Review of the National Gene Technology Scheme 2017

CONSULTATION PAPER:
Overarching Issues for consideration under the Review

November 2017

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PURPOSE OF THIS DOCUMENT

This paper is being released to promote discussion about the National Gene Technology Regulatory Scheme (the Scheme), as part of the 2017 Review of the Scheme (the Review). The paper provides background and contextual information. It also provides a high level summary of findings from the written submission process undertaken as part of the first phase of consultation. It does not provide analysis or put forward policy options. Its purpose is to assist further discussion in the next stage of the consultation process.

For further detail on the rationale supporting issues selected, please refer to individual submissions to Phase 1 consultation at http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-technology-review

HOW TO USE THIS DOCUMENT

This document is part of a suite of materials to support the wide consultation on the Scheme, and to help explore possible policy approaches. It should be read in conjunction with the companion pieces:

- Legislative and Governance Forum on Gene Technology communique announcing the third review of the National Gene Technology Regulatory Scheme;[1] and
- 2017 Review Background Paper.[2]

Chapter 3 of this document outlines the overarching themes to be explored in Phase 2 consultation. Focus issues are communicated throughout the chapter, followed by questions to explore these issues.

Responses to these questions, together with feedback from other Phase 2 consultation mechanisms such as workshops and webinars, will help inform the findings of the Review Report. A draft report is anticipated for stakeholder consideration in March 2018.

[1] available at http://www.health.gov.au/internet/main/publishing.nsf/Content/mr-yr17-gene-technology
[2] available at 2017 Review of the National Gene Technology Regulatory Scheme-Background Paper July 2017

PRINCIPLES UNDERPINNING THE REVIEW

In progressing the Review, there are a number of evolving 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.

CHAPTER ONE

BACKGROUND AND CONTEXT

OVERVIEW

The 2017 Review of the National Gene Technology Scheme (the Review) is being undertaken as a partnership between the Commonwealth and States and Territories under the Intergovernmental Gene Technology Agreement (GTA, 2001, reaffirmed in 2008[3]).

The aim of the current Review is to bring together research, investigations, findings, and viewpoints, to ensure that we have a regulatory scheme that continues to protect the health and safety of humans, and the environment, while also supporting appropriate flexibility and innovation.

In short, all Australian Government's recognise, through the agreed Terms of Reference for the Review (below), that we need to futureproof and modernise the Scheme so it is well positioned to continue to protect people and the environment, providing a sustainable approach to regulation that supports evolving science and encourages innovation.

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.

[3] Commonwealth Department of Health website, The Gene Technology Agreement, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-agreement

BACKGROUND TO THE SCHEME

The Scheme came into effect on 21 June 2001, under the *Gene Technology Act 2000* (GT Act),[4] replacing the previous voluntary system of oversight. The Scheme is designed to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with Genetically Modified Organisms (GMOs).

The Scheme is underpinned by the GTA [5] - an inter-governmental agreement which sets out the understanding between Commonwealth, State and Territory governments regarding the establishment of a nationally consistent regulatory system for gene technology.

The Scheme comprises Commonwealth, State and Territory legislation to allow for the constitutional reach of each level of government in regulating GMOs. The Scheme operates together with other Commonwealth, State and Territory 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.

The Scheme does not regulate those aspects of genetic modification which were already regulated under pre-existing regulatory schemes, and is referred to as a 'gap filler' regulatory scheme for this reason. It was specifically designed to dovetail neatly with the other regulatory schemes. The complex regulatory landscape is represented in **Figure 1: Overview of the Gene Technology Landscape in Australia**.

[4] Federal Register of Legislation, Gene Technology Act 2000 available at https://www.legislation.gov.au/Details/C2016C00792

[5] Commonwealth Department of Health website, The Gene Technology Agreement, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-agreement

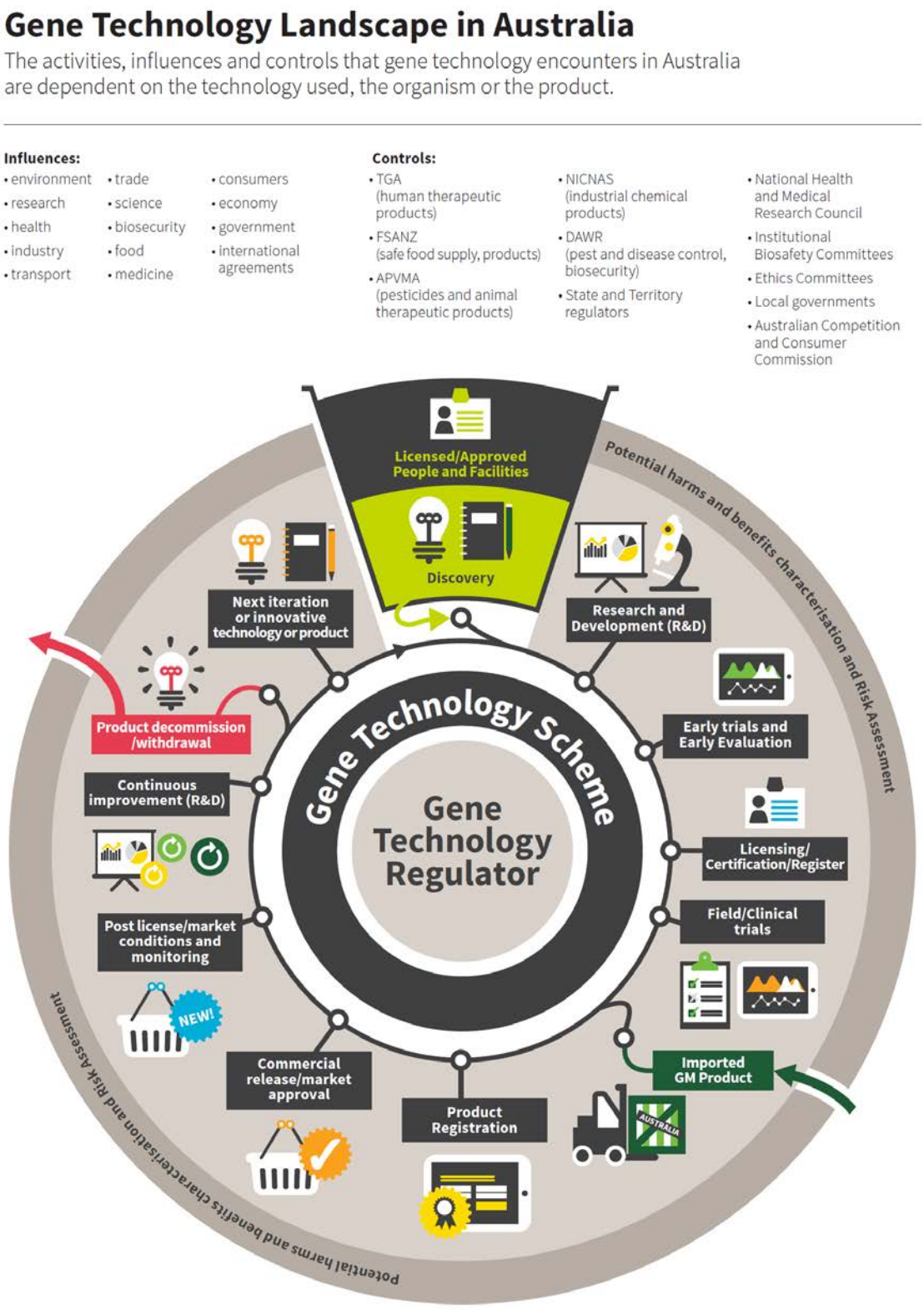

Figure 1: Overview of the Gene Technology Landscape in Australia[6]

[6] Acronyms expanded in Glossary

PREVIOUS REVIEWS OF THE SCHEME

Two previous reviews (in 2006 and 2011) 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. Both reviews confirmed that the policy objectives of the Scheme were still appropriate at the time. Resulting from each of the reviews, legislative amendments were made to improve the operation of the Scheme.

The 2006 statutory review was comprehensive in scope, covering issues that had emerged or changed significantly since the GT Act was passed. It examined whether the policy objectives of the GT Act remained valid. The recommendations from the review encompassed changes to improve the operation of the GT Act, including increasing the powers of the Gene Technology Regulator (the Regulator) in cases of non-compliance, and reducing reporting requirements.

