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ISSUES PAPER

National Gene Technology Scheme
An Australian, State and Territory Governments Collaboration

Implementing Recommendations of the Third Review of the National Gene Technology Scheme: Phase 1

Modernising and future proofing the National Gene Technology Scheme

Implementing recommendations of the Third Review of the National Gene Technology Scheme

Design 2B Advertising and Design

Contents

Acronyms

Acronym	Term
CCI	Confidential Commercial Information
COAG	Council of Australian Governments
CRISPR	Clustered Regularly-Interspaced Short Palindromic Repeats
DIR	Dealings involving intentional release into the environment
DNA	Deoxyribonucleic acid
DNIR	Dealings not involving intentional release into the environment
EDD	Emergency dealing determination
FSANZ	Food Standards Australia New Zealand
GM	Genetically modified
GMO	Genetically modified organism
GT	Gene Technology
GTSC	Gene Technology Standing Committee
IBC	Institutional Biosafety Committee
NHMRC	National Health and Medical Research Council
NLRDs	Notifiable low risk dealings
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator
PC	Physical containment
RARMP	Risk assessment and risk management plan
SDN	Site-directed nuclease
TALENs	Transcription activator-like effector nucleases
TGA	Therapeutic Goods Administration
ZFN	Zinc Finger Nuclease

Purpose of this paper

This paper is part of a consultation process to support the implementation of the recommendations arising from the Third Review of the National Gene Technology Scheme (the Review). It assumes knowledge of the Final Report on the *Third Review of the National Gene Technology Scheme, October 2018* (Final Report) and does not seek to reopen issues already considered through the Review. The paper builds on the extensive input already provided through stakeholder submissions, in a manner that supports a collaborative approach to workable solutions.

This paper informs the first phase of open consultation to progress the Review recommendations prioritised by the Ministerial Forum under their Action Plan. The first three key priorities to be addressed are definitional issues, risk proportionate regulation and reducing regulatory burden through streamlining. This paper provides discussion on each of these and seeks feedback on key factors that will guide the assessment of options for change.

Overview

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 to protect the environment, from the risks associated with the dealings or activities with genetically modified organisms (GMOs).

In Australia, activities involving GMOs (living things that have been modified by gene technology) are subject to regulatory oversight using a risk-based approach.

Regulation through the Scheme is a joint responsibility of all state and territory governments and the Commonwealth Government, outlined by the intergovernmental Gene Technology Agreement 2001 (the Agreement). Commonwealth and state legislation provides national coverage for the regulation of GMOs, working in conjunction with, and complementing, other regulatory frameworks that deal with genetically modified (GM) products.

The Third Review of the National Gene Technology Scheme (the Review) involved more than a year of consultation with the many and diverse stakeholders. The Review focused on future-proofing the Scheme, in a global environment where governments and citizens are discussing access to new technologies and the perceived benefits, as well as regulatory approaches to manage future advances in both gene technology and biotechnology more broadly.

The Legislative and Governance Forum on Gene Technology (the Forum) is the ministerial body charged, through the Agreement, with responsibility for governing and ensuring the national

consistency of the Scheme. In October 2018, the Forum endorsed the Final Report, outlining recommendations addressing technical, regulatory, governance and social and ethical issues – some of which required further investigation. The Forum also agreed to an Action Plan to implement the recommendations over the short, medium and long term.

The Forum Action Plan has determined priorities for 2019–20. These include commencing work to:

- Update definitions to ensure the Scheme remains fit-for-purpose and agile in an environment of rapidly developing technology, while supporting innovation now and into the future (Part 1).
- Ensure risk proportionate regulation through risk tiering. This work will seek to consider appropriate levels of regulation, ranging from technologies with histories of safe use through to emerging technologies. This will ensure regulation remains commensurate with risk, supports innovation and reduces unnecessary regulatory burden, while maintaining adequate protections for people and the environment. This paper discusses the regulatory gaps and overlaps within the whole system, and explores possible ways in which these might be addressed (Part 2).
- Reduce regulatory burden through streamlining administrative processes and regulatory requirements. This is the focus of Recommendation 10 and is closely linked to Recommendation 9, which looks to introduce additional risk tiering. The Review identified specific areas that could be better streamlined, including for low-risk dealings, facility certifications and variations. Introducing changes to improve the timeliness of application processing were also identified areas for improvement (Part 3).

Part 1
Definitions to support the National Gene Technology Scheme

Introduction

Definitions in the *Gene Technology Act 2000* (the Act) were originally cast broadly to ensure they did not become outdated and remained effective in response to rapidly changing technology. The recent *Third Review of the National Gene Technology Scheme* (the Review)[1], highlighted the need to update some definitions to clarify the scope of regulation in light of technological advances. This update also serves as an opportunity to future-proof the National Gene Technology Scheme (the Scheme), and to consider whether any new definitions are required.

When the definitions were first drafted in the late 1990s, the Scheme was primarily focused on the agricultural sector. Since that time, technological advances have led to an expansion in applications and uses in other areas, including in medicine and industrial production. The relevance of some terms have changed with the emergence of some of these technological advances. The Review recognised the need to consider how humans receiving germline therapies, or those who may inherit genetic changes due to these therapies, are captured by the Act.

To an extent, definitional modifications, supported by guidance material provided by the Regulator, could address many of the existing concerns. For example, exclusion of humans from the definition of a GMO would clarify that humans receiving gene therapies are not treated as GMOs. This could, however, create a regulatory gap in relation to ensuring the safety of research into human gene therapies that could be heritable, and their medical applications.

Modifying legislative definitions may not be the only, or even the most immediate, way to address the issues identified through The Technical Review of *Gene Technology Regulations 2001* and the Third Review. Indeed, it is important to first clarify the regulatory system in which the current or modified definitions will apply. As broader system issues are also currently being considered, a number of challenges do exist.

This part summarises the issues that relate to definitional modifications or additions, and explores the rationale for change. The section also explores approaches to modifying definitions which take account of the broader change agenda, including a framework for how and when any definitional updates might be implemented.

1 This paper assumes knowledge of the Final Report on the *Third Review of the National of the National Gene Technology Scheme, October 2018* (Final Report) – https://www.health.gov.au/internet/main/publishing.nsf/Content/011C554B9847D6F0CA258169000FCBBE/$File/Final-Report-Oct2018.pdf

1. The Third Review's findings and recommendations

The Review found that while the Scheme is working well overall, it needs to remain agile to deal with rapidly developing technologies, changing trends in the application of gene technology and international developments. The Review also highlighted the need to improve public awareness and address community concerns about gene technology.

Two recommendations of the Review relate directly to definitional considerations.

RECOMMENDATION 4:

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

RECOMMENDATION 6:

a) the definition of a genetically modified organism under the *Gene Technology Act 2000* (Cth) be amended to clarify that humans are not [considered to be] GMOs; and that

b) subject to consideration, the COAG (Council of Australian Governments) Health Council might also consider whether additional regulatory oversight is needed for humans who may receive or inherit germline therapies (or other somatic therapies not within the remit of the Scheme). The COAG Health Council should also consider which regulatory (or other) body would be most appropriate to undertake such oversight.

