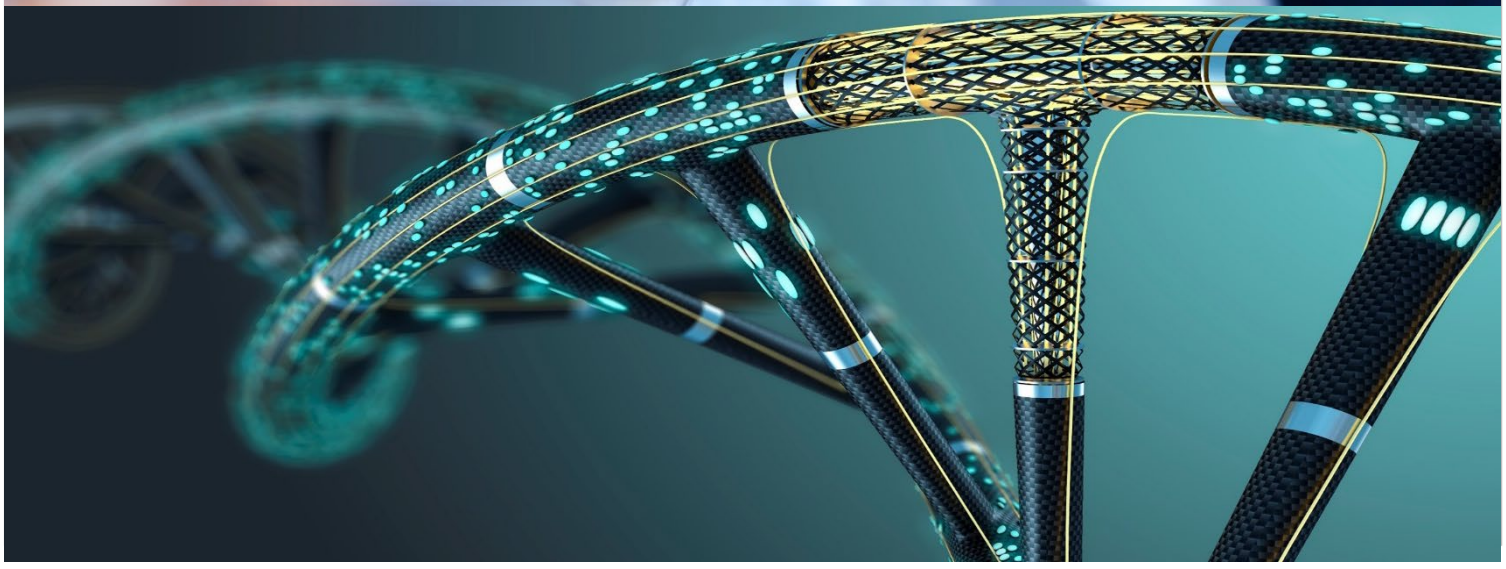
Australian Government
Department of Health and Aged Care

Consultation Paper

Draft Gene Technology Amendment Bill



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Abbreviations

ABBREVIATION	MEANING
AHEC	Australian Health Ethics Committee
AICIS	Australian Industrial Chemicals Introduction Scheme
APVMA	Australian Pesticides and Veterinary Medicines Authority
C-RIS	Consultation Regulation Impact Statement
CCI	Confidential commercial information (as defined)
Criminal Code	*Criminal Code Act 1995 (Cth)*
D-RIS	Decision Regulation Impact Statement
DAFF	Department of Agriculture, Fisheries and Forestry
DCCEEW	Department of Climate Change, Energy, the Environment and Water
DIR	Dealings Involving Intentional Release
DNIR	Dealings Not Involving Intentional Release
Draft Bill	*Draft Gene Technology Amendment Bill*
FOI Act	*Freedom of Information Act 1982 (Cth)*
FSANZ	Food Standards Australia New Zealand (FSANZ)
GM	Genetically modified
GM products	a thing (other than a GMO) derived or produced from a GMO
GMO	Genetically modified organism
GMO Record	Record of GMO Dealings
GT Act	*Gene Technology Act 2000 (Cth)*
GT Regulations	Gene Technology Regulations 2001
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTMM	Gene Technology Ministers' Meeting
GTSC	Gene Technology Standing Committee
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
Legislation Act	*Legislation Act 2003 (Cth)*

ABBREVIATION	MEANING
Maeve's Law	*Mitochondrial Donation Law Reform Act 2022 (Cth)*
Minister	Commonwealth minister responsible for gene technology
NHMRC	National Health and Medical Research Council
NLRD	Notifiable Low Risk Dealing
OGTR	Office of the Gene Technology Regulator
RARMP	Risk Assessment and Risk Management Plan
Regulatory Powers Act	*Regulatory Powers (Standard Provisions) Act 2014 (Cth)*
RIHE Act	*Research Involving Human Embryos Act 2002 (Cth)*
TGA	Therapeutic Goods Administration
The Agreement	Gene Technology Agreement 2001
The department	Australian Government Department of Health and Aged Care
The Regulator	The Gene Technology Regulator
The Scheme	National Gene Technology Scheme
The Third Review	Third Review of the National Gene Technology Scheme

Introduction

The National Gene Technology Scheme

The National Gene Technology Scheme (the Scheme) is a collaboration between all Australian governments, supporting a nationally consistent regulatory system for gene technology in Australia. It is designed to protect the health and safety of people, and the environment, from the risks associated with gene technology.

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

The Scheme arose from the need to provide regulatory oversight for GMOs not regulated under existing regulatory schemes. The regulatory model summarised in Figure 1 enables expertise on gene technology and GMOs to be centralised with the Gene Technology Regulator (the Regulator) and is designed to minimise overlap between other Commonwealth regulators and agencies whose work intersects with the Scheme.

The Scheme is described in the intergovernmental Gene Technology Agreement 2001 (the Agreement) and is overseen by the Gene Technology Ministers' Meeting (GTMM), comprising of ministers with responsibility for gene technology from all Australian governments. The Scheme comprises the Agreement, the Gene Technology Act 2000 (Cth) (GT Act), the Gene Technology Regulations 2001 (Cth) (GT Regulations), and corresponding state and territory legislation to ensure consistent national coverage for the regulation of GMOs in Australia.

The GT Act establishes an independent statutory office holder, the Gene Technology Regulator (the Regulator). The Regulator is responsible for making decisions and exercising powers under the GT Act and corresponding state legislation. The Regulator is supported by the Office of the Gene Technology Regulator (OGTR).

The Third Review

Periodic reviews of the Scheme have been undertaken since its commencement in 2001, as required under the Agreement. Between 2017 and 2018, the Third Review of the National Gene Technology Scheme (the Third Review) was undertaken.

While the Third Review found that, overall, the Scheme is working well, the Review outlined 27 recommendations designed to improve and strengthen the Scheme, while ensuring it is appropriately agile and supports innovation.

Decision Regulation Impact Statement

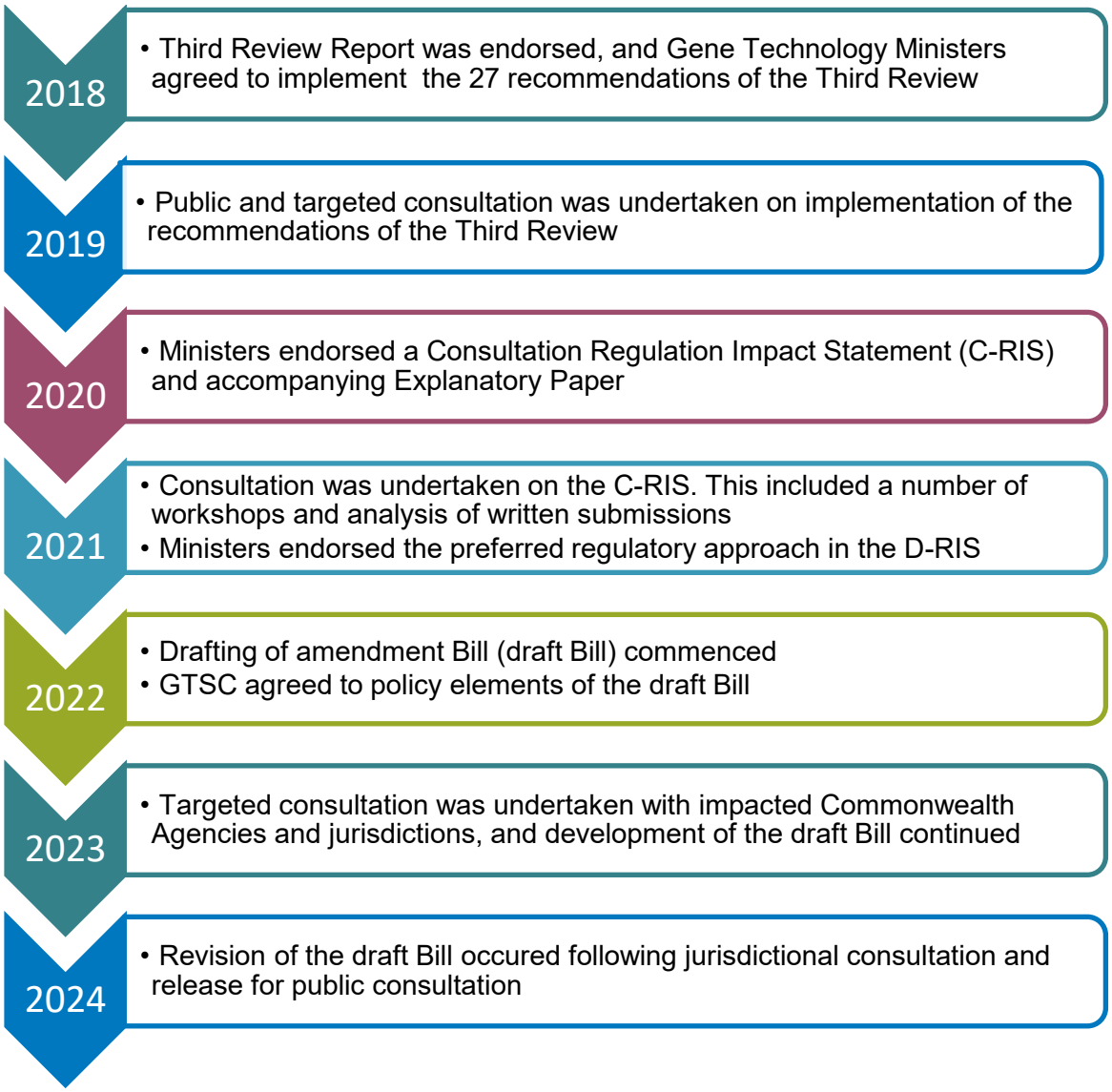
Not all of these recommendations required changes to the legislation. In response to the final Third Review report, a Decision Regulation Impact Statement (pmc.gov.au) (D-RIS) was developed to explore how best to modernise and future-proof the Scheme.

Despite the challenges presented by the COVID-19 pandemic, the D-RIS was progressed, presenting three policy options to implement the recommendations of the Review. Of the three policy options, consultation with stakeholders identified a preferred regulatory model where dealings with GMOs would be classified into authorisation pathways according to the level of risk they pose, a model referred to as the risk-tiering framework. The GTMM endorsed this model in 2021.

In such a model, the legislation would contain a mix of principles and prescriptive rules that would provide sufficient flexibility for the regulatory system to respond to scientific advances in a timely manner, while ensuring that risks to public health and the environment are managed proportionally and the Scheme remains fit for purpose.

The Australian Government Department of Health and Aged Care (the department) has subsequently developed the necessary legislative changes to give effect to the risk-tiering framework. This work has occurred in consultation with the Gene Technology Standing Committee (GTSC), which comprises of Commonwealth, state and territory government representatives who provide high-level support to the GTMM and coordinate advice on behalf of all relevant portfolios in their state or territory governments.

Below is a chronological overview of key decisions and actions since 2018:



Focus of this Consultation

Extensive consultation has already been undertaken through the Third Review, and the subsequent C-RIS. Following that consultation, Ministers endorsed the preferred regulatory model as outlined in the D-RIS, including risk-tiering. The focus of this consultation is on implementation of the already agreed approach and does not seek to revisit these measures.

This consultation provides an opportunity for all impacted industry, regulated entities, academic institutions, researchers, and interested members of the public to consider the proposed amendments to the legislation and its practical operation.

Drafting of the Gene Technology Amendment Bill (draft Bill) is well progressed, however some important parts of the draft Bill are yet to be finalised, including the parts relating to confidential commercial information (CCI), the use and disclosure of Regulator information,

and transition to the new scheme. The final drafting of these parts of the draft Bill will take account of feedback received during the process and assist in settling these final provisions. This consultation paper describes the proposed changes to the GT Act by reference to eight key themes. The paper is designed to be read together with the draft Bill.

Also included as part of the consultation documentation is a future law compilation, that shows how the GT Act would read if amended by the draft Bill in its current form. Please note that changes to the draft Bill may occur as a result of feedback received before the Bill is introduced into the Commonwealth Parliament.

Mapping of the items of the draft Bill against the themes is set out at Attachment A. The consultation opens on **13 September 2024** and closes on **8 November 2024.**

Specific consultation questions are included throughout the consultation paper to guide input however stakeholders are also encouraged to provide input on all aspects of proposed changes contained in the draft Bill or this paper.

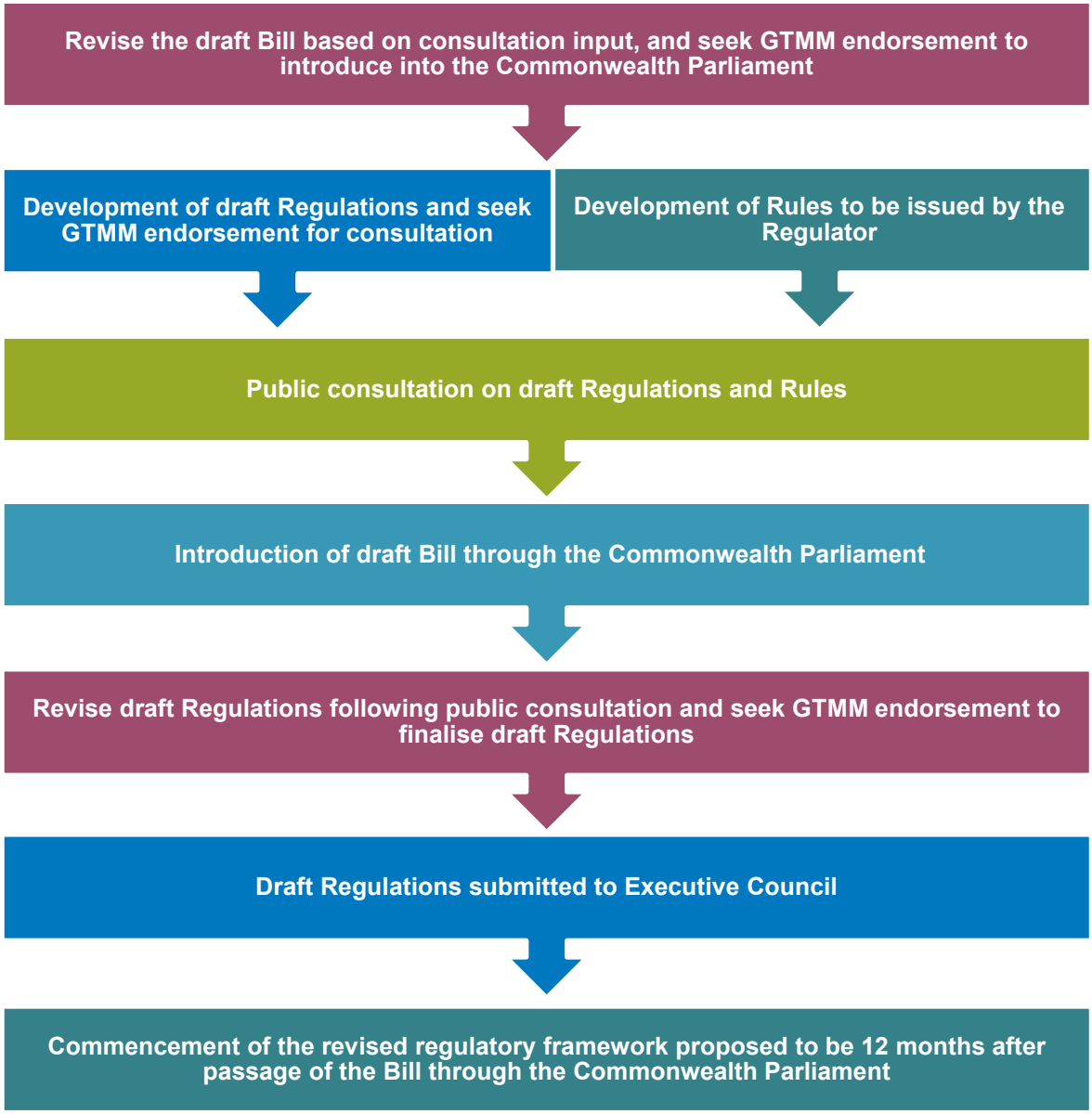
Consultation responses should be provided via the survey in the consultation hub. Where possible, reasoning and supporting information should be included. Providing consultation responses via the survey in the consultation hub will ensure that input can be clearly considered against the relevant proposed amendments.

