



National Gene
Technology
Scheme

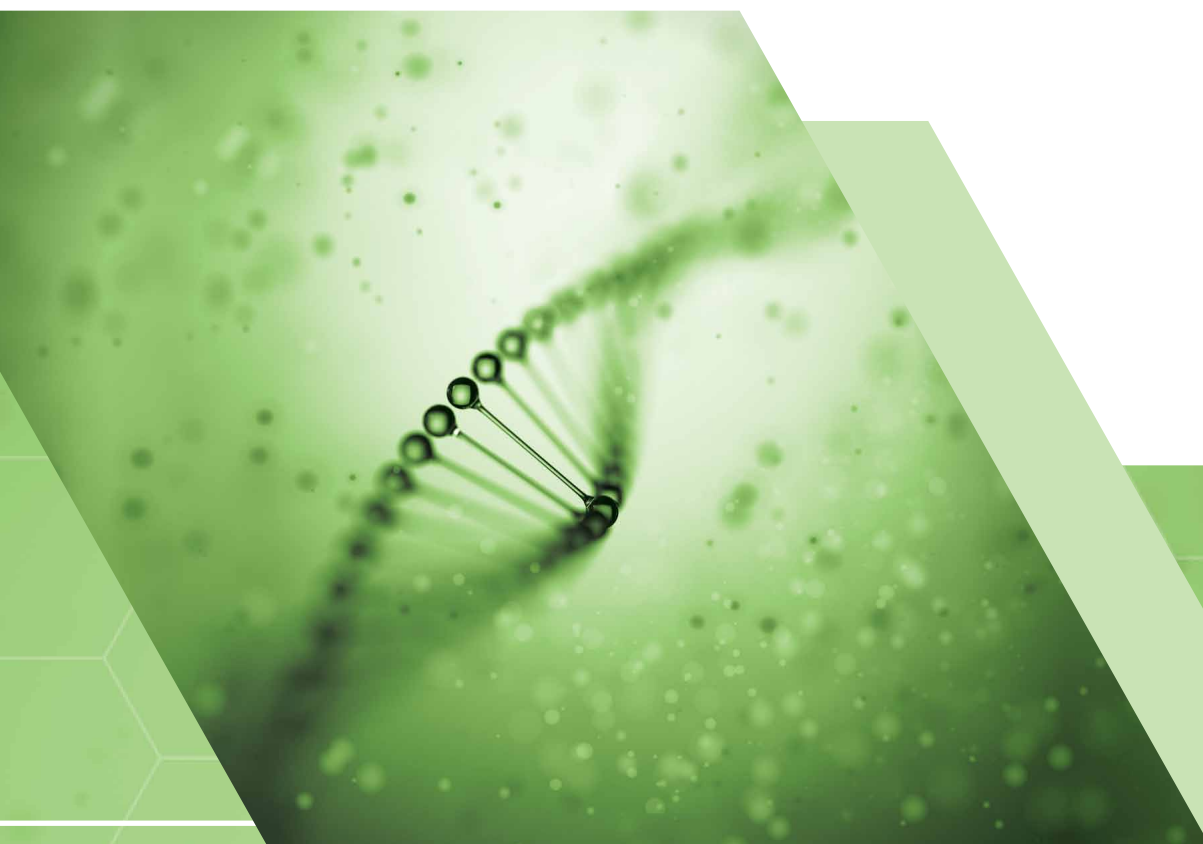
An Australian, State and Territory
Governments Collaboration

The Third
Review of the

Gene Technology Scheme

March 2018

PRELIMINARY REPORT



The Third Review of the National Gene Technology Scheme

© 2018 Commonwealth of Australia as represented by the Department of Health

Creative Commons Licence

This publication is licensed under the Creative Commons Attribution 4.0 International Public License available from <https://creativecommons.org/licenses/by/4.0/legalcode> ("Licence"). You must read and understand the Licence before using any material from this publication.

Restrictions

The Licence may not give you all the permissions necessary for your intended use. For example, other rights (such as publicity, privacy and moral rights) may limit how you use the material found in this publication.

The Licence does not cover, and there is no permission given for, use of any of the following material found in this publication:

- the Commonwealth Coat of Arms. (by way of information, the terms under which the Coat of Arms may be used can be found on the Department of Prime Minister and Cabinet website <http://www.dpmc.gov.au/government/commonwealth-coat-arms>);
- any logos and trademarks;
- any photographs and images;
- any signatures; and
- any material belonging to third parties.

Attribution

Without limiting your obligations under the Licence, the Department of Health requests that you attribute this publication in your work. Any reasonable form of words may be used provided that you:

- include a reference to this publication and where, practicable, the relevant page numbers;
- make it clear that you have permission to use the material under the Creative Commons Attribution 4.0 International Public License;
- make it clear whether or not you have changed the material used from this publication;
- include a copyright notice in relation to the material used. In the case of no change to the material, the words "© 2018 Commonwealth of Australia (Department of Health)" may be used. In the case where the material has been changed or adapted, the words: "Based on Commonwealth of Australia (Department of Health) material" may be used; and
- do not suggest that the Department of Health endorses you or your use of the material.

Enquiries

Enquiries regarding any other use of this publication should be addressed to the Branch Manager, Communication Branch, Department of Health, GPO Box 9848, Canberra ACT 2601, or via e-mail to copyright@health.gov.au

Design

2B Advertising and Design

Contents

| | |
|---|------------|
| Acknowledgement | vi |
| Release of this <i>Preliminary Report</i> | vi |
| Executive summary | vii |
| Third Review of the Scheme | vii |
| Consultation approach | viii |
| Review findings | viii |
| International context | x |
| Scope of the Review | x |
| Review progress and next stage | x |
| List of Review Findings | 1 |
| Introduction | 7 |
| Terms of Reference | 7 |
| Principles underpinning the Review | 7 |
| Organisation of this Report | 8 |
| Supporting documents | 8 |
| Out of scope | 9 |
| Chapter one: Review findings | 10 |
| Chapter 1.1 Overarching findings | 11 |
| Finding 1 Object of the <i>Gene Technology Act 2000</i> | 11 |
| Finding 2 The Gene Technology Agreement 2001 | 12 |
| Chapter 1.2 Review Theme One – Technical Issues | 13 |
| Finding 3 Classification of new technologies | 14 |
| Finding 4 Emerging applications: Synthetic biology | 17 |
| Finding 5 Emerging applications: Human germline gene therapy | 18 |
| Finding 6 Intentional environmental release: Biological control | 20 |
| Finding 7 Emerging applications: Gene drives | 23 |
| Chapter 1.3 Review Theme Two – Regulatory Issues | 25 |
| Finding 8 Regulatory triggers | 26 |
| Finding 9 Risk tiering and appropriate regulation of environmental releases | 28 |
| Finding 10 Streamlining regulation | 31 |
| Finding 11 Operation of the GMO Register | 34 |
| Finding 12 Accessibility and managing new potential harms | 36 |
| Findings 13 and 14 Future-proofing regulation and principles based regulation | 37 |
| Finding 15 Market access and international trade | 40 |

| | |
|---|-----------|
| Chapter 1.4 Review Theme Three – Governance Issues | 43 |
| Finding 16 Credibility, integrity and legitimacy of the Scheme | 44 |
| Finding 17 National consistency of the Scheme: Governance | 47 |
| Findings 18 and 19 Adaptability, flexibility and national consistency of the Scheme: Moratoria legislation | 48 |
| Finding 20 Harnessing the economic and health benefits of gene technology: Benefit consideration | 52 |
| Finding 21 Harnessing the economic and health benefits of gene technology: Regulatory burden | 53 |
| Findings 22 and 23 Clarity on policy considerations of the Scheme | 54 |
| Findings 24, 25 and 26 Coordination with other regulators | 56 |
| Findings 27 and 28 Funding model | 59 |
| Chapter 1.5 Review Theme Four – Social and Ethical Issues | 61 |
| Findings 29 and 30 Public understanding and confidence in the Gene Technology Scheme | 61 |
| Findings 31 and 32 Public understanding and confidence in the Gene Technology Scheme: Safety concerns and post market review | 63 |
| Finding 33 Transparency and access to information for the Australian public | 66 |
| Chapter two: What is the Gene Technology Scheme and how does it work? | 69 |
| The Gene Technology Agreement 2001 | 72 |
| The role of states and territories in the Scheme | 72 |
| Governance of the Scheme | 73 |
| The Legislative and Governance Forum on Gene Technology | 74 |
| The Gene Technology Standing Committee | 74 |
| The Gene Technology Technical Advisory Committee | 74 |
| The Gene Technology Ethics and Community Consultative Committee | 75 |
| Interface with other legislation | 75 |
| Designated Areas Principle | 76 |
| Who is the Regulator and what do they do? | 77 |
| How and why is gene technology used in Australia? | 79 |
| Gene technology in an international context | 80 |
| Chapter three: The Third Review of the Gene Technology Scheme | 82 |
| Why is the Review being conducted? | 83 |
| Purpose and design | 83 |
| Review governance | 84 |
| Review consultation approach | 84 |
| Other reviews and inquiries | 87 |
| Other research | 88 |
| Previous reviews of the Scheme | 88 |
| Regulatory reform agenda | 89 |
| Next steps | 89 |

| | |
|---|------------|
| Appendices..... | 91 |
| Appendix 1 Glossary..... | 92 |
| Appendix 2 Matters out of scope of the Review..... | 95 |
| Food labelling..... | 95 |
| Herbicide and pesticide use..... | 95 |
| Appendix 3 Functions of the Regulator..... | 96 |
| Appendix 4 GMO Authorisation Categories..... | 97 |
| Exempt dealings and NLRDs..... | 97 |
| Licences..... | 97 |
| GMO Register..... | 99 |
| Emergency Dealing Determination..... | 99 |
| Appendix 5 OGTR Monitoring and Compliance..... | 100 |
| Monitoring..... | 100 |
| Compliance and enforcement..... | 100 |
| Practice reviews..... | 100 |
| Post-release review..... | 101 |
| Appendix 6 Expert Advisory Panel..... | 102 |
| Biographies..... | 102 |
| Appendix 7 Outcomes of Phase 1 Consultation..... | 104 |
| Submissions provided to Phase 1..... | 104 |
| What did we find in Phase 1 consultation?..... | 105 |
| Appendix 8 Outcomes of Phase 2 Consultation..... | 106 |
| Submissions provided to the online survey in Phase 2..... | 106 |
| What did we find in Phase 2 consultation?..... | 107 |

Figures

| | |
|---|----|
| Figure 1 National Gene Technology Regulatory Scheme governance, advisory and consultation structures..... | 46 |
| Figure 2 Overview of the Gene Technology Landscape in Australia..... | 70 |
| Figure 3 National Gene Technology Regulatory Scheme governance, advisory and consultation structures..... | 73 |
| Figure 4 Gene Technology Scheme interface with other Commonwealth regulatory schemes..... | 75 |
| Figure 5 Map of Gene Technology Stakeholders..... | 85 |

Tables

| | |
|---|-----|
| Table 1 – Stakeholder streamlining proposals..... | 32 |
| Table 2 – Members of the Legislative and Governance Forum on Gene Technology as at 28 March 2018..... | 44 |
| Table 3 – Expert Advisory Panel to the Third Review of the National Gene Technology Scheme..... | 102 |
| Table 4 – Submissions to Phase 1..... | 104 |
| Table 5 – Submissions to Phase 2..... | 106 |

Acknowledgement

The Third Review of the National Gene Technology Scheme (the Review) has been an extensive undertaking by Australian governments, and 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 the 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 *Preliminary Report*

This Preliminary Report presents stakeholders with the findings of the Review to date.

Overall, many sources have provided input for the Review to consider. This input, together with consideration of related reports, reviews and adjunct research, has led to the development of 33 findings which are presented herein.

These findings reflect the views and suggestions made by stakeholders. Views often vary considerably, and progression of any proposed solutions would necessarily require administrative and legal consideration.

The release of the *Preliminary Report* aligns with the commencement of the third phase of the consultation process for the Review.

Stakeholders are invited to provide their feedback on the findings as outlined in this document. In particular, the Review is seeking comment to refine the findings where necessary, including whether there are any major considerations that have been missed. This can be done through an online submission process.

As a next step, it is anticipated that the final report, including any recommendations informed by this consultation phase, will be provided to Australian governments for their consideration in the second half of 2018.

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, and 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 Gene Technology Agreement 2001 (the Agreement). The Scheme consists of the Agreement, the *Gene Technology Act 2000 (Cth)* (the Act),¹ the Gene Technology Regulations 2001 (Cth) (the Regulations) 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 other regulatory frameworks that deal with genetically modified (GM) products.

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 dealings with GMOs.'*²

The Scheme regulates gene technology using a risk-based approach,³ where higher risk activities with GMOs are subject to greater regulatory oversight. Additional information about the current operation of the Scheme can be found in [Chapter 2: What is the Gene Technology Scheme and how does it work](#).

Third Review of the Scheme

Regular reviews of the Scheme are required under the Agreement. Since the commencement of the Gene Technology Scheme in 2001, two reviews have been conducted (in 2006 and 2011). These reviews 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, reviewing how well the Scheme had been meeting its purpose.

The Third Review of the Scheme (the Review) has also focused on the ongoing achievement of the policy objectives of the Scheme, but has done so with the need to look to the future, taking into account the rapidly developing and innovative area of gene technology. The Terms of Reference for the Review can be found on [page 7](#).

Separate to the reviews of the Scheme, the Regulator can conduct Technical Reviews of the Regulations, to consider enhancements for the operation of the Scheme. These may also lead to legislative amendments.

This current Review has also been mindful that globally, governments and citizens are discussing appropriate regulatory approaches to manage future advances in gene technology, and biotechnology more broadly.

The Review's governance structure reflects the Scheme's national governance structure. In addition, the Review was designed to harness the views of government and non-government stakeholders across Australia. Similarly, to address the complex scientific and regulatory nature of gene technology, the Review accessed expert technical advice, where required.

1 *Gene Technology Act 2000 (Cth)* (Austl.), available at <https://www.legislation.gov.au/Details/C2016C00792>

2 Currently, the regulation of GMOs does not take into account any potential benefits of GMO dealings.

3 Office of the Gene Technology Regulator. (2013). *Risk Management Framework*. Retrieved March 19, 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)

Consultation approach

All Australian governments understand the importance of thorough consultation to inform this Review. The Review consultation process has involved three 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 (current phase)

Phase 1 and 2 consultations included almost 160 written and online submissions, eleven face-to-face consultation workshops, two online webinar sessions, and numerous bilateral meetings with specific stakeholders.

Phase 3 consultation provides stakeholders with another opportunity to contribute to the Review outcomes. Additional information about the conduct of the Review, including how to participate in Phase 3, can be found in [Chapter 3: The Third Review of the Gene Technology Scheme](#).

Review findings

Through the public consultation processes, further informed by discussions with the Gene Technology Regulator, other experts, and other relevant bodies, a diverse range of views were heard. This input, together with consideration of related reports, reviews and adjunct research, has led to the development of 33 findings, which identify both:

- 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.

The findings are presented in Chapter 1, and grouped under themes (described below):

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

It became apparent early in the consultation that, given the complexity and scope of the Scheme, it is not well understood by all stakeholder segments.

During the Phase 3 consultation stakeholders should consider the Review findings as a whole package, and in the context of the Scheme's design and operation. This context is provided in the detailed discussion of the findings in [Chapter 1: Review findings](#) (Chapters 1.1 to 1.5), and background on the Scheme in [Chapter 2: What is the Gene Technology Scheme and how does it work](#).

Phase three consultation feedback will be analysed to inform the development of the Review recommendations for the Final Report to all Australian governments.

Overarching findings

The legislative framework, and the Agreement that establishes a nationally consistent gene technology regulation scheme, remain central to the operation of the Scheme.

The Review has two findings which relate to the object of the *Gene Technology Act 2000* and the operation of the Agreement respectively.

