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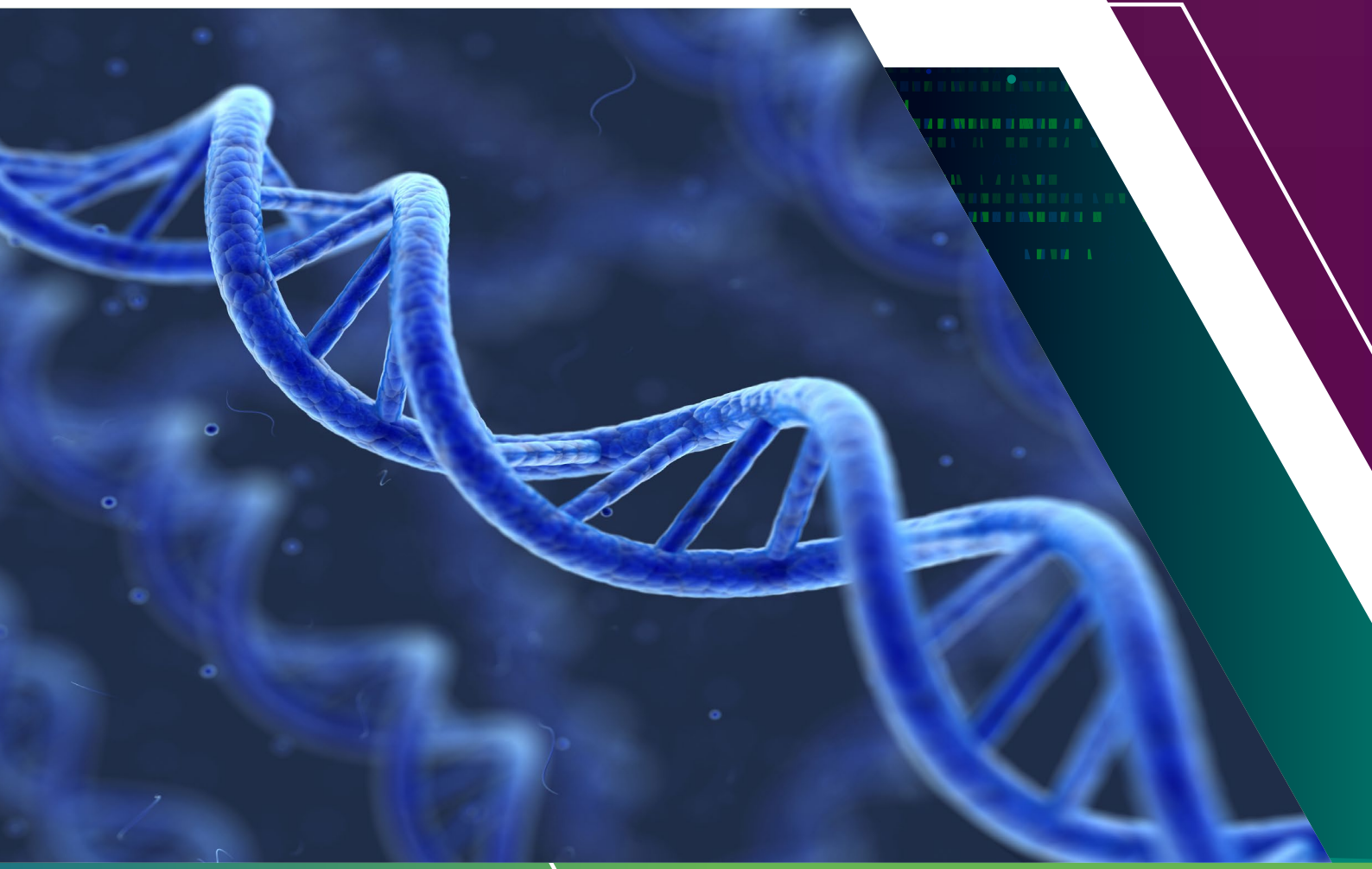
EXPLANATORY PAPER

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*

Explanatory paper

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Chapter 1
Background and context

Background and context

Following extensive consultation, *the Third Review of the National Gene Technology Scheme* (Third Review) made 27 recommendations relating to gene technology.

Overarching recommendations included maintaining the objects of the *Gene Technology Act 2000* (the GT Act) and also maintaining the Gene Technology Agreement, which describes the relationship between States, Territories and the Commonwealth with respect to the policy and regulatory oversight of gene technology in Australia.

The Third Review did, however, identify the need to update and enhance the operations of the Gene Technology Scheme (the Scheme) to ensure that it is fit-for-purpose into the future and is responsive to rapid changes in technology. Recommendations related to a wide range of technical, regulatory, governance and social issues, with four priority recommendations identified.

- 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 flexibility to move genetically modified organisms (GMOs) between authorisation pathways 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.

To guide the implementation of these priority recommendations, the Gene Technology Standing Committee (GTSC) released an Issues Paper in September 2019 describing high level approaches for:

- enabling greater regulatory flexibility and capturing emerging technologies (including through changes to key definitions in the legislation)
- ensuring risk proportionate regulation by enhancing risk tiering and regulatory approaches
- streamlining regulatory requirements and processes to reduce regulatory burden (including to better harmonise across regulators).

Following review of stakeholder submissions to the Issues Paper, the Forum agreed to implement the priority recommendations by adopting a proportionate regulatory model. Key features of the option agreed by the Forum include:

- reducing the level of prescription in some areas of the primary legislation (the GT Act) and including higher level rules and principles with a greater focus on outcomes
- enabling some technical issues to be dealt with in delegated legislation; continuing to ensure oversight by the Forum and the Parliament while providing a more flexible mechanism for making timely amendments to respond to changes in technology and changes in risk understanding (within the framework of the GT Act)
- enabling certain technical and procedural matters to be delegated to the Gene Technology Regulator (the Regulator) (within the parameters set by the GT Act and the *Gene Technology Regulations 2001* (the GT Regulations)).

Better utilising the different types of legislation (e.g. primary and secondary) for different purposes enables the regulatory scheme to be more responsive, more proportionate, more risk-based and better accommodates technological advances into the future. Strong protections for both people and the environment are maintained through the strong governance arrangements and the many accountabilities embedded in the Scheme. These protections would continue to be upheld through the Regulator's monitoring and compliance powers.

Purpose of this Explanatory Paper

Against this backdrop, the purpose of this Explanatory Paper is to describe the operational implementation detail necessary to give effect to both the priority recommendations of the Third Review and the Forum's preferred implementation approach described above. Specifically, this Paper details the options described in the accompanying Consultation Regulation Impact Statement (RIS) *Modernising and future-proofing of the National Gene Technology Scheme* that are a change from the status quo (Options B and C).

This paper describes:

- key definitions proposed to be amended to ensure the appropriate level of prescription in the primary legislation, while also enabling greater flexibility and responsiveness through the use of delegated legislation
- how risk tiering could be introduced into the Scheme to facilitate flexibility, ensure the level of regulation remains proportionate to risk, and protect against both under regulation and overregulation
- the essential enablers proposed to support the implementation of risk tiering and to reduce administrative burden on stakeholders
- other technical changes proposed to the legislation to support the reform processes and enable the streamlining of legislative and administrative processes
- the key similarities and the key differences between Options B and C.

Stakeholder comments are invited on the proposals outlined in this paper and will inform the Forum's consideration of the implementation details.

Regulation Impact Statement

Stakeholders are also invited to comment on the accompanying RIS (refer separate document).

As described in the RIS, the primary objective of 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 role of the Regulator, 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 by managing those risks through regulating certain dealings with GMOs, will not change as part of this reform.

The RIS sets out how the status quo (Option A) compares to two options for implementing the priority recommendations of the Third Review (within the scope of the approach agreed by the Forum), including an analysis of the likely impacts and benefits of the options. Two of the options outlined in the RIS (Option B and Option C) are further detailed in this paper.

