authorising the commercial release of safflower genetically modified for high oleic acid composition was announced 27 June 2018. The release of GM safflower may enter general commerce, for use in industrial oil production and animal feed. There is no intention to use the GM safflower in human food. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir158>

159 Cotton Australia, *Biotechnology and Cotton*. Retrieved March 21, 2018, from <http://www.cottonaustralia.com.au/cotton-library/fact-sheets/cotton-fact-file-biotechnology> Mecardo (2018) *Analysis of price premiums under the South Australian GM moratorium*. Retrieved July 10, 2018, from [http://www.grainproducerssa.com.au/uploads/media/Projects\\_and\\_Policy/FINAL\\_Analysis\\_of\\_price\\_premiums\\_under\\_the\\_SA\\_GM\\_moratorium.pdf](http://www.grainproducerssa.com.au/uploads/media/Projects_and_Policy/FINAL_Analysis_of_price_premiums_under_the_SA_GM_moratorium.pdf)

160 Office of the Gene Technology Regulator, *Table of applications and authorisations for Dealings involving Intentional Release (DIR) into the environment*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1>

## Gene technology in an international context

The Scheme sits within a complex international regulatory setting. It is important that this context is taken into account when considering any changes to regulation in Australia. This includes considering Australia's obligations under international treaties, guidelines and accepted international standards, as well as how gene technology is regulated in other countries.

### International treaties

#### The Convention on Biological Diversity

A key international treaty relating to gene technology is the United Nations Convention on Biological Diversity (CBD). The main objectives of the CBD are the conservation of biological diversity,<sup>161</sup> the sustainable use of the components of biological diversity, and the fair and equitable sharing of benefits arising out of the utilisation of genetic resources.<sup>162</sup> Australia has been a party to the CBD since it came into force on 29 December 1993, and continues to be an active party to the Convention.

There are two supplementary protocols to the CBD also relevant to gene technology; the Cartagena Protocol,<sup>163</sup> and the Nagoya Protocol, the latter of which Australia is a signatory.<sup>164</sup> Although Australia has not ratified these protocols, we continue to participate in and contribute to relevant protocol activities. Australia participates in meetings to stay informed of key issues and to work with like-minded countries, to ensure that the protocols are workable, consistent with other international obligations and are achieving environmental objectives.

#### Other relevant international agreements

There are a number of other international agreements and mechanisms also relevant to Australia's regulation of gene technology. These include:

- the World Trade Organisation (WTO) Agreement on Sanitary and Phytosanitary Measures;<sup>165</sup>
- the Codex Alimentarius;<sup>166</sup> and
- the Organisation for Economic Cooperation and Development (OECD) Working Party on Biotechnology, Nanotechnology and Converging Technologies.<sup>167</sup>

These and other relevant agreements provide international guidelines and standards that are being considered in reviewing the regulation of gene technology in Australia.

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161 The CBD defines biological diversity as "the variability among living organisms...this includes diversity within species, between species and of ecosystems". See *Convention on Biological Diversity, Article 2*. Retrieved July 10, 2018, from <http://www.cbd.int/convention/text/default.shtml>

162 Convention on Biological Diversity, *Introduction*. Retrieved July 10, 2018, from [www.cbd.int/intro/default.shtml](http://www.cbd.int/intro/default.shtml)

163 The Cartagena Protocol seeks to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology. See Convention on Biological Diversity, *The Cartagena Protocol*. Retrieved July 10, 2018, from <http://bch.cbd.int/protocol/background/>

164 The Nagoya Protocol provides a framework for the fair and equitable sharing of benefits arising from the use of genetic resources. Convention on Biological Diversity, *The Nagoya Protocol*. Retrieved July 10, 2018, from <http://www.cbd.int/abs/about/>

165 The World Trade Organisation (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS) is an international agreement that sets out the WTO rules on how governments can apply food safety and animal and plant health measures. For more information, see World Trade Organisation, *Sanitary and phytosanitary measures*. Retrieved July 10, 2018, from [http://www.wto.org/english/tratop\\_e/sps\\_e/sps\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/sps_e.htm)

166 The Codex Alimentarius are international food standards, guidelines and codes of practice that contribute to the safety, quality and fairness of international food trade. For more information, see Food and Agriculture Organization of the United Nations, *About Codex Alimentarius*. Retrieved July 10, 2018, from <http://www.fao.org/fao-who-codexalimentarius/about-codex/en/>

167 The Organisation for Economic Cooperation and Development Working Party on Biotechnology, Nanotechnology and Converging Technologies aims to address policy issues related to biotechnology, nanotechnology and their convergence with other technologies. For more information, see Department of Industry, Innovation and Science, OECD. Retrieved July 10, 2018, from <http://www.oecd.org/sti/emerging-tech/>

## Regulation of gene technology in other countries

When reviewing Australia's domestic regulation of gene technology, it is important to be informed on developments in the regulation of gene technology in other countries. Currently, there is no clear international consensus on the best way to regulate gene technology, with countries taking a variety of different approaches.

While Australia predominately regulates on the basis of the process used to create a GMO, in some other countries regulation is based more on the nature of the product itself, rather than the process through which it is produced. In some jurisdictions, for example the European Union (EU), regulation of GMOs is achieved on the basis of 'the technique used and the characteristics of the end product'.<sup>168</sup>

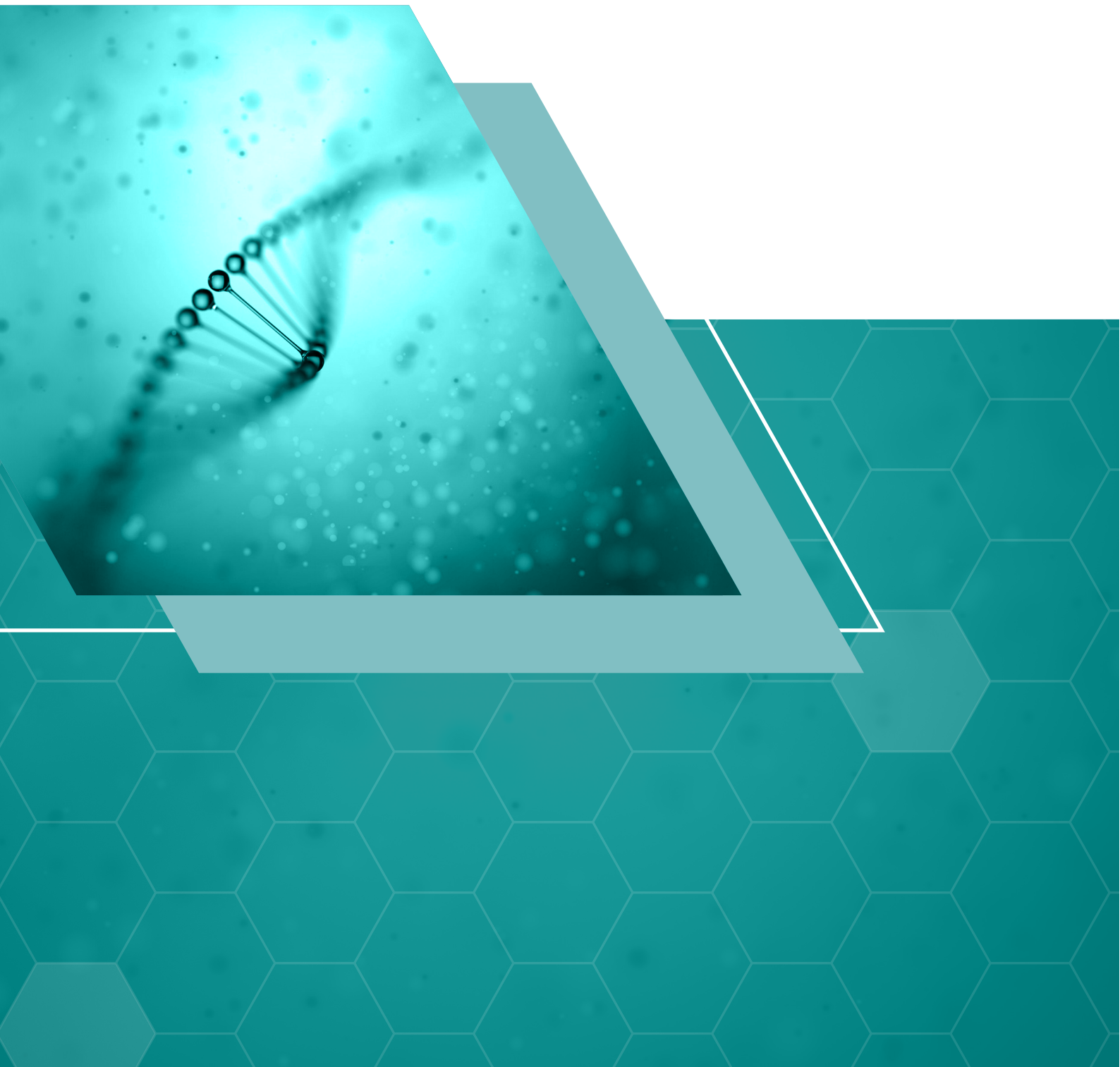
Being aware of the differences between regulatory systems in other countries is important to understanding the broader environment in which Australia's gene technology Scheme operates. This helps ensure that domestic regulation (which may operate differently) remains compatible and can interact effectively with our international counterparts.

Overall, the international context of gene technology regulation is complex, and the lack of internationally accepted regulation norms in this area leads to divergence in regulatory approaches between countries. Polarised views on GMOs and the social and ethical questions they raise are ubiquitous, and as technology continues to swiftly progress, these are issues that all countries will continue to grapple with.