Questions during the consultation period may be directed to: gene.technology.implementation@health.gov.au.

Next Steps

Prior to the revised regulatory framework coming into effect, the following high-level activities will occur.

These activities will all be progressed as quickly as possible subject to Ministerial agreement and within the requirements of the Commonwealth Government legislation process. Registered stakeholders will be updated as the draft Bill progresses through the Commonwealth Parliament.



Chapter 1: Scope of Regulation

The pace of scientific discovery in the field of gene technology is accelerating, and key definitions in the GT Act that establish which GMO activities are within the scope of regulation have become outdated. The framing of current definitions can lead to uncertainty as to whether some new technologies or organisms not previously considered are within the scope of regulation, which can stifle innovation. The scope of the Scheme in established around four interrelated definitions in the GT Act: 'organism', 'gene technology', 'GMO' and 'deal with' (in relation to a GMO).

Changes are proposed to the three definitions: 'deal with' (section 12A), 'gene technology' (section 12B) and 'GMO' (section 12C), to recognise advances in technology since the Scheme commenced.

The GT Regulations will continue to be able to prescribe additional techniques which are not considered to be gene technology, and prescribe things which are and are not considered to be a GMO, for the purposes of the Scheme.

In addition, it is proposed that the GT Regulations will also be able to prescribe additional dealings for the purposes of the 'deal with' definition. This will allow the Scheme to be responsive to advances in technology.

Recommendation 4 of the Third Review is to update, where required, existing definitions in the GT Act to clarify the scope of regulation in light of ongoing technical advances. To implement this recommendation, changes are proposed to three of the four core definitions in the GT Act. This ensures that the Scheme is clear in its scope and is sufficiently flexible to respond to advances in gene technology and scientific knowledge in the future.

Recommendation 6(a) of the Third Review specifically stated that the definition of 'genetically modified organism' in the GT Act be amended to clarify that humans are not considered to be GMOs in any circumstances. At Recommendation 6(b), the Third Review acknowledged the need for consideration to be given to whether additional regulatory oversight is needed for humans who may receive or inherit germline or other somatic therapies not within the remit of the Scheme and identify the most appropriate regulatory (or other) body to undertake such oversight. This approach recognises the role of the Scheme as a 'gap filler' for other existing regulatory schemes.

Proposed amendments to core definitions underpinning the Scheme related to these recommendations are summarised below.

Definition of 'deal with' (section 12A)

The current definition of 'deal with' comprises a list of activities with GMOs that are captured under regulation. The terms currently used in the definition are more relevant to activities

associated with agricultural applications and apply less so for medical uses of GMOs. In addition, there is a risk that activities not captured by the current definition of 'deal with', or the remit of other regulatory agencies, will require regulation in the future. To address these issues, the following amendments are proposed.

Elevating 'use' and 'supply' to primary dealings

The 'use' and 'supply' of a GMO are currently only regulated in so far as they are incidental to another dealing. This, in part, recognises the role of other regulatory schemes in regulating the use of GMOs. Collectively, interconnected regulatory schemes address the safety of the process to develop GMOs, as well as the safety of subsequent GM products.

Section 12A of the GT Act as amended proposes to elevate the activities of 'use' and 'supply' of a GMO to primary dealings, with the effect that these will become dealings within the remit of the Scheme in their own right. The GT Act as amended also now proposes to incorporate 'storage' of a GMO as a primary dealing, regardless of the purpose for which the GMO is being stored.

'Possession' of a GMO will remain as a dealing in so far as it is incidental to other activities captured in this definition.

'Storage' of GMOs

The definition of 'deal with' also now includes 'storage'. As a result of this change to the 'deal with' definition, persons storing GMOs would also need an appropriate authorisation to do so.

This proposed amendment may impact persons currently dealing with GMOs in one of two ways. Firstly, persons that are currently authorised to undertake dealings with a GMO, and who 'store' the GMO in the course of such dealings, would need to obtain authorisation before their original authorisation ends, to be able to legally continue to store the GMO. Secondly, persons currently storing GMOs without dealing with a GMO in any other way, will need to obtain authorisation to continue storing them under the amended legislation. Further information on transition of existing authorisations can also be found in Chapter 8 of this paper.

Enabling the GT Regulations to prescribe additional dealings

To supplement the revised definition, the GT Act as amended proposes that additional dealings will also be able to be prescribed by the GT Regulations. This will help to future proof the Scheme by avoiding the need for further terms to be added to the definition in the GT Act, while ensuring that the Scheme can still respond to advances in technology. This same approach is currently used for other core definitions in the GT Act, including the definition of 'GMO'.

The proposed amendments are intended to ensure that all future activities involving GMOs are regulated under the GT Act or another regulatory scheme, and there are no gaps in regulation of GMOs.

Noting the role of the Scheme as a 'gap filler', the proposed amendments will provide broad regulatory coverage of activities with GMOs. As discussed in Chapter 2 below, complementary amendments are proposed through the introduction of a new section 15A to minimise regulatory overlap where relevant risks are already sufficiently managed by another regulatory scheme.

Meaning of 'gene technology' (section 12B)

While the Third Review noted that the definition of 'gene technology' has largely endured, it acknowledged that changes were required to reflect scientific advances. The proposed amendments are outlined below.

Synthesis of genes or other genetic material

Feedback received during the Third Review consultation identified that a limitation of the current definition of gene technology is that it primarily relates to the modification, but not the creation, of genes or genetic material. With advances in science, it is now possible to create genes or genetic material in addition to modifying them. The intent of the Scheme is that such techniques would be within the remit of what is 'gene technology'. Proposed amendments to the definition of 'gene technology' contained in the GT Act as amended clarify that for the purposes of the Scheme, gene technology means a technique for the synthesis or modification of genes or other genetic material, subject to a number of listed exceptions.

Mitochondrial donation techniques excluded

Mitochondrial donation is an in vitro fertilisation based assisted reproductive technology. It has the potential to prevent mitochondrial disease in babies born to mothers who may otherwise pass on the disease.

The Research Involving Human Embryos Act 2002 (Cth) (RIHE Act) was amended via the Mitochondrial Donation Law Reform (Maeve's Law) Act 2022 (Cth) (Maeve's Law). Maeve's Law inserted a new section 47 into the RIHE Act to deal with the interaction between the RIHE Act and the GT Act. This was necessary to ensure that there is a single regulator responsible for the approval of mitochondrial donation techniques in humans, and for associated research and training. Regulation by both the National Health and Medical Research Council (NHMRC) and the Regulator would be inefficient and duplicative, particularly considering the comprehensive and detailed regulatory scheme introduced into the RIHE Act through Maeve's Law.

The GT Act as amended includes a number of proposed amendments to retain the existing regulatory settings put in place by Maeve's Law and to make the Scheme easier to navigate. These include the addition of proposed paragraph 12B(c), the introduction of two new definitions for 'mitochondrial donation licence' and 'mitochondrial donation technique', and the proposed repeal of section 47 of the RIHE Act (see Chapter 7 below).

Including techniques via the GT Regulations

Previous consultation throughout the Third Review identified that, with rapid advances in gene technology, it is desirable for the legislation to have flexibility to respond effectively by enabling the GT Regulations to specify additional techniques to be 'gene technology'. While the D-RIS contemplated such an approach, it has since been reconsidered because the definition of gene technology is central to the Scheme and is sufficiently broad. Allowing the GT Regulations to prescribe additional techniques could lead to unintended consequences, including modifying the scope of the Scheme.

The GT Regulations will continue to specify techniques, and classes of techniques, which are not gene technology for the purposes of the GT Act.

Meaning of 'genetically modified organism' (section 12C)

The current definition of 'genetically modified organism' is cast broadly to capture under regulation any organism that has been modified by gene technology, has inherited traits due to the use of gene technology, or has been prescribed to be a GMO in the GT Regulations. Amendments to the definition are proposed to ensure it remains fit-for-purpose in the context of rapidly advancing technologies as described below.

Specifying GMOs via the GT Regulations

It is proposed that the Regulations will continue to be able to be used to specify what is or is not a GMO. While it is not anticipated that such regulations would be prescribed for the purposes of this definition at this time, it is important to note that if amendments were ever proposed in the future, they would be subject to a separate consultation process and endorsement by the GTMM.

Organisms that have been produced by gene technology

The current definition of 'GMO' in the GT Act does not capture organisms that have been created by gene technology. In the future, through advances in synthetic biology, it may be possible to create organisms without modifying a pre-existing organism. An amendment to the definition of GMO 's therefore proposed at section 12C to capture organisms that are produced by gene technology.

Exclusion of human beings

The Third Review recommended that the definition of 'GMO' be amended to clarify that human beings are not GMOs for the purposes of the Scheme. This maintains the original intent of the Scheme, which was to exclude humans. The range of requirements that GMOs are subject to under the Scheme are not appropriate to apply to human beings.

The current exclusion of humans that have undergone somatic cell gene therapy reflects that at the inception of the Scheme the only type of human gene therapy that was available was somatic cell gene cell therapy. Somatic cell gene therapy can be used as a treatment but does not produce genetic changes in the cells that produce sperm and eggs. Somatic cell gene therapy therefore does not produce changes that can be inherited by the next generation.

In contrast to somatic cell therapies, germline gene therapies involve genetic changes to the cells that produce sperm or eggs that could be inherited by future generations.

Under this proposed amendment to the definition, a human being will not be a GMO for the purposes of the GT Act in any circumstances.

The proposed amendments do not affect the continuing oversight of recipients of germline therapies through the Prohibition of Human Cloning for Reproduction Act 2002 and RIHE Acts.

Changes to other definitions

Some definitions in section 10 of the GT Act are also proposed to be amended or new definitions included to reflect changes throughout the GT Act as amended, or improve clarity and readability of the legislation. Some examples include the addition of a definition for 'authorised compliance officers' and 'authorised inspectors', together with a change to the definition of CCI.

Changes have also been made throughout the draft Bill to align all periods to be described by reference to 'business day', which will be defined in section 10 of the amended GT Act as a day that is not a Saturday, a Sunday a public holiday in the Australian Capital Territory, or another day specified in the regulations. While this is the current approach by virtue of regulation 8 of the GT Regulations, it ensures clarity for stakeholders across Australia interacting with the Scheme and the OGTR.

No amendment for binding determinations

Recommendation 13 of the Third Review proposed that to better respond to scientific advances and understanding of risks, consideration should be given to enabling the Regulator to make decisions on how the Scheme applies to any technological developments until such time as a policy approach has been agreed. Throughout consultation and drafting,

consideration has been given to enabling the Regulator to make binding determinations to clarify whether certain organisms or techniques do, or do not, meet the definition of ‘GMO’ or ‘gene technology’ for the purposes of the GT Act.

Binding determinations would only clarify legal ambiguity in the definitions if they could have the effect of altering the scope of the Scheme’s regulation. It is not considered appropriate for the scope of the Scheme’s regulation to be altered without ministerial consideration. Accordingly, it is proposed that the status quo be maintained, and no determination-making power be inserted into the GT Act. The Regulator will continue to issue written guidance to stakeholders on the application of key definitions in the GT Act, where appropriate.

One function of the Regulator under section 27 of the GT Act is to advise the GTMM on the effectiveness of the legislative framework for the regulation of GMOs, including possible amendments of relevant legislation. More regular reviews of the GT Regulations, initiated by the Regulator, and making risk-based recommendations to the GTMM about potential amendments to parts of the GT Regulations will improve responsiveness to technological advances. This will strengthen the operation of the Scheme.

Questions

1. Do the proposed amendments to the definitions of ‘deal with’, ‘gene technology’ and ‘genetically modified organism’ provide sufficient clarity about what is captured under the Scheme?

2. Do you consider the proposed amendments to key definitions provide greater clarity with respect to the scope of regulation?

3. Do you consider the proposed amendments to key definitions help to future-proof the Scheme?

Chapter 2: Risks considered under the Scheme

At its inception, the Scheme was designed to complement the remit of other agencies and regulators that already governed aspects of GMOs and GM product regulation. The GT Act provided a regulatory framework to manage risks to humans and the environment from GMO dealings, alongside how other agencies regulated their use. Today, the Scheme's framework allows the Regulator and the OGTR to work in cooperation with these other regulators.

Proposed section 15A of the GT Act as amended will allow the Minister and the Regulator to decide not to consider specified risks considered under other legislation, or a risk to a weed, pest or pathogen, in certain circumstances.

The Minister and the Regulator will still be required to consider relevant risks to human health and safety, and the environment, posed by dealings with GMOs that are not managed by other regulators or under other legislation.

Recommendation 21 of the Third Review recommended clarifying the intersection between work undertaken by the Regulator and other Commonwealth regulators, including identifying any emerging areas where legislative or administrative changes could be made to reduce any unnecessary regulatory overlap. Regulatory overlap may result in increased costs and regulatory effort that is not justified by the level of risk posed by an activity.

Currently, the GT Act requires the Regulator to consider risks to people and the environment posed by dealings with GMOs (for example, when assessing licence applications), even where that would overlap to some degree with the work of other regulators. Further, the proposed expansion of the 'deal with' definition to include all uses of a GMO will impact the regulatory interface between the OGTR and other regulators. To mitigate unnecessary regulatory overlap, amendments are proposed to Division 3 of Part 2 of the GT Act as outlined below.

Minister and Regulator not required to consider certain risks – regulatory interface (subsection 15A(2))

In some instances when the Regulator is considering the risks posed by a dealing, certain risks may overlap with the efforts of other regulators operating under other Commonwealth legislation. This type of regulatory overlap may increase because the proposed amendments to the definition of 'deal with' will expand the activities regulated by the Scheme.

The proposed new subsection 15A(2) is intended to address this potential regulatory overlap by allowing the GT Regulations to specify particular risks that are not required to be

considered by the Regulator if they are considered under other relevant Commonwealth legislation, including the Agricultural and Veterinary Chemicals Code Act 1994, the Food Standards Australia New Zealand Act 1991, the Industrial Chemicals Act 2019; or the Therapeutic Goods Act 1989.