Chapter 2
Key similarities and differences between Options B and C

Overview of key similarities and differences between Options B and C

As described in the RIS and further detailed in this paper, Options B and C share the following similarities:

- ***Updated definitions*** – both options present the same proposed changes to definitions in the legislation that clarify whether new technological developments are within the scope of regulation. The proposed changes also ensure that the legislation is flexible enough to enable the Scheme to respond rapidly to advances in gene technology and scientific knowledge through the delegated legislation, which while still subject to Parliamentary oversight, can be made and amended more quickly than primary legislation.
- ***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.
- ***Essential enablers*** – Office of the Gene Technology Regulator (OGTR) IT system upgrades to deliver an automatic data management system and integrated portal and an improved user interface for stakeholders is proposed under both options.
- ***Technical changes*** – both options would include the details outlined in Chapter 6 of this paper, which propose largely minor and machinery changes to enable existing processes to be streamlined, the complexity of the legislation to be simplified, redundant legislation to be removed and regulatory and administrative burden to be reduced.

The key differences in the options are in respect of the new authorisation pathways:

- Option B presents a risk tiering model, in which 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.

Overview of risk tiering approach under Option B

As described in the RIS, Option B proposes a risk tiering model in which dealings with GMOs would be classified into three categories according to their indicative risk. Under this model, the following existing authorisation pathways in the GT Act would be retained:

- a listing on the GMO Register (note that changes proposed to the GMO Register to enable more efficient operation are detailed in the RIS)
- specification on an Emergency Dealing Determination
- an inadvertent dealing licence.

However, changes would 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 categories, according to their indicative risk. That is, the potential maximum level of risk of the dealing, taking into account matters such as the characteristics of the GMO, the type of dealings, the specific gene technology applied to create the GMO, dealings assessed by other regulators (including international assessments) and whether effective risk management measures are known.

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

The new authorisation pathways under this model would be:

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

These proposed authorisation pathways are discussed further in Chapter 4 (following discussion of key definitions that support the new approach to risk tiering).

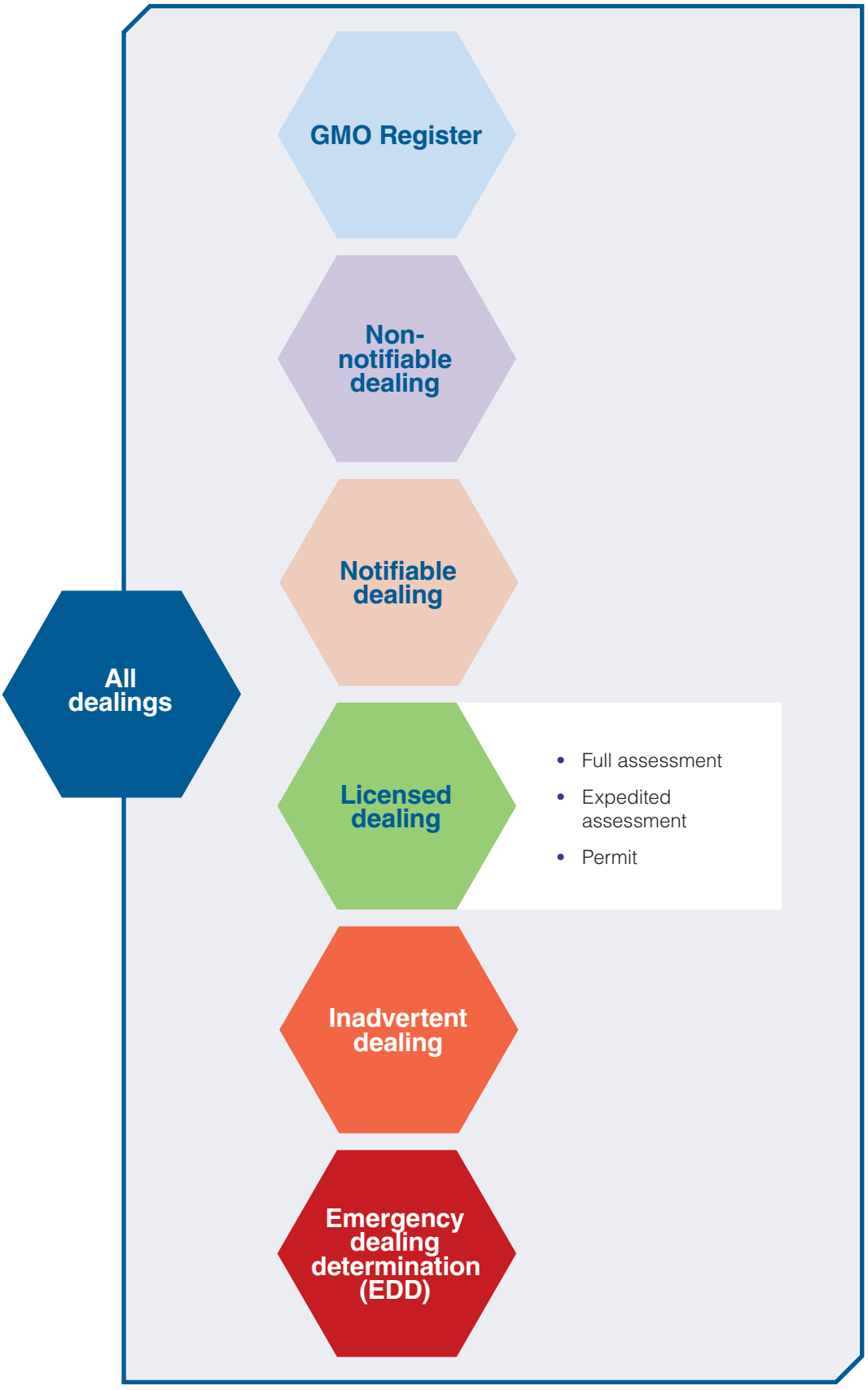


Figure 1: *Whole of scheme authorisation pathways under Option B.*

Overview of risk matrix approach under Option C

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

- a listing on the GMO Register (with the listing process streamlined as described under Option B)
- specification on an Emergency Dealing Determination
- an inadvertent dealing licence.

As for Option B, it is proposed that changes would be made to the following authorisation types:

- an exempt dealing as described in the 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

The key difference under Option C is that 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 under Option B). 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.

Having categorised the dealing into one of these three categories, risk indicators would then be overlayed (creating a risk matrix) to determine the relevant authorisation pathway for that dealing. Consistent with Option B, the 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).

As indicated in Figure 2 below, not all authorisation pathways would be relevant to all dealing types.

Option C therefore presents a matrix whereby the primary consideration for categorisation is the nature of the dealing (i.e. 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). 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.

