



National Gene
Technology
Scheme

An Australian, State and Territory
Governments Collaboration

DECISION REGULATION
IMPACT STATEMENT

Modernising and
future-proofing the National
Gene Technology Scheme

JULY 2021

Modernising and future-proofing the National Gene Technology Scheme: Proposed regulatory framework to support implementation of the Third Review of the Scheme
Decision Regulation Impact Statement

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1. Executive summary

This Decision Regulation Impact Statement (Decision RIS) is about modernising and future-proofing the National Gene Technology Scheme, a framework for the regulation of activities with genetically modified organisms (GMOs). It considers three policy options to implement the recommendations of the Third Review (the Review) of the National Gene Technology Scheme (the Scheme). The three options analysed were:

- **Option A:** Maintain the status quo – no changes to the current regulatory scope or activities of the Gene Technology Regulator.
- **Option B:** Risk-tiering model – dealings with GMOs would be classified into three authorisation pathways according to their indicative risk.
- **Option C:** Matrix model – the nature of the dealing with the GMO would be the determinative factor for categorisation.

Stakeholder feedback indicated a strong preference for Option B across most stakeholder groups.

On balance, Option B would appear to have the highest net benefit, taking into account its potential for improved and more efficient pathways for authorisation and its increased flexibility to implement mechanisms that would protect human health and safety and the environment.

Option B would be expected to:

- maintain overarching protection goals in line with the object of the Scheme – to protect human health and safety and the environment;
- introduce a new system of authorisations that would allow treatment of activities with GMOs according to their level of risk with limited disruption to the current practices undertaken by regulated stakeholders to comply with the Scheme;
- introduce flexibility to respond to rapidly evolving advances in the field of gene technology and its application; and
- foster innovation and increase the competitiveness of the Australian biotechnology sector by providing clarity and certainty in the regulatory framework, and by reducing regulatory burden for GMO activities when warranted.

This Decision RIS recommends Option B as the preferred option to implement the recommendations of the Review of the Scheme.



2. Purpose of this regulation impact statement

In Australia, activities with genetically modified organisms (GMOs), living beings whose genetic make-up has been modified artificially, are regulated under the National Gene Technology Scheme (the Scheme). The Scheme is governed by a Ministerial Council now referred to as the Gene Technology Ministers' Meeting (GTMM; previously known as the Legislative and Governance Forum on Gene Technology).

In July 2017, the GTMM formally commenced *the Third Review (the Review) of the National Gene Technology Scheme*.¹ The aim of the Review, conducted from July 2017–August 2018, was to assess the operation of the Scheme with respect to its policy objectives. The Review also sought to identify areas where changes may assist to future-proof and modernise the Scheme, to help ensure efficiency and timeliness of responses to emerging technologies.

The Review concluded that, overall, the Scheme is working well. The majority of stakeholders who contributed to the Review also agreed that, since its inception, the Scheme has operated successfully in assessing and managing the risks posed by GMOs. While the Review recognised that the foundation of the Scheme is sound and therefore should be preserved, opportunities for enhancements to update and modernise the Scheme were also acknowledged.

The Final Review Report, endorsed by the GTMM and published in October 2018, outlined 27 recommendations, of which four were considered an initial priority. In July 2020, the GTMM agreed that outcomes sought through key Review recommendations would best be achieved by adopting a proportionate regulatory model. In such 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 continue to be appropriately managed.

Improved legislative flexibility would ensure that regulation (and regulators) can efficiently and effectively identify, respond to and manage emerging risks, ensure safeguards and appropriately 'capture' rapidly evolving novel technologies. It should not be misconstrued as, nor is it intended to be, a means to make it easier to get approval for GMOs.

¹ Department of Health, *The Third Review of the National Gene Technology Scheme: Review Report*, Department of Health, Australian Government, October 2018, accessed 18 May 2021.

It is also not the intent to alter in any way the *Gene Technology (Recognition of Designated Areas) Principle 2003*, established under the Scheme and Agreement, recognising that each state or territory has the power under its own laws, known as ‘moratoria legislation’, to designate areas as ‘GM crop areas’ or ‘non-GM crop areas’ for marketing purposes.

This Decision Regulation Impact Statement (Decision RIS) has been prepared to provide a recommendation to GTMM Ministers on the preferred option for implementing a proportionate regulatory model that gives effect to key Review recommendations.

To inform this Decision RIS and the preferred option, an extensive public consultation process has been undertaken from the commencement of the Review in 2017 (see Section 8 for a detailed description on the consultation process).

The last round of consultation was undertaken from December 2020 to March 2021, and included:

- a Consultation Regulation Impact Statement (Consultation RIS), describing options for implementing key Review recommendations and seeking stakeholder views on the impacts of each of the options;²
- an Explanatory paper, providing further technical detail on what implementation of the options outlined in the Consultation RIS may look like and containing questions for stakeholders that could help inform implementation of the preferred option, once endorsed by the GTMM;³ and
- targeted consultation sessions with stakeholder groups.

This Decision RIS has been prepared in accordance with COAG best practice regulation requirements.

2 Department of Health, *Consultation Regulation Impact Statement: Modernising and future-proofing the National Gene Technology Scheme: Proposed regulatory framework to support implementation of the Third Review of the Scheme*, Department of Health, Australian Government, December 2020, accessed 18 May 2021.

3 Department of Health, *Explanatory Paper: Consultation Regulation Impact Statement: Modernising and future-proofing the National Gene Technology Scheme: Proposed regulatory framework to support implementation of the Third Review of the Scheme*, Department of Health, Australian Government, December 2020, accessed 18 May 2021.



3. Background

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).

Gene technology is used in basic research conducted in universities and research organisations, to study the role of genes, and uncover biological processes such as disease, and plant and animal development. The same universities and research organisations, as well as private companies, also use gene technology to make GMOs and GM products that have a direct pharmaceutical, agricultural or industrial application. This is part of the biotechnology or life science sector, which uses living beings, unmodified or genetically modified, to develop products for commercialisation.

A report found that 1,852 organisations constituted the Australian biotechnology sector as of 2019, 55% of which are industry-based.⁴ The organisations employ approximately 243,406 people. The Australian life sciences industry is dominated by medical technologies and digital health companies (387), followed by pharmaceutical companies (340) and then food and agriculture companies (290). About 86% of these industry companies (875) are classified as small to medium enterprises. In terms of the economic impact of the sector, there are currently 161 life sciences companies on the Australian Securities Exchange (ASX), which have a market capitalisation of approximately \$170 billion.

For the biotechnology sector, time is a key factor for success. The faster a product can go through the development pipeline, the more chances the company has of putting the product on the market before competitors. Demonstrated ability to take products to market stimulates revenue for biotechnology companies, which can then switch resources to new product candidates.

A strong biotechnology industry (supported by a robust regulatory scheme) benefits the Australian community by allowing scientific developments to become available sooner. These developments include medicines for patients, crops adapted to future climate regimes for farmers, and more sustainable ways to source high value products for industry.

4 AusBiotech Ltd (AusBiotech), *Australia's Life Sciences Sector: Snapshot 2019*, October 2019, accessed 21 May 2021.

The Australian gene technology regulatory framework is an asset. It protects the Australian community and the environment from GMOs that are alive and have the capacity to survive and establish in the environment, which may lead to unintended harms. However, it is of utmost importance that the regulatory framework achieves its purpose in an effective way, without being an unnecessary barrier for the progress of basic research and the biotechnology industry, which also contribute to the wellbeing of the community and the environment.

Regulation of Genetically Modified Organisms – the National Gene Technology Scheme

In Australia, GMOs are regulated under the National Gene Technology Scheme (the Scheme). The Scheme arose from the need to provide regulatory coverage for GMOs and genetically modified products (GM products)⁵ not subject to other existing regulatory schemes.⁶

The Scheme is a national cooperative of all state, territory and Commonwealth governments, set out in the intergovernmental Gene Technology Agreement 2001 (the Agreement). The Scheme comprises the Agreement, the *Gene Technology Act 2000* (Cth) (the GT Act),⁷ the *Gene Technology Regulations 2001* (Cth) (the GT Regulations),⁸ and corresponding state and territory legislation. These Commonwealth and state laws provide national coverage for the regulation of GMOs.

The GT Act and delegated legislation are the primary pieces of legislation applying to gene technology. The object of the GT Act, and the Scheme, is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks by regulating 'dealings' (activities) with GMOs. The Scheme regulates gene technology using a risk-based approach,⁹ where higher risk activities involving GMOs are subject to greater regulatory oversight.

The GT Act establishes the statutory office holder, the Gene Technology Regulator (the GT Regulator), to administer the GT Act and corresponding state and territory legislation. The Commonwealth Department of Health provides staff who support the GT Regulator in the performance of their functions. These staff form the Office of the Gene Technology Regulator (OGTR).

The Agreement establishes a Ministerial Council, now known as the Gene Technology Ministers' Meeting (the GTMM), to govern the operation of the Scheme and the activities of the GT Regulator. The GTMM is comprised of Ministers with responsibility for gene technology from every state and territory, and the Commonwealth.

5 GM product means a thing (other than the GMO) derived or produced from a GMO.

6 Other regulatory schemes with partial responsibility for GMO regulation are those administered by Food Standards Australia New Zealand (FSANZ), Therapeutic Goods Administration (TGA), Australian Pesticides and Veterinary Medicines Authority (APVMA), Australian Industrial Chemicals Introduction Scheme (AICIS) and the Department of Agriculture and Water Resources and the Environment (DAWE).

7 *Gene Technology Act 2000* (Cth), accessed 3 May 2021 from the [Federal Register of Legislation](#).

8 *Gene Technology Regulations 2001* (Cth), accessed 3 May 2021 from the [Federal Register of Legislation](#).

9 Office of the Gene Technology Regulator (OGTR), *Risk Analysis Framework 2013*, OGTR, Department of Health, Australian Government, May 2013, accessed 21 May 2021.

Stakeholders under the Gene Technology Scheme

The scale of the gene technology regulatory scheme is modest in comparison to other Australian regulatory regimes. The following are the stakeholder groups under the Scheme.

Regulated entities

There are a limited number of regulated entities, with 180 organisations accredited by the GT Regulator as at June 2020. Most of the regulated entities are universities and publicly funded research organisations.

These undertake GMO work under Notifiable Low Risk Dealings (NLRDs) and exempt dealings and hold approximately 55% of the licences issued by the GT Regulator. Industry companies are also part of this stakeholder group. Companies hold 21% of licences issued under the Scheme. Over 95% of authorisations for dealings with GMOs over the duration of the Scheme have been for NLRDs.

Institutional Biosafety Committees

Institutional Biosafety Committees (IBCs) are committees of experts established within organisations to review research proposals from a biosafety point of view. IBCs review research proposals for NLRDs, assess whether the proposed GMO dealings qualify for a NLRD and what facilities or personnel are suitable for the dealings. IBCs also review applications for a licence and certify, prior to submission to OGTR, that the IBC has reviewed the application and considers that the application has been completed satisfactorily, and that proposed personnel are suitable for the dealings.

Government

The OGTR, which supports the GT Regulator in the performance on their roles under the GT Act, is currently fully funded through annual appropriations and, unlike all other GM product regulators, is not cost-recovered.¹⁰ This means that the OGTR does not charge for the assessment of applications and the issuing of licences and other authorisations.

Community

The Scheme has important indirect effects on the Australian people since it seeks to protect human health and safety and the environment by identifying risks posed by or as a result of gene technology, and to manage those risks through regulating certain dealings with GMOs.

The community also benefits from the technological advances developed by the biotechnology sector.

¹⁰ Note that Review Recommendation 22 requests that consideration be given to the most appropriate funding mechanism to support the ongoing operation to the Scheme, as well as to appropriate funding levels for the Gene Technology Regulator's activities, taking into account any changes to the Scheme. This recommendation will be revisited once the GTMM endorses an option to implement a proportionate regulatory model.

The Review of the Scheme

Under the Agreement, a periodic review of the Scheme is required. The Third Review of the Scheme was undertaken from 2017 to 2018, with the aim of informing and advising Australian Governments, represented through the GTMM, of means to strengthen and improve the Scheme so that it will be effective into the future. The Review involved extensive consultation with many and diverse stakeholders.

The Review concluded that, overall, the Scheme is working well and the core of the Scheme is sound and should be preserved. The Review also recognised that some issues have arisen with the Scheme over recent years that relate to the Scheme's ability to keep pace with emerging technologies.

To address these and other issues the final report, released in October 2018, outlined 27 recommendations, of which four were prioritised by the GTMM:

- *Recommendations 4 and 6* – Update existing definitions in the GT Act to clarify the scope of regulation in light of ongoing technological advances.
- *Recommendation 9* – Introduce a new risk-tiering framework that ensures regulation remains commensurate with the level of risk, and that there is flexibility to move GMOs between authorisation categories based on identification of new risks, a history of safe use and other additional factors.
- *Recommendation 10* – Reduce regulatory burden through streamlining processes and current regulatory requirements where appropriate.

Although the GTMM initially agreed to an Action Plan to implement the recommendations individually over the short, medium and long term, it was later proposed that, due to the considerable interconnectivity of all recommendations, a 'framework approach' to implementation was likely to be more efficient overall.

In response to initial consultation to inform implementation of Review recommendations, the GTMM endorsed an approach to deliver the outcomes sought through a proportionate regulatory model. The aim of this model is to provide a framework that ensures that risks to public health and the environment are appropriately managed, while enabling sufficient flexibility for the regulatory system to respond to scientific advances and new applications of gene technology in a timely manner. The revised framework would support more timely and responsive changes to address new technological developments, where warranted.



4. What is the policy problem?

Three key policy problems that require government action drove the development of the policy options presented in this Decision RIS.

The Gene Technology Scheme responds slowly to advances in the field of gene technology

The pace of scientific discovery in the field of gene technology is accelerating, as evidenced by the development of gene editing techniques and the emergence of the new scientific field of synthetic biology.

These recent scientific developments have highlighted the need to update the definitions in the GT Act.

Important definitions in the GT Act that establish which GMO activities are within the scope of regulation have become outdated. This is because they do not offer certainty on whether new gene technologies or novel GMOs are captured under regulation. This uncertainty can stifle innovation, since research organisations and industry are reluctant to invest in new technologies without knowing how these would be regulated.

The current mechanisms built into the Scheme to provide certainty about the regulatory scope have proven to be slow, taking an average of 4 years to be resolved. This issue was raised consistently by industry stakeholders during the Review. Stakeholders specifically referred to the 2016–2019 process to clarify whether organisms modified with certain gene editing techniques were within scope of regulation. This process required amendments to the GT Regulations, which took more than four years to complete. Agricultural seed companies raised in the submissions that they provided during the last amendments to the Regulations that investment and research into the development of such organisms was stalled until regulatory uncertainty was resolved.¹¹

¹¹ Office of the Gene Technology Regulator (OGTR), *Technical Review of the Gene Technology Regulations 2001: Decision Regulation Impact Statement*, OGTR, Department of Health, Australian Government, 2019, accessed 21 May 2021.

Improved certainty about regulatory scope, in shorter timeframes, would allow companies to develop GMO products and reach a commercialisation stage faster, giving them a competitive advantage.

There is also a risk that GMOs created with new technologies may inadvertently be seen to fall outside of the regulatory system due to this uncertainty. Although estimating the likelihood of this event occurring is difficult, it may result in situations where the risks posed by newly developed GMOs are not properly addressed, with potential adverse consequences to human health and safety and the environment.

Authorisation pathways in the GT Act are no longer suitable for new GMO applications

The current authorisation pathways in the GT Act distinguish two types of GMO activities or dealings: GMO dealings that take place under containment, and dealings that involve the intentional release of a GMO into the environment (which are subject to higher regulatory oversight). This split was appropriate 20 years ago when the Scheme commenced operation, since at that time most activities with GMOs consisted of scientific research taking place within laboratories (contained dealings), or releases of GM crops – either field trials or commercial releases (dealings involving the intentional release of the GMO into the environment). However, more recently, different types of GMOs are being developed for medical and industrial purposes, and these do not necessarily fit well into a system originally designed for GMO plants.