This may allow certain dealings with GMOs to be eligible for an alternative authorisation pathways under the risk-tiering framework described below, where some, or all of, the associated health and/or environmental risks are considered by another regulator. As a consequence, even though stakeholders would still need authorisation for their GMO dealings, data requirements and approval timeframes may be less than they are currently, because the risks have already been suitably assessed or considered by another regulator.

For example, regulations made for the purposes of paragraph 15A(2)(b) of the GT Act as amended may prescribe that the Regulator does not need to consider the risks that a GMO vaccine poses to a clinical trial participant, where such risks are managed under the Therapeutic Goods Act 1989. When making a decision on a licence application for the authorisation of a clinical trial to test the efficacy of a GMO vaccine, the Regulator would still be required to consider risks to other people, such as healthcare practitioners, and risks to the environment as these have not been considered by the Therapeutic Goods Administration (TGA).

Minister and Regulator not required to consider certain risks – weeds, pests or pathogens (subsection 15A(3))

In some circumstances, an intended purpose of GMO dealings may be to suppress or eradicate a specific weed, pest or pathogen. In such cases, the destructive effect of the GMO on the specific weed, pest or pathogen necessarily negatively affects the weed, pest or pathogen, which is part of the environment. The policy intention is that the negative effects of the relevant GMO dealings on the weed, pest or pathogen should not make it more difficult for the Regulator or the Minister to be satisfied that the risks of the GMO dealings can be managed.

For example, when making a decision on a licence application for the authorisation of cotton genetically modified to be resistant to the cotton bollworm, the Regulator must consider whether risks posed by the proposed dealings to the environment can be managed. The amended GT Act would provide that the Regulator is not required to consider the risks that the GM cotton poses to the cotton bollworm, since the modification is intended to kill this pest. This new provision is intended to confirm, rather than alter, current practice.

The terms ‘weed’, ‘pest’ and ‘pathogen’ will not be defined for the purposes of the GT Act. While these terms are defined in other Commonwealth, state and territory legislation, these terms will continue to be considered and applied by the Regulator or the Minister in the

context of a particular decision about risk to be made under the GT Act. This recognises that what constitutes a weed, pest or pathogen in one environment may not constitute a weed, pest or pathogen in another environment.

Question

4. Is the mechanism in proposed section 15A suitable to manage circumstances where dealings with GMOs may also be regulated under other regulatory schemes?

Chapter 3: Authorisation Pathways

The Scheme currently broadly distinguishes between 2 types of GMO dealings:

1. contained dealings, and

2. dealings involving intentional release of GMOs into the environment.

A revised framework, under which dealings with GMOs will be classified into categories according to their indicative risk, was supported by stakeholders through consultation on the C-RIS, and subsequently endorsed by GTMM as part of the D-RIS. Under this risk-tiering model, some of the existing authorisation pathways in the GT Act will be retained, and others will be modified or introduced. The revised authorisation pathways are intended to enable a more nuanced approach to regulation, based on indicative risk and risk management.

This proposed risk-tiering framework will allow regulatory effort to be better targeted to the oversight of GMO dealings that may pose higher risk, or for which there may be substantial uncertainty in the risk analysis. Where appropriate, and based on risk, this will lead to decreased regulatory requirement and faster authorisation processes for some GMO dealings.

The Third Review identified that the Scheme exists within an environment where understanding about science and inherent risks continues to evolve. A key area of focus of the Third Review was identifying opportunities to improve the flexibility and agility of the Scheme, while maintaining appropriate governance and oversight.

The reforms will do this by dealing with more matters through delegated legislation.

It is proposed that:

1. New authorisation pathways will be established by the GT Act;

2. The GT Regulations will describe dealings that fall within the authorisation pathways; and

3. The GT Act will allow for the Regulator to make rules that will further define and provide conditions for dealings within the permit, notifiable and non-notifiable dealing authorisation pathways, where allowed by the regulations.

Further detail will be provided in the amending Regulations and Rules in due course. It should be noted that the proposed Regulations and Rules will be subject to a separate consultation process and endorsement by the GTMM.

The GT Act currently provides for several categories of approvals (authorisation pathways) to undertake GMO dealings including:

- DIR licence (dealings involving intentional release of GMO into the environment),
- DNIR licence (dealings not involving intentional release of a GMO into the environment),
- Notifiable low risk dealings,
- Exempt dealings,
- GMO Register, and
- Emergency dealings.

The diagram at Figure 2 provides an overview of how authorisation pathways will change under the proposed reforms.

A high-level description of the proposed authorisation pathways under the revised framework is described below.

High-Level Overview

GMO licences – this is an existing authorisation pathway. Dealings carried out under a GMO licence will continue to be subject to conditions, and case-by-case risk analysis through a risk assessment and risk management plan (RARMP). The draft Bill proposes to remove the current binary distinctions between whether dealings with GMOs involve the release of the GMO into the environment or not. Instead, through the GT Regulations, new risk-based factors will be introduced to tailor consultation requirements and assessment timeframes for licensed dealings.

Similar to the current GT Act, under the revised authorisation pathways, all dealings with GMOs must be licensed, unless the dealing is eligible to be regulated by the Scheme under another authorisation pathway. However, applicants will also be able to apply for any dealing to be licensed, even if it is eligible to be regulated under another authorisation pathway.

GMO permits – this is a new pathway for dealings with GMOs that require express authorisation from the Regulator to proceed, but where conditions will be able to be applied through both the GT Act (statutory conditions) and the rules (based on prior experience with the GMO).

Conditions will be standardised, and not imposed on a case-by-case basis. As such these applications will be able to be considered more quickly than licensed dealings, as there will be no requirement for a RARMP to be prepared each time. Prior to issuing a GMO permit, the Regulator will need to be satisfied of an applicant's suitability to hold a GMO permit through applying a prescribed suitable person test.

Notifiable dealings (NDs) – this pathway has significant crossover with the current Notifiable Low Risk Dealing (NLRD) pathway. Under this proposed new pathway there will be two broad groups of notifiable dealings. Some notifiable dealings will need to be notified to the Regulator before they are commenced, while others will need to comply with requirements for Institutional Biosafety Committee (IBC) assessment that will be outlined in the GT Regulations, before they can commence.

Compared to NLRDs, the revised Scheme will broaden the classes of dealings that can be undertaken as notifiable dealings to include some GMO dealings that are not contained, for example, some dealings where another regulator assesses or manages relevant risks.

Non-notifiable dealings (NNDs) – this pathway replaces the existing 'exempt' dealings pathway. Persons undertaking a non-notifiable dealing will still need to ensure that the dealing is properly characterised as a non-notifiable dealing as specified in the GT Regulations, and no conditions will apply to this category of dealing. Distinct from exempt dealings, there will be no requirement in the GT Act that all non-notifiable dealings are contained, however it is intended that most classes of non-notifiable dealing specified in the GT Regulations will be contained dealings.

GMO Register – this is an existing authorisation pathway. The GMO Register is a list of dealings that the Regulator has determined pose minimal risk to the health and safety of people or the environment. The GT Act as amended proposes to enable the GMO Register to be used more effectively, as recommended by the Third Review, including by expanding the classes of dealings that are eligible to be included on the GMO Register.

Emergency dealing determinations – this is an existing authorisation pathway. The Minister can expedite the approval of dealings with a GMO in an emergency. EDDs have effect for up to six months, unless extended by the Minister. No substantive changes are proposed to this pathway.

It is intended that the proposed revised authorisation pathways will provide the Regulator with the ability to respond to changes in technology by publishing rules that can clarify the parameters set out in the GT Regulations. This provides regulated stakeholders with more risk-responsive oversight of GMO dealings, and will mean regulatory burden will be adjusted to match risk, and enable the Scheme to remain fit for purpose.

Revised structure of the Scheme to support risk-tiering

To enable a flexible and responsive approach to the revised authorisation pathways outlined above, it is proposed that in addition to the GT Act and the GT Regulations, the revised Scheme will also be underpinned by rules made by the Regulator. A comparison of the current and the proposed revised structure of the Scheme is summarised at Figure 3.

Rules are legislative instruments that can be made or amended more rapidly than regulations. Prescribing highly technical matters in lower-level legislative instruments such as rules is common across Australian regulatory schemes. The GT Act would prescribe consultation requirements the Regulator must follow when making rules (proposed sections 193B and 193C).

This proposed revised structure will ensure the Scheme remains responsive to rapidly changing technologies and continues to be fit for use. To implement the risk-tiering framework endorsed through the D-RIS, the revised structure will enable the following:

- The revised GT Act will establish updated and expanded authorisation pathways for GMOs and enable certain matters to be specified in the GT Regulations and rules made by the Regulator.
- The revised GT Regulations will describe classes of GMO dealings that are permit dealings, notifiable dealings and non-notifiable dealings, and authorisation requirements for notifiable dealings.
- The Regulator will make rules to further narrow classes of GMO dealings prescribed in the GT Regulations and impose conditions applicable to different classes of GMO dealings.

The proposed structure establishes a clear, cascading framework under which:

- There is parliamentary oversight over the GT Act which is also subject to agreement from the GTMM[1], and corresponding state and territory legislation;
- The Governor-General makes the GT Regulations, subject to agreement from the GTMM and the Minister being satisfied of risk-based matters specified in the GT Act; and
- The Regulator make rules that support the operation of the Scheme within the parameters set by the GT Act and the GT Regulations.

Transport, storage and disposal guidelines

The Regulator will continue to prescribe requirements for the transport, storage and disposal of GMOs, as currently occurs under the Scheme. These will no longer be issued as Guidelines but will be Rules made by the Regulator.

[1] Clause 40 of the intergovernmental Gene Technology Agreement, https://www.genetechnology.gov.au/sites/default/files/2022-01/gene-technology-agreement.pdf.

GMO Licences

The GT Act as amended proposes to repeal Divisions 3 and 4 of Part 5 of the GT Act. Part 5 of the GT Act currently describes the system for licensing dealings with GMOs and sets out the processes in relation to licence applications for Dealings Involving Intentional Release (DIR) and Dealings Not Involving Intentional Release (DNIR).

When the Scheme first began, many of the early licensed dealings with GMOs consisted of scientific research taking place within laboratories (contained dealings) or releases of GM crops, either in field trials or commercial releases (intentional release). Different types of GMOs and applications have since been developed such that a binary categorisation between dealings involving intentional release and those that do not, is no longer the most appropriate primary risk consideration for all licensable dealings. For clinical trials in particular, this distinction can constrain the Regulator's assessment of licence applications.

Whilst the 'licence' category will be retained under the GT Act as amended, the current subcategories of DIR (both general and limited and controlled releases) and DNIR licence will be removed. All licensable dealings will be assessed by the Regulator before the dealing commences. The extent of consultation and assessment timeframes will be graduated based on indicative risk to streamline assessment of lower risk applications.

An example of how licensed dealings will be regulated under the revised legislative structure of the Scheme is summarised within Figure 4.

Consultation on a RARMP

Under the GT Act as amended, it is proposed that the Regulator will continue to be required to prepare a RARMP in respect of all licence applications other than those for inadvertent dealings. In preparing the RARMP, the Regulator will be required to consider the risks posed by the proposed dealings to the health and safety of people and to the environment, and the means of managing those risks in such a way as to protect the health and safety of people and the environment.

Currently, the GT Act requires the Regulator to consult the public, and others, on RARMPs prepared for all DIR licence applications, but not for DNIR licence applications. With the removal of these licence subcategories, the GT Act as amended sets out new requirements for when the Regulator must publicly consult on a RARMP.

The reforms propose that public consultation on RARMPs will be focussed on providing the Regulator with additional relevant information for decision-making, including what conditions may need to be applied to GMO licences. If the Regulator is satisfied any dealing proposed to be authorised by a GMO licence would involve a GMO that is derived from a parent organism new to Australia, or a GMO that displays a novel trait that occurs because of gene technology, section 49 of the amended GT Act will require the Regulator to publicly consult

on this application. In addition, the Regulator will be able to consult the public on any RARMP if they consider it to be in the public interest to do so.

Similar to existing requirements, the Regulator will be required to consult persons or bodies prescribed by the GT Regulations on RARMPs. The GT Regulations will prescribe different persons or bodies dependent on the type of licence application, for example, the states, territories, Commonwealth agencies or the GTTAC.

However, under subsection 49(2) of the GT Act as amended the Regulator will not be required to consult the public on a RARMP if each dealing proposed to be authorised by the GMO licence will be contained, involves administering the GMO into a human for therapeutic purposes or involves using a GMO to manufacture therapeutic goods.

The Regulator will no longer be required to consult on general release licence applications prior to preparing a RARMP. As a result, the matters that the Regulator must consider when preparing a RARMP are proposed to be streamlined. In particular, the GT Act as amended does not require the Regulator to explicitly consider advice from certain entities, such as local government authorities, when preparing a RARMP.

Suitable person test

The GT Act as amended proposes repealing section 58 of the GT Act and inserting a new Part 5AA (discussed below) which sets out matters to be considered in deciding whether a person is suitable to hold a GMO licence. Consistent with the current GT Act, the Regulator will not be able to issue a GMO licence unless satisfied that the applicant is a suitable person to hold the licence.

Conditions of GMO licences

The GT Act as amended proposes that a GMO licence will be subject to conditions set out in Part 5AA (discussed below), in rules made by the Regulator and conditions imposed by the Regulator at the time of issuing or varying the licence. Licence conditions would no longer be able to be prescribed by the GT Regulations, noting that none have been prescribed to date.

Suspension, cancellation and variation of licences

Under the GT Act as amended, it is proposed that the Regulator will continue to be empowered to vary GMO licences on their own initiative, or on application by the GMO licence holder. To maintain the policy intent of current restrictions on licence variations, the draft Bill proposes to amend section 71 of the GT Act and insert new section 71A. These amended provisions will provide updated restrictions on licence variations at sections 71 and 71A to ensure that proposals to extend the authorisations to conduct dealings with GMOs included in a GMO licence are considered under the initial licence issue provisions rather than the licence variation provisions where appropriate.

Proposed amendments at section 72 of the GT Act will also remove reference to applicants requesting that a GMO licence be suspended or cancelled. The intent is that if the holder of a GMO licence no longer wishes to have the licence, the licence holder will surrender the licence under section 69 of the GT Act with the consent of the Regulator.

Inadvertent dealings licences

Inadvertent dealings licences are temporary licences intended to allow persons who have unintentionally come into possession of a GMO to safely dispose of it in a manner which protects the health and safety of people and the environment. Under the current GT Act, the Regulator may issue an inadvertent dealings licence for certain dealings for a period of 12 months if satisfied that the applicant came into possession of the GMO inadvertently.

Under the GT Act as amended, inadvertent dealings licences will continue to be available. Section 47 of the GT Act will be amended so that consideration of inadvertent dealings applications will continue to follow a simpler process than required for other application types. Three amendments to this class of licences are proposed.

Clarifying the definition of 'inadvertent'

The draft Bill seeks to clarify eligibility to make an inadvertent dealings application through inserting a new definition of 'inadvertent'. This is intended to ensure that the phrase 'coming into possession of a GMO inadvertently' more clearly applies where a person intentionally takes possession of a particular organism, believing the organism not to be a GMO, but the organism is a GMO. For example, this may occur where a person intentionally takes possession of a particular plant, not knowing it to be a GMO, but later discovers that the plant is a GMO.

Dealings that can be authorised under inadvertent dealings applications

The Regulator can currently issue an inadvertent dealings licence for dealings undertaken for the purposes of, or for purposes relating to, disposing of the GMO. The draft Bill proposes that inadvertent dealings licences would continue to cover the GMO dealings described at current section 46A of the GT Act, Amendments are proposed to also enable inadvertent dealings licences to be issued to authorise dealings for purposes limited to, or incidental to, exporting the GMO.