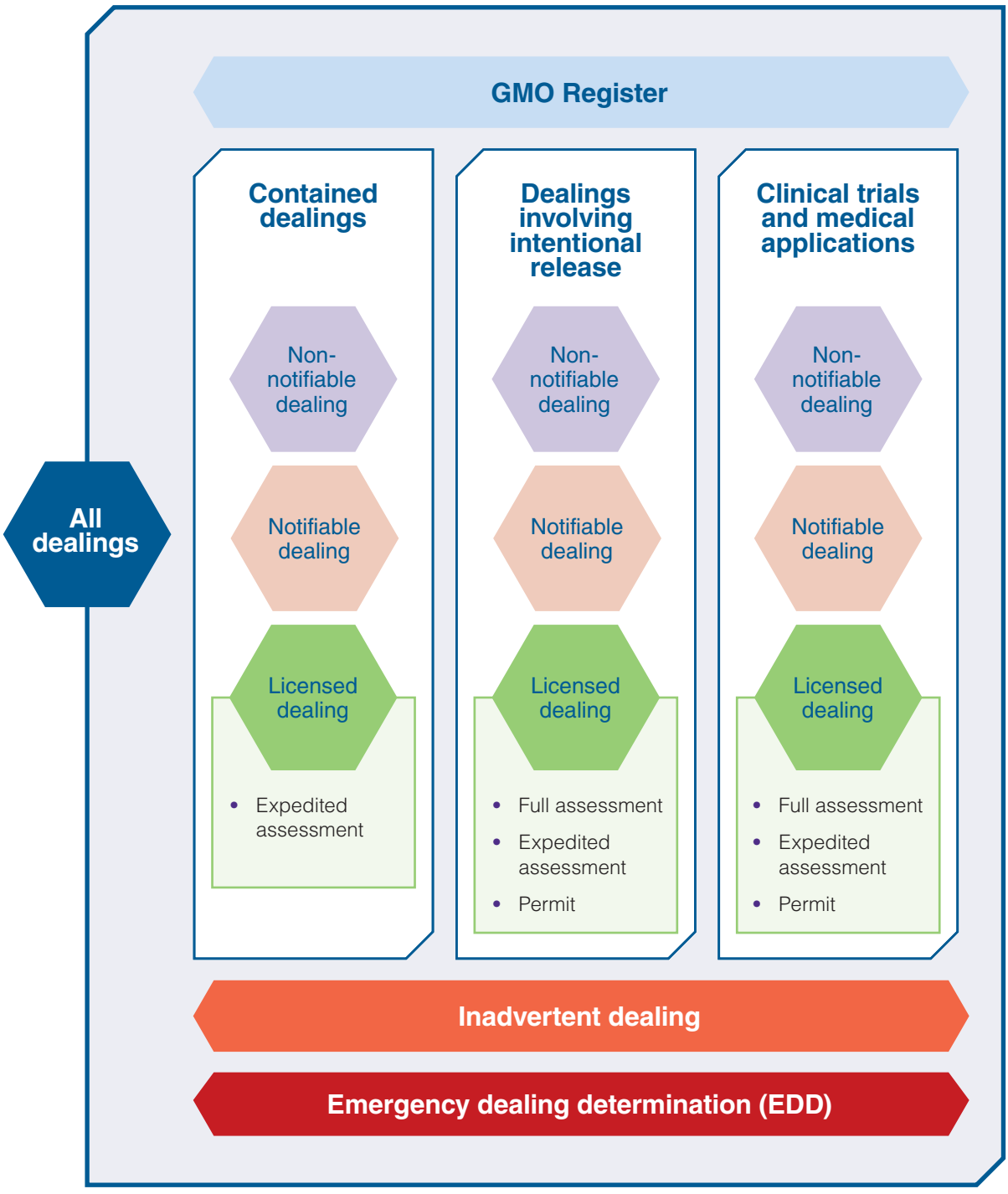


Figure 2: *Whole of scheme authorisation pathways under Option C.*

Important note

Feedback on this paper will inform the development of legislation to support the reform. Specific detail on matters relating to the implementation of the preferred model will be the subject of further consultation.

Chapter 3
Definitions

Overview of definitions

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

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.

Proposed changes to definitions would retain the strong framework of the GT Act, while also enabling:

- the primary legislation to properly reflect the current environment
- sufficient flexibility to respond to future advances in science, and
- the Regulator's understanding of risk indicators (principles) to be reflected in the legislation through amendments to the GT Regulations (which retains appropriate Forum and Parliamentary oversight).

Definition of gene technology

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

a) sexual reproduction; or

b) homologous recombination; or

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

There are three key issues with the current definition of *gene technology*:

- The definition of *gene technology* focuses on the modification of genes or genetic material but not the creation of genes or other genetic material. With advances in science, it is now possible to create genes or genetic material in addition to modifying them. Under the current definition it is not certain that such creation would be captured despite being consistent with the intent of the scheme (to manage risk associated with such novel gene technology). It is therefore proposed that the definition be amended to capture not just the modification of genes or other genetic material, but also their creation (other than through processes such as sexual reproduction, homologous recombination, etc.).

CASE STUDY

Until recently, organisms were 'modified' by physically changing the nucleotide sequence of their genome through the introduction of new DNA fragments and/or the modification of their genes. There are now machines that can chemically synthesise (make) any DNA or RNA fragment from a sequence specified in a document file. These DNA or RNA fragments can be joined together to make genomes. This process can be used to create a new organism.

The new organism may be designed to mimic a naturally occurring organism or may be modified. For example, polioviruses have been created by chemically synthesising copies of their genome and then incubating the genomes in cell extracts. The enzymes and metabolites in the cell extract use the information contained in the genome to make new infectious viruses.

It is unclear whether these viruses, which may mimic the naturally occurring viruses or be modified, are effectively captured under 'organism modified by a technique for the modification of genes or other genetic material'.

- There is a lack of clarity regarding what the current definition *gene technology* captures, and it is not always clear what 'modification of genes and other genetic material' means. As a result, there is an increasing set of techniques where it is not always clear whether the technique falls within or outside the definition of gene technology, despite the technology resulting in changes to the traits of the resulting organism.

CASE STUDY

Cells naturally regulate the expression of genes by adding or removing chemical marks on the nucleotide sequence of genes or on proteins that are associated to DNA and are responsible for its packaging. These marks are called epigenetic marks. Molecular biologists are able to change the epigenetic marks on specific genes or in whole genomes to modulate gene expression.

A construct can be introduced into plants to change the epigenetic marks on the DNA. These initial plants would be GM, but the construct could be removed in successive generations, giving rise to plants that do not contain the construct anymore but retain the epigenetic marks. It has been proposed that this can be used for breeding because sorghum, tomato and soybean plants with these modified epigenetic marks have been shown to be tolerant to stress.

With the current definition of gene technology, it is unclear whether the plants containing novel epigenetic marks are captured under regulation because there is uncertainty about whether or not 'modification of genes' includes modifications to epigenetic marks on genes.

- 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 (as flagged by the Review and agreed by the Forum).

The above issues could be collectively addressed by amending the definition of *gene technology*. The following is an indication of how the definition could be changed and is included by way of an example only:

gene technology *means any technique:*

a) for the ***creation*** *or modification of genes or other genetic material; or*

b) ***specified in the regulations*** *for the purpose of this paragraph*

but does not include:

c) sexual reproduction; or

d) homologous recombination; or

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

The inclusion of any technique in the regulations would continue to require consultation, the agreement of the Forum and Parliamentary oversight. This process would ensure regulatory creep is avoided. Consideration could also be given to mechanisms by which the Regulator could 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.

Key consultation questions – definition of gene technology

- Does the proposed definition of *gene technology* address the issues identified?
- Does the proposed definition of *gene technology* introduce any new issues?
- Are there any other desirable changes to the definition of gene technology that would address the issues identified in the Third Review and the objectives agreed by the Forum (e.g. to increase flexibility, future-proof the legislation, etc.)?
- Would interpretative guidance on the definition of *gene technology* issued by the Regulator be adequate, or should the Regulator have the capacity to make binding determinations that something is or is not a technique for the modification of genes or genetic material?

Definition of genetically modified organism

genetically modified organism *means:*

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

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

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

but does not include:

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

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

The limitation of the above definition is that it does not capture organisms that are created by gene technology (see, for example, the earlier case study of polioviruses). 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 *genetically modified organism* (or the Scheme, refer recommendation 5a of the Third Review).

CASE STUDY

In the future completely novel genomes may be introduced into empty cell chassis to create organisms that do not exist in nature. In this case, organisms would not be modified but instead created. This is the ultimate aim of synthetic biology and may represent where this new field might fall outside the regulatory scope of the GT Act.

The potential risks to human health and safety and the environment posed by these created organisms are not different to that of current GMOs, therefore it is recommended to follow a precautionary approach and capture them under regulation.

In addition, the Third Review recommended (refer recommendation 6a) that the definition of a *GMO* be amended to clarify that humans are not considered to be GMOs. Consideration as to whether additional regulatory oversight is needed for humans who may receive or inherit germline therapies (or other somatic therapies not within the remit of the Scheme), and which regulatory (or other) body would be most appropriate to undertake such oversight, is ongoing. Therefore, no changes to the definition to address recommendation 6a are proposed at this time.

It is therefore 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* as described above, as follows:

genetically modified organism *means:*

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

Key consultation questions – definition of GMO

- Does the proposed definition of *GMO* address the issues identified?
- Does the proposed definition of *GMO* introduce any new issues?
- Are there any other desirable changes to the definition of GMO which would address the issues identified in the Third Review and the objectives agreed by the Forum (e.g. to increase flexibility, future-proof the legislation etc.) noting that the Review also recommended that a process-based trigger be maintained as the entry point for the Scheme at the present, to allow for any potential risks associated with new technologies to be initially considered within the scope of the Scheme (refer recommendation 8)?

Definition of deal with

***deal with**, in relation to a GMO, means the following:*

a) conduct experiments with the GMO;

b) make, develop, produce or manufacture the GMO;

c) breed the GMO;

d) propagate the GMO;

e) use the GMO in the course of manufacture of a thing that is not the GMO;

f) grow, raise or culture the GMO;

g) import the GMO;

h) transport the GMO;

i) dispose of the GMO;

and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).

