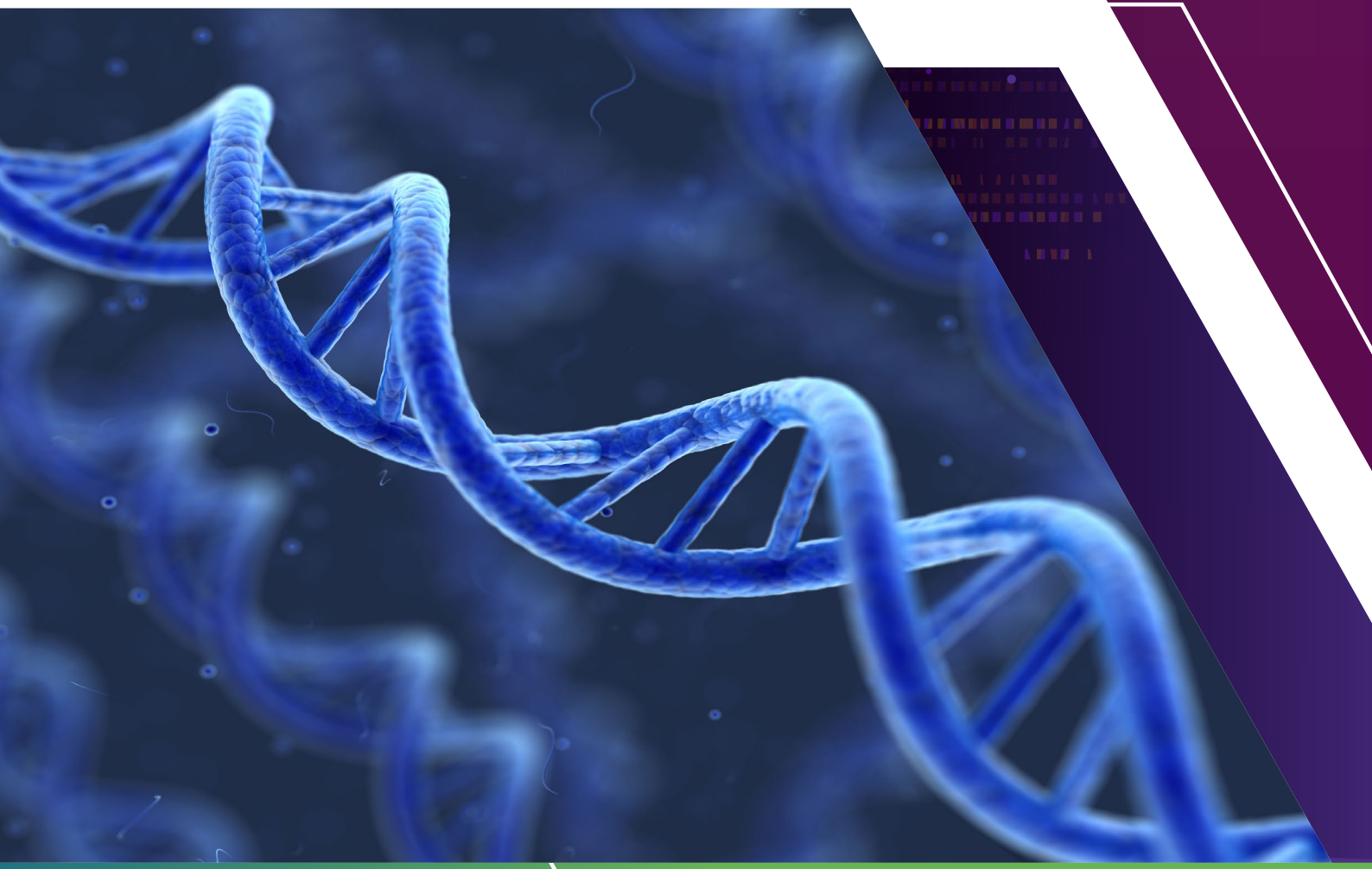
DECEMBER 2020

# CONSULTATION REGULATION IMPACT STATEMENT

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

## Modernising and future-proofing the National Gene Technology Scheme:

*Proposed regulatory framework to support implementation of the Third Review of the Scheme*



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



**Design** 2B Advertising and Design

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# 1. 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, known as the Legislative and Governance Forum on Gene Technology (the Forum).

In July 2017 the Forum 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 Forum and published in October 2018, outlined 27 recommendations, of which four were considered an initial priority. In July 2020, the Forum 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 will 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, nor it is intended to be, a means to make it easier to get approval for GMOs.

1 https://www1.health.gov.au/internet/main/publishing.nsf/Content/gene-technology-review

It is also not the intent to alter in any way the *Gene Technology (Recognition of Designated Areas) Principle 2003*, established under the National Gene Technology 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.

The purpose of this Consultation Regulation Impact Statement (Consultation RIS) is to:

a) describe options for implementing a proportionate regulatory model, as directed by the Forum, to give effect to key Review recommendations; and

b) seek stakeholder views on the impacts of each of the options.

The questions in this Consultation RIS aim to clarify whether the proposed options address the policy problems identified during the Review (and outlined in this document), and to collect information and data about the relative costs and benefits of each option.

The final decision on a preferred option to implement the Review recommendations will take into account the submissions received from stakeholders in response to this Consultation RIS. These submissions will be used to develop a Decision Regulation Impact Statement (Decision RIS). This document will identify the option with the greatest net benefit, based on an analysis of the identified costs and benefits. The Decision RIS will be provided to the Forum to assist their decision on whether the final recommended option in the RIS, or an alternative option, should be implemented.