By comparison, the 2011 review was relatively limited in scope and focused on the efficiency and effectiveness of the operation of the GT Act across the national scheme, and the interface between the GT Act and other regulation. The 2011 review produced minor and technical amendments to the GT Act to make gene technology regulation more efficient, effective and clearer.

The two previous reviews both concluded that within the context of the current policy settings, the GT Act and the Scheme were operating well. The 2011 review further concluded that:

- the Office of the Gene Technology Regulator (OGTR) was operating in an effective and efficient manner;
- the consultation processes in relation to applications under the GT Act were working well; and that
- the administrative operation of the Scheme was unlikely to have changed significantly in the last five years.

CURRENT POLICY SETTINGS

Currently regulated GMO dealings[7] are set by definitions in the GT Act, with exclusions to these made within the Gene Technology Regulations 2001 (the Regulations).

The current Australian approach to regulation of gene technology is considered to be a process driven approach, whereby dealings with an organism are subject to regulation if the process of gene technology was used in the organism's development. Some other countries use a product based approach to the regulation of GMOs; in these cases it is the characteristics of the final product which triggers the regulation.

The objective of the GT Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

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[7] 'Dealings' are defined under 'deal with' at s.10 of the GT Act, available at https://www.legislation.gov.au/Details/C2016C00792

The Scheme is intended to operate in a corresponding legislative setting, where each jurisdiction has their own legislation, which in turn refers powers to the Regulator to allow for a national approach to regulating gene technology. This approach was taken to enable national coverage across all potential licence holders when using the technology. It has proven to be very effective, and is a model for other legislation seeking nationally consistent application.

The GT Act (Part 3, The Gene Technology Regulator) confers functions and powers to the Regulator, including licensing, issuing guidelines, providing information to the public and maintaining international links. The Regulator also has the power to do all things necessary or convenient in the performance of their functions. They have the ability to delegate powers and functions as well as having discretion in the performance and exercising of their functions and powers.

SCHEME LEVERS

There is a range of policy and regulatory mechanisms that help achieve the broader objective of the Scheme (refer Appendix A).

Core to the effectiveness of a regulatory scheme is public trust that it is well designed and managed, and the rules are being followed. Accordingly, many of the regulator's functions aim to promote and optimise compliance. The Scheme provides the regulator with tools to regulate gene technology and support compliance to meet the objectives of the Scheme.

With this approach, and the use of the available tools, the Regulator can make decisions that manage the potential risks to protect the public and the environment, while also addressing the needs and concerns of the public.

OTHER REGULATORY SCHEME INTERSECTIONS

Other legislative schemes have references and linkages to the Gene Technology Scheme. Across the Commonwealth and state and territories there are over 30 pieces of interacting legislation and regulation.

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.

The Scheme was introduced in response to the need to regulate, pending the commercial release of agricultural crops. Over time there has been an increase in health-related applications reaching commercialisation, delivering health outcomes in the therapeutic product and clinical sectors. Accordingly, the intersections and interactions with health related agencies and regulators are increasing. The Scheme's interface with other regulatory schemes is represented in **Figure 2: Gene Technology Scheme interface with other Commonwealth regulatory schemes.**

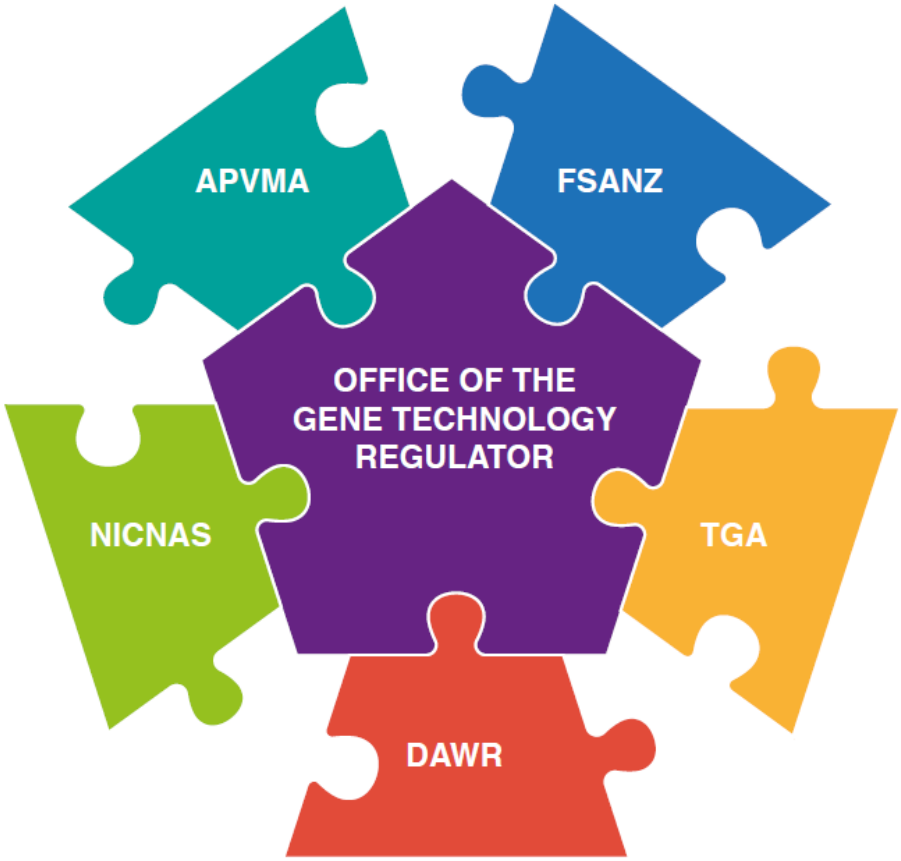

Figure 2: Gene Technology Scheme interface with other Commonwealth regulatory schemes[8]

[8] Acronyms expanded in Glossary

WHY IS IT IMPORTANT TO DO A REVIEW?

Under the GTA, a periodic review is required to be conducted by all governments, covering the GTA and the Scheme. These reviews provide a way to address technology advancements and develop understanding of potential risks which may challenge the scope and provisions of the Scheme. Regular review ensures regulation remains fit for purpose, supports industry and innovation, and provides confidence and assurance to the public and industry that the environment and their health and safety is being considered and protected.

While the Regulator can undertake reviews of the Regulations to improve the clarity of definitions and practices, any change in approach to what is to be regulated or not can only be done by the owners of the policy setting for the Scheme.

Governments and the public may consider the current policy setting and approach to managing the technology. Changes can then be made through both the legislation and other policy mechanisms.

CHAPTER TWO

CONSULTATION

All Australian governments recognise the importance of thorough consultation to inform this Review. 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, aimed at:

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

PHASE 1 CONSULTATION

Phase 1 was an open consultation process running from 25 July to 29 September 2017. Submissions were sought on the Terms of Reference for the review, as agreed by the Legislative and Governance Forum on Gene Technology.

In addition to the call for public submissions, findings from the following reports and reviews were considered:

- Technical Review of the Gene Technology Regulations;
- Productivity Commission Inquiry Report – Regulation of Australian Agriculture;
- Smart Farming Report – Inquiry into Agricultural Innovation; and
- 2006 and 2011 reviews of the National Gene Technology Scheme.

Research was also undertaken into specific areas to further define the issues presented, including emerging technologies, the basis of consumer concerns, and a longitudinal study of public perceptions.

PHASE 2 CONSULTATION

The aim of the second phase of consultation is to work with stakeholders to further understand and explore options and possible policy solutions for the issues identified in Phase 1.

Consultation is taking place through a range of mechanisms, including:

- online responses to this consultation paper;
- workshops with stakeholders;
- targeted meetings where required;
- interactive webinars; and
- market research.

PHASE 3 CONSULTATION

Building on the first two phases of consultation, the Review draft findings and proposed policy outcomes will be tested with stakeholders in Phase 3 consultations, anticipated in March 2018.