There are two key issues with the definition of *deal with*:

- Terms used in the definition are skewed towards activities that are relevant to agriculture, such that the definition is less relevant for dealings with, for example, vaccines, therapeutic goods, animals and microbes. A key criticism of the current definition is that it does not sufficiently describe activities that apply to all GMOs.
- Terms within the definition do not align with the concepts used by like regulators. Notably, the current definition does not expressly draw the *use* of a GMO within the scope of the Scheme unless the use occurs for the purpose of, or in the course of, a dealing. This, in part, recognises the role of existing regulatory schemes in regulating the use of the GMO or GM product, for example as a therapeutic, food or veterinary product, and the role of the Scheme as a 'gap filler'. However, without alignment in relation to the types of conduct caught, this can present interface issues with the other regulatory schemes and a potential for conduct to not be addressed by any of the schemes. Similarly, while a positive feature of the Scheme is that it facilitates the regulatory schemes working together to address the regulation of GMOs throughout their lifecycle (from research and development to the final product); there can be some duplication where regulators are dealing with the same matters.

CASE STUDY

There is no Australian product regulator responsible for oversight of fertilizers and other soil amendments, such as nitrogen fixing bacteria. GM nitrogen fixing bacteria are being developed in the USA to provide an environmentally sustainable source of nitrogen for cereal crops. If a company were to import the GM bacteria for sale to farmers in Australia, the only regulator to consider the product would be the OGTR.

Similarly, there is no Australian product regulator who would consider the release of a GMO for bioremediation purposes, so the OGTR would be the only regulator for products such as a bacterium modified to break down toxins in a water supply.

Currently the Regulator would only be able to regulate the import, transport and disposal of the GM nitrogen fixing bacteria product and the GM bacteria bioremediation product. Changes to the definition of 'deal with' are needed to allow the Regulator to appropriately regulate a broader range of activities with these, and similar, GMOs where the OGTR 'gap filler' role comes into play by including GMO dealings expected to be considered by a product regulator.

To avoid the need for further terms being added to the definition over time (with increasing specificity), consideration is being given to collapsing the current definition into three high level terms that provide relevant coverage; being *make, use* and *supply*. Consolidating the paragraphs into three concepts, with a non-exhaustive list of the types of activity or conduct that would fall into each, would promote a principles-based and future-proofed approach to GMO dealings. The following provides a conceptual example of how the definition could be consolidated.

***deal with**, in relation to a GMO, means the following:*

a) make the GMO, including to develop the GMO, produce the GMO, breed the GMO, propagate the GMO, manufacture the GMO and grow, raise or culture the GMO

b) supply the GMO, including to import the GMO, store the GMO and transport of the GMO

c) use the GMO, including to conduct experiments with the GMO, use the GMO in the course of manufacture of a thing that is not the GMO, release the GMO into the environment and dispose of the GMO

and includes possession of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (c).

Alternatively, a legislative note could be inserted under the definition with examples of the types of activities and conduct intended to be caught. While the examples would not be legislatively binding, it would support a principles-based approach to regulation (which is underpinning the Scheme reforms).

In order to address possible duplication of regulatory effort, consideration was also given to amending the definition of *deal with* to expressly exclude those activities authorised by another regulator.

While the same concepts may be applied (e.g. 'use'), the risk associated with this approach is that another regulator may not take the same considerations into account in making a decision, such that the authorisation may not reflect the consideration of matters relevant to the Regulator.

On balance, the preferred approach is therefore to enable consideration of the role and decisions of other regulators through the risk tiered approach described in Chapter 4. Where another regulator considers risks to human health and the environment posed by a GMO dealing, a lower risk tier could apply provided the activities had been authorised by the other regulator. The Regulator would also provide advice to inform the decision-making of other regulators. No change would be made to the oversight of the use of non-viable GM products.

Subject to responses to the consultation questions below, these approaches would be further examined and developed. The legal implications would be closely considered, for example, the relationship between the definition of *deal with* and the offence provisions of the GT Act.

Key consultation questions – definition of deal with

- Does consolidating the definition of *deal with* into the concepts of make, supply and use address the issues identified?
- Does consolidating the definition of *deal with* introduce any new issues?
- Is it preferable to consider the role of other regulators through the consideration of risk in the new pathways described in Chapter 4, or should the intersection be addressed through a revised definition of deal with?

Note that stakeholder feedback on the proposed changes to the definitions may lead to changes in the approach to resolving the issues described above or changes to related aspects of the legislation.

Chapter 4
Authorisation pathways

Overview of authorisation pathways

As described in Chapter 2, it is proposed that under either Option B or C changes could be made to four existing 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.

Replacing these four authorisation pathways with the three pathways illustrated below, as proposed under Option B, enables dealings to be distinguished on the basis of indicative risk (i.e. enabling a graduated and proportionate risk response).

OPTION B

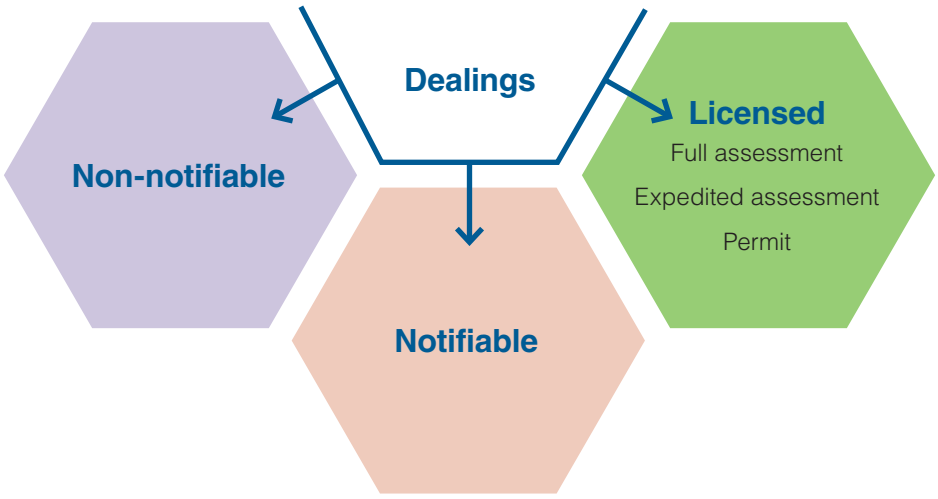


Figure 3: *New authorisation pathways to achieve risk tiering under Option B.*

Under Option B, eligibility criteria for each 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. Risk criteria would assign GMO dealings with a higher level of indicative risk to authorisation pathways that require case-by-case risk analysis.

This approach would enable the regulation to better align with the indicative risk posed by the dealing, thereby 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 GMO dealings that may pose higher risk, or for which there may be substantial uncertainty in the risk analysis. In addition, the 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 Regulator must consider prior to changing the eligibility criteria and who must be consulted. These matters are detailed below.

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 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
  - For example, the gene technology applied to create the GMO would be a relevant consideration. 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 pathways.
- consultation would inform the criteria by which different types of GMO dealings are categorised and there would be transparency regarding such categorisation
- the Forum would continue to set the parameters of the Scheme, but the 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 ensures 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.

Under Option C, categorisation of the dealing would be required in the first instance before risk indicators could be applied in respect of each category (thereby creating a risk matrix model).