In some instances, for example an incoming shipment of grain at the border or an imported high value therapeutic, it is preferable for a person inadvertently possessing these GMOs to be able to export the GMOs to the country of origin, rather than destroying the GMOs at the border. In such circumstances, export of the GMO would similarly maintain the objects of the GT Act.

Duration of inadvertent dealings licences

The draft Bill is also seeking to modify section 60 of the GT Act such that inadvertent dealings licences are no longer limited to 12 months duration. This is to allow for any longer-term activity which may be required in relation to the disposal of GMOs, such as monitoring the effectiveness of the destruction of a crop.

GMO Permits

New Part 5AAA as outlined in the GT Act as amended proposes to establish a new permit system, under which a person may apply to the Regulator for a GMO permit that authorises one or more permit dealings. This Part includes provisions setting out how GMO dealings eligible for authorisation under a GMO permit (permit dealings) will be specified in the GT Regulations and rules, decisions on permit applications, and matters regarding the suspension, cancellation and surrender of a permit.

Key elements of Part 5AAA of the GT Act as amended are summarised here. An example of how a specific class of permit dealings will be regulated under the revised legislative structure of the Scheme is summarised within Figure 4.

Dealings eligible to be authorised by a GMO permit (section 72AB)

The GT Act as amended propose to provide for the GT Regulations to specify classes of dealings with GMOs as permit dealings. Before the Governor-General can make such regulations, the Minister must be satisfied that any risk to the health and safety of people, or to the environment, posed by any dealing in the class is known, and can be managed through requiring a permit holder to be a suitable person to hold a permit and comply with standard conditions.

Decision on application for permit (section 72AD)

Similar to GMO licences, the Regulator must not issue a GMO permit unless satisfied that the applicant is a suitable person to hold a permit, having regard to the matters specified in section 72AM of the GT Act as amended. The draft Bill does not provide for GMO permits to be transferred, because it will be a straightforward process to obtain a new permit to authorise other suitable persons to undertake permit dealings. The Regulator must also not issue a GMO permit if satisfied that doing so would be inconsistent with a policy principle issued by the GTMM. There is currently only one Policy Principle issued by the GTMM recognise states and territories rights to designate under state and territory law special areas that are either for GM or non-GM crops for market purposes.

Conditions of GMO permits (section 72AE)

Some conditions for GMO permits will be included in the GT Act as amended and other conditions specific to classes of permit dealings will be prescribed in rules. The rules may also impose a particular condition for all permits. Conditions for specific types of dealings

with GMOs covered by a GMO permit will be standardised. For example, standard conditions for each plant species eligible for the plant field trial permit class will be specified in rules. If, for any reason, an applicant is not in a position to comply with the standard conditions for a permit dealing, they will be required to instead apply for a GMO licence.

Unlike GMO licences, GMO permits will not be able to be varied. This is because permit conditions are not applied on a case-by-case basis, but rather apply equally to all permits. As a result, variations to GMO permits could only be changed by amending the GT Act or Rules. Additionally, it will be a straightforward process to obtain a new permit for additional permit dealings.

Suspension and cancellation of permits (section 72AG)

Similar to GMO licences, the Regulator will be able to suspend or cancel a GMO permit in certain circumstances. Grounds for suspension or cancellation are described at new section 72AG of the GT Act as amended.

Other matters relating to GMO licences and GMO permits

Part 5AA of the GT Act as amended sets out the matters that must be taken into account by the Regulator when deciding whether a person is suitable to hold a GMO licence or GMO permit, and sets out statutory conditions that apply to all GMO licences and GMO permits.

Suitable persons (section 72AM)

Section 72AM of the GT Act as amended lists matters the Regulator will need to have regard to when deciding whether an individual or body corporate is suitable to hold a GMO licence or a GMO permit. It substantially reproduces section 58 of the current GT Act, with the inclusion of some additional considerations.

Conditions of all GMO licences and GMO permits (sections 72AN; 72ANA, 72AP; 72AQ & 72AR)

Division 3 of Part 5AA of the GT Act as amended includes several conditions that will apply to all GMO licences and GMO permits. It substantially reproduces sections 62 to 65 of the current GT Act, with some minor amendments.

It is important to note that conditions of GMO licences and GMO permits would generally not apply if the GMO licence or GMO permit is suspended unless explicitly provided for under the draft Bill.

Section 72AN of the GT Act as amended will impose a condition that requires a GMO licence holder to inform a person covered by the licence of any conditions that have been applied by the Regulator. In addition, it requires current or former holders of a GMO licence or GMO permit to inform any person who was covered by the GMO licence or GMO permit

that they are no longer covered. This may occur, for example, due to suspension or cancellation of the GMO licence or GMO permit.

Holders of a GMO licence or GMO permit will not be responsible for making people aware of the standard conditions that are applied through the GT Act or Rules. These standard conditions will be easily accessible to any person undertaking a dealing, and responsibility lies with a person undertaking a dealing to ensure they are aware of these conditions governing. However, holders of a GMO licence or GMO permit will be required to advise persons covered by a GMO licence or GMO permit of those conditions imposed at the time of issued or after the licence is varied by the Regulator.

A new section 72ANA in the GT Act as amended is proposed to require holders of suspended GMO licences or GMO permits to continue to maintain records that would be required if the GMO licence or GMO permit was not suspended.

In addition, similar to section 64 of the GT Act, section 72AP of the GT Act as amended proposes that it is a condition of both a GMO licence and a GMO permit that persons authorised by the licence or permit to deal with a GMO must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of monitoring the dealing.

Sections 72AQ and 72AR in the GT Act as amended also broadly replicate the existing sections 65 and 66 of the GT Act, however if a person is required to provide additional information to the Regulator under a condition of their GMO licence or GMO permit, this information must be provided within 48 hours.

Notifiable Dealings

Similar to permit dealings, the draft Bill provides for the GT Regulations to specify classes of dealings with GMOs as eligible to be authorised as notifiable dealings.

The draft Bill proposes that there will be two types of notifiable dealings – those that must be notified to the Regulator before they are undertaken, and those that may be undertaken as long as they are notified to the Regulator in accordance with the requirements set out in the GT Regulations or rules.

The new notifiable dealing pathway will largely resemble NLRDs under the current GT Act. NLRDs include dealings with GMOs that:

- are undertaken in containment, in an appropriate facility certified by the Regulator or approved in writing by the Regulator; and
- do not require tailored risk management conditions to manage risks to the health and safety of people and the environment.

Similarly to current NLRDs, this will be an authorisation pathway where dealings will need to be notified to the Regulator and there will be no case-by-case assessment of an application. It is anticipated most of the GMO dealings currently within the NLRD category will become notifiable dealings.

Before the Governor-General can make regulations that provide for a class of dealings to be notifiable dealings, the Minister will need to be satisfied that any risk to the health and safety of people, or to the environment, posed by any dealing in the class is known, and can be managed through conditions and authorisation requirements.

Unlike the current GT Act, the draft Bill proposes that the Regulator may impose conditions on notifiable dealings. These standard conditions will be applied through rules published by the Regulator and may include conditions specifying locations where the dealing can be undertaken, or training and expertise required for persons to undertake the dealing.

An example of how notifiable dealings will be regulated under the revised legislative structure of the Scheme is summarised within Figure 4.

Under the current Scheme, all NLRDs must be undertaken in containment, or in line with the requirements set out in the Regulator's Guidelines for the Transport, Storage and Disposal of GMOs (ogtr.gov.au). It is proposed that the types of dealings that could be undertaken as notifiable dealings under the GT Act as amended will be expanded compared to NLRDs and will no longer be restricted to contained dealings.

Where other Australian regulators have significant roles managing risks to people and the environment from activities within scope of the Scheme as identified in section 15A above, advice sharing between regulators may mean it would be appropriate to authorise certain dealings as a notifiable dealing rather than requiring a GMO licence or GMO permit.

For example, the Australian Pesticides and Veterinary Medicines Authority's (APVMA) registration of a live GMO vaccine includes consideration of risks to human health and the environment and takes into account advice sought from the Regulator. GMO dealings associated with the commercial supply of the APVMA-registered veterinary vaccine could be authorised under the revised framework as a notifiable dealing.

Under the GT Act as amended, it is proposed that authorisation requirements will be specified in the GT Regulations for each class of notifiable dealings. A dealing with a GMO by a person will be an authorised notifiable dealing if it falls within the class of notifiable dealings and the authorisation requirements for the notifiable dealing have been met. The authorisation requirements for notifiable dealings that are equivalent to current NLRDs will include assessment by an IBC before dealings are undertaken. This continues the current requirement for NLRDs. An authorisation requirement for other notifiable dealings will be notification to the Regulator prior to the dealings being undertaken.

The GT Regulations will also specify the role of IBCs and organisations undertaking dealings with respect to notifiable dealings with GMOs, or any other authorisation requirements that must be met for the class.

Non-notifiable dealings

Similar to how exempt dealings currently work under the Scheme, non-notifiable dealings are proposed to be a new category of dealings with GMOs that pose a very low risk: for example, contained research involving well understood organisms and processes for creating and studying GMOs.

The change in terminology reinforces that dealings within this category will remain within the scope of the Scheme, but do not require notification to the Regulator. It is proposed that dealings currently listed in Schedule 2 to the GT Regulations will generally be regulated under this authorisation pathway in the GT Act as amended. In addition to current exempt dealings, some other GMO dealings that are very low risk will be non-notifiable dealings.

The GT Act as amended proposes that the GT Regulations to specify classes of dealings with GMOs as non-notifiable dealings. Before the Governor-General makes such regulations, the Minister must be satisfied that any risk to the health and safety of people, or to the environment, posed by the class of dealings is known and can be managed without conditions relating to the dealings. Provided the dealing meets all the specifications of the class description, it will not be subject to any other requirements or conditions. Specifications of a class of non-notifiable dealings may include that some classes of non-notifiable dealings are required to be contained.

An example of how a specific class of non-notifiable dealings will be regulated under the revised legislative structure of the Scheme is summarised within Figure 4.

GMO Register

The GMO Register is a list of dealings the Regulator has determined pose minimal risk to the health and safety of people or the environment. At Recommendation 11, the Third Review recommended that changes be made to enable the GMO Register to be more effectively utilised within the Scheme. As of August 2024, there are 3 entries on the GMO Register.

Clarifying the status of GMO Register determinations & expanding the types of dealings that can be included on the GMO Register (sections 78 & 80).

The Third Review suggested considering whether to remove the requirement for a dealing to have been authorised by a licence before it is included on the GMO Register. Through consultation, stakeholders identified the desirability of better utilisation of the GMO Register, including where the GMO dealing has previously been authorised by the Regulator or

another regulator. Amendments to section 78 of the GT Act are proposed in the GT Act as amended, to enable additional dealings to be included in the GMO Register, being:

- dealings that are, or have been, authorised by a GMO permit;
- dealings that satisfy criteria prescribed by the GT Regulations.

Modernising requirements for inspection of the GMO Register (section 76)

Other proposed changes to the provisions relating to the GMO Register include modernising requirements for inspection of the GMO Register. To update the current requirement for the GMO Register to be kept in a computerised form, amendments are proposed to section 76 of the GT Act to require that the GMO Register must be made available for public inspection on the internet. This results in the consequential repeal of section 81 of the GT Act as the Regulator will no longer need to permit a person to inspect the Register.

Emergency Dealing Determinations (EDDs)

No significant changes are proposed to Part 5A of the GT Act, which contains provisions relating to emergency dealing determinations. Proposed amendments to sections 72B, 72C, 72D and 72E in the GT Act as amended are largely consequential and/or to align with other changes in the draft Bill. These changes are further discussed in Chapter 7 below.

Questions

5. Are the proposed changes to consultation on risk assessment and risk management plans for licence applications appropriate?

6. Are the provisions dealing with GMO permits sufficiently clear?

7. Are there any practical concerns about the operation of the proposed statutory conditions for GMO licences and GMO permits?

8. Compared to notifiable low risk dealings, does the proposed use of rules for notifiable dealings sufficiently enable the Regulator to respond to technological changes in a timely way?

9. Across the risk-tiering framework, does the proposed use of rules achieve more risk-responsive regulation and sufficient flexibility for the Regulator to adjust categorisation of GMO dealings over time?

10. What should be considered for regulations to prescribe criteria for GMO dealings eligible for inclusion on the GMO Register?

Chapter 4: Compliance, monitoring and enforcement

The draft Bill proposes to repeal and replace the existing Part 4 of the GT Act. Most offences will now be contained within Part 4 of the revised GT Act, rather than throughout the legislation.

Part 4, as proposed to be amended, also provides for new offences and introduces civil penalties in relation to breaches of conditions by the holders of the accreditation of organisations or the certification of facilities.

Risk proportionate regulation under the revised framework will reduce up-front regulatory oversight of some lower risk GMO dealings. A corresponding enhancement in monitoring and enforcement tools is therefore required to balance this change and ensure the OGTR has an appropriate suite of measures to uphold compliance with regulatory requirements.

In order to achieve this, the GT Act as amended adopts a significant number of provisions from the *Regulatory Powers (Standard Provisions) Act 2014 (Cth)* (Regulatory Powers Act). In doing so, the existing suite of compliance and enforcement tools available to OGTR is proposed to be expanded to include enforceable undertakings and infringement notices. To ensure the provisions remain fit for purpose in the context of gene technology, some modifications to standard provisions of the Regulatory Powers Act have been incorporated throughout the GT Act as amended, and some current compliance powers in the GT Act have been retained.

It is important to note that penalties in the revised framework in some cases are significantly higher than in the existing GT Act. The penalties have been formulated consistent with A Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers issued by the Commonwealth Attorney Generals Department, with maximum penalties reflective of potential risk to human health and the environment posed by non-compliance.

Approach to adopting the Regulatory Powers Act

OGTR currently uses a range of available compliance tools, however they are limited. The Regulatory Powers Act provides a template for monitoring and enforcement powers across Commonwealth legislation. Relevant provisions of the Regulatory Powers Act are proposed to be reproduced in the GT Act as amended, and this will provide the OGTR with a modern suite of compliance tools.

Amendments have been made to standard definitions from the Regulatory Powers Act to ensure they are fit for purpose in the context of the GT Act. For example, the Regulatory Powers Act refers in a number of provisions to ‘electronic equipment’. The GT Act as amended expands this by instead referring to ‘equipment’ more generally, which is defined

to include electronic equipment. This is necessary as OGTR inspectors may also need to operate other forms of equipment when undertaking monitoring activities, such as laboratory or farming equipment.

Inclusion of a central authorising provision (section 31A)

The current structure of Part 4 of the GT Act does not clearly delineate authorisation pathways, with limited visibility on the face of the legislation about the different requirements for each pathway. Section 31A of the GT Act as amended defines the concept of 'authorised GMO dealing'. This concept will then be used in the main offence (section 32 of the amended GT Act) and main civil penalty provision (section 32A of the amended GT Act) relating to unauthorised dealings with a GMO.

Offences

Fault-based offences in the GT Act as amended have been redrafted in the current Commonwealth drafting style, and penalties have been aligned with comparable offences in other Commonwealth legislation. Generally, the default fault elements in the Criminal Code Act 1995 (Cth) (Criminal Code) apply, and penalties have been set using Commonwealth penalty units.

Some other proposed changes to offence provisions include:

New offences for breaches of conditions for certification and accreditation (Further discussed in Chapter 5 below.

The offences in sections 192 (providing false and misleading information in connection with an application) and 192A (interfering with dealings with GMOs) of the GT Act have been relocated to Part 4 of the amended GT Act.