New GMO applications are emerging, especially in areas of medical research, where the distinction between contained dealings and dealings involving intentional release is no longer suitable or relevant. This is because:

- For many of these new GMO applications, the distinction between the two types of dealings does not correlate with the level of risk of the proposed dealings. This means that regulatory oversight is no longer aligned with the level of risk, which can lead to over regulation and to unnecessary costs for both government and stakeholders.
- For some of these new GMO applications, particularly those involving clinical trials, there is ambiguity as to whether the GMO dealings are contained or involve the intentional release of a GMO into the environment.

This leads to uncertainty for:

- a) regulated stakeholders, who are unsure about the required processes and timing to resolve their application; and
- b) the GT Regulator, who is forced to classify the application based on whether or not there may be intentional release of GMOs, rather than based on overall risk. This may result in the application being assessed as a higher-risk category than is warranted on a risk basis, leading to longer timeframes for reaching a decision (depending on the type of licence, resolving an application for a dealing involving the intentional release of a GMO into the environment [DIR] may take 7–12 months, while an application for a licence for a dealing not involving intentional release into the environment [DNIR] is assessed in 4 and a half months).

Medical and other non-agricultural licence applications have become the dominant applications for GMO licences. The percentage of licences granted for medical and other uses grew from 21% in 2015–16 (total number of granted licences was 14) to 79% in 2019–20 (total number of granted licences was 24).

Many of the medical applications incur an additional regulatory cost compared to other applications because applicants are uncertain of whether their application involves the intentional release of a GMO into the environment.

Of the 30 licence applications for clinical trials and commercial supply of therapeutics received by OGTR since January 2020, 18 required liaison with OGTR prior to the application being submitted to determine the right authorisation category for the application.

The level of work undertaken by the applicants and OGTR to resolve this uncertainty varied:

- 10 applications involved phone contact
- 4 applications involved email correspondence
- 4 applications involved pre-submission meetings between the OGTR and applicant.

In addition, 6 DNIR applications received during this time required reclassification to DIR. In one case, an applicant withdrew the application entirely as a result. This brings the number of applications that involved some uncertainty as to the right authorisation pathway to 24 (80% of the medical applications received by the OGTR).

This extra work to clarify the right authorisation category can take up to 4 weeks. This period typically occurs before an application is submitted and is in addition to the statutory timeframes to resolve applications. This means that the time required to obtain an authorisation is increased in comparison to other types of dealings. Delays have the potential to slow down patient access to new GMO therapeutics.

The apparent growing trend in the number of applications received for GMO dealings with medical and other uses is expected to continue into the future, as the Australian government is investing in promoting Australia as a leader in clinical trials and medical research.¹² Of the licences granted in 2019–20, 92% were related to medical uses (including cancer treatments, drug discovery and vaccines), 4% were for veterinary uses (vaccines) and 4% were for industrial uses. Therefore, this policy problem is expected to persist and may even increase.

¹² National Health and Medical Research Council (NHMRC), *Why Conduct Clinical Trials Australia*, NHMRC, Australian Government, 10 November 2020, accessed 18 May 2021.

The Scheme is no longer risk proportionate

Currently, there is only one authorisation pathway for dealings involving the intentional release of a GMO into the environment. This restricts the Regulator from applying proportionate regulation. 20 years of experience in regulating trials and commercial releases of GM crops and GM therapeutics have shown that some of these dealings are low risk, and that applied management conditions are effective. However, there is no mechanism to use these experiential factors to categorise dealings into more risk-proportionate authorisation pathways.

Additionally, the current authorisation pathways do not allow the processing of applications to take account of when other regulators regulate the same dealings. Regulatory duplication may result in increased costs and regulatory effort that is not justified by the level of risk.

Submitters to the Review provided examples of potential duplication between the OGTR and other regulators, including the Australian Pesticides & Veterinary Medicines Authority (APVMA) and the Therapeutic Goods Administration (TGA). The use of GMOs in animal medicines and human medicines requires an authorisation by the OGTR, as well as the APVMA and TGA respectively. This means that stakeholders need to submit an application to more than one agency to obtain the required authorisation to use a single GMO. In some instances, the assessments undertaken by the agencies are similar and consider the same risk aspects. In those instances, regulatory effort is duplicative and increases costs unnecessarily.

For example, if a company wants to introduce a GMO vaccine to protect pet dogs against a new viral disease, both a licence from the OGTR and registration by the APVMA are required. APVMA guidance has required granting of the OGTR licence prior to application to the APVMA. The timeframes for the OGTR assessment, covering human and environmental health and safety, is 255 working days (about 12 months). This would be followed by the APVMA assessment, covering human, environmental and target animal safety as well as product efficacy, with an assessment time of at least 12 months, depending on the modules applied. Therefore, obtaining the required authorisations can take more than two years. Since the assessments undertaken by OGTR and APVMA are overlapping to some degree, there is an opportunity to simplify regulatory processes.

Of the activities authorised by the 40 DIR licences issued by the OGTR since January 2016, 7 also required an authorisation from APVMA, 11 required a notification to or authorisation from TGA and, for 7, sale of the resulting GM food required an authorisation from FSANZ. Of the 68 DNIR licences issued by OGTR since June 2016, 38 also required a notification to or authorisation from TGA.

As shown in the section above, the number of GMOs used in animal and human medicines is rising, therefore regulatory duplication is an issue that is becoming more important. Duplicated regulation increases the timeframes to obtain necessary approvals, which may result in some technologies being lost to overseas markets or may delay the availability of medicines to Australian consumers.

Finally, the current mechanism in the GT Act to move GMO dealings from one authorisation pathway to another in response to new information about risk is a lengthy process that can take up to eight years. This results in long periods of time where regulatory oversight of certain dealings is not aligned with risk, leading to both over-regulation and under-regulation. In the 20 years since the inception of the Scheme, the Schedules in the GT Regulations have been amended in 2006, 2007, 2011 and 2019.



5. Objectives of government action

The object of the *Gene Technology Act 2000* (the GT Act) is to protect the health and safety of people, and to protect the environment. This is achieved by identifying risks posed by or as a result of gene technology and managing those risks through regulating certain dealings with GMOs.

In implementing recommendations from the Third Review, the objectives of government action are to:

1. Continue to protect the safety of humans and the environment through assessing and regulating certain dealings with GMOs.
2. Strengthen the regulatory framework to be responsive to emerging technologies, so it is possible to provide certainty on the level of regulatory oversight that is to be applied to new technologies in a timely manner.
3. Establish proportionate and risk-based regulatory pathways which reduce overregulation of low and very low risk GMOs and dealings that have a negligible risk to humans and the environment, and have regulatory effort directed towards the assessment of undetermined or higher risk dealings.
4. Address the duplicative regulation of GMOs between the GT Regulator and other product regulators.
5. Continue to support local oversight of risk management conditions, noting the important role of Institutional Biosafety Committees (IBCs).
6. Simplify and streamline the regulatory framework to remove unnecessary regulatory burden and reduce complexity for regulated entities and new entrants to the GMO market, including providing clarity about the application of the Scheme to certain GMOs dealings. This could in turn reduce business costs for regulated entities and potential entrants to the Scheme, including small-scale companies and researchers. Government action with respect to this policy objective would only apply to those areas of regulation where the streamlining of processes and the removal of regulatory burden does not compromise the protection of human health and safety and the environment.
7. Create a regulatory environment that accommodates increased competition and economic efficiency, including to facilitate increased collaboration between the private sector and researchers to enable new genetic technologies to realise economic, health and welfare benefits for the Australian community.
8. Where possible, align regulation with comparable international regulatory schemes and enable the better utilisation of international assessment information.



6. Options

This Decision RIS analyses two options to address Review recommendations (Options B and C). These options are compared to the base case, the *status quo* (Option A).

Options B and C propose a system of authorisation pathways that intends to be fit for purpose for current and future GMO applications and also incorporates authorisation pathways for GMO dealings that are low risk, have a history of safe use, or are under the remit of other product regulators with the aim to ensure that regulation is proportionate with risk.

Both options aim to provide certainty about the regulatory status of new technologies, by proposing updates to the definitions in the GT Act that would clarify whether new technological developments are within the scope of regulation.

Options B and C seek to increase the responsiveness of the Scheme to advances in the field of gene technology by introducing delegated legislation.¹³ Under these options, the GT Act would set broad parameters or principles about matters that are prone to change and/or technical or scientific in nature. The details about how to deal with these matters would be specified in delegated legislation, which could be made and amended more quickly than primary legislation.

A diagram showing the different authorisation pathways in Options A, B and C is available in an attachment to this document ([Attachment A](#)).

¹³ Delegated legislation is a term which covers legislation made by government agencies and the Governor-General under authority of Acts of Parliaments, which delegate this power to agencies.

Option A: Status quo – no changes to the current scope or activities of the Gene Technology Regulator

Overview

Under Option A (the base case), the current Scheme would continue to operate.

This option would see no changes made to the current focus of regulatory effort for the GT Regulator. The scope of activities and responsibilities of the GT Regulator would remain as they are for the purposes of identifying and assessing risks posed by, or as a result of, gene technology, and by managing any risks through the regulation of certain dealings with GMOs.

Current regulatory model

In Australia, certain dealings with GMOs are prohibited unless authorised under the *Gene Technology Act 2000* (the GT Act). Authorisation falls into one of the following categories:

- a listing on the GMO Register
- an exempt dealing as described in the Gene Technology Regulations 2001 (GT Regulations)
- a licence for Dealings involving Intentional Release of a GMO into the environment (DIR licence)
- a licence for Dealings Not involving Intentional Release of a GMO into the environment (DNIR licence)
- a Notifiable Low Risk Dealing (NLRD) for specified research described in the GT Regulations
- specification on an Emergency Dealing Determination (EDD)
- an inadvertent dealing licence.

Applying these authorisation types, the Scheme broadly distinguishes two types of GMO dealings (see **Attachment A**):

- contained dealings, and
- dealings involving intentional release of GMOs into the environment.

Contained dealings can be categorised in one of three ways: as an exempt dealing, as a notifiable low risk dealing (NLRD) or as a dealing not involving intentional release (DNIR), (for which a DNIR licence is required).

Dealings involving Intentional Release (DIR) must be authorised by a licence. The DIR category only distinguishes between dealings where release of a GMO into the environment is limited in time and space (e.g. for the conduct of research trials like experimental field trials, known as limited and controlled releases) and where no GMO remains in the environment after the licence has expired, and releases of a GMO into the environment that are not subject to such time and space limitations (e.g. a commercial release).

Option B:

Risk-tiering model – dealings with GMOs would be classified into three authorisation pathways according to their indicative risk

Overview

Option B would retain the core aspects of the Scheme. However, changes to specific areas are proposed to address Review recommendations.

Authorisation pathways

Option B presents a risk-tiering model. Under this model, the following existing authorisation pathways under the GT Act would be retained:

- a listing on the GMO Register
- specification on an Emergency Dealing Determination (EDD)
- an inadvertent dealing licence.

Changes would be made to the following authorisation types to enable dealings to be distinguished on the basis of indicative risk:

- an exempt dealing as described in the Gene Technology Regulations 2001 (GT Regulations)
- a licence for Dealings involving Intentional Release of a GMO into the environment (DIR licence)
- a licence for Dealings Not involving Intentional Release of a GMO into the environment (DNIR licence)
- a Notifiable Low Risk Dealing (NLRD) for specified research described in the GT Regulations.

Dealings authorised through any of the above four pathways would be classified into three overarching authorisation pathways according to the potential level of risk of the dealing, taking into account matters such as the characteristics of the GMO, the type of dealings and whether effective risk management measures are known.

Minor changes to the naming (for example, changing exempt dealings to non-notifiable dealings) would better reflect the regulatory requirements of the authorisation pathway (where a dealing remains within the scope of the regulatory framework despite being labelled as “exempt”).

The new authorisation pathways would be:

- non-notifiable dealings,
- notifiable dealings, and
- licensed dealings (which would be further classified into three types of licences on the basis of risk, to enable further streamlining of lower risk applications).

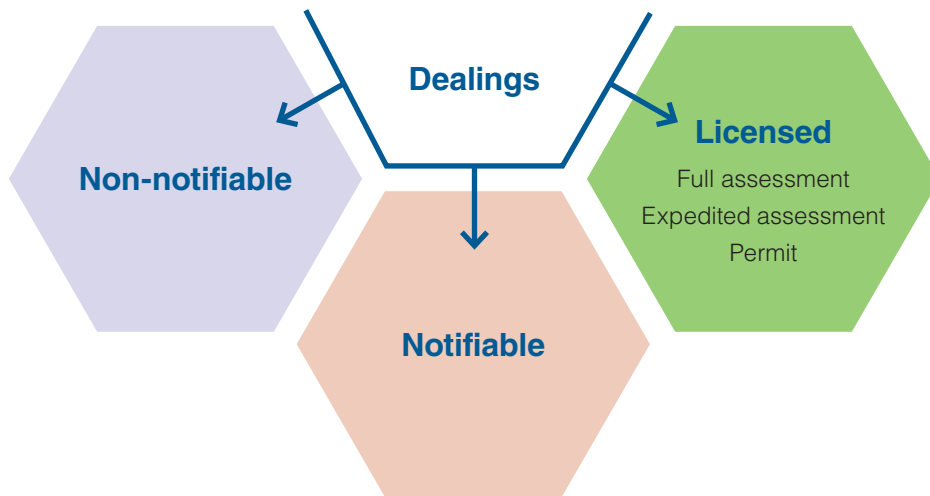


Figure 1: New authorisation pathways to achieve risk tiering under Option B.

Eligibility criteria for each authorisation pathway would be defined through specific listings or risk criteria, taking into account matters such as the parent organism, the introduced trait, the genetic modification responsible for the trait, the technology used to make the genetic modification and the type of dealings.

Under Option B, the GT Regulator would have the ability to make legislative instruments that specify the eligibility criteria for each authorisation pathway according to scientific information about risk. The primary legislation would specify mandatory matters that the GT Regulator must consider prior to changing the eligibility criteria, as well as who must be consulted.

Note: The GT Regulator would decide whether an application received by the OGTR meets the eligibility criteria for the authorisation pathway specified by the applicant. This is also the case under the current system.

Matters that the GT Regulator must consider in establishing eligibility criteria for various authorisation types could include:

- The gene technology applied to create the GMO.
 - If a specific gene technology can only be used to develop GMOs that present a very low risk, and a case-by-case risk analysis is not required to protect human health and safety and the environment, then dealings with such GMOs could be eligible for the non-notifiable or notifiable categories.
- Known risk management conditions.
 - If there is extensive regulatory experience regarding management measures that are effective in mitigating the risks posed by certain GMO dealings, then this information would support adding such dealings to lower risk authorisation categories, provided the known management measures are applied.

- Dealings assessed by other regulators.
 - Dealings with GMOs that currently require authorisation by the GT Regulator and another regulator could be classified into lower risk categories under Option B, where the other regulator:
 - ♦ considers the risks posed by the GMOs to human health and safety and to the environment in a similar way to the GT Regulator, and
 - ♦ is able to impose risk management conditions.
 - In those cases, the GT Regulator would provide advice to the other regulator during the processing of applications.
- Availability of relevant previous risk analyses.
 - Where the risk analysis of proposed GMO dealings would be significantly informed by relevant previous risk analyses, those GMO dealings could be eligible for authorisation under a lower risk category as determined by the GT Regulator.
- Availability of relevant international risk analyses.
 - Dealings with GMOs that have been assessed and authorised by reputable regulatory agencies overseas could be eligible for authorisation under lower risk categories. This is because the processing of applications could be streamlined in Australia by using the (comparable to Australian standards) overseas risk analysis provided with the application.
 - The findings of international risk analyses with respect to risks posed to human health and safety would, in most cases, continue to be relevant in Australia, such that the analyses could be directly applicable under the Australian regulatory framework. In contrast, the risks posed to the environment by the GMO may differ between countries. For example, a plant species may be a native species in one country and a weed in another. Therefore, the environmental considerations of international risk analyses may only be applicable in limited circumstances.