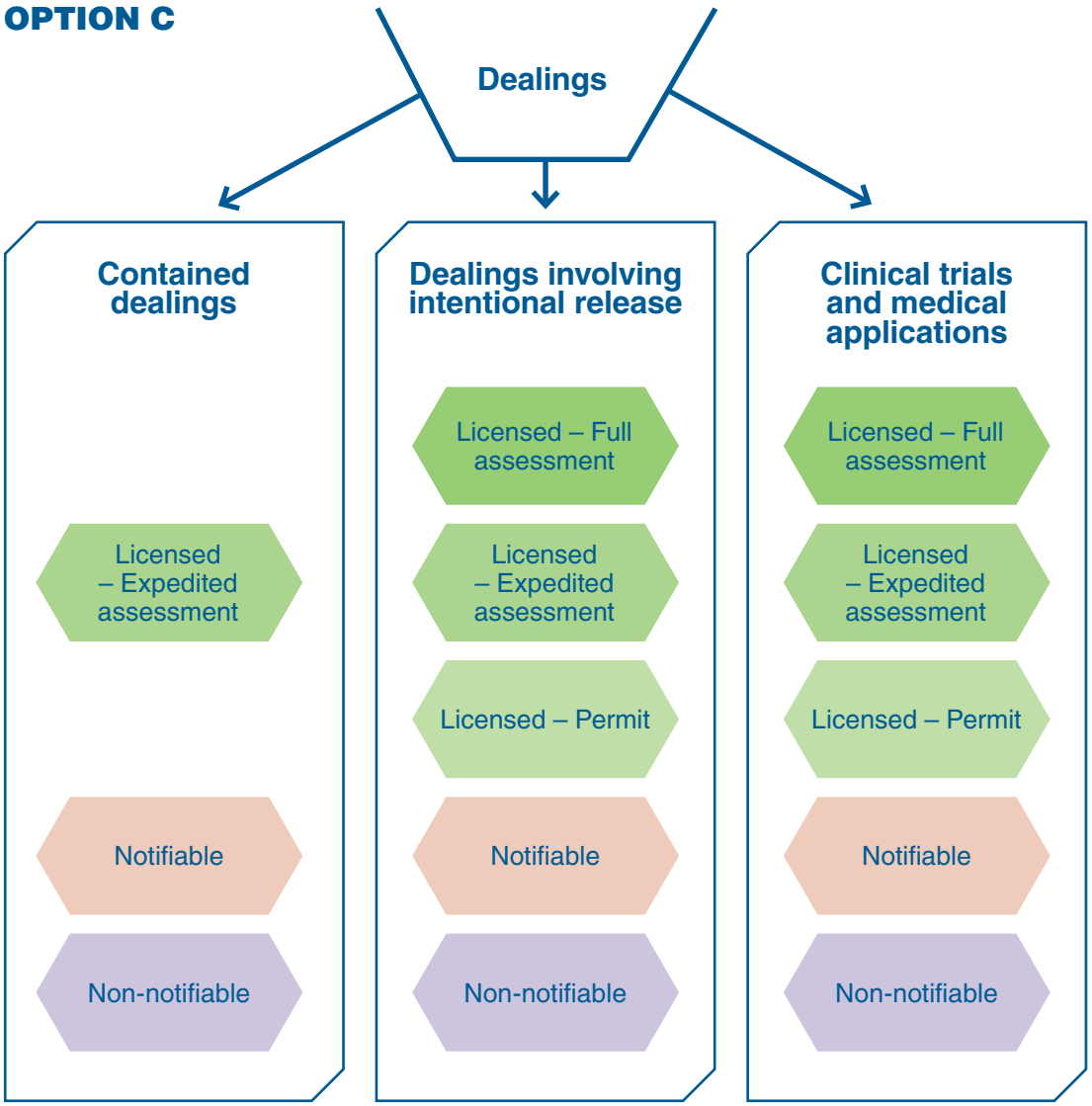


Figure 4: *New authorisation pathways to achieve risk matrix under Option C.*

Drawing on the risk tiering model described for Option B, the proposed key characteristics of each of the new authorisation pathways are illustrated in Figure 5 below.

The relevant GMO dealings and regulatory processes for each of these authorisation pathways is further detailed in Chapter 4. While the discussion in Chapter 4 is centred around the risk tiering model described under Option B, key considerations for how a risk matrix model under Option C would be differentially designed and applied is also identified.

	Non-notifiable dealings	Notifiable dealings	Licensed dealings
Indicative risk	• Very low	• Low	• Medium/High or uncertain
Requirements before commencement of activities	• Authorised automatically	• Pre-commencement notification • Self-assessment and assessment by IBC	• Pre-commencement assessment by OGTR
Regulatory outcome	• Activity permitted	• Activity permitted in accordance with risk management conditions	• Activity permitted if risks can be managed • Risk management measures imposed by OGTR
Requirements after commencement of activities	• None	• Annual reporting to the OGTR	• Reporting to the OGTR
Safeguards	• Only dealings that have been assessed as posing very low risk are included in this category	• Compliance audits and targeted post-commencement assessments • Information exchange with regulated stakeholders • Mandatory information gathering powers • Offences for non-compliance	• Compliance audits and targeted post-commencement assessments • Information exchange with regulated stakeholders • Mandatory information gathering powers • Offences for non-compliance
	Compliance activity by other regulators, where relevant		

Figure 5: *Schematic representation of the key characteristics of each new authorisation pathway for the purposes of the risk tiering models under Option B and Option C.*

Non-notifiable dealings

Relevant GMO dealings (very low risk dealings)

Under Option B and Option C, dealings currently classified as exempt dealings (specified in Schedule 2 to the GT Regulations) would come under the new 'non-notifiable dealings' pathway. This is currently dealings that do not involve an intentional release of a GMO into the environment nor involve a genetic modification other than a modification that has been described as exempt by the GT Regulations. For example, contained research into very well understood organisms using well established processes for creating and studying GMOs.

It is proposed that:

- the primary legislation (the GT Act) would describe the considerations required for categorisation of a dealing with a GMO as non-notifiable
- the Regulator would be enabled to determine (within the parameters set by the primary legislation and following public consultation) the types of dealings that are non-notifiable. These would be published in a determination to provide transparency, accountability and certainty for industry and other stakeholders.

Consistent with the recommendations of the Third Review and the proportionate regulatory model preferred by the Forum, this approach:

- ensures there continues to be a framework and accountability agreed by all governments (as reflected in the primary legislation)
- enables the Regulator to apply the principles described in the legislation to the wide range of dealings with GMOs
- provides flexibility to respond quickly and proportionally to changes in technology (again, within the risk-based parameters set by governments and subject to consultation).

Regulatory process

Consistent with the current approach to exempt dealings, dealings that come within the non-notifiable authorisation pathway on the basis of risk under Option B or Option C could be commenced without prior notification to the Regulator, provided the requirements for the authorisation pathway are met.

Further considerations for Option C

- It is proposed that having first categorised the type of dealing, non-notifiable dealings would be relevant to all three categories of dealing types (refer Figure 4).
- This would mean establishing what are very low risk dealings for the purposes of all three categories under Option C.
- While the legislation could specify relevant dealings (i.e. through legislative lists) that would be non-notifiable dealings for the purpose of each category, where features of the dealing are relevant to two or more categories, it would be necessary for the person undertaking the dealing to establish and provide evidence to support the relevant authorisation type.

Key consultation questions – Non-notifiable dealings

- What types of dealings would be appropriate to include in the non-notifiable pathway for Option B?
- For each of the three categories for Option C, what types of dealings would be appropriate to include in the non-notifiable pathway?
- What are the relevant risk indicators (to be established in the GT Act) that could guide the Regulator's determination of what is a very low risk dealing?
- What are the advantages and disadvantages of categorising dealings using existing concepts (e.g. contained dealings and intentional release) that do not account for risk or modern technology?
- Under Option C, what are the advantages and disadvantages of first categorising the dealing in the context of the non-notifiable dealing authorisation pathway?

Notifiable dealings

Relevant GMO dealings (low risk dealings)

Notifiable Low Risk Dealings (NLRDs) are currently described in Parts 1 and 2 of Schedule 3 to the GT Regulations. Under the current Scheme, NLRDs are activities with GMOs undertaken in containment (i.e. not released into the environment and suitable for Regulator-approved physical containment facilities, levels 1 to 3) that have been assessed as posing low risk to the health and safety of people and the environment provided certain risk management conditions are met. An NLRD may only be undertaken after it has been assessed as being an NLRD by an Institutional Biosafety Committee (IBC).

Under the new model it is proposed that, for notifiable dealings, the GT Act would:

- describe the considerations that influence whether a dealing with a GMO is low risk such that it can be classified as a notifiable dealing
  - For example, considerations that are currently required for listing GMO dealings as NLRDs such as whether the dealing with the GMO would involve any risk to the health and safety of people, or to the environment taking into account the properties of the GMO as a pathogen or a pest, and the toxicity of any proteins produced by the GMO, and any related risk management measures, would continue to be relevant to notifiable dealings.
- enable the Regulator to determine (within the parameters set by the primary legislation and following public consultation) the types of dealings that are notifiable. As for non-notifiable dealings, these would be published in a determination to provide transparency, accountability and certainty for industry and other stakeholders.
  - Note that the Regulator currently has the power under the GT Act to review whether a dealing with a GMO should continue to be an NLRD and to recommend changes to the Forum.