A companion paper has been prepared (the Explanatory Paper), which provides further technical detail on what implementation of the options outlined in this Consultation RIS document may look like. The Explanatory Paper also forms part of the consultation package and contains questions for stakeholders that could help inform implementation of the preferred option, once endorsed by the Forum. The development of this Consultation RIS has been guided by the Council of Australian Governments' (COAG) document: *Best practice regulation: A guide for ministerial councils and national standard setting bodies*.

# 2. Summary of the options contained in this RIS

The primary objective of the reform of the Scheme is to focus regulatory effort on delivering more flexible, streamlined and risk-based processes that future-proof the Scheme, enable efficiencies, and relieve regulatory burden where warranted. The object of the *Gene Technology Act 2000*, which 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 manage those risks through regulating certain dealings with GMOs, will not change as part of this reform.

This Consultation RIS has been prepared to scope two options for implementing Review recommendations within a proportionate regulatory model (Options B and C). These options are compared to the base case, the status quo (Option A).

Options B and C share the following similarities:

- *Updated definitions* – both options present the same updated definitions that clarify whether new technological developments are within the scope of regulation and also introduce a new mechanism to provide certainty about the regulatory status of new technologies.
- *Streamlined authorisation pathways* – each option presents a new system of authorisation pathways that differs from the status quo in the incorporation of streamlined authorisation pathways for GMO dealings that are low risk, have a history of safe use, or are under the remit of other product regulators.
- *Introduction of delegated legislation*[2] – in the presented options the *Gene Technology Act 2000* (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.

  Delegated legislation can be made and amended more quickly than primary legislation and would allow the Scheme to respond rapidly to advances in gene technology and scientific knowledge.

2 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.

These options differ by:

- *New authorisation pathways* – in Option B, the risk tiering model, GMO dealings are classified into authorisation pathways according to the level of indicative risk. In contrast, Option C 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.

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

Options B and C, compared to the base case (Option A), are expected to improve the Scheme's ability to respond to emerging technologies and to introduce efficiencies in the processing of applications for GMO dealings, streamlining those applications that are low risk. Overall, both options aim to reduce the cost of regulation by focusing regulatory effort on GMO dealings that are high risk, without compromising the object of the GT Act; that is the protection of human health and safety and the environment.

# 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).

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 (GM) products[3] not subject to other existing regulatory schemes[4].

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)[5], the *Gene Technology Regulations 2001* (Cth) (the GT Regulations)[6], and corresponding state and territory legislation. These Commonwealth and state laws provide national coverage for the regulation of GMOs, allowing the Regulator to administer legislation with state or territory jurisdictions.

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[7], where higher risk activities involving GMOs are subject to greater regulatory oversight.

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

4 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).

5 *Gene Technology Act 2000* (Cth) (Austl.). Retrieved July 10, 2018, from the Federal Register of Legislation.

6 *Gene Technology Regulations 2001* (Cth). Retrieved July 18, 2018 from the Federal Register of Legislation.

7 Office of the Gene Technology Regulator. (2013). Risk Analysis Framework. Retrieved July 10, 2018, from the Office of the Gene Technology Regulator.

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 Legislative and Governance Forum on Gene Technology (the Forum), to govern the operation of the Scheme and the activities of the GT Regulator. The Forum is comprised of Ministers with responsibility for gene technology from every state and territory and the Commonwealth.

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

- *Recommendations 4 and 6* – Update existing definitions in the GT Act to clarify the scope of regulation in light of on-going technological advances.
- *Recommendation 9* – Introduce a new risk tiering framework that ensures regulation remains commensurate with the level of risk and 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 Forum 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 Forum 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.

This Consultation RIS has been prepared to scope two options for implementing Review recommendations within a proportionate regulatory model (Options B and C). These options are compared to the base case, the status quo (Option A).

# 4. What is the policy problem?

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[8] found that 1,852 organisations constituted the Australian biotechnology sector as of 2019, 55% of which are industry-based. The organisations employ approximately 243,406 people. The Australian life sciences industry is dominated by the 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.

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.

8 Australia's Life Sciences Sector Snapshot 2019 conducted by AusBiotech.

The policy problems identified in this section have the potential to unnecessarily slow down the progression of a product on the path to market, which is detrimental to the industry and its international competitiveness.

Three key policy problems that require government action drove the development of the policy options presented in this Consultation 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 what GMO activities are under 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. 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.

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. The trust that regulated stakeholders and the community already have for the regulatory system could be strengthened even further if the Scheme could provide certainty on regulatory scope in a timely manner.

## *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 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 type 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 overregulation 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 that are unsure about the required processes and timing to resolve their application; and
  b) the GT Regulator, who is forced to make a decision on the classification of the application that may result in the application being unnecessarily assessed as a high-risk category, leading to longer timeframes for reaching a decision.

To illustrate this issue, the percentage of licences granted for medical and other uses grew from 21% in 2015–16 (total number of granted licences were 14) to 79% in 2019–20 (total number of granted licences were 24). This appears to demonstrate a growing trend in the number of applications received for GMO dealings with medical and other uses. This trend 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[9]. 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.

## *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. However, 20 years of experience in regulating trials and commercial releases of GM crops and GM therapeutics, supports the creation of new streamlined authorisation pathways for dealings that are low risk and where effective management conditions are known. This would reduce the cost of regulation and enhance the competitiveness of the Australian biotechnology industry, without compromising the object of the GT Act.

Additionally, the current authorisation pathways do not allow the processing of certain applications to be streamlined when other regulators also regulate the same dealings. Regulatory duplication results in increased costs and regulatory effort that is not justified by the level of risk. This is detrimental to competition.

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.

> ***Note:*** A more detailed discussion of the current problems with the system is available in the impact analysis of Option A.