The above two recommendations, in combination with Recommendation 9 (introducing risk tiering to ensure risk commensurate regulation and to introduce flexibility to move organisms between categories) and Recommendation 10 (streamlining regulatory requirements and processes), are overarching recommendations that have implications for all the other recommendations.

Definitional scope

The Review found that some definitions in the *Gene Technology Act 2000* and *Gene Technology Regulations 2001* may not appropriately classify a range of advances in technology. The aim is to update these definitions to appropriately capture and regulate genetically modified organisms that may pose a risk to the health and safety of people and the environment, while not over-regulating organisms that pose little or no risk (taking into account likely exposure and appropriate controls). Recent amendments to the Gene Technology Regulations[2] have taken steps towards this goal.

2 *Gene Technology Amendment (2019 Measures No. 1) Regulations 2019*, https://www.legislation.gov.au/Details/F2019L00573

However, further work is required to provide the regulatory clarity and flexibility required to ensure that any definitional changes do not result in perverse or unexpected outcomes.

Attachment A maps the interdependencies between the prioritised recommendations and other recommendations. While it may be possible to implement recommendations in interrelated clusters, a number of identified interdependencies will need to be taken into account in progressing this work. These interdependencies mean that it will be difficult to fully resolve definitional amendments, for example, before a number of other potential changes to the Scheme are addressed.

Definitional consistency

In both Australian and international contexts, the value of having definitional consistency is well understood in a number of regulatory schemes, as is recognition that definitions have a primary role in the classification of technologies and their regulatory requirements.

While there are moves towards international alignment of approvals on some fronts, full international harmonisation is unlikely in the near future, as each country has very different legislative frameworks and approaches to the regulation of GMOs.

Regardless, "any proposed change to definitions should take into account concurrent work, both nationally and internationally", to ensure any broader implications are addressed and to take advantage of any opportunities for consistency.

Humans as GMOs

The Scheme was not designed to regulate humans — including those who receive germline or somatic therapies and those who inherit modified traits.

While scientific advances in gene technology provide potential opportunities to treat significant medical conditions and genetic diseases, there are ongoing moral and ethical debates which must be considered. Regulatory oversight of the technology to genetically modify humans, either in ways that are not able to be passed on to offspring (somatic changes), or those that are heritable (germline changes) must also be considered.

Considerations also need to take account of the evolving international environment, as well as the benefits of national collaboration across the health sector, to identify appropriate mechanisms for managing human genetic treatments.

Connecting definitional matters with concurrent work

In light of the recent Senate Standing Committee on Community Affairs inquiry into the *Science of mitochondrial donation and related matters*[3], definitional issues (Recommendation 6) will need further consideration to ensure appropriate management of risks related to mitochondrial donation and other such techniques. Consideration of this new development also accords with the Legislative and Governance Forum on Gene Technology (the Forum) direction that *'any changes to definitions should take into account concurrent work, including relevant domestic reviews and ongoing work internationally'*.

3 Science of mitochondrial donation and related matters, extracted from: www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MitochondrialDonation

Impact on implementation timeline

The above developments, together with due consideration of other changes to the Scheme arising from Review recommendations, are likely to extend the timeframe for full implementation of all necessary definitional updates. However, this work is necessary to ensure the objective of the Act is maintained.

2. Objectives of definitional changes

With such complex interdependencies and long reaching implications, it is important that work to progress definitional updates is guided by agreed objectives. For example definitions within the Scheme must:

- maintain high level protection goals for human health and the environment;
- remove ambiguity and the potential for unintended interpretations;
- provide clarity around the scope of regulation for both existing and new technologies and their products;
- be based on rigorous scientific analysis;
- increase the transparency of, and maintain public confidence in, the regulatory framework;
- provide certainty in the applicable regulatory pathway;
- support a risk-proportionate model of regulation;
- help future-proof the Scheme and provide flexibility to meet changing technologies; and
- reflect national and international conventions in the usage of gene technology terms as much as possible, and avoid unintended consequences.

QUESTION 1:

What other objectives might guide the updating of definitions?

3. Definitional issues

The impact of definitions on regulatory flexibility

How and where a term is defined in the legislation can have a significant impact on how responsive the term is to change, and thus how effective it is.

The current regulatory framework defines a GMO and gene technology[4] in the *Gene Technology Act 2000*, as follows:

genetically modified organism means:

a) an organism that has been modified by gene technology; or

b) an organism that has inherited particular traits from an organism (the ***initial organism***), being traits that occurred in the initial organism because of gene technology; or

c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;

but does not include:

d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or

e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.

gene technology means any technique for the modification of genes or other genetic material, but does not include:

a) sexual reproduction; or

b) homologous recombination; or

c) any other technique specified in the regulations for the purposes of this paragraph.

The *Gene Technology Regulations 2001* then list some techniques that are not gene technology and organisms that are not GMOs.[5]

The current system, where broad definitions are included in the Act with specific exclusions in the Regulations, has proved satisfactory and workable to date. The Review recommended maintaining the *'process-based trigger as the entry point for the Scheme: that is the GMO definition framed around the gene technology process being applied to modify an organism'* (Recommendation 8). This was in recognition of the effectiveness of this structure to date, and the likely complexity of departing from a process-based trigger. However, as has been highlighted through the Review, it is not a system that responds efficiently to change. Any amendments – to the Act or the Regulations – take time, making it difficult to manage risk by quickly changing the scope of what is, or isn't, regulated.

4 Section 10 – Definitions, of the *Gene Technology Act 2000* https://www.legislation.gov.au/Details/C2016C00792

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

Capturing emerging technologies

For an organism to be regulated under the Scheme, it must first meet the definition of a GMO under the Act. This definition encompasses all organisms that pose a risk to human or environmental safety. Conversely, the definition of a GMO should not be so broad as to inadvertently include naturally occurring mutant organisms or those that pose negligible risk to human health or environmental safety.

The legislation is currently designed to regulate dealings with GMOs. To do this, it does not specifically regulate the technologies that can create GMOs. It is becoming clear that advances in technology are outpacing the current legislative framework's ability to respond in a timely manner. The use of definitions to determine what is regulated brings benefits and challenges.

While this issue will be further explored as part of the discussion of risk tiering and regulatory flexibility recommendations (Recommendations 9 and 13), principles-based regulation may be part of the way forward. Principles-based primary legislation sets out more general, higher-level provisions, focusing more on outcomes than specifying the process of how particular outcomes should be achieved. Operational detail is then prescribed in delegated legislation[6] and guidance materials and codes which enable greater regulatory flexibility and future-proofing.

QUESTION 2:

How might we improve the regulatory flexibility of definitions within the Scheme, whilst maintaining protections for human health and the environment?

6 Delegated legislation, also referred to as secondary legislation, is legislation made by a person or body other than Parliament. The function of delegated legislation is it allows the Government to amend a law without having to wait for a new Act of Parliament to be passed.