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<sup>168</sup> Custers, R. (2017). *The regulatory status of gene-edited agricultural products in the EU and beyond*. Emerging Topics in Life Sciences Sep 15, 2017. DOI: <http://dx.doi.org/10.1042/ETLS20170019>

# The Third Review of the Gene Technology Scheme



The Third Review (the Review) of the National Gene Technology Scheme (the Scheme) was designed to be a forward looking, inclusive and wide-reaching examination of Australia's national Scheme and its evolving policy setting. The Review's purpose is to inform and advise Australian Governments, represented through the Legislative and Governance Forum on Gene Technology (the Forum), of means to strengthen and improve the Scheme so that it will be effective into the future.

## Why is the Review being conducted?

Under the Gene Technology Agreement 2001 (the Agreement), a periodic review of the Scheme is required to be conducted.<sup>169</sup> Periodic reviews provide a way to address technological advances and develop an understanding of factors which may challenge the scope and provisions of the Scheme. Regular review of the Scheme ensures regulation remains fit for purpose, supports industry and innovation, and provides confidence and assurance to the public that the environment and their health and safety is being considered and protected.

The Review notes that the existing legislative and governance arrangements for the Scheme provide full regulatory coverage of gene technology across Australia. However, these arrangements, while appropriately rigorous, can lack the agility to keep pace with the exceptional rate of change in gene technology seen over the last few years, and which is expected to continue into the future. As a undertaking a review at this point was both necessary and timely.

The Gene Technology Regulator (the Regulator) can also undertake reviews of the Gene Technology Regulations 2001 (the Regulations) in order to improve the clarity of definitions and practices. However under the Agreement, changes to what is to be regulated can only be made by Ministers responsible for gene technology policy; collectively the Forum. This Review is being undertaken under the auspices of the Forum and so has the ability to consider policy settings and the scope of the Scheme (i.e. what is regulated).

## Purpose and design

This national, strategic Review was designed to be a forward looking, inclusive and wide reaching examination of Australia's gene technology Scheme and its evolving policy setting. The Review's purpose is to inform and advise Australian Governments, represented through the Forum, of means to strengthen and improve the Scheme so that it will be effective into the future.

The Terms of Reference for the Third Review, agreed by all jurisdictions, are outlined on [page 13](#).

## Review governance

All Australian Governments agreed to initiate the Third Review of the Scheme, with the Forum announcing the Review in July 2017. The Forum's work on the Review is being supported by the Gene Technology Standing Committee (the Standing Committee), along with a smaller Standing Committee working group. The Standing Committee has presented the Review's recommendations for presentation to all Australian Governments, represented through the Forum.

Given the technical nature of the Scheme, a panel of experts was engaged to support the Review and provide expert technical advice. Members were selected on the basis of their knowledge and experience, and were drawn from animal, plant, medical and regulatory best practice fields. Additional information on the Expert Advisory Panel is provided in [Appendix 6](#).

The Review of the Scheme is independent of the Regulator and the Office of the Gene Technology Regulator (OGTR). However, the Regulator does have a unique position in the gene technology landscape due to their visibility of issues across the sector and the fact that they work directly with multiple stakeholder groups, including government gene

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<sup>169</sup> Part 6 of the Agreement outlines the requirements for regular reviews of the policy settings of the Scheme.



technology policy areas, regulated stakeholders and the public. In line with best practice for reviewing a regulatory policy setting, the Regulator has, where necessary, provided technical advice to inform the Review.<sup>170</sup>

All Australian Governments recognise, through the agreed Terms of Reference for the Review, that it is necessary to future-proof and modernise the Scheme, so that it continues to protect people and the environment, supports evolving science, and encourages innovation.

## Review consultation approach

The importance of thorough consultation to inform this Review is acknowledged by all Australian Governments. There is increasing recognition, across private and public sectors, of the value of policy co-design, whereby all those with vested interests are engaged in both identifying and constructing solutions to what are often multi-perspective issues.

To achieve this, consultation to inform the Review was organised in three key phases:

1. Phase 1: identified key issues for consideration
2. Phase 2: collaboratively explored policy solutions to these issues
3. Phase 3: provided an opportunity to comment on the findings

The Review took place within a complex stakeholder environment, which includes the following stakeholder groups.

**FIGURE 15**  
Map of Gene Technology Stakeholders



170 Organisation for Economic Cooperation and Development. (2012). *Best Practice Principles for the Governance of Regulators, Chapter 1: Role Clarity*, p. 31. Retrieved March 20, 2018, available from <http://www.oecd.org/gov/regulatory-policy/governance-regulators.htm>

In addition, the Review acknowledges the significant concurrent activity in the gene technology related arena (other reviews and policy debates), both nationally and internationally (see [Other reviews and inquiries](#)). Where possible, related reviews, reports and consultations have been taken into account, or referenced where they have yet to be concluded.

## Phase 1 consultation

Phase 1 was an open consultation process running from 25 July to 29 September 2017. Submissions were sought to identify issues within scope of the Terms of Reference for the Review. This phase of consultation was supported with a Background Paper.<sup>171</sup>

In addition to the call for public submissions, findings from the following reports and reviews were considered:

- Technical Review of the Gene Technology Regulations (the Technical Review);<sup>172</sup>
- *Productivity Commission Inquiry Report: Regulation of Australian Agriculture*;<sup>173</sup>
- *Smart Farming Report – Inquiry into Agricultural Innovation* (the Smart Farming Inquiry);<sup>174</sup> and
- 2006 and 2011 reviews of the National Gene Technology Scheme.<sup>175, 176</sup>

Research was also undertaken into specific areas to further define the issues presented, including emerging technologies, the basis of community concerns, and a longitudinal study of public perceptions.

Outcomes of Phase 1 consultation are outlined in [Appendix 7](#).

## Phase 2 consultation

The aim of the second phase of consultation was to work with stakeholders to further understand the issues, and explore options and possible policy solutions for the issues identified in Phase 1.

Consultation took place through a range of mechanisms, including:

- online responses to the consultation paper;
- jurisdictional workshops;
- targeted meetings; and
- interactive webinars.

Outcomes of Phase 2 consultation are outlined in [Appendix 8](#).

## Phase 3 consultation

Phase 3 consultation commenced on 29 March 2018. This Phase was open for a period of 8 weeks, closing 24 May 2018. Building on the first two phases of consultation, the Review findings were presented to stakeholders within the Review *Preliminary Report*.

Stakeholders were invited to contribute to the final outcomes of the Review by submitting their feedback through an online submission process.

Outcomes of Phase 3 consultation are outlined in [Appendix 9](#).

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171 Department of Health. (2017). *Review of the National Gene Technology Regulatory Scheme – Background Paper*. Retrieved July 10, 2018, from <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-technology-review#background>

172 Office of the Gene Technology Regulator, *Technical Review of the Gene Technology Regulations 2001*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewregulations-1>

173 Productivity Commission. (2016). *Regulation of Agriculture*. Retrieved July 10, 2018, from <https://www.pc.gov.au/inquiries/completed/agriculture/report>

174 House of Representatives Standing Committee on Agriculture and Industry. (2016). *Smart farming – inquiry into Agricultural innovation*. Retrieved July 10, 2018, from [www.aph.gov.au/Parliamentary\\_Business/Committees/House/Agriculture\\_and\\_Industry/Agricultural\\_innovation/Report](http://www.aph.gov.au/Parliamentary_Business/Committees/House/Agriculture_and_Industry/Agricultural_innovation/Report)

175 Office of the Gene Technology Regulator, *Previous reviews of gene technology legislation*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/regs-process-1>

176 Department of Health, 2011 Review of the *Gene Technology Act 2000* (GT Act). Retrieved July 10, 2018, from <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-techact-review>

## Other reviews and inquiries

In addition to the feedback received through Phase 1 and Phase 2 consultation processes, the Review committed to consider and take into account the publicly available submissions to, and the findings of, other relevant reviews and inquiry processes.

### Technical Review of the Gene Technology Regulations 2001

In 2016, the Regulator initiated a technical review of the Regulations, with a view to providing clarity about whether organisms developed using a range of new technologies are subject to regulation as genetically modified organisms (GMOs). The Technical Review is seeking to ensure that new technologies are regulated in a manner commensurate with the risks they pose.

Following public consultation on options, the Regulator has also consulted on specific proposals to amend the Regulations. Key proposals relate to the regulation of some new technologies, the regulation of some RNA<sup>177</sup> interference techniques and the regulation of contained dealings with gene drive GMOs.

### Food Standards Australia New Zealand (FSANZ) Review

FSANZ is reviewing how the Food Standards Code applies to food derived using new breeding techniques. A public consultation process (which concluded on 19 April 2018) considered whether and how food derived from new breeding techniques should be captured for pre-market approval and whether definitions for 'food produced using gene technology' and 'gene technology' should be changed to improve clarity about which foods require pre-market approval.

At the time of drafting, FSANZ has published a preliminary report summarising the issues raised in submissions. The preliminary report, along with submissions, was published on the FSANZ website in August 2018.<sup>178</sup> The findings of the FSANZ review were broadly congruent with those of the Gene Technology Scheme Review, where stakeholders identified the potential for the implementation of risk tiering and a lessened regulatory burden for products with a long history of safe use. FSANZ aims to conclude the review by the beginning of 2019, at which time they will consider whether to prepare a proposal to amend the Code.

### Productivity Commission Inquiry

The Productivity Commission Inquiry covered a wide array of regulatory areas, the majority of which were out of scope for this Review. A consistent theme in submissions to the Productivity Commission Inquiry was support for regulation to be fit for purpose and proportionate to the risk of the associated activity. This Inquiry also examined the regulation and use of GMOs, and heard a range of views from stakeholders.

The Productivity Commission Inquiry focused on the economics of the application of GMOs, their health and safety and that of genetically modified (GM) derived food products. This Inquiry also made recommendations relating to the imposition of moratoria on GMOs.

### Smart Farming Inquiry

The Smart Farming Inquiry received wide ranging input across a broad spectrum of agricultural and horticultural practice. Much of it, however, is out of scope for this Review. A number of stakeholders expressed divergent views on the development and application of gene technology in Australia. Committee recommendations included that the Australian Government pursue reform options to ensure national consistency in the regulation of gene technology.