9 https://www.australianclinicaltrials.gov.au/why-conduct-clinical-trial-australia

# 5. Objectives of government action

Consistent with the findings of the Review and keeping in the mind the need to balance reducing regulatory burden while maintaining the object of the GT Act, 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 higher risk dealings. Address the duplicative regulation of GMOs as between the GT Regulator and other product regulators.
4. Continue to support local oversight of risk management conditions, noting the important role of Institutional Biosafety Committees (IBCs).
5. 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 clarity about the application of the Scheme to certain GMOs and dealings. This could in turn reduce business costs for regulated entities and potential entrants to the Scheme, including small-scale bodies 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 do not compromise the protection of human health and safety and the environment.
6. 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.
7. Where possible, align regulation with comparable international regulatory schemes and enable the better utilisation of international assessment information.

This Consultation RIS describes three options:

- **Option A: Status quo** – no changes to the current scope or activities of the Gene Technology Regulator
- **Option B: Risk-tiering model** – dealings with GMOs would be categorised according to their indicative risk
- **Option C: Matrix model** – the nature of the dealing with the GMO would be the determinative factor for categorisation

Options B and C propose amendments to achieve the objectives of the reform. Option A is the base case, and is used to highlight the impacts of keeping the current regulatory system.

# 6. Options

## 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, notifiable low risk dealing (NLRD) or 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).

## *Analysis*

As this option maintains the status quo, it is not expected that there would be any change (increase or decrease) in the risk to the health and safety of people or the environment. However, maintaining the status quo will not enable the recommendations of the Review to be implemented and existing problems would remain.

- The key problem with the existing approach is that 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.

- Continuing to distinguish dealings with GMOs by reference to the broad categorisation of whether a dealing involves intentional release of GMOs into the environment, restricts the GT Regulator from applying proportionate regulation. 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 a more nuanced consideration of risk (which is influenced not just by type of activity, but also by the history of use, the type of organism, the nature of the genetic modification, etc.).
  - In particular, the requirement for DIRs to be authorised by a licence restricts the extent to which risk proportionate regulation can be applied, as there is limited scope to treat DIRs differently. 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. Additionally, whether the clinical trial involves the release of a GMO into the environment is not always the key determinant of the level of risk of the trial. Other factors are generally more relevant, such as the parent organism, the introduced genetic modification and the setting in which the clinical trial would take place. This is in contrast to GM plant dealings, which were one of the main type of dealings at the inception of the Scheme, and where release of the GM plant into the environment is a key factor determining the level of risk.

**CASE STUDY: CLINICAL TRIALS**

For example, clinical trials involving the administration of a GMO to a human require a licence issued by the GT Regulator[10]. 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 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 days, or 170 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 and can result in overregulation of clinical trials that are very low risk (even if participants shed the GMO), and under-regulation of potentially higher risk clinical trials.

  - The GT Regulator also receives applications to urgently treat very ill patients with GMOs. Under the *Therapeutic Goods Act 1989*, the use of these unapproved therapeutic goods by an authorised health practitioner only requires notification to the TGA under the Special Access Scheme. 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, which could delay availability of an urgently needed treatment.

10 With the exception of somatic cell gene therapy that is excluded by definition from the gene technology scheme.

### 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.

The risks posed by use of a GMO therapeutic by one patient in one hospital differ from widespread use. However, the legislation requires the GT Regulator to follow the same licence assessment process.

- There is no opportunity to create a simplified or 'streamlined' regulatory pathway for dealings that may fall into a lower risk category (including those organisms that have a history of safe use, and where highly characterised organisms have been used).
  - 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), because there is no capacity for a more expedited approval based on known history and standardised risk management conditions.
- There is currently no capacity for the GT Regulator to consider the impact of any duplicative regulation of a dealing in determining how best to authorise a dealing. Dealings that fall into the remits of various regulators may be subject to duplicative regulatory oversight and applicants for those dealings may be subject to increased 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).

### HYPOTHETICAL CASE STUDY: PET VACCINES

For example, a company wants to introduce a GMO vaccine to protect pet dogs against a new viral disease. Currently, the commercial release of a GMO vaccine requires both a licence from the OGTR and registration by the APVMA. Current APVMA guidance requires 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 days. 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.

- The current authorisation pathways are not sufficiently flexible to respond to new information about the risk posed by a dealing. 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 requirements that are no longer evidence-based (for example, by moving the dealing into the exempt dealing category). Conversely, if new scientific information supports the position that a dealing poses a higher risk than previously thought, then the current Scheme does not enable the prompt classification of the dealing into a higher risk category. 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 definition of a GMO includes 'an organism that has been modified by gene technology', with 'gene technology' then being further defined. In addition to the broad definitions that identify the characteristics of a GMO and gene technology, 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.

Failure to realign categorisation to risk, and to enable sufficient flexibility for the regulatory system to respond to future scientific advancements, would result in a framework that continues to remain slow in its response to emerging technologies and less efficient than it should be (with regulatory effort not adequately aligned to risk).

The main problems with the existing Scheme, as identified in Part 4, would continue to exist.

## *Impact*

The above issues impact stakeholder groups differently. For the impact analysis in this Consultation RIS, four stakeholder groups are distinguished: regulated entities, Institutional Biosafety Committees (IBCs), government and the community.

The scale of the gene technology regulatory scheme is modest in comparison to other Australian regulatory regimes. 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 NLRDs and hold approximately 55% of the licences issued by the GT Regulator. Companies hold 21% of licences. Over 95% of authorisations for dealings with GMOs over the duration of the Scheme have been for NLRDs, a category imposing minimal regulatory burden.

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 and assess whether the proposed GMO dealings qualify for a NLRD. 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 any proposed facilities or personnel are suitable for the dealings.