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 Review identified that consultation should have a wide reach to stakeholders, with submissions broadly falling into the following categories:

Organisation Type	Number of Submissions
Company	12
Consumer	39
Consumer Group	6
Government	10
Industry Group	18
Research	24
Total	109

The Background Paper to Phase 1 consultation specified that, unless otherwise requested, all submissions on the Review would be published on the Department of Health website. In submitting a response, stakeholders were asked to indicate their position via a coversheet. Those submissions, where consent has been provided, can be found at http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-technology-review

WHAT DID WE FIND IN PHASE 1 CONSULTATION?

Bringing together all inputs, the following overarching points have 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.

OVERARCHING THEMES

There were many issues raised through Phase 1 consultation, which was aimed at identifying 'What are the problems that we need to consider for the Review?"

A number of positions emerged around the issues raised – from those who would seem to prefer a regulatory approach, to those who remain concerned about potential harm that gene technologies may pose for humans and the environment.

Most responses fell into four broad thematic areas:

- **Technical**– what are GMOs, what are the processes to make GMOs, what do they do and what are their benefits and risks?
- **Regulatory**– accommodating impacts and influences of gene technology on agriculture, medical advancements 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 consumer concerns, and broader equity and access issues.

These themes are explored in further detail in Chapter 3 'Review Themes'.

OVERVIEW OF SOME KEY ISSUES RAISED

A consistent issue mentioned in feedback is the advance in scientific knowledge and the fitness of the Scheme to adapt to, or regulate new technologies. There are strong and opposing views as to whether these technologies should be regulated under the GT Act. Medical and veterinary technologies and medicines that are being used overseas, but sparingly in Australia, are discussed. Time and the cost of regulatory approval are posed as factors that contribute to their under-development in Australia.

Some people endorse triggering regulation on the basis of the end product, not the process. They maintain that the practical reality is that it may not be possible to differentiate the product of a plant or animal breeding program utilising gene editing, from a conventional methodology that produces a plant or animal with an identical genome.

The impact of state moratoria on GM crops is cited, with farm owners both in support and opposed to the moratoria, citing their right to choose the production systems that suit their farm business. Issues related to moratoria include market access, product branding and the Low Level Presence (LLP) of gene technology products in non-GM grain or food products, and strategies to deal with LLP.

The lessons learned from over 20 years of the on-farm commercialisation of GM crops in Australia are raised. Enhanced farm productivity, improved weed control, reduced energy and chemical usage and agronomic improvement of farm systems are all cited as valuable developments. Agronomic challenges identified include herbicide tolerance in weeds or insects, the use of stacked traits in plant cultivars, and the appropriate on-farm management practices required to maximise benefits and minimise risk.

While the focus of Phase 1 consultation was on identifying issues, a number of suggestions for improvements to definitions in the GT Act were provided, as were suggestions on governance and decision-making processes within the Regulator and its advisory structures.

There is strong support for continued government funding of the Regulator, often citing the relative infancy of the gene technology industry in Australia, and the impact that cost recovery would have on researchers, particularly small private sector concerns.

CHAPTER THREE

OVERARCHING THEMES

REVIEW THEME ONE: TECHNICAL ISSUES

What are GMOs? What are the processes to make GMOs? What do they do and what are their benefits and risks?

OVERVIEW

Recent advances in technologies are likely to enable genetic changes in ways that are rapid, scalable, accessible and much more cost effective, posing challenges for the Scheme.

Section 10 of the GT Act contains a broad definition of 'gene technology' and thus also a broad definition of 'genetically modified organism'. The Regulations provide some exclusions to these definitions.

Although there are challenges in applying the current definitions to some new technologies, the Regulator is obliged to perform the functions required by the Act and apply the legislation as it stands today.

The Regulator has been proactive on this issue and in 2016 initiated the Technical Review of the Regulations (the Technical Review) to ensure the Regulations reflect current technology and scientific knowledge. The 2017 Review of the Scheme will take heed of stakeholder views expressed in the Technical Review, in addition to any other developments as the Review proceeds.

ISSUES RAISED

There are several considerations arising from Phase 1, which include the need to:

- Ensure the definitions within the Act remain fit-for-purpose.
- Survey and undertake a gap analysis of technical advancements (e.g. synthetic biology applications, or gene drive releases).
- Provide clarity and certainty for stakeholders under the Scheme, which will allow the prioritisation of research and investment decisions.

Phase 1 of the Review has noted technical input and questions in two main areas:

- Legislated definitions and their applicability to existing, recent and on the horizon techniques; and
- Dealings Involving Intentional Release of GMOs.

DISCUSSION

Classification of new technologies

Phase 1 of the review process has highlighted the effectiveness of the Scheme - to safeguard human health and the environment. It has also highlighted the complexity of many of the technical and scientific advances made in recent years.

The research and commercialisation of transgenic organisms under the Scheme has been in place for some time, and regulatory outcomes are generally predictable.

Technical advances are presenting unique applications for the science, and challenging existing definitions for regulatory authorities. This is not unique to Australia, as governments and regulators around the world are considering the same issues.

A number of stakeholders to the Review have clear views on whether new breeding technologies should be regulated under the Scheme. This group of new and emerging technologies feature a range of techniques with varying processes and outcomes. The distinguishing feature of gene editing for example, is that it can be used to make changes that are very small (down to one coding unit, a base pair or nucleotide); that may leave no footprint; may introduce no new DNA sequences; and that may be indiscernible from an organism that could occur naturally.

In the ongoing Technical Review of the Regulations, the Regulator considers that an interim approach, to continue to regulate some new technologies based upon the process used, best supports the effectiveness of the legislative framework at this time. This would clarify that use of a template to guide modifications results in GMOs which are subject to regulation. As an interim measure, the Technical Review would provide clarity while broader policy considerations are progressed in the Review of the Scheme[9].

Classification of new technologies **-** in taking into account the above, the Review will consider legislated definitions and their applicability to existing, recent and on the horizon techniques, in order to ensure definitions within the GT Act remain fit for purpose. Some questions to consider:

1. What technological advances can be foreseen that might pose regulatory challenges for the Scheme?
2. What are the potential impacts of the capability to make small edits in the DNA of an organism using no foreign DNA?
3. Under what circumstances might it be practical, efficient or appropriate to regulate gene editing under the GT Act when, from an enforcement perspective, it may not be possible to distinguish the products of gene editing from the products of conventional methods?

Emerging Applications

Synthetic biology is an application which can broadly be described as the design and construction of novel artificial biological pathways, organisms or devices, or the redesign of existing natural biological systems. The construction is done by chemical synthesis and enzymes in test tubes before the completed genetic unit is placed into a living cell. Ultimately this might include the construction of a complete genome.

Human germline gene therapy modifies reproductive cells with the intention of any changes being passed onto the patient's offspring and subsequent generations. Human germline therapies are being proposed to potentially be utilised in the future in order to address genetic diseases.

[9] 2016-17 Technical Review of the Gene Technology Regulations 2001, available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewregulations-1

Gene drives are an application which increases the rate at which certain genes are inherited by offspring of a sexually reproducing organism. The potential practical applications of this include the control of pest species, the protection of species from genetic diseases and the prevention of outbreaks of some human illnesses.

Emerging Applications - the emerging applications, and their definitional implications for research purposes, are another area the Review will focus on. A question to consider:
4. Do these applications of gene technologies present unique issues for consideration? If so, how might these issues be addressed by the Scheme?

Intentional environmental release

There are a number of invasive species in Australia that could be the subject of research on biological control agents, developed using gene technology. Vertebrate pests such as European carp and cane toads are cited as species that may be vulnerable to a control agent developed using existing methods or emerging technologies. These possibilities, however, may present different potential risks and ethical considerations, depending on the application and technology utilised.

The regulatory section of this consultation paper will seek views on whether such an environmental release poses risks that are not sufficiently addressed under a DIR.

Intentional environmental release – in summary, the Review is seeking further input on the prospect of the intentional release of a GMO or organism with changed characteristics, delivered by one of the new breeding technologies, into the environment. Some questions to consider:
5. What are the potential implications of the release of a GMO targeting an invasive species in Australia? 6. What are the technical issues to consider in the scenario of a GMO used to target an introduced plant, vertebrate or invertebrate pest?

Accommodating impacts and influences of gene technology on agriculture, medical advancements and research, while maintaining protection of people and the environment?