While some of the dealings that are currently NLRDs could become non-notifiable (if assessed to pose very low risk – for example, recent changes to the GT Regulations enabled two host organisms that are low risk but had not been used in research until recently, and therefore had not previously been considered, to be moved to the exempt dealings category commensurate with the level of risk), most of the GMO dealings currently within the NLRD category would continue as notifiable dealings.

In addition, this authorisation pathway could include other low risk dealings that are also regulated by other Australian regulators, for example:

- GMO dealings associated with commercial supply of a live GMO vaccine used to protect horses from a specific viral disease could be eligible for this authorisation pathway. Registration of a GMO veterinary vaccine by the Australian Pesticides and Veterinary Medicines Authority (APVMA) includes, among other things, assessment and management of risks to human health and the environment. To support APVMA's consideration of GMO veterinary vaccine applications, the Regulator would provide advice upon APVMA's request.

Regulatory process

The authorisation process to undertake a notifiable dealing would be similar to that of the existing NLRD process, in that notifiable dealings would need to be reported to the Regulator annually (using the online reporting form). Notifiable dealings reported to the Regulator would be published on the OGTR website as part of the Record of GMO Dealings.

Requirements applicable to notifiable dealings would include:

- compliance with any conditions or restrictions placed on the dealing including any containment conditions (where applicable)
  - For example, it would be conducted within a facility certified to either physical containment level 1 (PC1), PC2 or PC3 (as appropriate), or another facility specifically approved in writing by the Regulator, and in accordance with any conditions imposed on the facility.
- reporting to the Regulator and participation in audits conducted by the Regulator
- adverse event reporting to the Regulator
- that the dealing be conducted only as provided for in the determination and, where applicable, the IBC record of assessment
- that the dealing be conducted by people with appropriate training and/or experience
- that the GMO be transported, stored and disposed of according to the Regulator's Guidelines for the Transport, Storage and Disposal of GMOs, or alternative conditions specifically approved by the Regulator
- that changes to the dealing involve reassessment as per any conditions or requirements specified in the GT Regulations
- compliance with any requests from the Regulator to provide further information about the dealing and with any directions given by the Regulator.

What will be the ongoing role of IBCs?

IBCs play an integral role in the Scheme. Noting the value of having technical and scientific expertise within organisations to provide the day-to-day oversight of low risk dealings, IBCs would largely operate in the same capacity as currently.

Acting as the institutional 'eyes and ears' for the OGTR through on-site scrutiny, 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
- advising on the identification and management of the risks within an organisation's internal operations in relation to notifiable dealings, and
- monitoring compliance with legislative and risk management requirements.

The continuing role of IBCs reflects the effectiveness of regulatory monitoring at the organisational level and is consistent with the approach adopted in other like regulatory schemes where IBCs (or their equivalents, such as Human Research Ethics Committees (HRECs)) oversee research activities such as clinical trials.

Further considerations for Option C

- It is proposed that having first categorised the type of dealing, notifiable dealings would be relevant to all three categories of dealing types (contained dealings, dealings involving intentional release and clinical trials and medical applications, refer Figure 4).
- This would mean establishing what are low risk dealings for the purposes of all three categories under Option C.
- While the legislation could specify relevant dealings (i.e. through legislative lists) that would be notifiable dealings for the purpose of each category, where features of the dealing are relevant to two or more categories, it would be necessary for the person undertaking the dealing to establish and provide evidence to support the relevant authorisation type.
- This could mean there will be occasions where low risk dealings appear across all three categories and that for dealings with features relevant to two or more categories, authorisation through the notifiable pathway may be required for each category.
- To assist with the categorisation of a dealing, IBCs would continue to consider whether a dealing involves a release into the environment and whether such release is intentional.

Key consultation questions – Notifiable dealings

- What types of dealings would be appropriate to include in the notifiable pathway for Option B?
- For each of the three categories for Option C, what types of dealings would be appropriate to include in the notifiable pathway?
- What are 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?
- Under Option C, what are the advantages and disadvantages of first categorising the dealing in the context of the notifiable dealing authorisation pathway?

Licensed dealings

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 licensed 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). For example, where regulatory experience and scientific information establish that the risk for a particular dealing is at the lower end of the medium to high indicative risk categorisation, then the assessment of that application would be streamlined and involve reduced data requirements in line with the permit or expedited licence requirements described below.

All licensed dealings would share common post-commencement processes and safeguards. This would include:

- Risk management measures – If the risks associated with the activity can be managed, then the Regulator may allow the activity (by issuing a permit or licence) and may also impose risk management measures and/or conditions.
- Reporting and notification requirements (including through routine reporting, trigger-based notification and in response to the Regulator's information gathering powers).
- Iterative information exchange with regulated stakeholders to ensure the risk management conditions of a licence have the right settings.
- Monitoring and enforcement – Having commenced the dealing under the authority of a permit or licence, permit/licence holders would be subject to compliance audits and targeted post-commencement assessments. This would include monitoring of compliance with risk management conditions and enforcement through the application of offence provisions in the legislation.

Permit

Relevant GMO dealings

A type of licence known as a permit would be required for dealings that are medium indicative risk and do not require a case-by-case risk analysis.

This licence type would include GMO dealings with which the Regulator has extensive regulatory experience. Dealings would only be added to this licence type if a risk analysis undertaken by the Regulator determined that any risks posed by the dealings could be managed with a specific set of defined management conditions that have already been used in Australia and are confirmed to be effective in managing risk and, for field trials, effective in containing the GMO.

In addition, dealings with GMOs developed with new technologies could be authorised under permits if the risks posed by the dealings can be managed by an identified 'universal' set of licence conditions (again where such conditions have been clearly established as effectively managing risk).

The primary legislation (the GT Act) would describe the relevant considerations that must be taken into account in determining whether a dealing with a GMO may be subject to a permit, the Regulator would consult publicly on the dealings that could be so authorised (and any relevant risk management conditions) and the dealings able to be authorised in this way would be published in a determination.

Examples of dealings that could be included in this licence type are:

- dealings for which the Regulator has extensive regulatory experience regarding management measures that are effective in confining GMOs and mitigating any risks posed by certain GMO dealings, such as 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.
  - For example, a field trial of cotton genetically modified for herbicide tolerance. Most licences authorising field trials of this type of GM cotton contain the same or very similar conditions. On the basis of a risk analysis, the Regulator could identify a set of standard permit conditions that could manage the risks of any given field trial of herbicide tolerant GM cotton, taking into account the scale of the trial.
- dealings for a clinical trial involving a GM virus based on a viral vector backbone that has been authorised in the past by the Regulator, expressing a transgene or class of transgenes and/or displaying a modified trait that has been previously assessed by the Regulator.
  - For example, the Regulator has approved multiple licences for clinical trials using Adeno-associated virus based vectors expressing different clotting factor proteins for treatment of different types of haemophilia.
- Dealings with GMO therapeutics authorised through particular Therapeutic Goods Administration (TGA) pathways, where the number of patients to receive the therapeutic are limited.

- Administration of GMO therapeutics to patients under the TGA's Special Access Scheme, for example, the urgent treatment of a sick child infected with an antibiotic resistant lung infection with a GM bacteriophage could be eligible for this licence type. TGA can grant permission through the Special Access Scheme for registered health practitioners to provide urgent medical treatments, not included in the Australian Register of Therapeutic Goods (ARTG), for patients considered 'seriously ill'. The risk to human health or the environment of a single patient treated in a hospital is extremely low.
- For example, a GMO dealing involving administration of GMO therapeutics into patients under the TGA's Authorised Prescriber Scheme, which allows for a medical practitioner who is an Authorised Prescriber, to prescribe a class of patients with a particular medical condition for up to 5 years. The TGA determines whether the requirements for authorisation as an Authorised Prescriber have been met. Authorised Prescribers must apply for HREC approval and supply the TGA with reports biannually. If the GMO is manufactured overseas, import approval from the Department of Agriculture, Water and the Environment (DAWE) may also be required.
- For example, personal supply and use of a GMO therapeutic authorised through the TGA Personal Importation Scheme, which allows import of up to three months' supply at a time for therapeutics that are not included on the ARTG. Import may also require approval from DAWE.

CASE STUDY

A medical researcher has developed a GMO therapeutic to treat cancer and is proposing a clinical trial of the treatment. The GMO therapeutic is a GM HSV-1 virus that has been modified to selectively replicate in and destroy cancer cells. The GM virus has also been modified to express a protein that activates the trial participant's immune response to help target and destroy the cancer cells.