Option A is expected to have the following impacts on stakeholder groups:

- **Regulated entities** – This group would continue to experience additional cost where there is duplication of effort between regulators, where applications must be made for DIR licences, or where the reclassification of GMO dealings to lower risk categories is delayed. This may impact on research progress and investment and could slow industry development and reduce international competitiveness.

  The group is likely to experience uncertainty about the authorisation category that corresponds to certain applications, and therefore would need to query the GT Regulator to determine appropriate authorisation pathways. This could delay the assessment of applications and increase the cost of regulation as more time and work would be needed in order to obtain an authorisation.

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

- **IBCs** – This group would experience continued lack of certainty when considering applications for new technologies/organisms that do not readily fit within existing definitions, which could in turn impact their ability to fulfil their functions under the Scheme.

- **Government** – The lack of ability to regulate based on broad consideration of risk has potential to undermine confidence in the GT Regulator and the Scheme. This would continue to result in increased cost to government where regulatory effort is required under the existing Scheme but is not necessary.

  Regulatory classifications that are not up to date can impose over-regulation (increasing the cost of regulation for government), or under-regulation (potentially leading to unmanaged risks to human health and safety and the environment).

  Continuing uncertainty regarding regulatory scope and the regulatory requirements for activities with certain GMOs could undermine the ability of the GT Regulator to enforce compliance, as well as impact the ability of organisations or individuals to comply with legal requirements.

- **Community** –The community is indirectly impacted, potentially to the extent that costs are unnecessarily high or there are delays in bringing applications of gene technology to the market because of regulatory delays (e.g. for vaccines).

  While there is no apparent diminution in protection under Option A, failure to promptly reclassify a dealing into a higher risk category, in response to new information about risk, could lead to under-regulation and reduce the level of protection of the community.

  The availability of GMO treatments for very sick people under TGA's Special Access Scheme would continue to be delayed due to the requirements in the GT Act.

***Key consultation questions – Option A***

- Are there additional impacts of Option A that need to be taken into account?
- Please provide further information, including quantitative data, on the costs associated with maintaining the status quo.
- To what extent would maintaining the status quo stifle innovation?
- What are the benefits of maintaining the status quo?

# 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, which have been proven to work well and are supported by regulated stakeholders and the community. Only specific areas of the Scheme would be amended in order to implement key recommendations of the Review.

#### 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.

However, the process to make a listing on the GMO Register would be streamlined so this authorisation pathway can be better utilised (see below).

Changes would also be made to the following authorisation types to enable dealings to be distinguished on the basis of indicative risk (i.e. enabling a graduated and proportionate risk response):

- 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 instead be classified into three overarching authorisation pathways, according to their indicative risk. That is, 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.

Option B essentially streamlines authorisations under the Scheme with limited disruption to the existing structure of the authorisations that stakeholders are familiar with. In addition, 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”).

As illustrated below, 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).

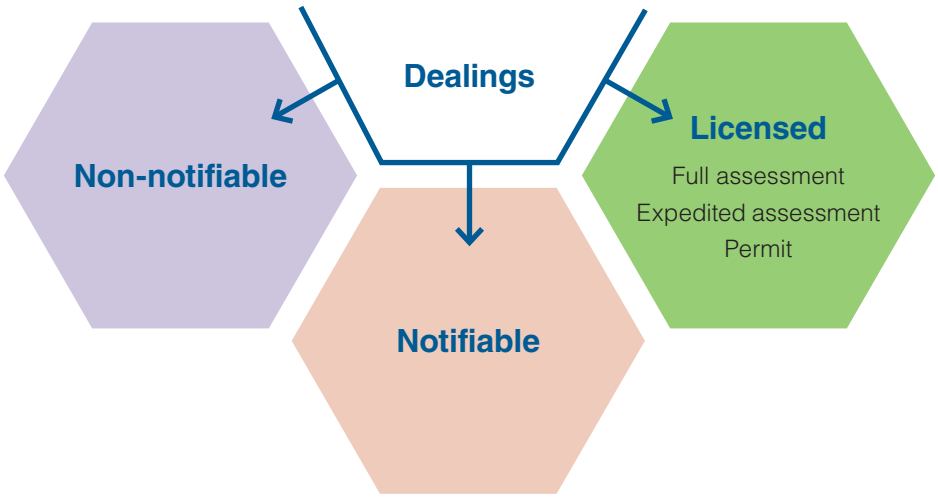



***Figure 1:*** *New authorisation pathways to achieve risk tiering under Option B.*

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.

#### CASE STUDY: LABORATORY DEALINGS AND FIELD TRIALS WITH KNOWN RISK MANAGEMENT CONDITIONS

Under Option B, 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. For example, 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.

- 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.

#### HYPOTHETICAL CASE STUDY: PET VACCINES

Drawing on the hypothetical case study above in relation to the introduction of a GMO vaccine to protect pet dogs against a new viral disease, under Option B the OGTR could provide advice to the APVMA during their assessment timeframe, leaving the APVMA as the authorising authority. Registration by the APVMA could qualify a GMO veterinary vaccine as a Notifiable Dealing, which reduces the overall assessment timeframe while maintaining OGTR's awareness of the GMO and technology used.

- 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.

**CASE STUDY: FIELD TRIALS WHERE CONSTRUCT OR GMO HAS BEEN PREVIOUSLY ASSESSED**

For example, if a field trial of a GM plant has been authorised in the past under a full assessment licence, or is a new transformation event of a construct previously assessed for a field trial licence, Option B would mean that a new field trial of the GM plant could be eligible for an expedited licence assessment.

This could also apply to GMOs obtained by crossing two previously authorised GMOs. A field trial of a plant obtained by crossing GMO X and GMO Y could be eligible for a lower risk category under Option B if field trials of GMO X and GMO Y have been previously authorised under a full assessment licence.