Regulating humans under the Scheme

A human who receives treatment that modifies their reproductive cells (germline), rather than their somatic non-reproductive cells (somatic), or who inherits modifications to germline cells, would appear to be within the scope of the Act. However, the Scheme was neither intended nor designed to regulate humans.

The Explanatory Memorandum to the Gene Technology Bill 2000 notes the intent of the current definition of a GMO, which excludes humans undergoing somatic cell gene therapy from being considered as GMOs:

> *[…] "human beings are excluded from the definition of a GMO to ensure that a person who has undergone somatic cell gene therapy (for example, treatment for cancer) is not a GMO (as defined in this legislation), thus requiring the person to be licensed for the rest of their lives because they have been modified by techniques of gene technology. The conduct of human gene therapy will, however, continue to be regulated by the TGA[7] and, in the case of research involving human trials, also overseen by the National Health and Medical Research Council. The Gene Technology Regulator would also be involved if the work involves a live or viable GMO (presenting possible occupational health and safety or environmental risks)"[8].*

While the Review recommended that the definition of a GMO in the Gene Technology Act be amended to clarify that humans are not [considered to be] GMOs, and some stakeholders have suggested modifying the definition to read a GMO 'does not include a human being', recent developments suggest that there may not be a simple solution. A key example is the current uncertainty about whether mitochondrial donation is a form of germline modification, and the need for regulatory certainty around this development.

7 Therapeutic Goods Administration
8 Gene Technology Bill 2000 – Explanatory Memorandum

The Senate Standing Committee on Community Affairs inquiry into the *'Science of mitochondrial donation and related matters'* [9] has recommended further work be undertaken, including considering *"whether mitochondrial donation is distinct from germline genetic modification"*. The committee also recommended the findings be used to inform future legislative process, and that the Minister for Health take the findings of the inquiry report to the COAG Health Council to progress the implementation of the report's recommendations with states and territories.

This recommendation is consistent with the Review's recommendation that *"subject to consideration, the COAG Health Council might also consider whether additional regulatory oversight is needed for humans who may receive or inherit germline therapies (or other somatic therapies not within the remit of the Scheme). The COAG Health Council should also consider which regulatory (or other) body would be most appropriate to undertake such oversight."*[10]

The two relevant acts regulating mitochondrial donation are the *Prohibition of Human Cloning for Reproduction Act 2002* (sections 13, 15, 18 and 20) and the *Research Involving Human Embryos Act 2002* (section 20).

The recommendation to exclude humans from the Scheme will require consideration by the COAG Health Council, in consultation with the National Health and Medical Research Council (NHMRC) and stakeholders.

This process will ensure that any intersection between the Gene Technology Act and the NHMRC legislation is thoroughly considered in line with Recommendation 21 of the Review, but will mean that the definition of a GMO will not be able to align with Recommendation 6 in the short term.

QUESTION 3:

What other issues should be taken into account when considering how best to ensure that humans are not regulated as GMOs?

9 Science of mitochondrial donation and related matters, extracted from: www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MitochondrialDonation

10 Final Report on the *Third Review of the National of the National Gene Technology Scheme, October 2018* (Final Report) p29 https://www.health.gov.au/internet/main/publishing.nsf/Content/011C554B9847D6F0CA258169000FCBBE/$File/Final-Report-Oct2018.pdf

Definitions and terms for potential updates

In addition to the definitions for 'genetically modified organism' and 'gene technology', the Review also identified other terms that may require updating, including 'deal with' and 'other genetic material'.

Stakeholders also identified additional terms that may require defining, including 'dealings', 'environmental release', 'somatic cell nuclear transfer', 'history of safe use', 'gene drive', 'null segregants' and 'trans-grafting'.

The need to have agreed definitions that distinguish mutagenesis, cisgenesis, intragenesis and transgenesis from other processes was also suggested. Terms related to new techniques such as CRISPR, SDN, TALENs, ZFN, ODM, epigenetic modifications, synthetic biology and gene silencing were also suggested as terms that could benefit from agreed definitions.

Any determination about which terms to define and how to define them, should be considered against the intended objectives (refer to Section 4.3 above). For example, definitions should provide legal clarity and consistency without adding complexity or compromising flexibility to ensure the Scheme's effectiveness into the future.

The field of synthetic biology is rapidly expanding and it is not clear what type of organisms can or cannot be generated. A definition that is valid now may not be fit for purpose in the near future, as it may become too restrictive and limited to understanding at a particular point in time. Therefore such a definition while temporarily removing ambiguity now may hinder the objective of future-proofing the scheme.

Careful consideration is also required to understand how the definitions impact on and operate across various sectors within the Scheme, particularly any interfaces with product regulators.

QUESTION 4:

Given the benefits and challenges of defining terms in legislation, what other mechanisms might be used to provide the clarity required?

Part 2
Risk-proportionate regulation through risk tiering and appropriate regulatory approaches

Introduction

Risk-proportionate regulation remains a contemporary approach to regulation which ensures regulation is undertaken in a way that does not impose any unnecessary requirements when managing any risks posed by an activity.

Appropriate regulatory oversight is needed where risk may exist, particularly where safety has not yet been established. However, reducing unnecessary barriers within a risk-proportionate framework can help exploration of new areas, for example the potential economic and health benefits of gene technology.

Risk tiering is one method that can help ensure regulatory effort is commensurate with risk. A risk tiered approach provides a systematic way of determining what level of regulation is appropriate, such as for particular characteristics, features or traits of a GMO, based on their level of risk to humans and/or the environment.

This approach would help reduce regulatory requirements that provide no additional protection for the health and safety of people or the environment, thereby focussing regulatory effort where the risks are unknown, difficult to quantify, less well characterised or known to be high.

Regulatory burden is only partially improved by risk tiering if there is no way to efficiently move between tiers or categories. Long timeframes for legislative change mean that it is not possible to quickly adapt to technological advances. There is an identified need to explore how the Regulator might respond more appropriately and flexibly. This might include the ability to efficiently move organisms between categories where their evaluated risk is reduced, or conversely where new risks or other relevant factors become apparent.

This part summarises the issues and findings that relate to risk proportionate regulation and explores the rationale for change.

1. The Third Review's findings and recommendations

The Third Review of the National Gene Technology Scheme (the Review) found regulators and stakeholders agreed that regulation should be commensurate with the level of risk.

Review Recommendation 9 relates directly to a risk-tiered approach to regulation.

RECOMMENDATION 9:

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

a) the level of regulation remains proportionate to risk, and protects against under regulation and over-regulation; and

b) where appropriate, there is flexibility to move organisms between categories, based on identification of new risks, a history of safe use, or other relevant factors.

Recommendation 20 has a similar intent to Recommendation 9.

RECOMMENDATION 20:

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

Risk proportionate regulation cannot be considered in isolation from Recommendations 10 and 13.

RECOMMENDATION 10:

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

RECOMMENDATION 13:

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

a) enabling the Gene Technology Regulator to make decisions on the applicability of regulation to any technological developments, until such time as a policy approach has been agreed; and

b) introducing elements of principles-based regulation to some parts of the Scheme, focusing on areas of the Scheme with a history of safe use.