The Regulator has experience with this type of GMO, having assessed the risks and developed appropriate risk management strategies for 6 previous clinical trials and commercial release applications for other GM HSV-1 based therapeutics with the same modified traits.

Under both options B and C, the new application could be authorised under a permit, using past regulatory experience and a history of safe use to streamline the assessment. For Option C, the application would additionally be categorised under 'Clinical trials and medical applications'.

Regulatory process

Applicants would apply to the Regulator for a permit prior to commencing the dealing.

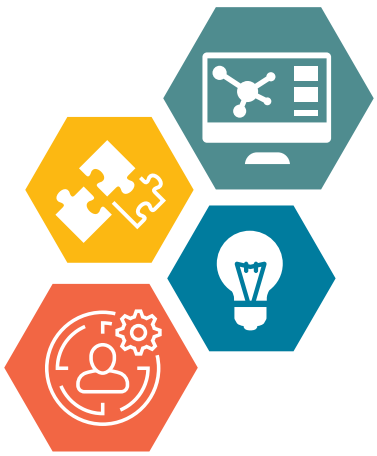
Applications for permits would be assessed in the shortest timeframe, as the Regulator would only make administrative, financial and compliance checks regarding the applicant (i.e. applicant suitability checks).

Following assessment, a permit would either be issued with standard conditions (as required), or the Regulator may refuse to issue the permit, or the application would be reallocated to a more appropriate licence type. Permits would only be issued if applicants certify that standard conditions can be met.

The common post-commencement processes and safeguards described above would apply.

Further considerations for Option C

- It is proposed that a permit (for medium indicative risk dealings) would be available across two of the three categories, that is 'dealings involving intentional release' and 'clinical trials and medical applications'.
- Permits would not be available for contained dealings because three contained dealings authorisation pathways (currently exempt dealings, NLRDs and DNIR) have already been found to provide graduated and proportionate levels of oversight for contained dealings.
- While some of the risk considerations described for Option B will also be applicable to Option C, the risk will necessarily be nuanced specific to the relevant category.
- The risk matrix enables risk considerations to inform the regulatory process so that within categories regulation can be applied proportionate to risk. For example, a more streamlined authorisation may be available for clinical trial applications that meet a series of criteria established by the Regulator that determine the clinical trial to be lower risk.
- Where dealings have features that are relevant to two or more categories, an authorisation may be required for each category, noting that within the different categories a more fulsome assessment might be required in order to obtain the relevant licence type.



Expedited assessment

Relevant GMO dealings

An expedited assessment could be used for GMO 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 Regulator, such that only some components of the proposed dealing would require assessment.

For example, an expedited assessment could be sought if:

- the dealing involves a variation on matters that would otherwise make it eligible for the permit category
  - For example, an open-ended timeframe in which to undertake a clinical trial or a field trial that is larger scale or has different containment measures than one which would otherwise meet the criteria for a permit.
- it is for a GMO dealing for which the Regulator has extensive regulatory experience with the species that has been genetically modified (parent species) but that requires a case-by-case risk analysis due to unfamiliarity with the introduced trait or the type of dealings. For example:
  - a field trial of GM canola genetically modified for enhanced photosynthesis or nitrogen fixation.
  - a clinical trial of a GMO therapeutic based on adeno-associated virus, expressing a new transgene or class of transgene and/or displaying a new modified trait.
- it is for a GMO dealing that occurs in a certified containment facility but requires a case-by-case risk analysis due to the parent organism and the introduced trait
  - For example, dealings currently authorised under DNIR and described in Part 3 of Schedule 3 to the GT Regulations.
- the proposed GMO dealings have been previously licensed by the Regulator and the risk analysis undertaken in the past would significantly inform assessment of the new application
  - For example, a new field trial of a GM plant that 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.
  - For example, a field trial of a plant obtained by crossing GMO X and GMO Y if field trials of GMO X and GMO Y have been previously authorised under a full assessment licence and standard permit criteria are not suitable.
  - For example, the commercial release of a GM vaccine if it has been commercially released in the past under a full assessment licence. For instance, if an organisation sought authorisation for the commercial release of a GM cholera vaccine similar to one previously authorised under a licence that was surrendered. As the risk analysis for GMO dealings proposed in the new application would be significantly informed by the risk assessment and risk management plan prepared for the surrendered licence, the new application could be streamlined under the new model.

- the dealings with the GMO have been assessed and authorised by reputable regulatory agencies overseas. The application process could be streamlined where the overseas risk analysis is available and could be considered by the Regulator. An assessment would however still be required to ensure that the findings of the international risk analyses are relevant to the Australian context.
  - For example, commercial release of GM soybean authorised for commercial release in Canada or the commercial release of a GM vaccine authorised in Europe.

CASE STUDY

A pharmaceutical company wants to supply a commercial GMO therapeutic in Australia for treatment of a rare debilitating muscle wasting disease that affects young children. Urgent treatment is required, as clinical studies have shown that early treatment results in better health outcomes for patients. The TGA has waived fees for the assessment for the GMO therapeutic, as it meets the criteria for TGA orphan drug designation status. The therapeutic is approved by overseas regulators, and risk assessments by the US Food and Drug Administration and the European Medicines Agency can inform OGTR's risk analysis. Currently, the authorisation pathway for this dealing depends upon whether or not it involves intentional release of a GMO to the environment. This application could be appropriate for an expedited assessment, as the TGA considers the health and safety of the patient, and the Regulator would consider the health and safety of people who are not the patient and protection of the environment.

CASE STUDY

A sponsor is conducting a clinical trial of a GM vaccine for prevention of influenza. The GM vaccine has been trialled overseas in Phase 1 studies. Phase 2 and 3 studies are proposed to be conducted in Australia. The GMO cannot reproduce in humans, and trial participants shed negligible amounts of the GMO, with no GMO detected one day after vaccination. However, as the GM vaccine is administered as an intranasal spray, instead of via a more contained route, such as injection, the GMO may not be contained. Currently, the GMO dealing is considered as a limited and controlled release into the environment, and requires assessment as a DIR licence application. Under both Option B and Option C, risk assessments conducted by other regulatory bodies, such as HRECs and overseas regulators, could support this application being authorised as an expedited licence. Under Option C, the only difference would be the additional step of categorising the dealing into the 'Clinical trials and medical applications' category.

Regulatory process

Applicants could apply to the Regulator for a licence using the expedited assessment form.

In addition to the administrative, financial and compliance checks undertaken for a permit, the Regulator would perform a risk analysis to determine if all risks can be managed and to identify risk management measures (this would involve preparing a risk assessment and risk management plan). An expedited assessment would involve consultation if the Regulator identified issues warranting consultation, or otherwise may involve limited or no consultation on the basis of one or more of the following;

- the Regulator has consulted on similar GMO dealings in the past,
- the Regulator has previously assessed and approved a similar GMO dealing and the proposed dealing would not involve intentional release to the environment or
- a comparable overseas regulator has approved the GMO for commercial use in another country.

Following an expedited assessment, the Regulator would either issue a licence (with conditions imposed based on the risk analysis) or refuse to issue a licence.

The common post-commencement processes and safeguards described above would apply.

Further considerations for Option C

- It is proposed that having first categorised the type of dealing, an expedited assessment (for medium-high indicative risk dealings) would be a relevant to all three categories of dealing types (refer Figure 4).

Full assessment

Relevant GMO dealings

It is proposed that a full assessment would be required for dealings with a high indicative risk or where there may be substantial uncertainty as to risk. This assessment would involve a case-by-case risk analysis and full consultation.

In essence, this licence type would be available for GMO dealings for which the Regulator has no or limited regulatory experience.

Under Option B, contained dealings, limited and controlled releases and broad releases (e.g. commercial plant releases) could be included in this licence type.

Regulatory process

Applicants would apply to the Regulator for a licence using the full assessment form.

Consistent with the other licence types, the Regulator would perform applicant suitability checks and 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 (GTTAC) and the public.

Processing full assessment licences would therefore involve three components: applicant suitability, writing a risk assessment and risk management plan and wide consultation with stakeholders and GTTAC. The timeframe for the assessment of these applications would depend on the breadth of consultations needed. For instance, it is anticipated that the assessment timeframe of a broad release of a novel GM animal may require more consultation than the commercial release of a GM field crop. Likewise, a commercial release of a GM plant and a field trial of a GM plant may require the same consultation and therefore have the same assessment timeframe.