OVERVIEW

A best-practice risk-based approach to regulation calls for a regulatory scheme to focus on harm prevention and achieving outcomes, and to choose the appropriate instruments to achieve performance. Regulatory effort should be placed on the highest levels of risk, and be designed to encourage innovation and reduce regulatory burden.

Public debate recognises the importance of regulations in the gene technology scheme in providing for the health and safety of people and the environment. This debate extends to the most appropriate way that the gene technology regulatory scheme should be structured and implemented to provide maximum benefit for regulated entities and for the community. If not designed well, the regulatory scheme can become a burden to business and stifle research and innovation, or may not provide the safety net the community should be afforded or expects.

The technical theme of this consultation paper explores the definitional issues presented in Phase 1 of the consultations, and their applicability to existing, recent and on the horizon techniques. This regulatory theme provides a basis for exploring how the gene technology regulatory scheme may be adapted to account for any changes in the definitions, using a best-practice, risk-proportionate approach, guided by regulatory mechanisms raised in the first stage of consultations.

ISSUES RAISED

The question of what should, and should not be regulated as a GMO was a key issue raised in Phase 1 consultations.

The 2016-17 Technical Review of the Regulations discusses amending the existing regulations to "exclude organisms from regulation as GMOs if the genetic changes they carry are similar to or indistinguishable from the products of conventional breeding".[10.] It may be appropriate for the Scheme Review to clarify if this exclusion applies to certain modifications in humans.

Some stakeholders identified potential gaps in regulation pertaining to the modification of humans. For example, the regulation of clinical trials under the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990* are limited to the use of therapeutic goods. As such, there is a need to ensure research conducted on disease-causing mutations in living adults and children are covered by either the regulatory scheme for gene technology or therapeutic goods. Furthermore, it should be noted that if changes were to be made to NHMRC's legislation this might have unintended consequences for the GT Act definitions, such as inadvertently defining and regulating humans as a GMO.

[10] OGTR, Technical Review of the Gene Technology Regulations 2001, Discussion paper: Options for regulating new technologies, p. 16. http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewdiscussionpaper-htm

Stakeholders also raised the possibility of considering alternative policy settings or regulatory triggers for the Scheme. Specifically, stakeholders identified the option to regulate based upon the potential risks inherent to the modified organism. This is often referred to as a product-trigger[11] and is the method of regulation underpinning Canada's approach to gene technology, where novel traits, products or organisms are the subject of regulatory risk assessments.

Stakeholders have highlighted the Review as an opportunity to explore how alternative regulatory triggers may work within the Australian regulatory landscape.

They also see merit in exploring mechanisms to further streamline, enhance and future-proof the existing regulatory structure and accommodate future waves of innovation in gene technology. This could include the identification of any gaps in regulation and of existing but 'underutilised' policy lever provisions within the Act, to facilitate the agility of the Scheme. [12]

The Technical Review also highlighted that organisms used, and how they are used in research and commercial applications, vary widely and have differing risk profiles. The issue of 'one-size-fits-all' regulation plays out at a number of levels within the Scheme, be it:

- Definitions to capture what is regulated (i.e. regulatory trigger);
- The structure of the Regulations to exclude certain techniques and GMOs (Schedules 1 and 1A of the Regulations), and
- Risk tiering within the legislation.

Phase 1 consultation recognised that governments and regulatory institutions around the world are working on how to best accommodate the continued advancements in the life sciences. When considering such changes to our regulatory structure, it will be necessary to take into account any developments in the international policy environment, as well as the intergovernmental aspects of our federated system. [13]

DISCUSSION

1. Regulatory triggers

Australia's gene technology regulatory Scheme is based on the protection of people and the environment. Under the current scheme, these protections commence when gene technology, as defined in the GT Act, is used to modify an organism. The resulting organism is then defined as a GMO. This type of regulation is generally referred to as having a 'process-trigger'[14]. As such, the definition of gene technology is key in determining whether an organism is a GMO under current legislation.

[11] Product Trigger: A from of regulation that emphasises 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 traits, as the salient threshold for promoting a regulatory response.
[12] See Appendix A for some existing levers.
[13] See Review Theme Three: Governance Issues below for a more detailed discussion of these matters.
[14] Process Trigger: A form of regulation emphasising the role of technique as the determining factor in constituting a GMO. Australia's GT Scheme is underpinned by a process trigger. As such the definition of gene technology has primacy in determining whether an organism is captured by regulation.

While the current Australian system is underpinned by a process trigger, it also focuses on any potential risks posed by the organism itself, for example in risk assessments, and containment measures.

Some stakeholders have questioned whether the process trigger remains the optimal approach to ensuring that the regulatory framework manages risk appropriately and proportionately. This is a key question which needs to be addressed in the Review, as each trigger presents a different set of opportunities and challenges for regulation. Stakeholders have different views on whether:

- The process trigger should be retained;
- A product trigger be implemented; or
- A hybrid model is developed that takes into account a mix of features such as class of organism, modification type, or source of genetic material.

Any change to the Scheme's trigger can have cascading effects for the regulatory definitions, processes and management issues. As many of the issues raised during Phase 1 are process trigger centric, consideration needs to be given to the relevance of an issue to a product-based scheme. For example, attention to the timeframe for licencing decisions, which stakeholders identified as a potential streamlining option for the existing regulations, may not be relevant or differ depending on which regulatory trigger is being considered. As a result, any potential policy solutions to such issues are dependent on the regulatory trigger in question, and the form this may take.

Regulatory triggers – In taking into account the above, the Review is considering the issue of regulatory triggers, and how best to undertake future policy design processes with both process and product trigger considerations in mind. Some questions to consider:
1. What do you think is the most appropriate regulatory trigger for Australia in light of extensions and advancements in gene technologies? 2. What factors need to be taken into account in the design of a product-based or a hybrid process/product regulatory scheme?

2. Streamlining Regulation

Alongside considerations of alternative regulatory 'triggers' are considerations of how to streamline the existing regulation, including:

- How to incorporate existing and growing bodies of knowledge, into regulatory outcomes, both in individual decisions and in defining classes of GMOs/dealings (e.g. exempt, NLRD, etc.);
- Truncating the timeliness for certain decisions (for example licencing timeframes)
- Consideration of a regulated entity's 'track record' for compliance;
- Amending application forms so they are less 'plant centric' (particularly for NLRDs);
- Examining the regulatory oversight and interface between regulators; and
- The potential for varying levels of risk assessment based on the introduced traits (particularly for environmental releases).

Stakeholders provided many examples of how to streamline existing regulation. However, two key concerns were amending the definitions to better address any potential risks posed

as a result of recent advancements in gene technology, as well as other functional efficiencies like the timeliness of licensing, variations or certifications.

Streamlining Regulation - Phase 1 consultations identified a number of functional efficiencies that could be applied to the Scheme. The Review is exploring these issues from perspective of the existing process-based regulatory scheme. Some questions to consider:
3. Are there any 'fixes' the scheme needs right now to remain effective? 4. How would you streamline the existing scheme? 5. What efficiencies could be gained through adjusting the interface between the Scheme and other regulators?

3. Risk tiering and appropriate regulation of environmental releases

Some stakeholders have highlighted the potential for the Regulator to apply differing levels of risk assessment to ensure the level of regulation is commensurate with risk. While this approach already exists in several forms within contained dealings, this approach has potential applications for environmental releases too. The risk assessments for clinical trials, field trials, or release of GMOs into the Australian environment are informed by biology documents formulated by the OGTR. These documents provide an overview of the baseline biological information relevant to a risk assessment.[15] The document provides particular reference to the plant's morphology, reproductive biology, development, biochemistry, and biotic and abiotic interactions. The biology documents are updated and enhanced as the scientific and agronomic knowledge pertaining to the plant species is increased.

As some biology documents are into their third or fourth version, with the plant regarded as highly characterised, some stakeholders to the Review maintain that a lower threshold of regulation is appropriate for such organisms.