Review theme one: Technical findings

The Review has reached a number of findings related to technical aspects of the Scheme. This includes consideration of existing definitions in the legislation and Regulations, and their ability to appropriately classify a range of advances in technology. These technical aspects are of central importance to the Review given the scope to 'future-proof' the Scheme.

The Review also has findings relating to emerging applications, including synthetic biology, human germline gene therapy, GMOs released into the broader environment and GM gene drive organisms. These findings discuss the regulation of these applications by the Scheme and how to best address possible risks associated with their application.

Review theme two: Regulatory findings

The Review has considered contemporary approaches to regulation, including what is considered a best-practice, risk-based approach to the regulation of gene technology. Review findings include discussion on the most appropriate 'regulatory trigger', and 'tiers' of regulation, to ensure that regulatory requirements are commensurate with risk. Related to these findings, consideration has been given to whether additional mechanisms should be available to help future-proof the Scheme, in light of anticipated ongoing technological advances.

There are also findings which relate to streamlining the Scheme's regulatory requirements, and whether the Scheme is suitably equipped to regulate work with GMOs undertaken outside of universities, research institutions or large companies.

Additionally, the Review has considered how the Scheme impacts market access and international trade, and the role for the Australian government in this area.

Review theme three: Governance findings

The Review has a number of findings regarding the credibility, integrity and legitimacy of the Scheme, including the legislative and governance oversight provisions, as well as maintaining the independence of the Regulator. Matters related to national consistency across the Scheme are considered. These include both the mechanisms for applying corresponding legislation across the country, and state and territory moratoria legislation.

Any potential benefits which may flow from a GMO are not currently considered in regulatory decision making, and whether this remains appropriate has been examined by the Review. The Review has also investigated whether the Scheme imposes any unnecessary regulatory burdens which may prevent any economic or health and welfare benefits of gene technology from being realised.

The Review presents findings on whether specific topic areas would benefit from additional policy direction (for example, the release of gene drive organisms into the environment). Further, findings have also been presented regarding the interface between the Office of the Gene Technology Regulator and other regulators, the level of funding required for the sustainable operation of the Scheme, and the most appropriate source of funding.

Review theme four: Social and ethical findings

The Review's social and ethical findings explore communication with the public (including the most appropriate body to undertake such communication activities) and the existing transparency measures for communicating regulatory data. These findings address ongoing concerns within some sections of the community about the safety of GMOs, and the ability of the Regulator to monitor commercialised GMOs for long-term impacts.

International context

When reviewing Australia's domestic regulation of gene technology, it is also important to be aware of how gene technology is regulated in other countries. The international context of gene technology regulation is complex, and currently there is no clear international consensus, with countries taking a variety of different approaches. Additional information about gene technology regulation in the international context can be found in [Chapter 2: 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, and has addressed the concerns that are within the scope of the Review. Some concerns raised by stakeholders are beyond the scope of the Review to consider and these topic areas are highlighted on [page 9](#) and in [Appendix 2: Matters out of scope of the Review.](#)

Review progress and next stage

The Review invites stakeholders to examine the full set of Findings in detail, along with the supporting information on the design and operation of the Scheme. Comment is sought to refine these findings where necessary, including whether there are any major considerations that have been missed. Further information on the Review can be found at <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-technology-review>.

The Review looks forward to receiving responses to this *Preliminary Report*.

List of Review Findings

Please note: any regulatory changes arising from these findings would be subject to administrative, legal and financial considerations.

| Finding | Term of Reference: |
|---|--------------------|
| Overarching Findings | |
| As with previous reviews of the Scheme, the Review has considered whether the object of the <i>Gene Technology Act 2000</i> remains appropriate. | 3 |
| Finding 1: The Review found that the object of the <i>Gene Technology Act 2000</i> remains appropriate and should be maintained. | |
| As with previous reviews of the Scheme, the Review has considered whether the Gene Technology Agreement (2001) continues to fulfil its purpose. | 3 |
| Finding 2: The Review found that the Gene Technology Agreement (2001) is working well and continues to facilitate effective national cooperation on gene technology. As such, the Gene Technology Agreement (2001) should be maintained. | |
| Review Theme One: Technical Issues | |
| Many of the definitions in the <i>Gene Technology Act 2000</i> and Gene Technology Regulations 2001 have remained unchanged since the Scheme was first established in 2001. | 1 |
| Finding 3: The Review found that there are existing definitions in the <i>Gene Technology Act 2000</i> 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'). | |
| 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. | |
| There is a lack of clarity for some stakeholders regarding the regulatory status of synthetic biology. | 1 |
| Finding 4: The Review found that synthetic biology is currently within the scope of the Scheme, and there is a high degree of support for this to continue. Work is currently being undertaken by the Australian Council of Learned Academies (ACOLA) which may further inform this issue going forward, including determining the most appropriate mechanism(s) to ensure the appropriate level of regulation of synthetic biology is applied. | |
| Making heritable changes to the human embryonic genome is prohibited in Australia; however, there remains a high level of interest in emerging science relating to the field of human gene therapies, and in ensuring that the Scheme is well placed to respond to any future changes that may arise. | 1 |
| Finding 5: The Review found that the Scheme was not designed to regulate humans, including those who have received or inherited germline therapies (or who have received somatic therapies that were not envisaged when the <i>Gene Technology Act 2000</i> was drafted). Therefore, the Scheme is not the most appropriate means to regulate the application of human gene therapies (including any ethical, legal and social issues). | |
| Any consideration of whether additional regulatory oversight is needed in this area may benefit from national collaboration across the health sector, to identify the most appropriate body to undertake this work. | |

| Finding | Term of Reference: |
|---|--------------------|
| <p>There is a need to determine the most appropriate approach for regulating the broader environmental release of genetically modified organisms (for example, genetically modified biological control agents or threatened indigenous species) under the Scheme.</p> <p>Finding 6: The Review found that there would be benefit in further work being undertaken to determine the most appropriate approach for regulating the broader environmental release of genetically modified organisms. Subject to administrative and legal considerations, this could include:</p> <ul style="list-style-type: none"> • 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 <i>Environment Protection and Biodiversity Conservation Act 1999</i>, the scheme set up by the <i>Biological Control Act 1984</i> and related state and territory laws, and the intersection of these laws with the <i>Gene Technology Act 2000</i>; • 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). | 1 |
| <p>There is an identified need to determine the most appropriate approach for regulating the environmental release of genetically modified gene drive organisms (as well as any additional requirements for contained work).</p> <p>Finding 7: While both contained work and any future environmental releases of genetically modified gene drives should be clearly within the scope of the Scheme, the Review found that there would be benefit in further work being undertaken to determine the most appropriate approach for regulating environmental release of genetically modified gene drive organisms (as well as any additional requirements for contained work). This could include mechanisms similar to those suggested for Finding 6.</p> | 1 & 2 |
| Review Theme Two: Regulatory Issues | |
| <p>For a regulatory scheme to impose regulatory requirements that are commensurate with risk, it is first necessary to have an appropriate ‘regulatory trigger’ to determine what falls inside and outside the scope of regulation.</p> <p>Finding 8: The Review heard strong arguments to support the maintenance of a process-based trigger as the entry point for the Scheme (i.e. a broad range of technologies, including new technologies, are within the scope of the Scheme).</p> | 1 & 2 |
| <p>For the Scheme to function effectively, it is important that regulatory requirements are commensurate with risk.</p> <p>Finding 9: The Review found that there are opportunities for additional risk tiering to be applied within the Scheme. An additional body of work could be undertaken to determine the most appropriate risk tiers and the types of regulatory requirements assigned to each tier.</p> <p>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 (see Findings 13 and 14), could be considered. Any changes should aim to ensure the level of regulation remains proportionate with risk and protects against over-regulation or under-regulation.</p> | 1 & 2 |

| Finding | Term of Reference: |
|--|--------------------|
| <p>Some stakeholders considered that certain regulatory processes could be more efficient and timely, without losing appropriate oversight.</p> <p>Finding 10: The Review heard 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.</p> | 2 |
| <p>The GMO Register provides a mechanism to authorise certain dealings with genetically modified organisms; however, to date only one dealing is listed on the GMO Register.</p> <p>Finding 11: 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:</p> <ul style="list-style-type: none"> 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. | 2 & 3 |
| <p>Concerns exist within the community regarding the activities of the 'DIY biology' community.</p> <p>Finding 12: The Review heard that there are 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.</p> | 1 & 2 |
| <p>There has been an exceptional rate of change relating to advances in gene technology since the previous review of the Scheme.</p> <p>Finding 13: The Review heard that there is a need for increased flexibility within the Scheme to enable it to appropriately respond to changes in scientific understanding and understandings of risk. Options to increase this flexibility that could be investigated further (subject to administrative and legal considerations) could include:</p> <ul style="list-style-type: none"> enabling the Gene Technology Regulator to make determinations or orders on the applicability of regulation to any technological developments. These determinations (or orders) could be recognised by the Gene Technology Regulations 2001, until such times that they are included in legislation; and introducing elements of principles-based regulation to some parts of the Scheme, initially focussing on areas of the Scheme with a history of safe use. <p>Finding 14: The Review heard that there may be scope to increase the agility of the Scheme, while maintaining appropriate oversight measures. This might include introducing mechanisms to enable certain activities of the Legislative and Governance Forum on Gene Technology to be driven by the Gene Technology Standing Committee.</p> | 2 |
| <p>The Review has considered whether Australia's current legislative arrangements are appropriate to support market access and international trade.</p> <p>Finding 15: The Review heard that the Australian government has an important role in coordinating internationally on matters relevant to market access and international trade. There is benefit in the Australian government, including the Gene Technology Regulator on regulatory matters, continuing to engage with appropriate international fora in this area and ensuring that any relevant international obligations continue to be met.</p> | 2 |

| Finding | Term of Reference: |
|---|--------------------|
| Review Theme Three: Governance Issues | |
| For the Scheme to function effectively, it is necessary for it to be credible and operate with integrity and legitimacy. | 3 |
| <p>Finding 16: The Review found that the operation of the Scheme has shown to be credible, and that the Scheme operates with integrity and legitimacy as evidenced by:</p> <ul style="list-style-type: none"> • high level governance oversight provided by all states and territories through the Legislative and Governance Forum on Gene Technology; • the independence and credibility of the Gene Technology Regulator; and • robust governance processes providing oversight of advisory structures and appointments. | |
| The constitutional power to regulate gene technology is shared between the Commonwealth government and state and territory governments. Alignment of state, territory and Commonwealth legislation assists the Scheme to operate efficiently. | 2 & 3 |
| <p>Finding 17: The Review heard that ensuring national consistency of the Scheme is valued, and that maintaining consistency between all state and territory Acts and the <i>Gene Technology Act 2000</i> helps provide certainty for stakeholders in relation to current regulatory requirements.</p> | |
| The <i>Recognition of Designated Areas Principle 2003</i> articulates that a state or territory has the power to designate, under its own laws, particular areas to be GM crop areas or non-GM crop areas (moratoria legislation). | 2 |
| <p>Finding 18: The Review found there are conflicting views among stakeholders regarding the advantages and disadvantages of state and territory moratoria legislation. Further, there is a lack of conclusive evidence on this matter, particularly on the economic effect of moratoria legislation, as economic calculations are context-specific and complex (based on non-stable factors).</p> <p>Finding 19: The Review 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.</p> | |
| Currently, consideration of benefits (e.g. potential economic, environmental and health benefits) is not within the scope of the Scheme. | 3 |
| <p>Finding 20: The Review found that consideration of benefits (e.g. potential economic, environmental and health benefits) should not be introduced at this time as it could risk the effective operation of the Scheme. Consideration of benefits may be an area of ongoing focus in future reviews.</p> | |
| Given the exceptional rate of change in relation to gene technology since the previous review of the Scheme, failure to keep pace with technological advances has the potential to stifle innovation in gene technology and may prevent any potential economic and health benefits from being harnessed by the community. | 1 & 2 |
| <p>Finding 21: 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 Findings 9 and 10).</p> | |

| Finding | Term of Reference: |
|---|--------------------|
| <p>There are a number of topics which may benefit from improved regulatory and policy clarity, to provide certainty to industry and the community, and greater transparency about decision making.</p> <p>Finding 22: The Review found that there is an opportunity for the Legislative and Governance Forum on Gene Technology (the Forum) to lead a forward work program to consider a range of matters. 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 a forward work program, the Forum might consider opportunities to leverage the role of the Gene Technology Standing Committee.</p> | 2 |
| <p>Policy clarity can be provided through the issuing of Policy Principles. Currently, Policy Principles can be issued on ethical issues, designated areas, or matters relating to dealings prescribed by the regulations.</p> <p>Finding 23: The Review found that consideration could be given to using the current provisions of section 21 of the <i>Gene Technology Act 2000</i> to enable Policy Principles to be issued on a wider range of topics.</p> | 2 |
| <p>The Scheme was developed to work alongside the regulatory schemes for human food, human therapeutics, veterinary medicines, agricultural chemicals and industrial chemicals, with the Office of the Gene Technology Regulator managing risks associated with live and viable genetically modified organisms. However it is acknowledged that the numerous intersecting pieces of legislation in this space may add to the complexity of gene technology regulation.</p> <p>Finding 24: The Review heard that there is lack of clarity for some stakeholders regarding the roles of the Office of the Gene Technology Regulator and genetically modified product regulators, which might be addressed through the development of a dedicated gene technology regulation web portal.</p> <p>Finding 25: The Review heard that 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 legislative changes.</p> <p>Finding 26: The Review heard that there are potential mechanisms in other schemes (for example, the <i>Therapeutic Goods Act 1989</i> Special Access Scheme) that could be adopted to strengthen the Scheme, and there may be benefit in additional investigation being undertaken.</p> | 2 |
| <p>The Review Terms of Reference direct the Review to consider funding arrangements to ensure sustainable funding levels, and to ensure that funding mechanisms are appropriate to support the operation of the Scheme.</p> <p>Finding 27: The Review heard that full cost recovery may have detrimental effects on 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 ongoing funding mechanisms to support the ongoing operation of the Scheme.</p> <p>Finding 28: The Review 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.</p> | 4 |

| Finding | Term of Reference: |
|--|--------------------|
| Review Theme Four: Social and Ethical Issues | |
| <p>Community support and the views of the general public are central to the successful operation of the Scheme, and previous reviews have highlighted the need to communicate appropriately with the public about gene technology.</p> <p>Finding 29: The Review heard that public understanding and confidence in the Scheme may be aided by additional communication mechanisms (building on existing bodies of work). There may be benefit in additional work to determine the most appropriate body to lead communication activities. Any additional communication activities would need to be appropriately funded.</p> <p>Finding 30: The Review heard that it is appropriate for the Gene Technology Regulator to continue to lead communication activities on topics related to the assessment of risk associated with gene technology.</p> | 2 |
| <p>There are diverse views across Australia regarding the value and risks associated with the application of gene technology. For there to be public trust in the Scheme, regulation must be well designed and managed, and there must be confidence that the rules are being followed.</p> <p>Finding 31: The Review found that despite current regulatory arrangements, there remain ongoing concerns within some sections of the community about the safety of genetically modified organisms, and in particular the safety of genetically modified foods.</p> <p>Finding 32: 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.</p> | 2 |
| <p>A high level of transparency and public access to information for the Australian public is necessary, to ensure public trust and the effective operation of the Scheme.</p> <p>Finding 33: 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 publically available, and through increased communication with the public (see Findings 29 and 30).</p> | 3 |

Introduction

The *Preliminary Report* for the Third Review (the Review) of the National Gene Technology Regulation Scheme (the Scheme) provides the Review's findings, together with background information about the governance and operations of the Scheme and the conduct of the Review. These findings reflect the views of stakeholders provided during consultation to date, noting that perspectives varying considerably across the range of issues explored.

This *Preliminary Report* is being released as part of the third consultation phase of the Review, which will inform the final report to be considered by all Australian governments.