The Review acknowledged that elements of risk tiering already exist within the current Scheme in the form of authorisation categories[11]. However, the Review found that there are other potential areas where risk tiering might be incorporated into the Scheme, and called for further investigation to determine the most appropriate tiers, or categories, for different applications of gene technology and the resulting GMOs. This further investigation should consider the inherent risk of a particular application/technology, types of gene and traits introduced and whether there is a history of safe use.

The Review highlighted the opportunity to develop a more simplified or streamlined pathway for organisms that have a demonstrably low level of risk, noting a long history of safe use.

Humans have been modifying living things for hundreds of years to improve them in various ways, for example crops grown for agriculture. Techniques used include selective breeding, plant cloning/grafting and chemical or radiation induced mutagenesis. These techniques may cause changes in the genome, similar to naturally occurring mutations. However using these techniques can be very 'hit and miss' potentially with many 'failures' before a commercially viable option is realised. Any safety issues arising are addressed during the many life cycles involved in developing a trait through to commercialisation.

The application of some new gene technology techniques, such as gene editing, have the potential to make the early 'sifting and sorting' process (to find an acceptable trait) much more efficient. The benefits for early research and trait identification are clear. However, there are many other steps involved in developing a new product line (be it selective breeding or a GMO) to the point where it is ready to be used therapeutically or released into the environment for cropping.

There is a view that the regulatory scheme should recognise this history and simplify regulation of well-studied traits and well-characterised GM plants.

A key issue identified through the Review was the potential inequalities arising from the 'one size fits all' basis of the Scheme. The Review acknowledged the need for increased flexibility within the Scheme so that changes in scientific understanding of risk can be responded to appropriately, to enable differentiated regulation based on relative risk.

11 Referred to as Exempt, Notifiable Low Risk Dealing (NLRD), Dealing Not involving Intentional Release (DNIR) and Dealing involving Intentional Release (DIR) categories.

2. Objectives of risk-proportionate regulation

When the Scheme was first established in 2000, gene technology and GMOs were relatively new. As gene technology was in its early stages and some risks were unknown, a more precautionary approach was taken.

During the intervening two decades, there has been considerable growth in the scientific understanding of gene technology techniques and risks associated with their applications and products. Over this period, for intentional release into the environment, the number of therapeutic/medical related applications has been increasing. Across all types of authorisations medical related applications represent approximately 70% of all applications received.

While further understanding about the science and risks continues to develop, regulatory experience could help design a more sophisticated system which is responsive, while continuing to be protective, responsible and scientifically rigorous.

It is important that work to progress a risk-proportionate approach is guided by agreed objectives, including that it should:

- efficiently respond to changes in scientific understandings of GMOs and the risks they may pose;
- facilitate reduced regulatory oversight where the risk is known to be low and/or there is a long history of safe use, and increased regulatory oversight where the risk is unknown, less well quantified/characterised or known to be high;
- address existing gaps and overlaps in the current system, including any inconsistencies in the regulation of GMOs that pose the same or similar level of risk;
- increase the transparency of the Scheme in terms of categorisation of risks and the criteria for assigning a GMO to a risk category;
- maintain public confidence in the regulatory system;
- maintain the rigour of the Scheme, without increased complexity or regulatory burden; and
- not compromise the Scheme objectives to protect human health and the environment.

QUESTION 5:

Are there any other key objectives/considerations that should be taken into account in designing a risk-proportionate approach to regulation?

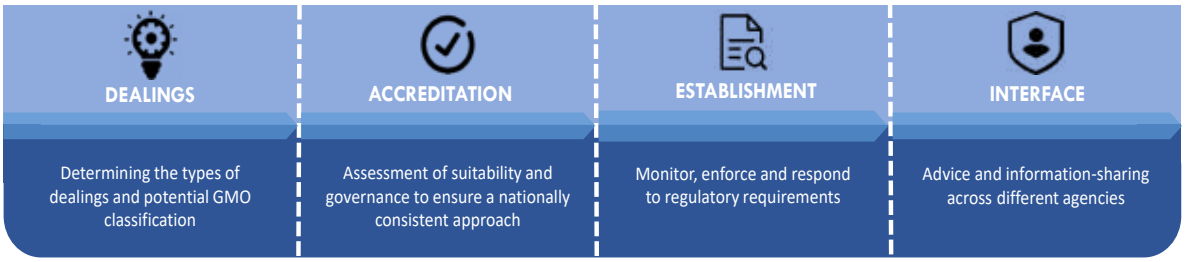
3. Enhancing risk-proportionate regulation

Risk proportionate regulation as a whole-of-system approach

The Review found that in order to 'future-proof' the Scheme, a body of work should be undertaken to review the existing risk tiering categories in order to develop a contemporary approach. Further investigation is required to determine the most appropriate tiers for different applications of gene technology and the types of regulatory treatment to be applied to each tier.

In Australia GMOs, dealings involving GMOs, and GM products are regulated within a system of interconnected regulatory schemes. By mapping out the various systems used to manage risk, it is then possible to better understand where the regulatory gaps and overlaps are, and hence the tiers required.

The key interfaces within the Scheme are shown below.



Risk tiering as a means to achieve risk-proportionate regulation

Currently, GMO dealings are divided into two main categories, based on whether or not they "involve intentional release of a GMO into the environment". Risk tiers are already established and working effectively for those dealings not involving the intentional release of a GMO into the environment (also known as contained dealings), with three risk tiers currently in place:

- Exempt dealings involve well known GMOs that have previously been assessed as posing negligible risk to humans or to the environment. The Regulations describe exempt dealings, and the only requirement is that GMOs are kept contained.
- Notifiable low risk dealings (NLRDs), also described in the Regulations, have been assessed as low risk provided standard risk management requirements are followed, and the GMOs are contained in certified facilities. NLRDs receive oversight from Institutional Biosafety Committees (IBCs) and are notified to the Office of the Gene Technology Regulator (OGTR).
- All other contained dealings with GMOs, which must be licensed, following case-by-case assessment by the Regulator. This assessment considers any risks posed by the dealing and the tailored licence conditions necessary to protect the health and safety of people and the environment.

Attachment B: Classes of GMO dealings under the *Gene Technology Act 2000*, provides details of the authorisation levels, including current examples.

A risk-tiered approach also applies to Physical Containment (PC) facilities and the activities conducted within them. There are 4 PC facility levels, PC1 to PC4, in ascending order of security and stringent containment. The required PC facility level for the containment of a GMO dealing is governed by the level of risk it potentially poses to human health and the environment.

However, the Review identified that further investigation was required to determine the most appropriate tiers for different applications of gene technology.

Introduction of additional risk tiers, or sub-tiers within existing authorisation levels, might help to better differentiate risks. Such an approach could help increase the transparency of the Scheme, clarify regulatory pathways and increase certainty of the requirements for stakeholders early in research and planning phases. However, a key consideration would be to minimise any complexity this adds to the Scheme. One way to achieve this may be by providing clear criteria that identify risk thresholds to assist in decision-making pathways for various organisms.

QUESTION 6:

What additional risk tiers could be considered and what criteria could be applied to determining what falls in or out of any required tiers?