Consistent with the current GT Act, the GT Act as amended also provides that it is an offence to breach a condition of a GMO authorisation. Some conditions will require an act or thing to be done within or by a particular time. Multiple and continuing offence provisions are currently incorporated in the GT Act for a number of offences. They are a tool to encourage compliance by imposing a cumulative penalty for ongoing non-compliance, specifically around reporting obligations.

Inclusion of civil penalty provisions

A civil penalty is a monetary fine imposed through the courts by a government agency for non-compliance. While the contravention itself may be similar to a criminal offence, and may involve the same or similar conduct, the process by which the offence is sanctioned is instead based on civil court processes. Civil monetary penalties play a key role in regulation.

An infringement notice is a notice issued by a regulatory agency setting out the particulars of an alleged non-compliance with a criminal offence or civil penalty provision. Persons to whom an infringement notice is issued may either pay the fine specified in the notice in full or elect to have the offence heard by a court. Notices are generally issued for minor offences that are regulatory in nature.

Currently the Regulator has few options to address non-compliance in between cooperative compliance and criminal prosecutions, and a more nuanced approach is needed. Civil penalty provisions and infringement notices issued by authorised compliance officers will provide the Regulator with compliance measures found in other modern regulatory schemes including Therapeutic Goods Act 1989, Industrial Chemicals Act 2019, Agricultural and Veterinary Chemicals Code Act 1994, and the Biosecurity Act 2015.

It is important to note that at section 33A of the GT Act as amended a licence holder could be liable for a civil penalty if their action or omission breaches a condition of a licence, even if they did not intend to breach the condition or were reckless to whether it would breach the condition.

A civil penalty provision corresponding to each offence has been included in the proposed Part 4 of the GT Act as amended. These civil penalty provisions will operate in accordance with Division 2 of Part 11 of the amended GT Act, which reproduces provisions from Part 4 of the Regulatory Powers Act. Penalties have been set taking account of similar civil penalty provisions in Commonwealth legislation, and to deter non-compliance. All civil penalty provisions will be subject to infringement notices.

Civil penalties and infringement notices will provide the Regulator with a modern suite of regulatory and enforcement tools in circumstances where prosecution is not warranted. Contraventions of a civil penalty provision that causes significant damage, or are likely to cause significant damage, are ‘aggravated contraventions’ (section 35A of the amended GT Act) and will attract higher maximum penalties.

Repeal of ‘strict liability’ offences

Strict liability offences are offences defined by the absence of any requirement of fault (intent, knowledge or recklessness), and are generally imposed to protect public health and safety or the environment.

Sections 33, 35B and 37 of the GT Act currently contain elements of strict liability. With the inclusion of civil penalties, there is no longer a particular need for strict liability offences as part of the enforcement regime, and equivalents to the current ‘strict liability’ offences not proposed to be included in the GT Act as amended.

Monitoring powers (Part 10)

Part 10 of the GT Act as amended proposes to confer powers on the Regulator to monitor whether the gene technology legislation has been, or is being complied with, and whether information given in compliance with the legislation is correct.

Consistent with the current GT Act, authorised inspectors will continue to be empowered to enter any premises with the consent of the occupier of the premises, or if the entry is made under a monitoring warrant.

Under the current Scheme, spot checks of premises where dealings with GMOs are being undertaken are a key mechanism to ensure the legislation, and conditions of dealings with GMOs and conditions of certifications, are being complied with. Accordingly, section 146 of the amended Act would also empower authorised inspectors to enter premises for the purposes of monitoring if entry is at a reasonable time, and

- the occupier of the premises is a person dealing with or has dealt with a GMO at the premises, the dealing with the GMO is, or was, authorised by a GMO licence or a GMO permit, and a relevant condition applies or applied to the person;
- the premises is a certified facility and the occupier of the premises is the holder of the certification; or
- the occupier of the premises is a person dealing, or who has dealt with, a GMO at the premises, the dealing with the GMO is, or was, specified in an Emergency Dealings Determination (EDD), and a condition of the determination applies or applied to the person.

Some monitoring powers will only be available to authorised inspectors entering premises with consent or under a monitoring warrant, such as the power to remove samples from the premises. The power to require persons to answer questions is only available to authorised inspectors under a monitoring warrant. Further, the proposed section 147B of the GT Act as amended will only permit authorised inspectors to use force against things when entering premises under a monitoring warrant. These provisions will provide limits for the exercise of these significant powers in line with modern regulatory regimes.

Investigation powers (Part 10A)

Part 10A of the GT Act as amended proposes to provide for investigation powers for the purposes of gathering material that relates to the contravention of offence and civil penalty provisions. Investigation powers are substantially reproduced from standard provisions of the Regulatory Powers Act, with some minor adjustments or definitional amendments as outlined above. Authorised inspectors will only be permitted to enter premises for the

purpose of exercising investigation powers with consent of the occupier or under an investigation warrant.

Part 10A of the GT Act as amended is largely comparable to powers contained in Part 11 of the current Act, however it proposes to:

- require certain persons to provide facilities and assistance to authorised inspectors executing a warrant and includes an offence;
- permit the Regulator to not return seized things if as a result of performing functions or powers under the amended GT Act, the thing is damaged or destroyed and it is not possible or reasonably practicable to return it; and
- permit the Regulator not to return a seized thing if that thing is an animal, plant or other organism or any part or product of an animal or plant (Section 155B(3)(d) and (e) of the GT Act as amended).

Additional monitoring and investigation powers (Part 10B)

Part 10B of the GT Act as amended proposes additional powers that are currently contained in the GT Act but are beyond the standard provisions of the Regulatory Powers Act. These additional powers are included to ensure that matters specific to the regulation of gene technology can be managed. Part 10B replicates the existing power in the GT Act to search and seize goods, baggage and other things in transit where there is reasonable belief that they contain, or are, evidential material. It also includes a new power to enable the Regulator to require information or documents be produced where there is a belief that a person has dealt, or is dealing, with a GMO and has information relevant to the Regulator's functions. Failure to provide such information will constitute an offence.

Emergency powers (Part 10C)

Powers available to authorised inspectors for dealing with dangerous situations have been moved to the proposed new Part 10C of the GT Act as amended and broadly replicate current section 158 of the GT Act). The powers enable inspectors to enter premises, search and secure things, and require a person to comply with the legislation in particular circumstances. The draft Bill amends the threshold for exercising emergency powers from an 'imminent risk of death, serious illness, serious injury or serious damage to the environment' to 'a significant risk to human health and safety or to the environment'. This change ensures the threshold for triggering regulatory action is applied consistently and is appropriate to maintain the objects of the Scheme.

Compensation for damage caused by exercising powers (sections 192B & 192C)

Existing provisions are proposed to be replicated and consolidated in Division 6 of Part 12 of the GT Act as amended, along with a new provision regarding compensation for the acquisition of property other than on just terms (new section 192C of the GT Act as amended). These provisions proposed to require the Commonwealth to pay the owner reasonable compensation in relation to damage and acquisition of property in certain circumstances. Section 192B of the GT Act as amended replaces section 163 of the GT Act, which describes the circumstances in which someone is entitled to compensation for damage. It has been revised to reflect the scope of the proposed new monitoring and enforcement powers conferred on the Regulator, and is consistent with standard provisions of the Regulatory Powers Act.

Section 192C of the GT Act as amended regarding compensation for the acquisition of property is proposed to ensure that if the amendments to the legislation do result in any inadvertent or unintended acquisition of property other than on just terms,2 the person from whom the property is acquired is entitled to compensation.

Enforcement powers (Part 11)

Part 11 of the draft Bill proposes to provide the Regulator with a broad suite of enforcement powers to respond to non-compliance, thus introducing more flexibility in how non-compliance is managed. This, in turn, incentivises compliance with the GT Act.

Proposed additions to enforcement powers are:

- the power to seek a civil penalty order from a court in response to contravention of a civil penalty provision (section 163 of the amended GT Act);
- the ability to issue infringement notices for breaches of civil penalty provisions (section 164A of the amended GT Act);
- the ability to enter into an agreement which can be enforced in court to ensure compliance (enforceable undertakings) (section 165 of the amended GT Act); and
- the power to apply for a court order directing compliance or compensation in response to a breach of an enforceable undertaking (section 165A of the amended GT Act).

The power of the Regulator to apply to a court for an injunction to compel compliance or prevent non-compliance would continue to exist under section 166 of the amended GT Act.

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[2] Within the meaning of section 51(xxxi) of the Constitution.

Before deciding such an application, a court would also have authority to grant an interim injunction under section 166A of the amended GT Act. Provisions relating to injunctions would be consistent with the Regulatory Powers Act.

The Regulator's ability to give directions as currently set out in section 146 of the GT Act will also continue, but it is proposed that the GT Act as amended will extend this power to also allow the Regulator to give directions to ensure that GMOs are transported, stored or maintained appropriately if a GMO licence or GMO permit is suspended or cancelled. It is also proposed that the Regulator will have the ability to give directions for destruction of a GMO if the GMO licence or GMO permit will be cancelled or surrendered.

Protections

The GT Act as amended also seeks to ensure appropriate protections for people performing functions under the legislation in good faith, or giving information to the Regulator, from criminal or civil liability.

The definition of 'authorised GMO dealing' in section 31A of the GT Act as amended provides that a dealing with a GMO is an authorised dealing if the dealing is done in the performance (or purported performance) of a function or power conferred by the GT Act or GT Regulations, or in providing assistance to the Regulator where the dealing is as the result of a request or direction made by the Regulator under the GT Act or the GT Regulations, or where the dealing is as a result of a requirement of an authorised inspector.

The provision is intended to ensure that OGTR inspectors and third parties acting on behalf of, or under the authority of, the Regulator do not commit the offence in section 32 of the GT Act as amended when dealing with GMOs in the course of performing their powers, functions or duties.

A new section 192D in the GT Act as amended proposes to protect persons from liability in civil proceedings when performing functions, exercising powers, or providing assistance to the Regulator in good faith. The provision is intended to protect the Regulator, a delegate of the Regulator, authorised inspectors, experts or persons assisting them, and third parties acting on behalf of, or under the authority of, the Regulator from civil liability.

Finally, in light of other amendments to the GT Act, there are different circumstances in which persons may, or must, give information to the Regulator. For example, if the holder of a GMO licence or a GMO permit becomes aware of risks to the health and safety of people, or to the environment, associated with the authorised dealings, those matters must be notified to the Regulator. Section 192 of the GT Act as amended replaces existing section 67 of the GT Act and ensures that persons giving information to the Regulator in the

circumstances described, are not liable to civil proceedings as a result of giving that information.

Questions

11. Do you understand the obligations and responsibilities that flow from the proposed offences and civil penalties relevant to your scope of regulated activities?

12. Do the proposed new enforcement powers strike a suitable balance with the risk-tiering framework, which would increase flexibility and enable a greater range of authorisations with reduced up-front assessment?

13. Should the circumstances where Authorised inspectors are able to enter premises at s146 of the amended GT Act without a warrant or consent be extended to allow for entry to premises where notifiable dealings are being undertaken?

14. Should the Regulator's powers to issue directions be extended to situations where the Regulator suspects that an unauthorized dealing with a GMO is taking place, if necessary to manage risks to people and the environment?

Chapter 5: Certification and Accreditation

Consistent with current arrangements, the draft Bill proposes that certain dealings with GMO will not be authorised unless conducted in certified facilities.

The draft Bill also introduces a new offence provision for breach of condition of a certification or accreditation.

The GT Act currently refers to guidelines issued by the Regulator specifying containment requirements that must be met for facilities to be certified and matters the Regulator must have regard to when deciding whether to accredit an organisation. The draft Bill enables rules to specify requirements for the certification of facilities or accreditation of organisations, as well as standard conditions of certification and accreditation. An applicant for accreditation will also be assessed on their suitability.

Proposed amendments: accreditation

There are four key amendments that are proposed in relation to accreditation as outlined below.

New offence provision

A key change is that the draft Bill proposes that there will be a new offence relating to breaches of conditions by holders of accreditation.

The role of accredited organisations is central to the revised regulatory framework. A new offence (section 33F of the amended GT Act) will be introduced for breach of a condition of accreditation by the holder of the accreditation. This offence will only be applicable to holders of accreditation.

Requirements and conditions to be specified in rules published by the Regulator

The draft Bill also proposes that rules published by the Regulator will be able to specify requirements that must be met for the Regulator to accredit an organisation.

The Regulator will continue to be able to directly impose conditions of accreditation, and the draft Bill also proposes for rules to specify conditions that apply to all accredited organisations.

Including decision criteria for accreditation in the GT Act

The GT Act currently sets out matters that the Regulator must have regard to when deciding whether to accredit an organisation. These relate to matters regarding IBCs and provides for matters to be specified in the Regulator's accreditation guidelines (which currently address suitability aspects). To ensure greater clarity of requirements and to elevate the need for

organisations to be ‘suitable’ to hold an accreditation, a set of decision criteria is proposed in the GT Act as amended. It is anticipated that criteria would include suitability and the capacity to meet conditions relevant to the accreditation.

Implementing decision criteria for accreditation would change the context of a matter the Regulator currently must have regard to, and whether an organisation has appropriate indemnity arrangements for its IBC members. Regulated stakeholder views are sought on whether it is appropriate to retain this concept, see consultation questions below. In addition, the draft Bill proposes that the Regulator will be able to decide to accredit an organisation even if a criterion for accreditation is not met, if conditions applied to the accreditation mean it is unnecessary.

Suspension or cancelling accreditation

The draft Bill proposes to remove the ability for accreditations to be suspended on request by the holder.

In addition, the draft Bill proposes that it will be a ground for suspending or cancelling accreditation if the requirements to become accredited are no longer met.

Proposed amendments: certification

Similarly to accreditation, the role of certified facilities is also central to the revised regulatory framework, also noting there is an increasing prevalence where persons are renting facilities where they undertake dealings, and therefore they are not the facility certification-holder.

The proposed new offence relating to breaches of conditions at section 33F of the GT Act as amended will also apply to holders of certification, and the Regulator will also be able to specify additional requirements for certification in rules.

Requirement for the holder of the certification

There are currently no limitations on who can apply for the certification of a facility, and then become the holder of the certification. Given the holder of the certification is responsible for complying with conditions and will potentially commit an offence if a condition of certification is breached, the GT Act as amended proposes to explicitly require a relationship between the holder of the certification and the facility to exist. To this effect, the GT Act as amended proposes to require the holder of the certification to be a person that has authority to admit and exclude persons from the facility, and authority to maintain the facility and the fittings and equipment within the facility. This requirement aligns with current standard conditions of certification, elevating this criterion to the primary legislation. This is appropriate because it is a central aspect of the certification process and is necessary for appropriate operation of the new offence and civil penalty for the holder breaching conditions of certification.

Other certification requirements

Section 84 of the GT Act as amended proposes to refer more broadly to 'certification requirements' which will be specified in rules made by the Regulator. This amendment also introduces criteria requiring the holder of certification to be the occupier of the premises and being able to meet the conditions of certification.

Provisions are also included in the GT Act as amended that propose to allow for the amendment of certification conditions at the time of transfer.

Questions

15. Do you have any concerns with the practical implementation of proposed amendments to certification and accreditation?

16. Should it continue to be a requirement for the accreditation of an organisation that the organisation has appropriate indemnity arrangements in place for the members of its Institutional Biosafety Committee(s)? If so, what type of indemnity arrangements should be regarded as appropriate?

17. Would the proposed offence for breach of accreditation conditions operate more fairly and clearly if organisations were directly accredited, rather than accreditation being held by the person who applied to accredit the organisation? Would such direct accreditation pose any difficulties for regulated entities?