The Terms of Reference and the principles underpinning the Review are outlined below:

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 progressing the Review, there are a number of principles that underpin the Review and the Scheme. These include:

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, with the sections structured to align with the themes identified in the Phase 2 *Consultation Paper*. The finding chapters of the *Preliminary Report* are structured as follows:

- **Chapter 1.1: Overarching Findings** – 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 Findings** – classification of new technologies, emerging applications and intentional environmental releases.
- **Chapter 1.3: Review Theme Two: Regulatory Findings** – regulatory triggers, risk tiering, streamlining regulation, DIY biology, future-proofing regulation, and market access and international trade.
- **Chapter 1.4: Review Theme Three: Governance Findings** – 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 Findings** – communication with the public, safety concerns, Scheme transparency, and disincentives to commercialisation.

Please note: any regulatory changes arising from these findings would be subject to administrative, legal and financial considerations.

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 findings. This is particularly relevant given the indicative level of awareness or misunderstanding of the regulatory system reflected in some stakeholder comment to date.

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

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

Supporting documents

This *Preliminary Report* is part of a suite of material to support the wide consultation of the Review, and development of the Final Report for all Australian governments.

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

- *Review of the National Gene Technology Scheme 2017, Consultation Paper*⁴ (Phase 2);
- Legislative and Governance Forum on Gene Technology *Joint Communique* announcing the Third Review of the National Gene Technology Regulatory Scheme;⁵ and
- *2017 Review Background Paper*.⁶

4 Department of Health, *Review of the National Gene Technology Scheme – Consultation approach 2017*. Retrieved March 20, 2018, from www.health.gov.au/internet/main/publishing.nsf/Content/gene-technology-review

5 Department of Health, *Legislative and Governance Forum on Gene Technology Joint Communique*. Retrieved March 20, 2018, from www.health.gov.au/internet/main/publishing.nsf/Content/mr-yr17-gene-technology

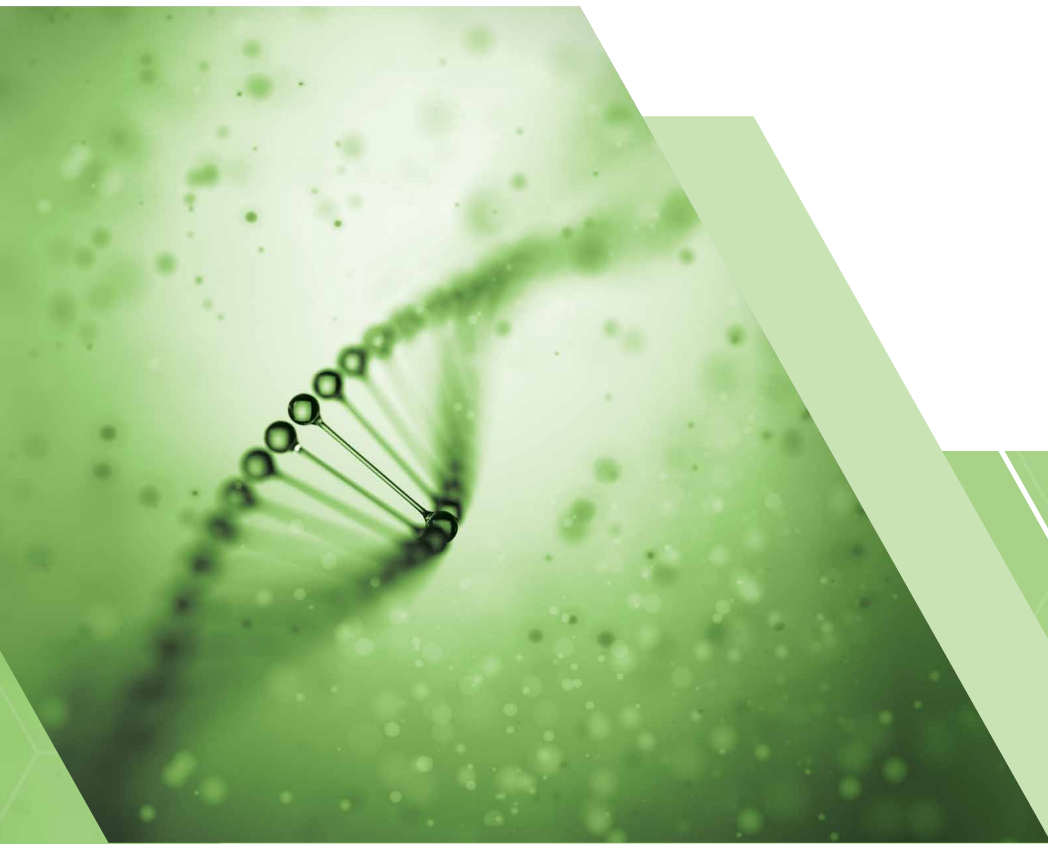
6 Department of Health. (2017). *Review of the National Gene Technology Regulatory Scheme – Background Paper*. Retrieved March 20, 2018, from www.consultations.health.gov.au/health-systems-policy-division/genetechreview2017/supporting_documents/2017%20Review%20of%20the%20Gene%20Technology%20Scheme%20%20Background%20Paper%20%20Web%20Accessible.pdf

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 maintains this broad approach, there are several topics raised by stakeholders that are beyond the scope of the current Review. These topics instead fall under the remit of other regulatory schemes, laws or regulatory forums. Key examples of out of scope topics raised by stakeholders include food labelling, and the regulation of herbicide and pesticide use. Further information has been provided at [Appendix 2: Matters out of scope of the Review](#).

Review findings



CHAPTER 1.1

Overarching findings

The Gene Technology Scheme (the Scheme) came into effect on 21 June 2001, under the *Gene Technology Act 2000* (the Act). This Scheme replaces 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.

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

Please note: any regulatory changes arising from these findings would be subject to administrative, legal and financial considerations.

FINDING 1

Object of the *Gene Technology Act 2000*

Stakeholders uniformly agreed the object of the *Gene Technology Act 2000* (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 contributing to the Review considered that the Scheme has operated successfully since its inception, 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).⁷

Some stakeholders did express 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 Findings 31 and 32.

While what is sometimes referred to as a 'precautionary approach'⁸ was seen as 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 Finding 20 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.

Finding 1 – The Review found that the object of the *Gene Technology Act 2000* remains appropriate and should be maintained.

This finding relates to Term of Reference 3.

⁷ Office of the Gene Technology Regulator, *Annual and Quarterly Reports under the Gene Technology Act 2000*. Retrieved March 20, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1 <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1#2017>

⁸ 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".

FINDING 2

The Gene Technology Agreement 2001

The Gene Technology Agreement 2001 (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.

The Review found that overall the Agreement is 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 establishes a Ministerial Council, the Legislative and Governance Forum on Gene Technology (the Forum), to govern the operation of the Scheme. The Forum membership includes ministers with responsibility for gene technology from each state, territory and the Commonwealth. 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.⁹

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 Finding 14).

A small number of stakeholders have 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 the formulation of additional Policy Principles if, and when, they are warranted (see Findings 22 and 23).

Finding 2 – The Review found that the Gene Technology Agreement (2001) is working well and continues to facilitate effective national cooperation on gene technology. As such, the Gene Technology Agreement (2001) should be maintained.

This findings relates to Term of Reference 3.

⁹ For more information on the role of the Standing Committee, see Department of Health, *Gene Technology Standing Committee*. Retrieved March 20, 2018, from 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 presents the Review's findings related to recent advances in technologies.

This 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, this section of the *Preliminary Report* discusses 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 legally accepted definition,¹⁰ there is wide agreement that the term 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, the intent when the Scheme was first established was to avoid the situation whereby a person who has undergone gene therapy becomes a GMO. Whether **human germline 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. Whether **GM gene drive organisms** (released either as biological control agents or for other purposes) require an additional level of regulatory oversight is explored in this section.

Please note: any regulatory changes arising from these findings would be subject to administrative, legal and financial considerations.

¹⁰ See glossary

FINDING 3

Classification of new technologies

When the Act and Regulations were 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, and has opened up many new applications that do 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.

During the consultation process, 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, whether or not an organism is regulated under the Scheme is determined by whether it meets 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 from the definition of GMO a range of organisms 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 intragenesis¹¹ constitute the introduction of any 'foreign nucleic acid'.¹² Stakeholders also identified other advances in gene technology (including but not limited to CRISPR, ZFNs and TALEN¹³) that will need to be considered when assessing the definition of techniques that produce a GMO (or if appropriate, the exclusions from this definition).

The Review recognises 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, it is also recognised that there is a lack of consensus among stakeholders as to how these definitions should be amended. One example is the question of whether there is a basis for further clarifying the definition of 'gene technology' to establish to what extent the scope captures 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 suggested that advances in technology (including ODM, SDN-1 and SDN-2, which have developed rapidly in recent years),¹⁴ should be excluded from the scope of the Scheme as they pose no additional risks compared to conventional breeding. It has been argued that these techniques produce changes that

¹¹ These techniques involve the introduction of DNA obtained from the same, or a cross-compatible species, into the genome of an organism.

¹² The Review notes that Schedule 1 to the Regulations (where the term 'foreign nucleic acid' is used) is currently under consideration by the Technical Review. The Technical Review is still ongoing, with public submissions on proposed amendments to the Regulations under consideration. 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.

¹³ (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) that are methods of 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 March 20, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewdiscussionpaper-htm

¹⁴ 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 March 20, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewdiscussionpaper-htm

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 contended that the existing definition of gene technology was intentionally drafted broadly to capture all forms of modification of genetic material and 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. The Review also notes there is a growing body of literature¹⁵ suggesting that for gene editing applications, where no 'foreign nucleic acid' is introduced, any changes in the edited genome are 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.

The Review also notes there have been a number of analyses looking at 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 compared with those found after random mutagenesis or conventional breeding.¹⁶ It has also been noted that the off-target effects are no different than those which occur in nature.¹⁷

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 the Review notes continued advances in the ability to 'conduct comprehensive genome-wide characterization for the detection of off-target sites'.¹⁸ However, the Review considers that 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.

The regulatory status of gene editing techniques is being considered around the world and the Review specifically notes recent developments in the United States of America and Europe.

The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) has applied a case-by-case assessment process to the set of techniques with the capacity to change the genomes of living organisms, but not introduce foreign DNA to the genome.¹⁹ The USDA APHIS has adjudicated that a number of food crop varieties produced using some recently developed techniques are not GMOs, and thus are not regulated.

The Advocate General to the European Court of Justice has recently (January 2018) provided a legal opinion (non-binding advice to the Court of Justice) on the exclusion of organisms obtained by mutagenesis from the GMO

15 Nicolai, 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: 10.3109/07388551.2013.823595

16 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: 10.1042/ETLS20170037

17 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: 10.1038/nbt.3568

18 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: 10.1042/ETLS20170037

19 United States Department of Agriculture, *Regulated Article Letters of Inquiry*. Retrieved March 20, 2018, available from www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/Regulated_Article_Letters_of_Inquiry

Directive of 2001. This directive regulates the deliberate release into the environment of GMOs and their placing on the market within the European Union (EU).²⁰ This opinion finds that 'mutagenesis techniques' may include some of the newer techniques referenced above, and that these techniques may be exempt from the obligations of the GMO Directive provided that they do not involve the use of recombinant nucleic acid molecules. Separate to regulation at the EU level, European member states can legislate with regard to organisms obtained by mutagenesis.

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

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

Secondary considerations are:

- 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).

Finding 3 – 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').

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.

This finding relates to Term of Reference 1.

²⁰ Court of Justice of the European Union. (2018). *Press Release No 04/18, 18 January*, Retrieved March 20, 2018, from www.curia.europa.eu/jcms/upload/docs/application/pdf/2018-01/cp180004en.pdf

FINDING 4

Emerging applications: Synthetic biology

Synthetic biology is an emerging application that covers 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,²¹ 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 of 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, which 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.²² Australia's Scheme utilises case-by-case, science-based assessment of environmental releases, in line with the Office of the Gene Technology Regulator (OGTR) Risk Analysis Framework 2013.²³

There was also agreement among stakeholders that **future** synthetic biology applications should continue to be closely monitored by the Scheme, to ensure regulation remains appropriate to address any emerging risks. Such applications however, were generally considered to be 'future possibilities'. 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.

The Australian Chief Scientist and the Commonwealth Science Council, through the Australian Council of Learned Academies (ACOLA), are examining the opportunities and issues synthetic biology may present in Australia in the coming decade. The Review considers it prudent to await the outcomes of the ACOLA Report on synthetic biology, due in mid-2018, in order to determine the extent of synthetic biology activity in Australia and possible mechanisms for the appropriate level of regulation of synthetic biology.

Finding 4 – The Review found that synthetic biology is currently within the scope of the Scheme, and there is a high degree of support for this to continue. Work is currently being undertaken by the Australian Council of Learned Academies (ACOLA) which may further inform this issue going forward, including determining the most appropriate mechanism(s) to ensure the appropriate level of regulation of synthetic biology is applied.

This finding relates to Term of Reference 1.

²¹ See glossary

²² Secretariat of the Convention on Biological Diversity, (2015). *Synthetic Biology: Technical Series No. 82*. Retrieved March 20, 2018, from www.cbd.int/ts/cbd-ts-82-en.pdf

²³ Office of the Gene Technology Regulator. (2013). *Risk Management Framework*. Retrieved March 19, 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)

FINDING 5

Emerging applications: Human germline gene therapy

This Review was designed to be forward-looking and to consider appropriate policy settings in an environment of rapidly developing technology. One implicated area is the field of human germline gene therapy. As described in the Consultation Paper, human 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, and 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*,²⁴ although some research may be authorised under the *Research Involving Human Embryos Act 2002*.²⁵ However, to ensure that 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.

In considering this issue, two areas for discussion have been identified:

- Social and ethical issues; and
- Implications of the definition of a GMO.

Social and ethical issues

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

Although some stakeholders suggested that a ban on human germline gene therapy for any purpose should be maintained until a society-wide consideration of the issue, the Review notes that 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.

Definition of GMO

The definition of a GMO in the Act²⁶ 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.²⁷

Any patient who receives treatment which modifies their germline²⁸ (reproductive) cells rather than their somatic²⁹ (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.

Stakeholder feedback raised questions regarding the appropriateness of this scenario and the flow-on implications. GMOs are subject to a range of requirements such as licencing, physical containment and transport restrictions that are clearly not appropriate to apply to human beings.

24 *Prohibition of Human Cloning for Reproduction Act 2002 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/C2017C00306

25 *Research Involving Human Embryos Act 2002 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/C2016C00968

26 *Gene Technology Act 2000 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/C2016C00792

27 *Gene Technology Regulations 2001 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/F2016C00615

28 See glossary.

29 See glossary.

The Review notes the Scheme was not designed to regulate humans.³⁰ 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'.³¹

While human germline therapies are currently prohibited in Australia as noted above, 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 the Act and the Regulations.

One proposal to address this issue is to amend the definition of a GMO 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. This amendment may result in another existing, or new, regulatory body needing to expand its scope of regulatory activity to ensure that appropriate regulatory oversight is provided in this area. Decisions on the most appropriate form of regulatory oversight for this area would need to involve all jurisdictions, and include broad consultation across the health sector.

Finding 5 – The Review found that the Scheme was not designed to regulate humans, including those who have received or inherited germline therapies (or who have received somatic therapies that were not envisaged when the *Gene Technology Act 2000* was drafted). Therefore, the Scheme is not the most appropriate means to regulate the application of human gene therapies (including any ethical, legal and social issues).

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

This finding relates to Term of Reference 1.

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

31 Interim Office of the Gene Technology Regulator. (2000). *Explanatory Guide to the Gene Technology Bill 2000*, p. 24. Retrieved March 20, 2018, from [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)

FINDING 6

Intentional environmental release: Biological control

The Review is investigating how to best address possible risks associated with intentional environmental releases (for example, the release of GM biological control agents or threatened native species genetically modified to be more resistant to disease or other threats)³² Through formal submissions and other consultation mechanisms, the following options were raised:

- a new licencing 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 licencing categories: Dealings involving Intentional Release into the environment (DIR), and Dealings Not involving Intentional Release into the environment (DNIR).³³ DNIR licenced activity takes place under containment most commonly in certified facilities, while DIR licenced 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, these licencing 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, as discussed in the Consultation Paper, 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)³⁴ 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.³⁵ Alternatively, a new licence category (with specific requirements relevant to biological control agents) could be considered.