Is risk tiering the only way to ensure regulation is risk-proportionate?

The Review initially considered the idea of risk tiering on the basis of the type of organism (e.g. plant, animal, microbe etc.). However, tiering on this basis was not broadly supported, as there may be different risks associated with different classes of organisms, and this approach might also lead to potential inconsistency and unnecessary regulatory complexity.

Stakeholders also highlighted the idea of streamlining regulation for lower risk categories, supported by appropriate compliance mechanisms (such as audits) to ensure the Scheme remains responsible and risk-proportionate (matters relating to streamlining are discussed in detail in Part 3).

QUESTION 7:

Is the introduction of additional risk tiers the only way to ensure regulation is proportionate to the level of risk?

Introducing flexibility into the Scheme

With the advent of new and cost-effective genetic modification tools that are more precise and easy to use, the use of gene technology in new and diverse fields (including medical and industrial sectors) is expanding world-wide. Introducing flexibility into the Scheme could help to reduce regulatory impediments to the uptake of technological advances. Regulation should provide guidance and certainty to researchers working with rapidly changing technology.

Given the rapid advances in technology, improved risk tiering is only part of the solution for more risk proportionate regulation. There needs to be more efficient mechanisms to move organisms between tiers or categories where new risks or other relevant factors become apparent, or when risk status decreases.

The Review recommended that, to better respond to changes in scientific understanding and understanding of risk, consideration should be given to enabling the Gene Technology Regulator to make decisions on the applicability of regulation to technological developments, until a policy approach has been agreed (Recommendation 13).

Enabling the Regulator to make decisions in relation to new techniques, or new applications of existing techniques, based on scientific knowledge and evidence of associated risks, would be consistent with a risk-proportionate approach. However, the boundaries for such decisions would need to be clear and agreed.

QUESTION 8:

What principles or criteria should be applied in moving an organism/technique across risk-tiers?

Introducing elements of principles-based regulation

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'.[12]

The Review recommended the introduction of a principles-based approach to some parts of the Scheme, focusing on areas with a history of safe use. As discussed above, this would enhance the responsiveness of the Scheme in a rapidly evolving scientific setting.

Attachment C: Contributing elements to a legislative principles-based approach

12 Organisation for Economic Cooperation and Development. (2012). *Best Practice Principles for the Governance of Regulators, Chapter 1: Role Clarity*, p. 31. Retrieved July 10, 2018, from Organisation for Economic Cooperation and Development.

What is principles-based regulation?

Principles-based legislation focuses on the achievement of overarching outcomes by the regulated entities.

According to Professor Julia Black, London School of Economics and Political Science, principles are 'general rules … they express the fundamental obligations that all should observe'[13]. Black states that principles-based regulation avoids 'reliance on detailed, prescriptive rules and relies more on high-level, broadly stated rules or principles'. Principles might apply 'in situations where no rule or guidance yet exists'.

Principles enable supervisors and enforcers to police the spirit of the rules, avoiding 'creative compliance' and the need for the rules to anticipate every possible situation.

Some characteristics of principles are:

- they are drafted at a high level of generality, with the intention that they should be overarching requirements that can be applied flexibly to a rapidly changing industry;
- they are purposive, expressing the reason behind the rule; and
- they have very broad application to a diverse range of circumstances.

In order to be operational, primary laws should be supported by delegated legislative instruments and guidance materials that are able to be adapted in a timely way in line with changes in technology and its applications.

QUESTION 9:

Are there any elements of the Scheme that would NOT benefit from a principles/outcome-based approach?

13 Black J, Hopper, M and Band C (2007). Making a Success of Principles-Based Regulation. Law and Financial Markets Review. Sourced from: https://www.researchgate.net/publication/263174265_Making_a_Success_of_Principles-Based_Regulation

Part 3
Streamlining regulatory requirements and processes to reduce regulatory burden

Introduction

Streamlining regulatory requirements through business process improvements is an ongoing consideration for the Gene Technology Regulator (the Regulator). To some degree, the Review provided greater clarity regarding specific options to progress streamlining of regulatory processes.

The Review identified a number of opportunities to streamline current regulatory arrangements across a range of areas, particularly for lower risk categories. These include revisiting, where appropriate, the current regulatory requirements for various classification levels, simplifying the regulatory processes such as application and facility certification processes, and harmonising relevant activities such as facility certifications and inspections undertaken by the OGTR.

The Review acknowledged that streamlining could help improve the operation of the Scheme, reduce unnecessary regulatory burden for stakeholders, and improve efficiency. While streamlining is an ongoing consideration in improving the operation of the Scheme, there may be some measures that could be implemented sooner, through more administrative mechanisms, while other measures might be subject to a legislative change process.

While consideration of a risk-proportionate approach to regulation focuses more on adjusting levels of regulatory oversight and addressing any potential regulatory gaps within the overall system, streamlining measures focus more on specific requirements and activities. These measures would make regulatory processes more efficient for regulated stakeholders, and address existing areas of duplication, overlap or inconsistency. As there are a number of bodies that undertake specific activities, the needs of the stakeholders that interact with the OGTR are taken into account in the following considerations.

This Part summarises the issues and findings that pertain to streamlining regulatory requirements and processes, taking into account the findings of the Review and a systems-mapping exercise that explored specific areas that might benefit from further streamlining.

1. The Third Review's findings and recommendations

Key issues raised by stakeholders in relation to streamlining included the time required for assessing applications, the 'one-size fits all' approach to new applications and applications for variations, and the potential overlap in the roles of the Regulator and Institutional Biosafety Committees (IBCs).

The Review heard from stakeholders that facility certifications and certification variations; reporting of notifiable low risk dealings (NLRDs); variations for dealings not involving intentional release to the environment (DNIR); and harmonising the inspection processes among regulators are key areas where further efficiency could be achieved. At a more immediate level, redesigning the application form for clinical trial applications and reviewing the classification levels of organisms were also found to be areas that could benefit from streamlining.

A summary of stakeholder proposals to streamline the existing regulatory requirements and processes can be found in the final report on the Review[14].

Recommendation 10 directly relates to streamlining.

RECOMMENDATION 10:

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

This recommendation has interdependencies with a number of other recommendations. Its implementation should be considered in conjunction with Recommendations 9 (introducing risk tiering to ensure risk commensurate regulation and the flexibility to move organisms between categories) and Recommendation 20 (regulation commensurate with risk). These two recommendations are the subject of consideration in Part 2 of this paper.

Recommendation 10 also relates closely to elements of Recommendation 21, particularly part (b) – reducing any unnecessary duplication amongst regulators.

RECOMMENDATION 21:

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

a) identifying opportunities to enhance communication mechanisms and linkages;

b) identifying any emerging areas where legislative or administrative changes can be made, to reduce any unnecessary duplication; and

c) adopting relevant effective mechanisms from other schemes (for example, the *Therapeutic Goods Act 1989* Special Access Scheme) where they may strengthen the Scheme.

14 ibid, (p42 & p43).