Risk tiering and appropriate regulation of environmental releases - the Review is exploring whether greater alignment of regulation with risk should be further developed for environmental releases. Some questions to consider:
6. What support exists for a regulatory framework providing for tiered risk? 7. What examples exist of licence applications to the Regulator that could be 'fast-tracked', under a risk tiering system, with evidence of scientific and technical integrity that the aims of the Scheme (protection of human health and the environment) will be delivered? 8. Under a regulatory framework to tier risk for environmental release, what efficiencies might be delivered to regulated stakeholders? 9. How could efficiency gains to the Regulator be quantified?

[15] Available at, http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/biology-documents-1

Some stakeholders have raised the potential for a risk-tiering approach to various classes of organisms. For example, that lower levels of risk are inherent to plants, or at least plants with a long history of commercialised release. These stakeholders maintain that such plant-based technology is some of the most researched technology on the planet and that the Regulators resources might be better spent on modifications that have been pre-assessed to be of higher-risk.

It is also possible to view the Regulator's draft proposal of Option 3 of the Technical Review as a means of risk tiering. The Review of the Scheme will also explore the implications of this proposal for other regulatory frameworks,[16] for example the application of SDN-1 techniques to the somatic modification of humans *in vivo.*[17]

The Review is exploring whether a distinction can be made between classes of organisms so the necessary controls can be applied to the highest risks, rather than applying a one size fits all approach. Some questions to consider:
10. What justification is there to regulate animals, plants or microbes differently? 11. In what way might different applications be treated differently (e.g. medical, agricultural, industrial, environmental, etc.)?

4. Accessibility and managing new potential harms

The state of the science is now such that technology has become easier and cheaper to use. This means it is now possible to use gene technology in high schools, whereas before it was the remit of universities, hospitals or industry. Today, this increased accessibility puts the technology within reach of DIY or 'backyard biologists', and beyond a more conventional laboratory framework.

Some stakeholders have raised the recent possibility of 'DIY-biology', or 'back-yard biology' as a new issue facing the Scheme. The potential for enhanced 'post-market' monitoring and compliance, as well as exploring strict liability, and appeal provisions within the Act, were also raised as issues.

Accessibility and managing new potential harms – Some questions to consider:
12. How might the Scheme accommodate the DIY-biology movement? 13. What measures might be warranted to identify potential long-term or 'down-stream' effects of gene technologies on humans and the environment?

[16] While changes to other regulatory frameworks are outside the scope of this Review, consideration will be given to potential implications, with a view to communicating any possible disconnects to the owners of such frameworks.

[17] Under Option 3, organisms modified using site-directed nucleases without templates to guide genome repair (i.e. SDN-1) would not be regarded as GMOs.

5. Future-proofing regulation and principles–based regulations

Phase 1 consultation has acknowledged the intricacies and strengths of the current regulatory setting, the interconnected body of legislation among other regulators, as well as with Australian governments, the international policy environment, and the diverse and divergent views expressed on these topics by stakeholders.

In the context of consistency with other regulatory agencies, a number of stakeholders raised the prospect of different agencies or regulators settling on non-harmonised definitions of new technologies, which may potentially affect regulatory coverage.

Further, some stakeholders emphasised the potential to consider principles-based regulation, as opposed to the prescriptive or rules-based regulations (as emphasised in the Schedules 1 and 1(a) of the Regulations).

Future-proofing regulation and principles–based regulations - Some questions to consider:
14. What opportunities are there for principles-based regulation in the Gene Technology Scheme? What advantages could be gained from doing this? What drawbacks are there from such an approach to regulation? 15. Are there any non-science aspects that would enhance the object of regulation, that do not place unnecessary burdens on the regulated community? How might these be considered?

6. Market access and international trade

Phase 1 consultation highlighted the need to better understand the potential impacts on market access for exporters of animal or plant derived commodities. The potential to deliver improved crop cultivars in a timely manner is particularly attractive to some Australian farmers competing on world markets, as productivity growth across Australian agriculture has plateaued over the past twenty years.

When regulators in overseas jurisdictions make regulatory decisions in respect to gene editing techniques, Australian exporters will need to be in a position to meet the needs of our trade partners.

Market access and international trade - The Review is exploring the practical implications to the Scheme of harmonising Australian regulation with the regulatory needs of trade partners. Another question to consider:
16. What are the potential impacts on market access for exporters of animal or plant derived food products?

How decisions are made and what views and evidence are considered.

OVERVIEW

The National Gene Technology Scheme was established to address a regulatory gap associated with a rapidly developing technology, within the context of existing regulatory schemes. Responsibility for the policy setting of the Scheme and determining who makes the decisions, is vested with ministers in the Commonwealth, state and territory governments. These arrangements are set out in the Gene Technology Agreement.[18] .

The Legislative and Governance Forum on Gene Technology (the Forum) provides governance oversight of the Scheme. Irrespective of who the lead Minister is in any jurisdiction, they are representing all portfolios with an interest in gene technology within their jurisdiction. This ensures the national Scheme is robust and representative of multiple policy and stakeholder perspectives.

In administering the legislation, the regulator has independence to make decisions that are based on the assessment of evidence. This includes assessment of data provided by applicants and published scientific literature, as well as the advice of expert committees, agencies and authorities. In deciding whether to issue a licence, the Regulator must also consider policy principles and policy guidelines issued by the Forum.[19]

ISSUES RAISED

During Phase 1 consultation, a number of issues relating to the governance structure were raised, particularly with respect to ensuring the Scheme is sufficiently agile, sound and reliable now, and into the future. These include:

1. Credibility, integrity and legitimacy of the Scheme
2. Agility and national consistency of the Scheme
3. Harnessing health and economic benefits of gene technology
4. Clarity on policy considerations of the Scheme
5. Coordination with international policy and regulatory forums
6. Ongoing applicability of government funding model.

DISCUSSION

1. Credibility, integrity and legitimacy of the Scheme

There is a strong argument, supported by stakeholder submissions, that the Scheme is well-designed and remains, at heart, fit for purpose – delivering the intended public benefits; safety and protection, as well as health, social, economic and environmental

[18] Commonwealth Department of Health website, The Gene Technology Agreement, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-agreement

[19] Office of the Gene Technology Regulator website, About the Regulator, available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/about-regulator-1

benefits. Submissions noted that demonstrating the Scheme's ongoing credibility, integrity and legitimacy requires continued transparency and accountability of the Scheme's governance arrangements and the Regulator's decisions.

As a 'gap filler' Scheme, there are many intersections and interfaces with other domestic regulatory frameworks. Therefore, any changes to the Scheme require all Australian governments to:

- Consider the prevailing policy setting;
- Collectively agree on policy responses including regulatory reforms;
- Introduce legislative amendments and non-legislative changes; and
- Consult with the Regulator and stakeholders on implementation and impacts.

Credibility, integrity and legitimacy of the Scheme – In taking into account the above the Review is exploring opportunities to maintain and enhance the transparency of, and trust in, the governance arrangements of the Scheme. Some questions to consider:

1. What will reassure the Australian public and regulated communities of the integrity of the Scheme?
2. What mechanisms could address the challenges that making changes in the Scheme might entail:
   - Domestically – across a federated government system experiencing different political agendas and community sentiments?
   - Internationally – relating to other agreements, trade agreements, and harmonised regulatory approaches?

2. Agility and national consistency of the Scheme

Some submissions to Phase 1 consultation raised that the governance arrangements could be better utilised to ensure the agility and consistency of the Scheme. There is concern that the current rate at which the policy setting is reviewed, and reforms progressed through the Forum, may not be sufficient to keep up with the rate of technology development; other regulatory reform cycles; and community values. The timeframes to implement reforms are correctly linked to the Forum's five yearly reviews and processes to change legislation across all jurisdictions.

Submissions highlighted that the technical knowledge needed to inform policy and reform decisions is readily available in existing policy, industry and expert forums, such as the GTSC, Gene Technology Technical Advisory Committee, or Institutional Biosafety Committees. Utilising these structures more effectively was raised as a more responsive and flexible way to update the Scheme, noting they would require the necessary skills, capabilities and links to interacting parties.

Agility and national consistency of the Scheme - The Review is exploring how to ensure the rate of adaptation of the Scheme keeps pace with changes in technology and community values. Some questions to consider:

3. What principles should guide the level at which a decision is made within the Scheme?
4. Does reviewing the Scheme every five years best address the needs of the Scheme? Is there a preferable option?
5. Is the existing role of the Forum the most suitable way of providing oversight and guidance for the Scheme?