Risk management plans

The Review noted the potential for additional mechanisms to be used within RARMP procedures in assessing more complex environmental releases; for example, the use of probability modelling for complex environmental releases

³² The review notes the development of GM biological control agents could be achieved through both the application of gene drive technology, or through other gene technology applications. This section of the *Preliminary Report* discusses the intentional environmental releases of biological control agents generally, while specific discussion of gene drive organisms is included in Finding 7.

³³ 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.

³⁴ The RARMP are conducted prior to a licencing 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 March 19, 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)

³⁵ 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 March 20, 2018, available from www.health.gov.au/internet/main/publishing.nsf/Content/gene-techact-review

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 dependant on the circumstances.

The Review notes that the 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.

The Review is also considering whether the release of a biological control agent would entail greater complexity, and as a consequence, whether it would require more extended timeframes (for application assessment and the preparation of RARMPs), and lead to additional matters that require consideration.

Environmental protection legislation

The intersection between the Scheme and existing environmental protection legislation could also 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.³⁶

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,³⁷ 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.

The Review also notes the 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.

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 underutilised, provisions of the Scheme – such as Policy Principles, Guidelines or Codes of Practice issued by the Forum – to solve some of the emergent issues the Scheme is facing (see Findings 22 and 23). This may include the issuing of a Principle, Guideline or Code relevant to the release of genetically modified biological control agents.

³⁶ 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 March 20, 2018, available from www.agriculture.gov.au/biosecurity/legislation/new-biosecurity-legislation and Department of the Environment and Energy, *Live Import List*. Retrieved March 20, 2018, available from www.environment.gov.au/biodiversity/wildlife-trade/live/import-list

³⁷ Australian Academies of Science. (2017). *Synthetic Gene Drives in Australia*. Retrieved March 20, 2018, available from www.science.org.au/support/analysis/reports/synthetic-gene-drives-australia-implications-emerging-technologies.

Post-release monitoring

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.³⁸

Additional work

While much of the detail for the above options is still to be worked through, the Review has found these should be the focus of any further work, noting a solution may utilise a combination of approaches. The Review further notes the complexity, and need for considered examination, particularly in creating a new licencing category, or when these releases may contain a gene drive.

Finding 6 – The Review found that there would be benefit in further work being undertaken to determine the most appropriate approach for regulating the broader environmental release of genetically modified organisms. 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).

This finding relates to Terms of Reference 1 and 2.

³⁸ 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 March 20, 2018, from www.oecd.org/sti/biotech/40986855.pdf

FINDING 7

Emerging applications: Gene drives

A key element for the Review is to consider extensions and advances in gene technology, to ensure the Scheme can accommodate continued technological development. One of these areas of development is the study of GM gene drive organisms, specifically organisms engineered to contain a synthetic gene drive element.

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.'³⁹ Put simply, gene drives increase the rate at which certain genes are inherited by offspring of a sexually reproducing organism, spreading the genes/traits through the population of a species faster than would occur normally.

There is a developing interest in the potential ability of synthetic gene drive systems to control invasive species in ways that avoid the indiscriminate effects associated with conventional control methods.⁴⁰ 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 main focus of gene drive research in this area currently 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. (See Finding 20 for further discussion on considering the benefits of gene technology applications such as gene drives.)

Any organism where a gene drive is introduced, or created using gene technology, would be classified as a GMO and regulated under the Act. Regulatory requirements would depend on whether the gene drive organism is contained or released into the environment.

The appropriate level of regulation for GM gene drive organisms in containment⁴¹ is being considered as part of the Technical Review. The Technical Review has put forward a proposal to require a Dealings Not Involving Intentional Release (DNIR) licence for contained dealings with GMOs that contain functional gene drives. This would ensure case-by-case evaluation of risks and tailored risk management of activities with these organisms.

As part of this case-by-case 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.

39 Office of the Gene Technology Regulator. (2016). *Guidance for IBCs: Regulatory requirements for contained research with GMOs containing engineered gene drives*. Retrieved March 20, 2018, from [www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/53139D205A98A3B3CA257D4F00811F97/\\$File/OGTR%20guidance%20on%20gene%20drives.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/53139D205A98A3B3CA257D4F00811F97/$File/OGTR%20guidance%20on%20gene%20drives.pdf)

40 Australian Academies of Science. (2017). *Synthetic Gene Drives in Australia*. Retrieved March 20, 2018, available from www.science.org.au/support/analysis/reports/synthetic-gene-drives-australia-implications-emerging-technologies

41 '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.

No GM gene drive organisms have yet been proposed for release in Australia. However, 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.⁴² This would ensure 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.⁴³ 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 licencing 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 should be given to developing new Policy Principles, Guidelines or Codes of Practice;
- a moratorium should 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).

Finding 7 – While both contained work and any future environmental releases of genetically modified gene drives should be clearly within the scope of the Scheme, the Review found that there would be benefit in further work being undertaken to determine the most appropriate approach for regulating environmental release of genetically modified gene drive organisms (as well as any additional requirements for contained work). This could include mechanisms similar to those suggested for Finding 6.

This finding relates to Term of Reference 1.

42 The Review notes 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 gene drive organisms.

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

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). 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, needs to be determined. This can be done by assigning different types of work with GMOs, to different authorisation categories. This section of the *Preliminary 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 2](#).

Please note: any regulatory changes arising from these findings would be subject to administrative, legal and financial considerations.

FINDING 8

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 regulations 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 regulatory 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.⁴⁴

A primary concern for all 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 put forward in favour of a product trigger include that:

- 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,⁴⁵ 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 argue that a process trigger is more appropriate and proportionate to risk. Arguments put forward in favour of maintaining a process trigger include that:

- 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.

44 Canadian Food Inspection Agency, (2007). *Regulation of Agricultural Biotechnology in Canada*, Retrieved March 20, 2018, available from www.publications.gc.ca/collections/collection_2007/cfia-acia/A104-24-2007E.pdf

45 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.

These stakeholders also point 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 argue 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, conversely, any emerging risks.

On balance the Review acknowledged there is merit in continuing with the current process-based regulatory approach, noting that a product trigger could be considered again in the future as the Scheme progresses. However, some stakeholders emphasised the merit in considering further the potential for designated exit points to the Scheme, based on the eventual product. To this end 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, which is discussed further in Finding 9.

The Review notes that the continuing successful operation of the Scheme's process trigger is dependent on appropriate definitions of 'genetically modified organism' and 'gene technology'. These definitions are discussed further in Finding 3.

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 (see Finding 13 for further discussion on future-proofing).

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).⁴⁶ 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.⁴⁷

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.

Finding 8 – The Review heard strong arguments to support the maintenance of a process-based trigger as the entry point for the Scheme (i.e. a broad range of technologies, including new technologies, are within the scope of the Scheme).

This finding relates to Terms of Reference 1 and 2.

⁴⁶ 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.). Available at www.legislation.gov.au/Details/F2016C00615

⁴⁷ *Gene Technology Regulations 2001 (Cth)*, Explanatory Statement. Retrieved March 20, 2018, from www.legislation.gov.au/Details/F2001B00162/Explanatory%20Statement/Text

FINDING 9

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.

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. This in turn enables more regulatory attention and oversight to be given to higher risk groups, imposing greater regulation where the risks are higher, difficult to quantify or less well characterised. 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 DIR⁴⁸ and DNIR⁴⁹ licences, NLRDs⁵⁰ and exempt dealings,⁵¹ have different regulatory requirements assigned to them. These have been determined based on the level of risk posed by the organisms in that category.

-
- 48 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 March 21, 2018, from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dirclass-2
- 49 Dealing 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 March 21, 2018, from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dnirclass-2
- 50 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 March 20, 2018, from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/nlrclass-2
- 51 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.

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 only to the existing genome are made).
- 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 – see Finding 8 for further discussion of using a product-based trigger).
- The role of principles-based regulation in developing a risk tiering system (see Findings 13 and 14 for further discussion of principles-based regulation).
- 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 in 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 demonstratively 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. See Finding 8 for additional discussion on the most appropriate regulatory trigger for the Scheme.

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). See Findings 13 and 14 for additional discussion on future-proofing regulation.

Finding 9 – The Review found that there are opportunities for additional risk tiering to be applied within the Scheme. An additional body of work could be undertaken to determine the most appropriate risk tiers and the types of regulatory requirements assigned to each tier.

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 (see Findings 13 and 14), could be considered. Any changes should aim to ensure the level of regulation remains proportionate with risk and protects against over-regulation or under-regulation.

This finding refers to Terms of Reference 1 and 2.

FINDING 10

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 licenced 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)⁵² risk assessment by an IBC⁵³ 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 provide advice to Australian governments as to whether they are appropriate and feasible.⁵⁴ 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 (see Finding 9), some of the subsequent applications 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 tracking process.

An electronic submission process could also be used to facilitate reporting requirements and facilitate the sharing of information between regulatory agencies (so that the same information or data packages need not be provided multiple times to different agencies). See Findings 24, 25 and 26 for additional discussion regarding the interface between regulators.

52 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.

53 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.

54 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.

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.

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 1:⁵⁵

Table 1 – Stakeholder streamlining proposals

| Category | Stakeholder streamlining proposals |
|---|--|
| Facility certifications | <ul style="list-style-type: none"> Enabling IBCs to grant conditional approval for PC1 and PC2⁵⁴ facilities prior to formal certification by the OGTR, or devolving PC1 and PC2 facility certifications to IBCs. Accrediting individuals to undertake certification inspections and provide provisional facility certifications. Recognising pre-existing quality systems as a surrogate for certifications. |
| Facility certification extensions | <ul style="list-style-type: none"> Introducing an automated process for facility certification extensions; 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. Enabling facility certification to be provided following an organisational statement of which conditions have been met. |
| Notifiable Low Risk Dealings (NLRD) | <ul style="list-style-type: none"> Allowing IBCs to extend NLRDs where there is no change in risk level. Removing the requirement for new NLRD numbers to be issued when NLRDs are varied. Amending NLRD reporting requirements so that organisations report to their IBC, rather than the OGTR. |
| Dealings Not involving Intentional Release (DNIR) | <ul style="list-style-type: none"> Introducing an automatic approval system for DNIR extensions where there are no changes to the licence conditions. Reviewing the DNIR assessment timeframes (particularly for extensions); Devolving DNIR authorisations to IBCs. Extending the maximum length of dealing approval. |
| Dealings involving Intentional Release (DIR) | <ul style="list-style-type: none"> Redesigning the DIR application form for clinical trial applications. Devolving some DIR authorisations (small scale field releases of well-studied crops) to IBCs. |
| Classification levels | <ul style="list-style-type: none"> Reviewing the current classification levels for a number of organisms. |
| Harmonisation | <ul style="list-style-type: none"> Harmonising OGTR dealing (DNIR and DIR) inspections and certified facility inspections. Harmonising OGTR and Department of Agriculture and Water Resources facility certification inspections. Adopting the Australian/New Zealand Standards as a benchmark for certifying facilities. Standardising OGTR, Therapeutic Goods Administration (TGA), National Health and Medical Research Council (NHMRC) and International Air Transport Association transport (labelling) requirements. |

⁵⁵ 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)⁵⁶ 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;
- 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 longer the need for information to have CCI protections

Finding 10 – The Review heard 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 finding relates to Term of Reference 2.

⁵⁶ 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.

FINDING 11

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,⁵⁷ or through other categories introduced into the Scheme as discussed in Finding 9. An alternative authorisation mechanism that currently exists is through inclusion on the GMO Register (the Register).

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.

As at January 2018, there is 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 notes a number of potential impediments to entering GMOs on the Register that may be preventing 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.⁵⁸ 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 licenced 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 notes that if the OGTR was to move to a cost recovery model (see Findings 27 and 28), 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.

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

The Review has also identified that there may be 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.

57 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.

58 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.

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 suggests consideration 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.

Finding 11 – 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.

This finding relates to Terms of Reference 2 and 3.

FINDING 12

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'.⁵⁹ For example, at the time of the Review's consideration several 'DIY biology' kits were available for purchase.

Stakeholders have 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.⁶⁰ The Review found it would be beneficial for the Regulator to ensure that gene technology regulatory requirements are widely known, ensure good risk management practices are followed, and to provide guidance to the DIY biology community on responsible research. Effective public communication, discussed further in Findings 29 and 30, 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.

Finding 12 – The Review heard that there are 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.

This finding relates to Terms of Reference 1 and 2.

59 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 March 20, 2018, available from www.citizenscience.org/. Also see Biofoundry's website. Retrieved March 20, 2018, available from www.foundry.bio/

60 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 March 20, 2018, available from 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, doi.org/10.17226/24761

FINDINGS 13 AND 14

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.⁶¹ A number of stakeholders cited the inability to rapidly amend the scope of regulation as an impediment to the Scheme flexibly adapting 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.

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 Findings 27 and 28). 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

61 For example, when a researcher's work is not explicitly referenced within Schedule 1 and 1(a) of the Regulations.

and 1A.⁶² 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 conducted 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 could be to enable the Regulator to make determinations or orders on the applicability of regulation to any technological developments. These determinations (or orders) could be recognised by 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.

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.⁶³ It is less detailed and prescriptive than a rules-based regulation approach, and thus can potentially enable greater regulatory flexibility and future-proofing.⁶⁴

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.

62 Schedules 1 and 1A in of the Regulations 2001 specify organisms that are not considered GMOs and techniques that are not considered to be gene technology under the legislation.

63 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.

64 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 March 20, 2018, available from www.oecd.org/gov/regulatory-policy/governance-regulators.htm

Gene Technology Standing Committee formalisation

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 benefit in more formally recognising the Standing Committee. The Review notes that the Forum can already delegate bodies of work to the Standing Committee to support the Forum in fulfilling its functions (see Finding 22). However, recognition of the Standing Committee may enable it to perform additional duties to support the efficiency of the Scheme, such as agreeing consequential amendments to the Act, or endorsing the outcomes of periodic reviews of the Regulations. A Standing Committee work program and delegated duties could be determined 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.

Finding 13 – The Review heard that there is a need for increased flexibility within the Scheme to enable it to appropriately respond to changes in scientific understanding and understandings of risk. Options to increase this flexibility that could be investigated further (subject to administrative and legal considerations) could include:

- enabling the Gene Technology Regulator to make determinations or orders on the applicability of regulation to any technological developments. These determinations (or orders) could be recognised by the Gene Technology Regulations 2001, until such times that they are included in legislation; and
- introducing elements of principles-based regulation to some parts of the Scheme, initially focussing on areas of the Scheme with a history of safe use.

Finding 14 – The Review heard that there may be scope to increase the agility of the Scheme, while maintaining appropriate oversight measures. This might include introducing mechanisms to enable certain activities of the Legislative and Governance Forum on Gene Technology to be driven by the Gene Technology Standing Committee.

These findings relate to Term of Reference 2.

FINDING 15

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 have identified that the key factors affecting market access and international trade of GMOs are:

- 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 has been 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 difficulty presents a particular hurdle for small scale enterprise and publicly funded research organisations. Stakeholders proposed that the harmonisation of 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.⁶⁵ These thresholds for canola seed and grain were adopted in 2005 by Australian states and territories.⁶⁶ These thresholds are also agreed nationally by the Australian seed and grain industries.

Stakeholders also identified the related issue of countries maintaining a zero tolerance⁶⁷ for LLP of GMOs unapproved in the importing country (sometimes occurring because of asynchronous approval timetables).⁶⁸

65 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 March 20, 2018, from www.agriculture.gov.au/SiteCollectionDocuments/ag-food/biotech/for_printing_gm_sampling_and_testing.pdf

66 Excepting Queensland, Tasmania and the Northern Territory.

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

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

The Review understands 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 notes ongoing Australian government involvement, including the Gene Technology Regulator on regulatory matters, in this area.⁶⁹ LLP is discussed further in Findings 22 and 23.