Recommendation 10 also interfaces with Recommendation 11 (better use of the GMO Register) and Recommendation 12 (reviewing current monitoring activities). These interdependencies need further exploration in terms of streamlining the regulatory arrangements.

Scope for streamlining

It may be possible to streamline certain requirements and processes more readily than others. Entities with roles under the gene technology legislation for example, IBCs, may also regularly identify ways to improve the efficiency of their internal operations. Some streamlining solutions may require better use of IT systems, and others may involve better role clarity about the processes.

It also may be useful to undertake educational programs to promote better practices among the various entities to minimise duplication and improve operational efficiency.

Work already under way

As stated above, a number of streamlining initiatives require more administrative than legislative change. The OGTR has initiated several continuous improvement projects to streamline administrative processes. These have involved consultation with regulated stakeholders at various stages of development to ensure that new processes reduce administrative burden. Examples include:

- Development of online forms to facilitate the submission of information and the processing of applications. Forms already available on the OGTR website are:
  1) certification of a Physical Containment Facility form;
  2) NLRD reporting form;
  3) accredited organisation annual report to the Regulator; and
  4) expert advisory committee nomination forms.
- Review of the PC3 facility guidelines.
- Consideration of how to improve licence conditions for future limited and controlled (field trial) plant licences.

These improvements are being undertaken with limited resources and don't require any legislative changes. Other streamlining initiatives could be identified to improve administrative processes without legislative change.

2. Objectives of streamlining measures

Streamlining regulatory requirements and processes impacts on all entities operating within the system. With such complex interdependencies, it is important that work to progress any streamlining initiatives is guided by agreed objectives. For example, streamlining should:

- maintain high level protection standards for human health and the environment;
- maintain public confidence in the regulatory system;
- support the Scheme to function as effectively and efficiently as possible;
- provide clarity around regulatory requirements and regulatory processes;
- ensure process improvements relating to applications for licences, organisation accreditation, facility certification and reporting of dealings ;
- remove ambiguity and the potential for unintended consequences;
- maintain the transparency of the regulatory framework;
- support a risk-proportionate model of regulation; and
- help future-proof the Scheme, by allowing the flexibility for further process improvements.

QUESTION 10:

What other objectives might guide streamlining of regulatory requirements?

3. Streamlining regulatory requirements and processes

Streamlining regulatory requirements

The Review identified areas within the Scheme where streamlining could produce benefits to the regulated community in terms of minimising time delays, and complexity and duplication in some regulatory processes. Key areas identified included facility certification, accreditation, GMO dealing authorisations, Confidential Commercial Information (CCI) provisions and other regulatory requirements.

There was strong support from stakeholders for implementing a simplified regulatory pathway for 'organisms that have a demonstrably low level of risk, organisms that have a history of safe use, organisms where no foreign DNA has been introduced, and where a highly characterised organism has been used'[15]. To implement a simplified regulatory pathway for 'low-risk' organisms, it is necessary to first establish the criteria to assign an organism to a risk category.

15 The Third Review of the National Gene Technology Scheme –October 2018 – Final Report (p40).

As identified by stakeholders, some of the areas where the regulatory requirements could be streamlined may include:

- reviewing the current classification levels for various organisms;
- reviewing schedules contained in the Regulations, more regularly;
- having a separate, simplified pathway for approving low-risk dealings and dealings involving low-risk organisms and techniques;
- reconsidering data requirements for the various authorisation categories;
- considering the feasibility of provisional or conditional approvals of facilities, subject to applications meeting prescribed criteria, noting these criteria must first be established;
- streamlining the process for extending some GMO dealing approvals, both in terms of the timeframe and in the minor nature of variations of organisms or techniques, where risk level remains the same;
  - criteria for assessing whether the risk level remains the same will need to be established;
  - it is also necessary to establish who has the responsibility to assess whether the risk level remains the same;
- considering a streamlined regulatory approach for small-scale field trial releases;
- aligning facility requirements with other similar regulators; and
- reconsidering consultation requirements for the higher authorisation levels.

These mechanisms require further careful consideration, and may involve a legislative amendment process.

QUESTION 11:

Are there any particular issues to be considered when streamlining any of these regulatory requirements?

QUESTION 12:

What mechanisms or tools would reduce the regulatory and administrative burden on the end user interacting with the regulator/regulatory system?

Streamlining regulatory processes

Throughout the Review, stakeholders also suggested process improvements. These ranged from removing the requirement for new NLRD numbers to be issued when NLRDs are varied, to devolving the responsibility for low-risk authorisations to IBCs.

Stakeholders also made specific suggestions on ways to streamline the regulatory processes, for example:

- reconsidering the duration/length of dealing approvals for various authorisation categories;
- better use of information technology systems, including a mechanism to track the progress of applications;

- accreditation process – taking into account whether an organisation has multiple IBCs, and whether an organisation has a strong track record of compliance;
- facility certification process including extension of certification, both in terms of timeframe and minor infrastructure variations;
- harmonising OGTR's compliance monitoring inspections and building inspections;
- addressing potential inefficiencies in requirements associated with CCI, particularly the impact of these provisions on licence application assessments;
- reporting processes; and
- changes to application forms.

Most of these mechanisms would require changes to administrative processes, noting that the OGTR has implemented a number of measures to improve the operation of the Scheme since the commencement of the Review.

QUESTION 13:

Are there any particular issues to be considered when streamlining any of these regulatory processes?

QUESTION 14:

Are there any other key processes that might be streamlined without impacting the safety of people or the environment?

Harmonising activities across the various regulators

GMOs, dealings with GMOs, and GM products are regulated within a system of interconnected regulatory schemes. Collectively, these schemes address the safety of a GMO throughout its lifecycle as it moves along an integrated regulatory pathway.

For example, in the case of a GM food product, the OGTR regulates the research and development, field trial and commercialisation phases of a GM crop. When that crop delivers a food product, its commercial use is regulated by FSANZ.

The interactions between the various stakeholders — both within and outside the Scheme, including other regulators — are not necessarily linear, and are often complex. For example, during the Review some stakeholders identified that harmonising relevant activities such as facility certifications and inspections, would help streamline processes.

QUESTION 15:

What specific areas are suitable for harmonisation between regulators? Are there any overlaps that could be removed?

Role of IBCs in a co-regulatory model

The role of an IBC spans its institutional commitments and requirements under s98 of the Act, including guidelines issued by the Regulator in relation to the accreditation requirements to be met by the organisation. An example is the establishment and maintenance of IBCs. For an organisation to be accredited it must establish, or have access to, an IBC.

IBCs assess whether or not proposals submitted by a person or organisation are sufficiently low risk and contained to be managed within the research environment (NLRDs). IBCs also review applications for field trials and full licence. IBCs assess the suitability of people undertaking the dealings and facility/containment requirements. They 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.

IBCs assist organisations by providing an interface with the OGTR and advising on the identification and management of the risks associated with dealings involving GMOs. IBCs must possess the requisite collective technical and scientific expertise. They must be consulted with, and used by organisations as required, for example, where the Regulations require that a NLRD requires assessment by an IBC.