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<sup>177</sup> See [Appendix 1: Glossary](#).

<sup>178</sup> Preliminary report: Review of food derived using new breeding techniques – consultation outcomes. Retrieved August 10 2018 from <http://www.foodstandards.gov.au/consumer/gmfood/Pages/Review-of-new-breeding-technologies-.aspx>

## Other research

### Market research

In February 2018, Quantum Market Research was engaged to further explore public attitudes, knowledge and beliefs about GMOs. This research explored the views of a representative sample of Australians, across a breadth of demographics, through the conduct of 12 focus groups and some 1,500 surveys. In brief, participants were asked to respond to a series of questions which focused on identifying information requirements for the public and testing the appropriateness of regulatory approaches. A summary of the outcomes of the research is provided at [Appendix 10](#).

### Other materials

While the Review findings are significantly informed by stakeholders' submissions, the Review has also taken note of relevant reports, reviews and academic publications.

Relevant research and publications used to inform the Review have been footnoted throughout the Report. A list of other materials considered by the Review is at [Appendix 11](#).

## Previous reviews of the Scheme

Since the commencement of the Scheme in 2001, two previous reviews (in 2006 and 2011) have focused on the operation of the Scheme and whether the policy objectives were being achieved. While there was some consideration given to technical aspects, they were predominately retrospective in nature, looking at how the Scheme had been functioning prior to the reviews. Both reviews confirmed that the policy objectives of the Scheme were still appropriate at the time.

The 2006 statutory review was comprehensive in scope, covering issues that had emerged or changed significantly since the Act was passed. It examined whether the policy objectives of the Act remained valid.

The recommendations from the review encompassed changes to improve the operation of the Act, including increasing the powers of the Regulator in cases of non-compliance, and reducing reporting requirements.

By comparison, the 2011 review was relatively limited in scope. It focused on the efficiency and effectiveness of the operation of the Act across the national scheme, and the interface between the Act and other regulation. The 2011 review produced minor and technical amendments to the Act to make gene technology regulation more efficient, effective and clearer.

### Implementation of previous recommendations

Legislative amendments to improve the operation of the Scheme were made as a result of each review. These legislative changes were implemented through the:

- *Gene Technology Amendment Act 2007*<sup>179</sup> and the Gene Technology Amendment Regulations 2007;<sup>180</sup> and
- *Gene Technology Amendment Act 2015*.<sup>181</sup>

The Review acknowledges that some recommendations from previous reviews have not yet led to change, including legislative amendments. Where previously raised issues remain outstanding, these have been addressed by the current Review, including through [Recommendation 1](#), and will be reflected in a proposed action plan.

179 *Gene Technology Amendment Act 2007* (Cth) (Austl.). [Federal Register of Legislation, Gene Technology Amendment Act 2007. Retrieved July 10, 2018, from <https://www.legislation.gov.au/Details/C2007A00099>]

180 *Gene Technology Amendment Regulations 2007* (Cth) (Austl.). [Federal Register of Legislation, Gene Technology Amendment Regulations 2007. Retrieved July 10, 2018 from <https://www.legislation.gov.au/Details/F2007L01317>]

181 *Gene Technology Amendment Act 2015* (Cth) (Austl.). [Federal Register of Legislation, Gene Technology Amendment Act 2015. Retrieved July 10, 2018, from <https://www.legislation.gov.au/Details/C2015A00121>]

## Regulatory reform agenda

In considering changes to the Scheme, the Review recognises the need for consistency with broader government regulatory reform agendas. These agendas focus on pursuing regulatory reforms that remove barriers to competition, innovation and growth; reducing compliance burden; and building on the ongoing commitment to cut red tape, improve regulator performance and strengthen Regulatory Impact Analysis processes.<sup>182</sup>

An important part of these regulatory reform agendas is to strike an appropriate balance between reducing the cost of regulation overall, to support innovation and investment, with the need for appropriate regulation to protect health, community safety and the environment.<sup>183</sup> This aspect is especially relevant to gene technology regulation, given the underlying objective of the Act.

When considering regulatory reform, it is also important to take into account the international context, and consider any impact that changes to Australian regulation may have on trade and interactions with other countries. For example, a reduction in Australian regulation may cause challenges for trading into markets where there are differences in regulatory approval requirements. Thus, any moves to change regulation should be carefully considered to ensure that domestic regulation does not pose a barrier to international collaboration, market access and trade with international trading partners.

## Next steps

The Review was undertaken by all governments through the Forum, using a comprehensive consultation process that included government and non-government stakeholders. As such, the recommendations are those of all governments. Through the Forum, all governments will collectively make decisions on the progression of the recommendations, through an agreed Action Plan, in lieu of publishing a separate All Governments Response.

Following Legislative and Governance Forum on Gene Technology agreement and endorsement of the recommendations from this third Review, work will need to be undertaken to progress implementation of its recommendations. A number of the Review's outcomes highlight the need for further consideration, particularly in the context of relevant concurrent national and international debate and reviews. Any related planning to address these issues would, where necessary, involve further consultation with stakeholders.

Drafting of legislative amendments may be informed by public consultation, and could cover the matters included in recommendations, as well as minor administrative changes.

Any legislative amendments to the Commonwealth Act and Regulations then need to be agreed by all states and territories, through the Forum, prior to being considered by the Australian Parliament. Following the passage of any amendments to the Commonwealth Act and Regulations, corresponding state and territory legislation will be amended (automatically for states and territories with lock-step, or through parliamentary processes).

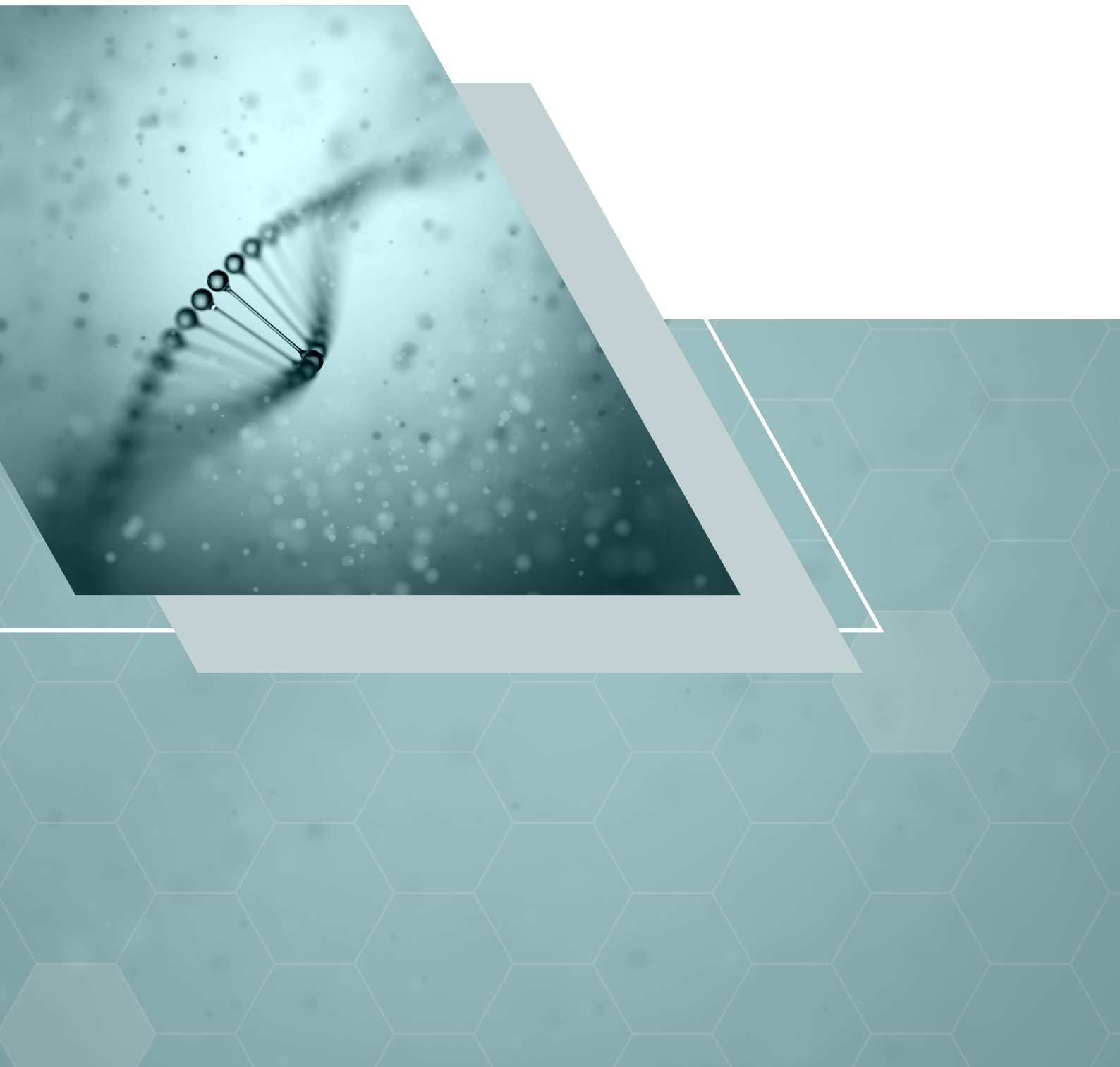
Stakeholders must continue to abide by the current provisions of the Commonwealth Act and Regulations until any new legislative amendments come into force.