Similarly, the legislative amendment process and timeframes are the same for major reform amendments and minor administrative amendments. All changes that impact the Scheme must go through the Forum, and once the Commonwealth legislation is passed, jurisdictions develop or adopt legislation to complement it.

As such, timeframes are based on the federated arrangement: including jurisdictions' legislation protocols, consultation requirements, and competing parliamentary priorities. These circumstances affect the responsiveness of the Scheme to minor amendments that underpin national consistency.

Another question to consider:

6. What criteria should be used to determine what legislative amendments are minor and could be progressed without going to the Forum?

The spectrum of Phase 1 submissions disputed the nature of the policy principle that recognises states and territory designated areas, where genetically modified crops may not be grown commercially, on the basis of market or trade interests. Strong arguments ranged from support for the feature because it enables agility within the Scheme, to opposition because it adds regulatory complexity and burden for some stakeholders.

GM moratoria remains a debated element of the Scheme and the Review is seeking to understand the factors and practical implications for all stakeholders. Some other questions to consider:

7. What evidence is there to support economic and trade advantages of GM moratoria – or indeed, the absence of GM moratoria?
8. How could regulated stakeholders access the benefits of a national scheme, whilst ensuring jurisdictions are able to effectively trade in the international context?
9. What other mechanisms could be utilised in order to realise the outcomes currently achieved through moratoria?

3. Harnessing the economic and health benefits of gene technology

A number of stakeholders suggest that, to continue to protect people and the environment into the future, the Scheme needs to keep pace with recent advances and horizon technologies. Without this, innovation in gene technology, and its applications in the health, environment, agriculture and manufacturing domains, could be stifled.

Some stakeholders are concerned that this could impact Australia's ability to access new technologies (and their benefits) not originally anticipated when the Scheme was first designed.

Harnessing the economic and health benefits of gene technology - The Review is exploring how the Scheme can harness any emerging benefits of gene technology that were not anticipated at the establishment of the Scheme. Some questions to consider:
10. Are existing mechanisms, when used effectively, sufficient to ensure the emerging health, environmental and manufacturing benefits of gene technology that were not anticipated at the establishment of the Scheme, can be harnessed for Australians? 11. Should other policy principles be developed that are tailored to horizon technology management?

It is clear through responses to Phase 1 consultation that, even with increases in the body of knowledge about the actual risks gene technologies engender, the application of the 'precautionary approach'[20] is still debated.

Interestingly, while horizon technologies are increasingly being applied within the health field, stakeholders have indicated relative acceptance of these developments, despite the potential costs and uncertainties that currently exist.

Conversely, where current regulatory arrangements determine a horizon technology merits full consideration, the perceived regulatory burden may mean that it never gets the chance to be explored, and the potential benefits never realised.

Some stakeholders have proposed that, in making regulatory decisions, the Regulator should have the ability to take into account the magnitude of potential economic, environmental and health benefits.

Some other questions to consider:
12. What other factors could be considered in the regulatory decision? 13. What data sets are required to assist the regulator to consider benefits in addition to the risks?

4. Clarity on policy considerations of the Scheme

The GTA requires the Scheme to be nationally consistent and science-based. It also embeds the requirement for the Regulator to take into account policy principles developed by the Forum based on social, cultural, ethical and other non-scientific matters. However, economic benefit, efficacy or broader policy considerations are a matter for the regulators of the GM products derived from GMOs.

[20] The Gene Technology Act (section 4(aa)), outlines a 'precautionary approach', where regulatory actions are not postponed due to a lack of scientific certainty, and are balanced with efficiently protecting human health and safety and the environment.

Some Phase 1 submissions suggested improved regulatory and policy position clarity is needed to provide certainty to industry and the community, and greater transparency about decision making. This in turn assists with choice; including about research and development investments, regulatory compliance actions, marketing strategies, and consumer spending.

Some stakeholders noted that clarity can be provided through legislative instruments, such as the Forum's Policy Principles, Policy Guidance and Codes of Conduct to govern the activities of the Regulator and the operation of the Scheme. Clarity may also be facilitated by the Forum's coordination with other policy and regulatory forums on matters related to genetically modified products.[21] For any of these options, there are different timeframes to develop and implement changes to improve clarity.

A number of submissions highlight that some gene technologies may create outcomes that push ethical boundaries or compete or conflict with holistic policy solutions that could achieve the same outcome.

In addition, as gene technology becomes cheaper and easier, access also becomes easier. Emerging non-laboratory or 'DIY' gene technology is currently captured within the framework. However, there may be questions as to whether compliance mechanisms appropriately address DIY gene technology. [22]

For these reasons, stakeholders indicated clarity is required on the Scheme's approach in a number of areas that include, but are not limited to:

- Potential benefits of some/all gene technologies, for people and the environment;
- Risk appetite for, and acceptance of multiple genetic modifications in an organism;
- Management of DIY experimentation;
- Acceptance of Low Level Presence (LLP) standards for GM products and their co-existence with non-GM crops;
- Linkages to other policy domains such as genetic profiling (e.g. genomics);
- Linkages and interfaces with other regulatory schemes, domestically and internationally (e.g. for harmonisation of definitions and regulatory requirements to reduce regulatory burden).

Clarity on policy considerations of the Scheme – In taking into account the above, the Review seeks to identify areas where clear policy positions could enhance the Scheme and support compliance with regulation. Some questions to consider:
14. What aspects of gene technology would benefit from greater policy position clarity? 15. What other mechanisms would provide suitable policy clarity that would enhance the Scheme and support compliance?

[21] Commonwealth Department of Health website, Legislative and Governance Forum on Gene Technology, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-gtmc.htm

[22] See Review Theme Two: Regulatory Issues above for more on the subject of DIY-biology

5. Coordination with international policy and regulatory forums

The Regulator maintains links with other organisations and regulators (domestically and internationally) that deal with gene technology, genetically modified organisms, or products to promote harmonisation of risk assessments and monitor international practice.

Recent and anticipated science and technology developments, like synthetic biology,[23] may involve processes and end products that cross regulatory boundaries, such as chemical and therapeutic frameworks. With the anticipated growth in the gene technology sector, there is likely to be a corresponding increase in regulatory transactions in the gene technology Scheme, and the interfacing product frameworks.

Submissions noted that for an effective, efficient, integrated regulatory environment, the regulatory interfaces need to be well defined so there are no gaps in protections, and no duplication of work for the applicants and regulators.[24] The assessment of risks across the spectrum of regulation should be consistent and complementary to prevent unnecessary regulatory burden that can be a barrier to innovation and competitiveness.

Coordination with international policy and regulatory forums - The Review is seeking to identify any regulation gaps and overlaps at the interface of the Scheme and other product regulators. Some questions to consider:
16. What are the pressure points at the boundaries between regulatory schemes that are caused by regulatory gaps or overlaps? 17. How can existing coordination functions be utilised more effectively to support the Scheme to be agile and facilitate transitions across regulatory framework boundaries? What other activities would enhance this?

6. Funding model

The outcomes of this Review are intended to inform the future consideration of funding models. Even so, as the application of gene technologies increase, there are implications for funding and resources to deliver the Scheme's objective. Given that much of the discussion to inform this Phase of the Review will explore potential changes to the regulatory framework, it is arguably more appropriate that future funding options will be considered more fully as the Review consultation continues.

Funding model - Some questions to consider:
18. What amendments to the funding model would support an agile Scheme that will cope with increased future activity? 19. How could some aspects of the Scheme be funded through other mechanisms that will support innovation and competition in gene technology, whilst retaining public confidence in the Scheme?

[23] See Glossary

[24] Noting regulatory framework funding mechanisms vary and have different impacts on (a) costs borne by the regulated community, (b) government spending and revenue, and (c) costs borne by the community

REVIEW THEME FOUR: SOCIAL AND ETHICAL ISSUES

How to consider and address consumer concerns, and broader equity and access issues.

OVERVIEW

A number of reviews have highlighted the need to educate and inform the public about gene technology. 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. The Office of the Gene Technology Regulator (OGTR) provides a role in delivering information to the public about the regulation and risks of GMOs.