- 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 if the Forum agrees to either Option B or C, following public consultation.

The following table further details the intended operation of the new authorisation pathways.

| Authorisation pathway | INTENDED OPERATION OF THE AUTHORISATION PATHWAY |
|---|---|
| **Non-notifiable dealing** | *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.*<br>• This authorisation pathway would include contained dealings currently classified as exempt dealings (Schedule 2 to the GT Regulations).<br>• 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** | *Dealings with GMOs eligible for self-assessment and notification.*<br>• This authorisation pathway would include contained dealings currently classified as NLRDs in Parts 1 and 2 of Schedule 3 to the GT Regulations.<br>• The scope of this category could be expanded to allow:<br>– GMO dealings where other regulators assess risks to people and the environment (e.g. veterinary vaccines authorised by APVMA) |
| **Licensed dealing** | *Dealings with GMOs that require a licence, where the level of assessment and regulation is graduated.* |
| | 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:<br>• Dealings for which the risks are known and can be managed through standardised conditions (e.g. certain clinical trials and field trials).<br>• Dealings that the GT Regulator has experience authorising and that meet certain criteria regarding use, traits, understanding of parent organism, etc. |
| | An **expedited assessment** would be required for dealings with a medium-high indicative risk that require a case-by-case risk analysis and tailored licence conditions. 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.<br>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).<br>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. |
| | A **full assessment** would be required for dealings with a high risk or uncertain 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. |

> ***Note:*** Further detail about the authorisation pathways to reflect Option B is set out in the Explanatory Paper.

The following sections in the Consultation RIS propose amendments to the GMO Register and the definitions in the GT Act that apply to both Option B and Option C.

## 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
- 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.

### Definitions

In addition to risk tiering, changes are also proposed to some key definitions in the GT Act. These changes will support the implementation of recommendation 4 made by the Third Review.

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 will be maintained under Options B and C. However, maintaining the mode of action requires the updating of the definitions, which are 20 years old.

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.

> ***Note:*** Further details on the proposed changes are discussed in the Explanatory Paper.

## *Analysis*

Option B better aligns regulation with the indicative risk posed by the dealing, removing unnecessary regulatory burden from the Scheme, while continuing to protect people and the environment. By introducing risk-tiers, regulatory effort and resources would be better targeted to the oversight of higher or unknown risks.

Under this model:

- the appropriate categorisation of a dealing would be distinguished on the basis of indicative risk, which 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
- consultation would inform the categorisation of different types of GMO dealings and there would be transparency regarding such categorisation

- the Forum 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 Forum. This would ensure the Scheme remains responsive to new scientific evidence (and knowledge gained through history of use) and that the regulation remains commensurate with the level of risk
- the Forum 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. This policy principle was established under the National Gene Technology Scheme and Agreement 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.

Because this model streamlines existing authorisations that are already well understood by stakeholders, the proposed shifts in categorisation should not be challenging for stakeholders. Risk tiering on the basis of risk indicators that will be legislated and known to stakeholders, to enable effective categorisation, also protects IBCs and researchers from difficult judgements as to whether a GMO is being dealt with in the right way.

## *Impact*

This option impacts stakeholder groups differently:

- **Regulated entities** – The regulatory costs of NLRDs would remain unchanged. However, regulated entities would experience reduced cost and timeframes associated with seeking a licence for which the applicable pathway is a permit or an expedited assessment (i.e. for lower risk dealings or known dealings with GMOs). Entities would also be afforded greater regulatory certainty. This would ensure that the pathway to commercialisation is faster, increasing the competitiveness of the sector.
- **IBCs** – IBCs would largely operate in the same capacity as currently. IBCs would continue to be responsible for providing an interface between organisations and the OGTR, undertaking assessments of the people and facilities proposed to be involved in notifiable dealings, and advising on the identification and management of the risks within an organisation's internal operations in relation to notifiable dealings.

  IBCs would 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 any proposed facilities or personnel are suitable for the dealings.

  However, under Option B, authorisation pathways would no longer require a judgement as to whether the dealing involves the release of a GMO into the environment, nor whether such release is intentional (noting that this judgement can be challenging, particularly in relation to emerging uses and the medical field). This would make the consideration of licence applications easier for IBCs.

- **Government** – The improved ability to regulate based on a broader consideration of risk should increase confidence in both the GT Regulator and the Scheme. While there would be increased costs in the short term (as the result of improvements to IT systems and guidance materials to support the new categorisation of dealings), in the longer term the costs borne by government (relating to administration of the Scheme) would be reduced on an application by application basis, as the result of more efficient and proportionate regulation (where regulatory effort is better matched to risk).
- **Community** – The advantage for community is the continued protection of health and the environment, and an increased confidence that the regulatory treatment of a GMO dealing is based on consideration of a wider range of relevant factors (not just whether a GMO is being intentionally released). This model would continue to provide transparency regarding dealings in each category. Additionally, the benefits of gene technology would be made available to the community in shorter timeframes.

***Key consultation questions – Option B***

- Would Option B address the identified policy problems?
- Please outline any additional impacts of Option B that have not been identified in the current impact analysis.
- Please provide further information, including quantitative data, on any costs and benefits to your organisation associated with Option B.
- Please outline any risks or additional considerations that need to be taken into account with regard to this option.
- How might Option B promote science innovation?

***Note:*** the Explanatory Paper contains additional questions about Option 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. Several of the proposed amendments under Option B would also apply under Option C:

- the amendments to the definitions of 'GMO', 'gene technology' and 'deal with';
- the streamlining of the process of making a listing on the GMO Register; and
- the GT Regulator would specify the eligibility criteria for the authorisation categories, based on the application of principles and criteria agreed by the Forum.

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, with the listing process streamlined as in Option B
- 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 three 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.