Note: Details on how the eligibility criteria for authorisation categories could be implemented, including how different regulatory agencies may interact and which international risk analyses could be considered by the GT Regulator to streamline an application, would be the subject of future consultations.

Details on the intended operation of the new authorisation pathways is available at [Attachment B](#).

Option C:

Matrix model – the nature of the dealing with the GMO would be the determinative factor for categorisation

As with Option B, Option C would retain the main characteristics of the Scheme and would only involve making specific changes to the GT Act.

The key difference between these two options is the proposed system of authorisation pathways.

Overview

Consistent with Option B, Option C would retain the existing authorisation pathways:

- a listing on the GMO Register
- specification on an Emergency Dealing Determination (EDD)
- an inadvertent dealing licence.

As for Option B, changes would be made to the following authorisation types:

- an exempt dealing as described in the Gene Technology Regulations 2001 (GT Regulations)
- a licence for Dealings involving Intentional Release of a GMO into the environment (DIR licence)
- a licence for Dealings Not involving Intentional Release of a GMO into the environment (DNIR licence)
- a Notifiable Low Risk Dealing (NLRD) for specified research described in the GT Regulations.

However, dealings currently authorised through any of the above four pathways would be categorised on the basis of the dealing type (rather than being categorised on the basis of indicative risk as described in Option B). Under Option C, new categories would be created on the basis of three kinds of dealings:

- contained dealings
- dealings involving the intentional release of a GMO into the environment, and
- clinical trials and medical applications.

Within these three categories, and consistent with the authorisation pathways described for Option B, authorisation pathways under Option C would include:

- non-notifiable dealings
- notifiable dealings, and
- licensed dealings, where there are three types of licence (permit; expedited assessment and full assessment).

While the authorisation pathways are consistently described across the two options, instead of risk tiering, Option C instead presents a matrix whereby the primary consideration for categorisation is the nature of the dealing. Any risk associated with that dealing is a secondary consideration that would inform where the dealing falls in the matrix once the relevant category is established. The authorisation pathways available for clinical trials would be the same for Option B as for Option C, this being achieved in Option C by establishing a new category of authorisations dedicated to medical applications.

Within the 3 categories, Option C incorporates new authorisations for lower risk tiers for environmental releases, and clinical trial and medical applications (e.g. permits and expedited assessments). These authorisations would enable applications involving traits and parent organisms that are familiar to the GT Regulator, and for which risk management measures are well established, to be subject to more streamlined regulatory assessment. It would also enable a more streamlined authorisation for those clinical trial applications that meet a series of criteria established by the GT Regulator that determine the clinical trial to be lower risk.

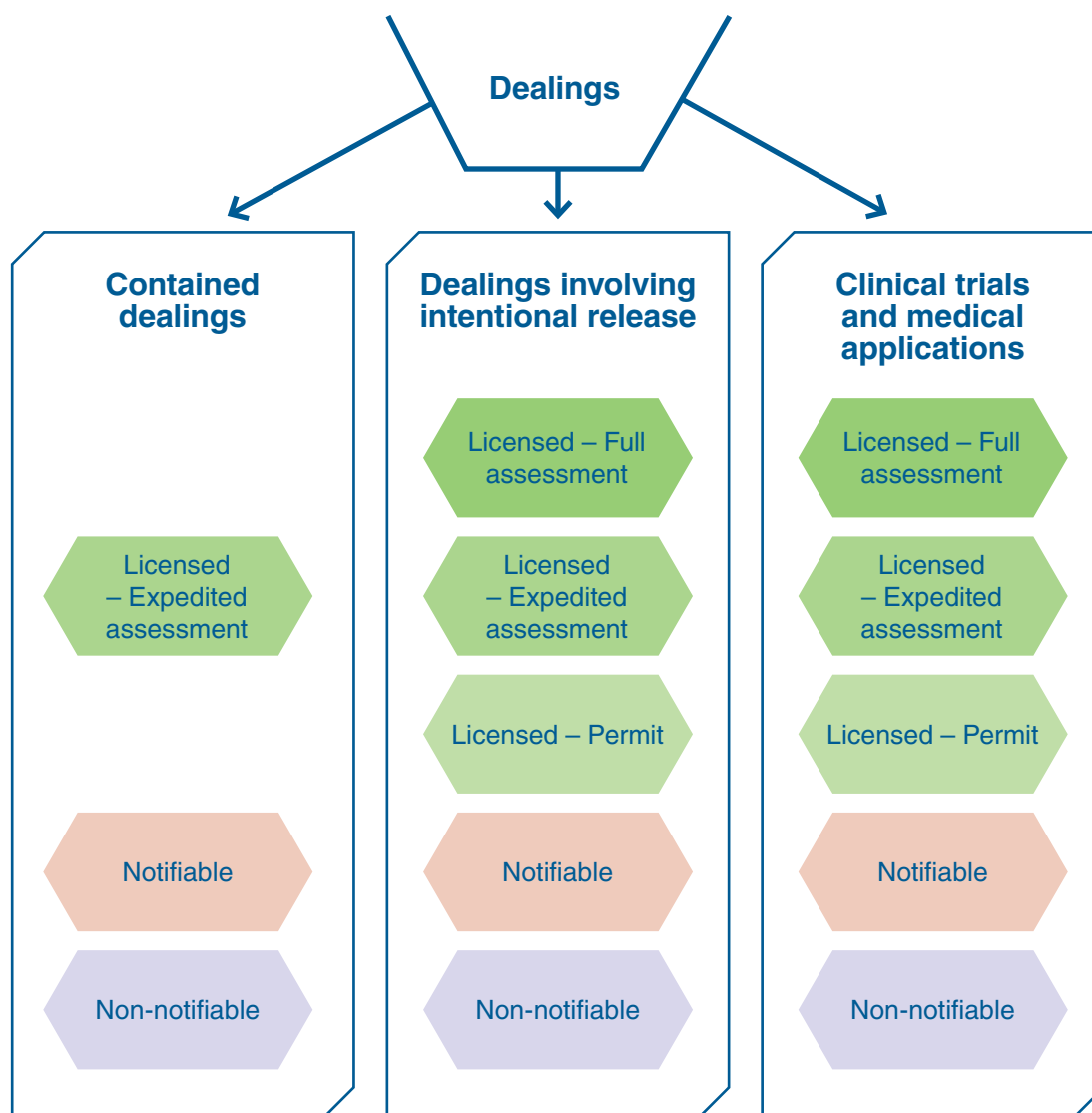


Figure 2: New authorisation pathways to achieve a risk matrix under Option C.

As for Option B, the relevant criteria establishing the levels of authorisations within each of the categories would be achieved through delegated legislation made by the GT Regulator, to facilitate sufficient flexibility to move GMO dealings between the authorisation pathways as new scientific or regulatory evidence becomes available.

Other proposed amendments that apply to both Option B and Option C

In addition to risk tiering, Options B and C propose:

- Amendments to some key definitions in the GT Act, which would support the implementation of Review recommendation 4.
- Changes to the process to make a listing on the GMO Register, to increase the usage of this authorisation pathway.

Details of these proposals can be found at [Attachment C](#).



7. Impact Analysis

This section outlines the expected impacts of each option, taking into account information provided by stakeholders during the public consultation on the Consultation RIS and Explanatory paper. Although the consultation documents and targeted consultation sessions encouraged stakeholders to submit quantitative data on the costs and benefits of the options, most of the information provided by stakeholders was qualitative in nature. Many submitters expressed that they were not able to provide a quantitative estimation of the potential costs and benefits to their organisation because these relate mainly to the creation or loss of research opportunity and innovation, and this is very hard to quantify. For this reason, the impact analysis in this Decision RIS is predominantly based on qualitative information.

Factors considered in the impact analysis

Factors that have been taken into account when analysing the impacts include:

- how each option would address the policy problems outlined in Section 4 and meet the objectives of government action identified in Section 5;
- the net benefit of each option (i.e. how its benefits compare to its costs);
- impacts on innovation under each of the options;
- any risks associated with the options and how these risks could be mitigated; and
- whether the changes might be open to unintended non-compliant behaviour, or may create any undesired incentives/disincentives.

Option A – Impact Analysis

The *status quo* would not result in any change (increase or decrease) in the risk to the health and safety of people or the environment. However, maintaining the *status quo* would mean that existing problems would remain.

- The current licensing categories are based around whether or not the GMO is proposed to be released into the environment. When the Scheme was first developed, the main focus of gene technology was on agricultural applications and the authorisation pathways were largely predicated on plant field trials and commercial applications. Increasingly, applications of gene technology are occurring outside these traditional areas, and the existing pathways do not adequately accommodate these (based on risk and resource). It is not always clear whether a dealing involves intentional release into the environment or not.



CASE STUDY: WATER TEST KIT

Drinking water containing arsenic makes people sick worldwide. International scientists have developed a device to test whether drinking water contains arsenic.

The device holds GM bacteria that can detect arsenic in the water. When the water being tested contains arsenic, the GM bacteria glow and the device warns the user that the water is unsafe for drinking.

Currently, categorisation depends on whether this application is for dealings that are contained or for dealings involving the intentional release of a GMO into the environment. This is difficult to determine because, although the GM bacteria are contained within the device, they may be released if the device is broken when used or disposed of outdoors.

- Distinguishing GMO dealings by reference to the broad categorisation of whether a dealing involves intentional release of GMOs into the environment, restricts the GT Regulator from applying a regulatory mechanism that is targeted at the risk posed by the GMO dealing being contemplated. Currently, dealings can only be authorised in a limited number of ways. The primary factor driving categorisation is one risk factor (environmental release), rather than more relevant risk factors like history of safe use, the type of organism, the nature of the genetic modification, and the setting in which the clinical trial would take place, etc.

This is particularly problematic when the release into the environment is not the key determinant of the risk posed to human health and the environment. For example, increasingly, the GT Regulator is receiving applications for human clinical trials where the concepts of containment and intentional release do not as readily or simply apply.



CASE STUDY: CLINICAL TRIALS

Clinical trials involving the administration of a GMO to a human require a licence issued by the GT Regulator. The type of licence required depends on whether or not the clinical trial involves the intentional release of the GMO into the environment. If the GMOs would be 'contained' within the participant, the trial requires a DNIR licence which has a statutory assessment timeframe of 90 working days. However, if the GMO might be released into the environment (for example, because the GMO would be shed by participants) then the trial requires a DIR licence which has a statutory assessment timeframe of 150 working days, or 170 working days if significant risk is identified.

This criterion used to categorise clinical trials does not consistently reflect the risk posed to human health and the environment by clinical trials that are very low risk (even if participants shed the GMO), or by higher risk clinical trials (even if participants do not shed the GMO).

- The GT Regulator received one application to urgently treat a very ill patient with a GMO (see case study below). Under the *Therapeutic Goods Act 1989* (Cth) (Special Access Scheme [Category A]), the use of an unapproved therapeutic good by an authorised health practitioner only requires notification to the TGA after the patient has been treated. However, under the GT Act, either a DNIR or a DIR licence is required. The GT Regulator must follow all the administrative steps specified in the legislation for the processing of these applications. The GT Regulator had to follow all the requirements in the GT Act in a record time to not jeopardise the treatment of the patient. Nevertheless, OGTR worked intensively with the applicant over a few weeks as they prepared the licence application, so as to be in the position for OGTR to grant the approval quickly. The GT Regulator may receive more applications like this in the future.



CASE STUDY: SPECIAL ACCESS SCHEME

A hospital wants to use a GM bacteriophage (a virus that kills bacteria) to treat a child with cystic fibrosis for a bacterial lung infection that has not responded to antibiotics. Urgent treatment is required and the TGA has granted permission through the Special Access Scheme to treat the child with the potentially life-saving yet unapproved treatment.

Use of a GMO therapeutic by one patient in one hospital may pose a much lower risk than a more widespread use of the GMO therapeutic, for instance in a clinical trial. However, the legislation requires the GT Regulator to follow the same licence assessment process to authorise these dealings even if they present different levels of risk.

- For lower risk applications (including those organisms that have a history of safe use, and where highly characterised organisms have been used), regulatory pathways are fixed, resulting in unnecessary regulatory burden.
 - For example, there are certain GMO field trials (such as BT cotton) that the GT Regulator has licensed many times over, and for which there is a strong understanding of risk and known risk management conditions. Despite this, each application must be considered separately via a licensing pathway, requiring consultation and preparation of a lengthy risk assessment and risk management plan. However, these processes do not improve risk management outcomes because established risk management conditions have already been demonstrated to be effective.
- There is currently no capacity for the GT Regulator to take into account the impact of any duplicative regulation of a dealing. Dealings that fall into the remits of various regulators may be subject to regulatory oversight that covers matters that have already been assessed for risk, subjecting applicants to additional costs. The following were provided by submitters to the Review as examples of potential duplication between the OGTR and other regulators:
 - the OGTR and APVMA with regard to the regulation of plants that incorporate a pesticide
 - the OGTR and APVMA with regard to the regulation of GM veterinary medicines
 - the OGTR and TGA with regard to the regulation of human therapeutics
 - the OGTR and TGA with regard to the requirement to report adverse events associated with GM pharmaceutical products (and inconsistencies between timeframes for reporting to each agency).
- The current authorisation pathways are not responsive to new information about the risk. For example, where there is evidence that the existing regulatory requirements are no longer necessary given new information or experience of safe use, the current Scheme does not readily enable removal of regulatory requirements (for example, by moving the dealing into the exempt dealing category). Conversely, if new scientific information supports the position that a dealing poses an undetermined or higher risk than previously thought, then the current Scheme does not enable categorisation that involves increased regulatory oversight. The response to scientific innovation and new scientific data about risk is mostly delayed by the lengthy process associated with changes to the GT Regulations.
- Currently, for an organism to be regulated under the Scheme, it must first meet the definition of a GMO under the GT Act. The GT Regulations exclude a range of organisms from the definition of a GMO, as well as specific types of techniques from the definition of gene technology. However, advances in both gene technology and the creation of organisms from that technology have created uncertainty as to whether new techniques and organisms are within (or excluded from) the scope of the Scheme. This in turn restricts the degree to which the legislative definitions are able to appropriately classify the range of advances in technology into the current authorisation pathways.

Impacts

Under the *status quo*, authorisation pathways do not always align well to risk, nor enable flexibility to respond to future scientific advancements. The current regulatory framework is slow in its response to emerging technologies and, in some instances, results in unnecessary regulatory delays for applicants as shown for GMO dealings for medical applications.

Continuing uncertainty regarding regulatory scope and the regulatory requirements for activities with certain GMOs is likely to impact research progress and willingness to invest in emerging technologies. This would in turn reduce international competitiveness.

Option A has proven to be successful in protecting human health and safety and the environment.

There is a risk that GMOs created with new technologies may inadvertently be seen to fall outside of the regulatory system due to uncertainty regarding regulatory scope. Regulated stakeholders may interpret the current definitions in the GT Act and assume incorrectly that their new development is not captured under regulation. This would lead them to undertake GMO dealings without applying for appropriate authorisations that impose risk management measures. This may result in situations where the risks posed by newly developed GMOs are not properly addressed, with potential adverse consequences to human health and safety and the environment. The likelihood of this occurring is very low because regulated stakeholders under the Scheme typically approach the GT Regulator when they are uncertain as to the regulatory status of their development.