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, included GM, non-GM or organic. They maintain 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)⁷⁰, 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 practise could deliver co-existence. The Review notes 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 Organisation (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.

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.

Further, 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.

69 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 March 20, 2018, from 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 March 20, 2018, from 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 March 20, 2018, from www.fao.org/input/download/standards/10021/CXG_045e.pdf.

70 Productivity Commission. (2016). *Regulation of Agriculture*. Retrieved February 19, 2018, available from <https://www.pc.gov.au/inquiries/completed/agriculture/report>

The Review recognises the need for appropriate levels of well-targeted regulation for these stakeholders that does not impose unnecessary burdens. Refer to Finding 9 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 notes 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 is determined as part of usual governmental processes.

World Trade Organisation 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 Measures⁷¹ and the Technical Barriers to Trade agreement.⁷² 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.

Finding 15 – The Review heard that the Australian government has an important role in coordinating internationally on matters relevant to market access and international trade. There is benefit in the Australian government, including the Gene Technology Regulator on regulatory matters, continuing to engage with appropriate international fora in this area and ensuring that any relevant international obligations continue to be met.

This finding relates to Term of Reference 2.

71 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 March 20, 2018, available from www.wto.org/english/tratop_e/sps_e/sps_e.htm.

72 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 March 20, 2018, available from 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 work with the existing regulatory schemes to address the rapidly developing area of gene technology.

The Scheme comprises Commonwealth, state and territory legislation to allow for the constitutional reach of each level of government in regulating genetically modified organisms (GMOs). The Scheme operates together with other jurisdictional regulatory schemes relevant to GMOs and genetically modified (GM) products, covering food, human therapeutic goods, pesticides and veterinary medicines, industrial chemicals, biosecurity and protection of the environment.

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* (the Act) and corresponding state and territory laws.

This section of the *Preliminary Report* explores 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 are also considered. These include both the mechanisms for applying **corresponding legislation** across the country, and state and territory **moratoria legislation**.

Currently, 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. Whether this remains appropriate is discussed within this section of the *Preliminary Report*.

Considering 'benefit' in another sense (separate to a factor of regulatory decision making), this section of the *Preliminary Report* also discusses whether the current Scheme imposes any **unnecessary regulatory burdens** which 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 has 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) and the Australian Pesticides and Veterinary Medicines Authority (APVMA). This section of the *Preliminary Report* looks at the **interface between the Office of the Gene Technology Regulator (OGTR) and these other regulators**.

Finally, the **level of funding** required for the sustainable operation of the Scheme and the most appropriate **source of funding** are discussed.

Please note: any regulatory changes arising from these findings would be subject to administrative, legal and financial considerations.

FINDING 16

Credibility, integrity and legitimacy of the Scheme

As described in the Consultation Paper, there is a high level of stakeholder support for the Scheme. It is seen by the majority of stakeholders as well-designed and 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.

The Third Review of the Scheme (the Review) recognises, however, that some stakeholders do 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 a ministerial forum – the Legislative and Governance Forum on Gene Technology (the Forum). The Forum is comprised 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 28 March 2018

| Jurisdiction | Minister | Portfolio |
|--------------|----------------------------------|---|
| Cth | Senator the Hon Bridget McKenzie | Minister for Rural Health, Sport and Regional Communications |
| QLD | The Hon Leeanne Enoch MP | Minister 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 | Department of Primary Industries and Water and Minister for Racing |
| NT | The Hon Ken Vowles | Minister for Primary Industry and Resources, and Arafura Games |
| SA | The Hon Stephen Wade MLC | Minister for Health and Wellbeing |
| WA | The Hon Alannah MacTiernan MP | Minister for Regional Development, Agriculture and Food, and Minister assisting the Minister for State Development, Jobs and Trade. |

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*,⁷³ the *Privacy Act 1988*,⁷⁴ the *Freedom of Information Act 1982*,⁷⁵ the *Work Health and Safety Act 2011*⁷⁶ and the *Public Service Act 1999*.⁷⁷

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 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 1 – National Gene Technology Regulatory Scheme governance, advisory and consultation structures.

⁷³ *Public Governance, Performance and Accountability Act 2013 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/C2017C00269

⁷⁴ *Privacy Act 1988 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/C2018C00034

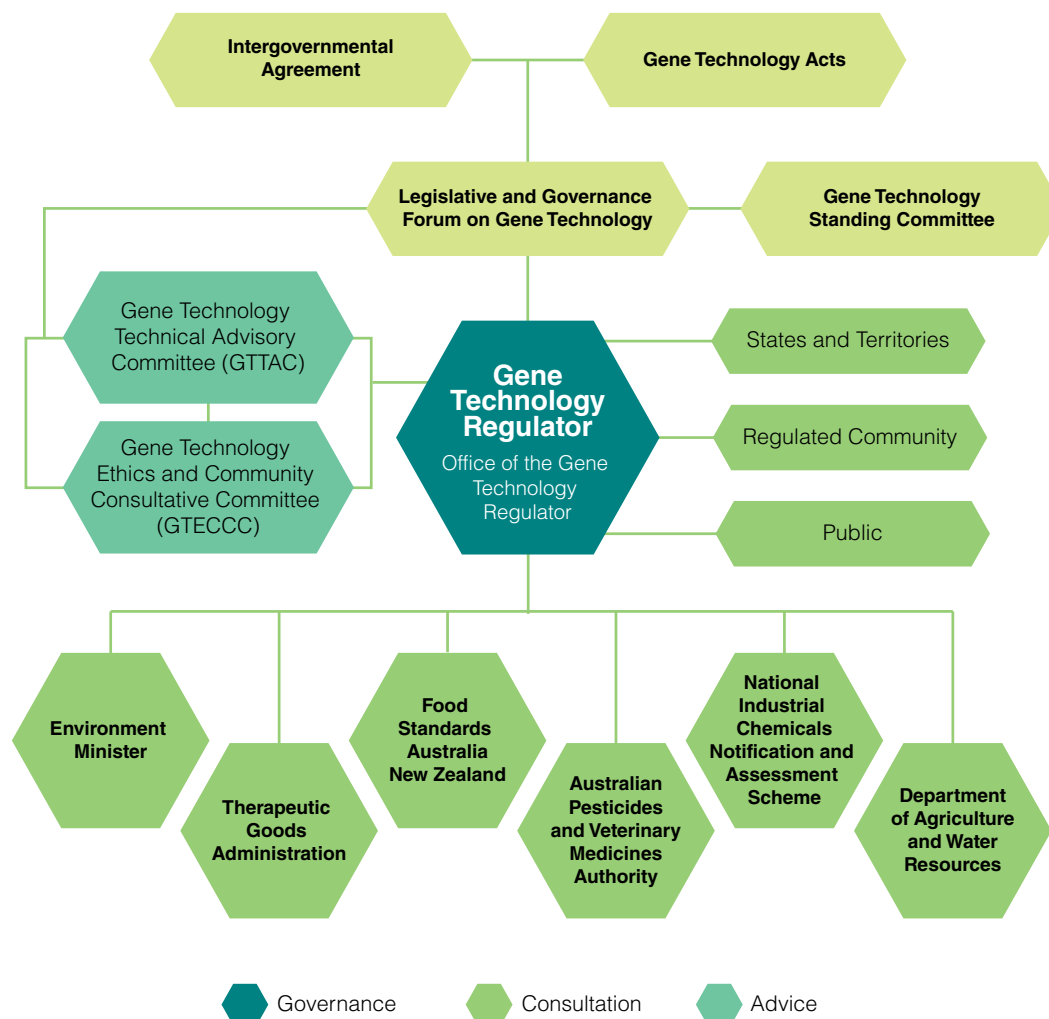
⁷⁵ *Freedom of Information Act 1982 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/C2018C00016

⁷⁶ *Work Health and Safety Act 2011 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/C2017C00305

⁷⁷ *Public Service Act 1999 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/C2017C00270

FIGURE 1

National Gene Technology Regulatory Scheme governance, advisory and consultation structures (source: OGTR)



Some stakeholders perceive that potential conflicts of interest applying to members on the advisory committees undermine the integrity of the Scheme and its advisory structures. However, the Gene Technology Regulations 2001 (the Regulations) do specify clear procedures, consistent with best practice governance, to deal with potential or real conflicts of interest. 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. If any conflicts are present, the member must not be present during discussions, or take part in any decisions about that matter. The Review believes these procedures appropriately manage any potential conflicts of interest, helping to ensure the integrity and credibility of the Scheme.

Further discussion on the transparency and accountability of the Scheme can be found in Finding 33.

Finding 16 – The Review found that the operation of the Scheme has shown to be credible, and that the Scheme operates with integrity and legitimacy as evidenced by:

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

This finding relates to Term of Reference 3.

FINDING 17

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 a 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.

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, it is important that they remain consistent. This is especially relevant when the Commonwealth Act is updated. Inconsistency could result in confusion and uncertainty for regulated organisations regarding which provisions apply. It could also create potential compliance issues for organisations and the Regulator, and potentially undermine risk management. Legislative inconsistency could also mean 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. This mirroring approach can 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.

Finding 17 – 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.

This finding relates to Terms of Reference 2 and 3.

FINDINGS 18 AND 19

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 and territory, and Commonwealth laws from arising. The Principle gave effect to the agreement 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 rescinded their legislation, or have retained moratoria legislation, but with no active prohibitions in place which relate to Australia's commercially approved GMOs.

Some stakeholders have suggested 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. The Review notes that removal of this Principle would not necessarily have this effect if the states and territories were to maintain their current legislation. The Review notes 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.

The Review notes that the existence of moratoria legislation has been, and continues to be, a controversial issue.⁷⁸ Many stakeholders have expressed strong feelings about the (positive or negative) impact of moratoria, and these opposing views are summarised below.

Concern about the existence of moratoria legislation

Throughout the Review process, a large number of stakeholders expressed concern about the existence of jurisdictional moratoria legislation, including concerns that because of these pieces of legislation:

- Australia's regulatory burden is not commensurate with the risks posed by the products of biotechnology;
- the ability to deny access to the technology at the state level was seen to reduce the effectiveness of the Scheme;
- branding of non-GM can create confusion in the public, who may equate this 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 imposed; and
- there is investment uncertainty for applicants who are potentially unable to commercialise their products in key markets.

78 Productivity Commission. (2016). *Regulation of Agriculture*. Retrieved February 19, 2018, available from www.pc.gov.au/inquiries/completed/agriculture/report

These stakeholders have argued 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 crop-free 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, in the period 2005 to 2015, due to the state and territory moratoria on the commercial cultivation of GM canola.⁷⁹

These stakeholders also argue 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 there is little evidence to determine that South Australia has achieved a premium for its non-GM canola crop due to the moratorium on GM technology.⁸⁰ Examples were also presented showing that non-GM price premiums could be higher in jurisdictions without moratoria, than in jurisdictions with active moratoria legislation.

Some market data provided to the Review shows that non-GM canola in WA over the three years to January 2018 has delivered regular price premiums between 4% and 10% compared to GM canola, however daily canola prices can be volatile.⁸¹ Analysis of canola values in Victoria over the same period have shown regular premiums for non-GM canola between 5% and 10%.⁸² Stakeholders to the Review have 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.⁸³

The Review notes 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). Such certification schemes would operate independently of the Act.

Many of these arguments were also presented to the *Productivity Commission's Inquiry Report: Regulation of Australian Agriculture* (2017)⁸⁴ and the House of Representatives Standing Committee on Agriculture and Industry's *Smart Farming – Inquiry into Agricultural Innovation* report (2016)⁸⁵. Both inquiries identified removal of state and territory moratoria on genetically modified crops as a matter for government consideration.

79 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.

80 Whitelaw, A. (2017). *Controversial canola. Mecardo Expert Analysis*. Retrieved March 20, 2018, available from www.mecardo.com.au/commodities/analysis/controversial-canola.aspx

81 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%.

82 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%.

83 Government of Western Australia, Department of Primary Industries and Regional Development, *Genetically modified crops in Western Australia*. Retrieved March 20, 2018, available from www.agric.wa.gov.au/genetic-modification/genetically-modified-crops-western-australia

84 Productivity Commission. (2016). *Regulation of Agriculture*. Retrieved February 19, 2018, available from <https://www.pc.gov.au/inquiries/completed/agriculture/report>

85 House of Representatives Standing Committee on Agriculture and Industry. (2016). *Smart farming – inquiry into Agricultural innovation*. Retrieved March 21, 2018, available from www.aph.gov.au/Parliamentary_Business/Committees/House/Agriculture_and_Industry/Agricultural_innovation/Report

Support for moratoria legislation

The existence of moratoria legislation is a highly contested topic, with some stakeholders (including some jurisdictions) arguing strongly 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 genuinely free from genetic modification;
- protects the 'clean and green' attribute of some jurisdictions' brand, without which both markets and individual businesses would be damaged 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 the benefits of brand differentiation;
- addresses concerns about the future commercialisation of GM wheat in jurisdictions with moratoria legislation should it be approved by the OGTR in the future (some stakeholders argued that there are clear market signals from international and domestic customers that strong reservations exist concerning GM wheat);⁸⁶ and
- enables state and territory Parliaments to consider social, cultural, ethical and other non-scientific matters, including public values and sentiment, before any licensed GMO is released.

These stakeholders have also argued that the economic benefits of retaining moratoria legislation are likely to be substantial and to exceed the costs of extending current moratoria.⁸⁷ These arguments focussed on broader economic benefits associated with the ability to use 'non-GM' branding, which can be applied by all producers in that state or territory, rather than focussing solely on cotton and canola (which are the only commercially grown GM crops in Australia).

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

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 surrounding 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 recognises that, ultimately, whether or not to retain this legislation is a matter for states and territories to determine. The Review suggests that any existing and ongoing work undertaken by states and territories to review their moratoria legislation could be combined and made publically available to consolidate an evidence base to support further consideration being given to this matter by the relevant jurisdictions.

⁸⁶ WA Legislative Council (2006). *Hansard*, p. 2453, Wednesday, 10 May 2006.

⁸⁷ Government of Tasmania, *Genetically Modified Organisms Control Act Amendment Bill 2014: Decision Regulatory Impact Statement Summary*. Retrieved March 20, 2018, from www.dpipwe.tas.gov.au/Documents/Decision%20Regulatory%20Impact%20Statement%20-%20GMO%20Amendment%20Act%202014%20Summary.pdf

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 have 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, the introduction of compensation schemes for economic loss is a matter for jurisdictional governments to consider (being outside of human health and safety and the environmental considerations). The Review notes 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.⁸⁸

The recent update to the *Guideline for responding to contamination by prohibited substances or materials in the organic supply chain*⁸⁹ is also of interest to the Review. This Guideline is used in conjunction with the *Export Control (Organic Produce Certification) Orders*⁹⁰, 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 negligent, accidental or intentional introduction or use of prohibited substances (including GMOs) into an organic or biodynamic production system.

The Review additionally notes 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 Findings 13 and 14.

Finding 18 – The Review found that there are conflicting views among stakeholders regarding the advantages and disadvantages of state and territory moratoria legislation. Further, there is a lack of conclusive evidence on this matter, particularly on the economic effect of moratoria legislation, as economic calculations are context-specific and complex (based on non-stable factors).

Finding 19 – The Review 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.

These findings relate to Term of Reference 2.

⁸⁸ 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 March 21, 2018, available 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)

⁸⁹ 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 March 20, 2018, from www.agriculture.gov.au/export/controlled-goods/organic-bio-dynamic/organic-notice/2018/2018-01

⁹⁰ *Export Control (Organic Produce Certification) Orders (Cth)* (Austl.). Available at www.legislation.gov.au/Details/F2005C00434

FINDING 20

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

The regulation of gene technology in Australia currently focuses on the consideration of 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 does not consider any potential benefits which may flow from that GMO.