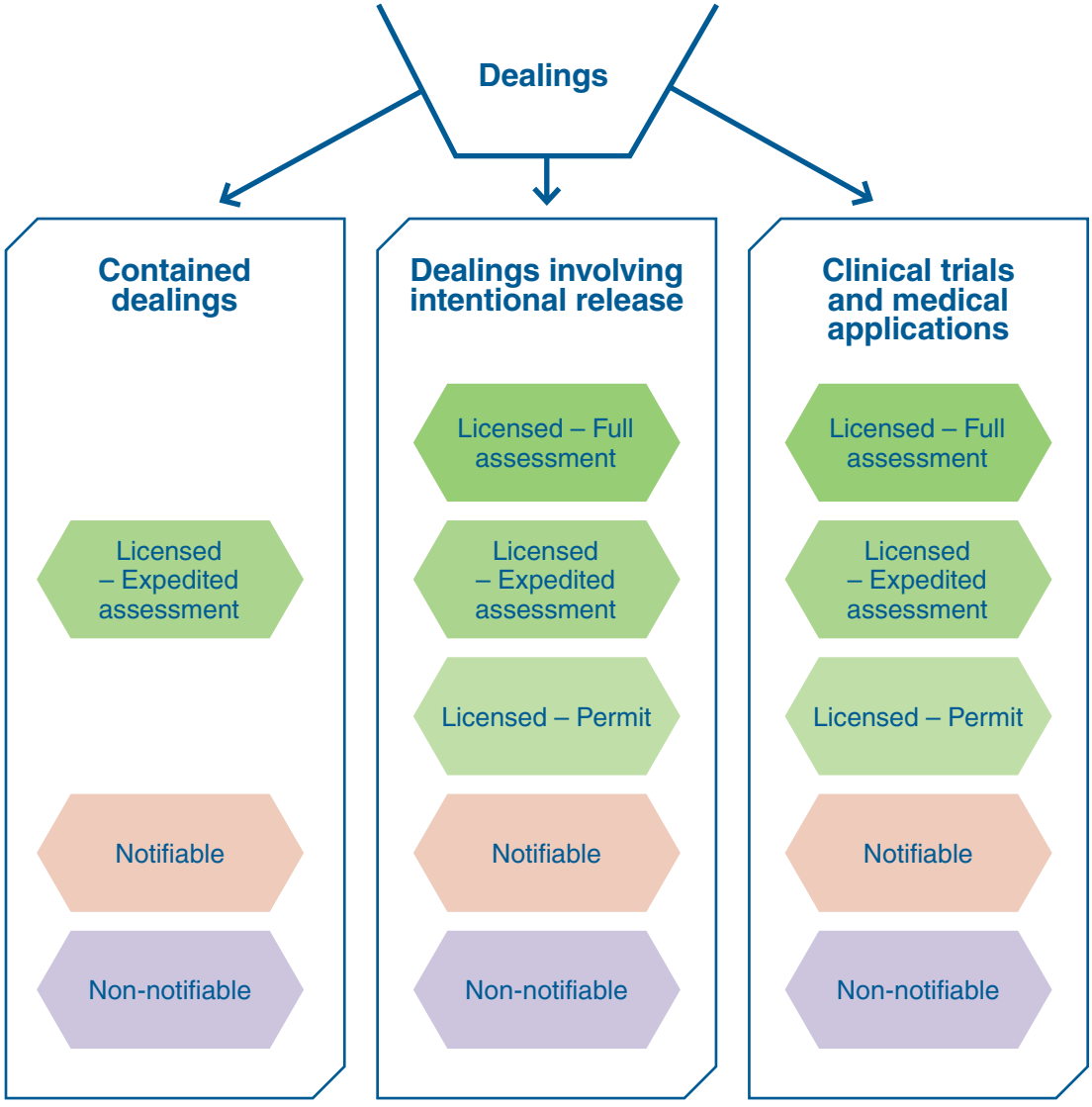



***Figure 2:*** *New authorisation pathways to achieve a risk matrix under Option C.*

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 organisms between the authorisation pathways as new scientific or regulatory evidence becomes available.

Changes to definitions in the GT Act described for the purposes of Option B would also be made under Option C.

## *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.

Under this model:

- 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. 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).

- There would also 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.

### 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, and also 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.

- Concepts that are familiar to stakeholders are maintained (e.g. dealings involving intentional release). However, the concern (as identified through the Review) is that these concepts are dating and do not account for risk, nor enable a system of modern regulation whereby the law can stay abreast of scientific developments and advances in regulatory understanding of gene technology.
- A more complex matrix of authorisation pathways is required in order to ensure regulation is appropriately aligned to risk. This is because once the dealing has been categorised as contained, involving intentional release of a GMO into the environment or clinical trials, further categorisation would be required in order to determine the most appropriate authorisation pathway (based on broader risk considerations). As a result of the increased number of authorisation pathways, new category delineation issues would arise for Option C.
- Compared to the status quo, regulated stakeholders involved in medical research would benefit under Option C, as there would be a dedicated authorisation category for clinical trials. The same immediate benefits would be available through Option B. However, Option B and Option C differ in their flexibility to respond to future developments. Should new GMO dealings arise that do not comfortably fit in the three overarching categories of Option C (i.e. contained dealings, dealings involving release, clinical trials and medical applications), time-consuming legislative amendments would be required to change the system of authorisation pathways. By contrast, the risk-based criteria determining categorisation in Option B provides more flexibility.

## *Impact*

The above issues impact stakeholder groups differently:

- **Regulated entities** – 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. It also provides the same clinical trial authorisation pathways as Option B.