The reclassification of dealings into new authorisation categories in response to new information about risk requires amending the GT Regulations, and this process takes up to eight years. Therefore, in some limited circumstances, regulatory oversight may be delayed, or there may be a period in which the dealing is under regulated.

Regulatory delays in bringing applications of gene technology to the market (e.g. for vaccines) can mean loss of the availability of GMO treatments for patients. Medical research organisations expressed concern the *status quo* reduces opportunities for Australian patients to benefit from cutting-edge therapies through clinical trials.

Option B – Impact Analysis

Option B proposes a risk-tiering framework that treats GMO dealings according to the level of indicative risk. By introducing risk tiers, regulatory effort and resources would be better targeted to the oversight of higher or undetermined risks.

The appropriate categorisation of a dealing would take into account not just whether the GMO was being intentionally released into the environment, but a wider range of factors including history of use, parent organism, nature of modification, experience in applying management conditions and the involvement of other regulators.

Dealings undertaken in a laboratory that has been certified by the GT Regulator, or field trials of certain GM plants that apply limits and controls used in the past to effectively prevent the dispersal and the persistence of the GMO in the environment, would be categorised as requiring lower risk authorisations. Previous licence assessments and monitoring outcomes may support lower risk authorisations applying for field trials of GM plants where the combination of parent species, trait and limits and controls is familiar to OGTR.



HYPOTHETICAL CASE STUDY: PET VACCINES

Under Option B, the introduction of a GMO vaccine to protect pet dogs against a new viral disease could be eligible for a lower risk category. Registration by the APVMA could qualify a GMO veterinary vaccine as a Notifiable Dealing, as long as the OGTR could provide advice to the APVMA during their assessment timeframe, leaving the APVMA as the authorising authority. This would reduce the overall assessment timeframe while maintaining OGTR's awareness of the GMO and technology used.

Under this model:

- consultation would inform the categorisation of different types of GMO dealings
- the Gene Technology Ministers' Meeting (GTMM) would continue to set the parameters of the Scheme, but the GT Regulator would have greater capacity to categorise GMO dealings (as non-notifiable, notifiable and licensed) following consultation, and based on the application of principles and criteria agreed by the GTMM. This would seek to ensure the Scheme remains responsive to new scientific evidence (and knowledge gained through history of use).
- the GTMM would continue to be able to issue policy principles and policy guidelines that the GT Regulator must have regard to when deciding an application for a GMO licence. The existing *Gene Technology (Recognition of Designated Areas) Principle 2003* would also continue to recognise that each state or territory has the power under its own laws, known as 'moratoria legislation', to designate areas as 'GM crop areas' or 'non-GM crop areas' for marketing purposes.

Risk tiering on the basis of risk indicators would ensure that authorisation pathways are fit for current and future GMO dealings.

Impacts

Under this option, certain activities with GMOs would be eligible for authorisation pathways that have a lower regulatory burden, (i.e. notifiable dealings; permits and expedited licences). Option B would allow leveraging regulatory experience and oversight by other regulators to adjust regulatory oversight.

Administrative costs

Option B is expected to provide more clarity with regard to the type of authorisation required for different GMO applications. Authorisation pathways under Option B would be a better fit for medical GMO applications in comparison to Option A. Clinical trials with GM techniques and GMOs would no longer require a judgement on whether the trial involves the intentional release of the GMO into the environment. Therefore, the additional pre-submission consideration of applications undertaken by applicants and the OGTR would no longer be required, which would reduce the cost of making such applications.

One submission provided information on the cost to their organisation of determining whether a medical application is eligible to be authorised under a DIR or DNIR. Resolving this uncertainty involves liaising with the OGTR, additional consideration of an application by the IBC, and documenting and communicating decisions. According to the submitter, completing this process takes an average of 13 working hours, undertaken by several people within the organisation with an average salary of \$73/hour. This would bring the cost of determining the appropriate type of authorisation to approximately \$950 per application.

As noted in the policy problem section, since January 2020, 24 applications submitted to the Regulator required OGTR clarification about the type of licence was needed. Assuming that the same number of applications would no longer require clarification by the OGTR every year, under Option B the total savings for regulated entities would be approximately \$22,800 per year (\$950 x 24 medical licence applications).

The administrative cost for regulated organisations associated with meeting compliance requirements (notifications to the Regulator, meeting licence conditions, reporting obligations, etc.) would remain unchanged, as compliance requirements for non-notifiable, notifiable and licensed dealings under Option B are equivalent to those of the current exempt, NLRDs and licensed dealings under Option A.

Delay costs

Analysis of application types submitted to the OGTR over the past five years suggests that the assessment of a significant proportion of applications could be streamlined. Shorter timeframes to obtain an authorisation and reduced data requirements to make an application would result in substantial reductions in regulatory burden.

It is possible to estimate to what extent Option B would have reduced the total assessment time of the applications received by OGTR in the past 2 to 5 years (see case studies below). For these calculations, the following statutory timeframes were assumed for the authorisation pathways under Option B: 150 days for a full assessment licence, 90 days for an expedited licence and 30 days for a permit. This is compared to the statutory timeframes under Option A: 255 days for a broad release DIR licence, 150 days for a limited and controlled DIR licence and 90 days for a DNIR.

Note: that days are working days, not calendar days.

CLINICAL TRIALS AND COMMERCIAL THERAPEUTICS

OGTR issued 6 DIR and 26 DNIR licences in the last 2 years for clinical trials and commercial therapeutics. The following assessment time was needed to reach a regulatory decision:

6 DIR and 26 DNIR licences = **3240 working days**

Under the proposed risk tiering of Option B, it is estimated that 50% of these DIR licences could become expedited licences and 35% of DNIR licences could become permits. The total licence application assessment time would decrease to:

7 full assessment and 16 expedited and 9 permits = **2820 working days**

GM CROP APPLICATIONS

OGTR issued 15 field trial DIRs and 6 commercial DIRs in the last 5 years for field trials and commercial releases of GM crops. The following assessment time was needed to reach a regulatory decision:

15 field trial DIRs and 6 broad release DIRs = **3780 working days**

Under the proposed risk tiering of Option B, it is estimated that 40% of plant field trial licences could become an expedited licence or permit and 67% of commercial crop licences could become expedited licences. The total statutory licence application assessment time would decrease to:

11 full assessment and 8 expedited and 2 permits = **2430 working days**

Note that the number of working days under Option B may be slightly underestimated because full assessment licences may take more than 150 days to assess depending on the assessment work required. On the other hand, uptake of the permit category is likely to be greater than these numbers indicate because it is likely some applicants would design their applications to fit the eligibility criteria for permits.

This reduction in time to obtain a regulatory decision is expected to benefit regulated entities. Reduced timeframes would speed up the path to market, allowing companies developing GMOs to realise returns for their research investments faster. Regulatory savings for companies would depend on the benefits they make when selling their GMOs in the market for a longer period.

For instance, under the assumptions detailed above, and for commercial GM crop applications eligible for the expedited licence pathway, this would reduce the timeframe to assess an application from 255 days to 90 days. This would allow a seed company to sell GM seeds for one additional growing season. Assuming that a seed company earns \$100,000 by selling GM seeds (e.g. GM canola or GM cotton) to Australian farmers in one growing season,¹⁴ this amount would be the regulatory savings that Option B would bring to such company.

Four GM crop commercial applications received in the last five years could become expedited licences under Option B. If this allowed companies to sell GM seeds for one extra growing season,

¹⁴ This is a conservative figure.

assuming a benefit of \$100,000 this means a regulatory saving of \$400,000 in five years, or \$80,000 per year.

The benefits of commercial GMO therapeutic licences that become expedited would also add to the regulatory savings of Option B.

Shorter timeframes would also allow research organisations and companies to perform more trials in a given period. Trial results would therefore become available faster, which would speed up the pace of scientific discovery and innovation. This would also be expected to help research organisations, (especially small and medium biotechnology companies) to secure funding, as more proof of concept trials could be undertaken. If proof of concept trials are positive, these would encourage investors to fund product development.

It is expected that these changes would facilitate more widespread use of gene technology, which may result in the growth of the biotechnology industry and promote scientific innovation by giving researchers flexibility to explore new technologies and ideas.

Substantive compliance costs

The only cost that submitters raised in relation to this option was the cost associated with adapting organisations' regulatory practices to the new system. This would consist mainly of training the organisations' personnel on the amended Scheme and adapting organisations' procedures. This would be a one-off cost, and the magnitude of the cost may vary depending on the type of activities undertaken for training by each organisation. It is envisaged that training activities could be as simple as preparing a presentation outlining the changes in the Scheme and circulating the presentation among researchers. Assuming that preparing such a presentation would take 2 hours' work, and that this needs to be undertaken in the 180 organisations accredited under the Scheme, then the cost would be approximately \$26,000 (2 hours x \$73 x 180). Spreading this cost over ten years results in an annual cost of approx. \$2,600.

OGTR would provide comprehensive guides and information sessions on the new system to mitigate this cost for organisations.

The implementation of any changes to the regulatory framework would incur a one-off cost for the GT Regulator. OGTR would have to update its IT system to support the preferred option, including changing application forms; developing guidance material to inform regulated stakeholders on the changes to the Scheme; and adapting their internal operations to deal with the new streamlined authorisation pathways.

In terms of ongoing costs, Option B is not expected to require additional budget allocation to OGTR. It is anticipated that the new authorisation pathways would reduce the evaluation work that the OGTR does annually, but since it is also expected that the number of applications would increase, there would also be an increase in the amount of monitoring activities undertaken to ensure compliance with the conditions of authorisations.

Risks

It may be perceived that the availability of regulatory pathways that are streamlined under Option B poses the risk that, in certain situations, applications may be subject to less regulatory oversight than they actually warrant. For instance, if applicants wrongly apply for a lower risk authorisation or GMO dealings pose higher risks than previously assessed based on available scientific data.

However, this is extremely unlikely because the following protections are in place to manage such situations:

- the GT Regulator would decide whether an application received by the OGTR meets the eligibility criteria for the authorisation pathway specified by the applicant and would reject the application when the criteria are not met
- the process of specifying which dealings are eligible for the different authorisation pathways would require the GT Regulator to prepare a risk analysis that supports the determination and consult with relevant experts, governments and the public, prior to making a decision
- monitoring powers available under the GT Act and the requirement for stakeholders to report any adverse effects posed by GMO dealings would ensure the GT Regulator's awareness of the risks posed by the different GMO dealings. The GT Regulator would be able to reclassify GMO dealings in response to new information about risk.

Option B would uphold the protection of human health and safety and the environment. This is because regulatory scope would remain unchanged (the same type of modified organisms that fall under regulation under Option A would fall under regulation under Option B) and activities with GMOs would be regulated in the same manner.

It is expected that Option B would be more responsive to scientific advancements, due to the introduction of delegated legislation. Under Option B, the GT Regulator would be empowered to determine which GMO dealings are eligible for the different authorisation pathways, within constraints set by the legislation. If new information supported that dealings posed higher risks than anticipated, the Regulator could reclassify the dealings in a higher regulatory oversight category. This is expected to be able to be completed in shorter timeframes compared to amending the GT Regulations, as occurs under Option A. In the past, amending the Regulations to reclassify certain GMO dealings into a different category has taken 4–8 years. This means that the time a GMO dealing is underregulated while waiting for a reclassification would be reduced under Option B. This would increase the level of protection for human health and the environment compared to Option A.

GMOs created with new technologies would be less likely to be seen to fall outside of the regulatory system under Option B. This is because under Option B, definitions in the GT Act would be updated to provide clarity as to which future developments would be captured under regulation. The GT Regulator would also be allowed to either issue guidelines or binding determinations that would clarify whether technological developments meet the definitions in the GT Act. Therefore, regulated stakeholders would be supported in their interpretation of the definitions by the guidance issued by the GT Regulator, decreasing the chances of regulated stakeholders wrongly interpreting that their developments do not meet the definitions in the GT Act and then not applying for appropriate authorisations. This results in improved oversight and management of adverse consequences to human health and safety and the environment.

The benefits of gene technology would also be made available to the community in shorter timeframes compared to Option A.

Summary of Option B

Option B would appear to address the policy problems identified. It provides authorisation pathways that would better fit current and future GMO applications, particularly with respect to GMOs developed by the medical sector. By introducing new streamlined authorisation pathways, Option B would be more risk commensurate. Option B would also be expected to provide greater certainty regarding the regulatory status of new developments.

Option B is expected to result in significant savings for applicants in processing times. For clinical trials and commercial therapeutics, it is estimated that 50% of DIR licences could become expedited licences and 35% of DNIR licences could become permits with reduced licence application times of **420 days, or 13%**.

For GM crop applications, it is estimated that Option B would result in 40% of plant field trials licences and 67% of commercial crop licences being expedited, such that assessment times would be reduced by **1350 days, or 35%**.

Regulatory cost savings for regulated entities have been estimated at \$100,200 per year.

Administrative costs	Delay costs	Substantive compliance costs	Total
-\$22,800	-\$80,000	+\$2,600	-\$100,200

The level of protection afforded by Option B would be slightly increased, as dealings could be reclassified to higher oversight categories if needed in a timelier fashion.

The shorter timeframes to get an approval for some applications under Option B may also encourage increased scientific research and investment in the field of gene technology and allow the community to access novel products developed with gene technology in a timelier manner.

Option C: Impact Analysis

Option C requires an increased delineation as to the nature of the dealing. This means stakeholders must determine the key aspect of the dealing in order to categorise accordingly.

Administrative costs

There would continue to be a primary categorisation of the dealing as 'contained' or 'involving intentional release of a GMO into the environment', but a third category would be added for clinical trials and medical applications. As such, Option C would improve the categorisation of GMO dealings undertaken in the medical field. Therefore, the additional pre-submission consideration of applications undertaken by applicants and the OGTR would no longer be required, reducing the cost of making such applications by approximately \$22,800 a year (as estimated under Option B).

However, some of the problems with Option A would continue with Option C, since the classification of some GMO dealings into 'contained' or 'involving intentional release of a GMO into the environment' categories would continue to be ambiguous.



CASE STUDY: BIOBRICKS

International scientists are developing bacteria to make a new building material that resembles concrete and can be used to make bricks of an environmentally sustainable alternative to concrete. To make the material, scientists put bacteria in a mixture of warm water, sand and nutrients. The microbes then produce calcium carbonate, gradually cementing the sand particles together. After a few days of storage, most bacteria in the bricks gradually begin to die out.

If an Australian applicant wanted to build a wall in the field with bricks made with GM bacteria and measure some physical parameters, under Option B this application would be assessed according to the level of risk.

Under Option C it would be uncertain whether this application is for dealings that are contained (since the GM bacteria are contained in the bricks and would not be able to disperse) or for dealings involving intentional release of a GMO into the environment (because the wall would be built in the open environment).

In these instances, regulated entities would have to invest additional time in making enquiries to the GT Regulator to determine which authorisation pathway applies to their application, increasing regulatory burden compared to Option B. Assuming that the OGTR would receive one query per year to clarify the eligibility for an authorisation pathway, and that the work involved to address this query is the same as for clinical trial applications (13 working hours at \$73 per hour), Option C would have an additional regulatory cost of \$950 compared to Option B.

The administrative cost for regulated organisations associated with meeting compliance requirements (notifications to the Regulator, meeting licence conditions, reporting obligations, etc.) would remain unchanged as compliance requirements for non-notifiable, notifiable and licensed dealings under Option C are equivalent to those of the current exempt, NLRDs and licensed dealings under Option A.

Delay costs

As for Option B, there would be decreased timeframes for organisations seeking to undertake lower risk dealings because of the availability of the notifiable, permit and expedited licence pathways.