Following a full assessment, the Regulator would either issue a licence (with conditions imposed based on the risk analysis) or refuse to issue a licence.

The common post-commencement processes and safeguards described above would apply.

Further considerations for Option C

- It is proposed that a full assessment would only be necessary for two of the three categories of dealings, that is 'dealings involving intentional release' and 'clinical trials and medical applications'.
- Where dealings are contained, a full assessment would not be required given that any risks associated with these dealings are sufficiently managed by the containment conditions applied.

Key consultation questions – Licensed dealings

- What risk indicators would inform the split between a permit, an expedited assessment or a full assessment for Option B?
- For Option C, what risk indicators would inform the split between a permit, an expedited assessment or a full assessment for the categories 'dealings involving intentional release' and 'clinical trials and medical applications'?
- Under Option C, what are the advantages and disadvantages of first categorising the dealing before using risk indicators to determine the relevant licence type?

Important note

Regulation of the environmental release of gene drive GMOs is being considered separately to this process (for recommendation 7b of the Third Review). While the assessment of the environmental release of gene drive GMOs may differ to the assessment of other GMOs, it may still fall within the proposed risk tiering framework.

Chapter 5
Essential enablers

Details of essential enablers

An upgrade of the OGTR's IT system to enable an automatic data management system and integrated portal and user interface for stakeholders is critical to managing the receipt, evaluation, and approval of applications for authorisations, certifications and accreditations, and for monitoring organisations that undertake work with GMOs to ensure compliance with authorisations.

The current OGTR databases are manually operated and maintained internally. Replacing these databases is a pressing need for the OGTR as it currently requires significant resources to maintain. An improved data management system would:

- deliver significant benefits (and time savings) for stakeholders as the system would better support online applications and real time notifications (for IBCs and applicants). The Third Review identified that the application process was a key area that would benefit from streamlining.
- translate to considerable time and effort savings for the OGTR
- would streamline OGTR's compliance monitoring and internal reporting requirements
- enable improved searching capacity for all stakeholders (increasing the transparency of the regulatory scheme).

Implementing an automatic data management system would:

- complement the online smart forms currently in use by stakeholders
- automate many internal administration processes
- streamline the application process for facility certifications and licences
- offer real time tracking of application status and real time issuing of OGTR application identifiers for applications to the benefit of applicants and other stakeholders

- permit real time submission of information to the OGTR (thereby reducing the administrative burden on stakeholders who are currently collating information for a one-time submission in accordance with the regulatory timeframe)
- enable timely public reporting (as it would capture IBC assessments on the GMO Record given the real time alerts to the OGTR)
- support the function of the Regulator to provide information and advice to other regulatory agencies about GMOs and GM products
- streamline the process for sharing information with other regulators (e.g. a system that supports interoperability would enable an alert to be sent to Food Standards Australia New Zealand (FSANZ) when an application made to the Regulator requires the advice in relation to a risk assessment by FSANZ).

Key consultation questions – Essential enablers

- What current processes (that are unnecessarily burdensome) could be resolved by an improved IT system?
- What other advantages could be gained from the implementation of an automatic data management system?

Chapter 6
Streamlining and other technical changes

Details of other technical changes

The opportunity to streamline the legislation and reduce unnecessary regulation is supported by a range of other technical changes described below. These changes are consistent with the Commonwealth principles for clearer laws in that changes would enable existing processes to be streamlined, the complexity of the legislation to be simplified (including to improve readability) and redundant legislation to be removed.

Further development of proposals described elsewhere in this document could result in additional technical changes. For example, further consideration of oversight and governance of GMO dealings in some risk tiers could lead to changes to the current roles and responsibilities of accredited organisations and IBCs and current certification processes. Similarly, consideration of consultation and information publication requirements for risk tiers may lead to changes to confidential commercial information (CCI) provisions.

Technical changes proposed to support the reforms and to improve the legislative scheme include, for example:

- There are a number of redundant provisions in the legislation that, in line with the principles for clearer laws, should be removed at the next opportunity. Some provisions are transitional only, such that the relevant period has passed, and the provision is no longer needed. Others contain terms that can be removed as they are no longer used in the legislation, for example, subsection 138(9) of the GT Act provides a definition for the term *designated notification*, however, subsequent to earlier changes to section 138, the term is no longer used and subsection (9) could therefore be deleted.
- Replace the current requirements regarding the disclosure and management of conflicts of interest in relation to advisory committees with standard contemporary provisions (refer regulation 20 of the GT Regulations).
- Ensuring the risk assessment and risk management provisions of the GT Act link to amended risk tiers in a way that supports best practice risk analysis.

- Section 129 of the GT Act establishes a special account known as the Gene Technology Account (the Account). Section 130 specifies the purposes for which the Account can be credited. While it is a function of the Regulator to provide information and advice to other regulatory agencies about GMOs and GM products (e.g. FSANZ, APVMA and DAWE), there is some uncertainty as to whether the Regulator can receive funds from other Commonwealth Departments or regulatory bodies for the provision of these advisory services. It is therefore proposed that section 130 of the GT Act be amended to expressly identify amounts paid by Commonwealth Departments and statutory bodies for services provided by the Regulator, as this would provide flexibility for the payment of amounts relating to the provision of specialist advisory services.
- Expand the circumstances under which the time for processing applications to vary licences can be 'paused' (refer to regulations 8 and 11 of the GT Regulations) in order to facilitate protection of stakeholders' CCI. For the purposes of subsection 71(7) of the GT Act, regulation 11A sets out the time in which the Regulator must decide an application to vary a licence (i.e. 90 days). Consistent with the time for deciding an application for a licence and the circumstances in which in days will not count towards the decision making period (refer regulation 8), it is proposed that regulation 11A be amended to ensure the Regulator can 'pause the clock' if an application is made under section 184 of the GT Act (for specified information given in relation to the application to be declared CCI by the Regulator for the purposes of the GT Act). Aligning application decision timeframes in this way would ensure the appropriate time needed for the Regulator to consolidate all the relevant information and to first determine the CCI application, before any information regarding a decision on a licence variation application is required to be published.
- Update the current requirements for CCI applications to better align with contemporary provisions of other regulators.
- Amend section 27 of the GT Act (which sets out the functions of the Regulator) to clarify that the Regulator may undertake international capacity building activities, including to respond to requests for advice and training by overseas governments to assist in establishing an appropriate regulatory regime for GMOs (i.e. the functions would explicitly include activities to promote information-sharing with other countries more broadly than just with overseas agencies that regulate GMOs).
- Minor and machinery changes that are consequential to the amendment and introduction of legislation that the legislation references. For example, regulation 9 of the GT Regulations would be amended to correct the reference to the name of the agency that regulates industrial chemicals (as name of this Agency changed as at 1 July 2020).

Key consultation questions – Streamlining and other technical changes

- Are there other opportunities to streamline or improve the clarity of the legislation?

Appendix A
Glossary of terms

Term	Definition
APVMA	Australian Pesticides and Veterinary Medicines Authority – the government statutory authority responsible for the registration of all agricultural and veterinary chemical products into the Australian marketplace.
ARTG	Australian Register of Therapeutic Goods
COAG	Council of Australian Governments – the peak intergovernmental forum in Australia.
CCI	Confidential Commercial Information
DAWE	Department of Agriculture, Water and the Environment
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 Regulator, from small field trials to general releases.
DNIR	Dealings Not involving an Intentional Release of GMOs into the environment
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*
GTTAC	Gene Technology Technical Advisory Committee – a statutory committee providing expert scientific and technical advice to the Regulator and Forum.
HREC	Human Research Ethics Committee – review all research proposals involving human participants to ensure that they are ethically acceptable. There are more than 200 HRECs in research organisations across Australia.
IBC	Institutional Biosafety Committee – IBCs provide the collective technical and scientific expertise to review, assess and advise on the identification and management of risks associated with all dealings that are likely to be put to it by the requesting organisation.
NLRD	Notifiable Low Risk Dealing
OGTR	Office of the Gene Technology Regulator – staff supporting the Gene Technology Regulator.
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.
TGA	Therapeutic Goods Administration – Australia's regulatory authority for therapeutic goods. TGA ensures therapeutic goods available in Australia are of an acceptable standard.
Third Review	*Third Review of the National Gene Technology Scheme*