The Regulator also meets the requirements of the *Gene Technology Act 2000* (GT Act) to consult widely on applications made under the GT Act. The Regulator seeks advice from prescribed experts, agencies and authorities on an application, and also seeks advice from local government areas of Australia. Notifications of application are posted on the OGTR website and provided to people and organisations that have registered with the OGTR to receive information on the activities of the OGTR.

The national gene technology scheme currently provides for consideration of ethical and social considerations. The Gene Technology Ethics and Community Consultative Committee is legislated by the GT Act to provide advice on: ethical issues relating to gene technology; community consultation in respect of the process for applications under the GT Act; and matters of general concern identified by the Gene Technology Regulator in relation to applications made under the GT Act and of general concern in relation to GMOs.[25]

The Regulator conducts a longitudinal survey on community attitudes to gene technology. The findings of these reports are useful to develop approaches to engage with the community on these issues. The most recent publicly available report is available on the OGTR's website.[26]

ISSUES RAISED

Concerns have been raised in Phase 1 submissions relating to ethical issues from the perspective of the technical definition, regulatory treatment of GMOs, or governance arrangements of the Scheme. These include:

- Potential risks of gene drive organisms and how they could be managed;
- Consideration of how humans are treated by the Scheme, and application of new technologies to research on humans and embryos;
- Transparency of commercial GM crop locations.

In order for the regulatory scheme to engender public confidence and trust, it is important that discussion on these ethical issues is conducted in a balanced manner and does not preclude consideration of the Scheme's science-based risk assessment processes.

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[25] Office of the Gene Technology Regulator website, The Gene Technology Ethics and Community Consultative Committee (GTECCC), available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/gteccc-2

[26] available at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-other

The technical, regulatory and governance themes of this consultation paper are the appropriate areas to explore these specific issues in more detail.

This theme focuses on how all participants in the gene technology scheme, from government and regulators through to industry, organisations and the community, can work together to ensure confidence in the regulation of gene technology is strong. It also seeks to explore how choice may be made available to all members of the community.

DISCUSSION

1. Public understanding and confidence in the Gene Technology Scheme

Submissions to Phase 1 highlight that 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. Consideration needs to be given on how best to achieve this public trust, and enable the community to best understand the benefits and risks of a complex, science-based technology. Regulation also benefits both businesses and consumers by providing clarity about what is expected and acceptable in the Australian context.

Public understanding and confidence in the Scheme - It is important for the Review to identify where public understanding and confidence is strong, so this can be maintained, as well as opportunities for greater understanding. Some questions to consider:

1. How do we help the community to best understand the benefits and risks of a complex, science-based technology?
2. Where does the community have confidence in the gene technology regulatory scheme? How can this be maintained?
3. Where is there a lack of community confidence in the gene technology regulatory scheme? Why might this be, and how can confidence be built?
4. What does the public need to know?
5. Who is best placed to provide that information?

2. Access, equity and choice for Australian consumers and patients

The development to commercialisation of gene technology has grown rapidly over the last five years. There is more medical research resulting in a commercial product which requires an environmental release authorisation.

Some stakeholders maintain that there is potential for significant public benefit as a result of this growth. Whilst ethical considerations will continue to play an important role in the development of these technologies, there is a need for public guidance as to when and why social licence[27] should be afforded to the adoption and embedding of gene technology into the culture, lifestyle, economy and health sector.

Labelling requirements of GM food was raised in a number of submissions. Food Standards Australia New Zealand is the responsible agency for food labelling requirements.[28]

[27] The level of acceptance or approval by local communities and stakeholders of a technology
[28] available at: http://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx

The Review does not have the authority to consider the remit of other regulatory schemes. Consumer choice - and information available to consumers - is however an important consideration for any regulatory scheme that interacts with the gene technology scheme.

Access, equity and choice for Australian consumers and patients - The Review is seeking to better understand how to balance consumer choice within the scope of the Scheme. Some questions to consider:
6. What does the public need in order to accept the increasing availability and range of use of gene technologies? 7. What does the public need in order to determine whether to provide social licence for the adoption and embedding of gene technology into the culture, lifestyle, economy and health sector? 8. What are the ethical considerations for enabling access to medical treatments?

3. Access and equity for Australian agricultural research and development and industry

Phase 1 submissions noted that the Scheme needs to be maintained in a way that allows producers to be able to use the on-farm production system of their choice. This argument plays out both for farmers wishing to have non-GM crops, as well as for those who wish to farm GM crops. Industry has noted the importance of access to technology and techniques to enable agricultural technologies to be extended to a greater range of useful crop plants.

Some stakeholders further discussed competitive barriers for domestic and international trade. This includes possible consideration of proposed approaches for Low Level Presence[29] which might include thresholds, and recognition of international risk assessments.

Some submissions expressed concern that Australia does not have a significant or efficient transformation of research and development, to commercialisation. Where this is the case, they noted that regulatory barriers should be identified and strategies developed to ensure real long-terms benefits can be realised, whilst continuing to ensure the health and protection of people and the environment.

Access and equity for Australian agricultural research and development and industry - The Review is seeking to explore and better understand factors relating to choice and the potential impacts on trade, alternate farming techniques and the broader environment. Some questions to consider:
9. How do we ensure that information is available to the community on the value of GM and what it can do? Who is responsible for providing this, and why? 10. Is the Scheme putting up barriers to research and development and commercialisation of agricultural applications?

[29] 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

GLOSSARY

Term	Definition
APVMA	Australian Pesticides and Veterinary Medicines Authority
Biosecurity	Regulatory work undertaken by the Department of Agriculture and Water Resources, managing importation of biologicals.
Cisgenic	Gene modification that utilises genes from the organism's compatible gene pool.
CRISPR	(Clustered regularly-interspaced short palindromic repeats): a tool in molecular biology for deleting, replacing or editing DNA. CRISPR has unprecedented precision ease over editing genes in many species.
DAWR	Department of Agriculture and Water Resources
DIY Biology	The use of gene technology by hobbyists outside the traditional research and industry structures, also referred to as 'biohacking'.
Forum	Legislative and Governance Forum on Gene Technology
FSANZ	Food Standards Australian New Zealand
"gap filler"	The design of the Scheme to regulate GMOs that existing regulatory schemes were not regulating (for human food, human therapeutics, veterinary medicines, agricultural chemicals and industrial chemicals). It also refers to the regulation of GMOs in the research sector.
Gene Drive	Gene drives are genetic elements that are favoured for inheritance, and which can therefore spread through sexually reproducing populations at a greater rate than genes with standard Mendelian inheritance.
Gene 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 GT Act
Genetically modified organism	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.
Genetic engineering	Introduction of DNA, RNA, or proteins manipulated by humans to effect a change in an organism's genome or epigenome
Gene transference	(Horizontal gene transfer). Movement of genes between populations of otherwise distinct species.
Genome	The complete sequence of DNA or RNA in an organism.
Genomics	The study of an organism's entire genetic makeup.
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.

Term	Definition
GMO	See Genetically modified organism
GM product	See Genetically modified product
GT Act	The Gene Technology Act 2000 (Cth)
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 Committee
LGFGT	Legislative and Governance Forum on Gene Technology
Lock-step	When changes are made to the GT 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.
NHMRC	National Medical Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
OGTR	Office of the Gene Technology Regulator
Organism	Any biological entity that is viable; or capable of reproduction, or capable of transferring genetic material.
Process Trigger	A form of regulation emphasising the role of technique as the determining factor in constituting a GMO.
Product Trigger	A form of regulation that emphasises 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 traits.
R&D	Research and development
Regulator	The Gene Technology Regulator
Review	2017 Review of the National Gene Technology Regulatory Scheme
Risk tiering	The use of differing levels of regulation to address the differing levels of inherent risk associated with certain organisms or modifications.
Scheme	National Scheme for the Regulation of Gene Technology
SDN-1	Use of site-directed nucleases to cause unguided repair of a targeted double-strand break (i.e. no template is used).
Somatic modification	Modifications to an individual which would not be passed on to its offspring.
Stacked traits	The insertion of multiple modifications within the one organism.