Option C has the potential to reduce timeframes to the same extent as Option B because the same streamlined authorisation pathways would be available under both options. Under Option C, 75% of assessments for medical applications, including clinical trials, could be streamlined, as well as up to 50% of plant field trial and commercial release applications.

However, there would be circumstances in which a GMO dealing may fall under more than one category. In those cases, stakeholders would have to apply for more than one licence under Option C, while under Option B one application would suffice. This would increase the cost of a project for regulated entities and the time required to obtain all authorisations for a given project compared to Option B.



CASE STUDY: VACCINE LETTUCE

Plants can be genetically modified to produce a protein (antigen) from a virus causing disease. A person or animal eating this GM plant would become immunised against the virus because the antigen in the plant would stimulate the immune system in the gut. This type of GM plant is called an edible vaccine and could be a good alternative to conventional vaccines. While edible vaccines are at early stages of development overseas, it is possible that the OGTR could receive an application for a trial of GM lettuce that can work as an edible vaccine against hepatitis B.

If the applicant intends to do a field trial to determine how well the GM lettuce grows in the Australian environment, as well as conduct a human clinical trial to determine if eating the GM lettuce protects participants against hepatitis B, then Option B enables this to be assessed as a single application, resulting in one licence. Under Option C, two applications may need to be submitted: one for the field trial and another for the clinical trial.

To account for this factor, a 5% increase in the working days to a regulatory decision has been applied to Option C compared to Option B.

For clinical trials and commercial therapeutics, it is estimated that Option B would result in 50% of DIR licences becoming expedited licences and 35% of DNIR licences becoming permits, reducing licence application times from 3240 working days to 2820 working days.

For GM crop applications, it is estimated that Option B would result in 40% of plant field trials licences and 67% of commercial crop licences being expedited, such that assessment times would be reduced from 3780 working days to 2430 working days.

If a 5% increase to the above working days is applied to estimate Option C's shortening of timeframes:

- For clinical trials and commercial therapeutics, it is estimated that Option C would result in a reduction of licence application times from 3240 working days to 2961 working days.
- For GM crop applications, it is estimated that Option C would result in a reduction of assessment times from 3780 working days to 2552 working days.

Shorter timeframes to obtain an authorisation and reduced data requirements to make an application would result in substantial reductions in regulatory burden, as explained, for Option B.

Expedited commercial GM crop licences would reduce the timeframe to assess an application from 255 days to 90 days, allowing seed companies to sell GM seeds for one additional growing season. Assuming that a seed company earns \$100,000 by selling GM seeds (canola or cotton) to Australian farmers in one growing season (this is a conservative figure), this amount would be the regulatory savings that Option C would bring to such company.

Four GM crop commercial applications received in the last five years could become expedited licences under Option C. If this allowed companies to sell GM seeds for one extra growing season and assuming a benefit of \$100,000, this means a regulatory saving of approximately \$400,000 over five years, or \$80,000 per year. The benefits of commercial GMO therapeutic licences that become expedited would also add to the regulatory savings of Option B.

Substantive compliance costs

Most stakeholders identified that adapting organisations' regulatory practices to Option C would incur a cost. It is expected that this cost would be slightly greater than for Option B, because the system would be more complex.

Assuming that the training activity requires preparing a presentation outlining the changes in the Scheme and circulating the presentation among researchers, it is assumed that preparing such presentation would take 4 hours work for Option C. Since this needs to be undertaken in the 180 organisations accredited under the Scheme, then the cost would be approximately \$53,000, (4 hours x \$73 x 180). Spreading this cost over ten years results in an annual cost of \$5,300.

As for Option B, OGTR would provide comprehensive guides and information sessions on the new system to mitigate this cost for organisations.

The implementation of changes to the regulatory framework would incur a one-off cost for the GT Regulator. OGTR would have to update its IT system to support the preferred option, including changing application forms; developing guidance material to inform regulated stakeholders on the changes to the Scheme; and adapting their internal operations to deal with the new streamlined authorisation pathways.

In terms of ongoing costs, Option C is not expected to require additional budget allocation to OGTR. It is anticipated that the new authorisation pathways would reduce the evaluation work that the OGTR does annually, but since it is also expected that the number of applications would increase, there would also be an increase in the amount of monitoring activities undertaken to ensure compliance with the conditions of authorisations.

Risks

Option C may become outdated in the future for some GMO dealings developed that do not comfortably fit in the three overarching categories of 'contained', 'involving release' and 'medical applications'.

This would cause uncertainty regarding the categorisation of some applications and increase administrative burden. Time-consuming legislative amendments would be required to change the system of authorisation pathways.

As for Options A and B, Option C would uphold the object of the Scheme, since the scope of regulation would remain unchanged and the same range of activities with GMOs would still fall under regulation. As for Option B, regulatory oversight would be better aligned to the level of risk under Option C. In addition, it is expected that the Scheme would also respond to scientific advancements in a timelier manner due to the introduction of delegated legislation. This would increase the level of protection of the community and the environment compared to Option A (as GMO dealings would be expected to be able to be reclassified to higher authorisation pathways in a timelier manner).

GMOs created with new technologies would be less likely to fall outside of the regulatory system under Option C. Under Option C, definitions in the GT Act would be updated to provide clarity as to what future developments would be captured under regulation and the GT Regulator would be allowed to either issue guidelines or binding determinations that would clarify whether technological developments meet the definitions in the GT Act. Therefore, regulated stakeholders would be supported in their interpretation of the definitions by the guidance issued by the GT Regulator, decreasing the chances of regulated stakeholders wrongly interpreting that their developments do not meet the definitions in the GT Act and not applying for appropriate authorisations. This results in improved oversight and management of adverse consequences to human health and safety and the environment.

Under Option C, the benefits of gene technology would be made available to the community in shorter timeframes compared to Option A.

Summary of Option C

Option C would go some way to addressing the policy problems. Option C provides a system of authorisation pathways that would better serve GMO applications developed by the medical sector. This would reduce the problems that have arisen with respect to these types of GMOs. However, it does not offer the same level of future-proofing as Option B, as new GMO dealings may be developed in the future that do not fit comfortably in the three overarching categories of Option C.

By introducing new streamlined authorisation pathways, Option C would be more risk commensurate. However, Option C does so in a more complex way than Option B by increasing the number of available pathways for authorisation. Accordingly, it would have slightly higher regulatory costs than Option B.

Option C would reduce the timeframe for GMO therapeutic applications by **279 days, or 8.6%**. For GM crop applications, it is estimated that Option C would result in a reduction in assessment times by **1128 days, or 32.5%**.

Regulatory cost savings for regulated entities have been estimated at \$96,500.

Administrative costs	Delay costs	Substantive compliance costs	Total
-\$21,800	-\$80,000	\$5,300	-\$96,500

The level of protection afforded by Option C would be slightly increased compared to Option A as dealings could be reclassified into higher oversight categories if needed in a timelier fashion.

The shorter timeframes to get an approval for some applications under Option C may also encourage scientific research and investment in the field of gene technology. However, Option C may increase the number of applications required under the Scheme for a given project and involve more enquiries to the OGTR in relation to appropriateness of authorisation pathways compared to Option B.



8. Consultation

All Australian governments understand the importance of thorough consultation to inform the Review and the implementation of the Review recommendations. A comprehensive stakeholder engagement plan has informed consultation with relevant stakeholders since the commencement of the Review. A summary of the consultations undertaken during the Review, and the initial phases of the implementation of Review recommendations, is available at [Attachment D](#).

Consultation on the Consultation RIS and Explanatory paper (December 2020 – March 2021)

The Consultation RIS integrated the consultation outcomes from the Review and the initial implementation phase of the Review. The aim of the Consultation RIS was to present two reform options (for comparison against maintaining the *status quo*) to address key recommendations arising from the Review. It also sought to gain information from regulated stakeholders, government and the public about the impacts of each reform option. Information gathered from stakeholders through the Consultation RIS enabled an analysis of the impacts of each option, which is presented in this Decision RIS (see Section 7).

Further consultation on the technical implications relating to the implementation of Options B and C was undertaken in parallel, through questions put forward in the Explanatory paper.

Consultation method

The Consultation RIS was announced on the Department of Health website and published on the department's online Consultation Hub platform. Notification of the thirteen week public comment period and the invitation to submit was promoted through website announcements and via an alert to OGTR News subscribers (655 contacts), OGTR contacts for regulated organisations (303 contacts) and 693 stakeholders that participated in previous consultation rounds and/or are subscribers to the National Gene Technology Scheme website.

The most appropriate consultation approach to enable adequate opportunity and support for stakeholders in providing a submission was selected, taking into account Covid-19 restrictions on travel and meetings. The following activities were undertaken:

- a dedicated email inbox was maintained for stakeholders to submit any questions or concerns regarding the consultation;
- a reminder email was sent to subscribers prior to the closing date of the Consultation RIS public comment period; and
- four consultation information sessions (videoconference or webinar) were held during the consultation period; two were open to the public, while the others targeted regulated organisations. The aim was to clarify any doubts/questions about the proposed policy options and encourage stakeholders to provide information on the costs and benefits of the proposed options in their submissions, including quantitative data. In total, more than 200 participants attended the sessions.

Submissions

The public comment period for the Consultation RIS was open from 14 December 2020 to 17 March 2021. Over the thirteen-week public comment period, 52 submissions were received from a wide range of stakeholders including:

- 28 regulated organisations, including Institutional Biosafety Committees (IBCs)
- 11 industry groups and associations
- 5 government agencies
- 5 non-governmental organisations
- 3 members of the public.

Non-confidential submissions were made available on the Department of Health website. Stakeholders were notified of the publication of the submissions received via email.

How the information provided by stakeholders has been used

A summary of the consultation feedback is provided below. Specific information provided by stakeholders in relation to the benefits and costs of each option was used to perform impact analysis in the Decision RIS (see Section 7 of this document).

Submitters also responded to the questions contained in the Explanatory paper. In this regard, stakeholders raised issues or provided suggestions in relation to the proposed risk indicators to be used to classify dealings in authorisation pathways; the changes to the GMO Register; and changes to the definitions in the GT Act. A summary of stakeholders' views in relation to these matters is available at [Attachment E](#). This information would inform detailed development of a preferred option once endorsed by the GTMM, as well as the preparation of draft legislation. There would be an opportunity for stakeholders to comment on draft legislation in the future, as well as the associated Regulations and guidance materials.

Stakeholders' preferred option

Most submitters supported Option B as the preferred option to implement the recommendations of the Review. The breakdown of preferences was as follows:

- 37 submitters supported Option B;
- 7 submitters supported Option C;
- 3 submitters supported Option A;
- 2 submitters supported both Options B and C;
- 3 submitters did not identify a preferred option.

Supporters of Option B in general agreed that the *status quo* (Option A) is no longer suitable to deal with the current scientific landscape and concurred with the policy problems and objectives of government action identified in the RIS.

They supported Option B as the best option to implement Review recommendations because this option imposes regulation in a manner that is proportionate to the level of risk, with the benefit of simplicity and transparency when compared with Option C.

Option B would also allow the Scheme to respond flexibly to advances in the field of gene technology, as new GMO dealings could be easily categorised in the authorisation pathways of this option, according to their level of risk.

Of the seven supporters of Option C, two were NGO groups and the other five were research organisations. They acknowledged that the current system needs updating to deal with scientific advancements. They preferred Option C to implement Review recommendations because the overarching categories in this option (contained dealings, dealings involving intentional release into the environment, and medical applications) allow a clear distinction between applications for GM plants and medicinal therapies, which aligns with the current work of research organisations and the OGTR, and would remove ambiguity relating to dealings. In their opinion, this option could also be expanded over time to add more overarching categories, should that be needed, to accommodate new types of dealings in the future.

The three supporters of Option A were two NGO groups and one peak industry group. They considered that Option A has worked well in protecting human health and safety and the environment and did not agree that this option is stifling innovation. They did not agree with the objective of government action aiming to streamline processes and instead preferred increased checks and balances on any dealings with GMOs. They considered that both Options B and C would involve the deregulation of dealings with GMOs and that this could lead to harm to humans and the environment. In order to address this concern, the impact analysis places more focus on the object of the Scheme, to protect human health and safety and the environment, and presents other objectives of government action as subordinate.

Of the two submitters supporting both options B and C, one was a research organisation that considered that both options represented an improvement compared to the current system. This submitter stated that only small adjustments would be needed for this organisation to implement either of these options. The other submitter saw different benefits arising from each option and was undecided as to which option was best.

Three submitters did not state a preference for an option. They argued that either they needed more information on specific details to select one option, none of the options would modernise and future-proof the Scheme unless certain GMOs are excluded from regulation, or simply put forward new proposals to improve the Scheme.

Other issues raised by stakeholders

Many submitters commented that the full benefits and costs of Options B and C could not be determined at this stage because the Consultation RIS did not specify the fine operational details of the proposals. Many submitters would have liked to have been provided with more information about the timeframes for the assessment of applications for a permit, expedited licence or full licence or the amount of data that would be required from applicants to make an application for any of these licences. However, the aim of this consultation process was to obtain information that would support the selection of a preferred option to implement Review recommendations, for which the full detail can then be developed.

One point that was raised by many submitters involved in agricultural applications of biotechnology was that the Consultation RIS did not provide information on how gene edited organisms carrying modifications, that could have occurred naturally or through conventional breeding, would be treated under a new regulatory framework. They deemed this as unsatisfactory because this matter is the main concern of their industry/organisation. However, this matter would be determined once a preferred option has been endorsed and in the next phases of implementation.

Stakeholders' views on Option A

The majority of submitters agreed with the policy problems outlined in this Decision RIS and therefore thought that Option A no longer represented an efficient way to regulate activities with GMOs.

Stakeholders commented that under Option A, the timeframes for authorisation of licensed dealings can be a hurdle that makes organisations lose their competitive edge.

As an example, a stakeholder commented that “the length of the application and time taken to obtain authorisation for field trials of GM crops deters some researchers who have no experience in such applications”. GM technologies may be overlooked in favour of other means of producing a non-GM plant that is easier and faster for researchers to trial in the field. However, it is not always possible to introduce a trait into a plant without using gene technology. Along these lines, one submitter stated that “it is impossible to quantify the cost associated with lost opportunity when products are not developed”.

The requirement for DIRs to undergo the full assessment process was also identified as a setback for receiving competitive grant funding. This is because funding agencies are often reluctant to award funding for GM trials without OGTR approval first being obtained, but researchers are unlikely to dedicate the time to apply for a DIR licence without first securing funding. In addition, the longer timeframes to obtain approval for DIRs means that researchers cannot access funding that is available for shorter-term projects.

All nine medical research organisations that participated in the consultation were convinced that the field of medical research and clinical trials is going to expand strongly in the near future and that keeping the *status quo* may increase the incurred regulatory costs. They claimed that the costs would arise from the overregulation of clinical trials and gene therapies that are low risk, as well as from the uncertainty as to what authorisation pathway corresponds to different clinical trials. According to submitters, uncertainty around the regulatory system deters companies from investing resources to facilitate local clinical trials or proceeding with applications for regulatory approval.

Submitters from medical research organisations claimed that the current processes do not provide enough flexibility to support clinical trials efficiently and the timeframes for assessments reduce agility and delay clinical trials commencing. They predicted that if Option A continues, Australia will lose competitive advantage and research companies will undertake their clinical trials in other countries. They claimed that this effect will be more prominent for small/medium sized companies who will be reluctant to invest in the Australian market for medical research.

In general, regulated stakeholders agreed that the current framework does not provide the agility to process applications addressing new technologies. This affects patients' access to cutting edge treatment or the ability of the Australian biotechnology sector to keep pace with international competitors.

Stakeholders' views on Option B

Most submitters supported the view that Option B addresses the policy problems described in the RIS. In their opinion, the focus on risk rather than the nature of the dealing aligns the Scheme to the purpose of protecting health and safety of humans and the environment. Option B would also ensure that each of the different sectors involved in gene technology (agriculture, health and environment) would be properly regulated by the Scheme.