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182 Australian Government (2015), *Annual Red Tape Reduction Report*, 2015. Retrieved July 10, 2018, from [http://www.pmc.gov.au/sites/default/files/publications/2015\\_annual\\_red\\_tape\\_reduction\\_report.pdf](http://www.pmc.gov.au/sites/default/files/publications/2015_annual_red_tape_reduction_report.pdf)

183 Australian Government (2015), *Annual Red Tape Reduction Report*, 2015. Retrieved July 10, 2018, from [http://www.pmc.gov.au/sites/default/files/publications/2015\\_annual\\_red\\_tape\\_reduction\\_report.pdf](http://www.pmc.gov.au/sites/default/files/publications/2015_annual_red_tape_reduction_report.pdf)

# Appendices



## APPENDIX 1

# Glossary

Term	Definition
The Act; the Commonwealth Act	The <i>Gene Technology Act 2000</i> (Cth).
The Agreement	Gene Technology Agreement 2001.
Biosecurity	Regulatory work undertaken by the Department of Agriculture and Water Resources, to prevent, respond to and recover from pests and diseases that threaten the economy and environment.
Cisgenic	Gene modification that uses genes from the organism's compatible gene pool.
Charging Framework	Australian Government Charging Framework. This framework has been introduced to improve consistency of charging activities and help determine when it is appropriate to charge for a government activity.
Consultation Paper	Review of the National Gene Technology Scheme 2017 Consultation Paper: Overarching Issues for consideration under the Review.
Dealings	Dealings with GMOs are defined in section 10 of the Act as conducting experiments, making, developing, producing or manufacturing, breeding, propagating, growing, raising or culturing, importing, transporting, or disposing of a GMO, and using a GMO to manufacturing something that is not the GMO.  The definition also includes the possession, supply or use of the GMO for the purposes of, or in the course of, any of the above dealings.
DIY biology	The use of gene technology by hobbyists outside the traditional research and industry structures; also referred to as 'biohacking' by some.
Exempt dealings	Exempt dealings are a category of dealings with GMOs that have been assessed over time as posing a very low risk (i.e. contained research involving very well understood organisms and processes for creating and studying GMOs).
The Forum	Legislative and Governance Forum on Gene Technology.
Gene Drive	Gene drives are genetic elements that are favoured for inheritance, and which can therefore spread through sexually reproducing populations at a greater rate than genes with standard Mendelian inheritance.
Gene (or genome) editing	A technique that allows insertion, deletion, or modification of DNA to silence, activate, or otherwise modify an organism's specific genetic characteristics.
Gene technology	Any technique for the modification of genes or other genetic material- as defined in the Act.
Genetically modified organism (GMO)	An organism that has been modified by gene technology.
Genetically modified product	A thing derived or produced from an organism that has been modified by gene technology.



Term	Definition
Genome	The complete sequence of DNA or RNA in an organism.
Genomics	The study of the structure, function, evolution and mapping of genomes.
Germline modification	Modification of a cellular lineage in sexually reproducing organisms that produces the gametes (eggs and sperm) which transmit genetic material to the next generation.
GMO Record	A register containing information on all genetically modified organisms approved by, or notified to, the Gene Technology Regulator.
GMO Register	The GMO Register is a list of dealings that the Gene Technology Regulator has determined pose minimal risk and which are not required to be covered by a licence. Once a dealing has been entered on the GMO Register anyone can conduct the dealing, in accordance with any specified conditions.
Hybrid Trigger	A mechanism for regulation which utilises both process and product triggers, depending on what organism or product is being considered for regulation.
Lock-step	When changes are made to the Act these changes are automatically adopted by any other State which has lock-step legislation.
Low level presence (LLP)	The unintended presence, at low levels, of a genetically modified crop that is authorised for commercial use or sale in one or more countries but is not yet authorised in an importing country.
Mutagenesis	A method or process that causes mutations (changes in DNA sequence) in genes or genomes.
Organism	Any biological entity that is viable; or capable of reproduction, or capable of transferring genetic material.
Process Trigger	A form of regulation that focuses on the role of the techniques used to produce genetic modifications, rather than the nature of the modifications themselves.
Product Trigger	A form of regulation that focuses on the new or novel traits expressed within an organism, and/or the scale and nature of the modifications introduced into the organism, rather than the methods of producing those modifications.
Regulations	The Gene Technology Regulations 2001 (Cth)
Regulator	Gene Technology Regulator
Review; Third Review	Third Review of the National Gene Technology Regulatory Scheme
Risk tiering	The use of differing levels of regulation to address the differing levels of inherent risk associated with certain organisms or modifications.
Scheme	National Scheme for the Regulation of Gene Technology
Somatic gene modification	Genetic modifications to an individual which cannot be passed on to its offspring.
Stacked traits	The insertion of multiple modifications within the one organism.
The Standing Committee	Gene Technology Standing Committee

Term	Definition
State moratorium	State legislation which puts restrictions on the dealings which can be undertaken with GMOs in that state, for marketing purposes.
Synthetic Biology	<p>While not formally defined, synthetic biology has been interpreted in various ways, including as:</p> <ul style="list-style-type: none"> <li>• the rational design and construction of novel nucleic acid or protein sequences, or combinations thereof, that would not be expected to arise through natural selection;</li> <li>• a further development and new dimension of modern biotechnology, that combines science, technology and engineering, to facilitate and accelerate the understanding, design, re-design, manufacture and/or modification of genetic materials, living organisms and biological systems; and</li> <li>• the design and engineering of novel biological components, devices and systems, and the re-design and re-engineering of existing, natural biological systems, to perform new functions in a modular, reliable and predictable way.</li> </ul>
Technical Review	The Gene Technology Regulator’s Technical Review of the Gene Technology Regulations 2001 (Cth).
Transgenic	A genetically modified organism containing one or more genes from another species.
Trigger	The factor which determines if a thing is considered by regulation or not.

## APPENDIX 2

# Matters out of scope of the Review

During the Third Review (the Review) of the National Gene Technology Scheme (the Scheme) consultation process, some stakeholders raised issues that were out of scope of the Scheme and of the Review Terms of Reference. These included issues related to food labelling and the use of herbicides and pesticides.

## Food labelling

A number of stakeholders raised genetically modified (GM) food labelling as a topic of concern. These stakeholders asserted that the labelling of GM foods was inadequate, or in some cases felt there was insufficient regulation of such food labelling in Australia.

Labelling of food products is the remit of Food Standards Australia New Zealand (FSANZ), and the Food Standards Code is the current legislative instrument outlining these labelling requirements in both Australia and New Zealand. Governance of the Code is overseen by the Australia New Zealand Ministerial Forum on Food Regulation (the Food Forum). The Food Forum membership is designed to reflect the whole-of-food-chain approach to food regulation.

Standard 1.5.2 – *Food Produced using Gene Technology* of the Food Standards Code, imposes pre-market assessment, approval and mandatory labelling requirements for GM foods. Although not specifically related to food labelling, FSANZ recently reviewed how the Food Standards Code applies to food derived using new breeding techniques.<sup>184</sup>

## Herbicide and pesticide use

A number of stakeholders raised herbicide and pesticide use in agriculture as a topic of concern, with specific reference to glyphosate use. These stakeholders asserted that glyphosate use is problematic, and further argued that glyphosate resistant traits introduced into genetically modified organisms (GMOs) in agriculture, leads to greater use of the herbicide.

The Review notes that the safety and efficacy of glyphosate, as well as the guidelines for safe use, are the remit of the Australian Pesticides and Veterinary Medicines Authority (APVMA). The Agricultural and Veterinary Chemicals Code is the legislative instrument outlining the requirements for the use of the product, in accordance with instructions approved by the APVMA.

The APVMA has recently conducted a review of the issue,<sup>185</sup> concluding “there is currently no scientific reason to reconsider the registration of glyphosate”, and that “all registered glyphosate products are safe provided they are used as per the label instructions”.<sup>186</sup> Any further information will be reviewed as it becomes available.

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184 See Food Standards Australia and New Zealand, *Food derived using new breeding techniques – review*. Retrieved July 10, 2018, from <http://www.foodstandards.gov.au/consumer/gmfood/Pages/Review-of-new-breeding-technologies-.aspx>

185 See Australian Pesticides and Veterinary Medicines Authority, *Glyphosate*. Retrieved March 21, 2018, from <http://www.apvma.gov.au/node/13891>. Also see Australian Pesticides and Veterinary Medicines Authority. (2016) *Regulatory position: consideration of the evidence for a formal reconsideration of glyphosate*. Retrieved July 10, 2018, from <http://www.apvma.gov.au/sites/default/files/publication/20701-glyphosate-regulatory-position-report-final.pdf>

186 See Australian Pesticides and Veterinary Medicines Authority, *Regulation of Glyphosate in Australia*. Retrieved July 10, 2018, from <https://apvma.gov.au/node/27261>

## APPENDIX 3

# Functions of the Regulator

Section 27 of the *Gene Technology Act 2000* provides that the functions of the Gene Technology Regulator are as follows:

The Regulator has the following functions:

- a)** to perform functions in relation to GMO licences as set out in Part 5;
- b)** to develop draft policy principles and policy guidelines, as requested by the Ministerial Council;
- c)** to develop codes of practice;
- d)** to issue technical and procedural guidelines in relation to GMOs;
- e)** to provide information and advice to other regulatory agencies about GMOs and GM products;
- f)** to provide information and advice to the public about the regulation of GMOs;
- g)** to provide advice to the Ministerial Council about:
  - i.** the operations of the Regulator and the Gene Technology Technical Advisory Committee; and
  - ii.** the effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation;
- h)** to undertake or commission research in relation to risk assessment and the biosafety of GMOs;
- i)** to promote the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies;
- j)** to monitor international practice in relation to the regulation of GMOs;
- k)** to maintain links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia;
- l)** such other functions as are conferred on the Regulator by this Act, the regulations or any other law.

## APPENDIX 4

# GMO Authorisation Categories

## Exempt dealings and NLRDs

**Exempt dealings** and **Notifiable Low Risk Dealings (NLRDs)** are routine laboratory techniques involving genetically modified organisms (GMOs) that have been used safely for many years, or which pose minimal risks when performed in contained conditions.<sup>187</sup> They do not require a case-by-case risk assessment.