Some stakeholders have proposed that, in making decisions, the Regulator should have the ability to take into account benefits such as potential health, environmental and economic benefits of the GMO. A theoretical example is 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' differ, and there are some stakeholders who contend 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 Findings 22 and 23).

Finding 20 – The Review found that consideration of benefits (e.g. potential economic, environmental and health benefits) should not be introduced at this time as it could risk the effective operation of the Scheme. Consideration of benefits may be an area of ongoing focus in future reviews.

This finding relates to Term of Reference 3.

FINDING 21

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

As described in the Consultation Paper and expressed in stakeholder feedback, there is a concern that 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 is 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 focussed on higher risk activity will allow it to better utilise available resources and lower risk activity can proceed with appropriate regulatory compliance (see Finding 9). Some stakeholders have 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 include:

- Concerns that pharmaceutical clinical trials may not be carried out in Australia due to timeframes and regulatory requirements of the current regulatory approval system. As a result, any new products 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 regulatory requirements related to facility certification and approval processes to be streamlined 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 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 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.

Finding 21 – 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 Findings 9 and 10).

This finding relates to Terms of Reference 1 and 2.

FINDINGS 22 AND 23

Clarity on policy considerations of the Scheme

Throughout the Review process, a number of topics have been raised by stakeholders that may benefit from improved regulatory and policy clarity. Policy clarity provides certainty to industry and the community, and greater transparency about decision making. As described in the Consultation Paper, this in turn assists with choice, including with respect to research and development investments, regulatory compliance actions, marketing strategies, and spending.

One mechanism to provide policy clarity would be for the Forum to exercise their authority, as empowered under 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.

For operational matters, policy clarity could be achieved through the development or updating of operational policies by the OGTR. Some stakeholders also suggested a continued engagement of the various regulators (including the OGTR, APVMA and FSANZ) forum should be maintained to progress matters relevant to multiple agencies.⁹¹

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 pest control agents) – see Finding 6;
- guidance on regulation for releasing gene drives into the environment – see Finding 7;
- consideration of benefits for some gene technology applications (for example, GM pest control agents) – see Finding 20;
- investigation of the regulation of non-transgenic applications of synthetic biology under the Scheme; and
- establishing Codes of Conduct for DIY-biologists – see Finding 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 for considering 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.

Work to provide policy clarity in these areas could be progressed by the Forum through the development of a forward work program, leveraging the Standing Committee or other appropriate organisations as required. Other areas identified by the Review as warranting additional consideration could also be incorporated into such a work plan.

Some stakeholders also suggested 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.

⁹¹ 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.

The Review notes, however, that the OGTR has an existing Unintended Presence Strategy⁹² and that Australia was one of 13 countries to endorse an International Statement on Low Level Presence⁹³ 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 Plant Houses; and
- Inadvertent dealings licences, which can be granted to enable disposal of an unapproved GMO.

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

Finding 22 – The Review found that there is an opportunity for the Legislative and Governance Forum on Gene Technology (the Forum) to lead a forward work program to consider a range of matters. 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 a forward work program, the Forum might consider opportunities to leverage the role of the Gene Technology Standing Committee.

Finding 23 – The Review 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.

These findings relate to Term of Reference 2.

92 Office of the Gene Technology Regulator, *Unintended Presence Strategy (Unapproved GMOs in seed for sowing)*. Retrieved March 20, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mon-unintended-1

93 Department of Agriculture and Water Resources, *International Statement on Low Level Presence*. Retrieved March 20, 2018, from www.agriculture.gov.au/ag-farm-food/biotechnology/international-statement-low-level-presence

FINDINGS 24, 25 AND 26

Coordination with other regulators

The Scheme was developed to work alongside the regulatory schemes for human food, human therapeutics, veterinary medicines, agricultural chemicals and industrial chemicals, with the OGTR managing risks associated with live and viable GMOs. However, it is acknowledged that the numerous intersecting pieces of legislation in this space 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 concerns from stakeholders 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 have 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 with 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 notes 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 Finding 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 areas 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 have 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 above identified potential solutions, the Review notes 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 notes that some areas of perceived duplication may serve a specific purpose. There is therefore a justifiable risk basis for continuing. However, the Review also recognises 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 issues of delays and inconsistency. Instead, OGTR is seen as requiring more resources. It was also noted that each regulator has their own area of expertise, which could be lost through the creation of a 'super agency'.

The Review notes 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 have also raised concerns regarding lack of harmonisation between OGTR and Department of Agriculture and Water Resources (DAWR) facility certification requirements.⁹⁴ This is discussed further in Finding 10.

Stakeholders also raised concerns about 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 FSANZ is currently reviewing 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').⁹⁵

⁹⁴ *Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016* made under subsection 174(1) of the *Biosecurity Act 2015* (Cth) (Austl.). Available at www.legislation.gov.au/Details/F2018C00130

⁹⁵ Food Standards Australia New Zealand, *Food derived using new breeding techniques – review*. Retrieved March 20, 2018, available from www.foodstandards.gov.au/consumer/gmfood/Pages/Review-of-new-breeding-technologies-.aspx

Mechanisms available in other schemes that could be adopted

The Review has 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 GM 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 Regulator and state and territory environmental protection agencies. It has been noted that the sharing of data on downstream environmental and health effects GMOs may inform the Regulator's future decision making, or post-market review actions.

Finding 24 – The Review heard that there is lack of clarity for some stakeholders regarding the roles of the Office of the Gene Technology Regulator and genetically modified product regulators, which might be addressed through the development of a dedicated gene technology regulation web portal.

Finding 25 – The Review heard that 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 legislative changes.

Finding 26 – The Review heard that 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.

These findings relate to Term of Reference 2.

FINDINGS 27 AND 28

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 **source of 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.

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

Some stakeholders have 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 have also highlighted the need for appropriate funding to address new gene technology applications, for example gene drive licencing, 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 have provided input on alternative funding options, primarily the introduction of a cost recovery funding model. Stakeholders have 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 would 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 notes that, in addition to the 2005–06 and 2011 reviews of the Scheme, which considered the introduction of a cost recovery mechanism among other matters, three focussed cost recovery reviews have also been undertaken (2000, 2002 and 2004). Previous reviews did not recommend the introduction of a cost recovery mechanism. The Review notes 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.

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 has 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 arrangement 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 this additional consideration is the Australian Government Charging Framework (the Charging Framework)⁹⁶, which has been introduced 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 also notes that other findings 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 Findings 9 and 10). It is therefore suggested that it would be prudent for further consideration on the most appropriate funding arrangements for the Scheme be completed following the progression of other relevant findings.

Finding 27 – The Review heard that full cost recovery may have detrimental effects on 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 ongoing funding mechanisms to support the ongoing operation of the Scheme.

Finding 28 – The Review 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.

These findings relate to Term of Reference 4.

⁹⁶ Australian Government, Department of Finance, *Australian Government Charging Framework*. Retrieved March 20, 2018, available from 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 and its applications and end products.

This chapter explores **communication with the public** (including which is the most appropriate body to undertake such communication activities).

Despite current regulatory arrangements, there remain ongoing concerns within some sections 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.

Please note: any regulatory changes arising from these findings would be subject to administrative, legal and financial considerations.

FINDINGS 29 AND 30

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.

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'.⁹⁷

The Third Review of the Scheme (the 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 topics are to extend to exploring benefits of gene technology. There is a recognised advantage in this remit not being

97 Productivity Commission. (2016). *Regulation of Agriculture*, p. 40. Retrieved February 19, 2018, available from www.pc.gov.au/inquiries/completed/agriculture/report

expanded so as not to jeopardise existing trust in the Regulator. 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^{98,99} have investigated the level of awareness and support for gene technologies in Australia. There is merit in building upon this market research to determine what information the public desire to know about gene technology and its applications in our society. Such research could also examine which agencies the public consider authoritative and trustworthy to collate and disseminate that 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 have highlighted the need for designated funding to develop and deliver such a campaign.

Finding 29 – The Review heard that public understanding and confidence in the Scheme may be aided by additional communication mechanisms (building on existing bodies of work). There may be benefit in additional work to determine the most appropriate body to lead communication activities. Any additional communication activities would need to be appropriately funded.

Finding 30 – The Review heard that it is appropriate for the Gene Technology Regulator to continue to lead communication activities on topics related to the assessment of risk associated with gene technology.

These findings relate to Term of Reference 2.

-
- 98 Instinct and Reason. (2017). *Community attitudes to gene technology*. Retrieved March 20, 2018, from [www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/327437B632158967CA257D70008360B1/\\$File/FINAL%20Report%20-%202017%20Community%20Attitudes%20to%20Gene%20Technology%20261017.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/327437B632158967CA257D70008360B1/$File/FINAL%20Report%20-%202017%20Community%20Attitudes%20to%20Gene%20Technology%20261017.pdf)
- 99 Instinct and Reason (2015). *Community attitudes to gene technology*. Retrieved March 20, 2018, from [www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/327437B632158967CA257D70008360B1/\\$File/Community%20Attitudes%20to%20gene%20technology%20Final%20Repor%202015.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/327437B632158967CA257D70008360B1/$File/Community%20Attitudes%20to%20gene%20technology%20Final%20Repor%202015.pdf)

FINDINGS 31 AND 32

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 Finding 33.

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

Some stakeholders have described a lack of public confidence in the long-term safety of GMOs in the environment and in the human diet, due to what they consider to be a lack of research in these areas. 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.

The Review notes however, that evidence concerning the safety of particular GMOs has been considered by the Regulator and forms the basis of risk assessment and risk management activities. It is also noted that Food Standards Australia New Zealand (FSANZ) also publishes responses to studies cited as evidence of adverse effects from GM foods.¹⁰⁰ However, despite the various mechanisms currently in place, the concerns raised by these stakeholders have persisted, with calls to broaden the scope of research considered by the Scheme.

Concerns about information and knowledge gaps

Some stakeholders also expressed concerns 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 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.

100 Food Standards Australia New Zealand, *Response to studies cited as evidence of adverse effects of GM food*, Retrieved February 19, 2018, available from www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx

Some stakeholders also called for GM foods to undergo additional (animal and human) testing, and for mandatory labelling requirements to apply. Under the current Scheme however, the Regulator has no authority to impose food labelling requirements. Mandatory labelling requirements for GM food 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, and 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 Finding 33.

Concerns about the safety of herbicides and pesticide 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 2013¹⁰¹ (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).

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.¹⁰²

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

101 Office of the Gene Technology Regulator. (2013). *Risk Management Framework*. Retrieved March 19, 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)

102 Office of the Gene Technology Regulator, *Allegations of non-compliance*. Retrieved March 20, 2018, from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/non-compliance-1

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.

Finding 31 – The Review found that despite current regulatory arrangements, there remain ongoing concerns within some sections of the community about the safety of genetically modified organisms, and in particular the safety of genetically modified foods.

Finding 32 –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.

These findings relate to Term of Reference 2.

FINDING 33

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 is 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 the labelling of GM foods was a primary object of concern. The Review notes that food labelling is not within the remit of the Regulator, and that the Australia New Zealand Food Standards Code (Standard 1.5.2)¹⁰³ is currently being reviewed. However, food labelling requirements are outside the scope of this Review. While it is not the remit of this Review to comment on food labelling – this is properly the remit of FSANZ – the Review does note there are only two commercially available crops grown in Australia: GM Canola, and GM cotton.¹⁰⁴

103 *Australia New Zealand Food Standards Code – Standard 1.5.2 – Food produced using gene technology (Cth)* (Austli.). Available at <http://www.foodstandards.gov.au/code/Documents/1.5.2%20GM%20foods%20v157.pdf>. This standard 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. In other words, when the refining process removes all of the substance that would make a plant a GMO in the first place, no label is required. This would be the case for, for example, 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.

104 The Review notes the 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. See Office of the Gene Technology Regulator, *Other reports*. Retrieved March 20, 2018, available from 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 ‘How the public can make submissions to the Regulator’ information page,¹⁰⁵ which outlines how the public can get involved in the assessment process for release of genetically modified organisms;
- GMO Record (described below);¹⁰⁶
- Field Trial Interactive Mapping;¹⁰⁷
- Operational policy publications;¹⁰⁸
- Publically available scientific documents (i.e. science strategy, risk analysis framework, biology documents, and fact sheets);¹⁰⁹
- Guidelines for working with GMOs;¹¹⁰
- Monitoring and Compliance protocols;¹¹¹ and
- Annual Reports tabled in Parliament.¹¹²

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,¹¹³ full RARMPs,¹¹⁴ and post-release licence conditions.¹¹⁵

In Australia, all Dealings involving Intentional Releases into the environment (DIR) involve a full public consultation process,¹¹⁶ as well as consultation with all state and territory governments, other prescribed Commonwealth entities,¹¹⁷ and the Scheme’s technical advisory committee prior to each DIR licencing decision.

105 Office of the Gene Technology Regulator, *How the Public can make submissions to the Regulator*. Retrieved March 20, 2018, from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/fact-public-htm

106 Office of the Gene Technology Regulator, *Record of GMO Dealings*. Retrieved March 20, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmorec-index-1

107 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 March 20, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/map

108 Office of the Gene Technology Regulator, *Operational Policies*. Retrieved March 20, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/policies-1

109 See Office of the Gene Technology Regulator’s website, Retrieved March 20, 2018, available from www.ogtr.gov.au

110 Office of the Gene Technology Regulator, *Accreditation process*. Retrieved March 20, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/accreditation-process

111 Office of the Gene Technology Regulator, *Monitoring and Compliance*. Retrieved March 20, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mc-index-1

112 Office of the Gene Technology Regulator, *Annual and Quarterly Reports under the Gene Technology Act 2000*. Retrieved March 20, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1

113 Notification of licence decisions outlines the Regulator’s decision to issue a licence following the assessment of an application. The transparency of the licence application process is considered by the Review to be 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.

114 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.

115 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 this licence, as well as reporting requirements.

116 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 this application. It explains how the public can access or obtain the consultation documents and the due date for submissions.

117 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 that 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 publically available and catering to different public information needs (communicating effectively at a broader level, as well as having more detailed information publically 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 (see Findings 29 and 30 for further discussion on communication with the public).

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. This is a public document and, for a minimum period of 30 days, any interested party has the opportunity to provide comment on the RARMP. 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.

Finding 33 – 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 publically available, and through increased communication with the public (see Findings 29 and 30).

This finding relates to Term of Reference 3.

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



CHAPTER TWO

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

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 2 – Overview of the Gene Technology Landscape in Australia.

FIGURE 2

Overview of the Gene Technology Landscape in Australia

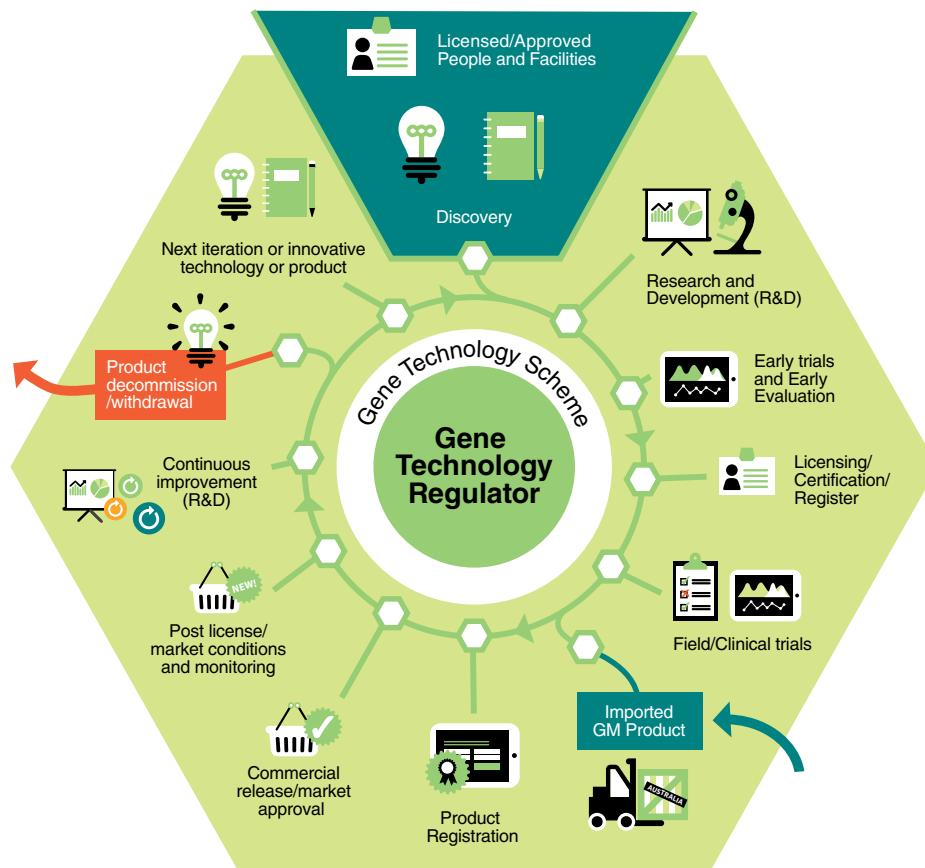
The activities, influences and controls that gene technology encounters in Australia are dependent on the technology used, the organism or the product.