Most submitters preferred Option B over C due to the simplicity of the authorisation pathways. By having just three authorisation pathways under one authorisation stream, submitters claimed that under Option B it would be easier for regulated organisations to determine the authorisation pathway applicable to GMO dealings and dealings would not fall under multiple pathways.

Submitters also supported the position that Option B would provide greater regulatory certainty, as applications for clinical trials with GM techniques and GMOs would no longer require them to make a judgement on whether the trial involves the intentional release of the GMO into the environment. Therefore, the making of such applications would, in their opinion, be streamlined.

Stakeholders pointed out that basing regulation on risk could have a positive impact on behavioural compliance because it would focus research and industry on the principle of risk management rather than regulatory categorisation. By being simpler, submitters also suggested that Option B would reduce the risk of incorrect categorisations.

Submitters raised that there would be a cost associated with adapting organisations' regulatory practices to the new system if Option B was implemented. This would mainly consist of training the organisations' personnel on the amended Scheme and adapting organisational procedures. Submitters agreed that this would be a one-off cost and that the benefits of Option B would outweigh this cost.

Submitters did not provide quantitative data on the cost associated with implementing a new system. In addition, submitters were somewhat divided when expressing the magnitude of this cost. Some submitters claimed that implementation of Option B would result in a significant cost to the organisation with regard to training. Others claimed that Option B was not anticipated to have significant consequences for their organisation, because it retains the core aspects of the Scheme with limited disruption to the existing structure of authorisations.

Submitters also commented that if the OGTR was resourced to provide comprehensive guides and information sessions on the new system, this would alleviate the burden for organisations.

One submitter was concerned that Option B may require more complex decision making from IBCs, which may increase costs. The submitter also added that to mitigate this, it would be imperative that the Scheme provides clear criteria and guidance material on the eligibility for the different authorisation pathways.

Stakeholders' views on Option C

By retaining the nature of the GMO dealing as the primary distinction for categorisation in authorisation pathways, most stakeholders believed that Option C does not fully align with the foundational principle of the Scheme, that the regulatory system must be based on scientific evidence and be risk-based.

Submitters agreed that the dedicated clinical trial category in Option C would make authorisation categories easier to navigate than the *status quo*, for those organisations involved in medical research. However, submitters saw the retention of the categories 'contained' and 'intentional release into the environment' as problematic, as this would continue to cause uncertainty regarding categorising certain applications for GMO dealings, requiring them to invest additional time in making enquiries to the GT Regulator to determine which authorisation pathway applies to their application.

Submitters also stated that the matrix of authorisation categories in Option C could complicate the process of determining the right authorisation pathway for a GMO dealing and increase the risk of assigning a GMO dealing to the wrong authorisation pathway.

In addition, submitters commented that Option C may become outdated in the future if new GMO dealings are developed that do not comfortably meet the three overarching categories of 'contained', 'involving release' and 'medical applications'. This would cause uncertainty regarding the categorisation of some applications for GMO dealings and increase administrative burden.

Most stakeholders identified that adapting organisations' regulatory practices and training staff and IBCs to Option C would incur a cost. Submitters expected this cost to be greater than for Option B, because the system would be more complex.

Submitters also raised that the day-to-day work of IBCs may also become more onerous under Option C if the matrix of authorisation pathways makes decision making more complex. In addition, IBCs would continue to have to make a judgement about whether the dealing involves the release of a GMO into the environment or whether such release is intentional when assessing certain GMO dealings.

One submitter raised the view that as IBC members in their organisation are volunteers from the research and operational community, there is concern that if assessing applications becomes more onerous, they may not wish to continue in their capacity as committee members.

Stakeholders' views on common proposals of Options B and C

Options B and C shared a few proposals in common (see section 6 of the Decision RIS). This section covers submitters' views in relation to these proposals.

Submitters' views on the benefits of shorter timeframes to make regulatory decisions

Both Options B and C propose the introduction of streamlined authorisation pathways for GMO dealings that are low risk or under the remit of other regulators. This means that under these options applications to undertake these GMO dealings would be assessed in shorter timeframes compared to Option A.

The vast majority of submitters agreed that shorter timeframes for the processing of licence applications would increase the competitiveness of the Australian biotechnology sector. Submitters commented that shorter regulatory timeframes would enable researchers to access different sources of funding, such as those for shorter-term projects, and allow them to conduct more trials in a given period. This would help ensure that the pathway to commercialisation is faster and would increase the competitiveness of the sector. Submitters also suggested that it would also make Australia a more attractive location for clinical trials.

Submitters also pointed out that shorter timeframes would give Australian researchers a competitive advantage when forming international collaborations and bringing innovative products to Australia. More efficient approval processes would also allow researchers to spend more time doing research.

Submitters' views on the introduction of delegated legislation made by the Regulator

Most submitters welcomed the proposal to specify eligibility for the different authorisation pathways in delegated legislation made by the Regulator. According to submitters, delegated legislation provides flexibility for the legislative framework to respond to future developments and allows the Scheme to more rapidly adapt to change and remain current. However, submitters also pointed out that the making of such delegated legislation would require transparent processes to maintain trust in the Scheme, and that clarity in the delegated legislation must be prioritised to ensure regulatory certainty is achieved.

Submitters indicated that providing regulatory certainty would facilitate more widespread use of gene technology, resulting in the growth of the biotechnology industry, and would also promote scientific innovation by giving researchers flexibility to explore new technologies and ideas.

Some submitters were opposed to enabling the Regulator to specify eligibility for the different authorisation pathways because, in their opinion, this would reduce the level of Parliamentary oversight over the Scheme. These concerns would be taken into account if this proposal is approved for implementation. Possible measures that could be put in place to ensure oversight include specifying consultation requirements prior to making such determination, and/or specifying that this type of legislative instrument made by the Regulator would be disallowable by Parliament.

Other issues raised by submitters

Some submitters were concerned that if dealings other than the current NLRDs were eligible to be authorised as notifiable dealings under Options B and C, IBCs may be required to assess these. Submitters were uncertain as to what type of assessment would be requested from IBCs and questioned whether current IBC scientific and technical expertise would be adequate to undertake such assessments.

Consideration of whether IBC oversight would be required to manage the risks of new dealings, (if added to the notifiable dealing pathway), would be undertaken in the next stages of implementation once the GTMM agrees to a preferred implementation option. Future public consultation would address the type of dealings proposed to be included in this category and the details of the IBC assessment required (if any).



9. Preferred option

Based on the analysis presented in this Decision RIS, the preferred option is Option B.

Option A has been successful in achieving the protection of human health and safety and the environment to date. However, it overregulates certain GMO dealings and does not offer a system of authorisation pathways that effectively accommodates current and future GMO dealings. This has the potential to slow down the progress of scientific discovery and the path to market for certain GMO products. Option A involves longer processing times and higher administrative costs for applicants.

Options B and C, compared to the base case (Option A), would better respond to emerging technologies and introduce efficiencies in the processing of applications for GMO dealings, streamlining those applications that are determined to be of low risk. Overall, both options would reduce the cost of regulation.

Option C would introduce new streamlined authorisation pathways. However, Option C also increases considerably the number of available pathways for authorisation, with the resulting level of complexity having the potential to increase regulatory costs for regulated entities compared with Option B. In addition, Option C would not completely solve the policy problem of the authorisation categories not being suitable for current and future applications, as it retains the split between contained dealings and dealings involving the intentional release of a GMO into the environment.

Option B would be expected to uphold the object of the Scheme in a more efficient way than Option A and Option C. Its simple system of authorisation pathways would allow the streamlining of applications that are low risk and have enough flexibility to categorise current and future GMO applications. The shorter timeframes to get an approval and reduced regulatory costs under Option B may also encourage scientific research and investment in the field of gene technology.

Option B is expected to result in significant savings for applicants in processing times. For clinical trials and commercial therapeutics, it is estimated that 50% of DIR licences could be expedited and 35% of DNIR licences could become permits with reduced licence application times of 420 days, or 13%.

For GM crop applications, it is estimated that Option B would result in 40% of plant field trials licences and 67% of commercial crop licences being expedited, such that assessment times would be reduced by 1350 days, or 35%.

Regulatory cost savings for regulated entities have been estimated at \$100,200 per year.

Therefore, the impact analysis supports that Option B would substantially address the policy problems and the priority recommendations of the Review, that it would better meet the object of the Scheme and the objectives of government action, and is likely to be the option with the greatest net benefit.



10. Other technical changes

The opportunity to modernise the GT legislation is supported by a range of other technical changes (refer to the Explanatory Paper) that could be implemented together with the preferred option identified through this RIS process. The technical changes proposed are largely minor, and are consistent with the Commonwealth principles for clearer laws. The proposed changes would enable existing processes to be streamlined, the complexity of the legislation to be simplified (including to improve readability), redundant legislation to be removed, and would reduce regulatory and administrative burden.



11. Implementation and review

Implementation

Should the GTMM agree to the preferred option in the Decision RIS, the following main issues would need to be addressed:

- the existing GT legislation would have to be amended to implement Option B (see below)
- OGTR would have to update its IT system to support the preferred option, including changing application forms; develop guidance material to inform regulated stakeholders on the changes to the Scheme; and adapt their internal operations to deal with the new streamlined authorisation pathways
- regulated organisations would need to educate staff on the changes to the Scheme and transition current authorisations to the new system. No changes in infrastructure would be required and operational procedures would remain the same or only change slightly (since compliance requirements under Option B are equivalent to those under Option A).

Amendment of the GT legislation

If agreed, the legislative amendments to implement Option B could be drafted in late 2021/early 2022, taking into account submissions received from stakeholders in response to the Explanatory Paper.

It is anticipated that the draft Bill and draft delegated legislation could be the subject of public consultations in late 2021/early 2022, following which the draft legislation would be finalised. If the finalised amendments are agreed by the GTMM and the Bill made by the Australian Parliament in 2022, the legislative amendments (new Bill and delegated legislation) could be phased in (to account for any necessary transitional arrangements) and could commence as early as mid-late 2023.

A period of at least 6 months between the making of the Bill and commencement is envisaged to:

- allow the OGTR to implement new processes, including a new IT system, that would support the administration of the amended legislation, and
- provide time for states and territories with mirror legislation to amend their legislation to be corresponding to the Commonwealth legislation.

A transitional period of at least 12 months is also being considered to allow stakeholders to meet compliance with the updated legislation. A range of education and awareness materials developed by OGTR would be made available through the transitional period.

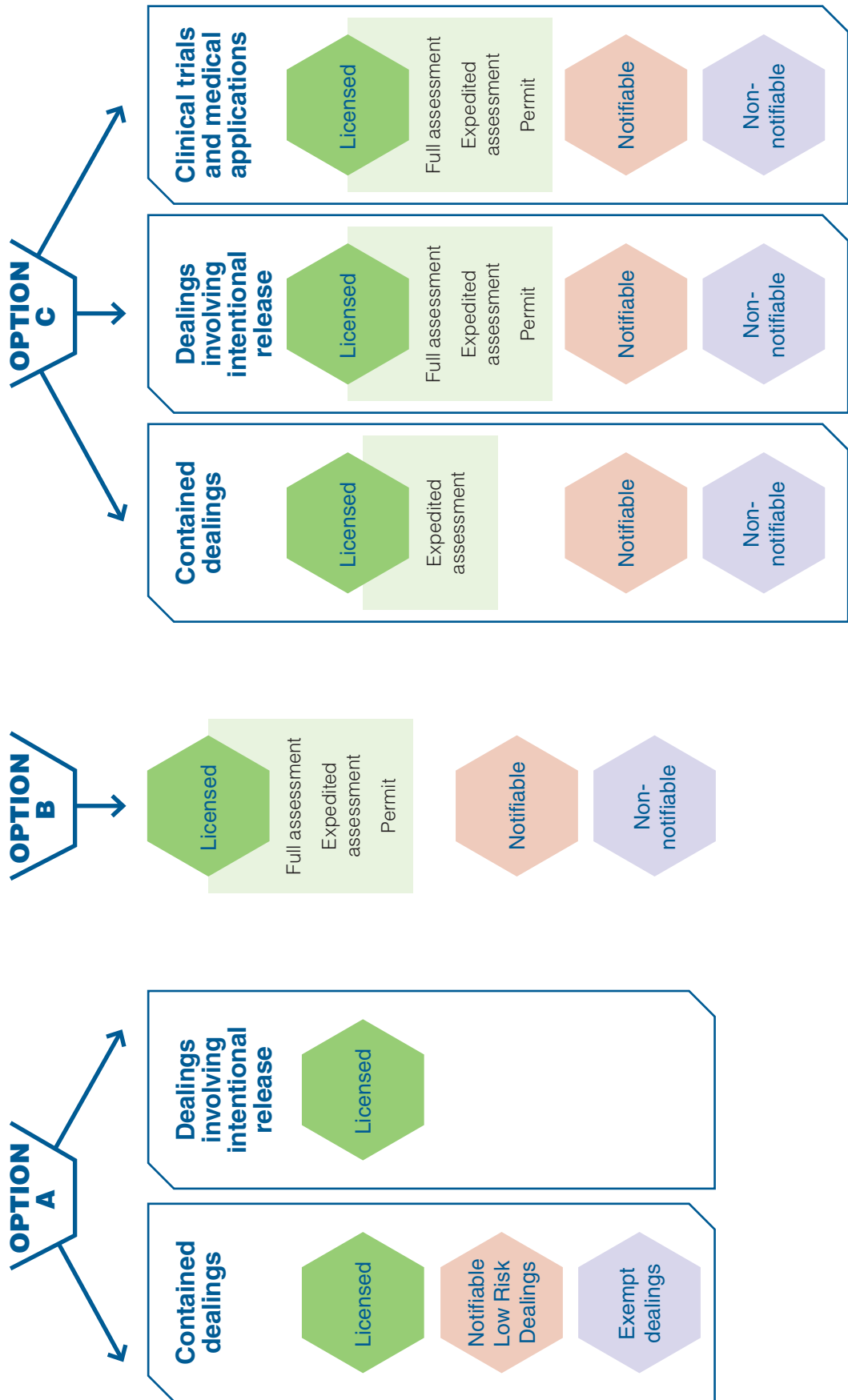
Review

Review of the updated Scheme will be conducted as per the scheduled review process specified in the intergovernmental Gene Technology Agreement, according to which reviews will be conducted at intervals of no more than five years. The GT Regulator may undertake a review of the eligibility for the different risk tiers at shorter intervals and/or in response to technological developments.