  Compared to Option A, there would be decreased cost and timeframes for organisations seeking to undertake lower risk dealings (because of the availability of the permit and expedited assessment pathways). However, the costs for regulated entities are expected to be greater than for Option B, because the system would be more complex, and GMO dealings would continue to be categorised based on dated concepts that do not reflect the level of risk posed by the dealing. Regulated entities may have to invest additional time and make enquiries to the GT Regulator to determine which authorisation pathway applies to their application.

- **IBCs** – Under Option C, IBCs would continue to operate in the same capacity as currently. IBCs would continue to be responsible for providing an interface between organisations and the OGTR, undertaking assessments of the people and facilities proposed to be involved in notifiable dealings, and advising on the identification and management of the risks within an organisation's internal operations in relation to notifiable dealings.

  IBCs would 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 any proposed facilities or personnel are suitable for the dealings.

  As for Option A, 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 (noting challenges associated with this and as described in the case studies above).

- **Government** – While there would be increased costs in the short term (as the result of improvements to IT systems and guidance materials to support the new categorisation of dealings), in the longer term the costs borne by government (relating to administration of the Scheme) will be reduced relative to Option A, but would be greater than Option B (because of the need to maintain more categories of dealings and more authorisation pathways based on such categorisation).

- **Community** – As for Options A and B, there would be continued protection of health and the environment. The main difference for consumers is that Option C may be more complex for people to navigate without that complexity correlating to an enhanced ability for the GT Regulator manage risk.

***Key consultation questions – Option C***

- Does Option C address the policy problems identified in the Consultation RIS?
- Please outline any additional impacts of Option C that have not been identified in the current impact analysis.
- Please provide further information, including quantitative data, on the costs and benefits to your organisation associated with Option C.
- Please outline any risks or additional considerations that need to be taken into account with regard to this option.
- Does Option C promote science innovation? If so, how?

***Note:*** the Explanatory Paper contains additional questions about Option C.

# 7. 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 machinery, and are consistent with the Commonwealth principles for clearer laws. The changes proposed 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.

# 8. **Conclusion**

The aim of this Consultation RIS is to present three reform options (one of them being maintaining the status quo) to address key recommendations arising from the Review, and to gain information from regulated stakeholders, government and the public about the impacts of each reform option. Information gathered through this Consultation RIS will enable a deeper analysis of the impacts of each option, which is required to identify and recommend a preferred option in the final Decision RIS. Factors that will be taken into account when analysing the impacts include:

- how each option will address the policy problems outlined in Section 4;
- the net benefit of each option (i.e. how its benefits compare to its costs);
- how innovative opportunities will be activated or incentivised under each of the options;
- any risks associated with the options and how these risks could be mitigated;
- whether the changes might be open to unintended non-compliant behaviour, or may create any undesired incentives/disincentives; and
- whether options could present any issues/incentives for the states and territories and the national consistency of the Scheme.

***Key consultation questions***

- In your opinion, what Option offers the greatest net benefit? Please provide reasons supporting your choice.

***Note:*** a table comparing Options A, B and C in relation to whether the options address the policy problems identified in this Consultation RIS (section 4) and accomplish the objectives of government action (section 5) is available in an attachment to this document (Attachment B).

# 9. Consultation and next steps

All Australian governments understand the importance of thorough consultation to inform the Review and the implementation of the Review recommendations.

## *Consultation to date*

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[11].
  - 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.

11 Department of Health (2017) *Review of the National Gene Technology Regulatory Scheme – Background Paper.*

- 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.
- 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[12]. 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 have been conducted so far to inform the implementation of Review recommendations:

- Phase 1: public consultation on an issues paper[13] to inform operational considerations and implementation of Review recommendations (Sept-Nov 2019); and
- Phase 2: consultation with the Forum on possible options for the implementation of key Review recommendations through a revised regulatory framework.

12 Department of Health (2018) *Review of the National Gene Technology Regulatory Scheme – Preliminary report.*

13 Department of Health (2019) *Implementing Recommendations of the Third Review of the National Gene Technology Scheme – Phase 1.*

## *Current consultation*

This Consultation RIS is part of the process to support the implementation of the Review recommendations. It seeks stakeholder views on the possible impacts of the presented options for regulated entities, IBCs, government and the community. Further consultation on the technical implications relating the implementation of Options B and C is being undertaken in parallel with this Consultation RIS.

The information received from stakeholders during this consultation will be used to develop a Decision Regulation Impact Statement (Decision RIS). This document will identify the option with the greatest net benefit, based on an analysis of the identified costs and benefits. The Decision RIS will be provided to the Forum to assist them to decide whether the recommended option in the RIS, or an alternative option, should be implemented. Stakeholders' input on the anticipated costs and benefits of each of the options is an important part of providing Forum ministers with an accurate and comprehensive Decision RIS to guide their decision.

This consultation is open from 14 December 2020 to 17 March 2021. Following analysis of submissions received, it is anticipated that a Decision RIS will then be prepared and presented to the Forum for endorsement in mid-2021. Further work would then follow to implement the preferred option, which would include undertaking further public consultations and drafting legislative amendments in 2021–2022.

## *How can I be involved?*

The Forum invites you to help the policy development process by providing a submission. Questions raised in this paper and in companion Explanatory Paper, will guide you in providing your input.

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

No responses will be provided to individual submissions. However, you may be contacted for further information or clarification of issues as necessary.