IBCs vary in size and number within an organisation. They are not required to have an oversight of exempt dealings, although some do. Some organisations have multiple IBCs whereas others access IBCs established by external organisations.

IBCs play an integral role in the co-regulatory model and assist ensuring compliance with the Scheme's requirements. The Review identified support for devolving certification of PC-1 and PC-2 facilities and approval of contained dealings to IBCs. Some IBCs indicated they would prefer to receive a targeted educational program, in particular, in assessing applications for high-risk dealings.

QUESTION 16:

What are some of the ways in which the role of IBCs could be strengthened to achieve efficiencies in a co-regulatory model?

4. Key considerations

It is recognised that streamlining could occur at various stages, and cannot be considered in isolation from risk tiering and the flexibility to move organisms between risk tiers (Please see Part 2: Risk-proportionate regulation through risk tiering and appropriate regulatory approaches).

Some of the broader considerations relating to streamlining are outlined below.

(i) Legislative requirements

It is important to explore if there are existing legislative impediments to a more streamlined approach, both in terms of regulatory requirements and regulatory processes. For example, the timeframe for mandatory consultations and any duplication in the roles of the Regulator and the regulated community including the IBCs.

Currently, legislative amendments may be the only avenue available to introduce changes to most regulatory requirements and processes.

It would also be useful to explore avenues whereby the Regulator could be empowered to make decisions, as required, in an environment of rapid technological developments.

(ii) Regulatory requirements

Differentiating regulatory requirements and processes, based on an agreed, well-defined set of criteria could help reduce the regulatory burden. This would help increase the flexibility for the Regulator to make administrative adjustments without the need for legislative amendments.

(iii) Data and information requirements

The length of mandatory consultation processes and the data and information requirements have been identified as causing delays in the approval process.

For example, the Review identified an opportunity to streamline the current CCI provisions. CCI declaration applications are often submitted to the OGTR together with the licence applications to which they relate, however, there is not a legislated link between the applications. CCI declaration applications can be time consuming, and processing both applications divides OGTR resources. For complex or unclear CCI applications, this puts pressure on licence application assessment statutory timeframes. Furthermore, as CCI declarations don't expire, the information remains confidential unless the CCI status is revoked. There are high penalties for disclosure of CCI by the OGTR, even where the information has been made publicly available by the CCI applicant and the level of protection is no longer practically required or justifiable.

Work is required to identify the most appropriate mechanisms to reduce the negative impact of CCI declaration applications on the efficient and effective assessment of licence applications. Mechanisms that could be considered include:

- increasing the statutory timeframe for licence applications including CCI provisions; and/or
- introducing a stop-clock which could pause the statutory timeframe for licence application assessments while CCI matters are being clarified; and/or
- requiring a CCI application to contain all the information necessary to assess the claim for CCI before the Regulator commences assessment of the associated licence application; or
- allowing the Regulator to refuse a CCI declaration application if the application is not correctly made; and/or
- introducing an expiry date for CCI declarations.

QUESTION 17:

What could be some avenues that would empower the Regulator to make decisions about changes to regulatory requirements and processes deemed low-risk?

NEXT STEPS

This consultation paper is part of a consultation process undertaken to support the implementation of the recommendations arising from the Third Review of the National Gene Technology Scheme. It specifically seeks stakeholder views to inform the principles, objectives and criteria that can be applied to definitional updates, enhancing the risk-proportionate approach and streamlining.

Stakeholder views will be consolidated and considered to inform the next step to identify options. Further consultation will be undertaken to consider options to update definitions, enhance the risk-proportionate approach and streamline processes and requirements. The consultation will ensure that any options are feasible and achieve the agreed objectives, and the impact of each option is properly considered. In line with principles of good regulatory practice and regulatory assessment requirements, further consultation will include draft and final Regulation Impact Statements.

A series of further consultation papers will be prepared and consulted to support implementation of other review recommendations, in line with the Forum Action Plan.

How can I be involved?

The Ministerial Forum invites you to participate in this process to help the policy development process by providing a submission. Questions raised in this paper will guide you in providing your input.

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

All submissions received by the due date will be analysed and considered to inform the next steps in the implementation process. No responses will be provided to individual submissions. However, you may be contacted for further information or clarification of issues as necessary.

It is intended that submissions will be published on the website.

Lodging your submission

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

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

ATTACHMENT A

Intersection of primary recommendations of the Review

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

Recommendation 6: The Review recommends:

a) the definition of a genetically modified organism under the *Gene Technology Act 2000* (Cth) (the Act) be amended to clarify that humans are not [considered to be] GMOs, and that

b) subject to consideration, the COAG (Council of Australian Governments) Health Council might also consider whether additional regulatory oversight is needed for humans who may receive or inherit germline therapies (or other somatic therapies not within the remit of the Scheme). The COAG Health Council should also consider which regulatory (or other) body would be most appropriate to undertake such oversight.

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

a) the level of regulation remains proportionate to risk, and protects against under-regulation and over-regulation; and

b) where appropriate, there is flexibility to move organisms between categories, based on identification of new risks, a history of safe use, or other relevant factors.

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

The following table demonstrates direct connections between the full list of recommendations and these primary recommendations.

Recommendation	4&6: Definitions	9: Risk tiering	10: Streamlining
1: Future-proofing the Scheme	• Updating definitions assists in future-proofing to capture technological advances under the scope of the Scheme.	• Essential for 'updating and enhancing the operations of the scheme'. • Facilitates flexibility for new risks and history of safe use.	• Assists to 'enhance operations of the scheme'.
2: Maintaining Object of the Act	• Contributes to the Act's ability to provide strong legislative protections and regulatory certainty.	• Assists in 'assessing and managing the risks to human health and safety and the environment'.	• Regulatory requirements and processes should reduce the regulatory and certification burdens without diminishing the object of the Act.
3: Maintaining the Agreement	–	–	–
4: Updating definitions	–	• Definitions relating to GMOs directly correspond to how that organism is assessed for risk.	• Having consistent definitions in a domestic and international contexts has a primary role in the classification of technologies and associated regulatory requirements.
5: Synthetic biology	• Synthetic biology should continue to be regulated effectively by the Scheme and should be reflected in definitions accordingly.	• Current risk tiering was largely deemed appropriate by the Review. • Regulation should remain appropriate to address emerging risks.	• Best regulatory mechanisms should be considered to ensure appropriate regulation.
6: Excluding humans from definitions and regulations	• The definition of a GMO includes humans who have undergone certain genetic procedures and this needs to be addressed.	• Care needs to be taken to ensure that no additional risks emerge if humans are removed from the legislation.	–
7: Environmental release	• Environment is currently defined in the Act. However, 'environmental release' is not defined and may benefit from being so.	• The Review recommends application of current risk assessment and management methods. • Future work would involve consideration of how new risk-tiers could be applied to environmental releases.	• The Review suggests new license category with additional requirements.