12. Abbreviations

Term	Definition
APVMA	Australian Pesticides and Veterinary Medicines Authority
Cth	Commonwealth
DIR	Dealings involving an Intentional Release of GMOs into the environment – all GMO dealings outside contained facilities require case by case assessment and licensing from the GT Regulator, from small field trials to general releases.
FSANZ	Food Standards Australia New Zealand – a statutory authority in the Australian Government Health portfolio. FSANZ develops food standards for Australia and New Zealand.
GMO	Genetically modified organism which has the meaning as provided in section 10(1) of the GT Act.
GM	Genetically modified – an organism, or product of an organism, that has been changed by gene technology.
GT Act	<i>Gene Technology Act 2000</i>
GT Regulations	<i>Gene Technology Regulations 2001</i>
IBC	Institutional Biosafety Committee – IBCs provide on-site scrutiny of NLRD proposals.
OGTR	Office of the Gene Technology Regulator – staff supporting the Gene Technology Regulator.
GT Regulator	Gene Technology Regulator – an independent statutory office holder responsible for administering the GT Act and corresponding State and Territory laws.
RIS	Regulation Impact Statement – an analysis of the costs and benefits of proposed changes to regulation, to support decision-makers.
Review	<i>Third Review of the National Gene Technology Scheme</i>
TGA	Therapeutic Goods Administration

Attachment A – Pictorial representation of the authorisation pathways under the three options presented in this Decision RIS



Attachment B – Intended operation of the new authorisation pathways under Option B

Authorisation pathway	Intended operation of the authorisation pathway
Non-notifiable dealing	<p><i>Dealings with GMOs that meet specific eligibility criteria do not need to be notified to the GT Regulator. Non-notifiable dealings remain within the scope of the Scheme and certain requirements must be complied with.</i></p> <ul style="list-style-type: none"> • This authorisation pathway would include contained dealings currently classified as exempt dealings (Schedule 2 to the GT Regulations). • The scope of the category would be expanded (beyond the current exempt dealings category) to allow other GMO dealings that are very low risk (where containment is not the key factor).
Notifiable dealing	<p><i>Dealings with GMOs eligible for self-assessment and notification.</i></p> <ul style="list-style-type: none"> • This authorisation pathway would include contained dealings currently classified as NLRDs in Parts 1 and 2 of Schedule 3 to the GT Regulations. • The scope of this category could be expanded to allow: <ul style="list-style-type: none"> – GMO dealings where other regulators assess risks to people and the environment (e.g. veterinary vaccines authorised by APVMA)
Licensed dealing	<p><i>Dealings with GMOs that require a licence, where the level of assessment and regulation is graduated.</i></p> <p>A permit would be required for dealings that are medium risk and do not require a case-by-case risk analysis. Through a transparent and consultative process, the GT Regulator would determine the criteria for a permit and specify dealings that are subject to defined conditions (i.e. known licence conditions). Examples of dealings that could be included in this category are:</p> <ul style="list-style-type: none"> • Dealings for which the risks are known and can be managed through standardised conditions (e.g. certain clinical trials and field trials). • Dealings that the GT Regulator has experience authorising and that meet certain criteria regarding use, traits, understanding of parent organism, etc. <p>An expedited assessment would be required for dealings with an undetermined or medium-high indicative risk that require a case-by-case risk analysis and tailored licence conditions.</p> <p>The appropriateness of an expedited (or reduced) assessment under this category reflects that some risks are already well understood by the GT Regulator, such that only some components of the proposed dealing need assessment.</p> <p>For example, an expedited assessment would be required if the dealing involves a variation on matters that would otherwise make it eligible for the permit category (e.g. an open ended timeframe in which to undertake a clinical trial; a field trial that is larger scale than one which would meet the criteria for a permit; a known parent organism with a novel trait).</p> <p>As for the permit category, through a transparent and consultative process the GT Regulator would determine the criteria for dealings that could be eligible for an expedited assessment.</p> <p>A full assessment would be required for dealings with a high risk or undetermined indicative risk. This category would include dealings for which the GT Regulator has no or limited regulatory experience. The GT Regulator would perform a risk analysis to determine if all risks can be managed and to identify risk management measures. The assessment of these applications would involve extensive consultations with government agencies, the Gene Technology Technical Advisory Committee and the public.</p>

Attachment C – Other proposed amendments that apply to both Options B and C.

In addition to risk tiering, Options B and C proposed:

- Amendments to some key definitions in the GT Act, which would support the implementation of Review recommendation 4.
- Changes to the process to make a listing on the GMO Register, to increase the usage of this authorisation pathway.

Definitions

The scope of the GT Act is established around three interrelated definitions; *organism*, *gene technology* and *genetically modified organism* (GMO); and the definition of *deal with*. The definitions of gene technology and GMO are currently cast broadly to capture, under regulation, any organism that has been modified by gene technology.

The mode of action for these definitions would be maintained under Options B and C. However, maintaining the mode of action requires the updating of 20-year-old definitions.

Under both Option B and Option C, minor changes would be made to the definitions of *gene technology* and *GMO* to ensure the Scheme appropriately applies to the current scientific environment, as well as to provide flexibility for the legislation to respond to scientific advances, while maintaining sufficient certainty as to the operation of the Scheme.

The definition of '*deal with*' is currently a list of activities/GMO applications that are captured under regulation. The terms used in the definition are skewed towards activities that are relevant to agriculture but apply less so for medical uses. Under Options B and C, the definition of '*deal with*' would also be amended to better reflect current activities with GMOs and to make sure that future applications are also captured under regulation.

Options B and C also propose enabling the Regulator to clarify understanding of what the definition does and does not include, for example issuing guidance regarding the interpretation of the term gene technology, or legally binding determinations on specific techniques.

Note: The amendments to the definitions in the GT Act would be drafted taking into account submissions received from stakeholders in this consultation round in response to the Explanatory Paper. For a summary of submitters' views on definitions please refer to **Attachment E**. New draft definitions would be the subject of future consultations.

The GMO Register

Under the GT Act, the GT Regulator may determine that a dealing with a GMO is to be included on the GMO Register if the dealing is, or has been, authorised by a GMO licence and the GT Regulator is satisfied that:

- any risks posed by the dealing are minimal; and
- it is not necessary for persons undertaking the dealing to be covered by a GMO licence in order to protect the health and safety of people and the environment.

After inclusion on the GMO Register, dealings no longer require authorisation by a licence but may still have conditions attached to their conduct.

Under the current arrangements, a determination by the GT Regulator to include a dealing on the GMO Register is a legislative instrument.

At the inception of the Scheme, the GMO Register was envisaged as a way to authorise GMO dealings with a history of safe use established after the dealings had been licensed for several years. However, the authorisation pathway is currently underutilised, and there are only two GMO dealings listed on the GMO Register.

A better usage of the GMO Register would ensure that the regulatory framework remains commensurate with the level of risk, by providing an avenue for the authorisation of dealings that pose a negligible risk based on scientific knowledge and accumulated regulatory experience.

To this aim, it is proposed that under Options B and C:

- the eligibility criteria for a listing on the GMO Register would be changed to remove the requirement for the dealings to have been previously authorised under a licence. This would open this authorisation category to notifiable dealings and dealings not previously authorised under the GT Act.
- the GT Regulator's determination to include a dealing on the GMO Register would become an administrative decision made by written instrument, instead of being made by a legislative instrument. Government and public oversight would be possible through the consultation steps that the GT Regulator would have to undertake before making a determination.

Attachment D – Summary of the consultations undertaken during the Review and the initial phases of the implementation of Review recommendations

Comprehensive and considered consultation was undertaken to inform the Review (refer Chapter 3 and Appendices 7–10 of the *Third Review of the National Gene Technology Scheme: October 2018 Final Report* (the Final Review Report)).

Consultation took into account the increasing recognition, across multiple sectors, of the value of policy co-design, whereby those with vested interest should be engaged in both identifying and constructing solutions to what are often multi-perspective issues.

The consultation process for the Review therefore involved three key phases (July 2017 – May 2018):

- Phase 1: identifying key issues for consideration.
 - This was an open consultation process, where submissions were sought to identify issues within scope of the Terms of Reference for the Review. This phase of consultation was supported with a Background Paper.¹⁵
 - In addition to the call for public submissions, findings from numerous reports and reviews were considered. Research was also undertaken into specific areas to further define the issues presented, including emerging technologies, the basis of community concerns, and a longitudinal study of public perceptions.
 - Outcomes of Phase 1 consultation are outlined in Appendix 7 to the Final Review Report.
- Phase 2: collaboratively exploring policy solutions to these issues.
 - The aim of the second phase of consultation was to work with stakeholders to further understand the issues and explore options and possible policy solutions for the issues identified in Phase 1.
 - Consultation took place through a range of mechanism, including:
 - ♦ Online responses to a public consultation paper;
 - ♦ Jurisdictional workshops;
 - ♦ Targeted meetings; and
 - ♦ Interactive webinars.
 - Outcomes of Phase 2 consultation are outlined in Appendix 8 to the Final Review Report.

¹⁵ Department of Health, *Review of the National Gene Technology Regulatory Scheme: Background Paper*, Department of Health, Australian Government, July 2017, accessed 18 May 2021.

- Phase 3: providing an opportunity to comment on the findings.
 - Phase 3 consultation built on the first two phases, with Review findings presented to stakeholders within the Review Preliminary Report.¹⁶ Stakeholders were invited to contribute to the final outcomes of the Review by submitting their feedback through an online submission process.
 - Outcomes of Phase 3 consultation are outlined in Appendix 9 to the Final Review Report.
- Market Research
 - In February 2018, a market research firm was engaged to further explore public attitudes, knowledge and beliefs about GMOs. This research explored the views of a representative sample of Australians, across a breadth of demographics, through the conduct of 12 focus groups and some 1500 surveys. In brief, participants were asked to respond to a series of questions, which focussed on identifying information requirements for the public and testing the appropriateness of regulatory approaches.
 - A summary of outcomes of the market research is provided at Appendix 10 to the Final Review Report.

Across all phases, over 320 submissions ultimately informed the recommendations outlined in the Final Review Report.

Two further formal consultations were conducted to inform the implementation of Review recommendations:

- Phase 1: public consultation on an issues paper¹⁷ to inform operational considerations and implementation of Review recommendations (Sept–Nov 2019); and
- Phase 2: consultation with the GTMM on possible options for the implementation of key Review recommendations through a revised regulatory framework.

16 Department of Health, *Review of the National Gene Technology Regulatory Scheme: Preliminary Report*, Department of Health, Australian Government, March 2018, accessed 18 May 2021.

17 Department of Health, *Implementing Recommendations of the Third Review of the National Gene Technology Scheme: Phase 1*, Department of Health, Australian Government, September 2019, accessed 18 May 2021.

Attachment E – Summary of submissions received in response to the Explanatory paper.

INTRODUCTION

The last round of public consultation on the implementation of recommendations made by the Third Review (the Review) of the National Gene Technology Scheme (the Scheme) opened between 14 December 2020 and 17 March 2021. The consultation was supported by two documents. The first one was the Consultation Regulation Impact Statement (Consultation RIS) – *Modernising and future-proofing the National Gene Technology Scheme*, which outlined two policy options (Options B and C) to implement a proportionate regulatory model that would give effect to priority Review recommendations. The Consultation RIS was accompanied by an Explanatory Paper that provided operational detail on how the proposed options in the Consultation RIS could be implemented in practice. Both documents contained questions for stakeholders. Questions in the Consultation RIS aimed to obtain information on the benefits and costs of the options while questions in the Explanatory paper related to the operational aspects of the implementation of the options. Answers to the questions in the Explanatory paper could help inform implementation of a preferred option, once endorsed by the GTMM.

Section 8 in the Decision RIS provides a summary of the information received from submitters in response to the Consultation RIS. This Attachment provides a summary of the views of submitters on the questions contained in the Explanatory paper.

Of the 52 written submissions received during this consultation round, 45 addressed the questions contained in the Explanatory paper. Most of these submissions were from regulated entities and IBCs.

DEFINITIONS

Chapter 3 of the Explanatory paper discussed definitional issues. Under Options B and C, changes are proposed to some key definitions in the *Gene Technology Act 2000* (the GT Act) to support the implementation of Review recommendation 4.

The scope of the GT Act is established around four interrelated definitions: *organism*, *gene technology*, *genetically modified organism* (GMO) and *deal with*. Subject to stakeholder views, changes are proposed to the definitions of *gene technology*, *GMO* and *deal with* to ensure the Scheme is effective, and that there is sufficient flexibility for the Scheme to respond to advances in gene technology and scientific knowledge into the future.

42 of the 52 submissions received through this consultation round provided responses to the questions in the Explanatory paper in relation to the proposed changes to the definitions. Whilst most submitters agreed there is a need to update the existing definitions, there were some differing views on the proposed changes.

Definition of gene technology

The definition of gene technology is discussed on pages 10 to 13 of the Explanatory paper. Under both Option B and C, it is proposed that the definition of gene technology be modified to address the lack of clarity regarding which techniques fall within the current definition. Three key changes to the definition were proposed:

1. Adding the word *creation* to the definition of gene technology as in 'gene technology means any technique for the *creation* or modification of genes or other genetic material'. This aims to clarify that the chemical synthesis of DNA or RNA is also considered gene technology.
2. Enabling techniques to be included via regulations. Currently, the definition of gene technology enables techniques to be excluded via regulations, but it does not also enable techniques to be included via regulations. With the rapid advances and changes in gene technology it is desirable for the legislation to have the flexibility to respond by including techniques.
3. Considering enabling the Regulator to clarify understanding of what the definition does and does not include, for example issuing guidance regarding the interpretation of the term gene technology, or legally binding determinations on specific techniques.

Adding the word 'creation' to the definition of gene technology

14 submitters supported this update to the definition of gene technology and recognised that the proposed definition would broaden the scope, ensuring new technologies would be captured. However, some of these submitters questioned whether the term 'creation' was the best word choice, as this is not a scientific term (some considered the word to be loaded with mythological meaning). Alternative words such as 'synthesis' were suggested as more appropriate.

Other submitters questioned whether the proposed change to the definition would raise ambiguity as to whether the chemical synthesis of DNA or RNA would then be regulated under the Scheme. But as other submitters pointed out, the Scheme regulates activities with GMOs, so unless the chemically synthesised material is used to modify or develop an organism, then the synthesis of nucleotides would not be captured under regulation.

9 submitters were opposed to the proposed change to the definition of gene technology. They argued that the definition is already broad and that the term 'modify' in the current definition already captures the chemical synthesis of DNA and RNA. They also alluded to the emotional/mythological connotations of the word 'creation'.

Enabling techniques to be included via regulations

In general, submitters that supported the addition of the word 'creation' in the definition of gene technology were also in favour of the proposal to include techniques via regulations as a mechanism to provide certainty on whether a technique is captured under regulation or not.

In contrast, submitters against the addition of the word 'creation' in the definition were also against this proposal. These submitters were against any amendment that may broaden the scope of gene technology. They argued that the definition is already broad and tends to capture all relevant techniques and that any uncertainty or regulatory gap that may arise in the future can be addressed with the currently available mechanism to capture GMOs via a listing in the regulations.

Considering enabling the Regulator to issue guidance or legally binding determinations

23 submitters were in favour of implementing a mechanism that would allow the Regulator to provide certainty as to whether a technique does or does not meet the definition of gene technology. Only 2 submitters were against this proposal but did not provide a reason explaining their position.

Of the submitters in favour, the majority (13 submitters) preferred legally binding determinations made by the Regulator as a mechanism to clarify whether a technique is to be considered gene technology. They argued that binding determinations provide more certainty and are less prone to inconsistencies in interpretation between regulated organisations. In their opinion, interpretative guidance leaves the decision on regulatory scope to IBCs who may consider obtaining their own legal advice, which can add considerable delays to the authorisation of GMO dealings. Submitters favouring binding determinations highlighted that the making of such determinations should be transparent, science-based and subject to review by the affected developers.

Some submitters also added that rather than making a binding determination on the regulatory status of techniques, it would be preferable that the Regulator was enabled to make determinations on whether an organism developed with a technique is or is not a GMO under the Scheme, since the Scheme does not regulate techniques but dealings with GMOs.

Submitters in favour of the Regulator issuing interpretative guidance thought that this mechanism offers flexibility to the different regulated organisations to interpret the guidance according to the type of activities or practices that they follow. In addition, these submitters also argued that interpretative guidance can be issued in a shorter timeframe and therefore would allow the Scheme to be more responsive to the development of new technologies.

OTHER SUGGESTIONS:

Some submitters provided additional suggestions in relation to the definition of gene technology:

A few submitters raised that subparagraph (b) of the definition which clarifies that homologous recombination is not gene technology may lead to uncertainty as to whether gene editing techniques are captured under regulation. This is because these techniques rely partly on homologous recombination mechanisms within cells.

A few submitters also raised that amendments to definitions should take into account the definitions used by other Australian regulators and international biosafety regulators for the sake of harmonisation.