Dealings that are exempt from licensing (exempt dealings) are those which are assessed to pose the lowest risk. These are subject to no requirements other than that they must not involve the release of the GMO into the environment.

NLRDs are activities with GMOs undertaken in containment (i.e. not released into the environment) that have been assessed as posing low risk to the health and safety of people and the environment, provided certain risk management conditions are met.<sup>188</sup> NLRDs must be:

- assessed by an Institutional Biosafety Committee (IBC);<sup>189</sup>
- notified to the Gene Technology Regulator (the Regulator);
- conducted in an appropriate facility certified by the Regulator (see below);
- carried out by people with appropriate training and/or experience; and
- transported, stored and disposed of in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*.<sup>190</sup>

## Licences

The *Gene Technology Act 2000* (the Act) provides a licensing system under which a person can apply to the Regulator for a licence authorising dealings with GMOs. Licence application forms issued by the Regulator specify the information required to support an application. The Office of the Gene Technology Regulator (OGTR) may provide advice to individuals and organisations to aid in the preparation of licence applications, including identifying specific data that would be required to inform the Regulator's risk assessment.

Each application for a licence to work with a GMO is subject to a comprehensive, science-based, case-by-case analysis process and the preparation of a Risk Assessment and Risk Management Plan (RARMP), as outlined in the Regulator's Risk Analysis Framework 2013.<sup>191</sup> The RARMP informs the Regulator's decision on whether to issue a licence, and which specific licence conditions to apply in order to manage risks.

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187 Office of the Gene Technology Regulator, *What authorisation do you need?* Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/authorisation-for-gmos>

188 Office of the Gene Technology Regulator, *What are Notifiable Low Risk Dealings (NLRDs)?*, Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/nlrddclass-2>

189 IBCs provide on-site scrutiny of low-risk contained dealings that do not require case-by-case consideration by the Regulator through independent assessment of NLRD proposals pursuant to regulation 13B – and on behalf of their organisation ensuring compliance with legislative requirements. IBCs are required to comprise a range of suitable experts and an independent person.

190 *Guidelines for the Transport, Storage and Disposal of GMOs (Cth) (Austl.)*. [Federal Register of Legislation, Guidelines for the transport, Storage and Disposal of GMOs, Retrieved July 10, 2018, from <https://www.legislation.gov.au/Details/F2011L00992>]

191 Office of the Gene Technology Regulator. (2013). *Risk Management Framework*. Retrieved July 10, 2018, from [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raffinal5-toc/\\$FILE/raffinal5\\_2.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raffinal5-toc/$FILE/raffinal5_2.pdf)

There are three types of licences that can be issued by the Regulator:

- Dealings involving Intentional Release (DIR) licences;
- Dealings Not involving Intentional Release (DNIR) licences; and
- Inadvertent Dealings licences.

Depending on the type of licence, application assessments may involve consultation with a range of relevant parties. For example, the Act requires the Regulator to invite written submissions from the public on RARMPs prepared for DIR applications. The Regulator must also seek advice from states and territories, Gene Technology Technical Advisory Committee (GTTAC), prescribed Commonwealth authorities and agencies, the Environment Minister and any local council that the Regulator considers appropriate.

The majority of **DIR licences** issued to date have been for experimental field trials (limited and controlled releases) or general/commercial releases of genetically modified (GM) plants. A small number of DIR licences have also been issued for GM vaccines for human or veterinary use, either for trial (limited and controlled release) or general/commercial release. The release of GM animals would also require a DIR licence.<sup>192</sup>

**DNIR licences** authorise dealings with GMOs which do not meet the criteria for classification as exempt dealings, NLRDs or DIRs. The majority of DNIRs involve work with GM pathogenic (disease-causing) organisms, or GMOs containing genes from pathogens or genes that encode toxins.<sup>193</sup> DNIRs can also be used to authorise clinical trials with non-transmissible GMOs. As with exempt dealings and NLRDs, work authorised under a DNIR licence must not involve the release of the GMO into the environment.

**Inadvertent Dealings licences** are temporary licences (no longer than 12 months) intended to allow people who have unintentionally come into possession of a GMO to dispose of it in a manner which protects the health and safety of people and the environment. Inadvertent Dealings licences can only be issued when the Regulator is satisfied that a person has come into possession of a GMO inadvertently. Consideration of Inadvertent Dealings applications follows a simpler process than required for other application types.<sup>194</sup>

Managing risks which may be associated with licensable dealings is achieved by imposing **licence conditions** that specify when, where and how certain activities with the GMO may be carried out. A number of licence conditions are specified in the Act and apply to all GMO licences. The Regulator may also impose additional licence conditions specific to each application. Failure to comply with the conditions of a licence is an offence under the Act.<sup>195</sup>

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192 Office of the Gene Technology Regulator, *What are Dealings involving an Intentional Release (DIR) of a GMO into the environment?* Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dirclass-2>

193 Office of the Gene technology Regulator, *What are Dealings NOT involving an Intentional Release (DNIR) of a GMO into the environment?* Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dnirclass-2>

194 Office of the Gene Technology Regulator, *What is an Inadvertent Dealing?* Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/inadvertentclass-2>

195 Office of the Gene Technology Regulator, *Licence Conditions*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/conditions-2>

## GMO Register

The GMO Register (the Register) provides an alternative mechanism for dealings with certain GMOs to be authorised.<sup>196</sup> The Register is a list of dealings that the Regulator has determined pose minimal risk, and do not require those conducting the dealing to be covered by a licence in order to adequately protect the health and safety of people or the environment. Once a dealing has been entered on the Register anyone can conduct the dealing, in accordance with any conditions specified in the Register.

To date, only one dealing has been entered on the Register – the commercial scale release of four lines of colour modified GM carnations.<sup>197</sup>

## Emergency Dealing Determination

The emergency provisions of the Act give the responsible Minister the power to expedite an approval of a dealing with a GMO in an emergency. This recognises that situations may arise in which a rapid approval of a dealing with a GMO may be required. An Emergency Dealing Determination (EDD) can only be made when there is an actual or imminent threat to the health and safety of people or the environment, and the proposed dealings would be likely to adequately address that threat. An EDD can be approved for up to six months, but may be extended by the Minister.<sup>198</sup> The EDD provisions have been used once, in 2007, to allow a GMO vaccine to be used to eradicate an equine influenza outbreak. This EDD was extended in 2008 to ensure the virus had been eliminated from the Australian environment.

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196 Office of the Gene Technology Regulator, *What are dealings included on the GMO Register*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmoregclass-2>

197 *Determination that dealings with genetically modified carnation lines be included on the GMO register (Register 001/2004)* (Cth) (Austl.). [Federal Register of Legislation, Determination that dealings with genetically modified carnation lines be included on the GMO register, Retrieved July 10, 2018, from <https://www.legislation.gov.au/Details/F2006L03771>]

198 Office of the Gene Technology Regulator, *What is an Emergency Dealing Determination?* Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/eddclass-2>



## APPENDIX 5

# OGTR Monitoring and Compliance

## Monitoring

Monitoring inspections are primarily undertaken to determine whether there is compliance with the *Gene Technology Act 2000* (the Act) or the Gene Technology Regulations (the Regulations). Other activities undertaken by monitoring personnel are:

- Providing advice to organisations on appropriate procedures to maintain compliance;
- Providing advice on how theoretical risk assessments would apply in operational situations; and
- Gathering information on possible adverse effects from the release of genetically modified organisms (GMOs).

The various types of monitoring are:

- Routine monitoring inspections – these are based on risk profiling and sampling of a range of dealings, locations where dealings are undertaken, and organisations who are conducting dealings;
- Follow-up visits – these are undertaken to follow-up on issues or to check the implementation of remedial action;
- Unannounced 'spot checks' – these are undertaken as a subset of the routine monitoring activities or as part of follow-up checks, incident reviews, or investigations.<sup>199</sup>

## Compliance and enforcement

To achieve its compliance and enforcement objectives, the Office of the Gene Technology Regulator (OGTR) uses a range of flexible and targeted measures to promote adherence to regulatory requirements.

The OGTR employs cooperative compliance measures such as communication and education activities, timely provision of information and advice, persuasion, cooperative assistance and collaboration.

Where non-compliance is detected, the OGTR has available to it a range of responsive enforcement sanctions that escalate in severity as the need arises. These include suspension or cancellation of certifications, accreditations and/or licences, injunctions, directives and criminal prosecution.<sup>200</sup>

## Practice reviews

Practice reviews are used to determine whether licence conditions can be, and are being, effectively implemented. The Gene Technology Regulator (the Regulator) may initiate practice reviews in response to observations made during monitoring activities, or to follow up on incident reports that may relate to non-compliance with licence conditions by accredited organisations. An accredited organisation may also request a practice review to assess the effectiveness of systems used by its Institutional Biosafety Committee (IBC) to ensure that dealings are being conducted in accordance with the Act.

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199 Office of the Gene Technology Regulator, *Monitoring Protocol*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mc-protocols-1>

200 Office of the Gene Technology Regulator, *OGTR Compliance and Enforcement Policy*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mc-protocols-1>

The Regulator may also initiate themed reviews which investigate how a variety of accredited organisations comply with common requirements, such as those relating to disposal contained in the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*, or manage the conduct of dealings in shared certified facilities.

Practice reviews provide assurance to both the Regulator and accredited organisations that the regulated community has the capacity to comply with the legislation. These reviews also enable the Regulator confirm the effectiveness of licence conditions and certification requirements in managing risks posed by dealings with GMOs.

Additional information on OGTR monitoring and compliance activities are included in the various OGTR Monitoring Protocols and the *OGTR Compliance and Enforcement Policy*.<sup>201</sup>

## Post-release review

Some commercial release Dealings involving Intentional Release (DIR) licences, particularly those requesting unrestricted release, incorporate a requirement for ongoing oversight of risk management plans. This may be achieved through identified post-release review activities.