Recommendation	4&6: Definitions	9: Risk tiering	10: Streamlining
8: Process-based trigger	• Clarifying the definitions of 'gene technology' and 'GMO' should help ensure the process-based trigger remains effective.	• Ensuring that regulatory requirements are commensurate with risk through introducing more risk tiering. • The role other regulators play is a key element of risk management.	• The product regulators help ensure that regulatory requirements are commensurate with risk. Streamlining will assist this.
9: Risk tiering	• Definitions should help clarify what needs to be regulated and how.	–	• Recognition of the role other regulators play in terms of risk mitigation • Risk tiering can streamline regulation for lower-risk categories.
10: Streamlining processes	• Having consistent definitions in domestic and international contexts, where possible, helps classification of technologies and associated regulations.	• Risk tiering can assist to streamline regulation for lower-risk categories. • Recognition of other Regulator's risk management practices may assist with streamlining processes.	–
11: GMO register	• Proposed changes may benefit from greater clarification in definition of 'history of safe use'.	• Would serve greater purpose as a mechanism to regulate low-risk GMOs via new lower-risk tiers.	• Register provides mechanism within the Scheme to regulate GMOs without specific authorisation for dealings.
12: Monitoring and enforcement	• 'DIY biology' and 'home lab' may need to be defined in the legislation.	• 'DIY biology' and democratisation of science should be accompanied by monitoring of scope and risks.	• The Scheme's current monitoring and enforcement was deemed adequate by the Review.
13: Regulation of new technology	• Clarifying the definitions should enable the Regulator to better respond to changes in scientific understandings.	• Flexibility to respond to changes will allow better understanding of risks from new technologies.	• Streamlining via enabling the regulator to make interim decisions is identified as a pathway to introduce more agility into the Scheme.

Recommendation	4&6: Definitions	9: Risk tiering	10: Streamlining
14: Governance and legislation	• Administrative and legislative options should be considered in updates made to definitions.	• Provides a clear structure to facilitate decision making	• Empowering the GTSC to more effectively consider and recommend legislative changes. • Allowing the LGFGT to delegate some work to GTSC.
15: International engagement	• In clarifying definitions, consideration should be given to international definitions and any potential trade implications.	• International research is critical to maintain the most contemporary risk framework. • Aligning the Australian system where possible will help international trade.	• The Review supports, where possible, coordination, harmonisation of policy positions and regulatory approval processes.
16: Maintaining governance mechanisms	• Appropriate frameworks assist good governance.	• Appropriate frameworks assist good governance.	• Legislative oversight should keep the Scheme agile.
17: National consistency	• All applicable legislation should align for the scheme to work	• All applicable legislation should align for the scheme to work	• All applicable legislation should align for the scheme to work
18: Moratoria	• Definitions should give due consideration to different requirements	• Consideration should be given to different approaches and international alignment.	-
19: Benefits in regulatory decisions	-	• The Review concluded a continued focus on technology risks and their management was appropriate.	• Consideration of benefits should not become a factor in regulatory decisions.
20: Regulation remaining commensurate with risk	• Definitions should help ensure appropriate risks remain within the scope of the Scheme.	• Reforms should ensure the Scheme is commensurate to level of risk posed. • OGTR will focus on higher-risk activity. • Lower-risk activity can proceed with appropriate regulation.	• A focus on higher-risk activity will allow better utilisation of resources. • The Scheme should not impose unnecessary regulatory burdens.

Recommendation	4&6: Definitions	9: Risk tiering	10: Streamlining
21: Intersection between the Regulator and legislation	• Ensuring, where possible, that definitions are consistent with other regulators.	• Identify potential mechanisms in other schemes.	• Identify and investigate solutions to overlapping regulatory oversight.
22: Funding mechanisms and levels	-	• If proposed changes accepted, has the potential to affect resource allocation.	• If accepted, proposed changes would have a positive impact on resource allocation.
23: Communication with public	• Definitions should be able to be easily communicated to aid public understanding of the Scheme.	• The public need to understand what the proposed changes are and feel confident that their interests are protected.	• Clear communication would reduce queries from the public, which would have positive impact on OGTR's workload and resources.
24: Regulator communication of risk	• Clarifying the definitions could aid the Regulator in communicating risk.	• The public needs an understanding of how risks are managed.	• A comprehensive understanding of how/why processes help risk mitigation.
25: Regulator increasing transparency and understanding of risk	• Clarifying the definitions could aid the Regulator in increasing transparency and understanding of risk.	• OGTR considers the risk of GMO and the environment where it will be.	• Transparent processes should help broader public understanding of how risk is managed.
26: Science-based review of monitoring	• Definitions should take account of monitoring needs.	• Some stakeholders suggested the Regulator should have power to commission research as needed for regulatory and information gaps.	• Processes should align with scientific need and monitoring outcomes to ensure risk is mitigated.
27: Publically available Regulator information	• Clarifying the definitions could aid the Regulator in the provision of public information.	• The public need to understand what the proposed changes are and feel confident that their interests are protected.	• Public information would reduce queries from the public, which would have a positive impact on OGTR's workload and resources.

ATTACHMENT B

Table: Classes of GMO dealings under the *Gene Technology Act 2000*

Category	Licence required	Containment	Example
Exempt	No	No intentional release to the environment	Bacteria transformation and culture for research purposes
NLRD	No, dealings must be assessed by IBC; notified in annual report	Yes PC1 or PC2 (usually)	Development of antibiotic resistance in bacteria Development of disease-resistant banana plants
DNIR	Yes, applications must be reviewed by IBC; RARMP prepared and licence decision by the Regulator	Yes ≥ PC2 (usually) and other conditions will apply	Development of vaccine for Hepatitis C Virus (Hep C)
DIR (limited and controlled)	Yes, applications must be reviewed by IBC; RARMP prepared, consultation on RARMP and licence decision by the Regulator	Containment measures will be required based on size/scope of release sought by applicant; and other licence conditions will apply	Limited and controlled release (field trial) of bread wheat and durum wheat genetically modified for enhanced rust disease resistance A GM respiratory syncytial virus vaccine for use in clinical trials
DIR (except for limited and controlled releases)	Yes, applications must be reviewed by IBC; consultation on application, RARMP prepared, consultation on RARMP and licence decision by the Regulator	Containment measures may be required, determined on a case-by-case basis, and other licence conditions will apply	Commercial release of herbicide resistant canola Commercial supply of influenza vaccine
Inadvertent dealing	Yes, licence decision by the Regulator only for the purposes of disposal of the GMO	Containment and/or disposal measures will apply	Authorisation to dispose of GM Petunia (if inadvertently in possession)
GMO Register	No, but must be previously licensed; review of related RARMPs	Containment measures may be required	Commercial scale release of four lines of colour modified GM carnations
EDD	No, determination by the minister, subject to advice of threat and utility of GMO from competent authorities and risk assessment advice from the Regulator	Containment and/or disposal measures may be included in EDD conditions	Production of equine influenza vaccines

Notes: DIR = dealings involving intentional release to the environment; DNIR = dealings not involving intentional release to the environment; EDD = emergency dealing determination; GMO = genetically modified organism; IBC = Institutional Biosafety Committee; NLRD = notifiable low-risk dealing; PC = physical containment; RARMP = risk assessment and risk management plan.

ATTACHMENT C