Submitters from the field of agricultural biotechnology provided an alternative definition for gene technology, with the intent to exclude from regulation those organisms modified by gene editing techniques. In their opinion, such organisms do not represent a biosafety risk any different from organisms that already exist in nature and therefore should not be regulated.

Definition of Genetically Modified Organism

The definition of GMO is discussed in pages 13 and 14 of the Explanatory paper. The current definition of GMO captures organisms that have been modified by gene technology, have inherited traits due to the use of gene technology or have been declared to be a GMO in the regulations.

The limitation of the current definition is that it does not capture organisms that are created by gene technology. In the future, through advances in synthetic biology, it may become possible to create complex organisms without modifying a pre-existing organism, such that they would not come within the definition of GMO. Under Options B and C, it is proposed that a small change to the definition of GMO (to refer to an organism that has been 'created' by gene technology) could address this issue, in line with the approach to the definition of gene technology.

35 submitters provided comments on the proposed new definition of GMO. Out of these submissions, 24 supported the new definition and were in agreement that the amendment would address developments in the field of synthetic biology.

11 submitters did not agree with the amendment. These were the same submitters that were opposed to adding the word 'creation' to the definition of gene technology. They argued that there is already a possibility of addressing any uncertainty by declaring that specific synthetic organisms are GMOs through listing them in the regulations and that the word 'creation' is not an appropriate term to be used in this case.

The Explanatory paper also outlined that the Third Review recommended that the definition of a GMO be amended to clarify that humans are not considered to be GMOs (recommendation 6). However, no changes to the definition were proposed at this time because consideration is ongoing as to whether additional regulatory oversight is needed for humans who may receive or inherit germline therapies and which regulatory (or other) body would be most appropriate to undertake such oversight.

Only a few submitters mentioned this topic in their submission. In general, they agreed that therapeutic techniques that modify genes and genetic material in patients are going to become more common in the future and that therefore this issue should be addressed.

Definition of deal with

The definition of deal with is discussed in pages 15 to 17 of the Explanatory paper. The current definition comprises of a list of activities/GMO applications that are captured under regulation. However, the terms used in the definition are skewed towards activities that are relevant to agriculture and apply less so for medical uses. In addition, there is a risk that new dealings may arise in the future that will not be captured by the list of activities in the definition of deal with or be within the remit of other regulatory agencies. This would create a regulatory gap.

To address these issues, it is proposed that under Options B and C the definition of deal with would be amended to better reflect current activities with GMOs and to make sure that future applications are also captured under regulation. The Explanatory paper asked submitters to consider:

1. A proposed new definition that collapses the current definition into three high level terms that provide relevant coverage; being *make*, *use* and *supply*.
2. Whether any regulatory duplication between the Scheme and other product regulators should be addressed through the new risk tiering pathways or through a revised definition of deal with.

Proposed new definition

32 submitters provided comments on the proposed amendment to this definition; with 21 favouring the amendment and 11 providing additional feedback and suggestions to further improve it. No submitters opposed this proposed new definition.

According to submitters, the new definition of deal with removes potential ambiguities as to what types of activities are under the scope of regulation and ensures regulation can remain abreast with developments in the field of gene technology.

Two submitters raised the concern that the proposed definition of deal with could broaden the scope of the regulation under the Scheme substantially.

It was suggested that prior to making this amendment, consideration be given to any impacts to other regulatory agencies and legislations and to the OGTR. One of these submitters suggested that OGTR may be impacted in the sense that the agency's object and expertise is to assess risks posed to human health and safety and the environment and certain activities with GMOs may warrant assessment of other factors like quality and efficacy.

Addressing regulatory overlap between different agencies

Of the 5 submitters providing comments to this question, 4 supported that any overlap between the OGTR and other regulatory agencies should be addressed through the new risk-tiering pathways proposed under Options B and C to avoid the risk of inadvertently excluding dealings that should be assessed under the Scheme. Other regulatory agencies may not consider all risks to human health and safety and the environment, therefore removing OGTR's oversight completely by excluding activities from the definition of deal with may create a regulatory gap.

Only one submitter supported addressing overlaps through the definition of deal with but did not provide reasons supporting this argument.

AUTHORISATION PATHWAYS

Chapter 4 of the Explanatory paper outlined the different authorisation pathways to be distinguished under Options B and C. It contained questions for stakeholders aimed at gathering information on the possible risk indicators that could be used to categorise dealings in the proposed authorisation pathways.

Non-notifiable dealings

This category, as described in the Explanatory paper (pages 22 and 23), would encompass dealings with GMOs that meet specific eligibility criteria and do not need to be notified to the Regulator. Non-notifiable dealings would, however, remain within the scope of the Scheme and would have compliance requirements.

It is proposed that this authorisation pathway would include contained dealings currently classified as exempt dealings (Schedule 2 to the GT Regulations) and that the scope of the category could possibly be expanded (beyond the current exempt dealings category) to allow other GMO dealings that are very low risk.

31 submitters provided comments regarding the non-notifiable dealings pathway. The vast majority of submissions supported the availability of this authorisation pathway under the Scheme.

In contrast, three submissions advocated that no dealing should fall into this category and that all dealings should at a minimum be categorised as 'notifiable'. These stakeholders were from non-governmental organisations and an organic industry representative. They provided this view based on their perception that 'non-notifiable' signifies a lack of regulation and their belief that more checks and balances are required for any GMO dealings.

WHAT TYPE OF DEALINGS WOULD BE APPROPRIATE FOR THIS PATHWAY?

There was general support for this category to encompass dealings which are currently classified as 'exempt dealings'. Some submitters suggested that this pathway could also be appropriate for certain dealings that are currently classified as Notifiable Low Risk Dealings (NLRDs) or licensable dealings not involving intentional release (large scale fermentation dealings, dealings with GM mice undertaken in PC1 facilities, etc.).

Submitters were divided as to whether this pathway should be available for dealings involving intentional release of a GMO into the environment or clinical trials and medical applications. Some submitters believed that dealings involving intentional release into the environment should not be eligible for this pathway. Most of these submitters also thought that clinical trials and medical applications should also be excluded. Submitters believed that either these type of dealings warrant an assessment by the Regulator, or that they should be at least notifiable, so they are at least reported to the Regulator, which would maintain the level confidence that the public has on the Scheme.

A similar number of submitters supported that this pathway could apply to dealings involving intentional release of a GMO into the environment and clinical trials and medical applications if the GMOs pose negligible risk to human health and safety and the environment. Several examples were provided, including gene edited plants carrying modifications that could have happened in nature or arisen through conventional breeding methods or clinical trials with certain replication defective viral vectors.

RISK INDICATORS

Stakeholders suggested criteria which may serve as risk indicators and assist with determining the types of dealings that would fall into the non-notifiable dealings pathway. Most risk indicators provided by submitters aligned with those described in the Consultation RIS and Explanatory Paper.

Some of the suggested risk indicators were: the characteristics of the GMO (potential to cause harm, potential to spread into the environment, etc.), a long history of safe use and evidence of safety without adverse effects to the community or the environment, involvement of other regulators in regulating the dealing/product, etc.

Notifiable dealings

Notifiable dealings are discussed in pages 24 – 27 of the Explanatory paper. The authorisation process to undertake a notifiable dealing would be similar to that of the current Notifiable Low Risk Dealings (NLRDs), in that notifiable dealings would need to be reported to the Regulator annually. Notifiable dealings reported to the Regulator would be published on the OGTR website as part of the Record of GMO Dealings.

30 submitters expressed their views on the types of dealings that could be eligible for the 'notifiable dealings' pathway and the relevant risk indicators (principles) that could be considered in determining what a low risk dealing is for the purposes of categorisation as a notifiable dealing.

WHAT TYPE OF DEALINGS WOULD BE APPROPRIATE FOR THIS PATHWAY?

All submitters indicated that the current NLRDs should fall into the notifiable pathway.

Most submitters also agreed that dealings that have been assessed by another Australian regulator in a manner commensurate with the purposes of the Scheme could also be eligible for this authorisation pathway. However, some submitters were concerned about how the authoriser/ advisor model could work in practice.

They suggested that OGTR would need to exercise caution to ensure that appropriate advice is sought by the other regulatory agency and ensure the adequacy of other agencies' assessments where GMO dealings are involved.

Many submitters supported low risk clinical trials and dealings involving intentional release into the environment being eligible for this pathway. Some submitters specifically suggested that dealings with plants developed through cisgenesis or genome editing approaches (that mimic natural variants), or plants containing stacked traits where they are the result of conventional breeding of approved single traits, could be eligible for this pathway.

Only a few submitters suggested that dealings involving intentional release into the environment should not be categorised in the notifiable dealings pathway. For these submitters, all dealings involving intentional release into the environment warrant assessment by the Regulator.

One submitter argued that their recommendation was made based on the concern that if an IBC incorrectly categorised a dealing involving intentional release into the environment as a notifiable dealing, the detection of such mistake could take up to a year due to the annual reporting requirements.

RISK INDICATORS

In general, submitters agreed that the current risk indicators that are used to classify dealings in the current NLRD category would be applicable for this authorisation pathway. These include,

- History of safe use
- Understanding of the GMO and established risk mitigation strategies
- Pathogenicity, virulence or transmissibility of the GMO
- Potential to cause harm of the GMO
- Likelihood of having an effect on an ecosystem or subsequent beings/generations

Several respondents also suggested leveraging information, assessments and approvals of dealings and clinical trials made by other comparable international regulators (such as ACCESS, Project Orbis, and others).

Licensed dealings

Licensed dealings are discussed in pages 27–34 of the Explanatory paper. A licence would be required for GMO dealings for which the indicative risk is medium or high, or for which there may be substantial uncertainty as to risk level.

While all licensable dealings must be assessed by the Regulator before the dealing commences, the level of assessment and regulatory oversight applied to the dealing would be graduated on the basis of indicative risk (to enable further streamlining of lower risk applications). Under Options B and C, three different types of licences would be distinguished: permits, expedited assessments and full assessments. The Explanatory paper asked stakeholders what risk indicators could inform the split between a permit, an expedited assessment or a full assessment.

In general most submitters welcomed the introduction of three types of licences that would tailor regulatory processes to the level of risk of the dealings. Most submitters also agreed with the risk indicators already provided in the Explanatory paper.

Only a few additional points were raised by some submitters:

Risk indicators

- The use of previous relevant risk analyses to streamline assessment of GMO applications may lead to applicants being reluctant to be the first to submit an application for a type of GMO, as subsequent applicants may benefit from the data generated by the first applicant and be eligible for a lower risk category.

Permits

- Permits should be also available for dealings undertaken in certified facilities. Research models in current DNIRs are often well-known in the field or based on previous studies. Therefore, in their opinion, some dealings currently classified as DNIR could be eligible for a permit.
- For field trials of GM plants, permit and expedited pathways could be coupled with a certification process for GM field trial sites that meet defined licence conditions. This would provide certainty for organisations constructing new field trial sites, knowing that the site would be fit for purpose, and shorter licence application forms due to the site-specific aspects already having been addressed in the trial site certification.

Expedited assessments

- The term expedited might not be a suitable term for this pathway as this sets the level of expectation for stakeholders that timeframes would be significantly reduced and for the public it may suggest a less than sufficient risk assessment.

GMO Register

The GMO Register was discussed in page 24 of the Consultation RIS. The GMO Register developed as a way to authorise GMO dealings with a history of safe use after they had been licensed for several years with no adverse outcomes. Currently, the GMO Register is underutilised and only has two dealings listed.

Under both Option B and C it is proposed that a better usage of the GMO Register would ensure that the regulatory framework remains commensurate with the level of risk. To this aim, it was proposed to open eligibility for the GMO Register to more types of dealings and to allow the Regulator to include dealings in the GMO Register by written instrument rather than by legislative instrument.

Only 9 submitters contributed their views to the proposed changes to the GMO Register. Most submitters were supportive of a better usage of the GMO Register and a few agreed with the proposed amendments. However, some submitters thought that further work is required to determine the future role of the GMO Register and that this work should include consultation with regulated stakeholders. Only one submitter was against making the determination to include dealings in the GMO Register by administrative decision. The submitter was uncertain of the transparency of the consultations and the availability of review rights under this new arrangement.

ESSENTIAL ENABLERS – IMPROVING IT SYSTEMS

Chapter 5 of the Explanatory Paper describes how the Scheme could benefit from the efficiencies of updated technology to improve efficiency of assessments, record keeping and facilitate information sharing between regulated stakeholders, the OGTR and other regulatory agencies.

Regardless of which regulatory model is chosen going forward, it has been recognised that updating the current OGTR databases and systems in place is a pressing need. The current databases are manually operated, and upgrading would deliver significant benefits to regulated stakeholders and the OGTR.

Most stakeholders expressed general support for streamlining regulatory requirements, and utilising essential enablers to support the implementation of risk tiering and the reduction of administrative burden.

Out of the submissions received during the consultation, 14 respondents directly addressed the questions relating to essential enablers and improving IT systems, describing the key characteristics that would most enhance the current systems in place and provide benefit to the regulated community as well as providing savings in time and resources of the OGTR.

The key improvements that submitters recommended were:

1. The ability to obtain information on the status of applications with real-time tracking, notifications and reminders.
2. Automated data management to keep track of licence and facility certifications including providing information on organisations' certified facilities and features of those facilities.
3. Providing the ability to data share with interfacing regulatory agencies to streamline processes and reduce duplication as well as enabling data sharing between agencies where the OGTR is the advising agency rather than the decision-making agency.

In addition to these key desired aspects of the modernised IT system, stakeholders suggested that if authorisation pathways underwent changes, then tailored application forms or the incorporation of a decision tree could potentially assist with application processes. It was suggested that searchable similar approvals and leveraging useful practices from other countries would also be useful when considering specific improvements. Some submitters also recommended that the system's cyber security measures be enhanced to ensure the protection of commercially sensitive data and mitigate costly recovery efforts.

Overall, there was no opposition to improving the IT systems and there was consensus on the benefit to making improvements in this area. It was even suggested that updates to the IT systems may mitigate additional complexities arising from moving to an alternative regulatory model and assist with decision making.

DETAILS OF OTHER TECHNICAL CHANGES

Chapter 6 of the Explanatory paper described other technical changes to be implemented under Options B and C that would enable existing processes to be streamlined, the complexity of the legislation to be simplified and redundant legislation to be removed. A question in the Explanatory paper asked stakeholders to raise additional opportunities to streamline or improve the clarity of regulation.

Three submitters provided comments and suggestions in relation to the proposal in the Explanatory paper to update the current requirements for Confidential Commercial Information (CCI) applications to better align with contemporary provisions of other regulators.

These submitters expressed interest in removing administrative burden associated with applications for CCI declarations and described the challenges of currently transferring or revoking CCI. Submitters pointed out that solutions to these issues through this review process would be most welcome. Two submitters also recommended the adoption of data protection provisions similar to those available in the regulatory framework administered by the Australian Pesticides and Veterinary Medicines Authority.

One submitter suggested one opportunity for change in addition to the ones outlined in the Explanatory paper. The submitter raised concerns regarding the use of Section 54 of the GT Act. Section 54 provides anyone with the ability to request a copy of applications, except for any CCI. While the submitter recognised that regulatory transparency has an important role in supporting technology and product acceptance, they were concerned that Section 54 does not protect the data owner's rights. According to the submitter, the documents described in Section 54 can already be requested under the *Freedom of Information Act 1982 (Cth)* (FOI Act), therefore it is an unnecessary duplication in the GT Act.

GENERAL ISSUES RAISED BY SUBMITTERS

The vast majority of submissions received from regulated entities and IBCs expressed a strong desire for OGTR to be resourced to provide guidance material, new application forms and education/training following the making of any legislative amendments. They argued that this would reduce the implementation costs for regulated entities and would ensure a smooth transition to the new regulatory framework.