Chapter 6: Use and Disclosure of Information

Information that applicants, authorisation holders and others provide to the Regulator may have significant commercial value. In order to ensure that the value of this information is not diminished, and to ensure that information is only used appropriately and disclosed only to appropriate parties, the information use and disclosure provisions will be strengthened under the draft Bill.

Recommendation 10 of the Third Review recommended streamlining process and current regulatory requirements, where appropriate, to reduce regulatory burden. The Review specifically identified an opportunity for confidential CCI provisions in the GT Act to be streamlined, stating that there would be merit in the OGTR undertaking a body of work to identify the most appropriate mechanism to ensure that CCI applications:

- do not compromise the efficient and effective assessment of licence applications, or
- unnecessarily risk inadvertent disclosure of CCI.

The proposed streamlined approach to the handling of CCI is intended to address issues with current arrangements, which include:

- current processes for CCI declarations are resource-intensive and inefficient for stakeholders where the information for which a declaration is sought may never be publicly released or published by the Regulator;
- because CCI declarations are not time limited, information retains CCI status until actively revoked, even if the information no longer has the characteristics of CCI; and
- CCI provisions are no longer in line with best practice regulation and do not properly account for policy shifts across related Commonwealth laws, such as the *Freedom of Information Act 1982* (Cth) (FOI Act).

Proposed revised CCI framework

CCI has a proposed new definition at section 10 in the GT Act as amended that reflects two well-recognised categories of information. These are trade secrets, and commercially valuable information the value of which would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.

In line with the Third Review, new arrangements set out in Division 3 of Part 12 of the GT Act as amended streamline and improve the operation of CCI provisions in line with best practice regulation. The cornerstone of these changes is that the Regulator will consider claims that particular information is CCI only if the Regulator is considering publication of

information, for example, for public consultation on a RARMP in relation to a licence application.

The revised CCI publication provisions in the GT Act as amended propose that where the Regulator is proposing to publish information that is potentially CCI, the Regulator must notify a person who might reasonably wish to have the information protected from disclosure (usually the applicant for an authorisation under the GT Act). This will enable those who own or have provided commercially valuable information to make a non-disclosure application in relation to the particular information that the Regulator is proposing to publish on the basis that it meets the definition of CCI.

Under the GT Act as amended it is proposed the Regulator will retain the ability to publish CCI if it relates to field trial sites, or if it has been identified to be in the public interest to publish the information. In relation to field trial sites the non-disclosure applicant will be able to provide submissions in relation to whether significant damage to health and safety of people, the environment or property would be likely to occur if the locations were disclosed. The non-disclosure applicant will also have an opportunity to address whether there will be prejudice to them that outweighs the public interest in, disclosure of the CCI.

Following this, and prior to publishing the document, the Regulator would be required to give notice of her decision on these matters, and merits review would be available to those who had made a submission. No publication could occur until review rights had been exhausted.

To support the identification of CCI the Regulator would put in place a number of measures to ensure that those providing information in the course of making an application or other processes under the GT Act, take steps to identify if any information is claimed to be CCI. They would also be asked to identify if any other person has an interest in the information, and if so, the applicant's authority to deal with the information would be sought. The Regulator would take into account these matters, and any other relevant information, to determine if a person needs to be notified in relation to the proposed publication of potential CCI.

These provisions will be analogous to the decision-making model for government agencies and ministers currently provided by the FOI Act, which ensures third parties' commercial information and trade secrets are protected where an access request is made for documents containing such information.

The focus of these provisions will be to determine if particular information at a particular time i.e. the time of proposed publication, is CCI. This will mean that Regulator resources will no longer be required to determine if all information claimed as CCI by an applicant meets the definition of CCI, in circumstances where that information will never need to be considered for inclusion in a publication. It also means that that a decision by the Regulator in relation to

whether information is CCI and therefore should not be disclosed will relate only to a particular instance of proposed publication and will not determine the status of the information at a later date.

It is intended that the provisions will apply across all occasions that the Regulator is required to publish information such as for public consultation on a RARMP, and publication of committee resolutions. In addition, it will apply to any discretionary activities connected with the Regulator carrying out their functions such as providing information and advice on the regulation of GMOs by publishing a map of GMO field trial locations on the website.

Example – proposed revised CCI process

A person submits a licence application for a field trial of GM sunflower expressing the gene *HOT 1* from *Xanthorrhoea* which makes plants heat tolerant. The applicant seeks to protect the identity of *HOT 1* and the organism of origin from disclosure on the basis that the information has commercial value that would be destroyed or diminished if the information were disclosed. The applicant claims that the information is CCI at the time the licence application is made by identifying the relevant information and providing brief justification of how the information meets the definition of 'CCI' in the GT Act. The applicant asserts that the information is not known outside their company and is protected by confidentiality agreements.

Since the parent organism is novel, the Regulator is required to consult the public on the application.

Scenario 1: The Regulator is aware of the applicant's claim. The Regulator is satisfied that public consultation on a RARMP can be effectively undertaken by referring to *HOT 1* as *GENE 1* and *Xanthorrhoea* as 'an Australian plant'. Public consultation occurs without the formal non-disclosure process being undertaken, as the Regulator is not proposing to disclose the claimed CCI.

Scenario 2: The Regulator is uncertain whether the claimed CCI meets the definition of CCI, and proposes to include the identity of *HOT 1* and the organism of origin in the RARMP for public consultation. The Regulator notifies the applicant of the proposed publication. The Regulator's notification includes a copy of the RARMP. The applicant makes a non-disclosure application addressing the criteria in relation to CCI and the public interest. After considering the application, the Regulator is satisfied that the information does not meet the definition of CCI because it has now been published in a scientific journal. The Regulator notifies the applicant of their decision. After merits review rights have been resolved, the RARMP can be published. The statutory timeframe for the assessment of the licence application would be paused from the day the Regulator invites the CCI provider to make a non-disclosure application to the day merits review rights are resolved.

Use and disclosure of Regulator Information

Provisions in relation to the occasions when the Regulator may use and disclose information provided to them in the course of performing their functions have been comprehensively

overhauled to align them with modern provisions in Commonwealth legislation. In doing so the provisions recognise as a starting point the statutory duty of confidence which restricts the use or disclosure of information to the purpose for which it is obtained, unless explicitly permitted by legislation.

The draft Bill sets out comprehensive provisions that describe the circumstances in which the Regulator may use and disclose information collected by the Regulator including CCI. Primarily these provisions are aimed at enabling the Regulator to use and disclose information for the purposes of carrying out their functions under the GT Act.

In addition, use and disclosure will generally be permitted for all information if required or authorised under a Commonwealth law, if it has been ordered by a court or tribunal or is a disclosure to a Minister or a Minister's staff.

As the Regulator operates within a broader regulatory landscape proposed provisions in the GT Act as amended will enable the Regulator to disclose information, including CCI, to another government body within the states, territories, and Commonwealth, to enable or assist that body to carry out its functions. This will ensure that the Regulator can share important technical or compliance information with other regulators such as the TGA or the APVMA in relation to GMOs. However, the Regulator will not be permitted to share information with other regulators contrary to the data exclusivity obligations discussed below.

Restrictions on disclosure will continue to apply to information that is CCI (under the new definition). CCI will not be permitted to be disclosed except to GTTAC and Commonwealth or state agencies in relation to statutory consultation requirements, or to other government agencies as set out above. The CCI processes described above will apply in circumstances where publication of potential CCI is required or proposed by the Regulator as part of their functions and duties.

Section 45 of the GT Act will be repealed and replaced with a provision that will not permit the Regulator to use or disclose information provided by one applicant to grant a GMO licence to another applicant if the licence would otherwise be unable to be granted due to the second applicant providing insufficient information. Consent of the first applicant will overcome this provision.

The GT Act as amended proposes changes that ensure data exclusivity provisions are addressed in line with Australia's international obligations under current or future international agreements. Current agreements which oblige Australia to provide data exclusivity are: the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement); the Australia-United States Free Trade Agreement (Australia-US FTA); and the Comprehensive and Progressive Agreement for the Trans-Pacific Partnership (CPTPP). Under these agreements data exclusivity is required in circumstances where a

government agency requires as a "condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort.[3]"

New provisions will require the Regulator to comply with these requirements in circumstances where a GMO authorisation amounts to a marketing approval and the other conditions described above have been satisfied.

It is proposed that the current offence relating to unauthorised disclosure of CCI be removed in line with the conclusions reached in the government's final report into the Review of Secrecy Provisions at www.ag.gov.au/crime/publications/review-secrecy-provisions.

The Government has agreed to recommendation 3 of the Secrecy Review to enact a new general secrecy offence to enable the further reduction of specified secrecy offences and non-disclosure duties.

The Secrecy Review recommended the offence apply to Commonwealth officers and persons who perform services for or on behalf of the Commonwealth where the disclosure would be prejudicial to the effective working of government or where the information was communicated to them in confidence.

The Attorney-General's Department is giving further consideration to the appropriate elements of the offence having regard to the potential for the new offence to replace existing offences and to the kinds of harms that should appropriately be targeted. For example, this could include harms to individuals that can be caused by the improper disclosure of sensitive personal or commercial information that is entrusted to government, or harm to the administration of government that can be caused by improper disclosure of confidential information.

Consequently, it is proposed the secrecy offence currently found at section 187 of the GT Act will be replaced with provisions creating a duty not to disclose CCI (except as permitted by the GT Act as amended), to ensure that the offence contained in section 122.4 of the Criminal Code, as currently drafted, is enlivened. Further review of these provisions will be conducted in light of any further action to either amend or replace section 122.4 of the Criminal Code, as a consequence of the Secrecy Review.

[3] TRIPS Agreement Article 39(3), similarly worded obligations are contained in Australia-US FTA Article 17.10(1)(a) and CPTPP Article 18.47(1).

CCI and the GMO Record

Consequential to the changes relating to CCI, and in line with harmonising information access procedures with the FOI Act, it is proposed that access to the GMO record will be provided in accordance with the FOI Act. This will ensure that all third parties who are required to be consulted under the FOI Act in relation to relevant exemptions, including in relation to trade secrets and commercially valuable information, will have an opportunity to make a submission, balanced against the public interest in providing access to government information in relation to the regulation of GMOs.

Questions

18. Do the proposed amendments relating to CCI strike the right balance between protecting the valuable information of those involved in the research and development of GMOs and transparency relating to the regulation of GMOs?

19. Are the proposals for use and disclosure of Regulator Information sufficiently clear?

20. Do stakeholders have any concerns with the revised definition of CCI noting the change in scope from the existing definition?

21. Do stakeholders have concerns with the new approach to information related offences noting that the intention is to further refine in line with any changes made to the offences in legislation administered by the Commonwealth?

Chapter 7: Minor, Technical and Consequential Amendments

A number of proposed minor and consequential amendments throughout the draft Bill are summarised here.

Minor, technical, and consequential amendments to the GT Act

Changes to money provisions (Division 3 of Part 9)

Section 131 of the GT Act as amended proposes to enable the Regulator to waive and refund amounts payable to the Commonwealth (for example, application fees) under circumstances to be prescribed in the GT Regulations.

Enabling fees for all applications (s 178A)

Recommendation 22 of the Third Review is that future consideration be given to the most appropriate funding mechanisms to support the ongoing operation of the Scheme, and to appropriate funding levels for the Regulator's activities, taking into account any changes to the Scheme. Section 178A of the GT Act as amended proposes to enable the GT Regulations to specify application fees for all applications. The amendment effectively ensures that legislative mechanisms are in place for any potential cost recovery activities, similar to the current GT Act.

A separate consultation process will be undertaken on potential cost recovery prior to any fees being introduced into the Scheme, in line with the Australian Government Charging Framework.

Changes to reviewable decisions (s 179)

Each of the amendments to the reviewable decision table at section 179 of the GT Act as amended are consequential to changes made elsewhere by the draft Bill. This ensures review rights are afforded in relation to new decisions established as part of the reform, for example, a decision to refuse to issue a GMO permit.

Clarification of the regulation-making power (s 193)

A proposed new subsection 193(3) of the GT Act as amended seeks to clarify that the GT Regulations may incorporate other instruments or documents by referencing them, as in force from time to time, in the GT Regulations. This update reflects the introduction of the Legislation Act since the drafting of current section 193 of the GT Act. The Legislation Act provides for several limitations and requirements around the making of delegated legislation, including regulations.

Minor changes to s 78 (relating to the GMO Register)

Proposed changes at paragraph 78(1)(b) of the GT Act as amended seek to address a drafting issue with the current provision and clarify the initial policy intent. That is, the Regulator may determine that a dealing with a GMO be included on the GMO Register if satisfied that the thing concerned would have been a GM product but for regulations made for the purposes of paragraph 12C(c) of the GMO definition, where those regulations would result in the thing instead being a GMO.

Repeal of redundant provisions

The draft Bill repeals current section 194 of the GT Act regarding review for the operation of the GT Act, as the effect of the provision ceased following the fourth anniversary of the commencement of the initial Act. In practice, reviews of the Scheme are determined by the GTMM in line with the Agreement.

Consequential amendments to other Commonwealth legislation

Schedule 2 of the draft Bill sets out two consequential amendments to other Commonwealth legislation due to proposed amendments to the GT Act, as follows:

the FOI Act – as the FOI Act already provides for exemptions for information that are trade secrets or commercially valuable. As the secrecy provisions in the GT Act will be repealed, CCI will no longer be covered by a specific secrecy exemption under the FOI Act. This will be achieved by removing reference to subsections 187(1) and (2) of the GT Act in Schedule 3 to the FOI Act. This means in practice that anybody who may be affected by an access request under the FOI Act for documents which potentially contain CCI, will be consulted in accordance with the FOI Act, prior to any decision being made by the Regulator to provide access to those documents, A party who is consulted will have the opportunity to make a submission that the CCI is exempt material, or conditionally exempt material, under all relevant provisions of the FOI Act, including those relating to trade secrets and commercially valuable information.

the RIHE Act - to remove section 47. As discussed in Chapter 1, with the amendment to the definition of ‘gene technology’ and the inclusion of the definition of ‘mitochondrial donation licence’ in the GT Act, section 47 of the RIHE Act can now be repealed. At the time that section 47 was inserted into the RIHE Act, it was anticipated that the provision would be repealed when the appropriate amendment was made to the GT Act.

Certain powers cannot be delegated (section 29)

Section 29 of the GT Act currently enables the Regulator to delegate any of their powers or functions to prescribed individuals in certain circumstances. Some of the additional powers and functions proposed by the GT Act as amended are significant, and therefore should only

be exercised by the Regulator personally, or by persons with appropriate skills and expertise.

Accordingly, it is proposed that the amended GT Act will not allow the Regulator to delegate the internal review of decisions or making of the rules that relate to risk-tiering. A new subsection 29(1A) is also proposed to specify that certain enforcement powers, can only be delegated to specified officers.

Streamlining committee appointments

Part 8 of the GT Act currently provides for the establishment, membership, and functions of the GTTAC and the Gene Technology Ethics and Community Consultative Committee (GTECCC).

Section 108 of the GT Act requires the Minister to consult with the states and territories on appointments to the GTECCC. The Minister must also ensure that the GTECCC membership includes a person who is a member of the Australian Health Ethics Committee (AHEC), which is a committee established by the National Health and Medical Research Council Act 1992. In practice, the NHMRC generally nominates a single AHEC member. Given that there is a finite pool of potential AHEC members to nominate from, the value of consultation for this single membership is limited.

The GT Act as amended proposes amendments to section 108 to enable the Minister to advise, rather than consult, states and territories on the AHEC-GTECCC cross-membership.