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

## *Lodging your submission*

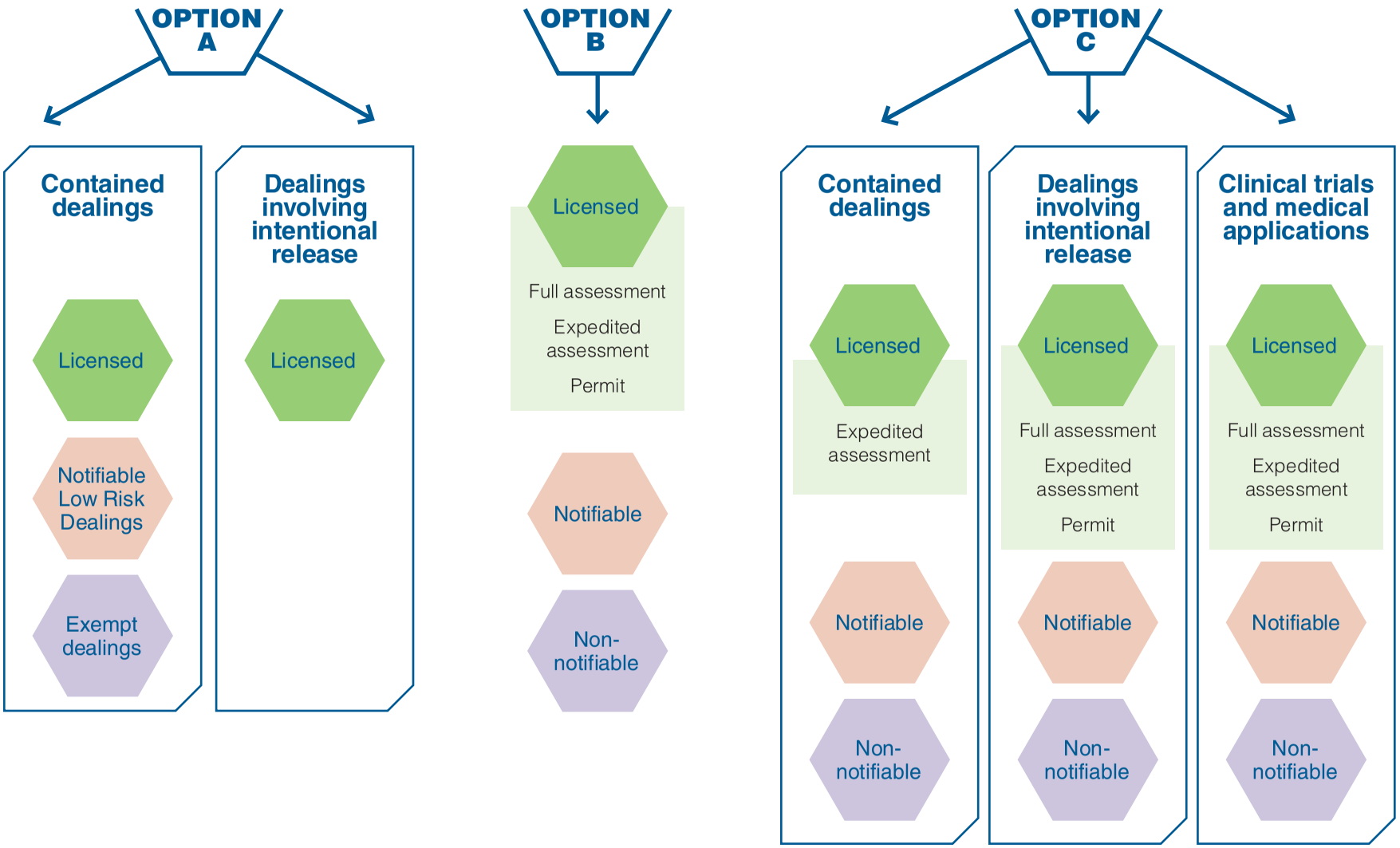
Submission should be lodged via the Citizen Space website. Submissions over 10,000 words are required to have an Executive Summary covering all key points in the submission.

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

# Appendix A
# **Glossary of terms**

| Term | Definition |
|---|---|
| APVMA | Australian Pesticides and Veterinary Medicines Authority |
| COAG | Council of Australian Governments – the peak intergovernmental forum in Australia. |
| 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 | *Gene Technology Act 2000* |
| GT Regulations | *Gene Technology Regulations 2001* |
| IBC | Institutional Biosafety Committee – IBCs provide on-site scrutiny of NLRD proposals through independent 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 | *Third Review of the National Gene Technology Scheme* |
| TGA | Therapeutic Goods Administration |

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



***Attachment B*** *– Table summarising whether the presented options in this Consultation RIS address the policy problems and achieve the objectives of government action.*

| | **Policy problem –** The Scheme responds slowly to advances in the field of gene technology (Review recommendation 4) | **Policy problem –** Authorisation pathways in the GT Act are no longer suitable for new GMO applications (Review recommendation 9) | **Policy problem –** The Scheme is no longer risk proportionate (Review recommendations 9 and 10) | **Objectives of government action achieved** |
|---|---|---|---|---|
| **Option A (status quo)** | **Not addressed** | **Not addressed** | **Not addressed** | **Objective 1 achieved** – protection of safety of humans and the environment |
| **Option B (Risk tiering model)** | **Fully addressed** – Both Options B and C introduce the same amendments to the definitions in the GT Act | **Fully addressed** – the new authorisation pathways classify GMO dealings based on their indicative risk | **Fully addressed** – both Options B and C introduce streamlined authorisation pathways for dealings that are low risk and/or regulated by other product regulators<br><br>Both Options allow for the prompt reclassification of a GMO dealing into a new authorisation category in response to new information about risk | **All objectives achieved** |
| **Option C (Matrix model)** | | **Partially addressed** – the introduction of a new overarching category for clinical trials and medical applications improves the categorisation of GMO dealings for medical purposes. However keeping the overarching categories of contained dealings and dealings involving the intentional release of a GMO into the environment makes the classification of certain GMOs dealings ambiguous | | **All objectives achieved with the exception of objective 5** as the regulatory framework would not be simplified by would increase in complexity |