Accordingly, the Regulator may impose licence conditions that require the licence holder to supply, or enable the Regulator to collect, specific information about the release after it occurs. This provides a mechanism for the Regulator to monitor specific indicator/s of harm that had been identified in the initial risk assessment. As such, post-release review mechanisms may be triggered where the initial risk estimate is greater than negligible, or there is relevant uncertainty (e.g. lack of consensus among expert advisors).

Post-release review is also used to collect information on possible adverse effect/s of released GMOs on human health and the environment. This could result in reports over the short and long term about any DIR licence.

Further, post-release review can be used to review Risk Assessment and Risk Management Plans (RARMPs) at any time after the licence is issued. Such reviews take into account any relevant new information, or may be triggered by findings from either of the other components of the post-release review. The purpose of a review would be to ensure the findings of the RARMP remain current.

If the findings of a post-release review demonstrate changes to the initial risk profile of the dealing, this could lead to review of the risk management plan and changes to the licence conditions.<sup>202</sup>

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201 Office of the Gene Technology Regulator, *Monitoring and Compliance Section Protocols*. Retrieved July 10, 2018, from <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mc-protocols-1>

202 Office of the Gene Technology Regulator. (2013). *Risk Management Framework*. Retrieved July 10, 2018, from [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raffinal5-toc/\\$FILE/raffinal5\\_2.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raffinal5-toc/$FILE/raffinal5_2.pdf)

## APPENDIX 6

# Expert Advisory Panel

Given the scientific and technical nature of gene technology, the Third Review (the Review) of the Gene Technology Scheme (the Scheme) sought expert technical advice (when required), by establishing an Expert Advisory Panel.

Members of the Expert Advisory Panel were selected on the basis of their experience and drawn from animal, plant, medical and regulatory best practice fields, shown in Table 3 – Expert Advisory Panel to the Third Review of the National Gene Technology Scheme. Members supported the Review in an advisory capacity only.

**Table 3: Expert Advisory Panel to the Third Review of the National Gene Technology Scheme**

Name	Expertise
Professor Ian Small	Plant gene technology
Dr Mark Tizard	Animal gene technology
Dr David Tschärke	Medical gene technology
Ms Claire Noone	Best practice regulation and governance

## Biographies

### Professor Ian Small

Ian Small's PhD at Edinburgh University was followed by a career with France's National Agronomy Research Institute (INRA) at the Plant Genetics & Breeding Station in Versailles and the Plant Genomics Unit in Evry. In 2005 he was awarded a WA State Premier's Research Fellowship and moved to Perth to become the Director of the ARC Centre of Excellence in Plant Energy Biology.

Currently, he is an ARC Laureate Fellow in the second incarnation of the Centre. Ian's work contributed to the development of INRA's breeding program for hybrid canola and other hybrid brassica crops. His research interests cover molecular biology and bioinformatics applied to the study of energy organelles (mitochondria and chloroplasts), with potential applications in agricultural, environmental and health biotechnology. Ian was selected as 'Scientist of the Year' in the 2014 WA Premier's Science Awards and elected a Fellow of the Australian Academy of Science in 2015. He has represented the Academy in recent panels discussing synthetic biology, new gene drive technologies and new plant breeding technologies.

### Dr Mark Tizard

Mark began his career in the UK in the early days of gene cloning, as part of the team that was first to identify and produce the malaria merozoite major surface antigen for vaccine studies (Holder et al, 1984, Nature).

He came to Australia and CSIRO following the impact of postdoctoral work in mycobacterial research with relevance to Australia (in Johne's disease) in which he identified, characterised and developed a unique marker for the disease causing agent.

Changes in CSIRO gave him the opportunity to explore the emerging field of RNA interference and microRNA biology. His group was the first to catalogue the microRNA repertoire of the chicken (Glasov et al, 2009, Genome Research), a model system in which he later developed a novel approach for RNAi delivery by minimal transgene. This involved developing and applying tools from another emerging field – gene editing. Improvements in these techniques from his lab have led to very efficient methods to edit the chicken genome, one spin off of which is a new method to remove males from the egg-layer industry without having to hatch and cull day-old chicks (the current practice) – though it is yet to go into industry practice.

With the advent of CRISPR technology, the ease of applying gene editing in poultry led Mark to broaden his horizons and to take a look at how these techniques might be applied in the genetic control of vertebrate pests. His current interests are in gene editing in the cane toad and exploring the possibilities of the new gene drive technology for fish and rodent pests.

## Professor David Tucharke

Professor David Tucharke is an NHMRC Senior Research Fellow and Head of the Department of Immunology and Infectious Diseases at the John Curtin School of Medical Research, the Australian National University (ANU). He has a BSc (hons) and PhD (1997) from the University of Adelaide and postdoctoral experience from the University of Oxford and Imperial College London, UK, the National Institutes of Health, Bethesda, MD, USA, and QIMR Berghofer Medical Research Institute, Brisbane. He has led an independent research group at The ANU since 2006.

Prof Tucharke has authored more than 90 papers and abstracts in the scientific literature, including the use of gene technology methods in virology, and has held national and international grants and fellowships worth more than \$10m. He has 12 years of experience as member and deputy chair of two Institutional Biosafety Committees (QIMR and ANU) and has convened, and still teaches into an undergraduate course on molecular gene technology at the ANU. He has communicated his science nationally, including ABC's Catalyst and Triple J. Prof Tucharke has ongoing research interests in understanding how viruses hide from and are exposed by the immune system.

## Claire Noone

Claire Noone is a Principal Consultant and Public Policy Practice Lead with Nous Group, an award-winning management consulting firm operating across Australia and the United Kingdom. In her role at Nous, Claire partners with private and public sector clients across a broad range of sectors including financial services, utilities, justice, health & human services. As a leading thinker in policy reform, regulatory design and regulatory practice, she is highly sought after by clients looking to design and implement new regulatory models for the future economy.

Claire has more than 20 years' senior executive and leadership experience across both federal and state government. Her experience extends across policy and legislation, regulatory theory and practice, strategic planning, corporate services, and service delivery across a number of portfolios. Before joining Nous, Claire was the Deputy Secretary, Regulation at the Department of Justice (Vic), prior to which she was the Acting Secretary of the Department. As the Director of Consumer Affairs Victoria she was responsible for major regulatory policy reform of the Australian Consumer Law and other significant national and state-based policy and legislative reform agendas.

Claire is renowned for her sharp analytical mind and her engaging and collaborative approach to working with clients and stakeholders.

Claire has an extensive track record in regulation:

- Day-to-day leadership and management of a large regulatory agency, Consumer Affairs Victoria including education and information services, compliance and enforcement, and licensing and registration
- Responsibility for major regulatory policy reform culminating in the Australian Consumer Law Several national reform programs including travel reform
- Appointed by the Victorian government to lead the review of WorkSafe Compliance and Enforcement
- Provided detailed and expert advice on the design of environmental regulation for a recent independent inquiry
- Experience in community engagement.

### Qualifications

- Doctor of Business Administration, RMIT University
- Masters of Business Administration, University of Melbourne – Melbourne Business School
- Bachelor of Laws / Bachelor of Arts, University of Melbourne
- Diploma of Education, University of Melbourne
- INSEAD Advanced Management Program, ANZSOG Executive Fellows Program, VLDC SELP

## APPENDIX 7

# Outcomes of Phase 1 Consultation

## Submissions provided to Phase 1

In response to the call for submissions, a total of 109 responses were provided in Phase 1 of the consultation. The Third Review (the Review) of the Gene Technology Scheme (the Scheme) identified that consultation should have a wide reach to stakeholders, with submissions broadly falling into the categories shown in Table 4 – Submissions to Phase 1:

**Table 4: Submissions to Phase 1**

Organisation Type	Number of Submissions
General Public	39
Research	24
Industry Group	18
Company	12
Government	10
Community Group	6
<b>Total</b>	<b>109</b>

The Background Paper to Phase 1 consultation specified that, unless otherwise requested, all submissions to the Review would be published on the Department of Health website. Those submissions, where consent has been provided, can be found at <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-consult-1>

## What did we find in Phase 1 consultation?

Bringing together all inputs, the following overarching points emerged:

1. The basis of the current Scheme is strong: it needs to be aligned with evolving information and technology, without losing its key objectives.
2. There is an emerging need for innovative solutions to the global challenge of how to sustainably feed, clothe and protect billions of people: ensuring health and safety, while maintaining diversity of plants and animals. However, the degree to which different biotechnologies contribute to this is contested.
3. Public trust and understanding is important for an accepted and efficient regulatory system- consideration needs to be given to how best to achieve this.
4. The potential risks associated with emerging science and applications may be different for different sectors – there may be value in considering whether regulatory processes for medical, agricultural and industrial applications need to be tailored to address this.

Many issues were raised through Phase 1 consultation, and on these issues, a wide variety of stakeholder views were expressed – from those who seemed to prefer a lighter-touch regulatory approach to those who are concerned about potential harm that gene technologies may pose for humans and the environment.

Most responses fell into four broad thematic areas:

- **Technical** – defining what GMOs are, the processes to make GMOs, what GMOs do, including their associated benefits and risks.
- **Regulatory** – accommodating impacts and influences of gene technology on agriculture, medical advances and research, while maintaining protection of people and the environment.
- **Governance** – how decisions are made and what views and evidence are considered.
- **Social and ethical** – how to consider and address community concerns, and broader equity and access issues.

## APPENDIX 8

# Outcomes of Phase 2 Consultation

## Submissions provided to the online survey in Phase 2

In response to the publication of the Consultation Paper, a total of 48 responses were received through the online submission survey. Respondents broadly fell into the categories shown in Table 5 – Submissions to Phase 2.

**Table 5: Submissions to Phase 2**

Organisation Type	Number of Submissions
General Public	19
Industry Group	10
Company	6
Research	6
Community Group	4
Government	3
<b>Total</b>	<b>48</b>

Stakeholders consulted included those involved in gene technology in relation to:

- research in the agriculture, therapeutic and manufacturing domains;
- the commercialising of agricultural, medical, and food products;
- marketing in commercial markets for food, agricultural, animal welfare or human therapeutics; and
- community members interested in assuring the ethical and social elements of the Scheme are maintained.