Removing codes of practice

The draft Bill repeals section 24 of the GT Act, which will remove the power of the GTMM to issue codes of practice. Under the current Scheme, codes of practice may be issued to form the basis for conditions the Regulator may impose under a GMO licence. No codes of practice have been issued under the current GT Act, and conditions are proposed to be contained in the amended GT Act or rules issued by the Regulator for the majority of authorisation pathways.

Streamlining Applications (Division 1A in Part 12)

At Recommendation 10, the Review recommended reducing regulatory burden through streamlining processes and current regulatory requirements where appropriate. The Review identified that this may include streamlining facility certifications and application processes.

There are different types of applications that may be made to the Regulator, including for example, applications for GMO licences, certification, accreditation, or variation of a GMO licence or certification. Currently, the different application provisions are spread throughout the GT Act.

The GT Act as amended includes a proposed new Division 1A in Part 12 of the amended GT Act to consolidate all matters relating to applications, and to create common requirements for applications. This approach streamlines the provisions, assists understanding, and ensures a consistent approach to all applications that can be made under the GT Act. The applications to which these provisions apply are listed in new section 178A of the GT Act as amended.

New Division 1A of Part 12 includes proposed common approaches to:

- How an application must be made – the GT Act as amended largely retains existing requirements, but provides for greater flexibility for the Regulator to approve the manner and form in which applications are made, and to specify documents and information that must accompany the application to support decision making.
- Circumstances in which an application may be withdrawn – the GT Act as amended retains the current policy whereby the applicant can withdraw an application at any time before the Regulator decides the application.
- Circumstances in which the Regulator may require an applicant to give further information – the GT Act as amended retains the existing approach whereby the Regulator can require the applicant to provide further information relating to an application within the timeframe prescribed. Failure to provide the information within that timeframe will mean that the application is taken to be withdrawn.
- Timeframe for making reviewable decisions – the GT Act as amended retains the current requirement for any applications for review of the decision to be made within the relevant period.
- Division 1A has the effect of broadening the application types for which a fee can be required. As outlined above, the imposition of fees and charges will be subject to additional consultation processes.

Consideration periods (section 178F)

The GT Act as amended also sets out proposed relevant consideration periods for different applications, and enables the GT Regulations to prescribe alternate consideration periods. For most of the application types, the existing timeframes for deciding an application have been retained, but are expressed in business days. This is reflected in the consideration periods in the table at subsection 178F(4).

Establishing consideration periods and periods that do not count towards the consideration period in the way set out in the proposed section 178F of the GT Act as amended ensures that intersecting applications and circumstances can be appropriately managed. For example, when the Regulator is awaiting a response from an applicant on a request for

further information relevant to consideration of the application, this period will be disregarded for the purposes of calculating the time to decide the application.

The intent is to use the GT Regulations to specify shorter licence application timeframes for applications that would not undergo public consultation. Because the complexity of applications that do not require public consultation varies, the GT Regulations will effectively apply further risk-tiering by setting consideration periods that are proportional to the consultation requirements and the complexity of the applications in the class. For example, the GT Regulations could prescribe that applications for a licence to authorise dealings undertaken in certified facilities with a novel GMO would require consultation with GTTAC and have a consideration period of 120 business days. If the GMO is not novel, there would be no consultation requirements and the consideration period could be set at 90 business days. Further consultation will be undertaken in regard to the provisions in the GT Regulations.

A comparison of consideration periods under the current GT Act and the proposed GT Act as amended is found below:

Current GT Act	**GT Act as amended**
Application for general DIR licence – 255 business days Application for limited and controlled DIR with significant risk – 170 business days Application for limited and controlled DIR with no risk – 150 business days Application for DNIR licence – 90 business days	Application for a GMO licence where the regulator did consult the public on a RARMP – 200 days Application for a GMO licence where the regulator did not consult the public on a RARMP – 150 days Regulations will specify shorter timeframes for some licence applications, proportional to the other consultation requirements and complexity of applications
Included, but no statutory time frame	Inadvertent dealings application – 90 days
Not applicable	Application for a GMO permit – 30 days
Application for variation of a GMO licence – 90 days	Application for transfer or variation of a GMO licence – 90 days
Application for certification – 90 days	Application for certification – 90 days
Included, but no statutory time frame	Application for variation or transfer of certification – 90 days
Application for accreditation – 90 days	Application for accreditation – 90 days
Included, but no statutory time frame	Application for variation of accreditation – 90 days

Rules issued by the Regulator

Rule-making parameters

Proposed section 193A of the GT Act as amended would empower the Regulator to make rules for prescribed matters that are required or permitted by the GT Act or the GT Regulations, with limitations. In addition to rules for risk-tiering, the Regulator will have the ability to make rules for accreditation, certification, and the transport, storage and disposal of GMOs. These rules will replace the current guidelines.

Rules made by the Regulator must not be inconsistent with the GT Act, the GT Regulations or a policy principle issued by the GTMM. Furthermore, rules made by the Regulator may not create an offence or impose a tax and will be subject to other standard limitations included across Commonwealth laws where a regulator or other delegate is empowered to make legislative instruments.

Consultation requirements

Proposed section 193B of the GT Act as amended sets out consultation requirements for draft rules. In addition, the general requirements contained in the Legislation Act 2003 for consultation on changes to Commonwealth legislation will also apply, under which decision makers must reasonably consult with stakeholders that might be impacted by any changes. Specifically, when making rules on risk-tiering classes or risk-tiering conditions the Regulator must:

- seek, and take into account, the advice of states and territories, and the Gene Technology Technical Advisory Committee (GTTAC); and
- publish the proposed rules on the internet, invite persons to make submissions within a specified period, and take into account any such submissions.

However, these standard consultation requirements do not apply to rules that are made or amended:

- for section 27A (rules for the transport, storage and disposal of GMOs), section 90 (rules for the certification of facilities) or section 98 (rules for accreditation of organisations) of the GT Act as amended;
- to correct an error;
- to make a minor or technical change; or
- to avoid a significant risk to human health and safety or to the environment (discussed below).

Minor or machinery changes of an administrative nature that do not substantially alter existing arrangements may be required from time to time. Previously, for example, amendments were required to the GT Regulations to replace the symbol for ‘micrograms’ with the full spelling of the term, due to certain devices displaying the symbol as ‘milligrams’.

Emergency rules

Section 193C of the GT Act as amended proposes to enable the Regulator to make emergency rules, or emergency amendments to rules, without following the prescribed consultation requirements, to avoid a significant risk to human health and safety or to the environment. However, general requirements set out in the Legislation Act 2003 (Cth) will still apply, that is the Regulator must still ensure appropriate consultation is undertaken in the circumstances.

Similar to the process for the making of EDDs by the Minister, the GT Act as amended proposes that rules issued by the Regulator in emergency situations cease to have effect after 6 months, the end of the period specified in the instrument, or when the instrument is revoked – whichever is first. The draft Bill does not incorporate options for renewal or extension of emergency rules. If the emergency rules or amendments are required for longer than 6 months, the Regulator will undertake the prescribed consultation process and amend the rules as appropriate, within the initial 6-month period.

Disallowance exemptions

Disallowance is the primary mechanism by which the Parliament exercises control over delegated legislation. The disallowance process allows either House of the Parliament to veto a legislative instrument.

The Legislation Act 2003 (Cth) provides that, generally, disallowance does not apply in relation to a legislative instrument (other than Regulations) if the enabling legislation supports the operation of an intergovernmental scheme and authorises the instrument to be made for the purposes of the scheme.

The GT Act as amended proposes that legislative instruments made under the GT Act (other than the GT Regulations) are exempt from disallowance. These amendments will make it clear within the GT Act that these legislative instruments (including rules made by the Regulator) are not subject to disallowance. This is consistent with similar provisions currently in the GT Act.

From a policy perspective, rules issued by the Regulator under the Scheme will be informed by understanding of risk and history of safe use. The ability for the Regulator to issue rules is crucial for the implementation of the risk-tiering framework. These exemptions from

disallowance will help to provide certainty for the Regulator and regulated entities on the operation of the Scheme.

State and territory adoption of rules

The Scheme comprises both Commonwealth legislation and corresponding laws enacted by the states and territories. In the interests of maintaining a nationally consistent Scheme, it is necessary that consequential changes will need to be made to corresponding state legislation.

Functions of the Regulator (s 27)

The functions of the Regulator are currently described in section 27 of the GT Act. To facilitate the revised structure of the Scheme, amendments to section 27 are proposed to facilitate the Regulator to:

- perform functions in relation to GMO permits;
- make rules;
- exercise monitoring, compliance and enforcement powers under the GT Act;
- provide information and advice to the Commonwealth Minister in relation to the operation of the GT Act and corresponding state legislation; and
- provide technical and procedural guidance in relation to GMOs.

An objective identified in the D-RIS is, where possible, aligning regulation with comparable regulatory schemes and enabling the better utilisation of international assessment information. To promote this objective, an additional function of the Regulator is proposed – that is, to promote an internationally consistent approach to GMO regulation, where appropriate.

Questions

22. Are there any concerns about the scope and process proposed for rules made by the Regulator?

23. Are there provisions in the GT Act as amended that would be difficult for regulated entities to apply or that would operate unfairly?

Chapter 8: Application, Savings and Transitional Provisions

Important: Arrangements to support the smooth transition of the Scheme are being developed and will be further informed by consultation feedback on the proposed changes to the GT Act and further discussions with State and Territory governments. However, the broad intent of transitional provisions is outlined below.

The reforms proposed in this draft Bill make significant changes to the existing regulatory framework. As such it is essential to allow for a smooth transition to the new regulatory framework.

The draft bill proposes that the new regulatory framework will commence 12 months after royal assent through the Commonwealth Parliament. This will allow for development of the amendment Regulations and Rules to be published by the Regulator, and other administrative activities including publication of application forms. This transitional period will allow regulated entities to prepare for commencement and consider implications of the new framework on their current authorisations, or any applications underway, and take any actions they consider appropriate for their circumstances.

Management of existing approvals

The intent of the transitional provisions is to minimise additional regulatory burden where appropriate and support ongoing efficient administration of the Scheme. As such, some pre-existing authorisations may be adjusted to bring them into the amended scheme, avoiding the need for variations or new applications to continue pre-existing activities.

However, there may be a need for some stakeholders to seek authorisations under the revised framework as highlighted below.

GMO dealings

DIR and DNIR licences issued by the Regulator under the current GT Act will continue to have effect after the commencement of the revised framework until the licence expires or is surrendered, or until the Regulator suspends or cancels the licence. The conditions of the licence will continue unchanged except in so far as the new statutory conditions will replace the existing statutory conditions (including in cases where the existing statutory conditions are reflected in the licence itself). The new statutory conditions will have some operation during a period of suspension or after the cancellation or surrender of the licence.

Licences issued before the commencement of the revised framework will be able to be varied under the sections covering the variation of GMO licences in the revised framework.

As outlined in Chapter 1 above the draft Bill proposes to amend the definition of 'deal with' to include use, storage and supply as primary dealings. This has the effect that some activities with GMOs that do not currently require any authorisation under the Scheme will become regulated dealings with GMOs after commencement of the revised framework. It is intended that, where an activity is not regulated under the current law as a dealing with a GMO, the activity is reasonably incidental to dealings with GMOs authorised by an existing licence, and the activity is regulated as a dealing with a GMO under the revised regulatory framework, transitional provisions will automatically extend the scope of the dealings covered by a licence to cover that activity.

NLRDs under the Scheme prior to commencement will fall within the new category of transitional notifiable dealings upon commencement, and NLRDs will cease to be a form of authorisation. Consequently, dealings authorised by NLRDs underway at the commencement of the amended GT Act will be able to continue with similar requirements after commencement, generally up to but not more than 5 years after they were originally assessed by an IBC. The authorisation provided by the transitional notifiable dealings will cover the expansion of the 'deal with' definition, in the same way as noted above in relation to licences. It will not be necessary for organisations to arrange for a new IBC assessment to be carried out after commencement in order to conduct dealings under a transitional notifiable dealing.

For the small number of matters where the existing NLRD no longer falls within a Notifiable Dealing category an application for the relevant level of authorisation, in most instances a licence, will need to be made within a year of commencement to bring the dealing into line with the new scheme's authorisation requirements.

Exempt dealings will cease to be a type of authorisation at commencement time. It is anticipated that all GMO dealings that are exempt dealings will become non-notifiable dealings, and those dealings could continue uninterrupted with unchanged requirements.

GMO dealings included on the GMO Register under the existing law will continue to be included on the Register after commencement time. Supply, storage and use as primary dealings will be taken to be authorised under the register entry.

If an EDD is in effect immediately before commencement of the amended GT Act it will continue uninterrupted.

CCI

Information declared to be CCI under the existing law will continue to be protected in accordance with the new law if the information meets the new definition of CCI. Declarations of CCI under the old law will not bind any later decisions in relation to that information that may be made in accordance with the new CCI process under the new Division 3 of Part 12.

CCI as described in the new definition will remain protected from use and disclosure except in the circumstances explicitly provided for in the Bill.

Certification and accreditation

Facility certifications issued under the current GT Act will continue with the same conditions imposed by the Regulator at the time of certification, or through subsequent variations. Any additional conditions imposed by the GT Act or rules under the new law will apply from commencement time.

Where a person holds accreditation on behalf of an organisation immediately prior to commencement time, the person will continue to hold the accreditation after the commencement time.

Under the current GT Act 'organisation' is not defined. This has led to some confusion about the exact nature of the entity being accredited. The bill inserts a new definition of organisation that provides that an ‘organisation’ can be a Commonwealth agency, a Commonwealth authority, a State agency, a body corporate or an individual.

Conditions of accreditation specified in rules issued by the Regulator will replace the conditions of individual accreditation instruments in effect prior to commencement. Penalties for breach of conditions under the new law will be applicable from commencement and the person who is the holder of the accreditation will be liable under the criminal and civil penalty provisions that apply to accreditation.

It is anticipated that the standard conditions under the rules issued by the Regulator will be substantially equivalent to the standard conditions contained in existing accreditation instruments, except where matters currently addressed in conditions will instead be addressed via criteria for accreditation. While it is not expected that organisations will be subject to any new standard conditions, a period of 12 months from commencement will be provided to organisations to comply with any new conditions which may be applied.

Applications under consideration during the transition period

The proposed transitional approach will enable applicants to submit applications, and OGTR to consider applications at a steady pace throughout the transition period.

GMO Dealings

Following commencement, applications for a DIR or a DNIR licence that are received during the transition period and have not yet been determined at commencement will be taken to be an application for a GMO Licence under the revised framework. These applications will be considered according to the revised framework outlined in the bill.

Prior to commencement of the amended GT Act, application forms will be published to support the reforms and new authorisation pathways. Applications will be able to be submitted prior to commencement using these forms, thus ensuring that the information requirements under the new scheme have been addressed in advance. This will help to avoid delays that may occur should the Regulator require additional information in order to make a decision under the new scheme after commencement. Decisions under the new scheme will not be made prior to the commencement of the amended GT Act.

Consideration timeframes will be prescribed for decisions in relation to licence applications made during the transition period. These will be calculated having regard to the original timeframe prescribed for the kind of licence application, the new time frame for that kind of application after commencement, and the date on which the application was made. In all circumstances the Regulator will have the ability to suspend the consideration period to seek additional information if necessary.

Accreditation and certification

Where a person has made an application for accreditation of an organisation, or certification of a facility during the transition period and that application has not been determined by commencement, then that application will be taken to have been made under the revised framework. The consideration period for that application will start at the commencement of the new framework, with the Regulator having the ability to suspend the consideration period to seek additional information if necessary.