Influences:

- environment
- research
- health
- industry
- transport
- trade
- science
- Intellectual property

Controls:

- biosecurity
- food
- medicine
- consumers
- economy
- government
- international agreements
- 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
- 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 Scheme operates in conjunction with other Australian regulatory schemes relevant to GMOs and GM products. These include agencies regulating:

- food (Food Safety 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)).

This relationship is represented in Figure 4 – Gene Technology Scheme interface with other Commonwealth regulatory schemes on [page 76](#).

The *Gene Technology Act 2000* (the Act)¹¹⁸ is the primary piece of legislation applying to gene technology. The Act and the *Gene Technology Regulations 2001* (the Regulations),¹¹⁹ 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’.¹²⁰ 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 excludes certain organisms from the definition so that organisms and techniques with a long history of safe use are not unnecessarily regulated.

118 *Gene Technology Act 2000 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/C2016C00792

119 *Gene Technology Regulations 2001 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/F2016C00615

120 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 Office of the Gene Technology Regulator (OGTR) regulates the research and development, field trial and commercialisation phases of a GM crop. When a crop becomes a commercialised food product then FSANZ regulates this aspect/segment of the lifecycle.

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),¹²¹ 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.

¹²¹ Department of Health, *The Gene Technology Agreement*. Retrieved March 21, 2018, available from www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-agreement

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 3 – National Gene Technology Regulatory Scheme governance, advisory and consultation structures:

FIGURE 3

National Gene Technology Regulatory Scheme governance, advisory and consultation structures¹²²



¹²² Sourced from Office of the Gene Technology Regulator, *Governance Arrangements for the Gene Technology Regulator*. Retrieved March 20, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/governance-1

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.¹²³ 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), which comprises senior officials (supporting their responsible Forum Minister) from all jurisdictions. Members provide their jurisdiction's views, as a whole, on the matters considered by the committee.

The Standing Committee co-ordinates 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.

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).

¹²³ Department of Health, *Legislative and Governance Forum on Gene Technology*. Retrieved March 21, 2018, available from www.health.gov.au/internet/main/publishing.nsf/Content/gene-gtmc.htm

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.

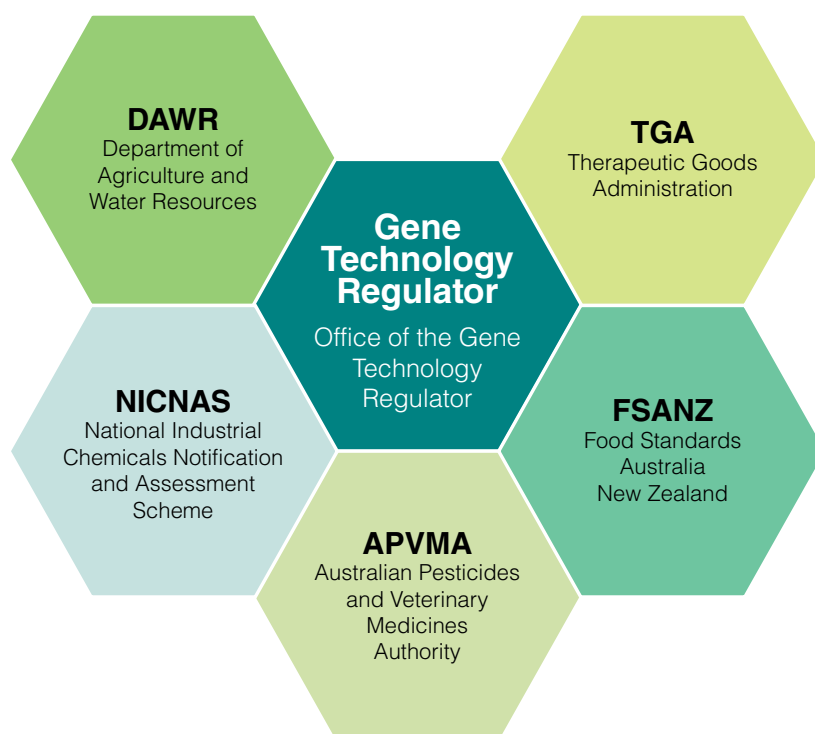
The GTECCC comprises members appointed by the Commonwealth Minister responsible for gene technology, following the same consultation process as for the appointment of GTTAC members. Members are appointed based on their skills and experience in relevant fields including community consultation, risk communication, 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 4 – Gene Technology Scheme interface with other Commonwealth regulatory schemes.

FIGURE 4

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 Principles¹²⁴ 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’.*¹²⁵

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.¹²⁶

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 March 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.

¹²⁴ Policy Principles are legislative instruments

¹²⁵ See section 21(1)(aa) of the *Gene Technology Act 2000 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/C2016C00792

¹²⁶ ‘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 Act¹²⁷ establishes the statutory office holder,¹²⁸ 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 Act¹²⁹ 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.¹³⁰ 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. This funding has not increased in over ten years.¹³¹

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.¹³² The Act requires that dealings with GMOs are authorised as:

- an exempt dealing;
- a notifiable low risk dealing (NLRD);
- a licenced dealing;
- a dealing included on the GMO Register; or
- specified in an emergency dealing determination.

127 Section 26 of the *Gene Technology Act 2000 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/C2016C00792

128 A statutory office holder is an individual appointed to a position established through legislation for a public purpose.

129 Section 27 of the *Gene Technology Act 2000 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/C2016C00792

130 Office of the Gene Technology Regulator, *Operations of the Gene Technology Regulator Annual Report 2016–17*. Retrieved March 21, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1

131 Department of Health, *Annual Reports*. Retrieved March 21, 2018, available from www.health.gov.au/internet/main/publishing.nsf/Content/Annual+Reports-3

132 Section 31 of the *Gene Technology Act 2000 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/C2016C00792

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.

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.¹³³ 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.¹³⁴

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.¹³⁵

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.

133 Office of the Gene Technology Regulator, *Application to certify facilities*. Retrieved March 21, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/certifications-1

134 Office of the Gene Technology Regulator, *Accreditation process*. Retrieved March 21, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/accreditation-process

135 Office of the Gene Technology Regulator, *Monitoring and Compliance*. Retrieved March 21, 2018, available from 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”.¹³⁶ 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.¹³⁷ 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.¹³⁸

Agricultural applications

The current commercially released GM crops in Australia, cotton and canola, 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.¹³⁹

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.¹⁴⁰

136 Section 27 of the *Gene Technology Act 2000 (Cth)* (Austl.). Available at www.legislation.gov.au/Details/C2016C00792

137 For more information on the Technical Review, see Office of the Gene Technology Regulator, *Technical Review of the Gene Technology Regulations 2001*. Retrieved March 21, 2018, from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewregulations-1

138 Office of the Gene Technology Regulator, *Table of authorisations for commercial therapeutic GMOs (subset list of licences involving Intentional Release)*. Retrieved March 21, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gm-1

139 Cotton Australia, Biotechnology and Cotton. Retrieved March 21, 2018, from 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 March 21, 2018, from www.grainproducerssa.com.au/uploads/media/Projects_and_Policy/FINAL_Analysis_of_price_premiums_under_the_SA_GM_moratorium.pdf

140 Office of the Gene Technology Regulator, *Table of applications and authorisations for Dealings involving Intentional Release (DIR) into the environment*. Retrieved March 21, 2018, available from 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,¹⁴¹ 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.¹⁴² 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.¹⁴³ Although Australia has not ratified these protocols, we continue to participate in and contribute to relevant protocol activities.

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;¹⁴⁴
- the Codex Alimentarius;¹⁴⁵ and
- the Organisation for Economic Cooperation and Development (OECD) Working Party on Biotechnology, Nanotechnology and Converging Technologies.¹⁴⁶

These and other relevant agreements provide international guidelines and standards that are being considered in reviewing the regulation of gene technology in Australia.

141 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 March 20, 2018, available from www.cbd.int/convention/text/default.shtml

142 Convention on Biological Diversity, *Introduction*. Retrieved March 20, 2018, available from www.cbd.int/intro/default.shtml

143 The Cartagena Protocol seeks to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology. The Nagoya Protocol provides a framework for the fair and equitable sharing of benefits arising from the use of genetic resources. See Convention on Biological Diversity, *The Cartagena Protocol*. Retrieved March 20, 2018, available from www.bch.cbd.int/protocol/background/; Convention on Biological Diversity, *The Nagoya Protocol*. Retrieved March 20, 2018, available from www.cbd.int/abs/about/.

144 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 March 20, 2018, available from www.wto.org/english/tratop_e/sps_e/sps_e.htm

145 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 March 20, 2018, available from www.fao.org/fao-who-codexalimentarius/about-codex/en/

146 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 March 20, 2018, available from www.industry.gov.au/industry/IndustrySectors/nanotechnology/InternationalLinkages/Pages/OECD.aspx

Regulation of gene technology in other countries

When reviewing Australia's domestic regulation of gene technology, it is also important to be aware of how gene technology is regulated 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.

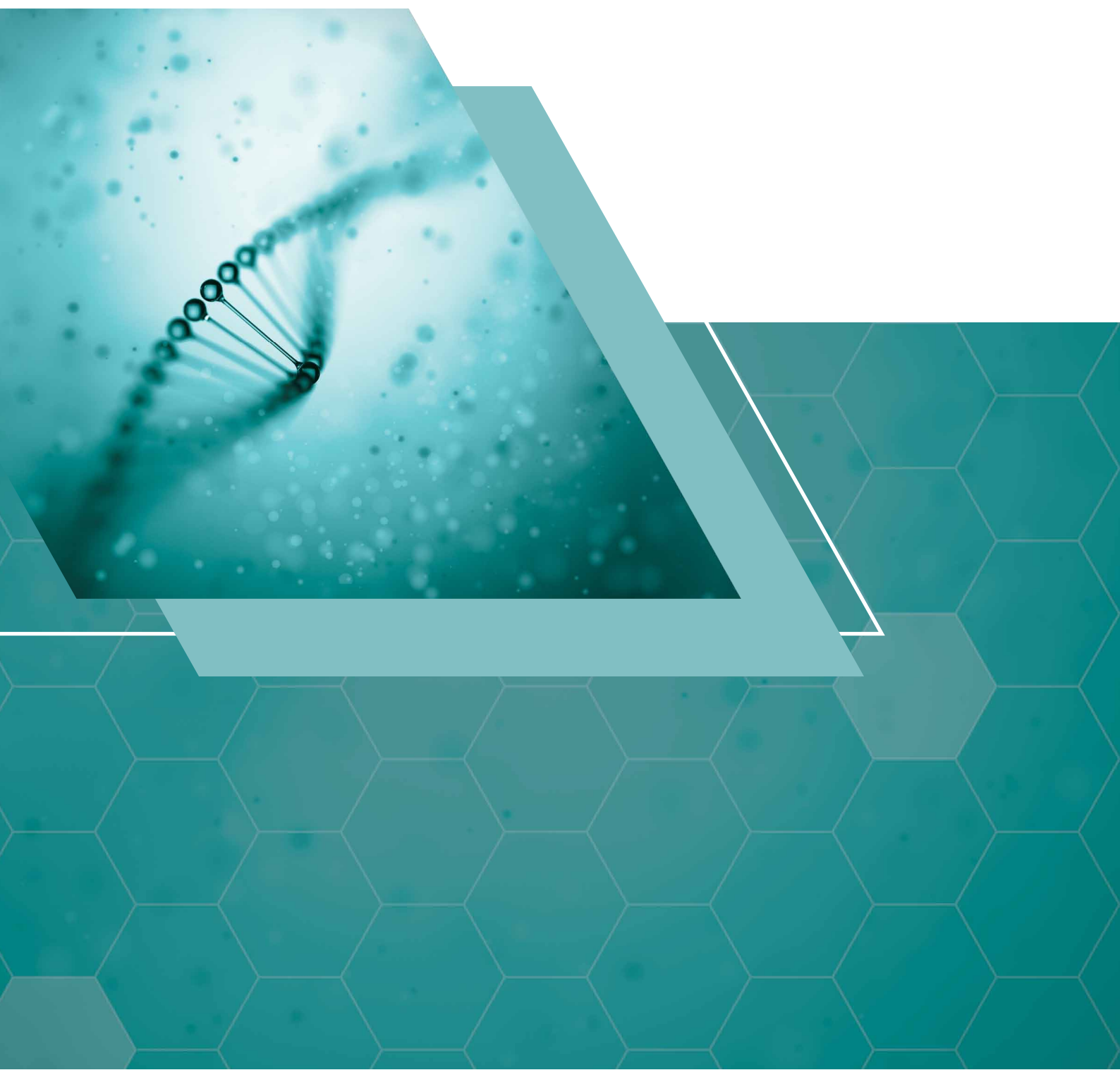
While Australia predominately regulates on the basis of the process used to create a GMO, in some other countries regulation is based more on the nature of the product itself, rather than the process through which it is produced. In some jurisdictions, for example the European Union (EU), regulation of GMOs is achieved on the basis of *'the technique used and the characteristics of the end product'*.¹⁴⁷

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.

¹⁴⁷ 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: 10.1042/ETLS20170019

The Third Review of the Gene Technology Scheme



CHAPTER THREE

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.¹⁴⁸ 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 expected to continue into the future. Thus, undertaking a review at this point is 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.

¹⁴⁸ Part 6 of the Agreement outlines the requirements for regular reviews of the policy settings of the Scheme.

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 will present the Review's draft recommendations for consideration by all Australian governments, represented through the Forum.

Given the technical nature of the Scheme, a panel of experts has been 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 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.¹⁴⁹

All Australian government's 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 has been organised in three key phases:

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

¹⁴⁹ 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 www.oecd.org/gov/regulatory-policy/governance-regulators.htm

The Review is taking place in a complex stakeholder environment, which includes the following stakeholder groups.

FIGURE 5
Map of Gene Technology Stakeholders



In addition, the Review acknowledges the significant concurrent activity in the gene technology related space (other reviews and policy debates), both nationally and internationally (see Other reviews and inquiries, below). 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.¹⁵⁰

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);¹⁵¹
- *Productivity Commission Inquiry Report: Regulation of Australian Agriculture*;¹⁵²
- *Smart Farming Report – Inquiry into Agricultural Innovation* (the Smart Farming Inquiry);¹⁵³ and
- 2006 and 2011 reviews of the National Gene Technology Scheme.^{154,155}

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

Building on the first two phases of consultation, the Review findings are being provided to stakeholders in this *Preliminary Report*, as part of Phase 3 of consultations.

Phase 3 consultation has been designed to present the findings of the Review to date and allow the opportunity for stakeholder comment. Phase 3 is open online from 28 March 2018 until 24 May 2018.