Term	Definition
State moratorium	State legislation which puts restrictions on the dealings which can be undertaken with GMOs in that state, for marketing purposes.
Substantial equivalence	Demonstration that a GMO or GM product is as safe as its traditional counterpart.
Synthetic Biology	An emerging area of research that can broadly be described as the design and construction of novel artificial biological pathways, organisms or devices, or the redesign of existing natural biological systems.
Technical Review	2016-17 Technical Review of the Gene Technology Regulations 2001.
TGA	Therapeutic Goods Administration
Transgenic	A genetically modified organism containing genes from another species.
Trigger	The factor which determines if a thing is considered by regulation or not.

APPENDIX A

Scheme policy and regulatory mechanisms

Scheme policy mechanisms

The Scheme uses policy mechanisms that include:

- An Intergovernmental agreement on a nationally consistent approach to regulation – the Gene Technology Agreement;[i]
- Intentionally broad *definitions* for the Scheme[ii,iii] to capture known and unknown technologies;
- A *'precautionary approach'* to account for any lack of scientific certainty;[iv]
- Two emergency response mechanisms (used in specific circumstances and after receiving specific advice) to address actual or imminent harm to people or the environment:
    - An Emergency Dealing Determination allows the Commonwealth Minister responsible for gene technology to expedite an approval of dealings with a GMO; [v]
    - An Emergency Regulation can be made under the Commonwealth Act to declare a particular thing, or class of things, to be a GMO; [vi]
- *to address science based issues* – Legislation to be administered by a regulator to:
    - assess evidence about risks;
    - consult with the public, experts and other agencies.
- *to address non-science issues* – Policy principles and guidelines that address social, cultural and ethical considerations can be issued by the ministerial council for gene technology (the Legislative and Governance Forum on Gene Technology, or LGFGT), and the Regulator cannot issue a licence that is inconsistent with these principles.[vii,viii]

Scheme regulatory mechanisms

The Scheme provides the regulator with tools to regulate gene technology and support compliance to meet the objectives of the Scheme. These include:

- Support and funding to:
    - Develop and communicate educational and guidance materials that provide transparency around how they make decisions and facilitate compliance with the rules;
    - Develop relationships and engage with a broad range of stakeholders to enhance confidence and trust in the regulator and the rules;
    - Research and monitor emerging issues and science to gather intelligence to inform regulatory operations and advice to the Scheme;
    - Seek advice from technical experts, other regulators, the regulated community and the public;
    - Appoint people with the necessary skills and expertise to provide technical advice, assess the risks and scientific evidence and monitor compliance;

- Provide appropriate facilities and resources necessary to undertake risk assessments and promote and monitor compliance; and
- Consider policy principles issued by the Forum to guide decision making.[ix]

- Legislated powers that allow the regulator to:
  - Develop regulations for the Governor-General of the Commonwealth to make for the regulatory framework;
  - Review regulations within the regulatory framework;
  - Approve licences and certify people, places, activities, organisms and products;
  - Place conditions on licences and certifications, which the regulated community must comply with;
  - Gather data to prepare advice and reports for government and the public to maintain transparency and accountability of decisions;
  - Monitor and enforce compliance; and
  - Take punitive actions against individuals and organisations that are non-compliant.[x]

A graduated approach to compliance management is proportionate to the risks posed by the non-compliance. It encourages voluntary compliance at a lower cost (to the regulator and the entity) than at higher compliance responses.[xi]

The hierarchy of possible compliance responses available to the regulator are outlined in Figure 3:[xii]

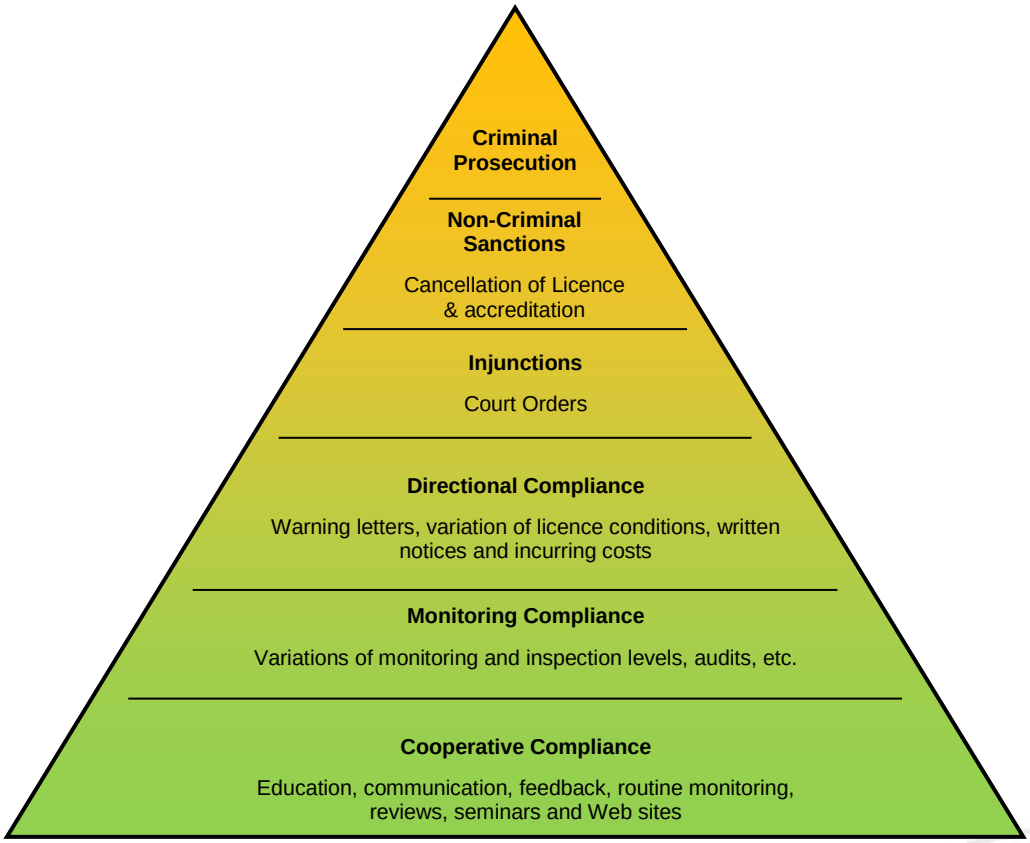

Figure 3: Hierarchy of compliance strategies

[i] Commonwealth Department of Health website, The Gene Technology Agreement, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-agreement

[ii] Further information and the definitions of a gene technology, a GMO, a dealing etc. are at: Federal Register of Legislation, Gene Technology Act 2000, Part 2, Division 2 – Definitions, available at https://www.legislation.gov.au/Details/C2016C00792

[iii] Federal Register of Legislation, Gene Technology Regulations 2001, Schedule 1A, Schedule 1, available at https://www.legislation.gov.au/Details/F2016C00615

[iv] The Gene Technology Act (section 4(aa)), outlines a 'precautionary approach', where regulatory actions are not postponed due to a lack of scientific certainty, and are balanced with efficiently protecting human health and safety and the environment.

[v] Commonwealth Department of Health website, Guidelines for emergency response under the Gene Technology Act 2000 and the Gene Technology Agreement, Part 2A –Emergencies, item 13, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/gtmc-emergency+response+guidelines

[vi] Commonwealth Department of Health website, Guidelines for emergency response under the Gene Technology Act 2000 and the Gene Technology Agreement, Part 2A –Emergencies, item 14, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/gtmc-emergency+response+guidelines

[vii] Commonwealth Department of Health website, The Gene Technology Agreement, Recitals available at http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-agreement

[viii] Federal Register of Legislation, Gene Technology Act 2000, Division 2 – Licence applications s.43, available at https://www.legislation.gov.au/Details/C2016C00792

[ix] Office of the Gene Technology Regulator, About the Regulator, available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/about-regulator-1

[x] Office of the Gene Technology Regulator, Monitoring and Compliance Section Protocols, Compliance and Enforcement Policy, and Monitoring Protocol, both available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mc-protocols-1

[xi] Australian National Audit Office, Administering Regulation, Achieving the right balance, page 46, available at https://www.anao.gov.au/sites/g/files/net616/f/2014_ANAO%20-%20BPG%20Administering%20Regulation.pdf

[xii] Modified from material supplied by OGTR