The consultation process for Phase 2 specified that, unless otherwise requested, all submissions on the Review would be published on the Department of Health website. Those submissions, where consent has been provided, can be found at <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-consult-2>



## What did we find in Phase 2 consultation?

1. As with Phase 1, a key issue raised in Phase 2 was the capacity of the Gene Technology Scheme (the Scheme) to respond to scientific and technological progress. The emergence of gene editing, and associated modification techniques, has proven a challenge for the existing Scheme. A number of stakeholders have suggested regulatory and definitional changes that they believe would provide clarity to all parties.
2. There were opposing views as to the appropriate regulation of some technologies within the Scheme. Some stakeholders supported broad and comprehensive regulation that would capture gene editing techniques. Others considered that in applying these techniques, organisms can be produced that are potentially indistinguishable from organisms that could occur in nature, and as such should be subject to lower levels of regulation.
3. A consistent theme put to the Third Review of the Scheme (the Review) was that regulation should be proportionate to risk. Some stakeholders supported the introduction of additional risk tiering to achieve this, and expressed the view that accumulated scientific and agronomic knowledge is sufficient to justify changes to the regulatory approval processes for some organisms. Other stakeholders opposed any lessening of regulation, and expressed uncertainty about the efficacy of the Scheme to protect human health and the environment.
4. There was support from some stakeholders for enhanced flexibility within the Scheme, by introducing a more principles-based approach to regulation, or by allowing the Gene Technology Regulator (the Regulator) to make determinations on the applicability of regulation to technological developments.
5. Some stakeholders have cited a number of administrative and regulatory changes that could streamline Office of the Gene Technology Regulator (OGTR) processes, reduce costs and simplify processes for Australian researchers. Improved use of IT, changes to facility certification requirements and harmonisation of the interface across regulators have all been suggested as potential streamlining measures.
6. Contrasting views were received in relation to bans on genetically modified (GM) cropping in some jurisdictions, with supporters maintaining that broad marketing advantages are delivered by the implementation of state or territory moratoria. Alternatively, some stakeholders viewed moratoria as disrupting the path to market for GM crop varieties, and expressed concern over potential longer-term consequences on research and development capacity in Australia.
7. The Review also heard concerns from some stakeholders about the safety of genetically modified organisms (GMOs) and the ability of the Regulator to monitor commercialised GMOs for long-term impacts. Concerns were also raised with the safety of GM foods and safety impacts of herbicide and pesticide use; however the Review notes that food and chemical regulation is beyond the scope of the Review.

## APPENDIX 9

## Outcomes of Phase 3 Consultation

## Submissions provided to Phase 3

In response to the publication of the Preliminary Report, a total of 166 responses were received through online submissions. Respondents broadly fell into the categories shown in Table 6: Submissions to Phase 3.

**Table 6: Submissions to Phase 3**

Organisation Type	Number of Submissions
General Public	1
Industry Group	9
Company	6
Research	12
Community Group	1
Online Campaign	132
Government	5
<b>Total</b>	<b>166</b>

Stakeholders consulted included:

- government agencies involved in regulating gene technology;
- companies involved in developing, marketing or seeking to market agri-food, therapeutic and veterinary products involving gene technology;
- research institutes and universities;
- industry groups; and
- members of the community and advocacy organisations concerned with the ethical and social issues raised by the regulation of genetic technology.

## What did we find in Phase 3 consultation?

The consultation process for Phase 3 sought stakeholder views on the 33 Findings presented in the *Preliminary Report*. Instructions specified that, unless otherwise requested, all submissions on the Review would be published on the Department of Health website. Those submissions, where consent has been provided, can be found at <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-consult-3>

1. There is a contrasting set of views on gene technology and how it should be regulated. Both perspectives appear to be based on differing interpretations of the currently available literature on the topic. This divergence pervaded the submissions received in the third phase of consultation. In general, those that work with GMOs want to maintain a scientific, risk-based approach to regulation that is focused on the risk posed by the GMO. Others hold that best reading of the scientific evidence on the risks posed by GMOs supports applying a highly precautionary approach to their regulation. These stakeholders want the highest level of regulation applied to all GMOs, including those produced using new technologies.
2. A contentious issue for the Third Review of the Scheme (the Review) was whether the existing regulatory trigger remains fit for purpose. In response to the finding that maintenance of the existing 'process trigger' basis of the

Scheme was preferred, many stakeholders involved in gene technology research reiterated the argument for a product basis. They reasoned that decades of accumulated knowledge on GMOs indicates any risk resides in the characteristics of an organism, and not the method by which the organism was produced. Community organisations, and some government agencies, advocated for the maintenance of the existing 'process-trigger'.

3. Findings relating to how the Gene Technology Scheme (the Scheme) should address recent scientific and technological progress in gene technology, including how the definitions apply, were widely commented on.
  - a. An online campaign and community group submission advocated for a highly-cautious approach to the regulation of any new technologies, and even some excluded technologies. These stakeholders also reasoned that the definitions in the Act were intended to capture new technology, the risks of which remain unknown. Many of the campaign submissions also maintained a focus on 'gene drive' technologies.
  - b. By contrast regulated entities stated that recent developments in gene technology can now achieve outcomes not conceivable when the definitions were first drafted. As such, some technologies now challenge the definitions, particularly those GMOs produced that mirror naturally occurring organisms. These stakeholders sought greater clarity in regulation, and agreed the definitions need to be carefully examined.
4. A consistent theme put to the Review was that regulation should be proportionate to risk, resulting in findings that there is cause to introduce greater risk stratification and streamlining mechanisms into the Scheme. Research institutions, industry groups and government agencies generally supported the introduction of additional risk tiering to achieve this, and expressed the view that accumulated scientific knowledge supports this measure. The principal difference between submissions was the extent of scientific consensus on the level of risk associated with GMOs. Community groups and members of the public mostly opposed risk stratification and any streamlining that is perceived to lessen any regulation.
5. There was support from some stakeholders for findings relating to introducing a more principles-based approach to regulation, specifically by allowing the Legislative and Governance Forum on Gene Technology to provide guidance to the regulator on new or emerging issues. Most industry groups applied a degree of caution to this measure. Such concern stemmed from the perception of such an arrangement allowing political – rather than scientific – considerations to steer the Scheme and its objectives.
6. Findings for opportunities for a number of administrative and regulatory changes that could streamline Office of the Gene Technology Regulator (OGTR) processes, reduce costs and simplify processes for Australian researchers were acknowledged and supported by stakeholders. Improved use of IT, facility certification processes, and harmonisation of the interface across regulators have all been suggested as potential streamlining measures. Most organisations acknowledged the importance of the OGTR continuing to make business improvements.
7. Responses addressed findings about the transparency of governance and regulatory activities and decisions. Stakeholders reiterated they valued the importance of the Australian community having access to trustworthy and reliable information on gene technology, and gene technology regulation in Australia.
8. Contrasting views were received in relation to findings about State-based moratoria on genetically modified (GM) crops. Supporters maintained that marketing advantages are delivered by such moratoria. Alternatively, some stakeholders viewed moratoria as detracting from the national consistency of the Scheme, and potentially undermining regulatory decision-making regarding the 'health and safety' aspects of licensing decisions. Both perspectives have been supported by investigations and data analyses.
9. Concerns were raised regarding 'DIY biology', in particular that equipment acquired through the internet might be used to create GMOs outside of registered laboratories. Submissions were generally in agreement with the findings, that going forward, further work was needed to ensure that this type of activity is appropriately regulated.

Where comments from Phase 3 had not already been captured from Phase 2, these have been addressed in this Report.

## APPENDIX 10

# Outcomes of Market Research

In February 2018, the Review commissioned market research to further explore public attitudes, knowledge and beliefs about GMOs on its behalf. This research explored the views of Australians, across a breadth of demographics, through the conduct of 12 focus groups, and some 1,500 surveys. In brief, participants were asked to respond to a series of questions which focused on identifying information requirements for the public and testing the perceived appropriateness of regulatory approaches.

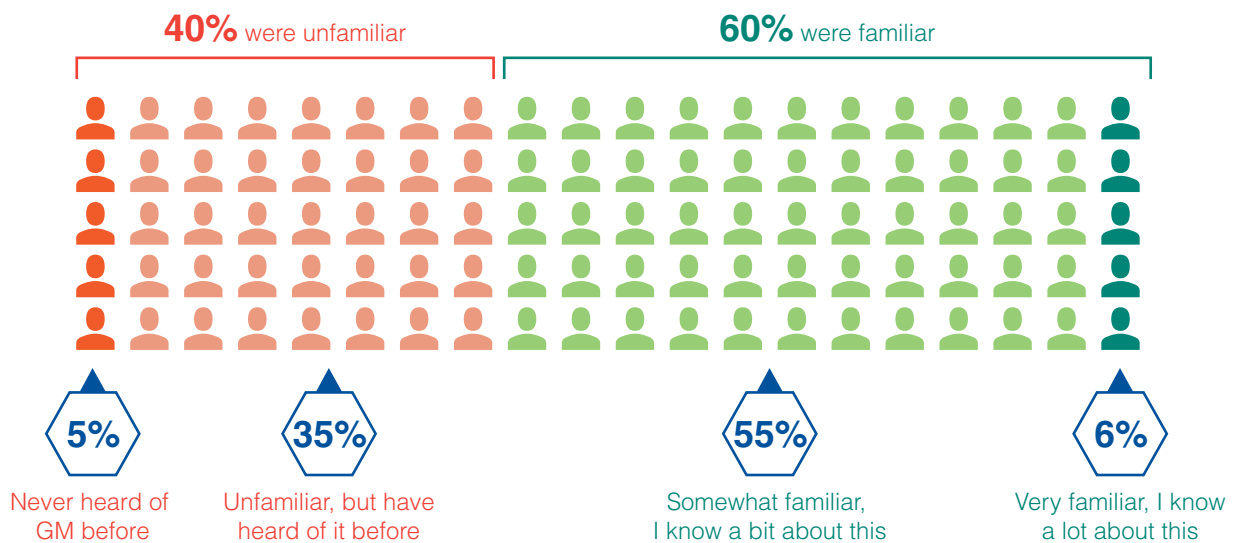
## Key Summary

***‘Three in five (60%) of Australians self-identified as at least ‘somewhat familiar’ with genetic modification’.***

The research found that familiarity with the concept of genetic modification, or ‘genetically modified’ (GM) varied considerably. Some 60% of those surveyed claimed to be familiar with the term, with 6% believing they know a lot about GM. Over 35% stated that while unfamiliar with the term they had heard of it before.