150 Department of Health. (2017). *Review of the National Gene Technology Regulatory Scheme - Background Paper*. Retrieved March 20, 2018, from www.consultations.health.gov.au/health-systems-policy-division/genetechreview2017/supporting_documents/2017%20Review%20of%20the%20Gene%20Technology%20Scheme%20%20Background%20Paper%20%20Web%20Accessible.pdf

151 Office of the Gene Technology Regulator, *Technical Review of the Gene Technology Regulations 2001*. Retrieved March 21, 2018, from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewregulations-1

152 Productivity Commission. (2016). *Regulation of Agriculture*. Retrieved February 19, 2018, available from <https://www.pc.gov.au/inquiries/completed/agriculture/report>

153 House of Representatives Standing Committee on Agriculture and Industry. (2016). *Smart farming – inquiry into Agricultural innovation*. Retrieved March 21, 2018, available from www.aph.gov.au/Parliamentary_Business/Committees/House/Agriculture_and_Industry/Agricultural_innovation/Report

154 Office of the Gene Technology Regulator, *Previous reviews of gene technology legislation*. Retrieved March 21, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/regs-process-1

155 Department of Health, *2011 Review of the Gene Technology Act 2000 (GT Act)*. Retrieved March 21, 2018, available from 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, which is still ongoing, also seeks 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 RNA¹⁵⁶ interference techniques and the regulation of contained dealings with gene drive GMOs.

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 focussed 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.

¹⁵⁶ See Glossary

Other research

While the Review findings are significantly informed by stakeholders' submissions, the Review has also taken note of relevant reports, reviews and academic publications. This has included:

- the Australian Council of Learned Academies (ACOLA) – *The Future of Precision Medicine in Australia*¹⁵⁷
- the Food Standards Australia New Zealand (FSANZ) – *Consultation paper: Food derived using new breeding techniques*¹⁵⁸
- the Opinion of the Advocate General, European Court of Justice – *The GMO Directive*¹⁵⁹

Other research and relevant publications used to inform the Review have been footnoted throughout the Report.

Market research

The Review has also commissioned a market research project to be undertaken prior to the finalisation of a Final Review Report to the Forum, to further explore public attitudes, knowledge and beliefs about GMOs. This project seeks to identify information requirements for the public and to test the appropriateness of regulatory approaches.

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.

157 Australian Council of Learned Academies. (2018). *The Future of Precision Medicine in Australia*. Retrieved March 21, 2018, available from www.acola.org.au/wp/pmed/

158 Food Standards Australia and New Zealand, *Food derived using new breeding techniques – review*. Retrieved March 21, 2018, from www.foodstandards.gov.au/consumer/gmfood/Pages/Review-of-new-breeding-technologies-.aspx

159 Court of Justice of the European Union (2018). *Advocate General's Opinion in Case C-528/16*. Retrieved March 21, 2018, from <https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-01/cp180004en.pdf>

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*¹⁶⁰ and the *Gene Technology Amendment Regulations 2007*,¹⁶¹ and
- *Gene Technology Amendment Act 2015*.¹⁶²

The Review recognises that some recommendations from previous reviews have not yet led to legislative amendments. Where previously raised issues are still concerns for stakeholders, these have been addressed by the current Review.

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.¹⁶³

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.¹⁶⁴ 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

Following Phase 3 consultation, stakeholder input will be used to inform translation of findings to draft recommendations. The Standing Committee will then provide these recommendations to the Forum for Ministerial consideration and endorsement.

This will inform an all Australian governments' formal response to the recommendations, which will in turn provide direction for the implementation of recommendations.

A number of the Review's findings highlight the need for further work to be undertaken, particularly in the context of relevant concurrent national and international debate and reviews. Any related work plan to address these issues would, where necessary, involve further consultation with stakeholders.

160 *Gene Technology Amendment Act 2007 (Cth)* (Austl.). [Federal Register of Legislation, *Gene Technology Amendment Act 2007*, available at: <https://www.legislation.gov.au/Details/C2007A00099>]

161 *Gene Technology Amendment Regulations 2007 (Cth)* (Austl.). [Federal Register of Legislation, *Gene Technology Amendment Regulations 2007*, available at: <https://www.legislation.gov.au/Details/F2007L01317>]

162 *Gene Technology Amendment Act 2015 (Cth)* (Austl.). [Federal Register of Legislation, *Gene Technology Amendment Act 2015*, available at: <https://www.legislation.gov.au/Details/C2015A00121>]

163 Australian government (2015), *Annual Red Tape Reduction Report*, 2015. Retrieved March 21, 2018, from www.pmc.gov.au/sites/default/files/publications/2015_annual_red_tape_reduction_report.pdf

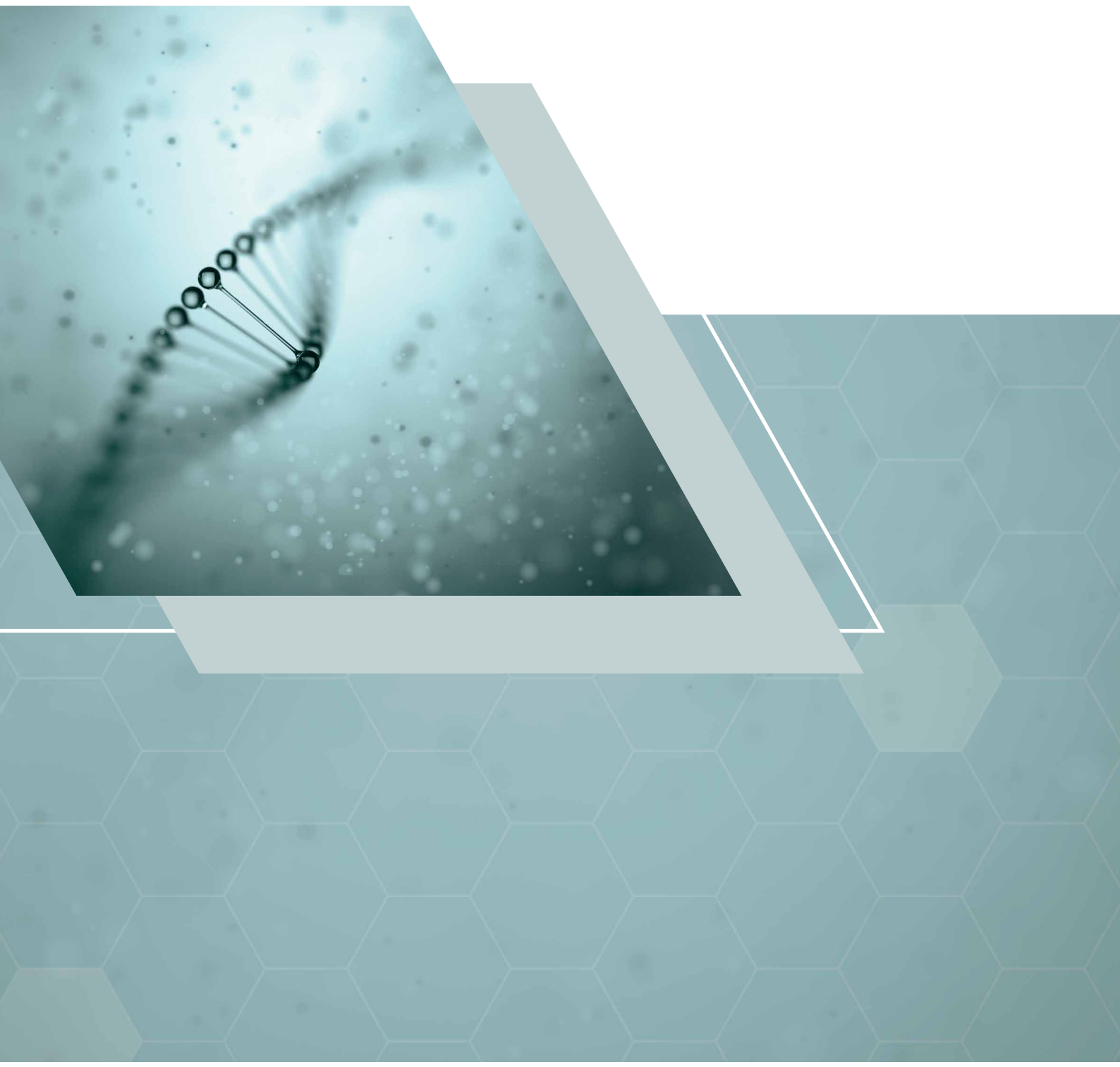
164 Australian government (2015), *Annual Red Tape Reduction Report*, 2015. Retrieved March 21, 2018, from www.pmc.gov.au/sites/default/files/publications/2015_annual_red_tape_reduction_report.pdf

Drafting of legislative amendments may be informed by public consultation, and could cover the matters included in recommendations, as well as minor administrative changes. These draft amendments 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 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.

Appendices



APPENDIX 1

Glossary

| Term | Definition |
|----------------------------------|--|
| ACOLA | Australian Council of Learned Academies |
| The Act; the Commonwealth Act | The <i>Gene Technology Act 2000</i> (Cth) |
| The Agreement | Gene Technology Agreement 2001 |
| APVMA | Australian Pesticides and Veterinary Medicines Authority |
| 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 |
| CBD | Convention on Biological Diversity |
| CCI | Confidential commercial information, as specified under section 185 of the Act |
| 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 <i>Consultation Paper: Overarching Issues for consideration under the Review</i> . |
| CRISPR | An acronym for 'clustered regularly-interspaced short palindromic repeats', but also used to refer to CRIPR associated site-directed nucleases (e.g. Cas9). A technique for gene (or genome) editing (deleting, replacing or editing DNA). See definition of gene (or genome) editing. |
| DAWR | Australian Government Department of Agriculture and Water Resources |
| 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. |
| DIR | Dealing involving Intentional Release. A license category within the Act for releases into the environment (i.e. for commercialized crops or field trials). |
| DIY biology | The use of gene technology by hobbyists outside the traditional research and industry structures, also referred to as 'biohacking'. |
| DNA | Deoxyribonucleic acid |
| DNIR | Dealings NOT involving an Intentional Release. A license category within the Act that does not involve the intentional release of a GMO into the environment. |
| EDD | Emergency Dealing Determination |
| 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 |
| FSANZ | Food Standards Australian New Zealand |
| 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. |

| Term | Definition |
|-------------------------------------|---|
| 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. |
| 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. |
| GM | genetically modified |
| GM product | See Genetically modified product |
| GMO | See Genetically modified organism |
| 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 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. |
| GT | Gene technology |
| GTECCC | Gene Technology Ethics and Community Consultative Committee |
| GTTAC | Gene Technology Technical Advisory Committee |
| Hybrid Trigger | A mechanism for regulation which utilises both process and product triggers, depending on what organism or product is being considered for regulation. |
| IBC | Institutional Biosafety Committees 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. |
| 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. |
| NHMRC | National Medical Health and Medical Research Council |
| NICNAS | National Industrial Chemicals Notification and Assessment Scheme |
| NLRD | Notifiable Low Risk Dealings 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. |
| OGTR | Office of the Gene Technology Regulator |
| Organism | Any biological entity that is viable; or capable of reproduction, or capable of transferring genetic material. |

| Term | Definition |
|---------------------------|---|
| PC | Physical containment. 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. |
| 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. |
| R&D | Research and development |
| RAF | Risk Analysis Framework. Guidance on the systemic application of legislation, policies, procedures and practices to risk analysis. |
| RARMP | Risk assessment and risk management plan. This forms the basis upon which the Regulator decides whether to issue a license or refuse a license, and what conditions to impose if a license is issued. |
| 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. |
| RNA | Ribonucleic acid |
| 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 |
| State moratorium | State legislation which puts restrictions on the dealings which can be undertaken with GMOs in that state, for marketing purposes. |
| Synthetic Biology | While not formally defined, synthetic biology has been interpreted in various ways, including as: <ul style="list-style-type: none"> 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; 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 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. |
| Technical Review | The Gene Technology Regulator's Technical Review of the Gene Technology Regulations 2001 (Cth). |
| TGA | Therapeutic Goods Administration |
| 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. |
| WTO | World Trade Organisation |
| ZFN | Zinc Finger Nuclease |

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 are currently reviewing how the Food Standards Code applies to food derived using new breeding techniques. Public consultation for the FSANZ review is underway. Interested stakeholders are encouraged to contribute to the current FSANZ consultation process.¹⁶⁵

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, is the remit of 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,¹⁶⁶ 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”.¹⁶⁷

165 See Food Standards Australia and New Zealand, Food derived using new breeding techniques – review. Retrieved March 21, 2018, from www.foodstandards.gov.au/consumer/gmfood/Pages/Review-of-new-breeding-technologies-.aspx

166 See Australian Pesticides and Veterinary Medicines Authority, *Glyphosate*. Retrieved March 21, 2018, from 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 March 21, 2018, from www.apvma.gov.au/sites/default/files/publication/20701-glyphosate-regulatory-position-report-final.pdf

167 See Australian Pesticides and Veterinary Medicines Authority, Regulation of Glyphosate in Australia. Retrieved March 21, 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.¹⁶⁸ They do not require a case-by-case risk assessment.

Dealings that are exempt from licencing (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.¹⁶⁹ NLRDs must be:

- assessed by an Institutional Biosafety Committee (IBC);¹⁷⁰
- 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*.¹⁷¹

Licences

The *Gene Technology Act 2000* (the Act) provides a licencing 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 2013.¹⁷² 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.

168 Office of the Gene Technology Regulator, What authorisation do you need? Retrieved March 21, 2018, from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/authorisation-for-gmos

169 Office of the Gene Technology Regulator, What are Notifiable Low Risk Dealings (NLRDs)?, Retrieved March 20, 2018, from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/nlrddclass-2

170 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.

171 Guidelines for the Transport, Storage and Disposal of GMOs (Cth) (Austl.). [Federal Register of Legislation, Guidelines for the transport, Storage and Disposal of GMOs, available at: <https://www.legislation.gov.au/Details/F2011L00992>]

172 Office of the Gene Technology Regulator. (2013). Risk Management Framework. Retrieved March 19, 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)

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, 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.¹⁷³

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.¹⁷⁴ 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.¹⁷⁵

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.¹⁷⁶

173 Office of the Gene Technology Regulator, What are Dealings involving an Intentional Release (DIR) of a GMO into the environment? Retrieved March 21, 2018, from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dirclass-2

174 Office of the Gene technology Regulator, What are Dealings NOT involving an Intentional Release (DNIR) of a GMO into the environment? Retrieved March 21, 2018, from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dnirclass-2

175 Office of the Gene Technology Regulator, What is an Inadvertent Dealing? Retrieved March 21, 2018, from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/inadvertentclass-2

176 Office of the Gene Technology Regulator, Licence Conditions. Retrieved March 21, 2018, from 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.¹⁷⁷ 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.¹⁷⁸

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.¹⁷⁹ 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.

177 Office of the Gene Technology Regulator, What are dealings included on the GMO Register. Retrieved March 21, 2018, from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmoregclass-2

178 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, available at: <https://www.legislation.gov.au/Details/F2006L03771>]

179 Office of the Gene Technology Regulator, What is an Emergency Dealing Determination? Retrieved March 21, 2018, available from 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.¹⁸⁰

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.¹⁸¹

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.

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.

180 Office of the Gene Technology Regulator, Monitoring Protocol. Retrieved March 21, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mc-protocols-1

181 Office of the Gene Technology Regulator, OGTR Compliance and Enforcement Policy. Retrieved March 21, 2018, available from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mc-protocols-1

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*.¹⁸²

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.¹⁸³

182 Office of the Gene Technology Regulator, Monitoring and Compliance Section Protocols. Retrieved March 21, 2018, from www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mc-protocols-1

183 Office of the Gene Technology Regulator. (2013). Risk Management Framework. Retrieved March 19, 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)

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 Tucharke | 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, characterized 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 lead 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 Tscharke

Professor David Tscharke 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 Tscharke 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 Tscharke 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 |
| Total | 109 |

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 |
| Total | 48 |

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.

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>