Question

24. Are there any concerns about the proposed approaches to transition to the reformed scheme?

Figures

Figure 1 Intersection with other Agencies

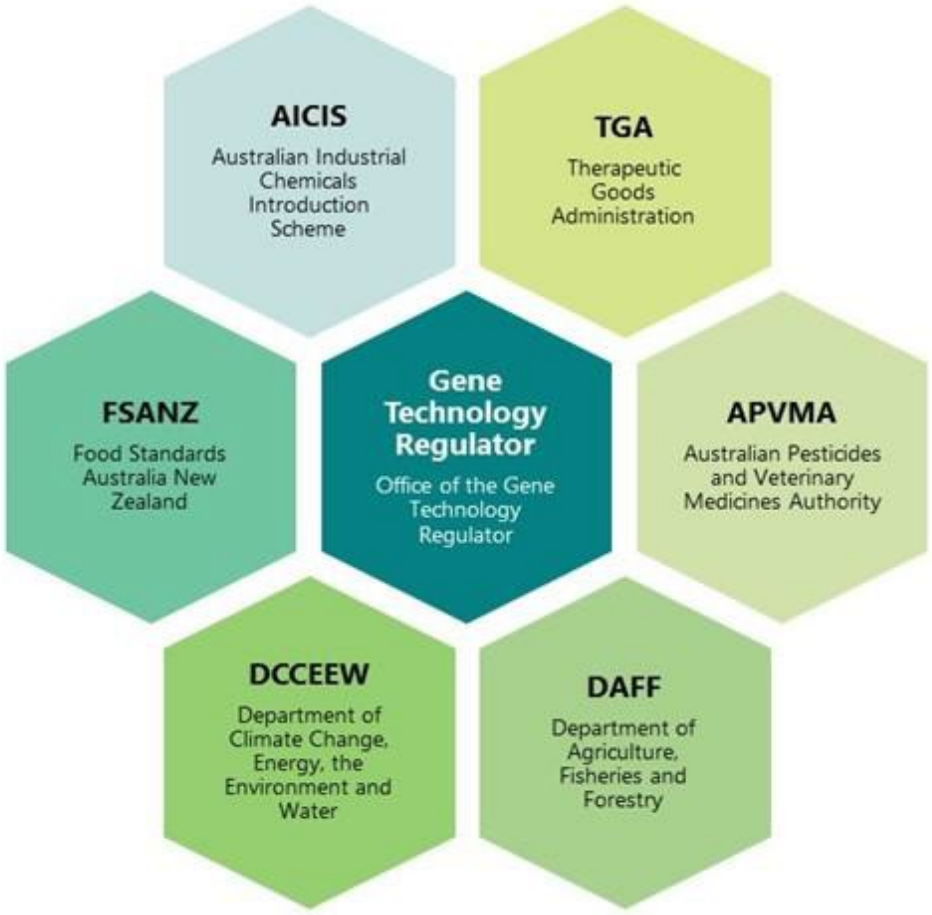

Figure 2 Proposed Changes to Authorisation Pathways

*Note that some dealings covered by a GMO licence currently may fall into lower authorisation pathways under the new regulatory approach (e.g. GMO permit or notifiable dealing).

Figure 3: Proposed changes to the Scheme's legislative structure

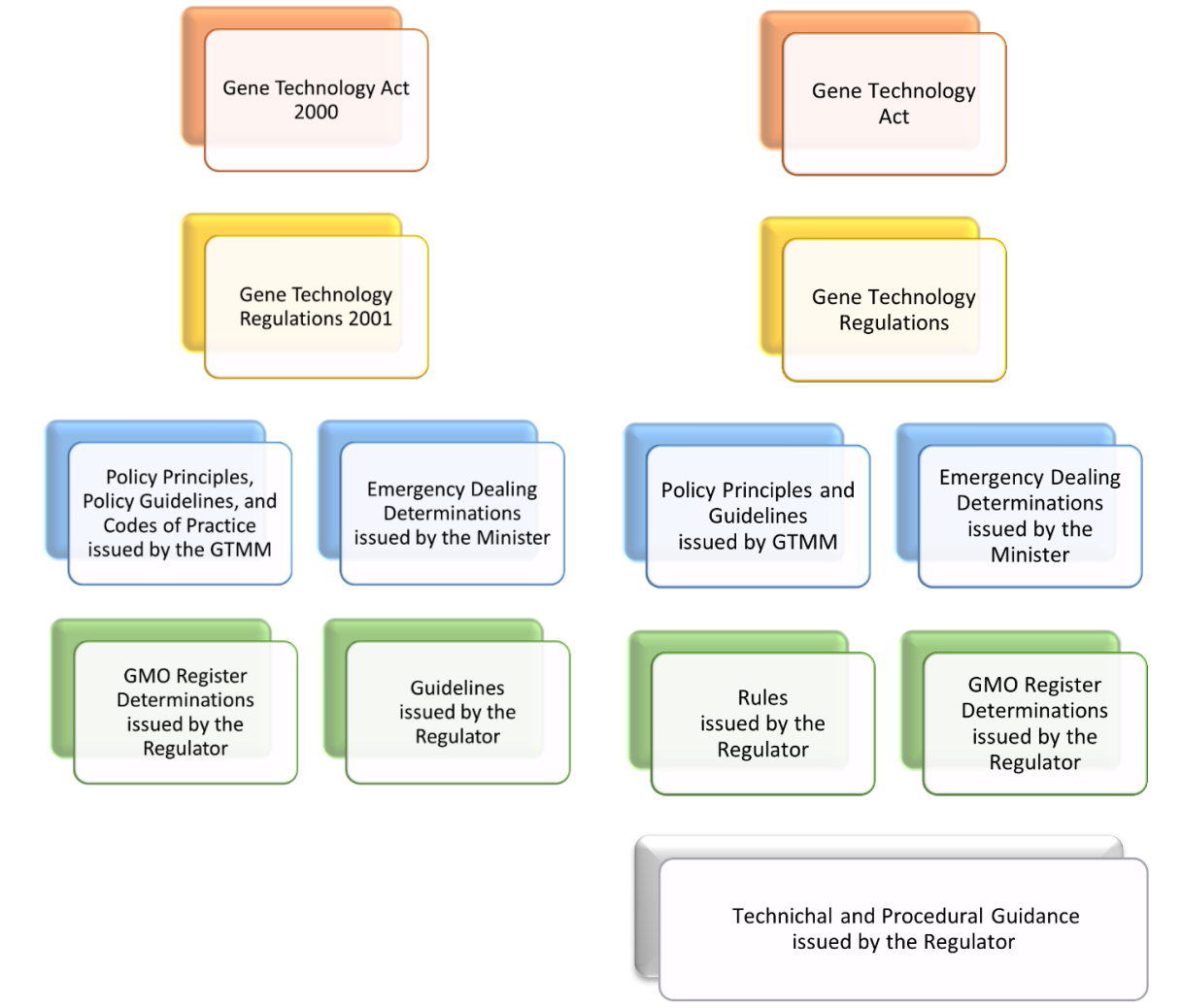

Figure 4: Practical examples – structure of the Scheme

	GT Act	GT Regulations	Rules
GMO licence	Enables GT Regulations to establish alternative consideration periods Prescribes some conditions Enables rules to prescribe conditions	Alternative consideration periods for certain classes of licences Specify dealings with GMOs that must be authorised by a licence E.g. dealings with GMO plants where the genetic modification is a gene drive or leads to the production of high toxin levels, a high-risk toxin or infectious particles	Conditions applying to all licences or to classes of licences
GMO permit	Enables GT Regulations to determine permit dealings Prescribes some conditions Enables rules to prescribe conditions	**Class X** Dealings with GM plants derived from a species that has low weediness potential and has been the parent organism of a previously authorised GMO Enables rules to further narrow Class X Dealings must be for the purpose of undertaking a field trial	Eligible plants are GMOs derived from wheat, cotton or banana Conditions applying to field trials of GM wheat, cotton or banana
Notifiable dealing	Enables GT Regulations to determine notifiable dealings Enables GT Regulations to set authorisation requirements Prescribes some conditions Enables rules to prescribe conditions	**Class X** Dealings with a GM plant undertaken in a certified facility Enables rules to further narrow Class X **Authorisation requirements** Dealings must have been assessed by an IBC as being a notifiable dealing prior to the dealing commencing	**Class X** Containment level for GM plants: PC2 Conditions applying to dealings with GM plants undertaken in certified facilities Dealing must be notified to the Regulator by 30 September of the next financial year
Non-notifiable dealing	Enables GT Regulations to determine non-notifiable dealings	**Class X** Dealings with host/vector systems that are not pathogenic or able to survive in the environment without human intervention, carrying a genetic modification that does not increase the capacity of the host or vector to cause harm Enables rules to further narrow Class X Dealings must be contained and not exceed a maximum production volume	Dealings with plant cell cultures and disarmed strains of *Agrobacterium tumefaciens*

Figure 4: Legend

This figure represents how the authorisation pathways are set at the different levels of legislation, using the regulation of dealings with genetically modified (GM) plants as an example.

Dealings with GM plants require a licence unless they are authorised by a GMO permit, or as a notifiable dealing or non-notifiable dealing. The eligibility criteria for each risk tier will be specified in the GT Regulations and rules. The GT Regulations will also specify 'designated dealings' that cannot be non-notifiable, notifiable or permit dealings. For instance, dealings with GM plants that express a high-risk toxin would require a licence in all circumstances and would not be permit dealings, notifiable dealings or non-notifiable dealing.

The GT Regulations may prescribe that dealings with GM plants are permit dealings if the dealings are for the purpose of undertaking a field trial outside a certified facility and the GM plants are derived from a plant species that have low weediness potential and have been the parent organism of GMOs previously authorised under a licence. The rules could further narrow the class of permit dealings described in the Regulations, for examples to specify wheat, cotton and banana as the only eligible parent organisms.

The GT Regulations may prescribe a class of dealings with GM plants that are conducted in containment as notifiable dealings, with the level of containment specified in the rules. The authorisation requirements that would need to be met for the dealing to be an authorised GMO dealing, would include an IBC assessing the proposed dealing. The rules would specify conditions including who must notify the dealing to the Regulator and when the notification must be complete.

The GT Regulations could prescribe that dealings with a low risk host/vector system carrying a low risk genetic modification are non-notifiable dealings if the dealings are contained and do not exceed a maximum production volume. The GT Regulations could mandate that the low risk host/vector systems are not pathogenic or able to survive in the environment without human intervention; and that the genetic modifications must not increase the capacity of the host or the vector to cause harm. The rules would specify allowed host/vector systems and modifications, for example dealings with plant cell cultures and disarmed strains of Agrobacterium tumefaciens where the donor nucleic acid introduced in the plant cells and/or Agrobacterium is not derived from a pathogenic organism, does not encode a toxin, does not result in the production of infectious particles and is not likely to increase the capacity of the plant cells or Agrobacterium to cause harm.

Attachment A

The Third Review recommended that a number of the elements of the Scheme be maintained. For example, the Review recommended maintaining:

- the objects of the GT Act (recommendation 2)
- the Agreement (with appropriate administrative revisions) (recommendation 3)
- a process-based trigger as the entry point for the Scheme to allow for any potential risks associated with new technologies to be initially considered within the scope of the Scheme (recommendation 8)
- maintaining current governance mechanisms to ensure that the Scheme's current levels of credibility, integrity and legitimacy are upheld (recommendation 16).

Each of these elements of the Scheme has been maintained, as recommended.

The Review also recommended several updates and enhancements to the Scheme. The following table describes these updates and enhancement as relevant to the draft Bill. Please note that a number of the recommendations related to administrative matters that are not reflected in the table below.

Third Review Recommendation (summarised)	How has the recommendation been addressed?	Amended GT Act references
Recommendation 4: Updating, where required, the existing definitions in the GT Act, to clarify the scope of regulation in light of ongoing technical advances.	The draft Bill amends, repeals and inserts definitions where necessary to clarify the scope of regulation, provide greater clarity, incorporate risk-tiering and reflect changes in drafting practice over the past 20 years. Key definitions have been updated including *deal with*, *gene technology* and *genetically modified organism*.	Sections 10, 12A, 12B and 12C
Recommendation 6(a): The definition of a GMO under the *Gene Technology Act 2000* be amended to clarify that humans are not considered to be GMOs.	The definition of genetically modified organism has been amended to exclude humans and to clarify the scope of the definition (as per recommendation 1).	Section 12C
Recommendation 7(a): Clarifying, and where necessary strengthening, the mechanisms for regulating the broader environmental release of genetically modified organisms.	The approach to risk-tiering enables risk-proportionate regulation to be applied to different dealings with GMOs. Rather than treating all releases of GMOs into the environment in a similar way, the reformed legislation recognises that there are different risks (and risk management conditions) that will be appropriate based on the type of GMO being released and how it is being released. For example, managing risks associated with a human shedding GMO vaccine is different to managing risk associated with the field trial of a crop.	Various Part 5, Part 5AA Part 5AAA Part 6

Third Review Recommendation (summarised)	How has the recommendation been addressed?	Amended GT Act references
Recommendation 9: 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.	Many of the amendments made through the draft Bill achieve this recommendation. For example, the creation of a new risk-tiered authorisation pathways (such as the permit), empowering the regulations to specify classes of dealings with GMOs within the authorisation categories and enabling the Regulator to make rules that further specify matters in relation to a class and to impose conditions on such dealings. Removing the binary distinction between dealings that involve intentional release of a GMO into the environment and those that do not. Specifying when the Regulator may and must publicly consult on a risk assessment and risk management plan (RARMP) for a licence application and exceptions to this (refer 4.4 of this paper). Aligning the threshold at which certain actions may be taken by the Regulator (i.e. to "avoid a significant risk to human health and safety or to the environment").	Various - Refer to Chapter 3 of this paper
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.	A number of amendments in the Bill streamline approaches to: CCI, applications to the Regulator, timeframes for consideration of applications, streamlining Committee appointment processes, improving operation of certification and accreditation etc.	Part 12
Recommendation 11: The Review recommends that changes be made to enable the GMO Register to be more effectively utilised within the Scheme.	Changes have been made to enable the Regulator to include a wider range of GMO dealings on the GMO Register, where the GMO dealing has previously been authorised by the Regulator.	Section 78
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	The new risk-tiering approach (enabling the Regulator to make rules within parameters agreed by all governments) enables the Regulator to appropriately manage GMOs with a history of safe use. There will continue to be full transparency about all dealings with GMOs approved by the Regulator. Separate consultation will be undertaken in relation to gene editing.	Part5 Part 5AA Part 5AAA Part 6

Third Review Recommendation (summarised)	How has the recommendation been addressed?	Amended GT Act references
agreed; and b) introducing elements of principles-based regulation to some parts of the Scheme, focusing on areas of the Scheme with a history of safe use.		
Recommendation 15: The Review recommends that the Australian Government, including the Gene Technology Regulator on regulatory matters, continues to: a) engage with appropriate international fora on matters relevant to market access and international trade; and b) ensure that any relevant international obligations continue to be met.	An amendment has been made to the functions of the Regulator to ensure clarity around the role of the Regulator and that such engagements can continue to occur.	Section 27
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.	Amendments across the draft Bill achieve this recommendation, including with respect to risk--tiered authorisation categories to ensure the Scheme is appropriately flexible and risk-based, in an environment where understanding about the science and risks is evolving.	Various
Recommendation 21: The Review recommends clarifying the intersection between the Gene Technology Regulator, other regulators and legislation.	New section 15A provides that the Minister and Regulator would not be required to consider certain risk that are already dealt with under a prescribed law (such as the *Therapeutic Goods Act 1989*). This recognises the intersection of laws, avoids duplicative consideration by the Regulator and provides certainty regarding the circumstances in which some of the health and/or environmental risks have already been considered by another regulator.	Section 15A

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All information in this publication is correct as at August 2024