**FIGURE 16**

Self-classified level of familiarity with the term ‘genetic modification (GM)’



Q4 To what extent are you familiar with the term ‘genetic modification (GM)’? Base: Total n=1,530

***‘Awareness of GM was primarily limited to crop applications. GM medication and other industrial applications were less well known’.***

Overall, the research indicated there are some misconceptions and a lack of knowledge around GM concepts. A large number of respondents indicated their view that there isn’t enough information available regarding the pros and cons of GM.

Respondents also raised concerns around the safety of genetic modification, indicating their belief that effects have not been observed and tested over the long term. Some did not know whether:

- the food was safe to eat or if medicines were safe;
- GM products are adequately tested before being licensed for sale in Australia; or
- there is sufficient regulation of GM products in Australia.

### FIGURE 17

Perceptions of genetic modification applications (qualitative interpretation)



***'Australians' definition of genetic modification was very broad – reflecting that there is significant confusion around what does/does not constitute GM'.***

Overall, 62% of Australians mentioned modification of DNA in their definition of GM.

The most common mention was in relation to the DNA of products or foods being changed from its natural state (41%), as well as mentions of changing the DNA of plants and crops (20%) and animals (10%). One in four (26%) Australians also mentioned that GM can be used to improve food quality.

Understanding of how DNA is modified was not clear to many. While around some understood that GM involves modification of DNA, they often did not discriminate between how that DNA was modified in their understanding of GM. Thus, modification via selective breeding was often mistaken for GM, as was modification, intentional or otherwise, of organisms via application of chemicals or radiation.

***'Providing farmers with crops that are disease or drought resistant was the most commonly understood application of GM'.***

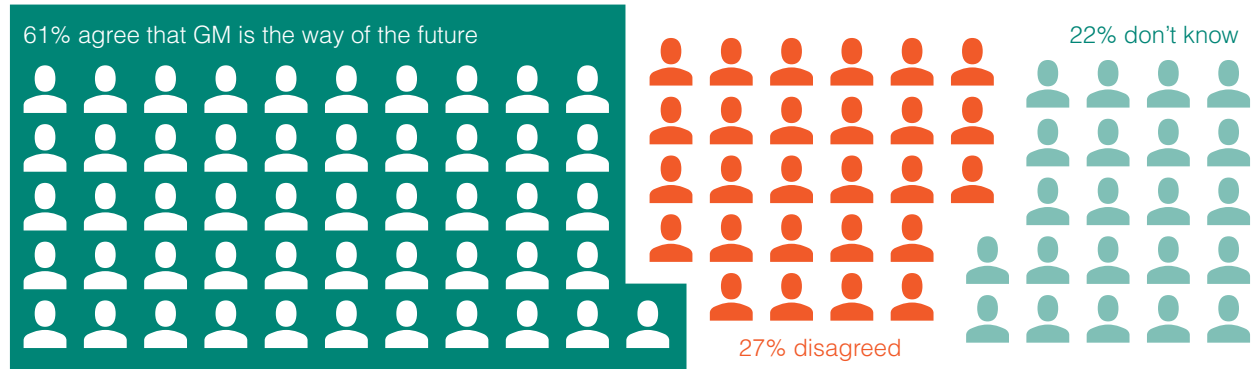
The majority of Australians believed that GM can potentially provide farmers with crops that are disease- or drought-resistant (76%) and provides hope for eradicating genetically inherited diseases (64%).

***‘The majority of Australians saw at least some need for GM’.***

When testing attitudes towards GM, the research indicates that respondents were more likely than not to acknowledge that there is a place for GM in today’s world. However, respondents commonly mentioned that GM isn’t something they typically think about. Further, they are not prompted to think about GM when they go shopping because GM labels aren’t something they typically see, so it is not top of mind.

**FIGURE 18**

The need (or otherwise) for genetic modification



***‘There was a prevalent expectation that big companies are profit driven and that, without adequate regulation, this may result in compromises which are not in the public interest’.***

There was a general acknowledgement in the focus groups that GM is an expensive and time consuming technology, and consequently, only large corporations and well-funded research institutes (such as universities and the CSIRO) have the ability to develop GM technologies.

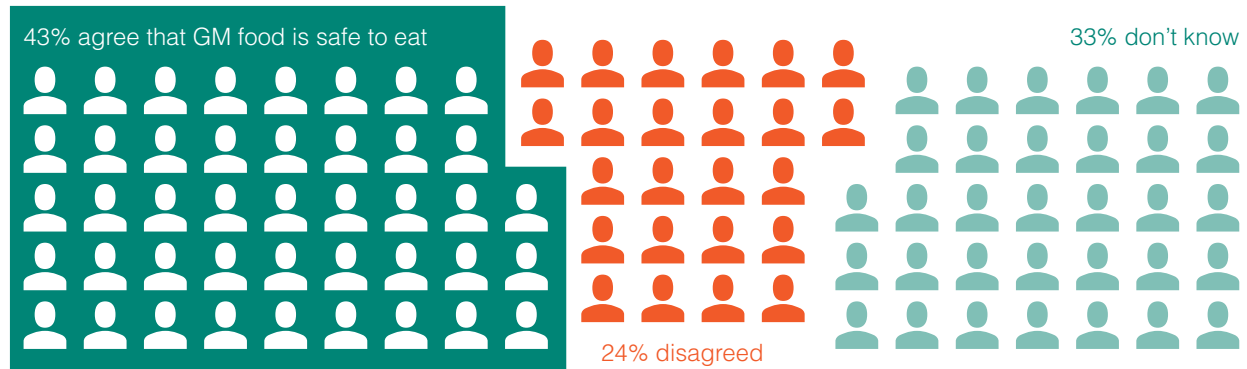
- In many cases, participants believed that this could result in companies being irresponsible in developing GM applications.
- Many respondents commented that despite this, the need to retain customers meant it was likely that companies would self-regulate to a degree.
- Nearly half (47%) of Australians consider that organisations that create GMOs put profit before safety, with only one in five (22%) disagreeing on this issue.

***‘There was a prevalent sentiment that health and safety concerns around consuming GM goods have not been, and cannot be, completely disproven’.***

Overall the sentiment toward GM is somewhat polarised. Amongst other things, half of the participants indicated GM could make the world a better place. Conversely, many others indicated they would prefer to avoid GM products, as the concept seems frightening to them.

**FIGURE 19**

Market research – Is genetically modified food safe to eat?



***‘Sentiment towards GM was highly polarised – there was no public consensus on what was perceived to be the positive vs. negative side of ‘the GM debate’.***

Safety of GMOs was an area of confusion for many. Focus groups found the majority of people believe they consume GM foods regularly, and given there have been no health scares or controversies over GM in Australia, they tacitly assume that any GM foods they do eat are likely to be safe.

- Overall, 43% of Australians agree that GM foods are safe to eat, but another 24% think they are not, and 33% don't know what to think.
- While 41% of Australians agree that GM medicines may not be safe, people in the focus groups indicated that if their doctor prescribed them a GM medicine, they would take it.
- Focus groups highlighted that most people didn't really know whether or not GM products in Australia are regulated or tested for safety.

***‘Overarchingly, there was a general preference for non-GM food. However, many believed that they were likely eating GM on a regular basis without it being labelled as such’.***

When given a choice between GM and non-GM food, only 3% of Australians indicated a preference for GM food. However, the remainder were nearly evenly split between a preference for non-GM food (44%) and an acknowledgement that other factors are at play in choosing food (42% “it depends”). In the focus groups, people tended to assume that foods containing GM do not need to be labelled as such, simply because the majority of them had never seen GM labelling (or had seen it so rarely – often just once – that they assumed it mustn't be mandatory).

***‘Nine in ten Australians felt that there was a need to educate the public about GM, particularly on the GM ingredients, how safety is assessed and what the overarching pros and cons of GM are’.***

The majority of respondents believed there is a need to provide the public with more information about GM foods; in particular, information that is unbiased, in relation to:

- which foods contain GM ingredients;
- how the safety is assessed;
- negatives and positives of GM; and
- how GM is regulated.

***‘Australian Medical Association, Scientists and Universities were the most trusted sources on the topic of GM. It is believed that these sources can provide an unbiased and regulated response to the public’.***

While trust in Government was lower, the research suggests this can be boosted if government messaging is consistent with that of the more trusted groups. There is a preference for groups to work together to ensure no-one's vested interests take precedence.

Finally, the research recommended that it would be beneficial to further develop and explore communication that addresses public misconceptions around GM, including what is and isn't GM. There is also a need to outline the regulatory process in a way that resonates with consumers.

***‘Although they may have assumed GM was regulated, the majority were unclear about how that may look in practice’.***

In relation to the regulation of GM, nearly half of the respondents didn't know whether GM is currently regulated in Australia, whilst 39% thought it was.



## APPENDIX 11

# Other materials considered by the Review

The following is a list of materials considered by the Third Review of the National Gene Technology Regulatory Scheme, including materials supplied by stakeholders (through submissions). This list is not exhaustive, and further references are listed in footnotes throughout the Review Report.

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