Australian Government
Department of Health, Disability and Ageing

Consultation Paper – January 2026

Gene Technology Amendment Regulations

Table of Contents

Introduction - Changes to the Gene Technology Regulations 2001

The National Gene Technology Scheme

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

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

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

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

The Third Review of the National Gene Technology Scheme

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

While the Third Review found that, overall, the Scheme is working well, the Review outlined 27 recommendations designed to improve and strengthen the Scheme, while ensuring it is appropriately agile and supports innovation. In 2021, Gene technology ministers endorsed the 27 recommendations of the Review. Many, but not all, of the recommendations require regulatory reforms for implementation.

The regulatory model endorsed by ministers proposes a framework where dealings with GMOs would be classified into a system of authorisation pathways that is fit for purpose for current and future GMO applications. Classifying GMO dealings according to the level of risk they pose, a model referred to as the 'risk-tiering' framework, would ensure that regulation is proportionate with risk.

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

An exposure draft of the proposed Gene Technology Amendment Bill (the draft Bill) and a related consultation paper were released for public comment between 13 September and 8 November 2024.

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

Focus of this Consultation

One of the key features of the proposed reforms is the increased use in delegated legislation (including the Regulations and proposed new Rules) to increase the flexibility and responsiveness of the Scheme to advances in the field of gene technology.

Following on from consultation on the draft Bill, this paper is aimed at providing stakeholders with context and further information about proposed related changes to the GT Regulations that will underpin the changes in the draft Bill and implement the recommendations of the Review.

A separate process will occur with respect to the development and consultation on proposed rules to be made by the GT Regulator. Stakeholders will have a separate opportunity to provide input on the proposed draft rules.

This provides an opportunity for all impacted industry, regulated entities, academic institutions, researchers, and interested members of the public to consider and give input on the proposed changes to the Regulations.

The paper below provides a summary of the current GT Regulations and proposed changes. Where relevant, reference is made to the appropriate part of the draft Bill providing for the making of the Regulations.

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

The consultation opens on Monday 5 January 2026 and closes on Sunday 1 March 2026

Specific consultation questions are included throughout the consultation paper to guide input.

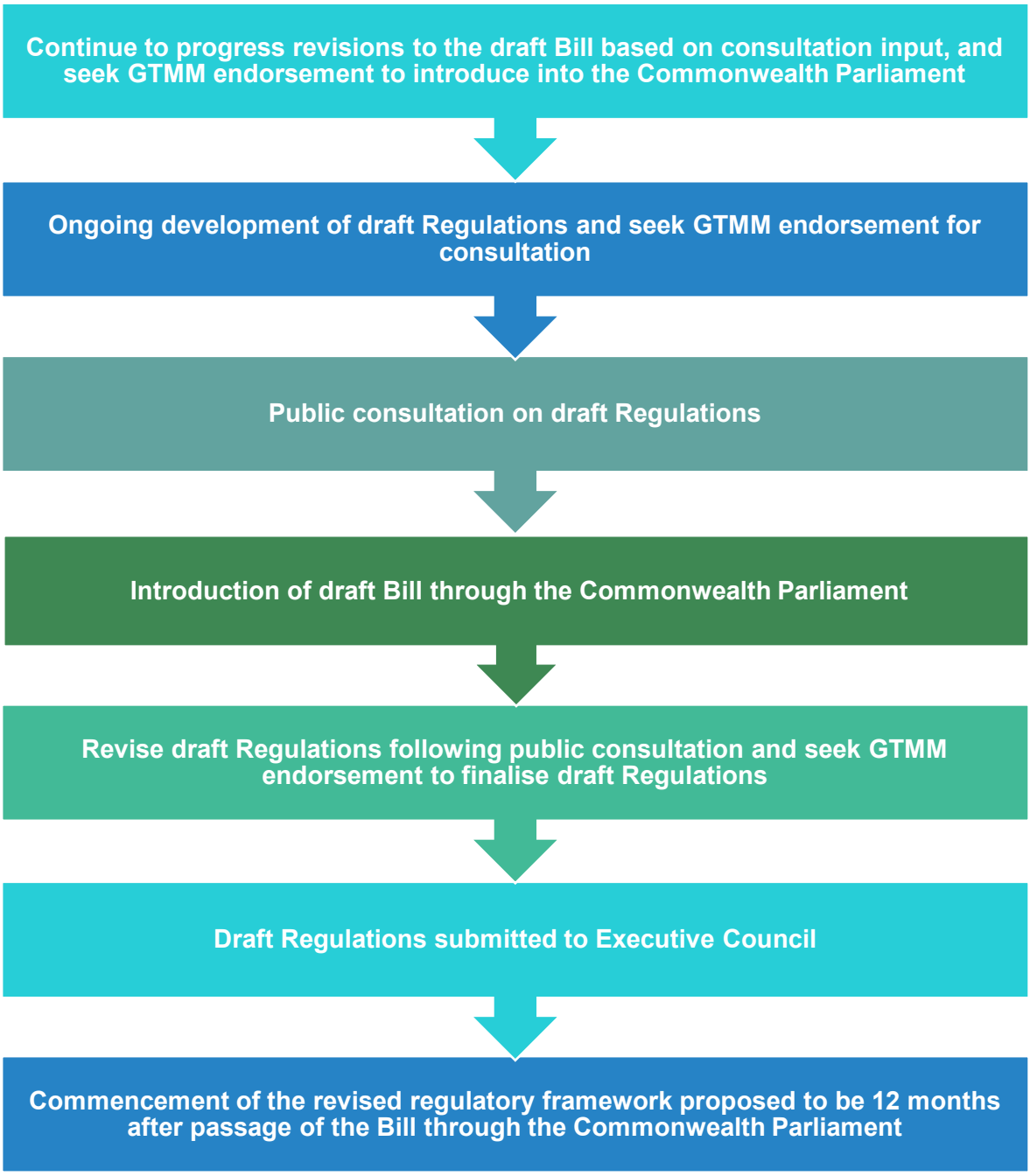
Consultation responses should be provided via the survey in the Department of Health, Disability and Ageing consultation hub. Where possible, reasoning and supporting information should be included. Providing consultation responses via the survey in the consultation hub will ensure that input can be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

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

Next Steps

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

These activities will all be progressed as quickly as possible subject to ministerial agreement and within the requirements of the Commonwealth Government legislation process.



*Rules to be issued by the Regulator will be developed separately to the proposed amendments to the GT Regulations and will be subject to a separate consultation process.

Key changes proposed to the Gene Technology Regulations 2001

This paper illustrates proposed key changes to the GT Regulations and the policy intent for how these changes would work in practice. It is important to note that the wording of the final provisions will be subject to change throughout the drafting process, or as a result of feedback provided through this consultation process.

It is also important to note that different types of legislation are subject to different approval pathways.

Type of legislation	**Approved by**
GT Act	Australian Parliament
GT Regulations	Federal Executive Council
Rules	Legislative instrument made by the Regulator

It is important to note that proposed rules to be made by the Regulator will be developed separately to the proposed amendment regulations. A separate consultation process will be undertaken.

To ensure that it is clear which parts of the current GT Regulations would be retained, current provisions are referenced even if no changes are proposed.

Regulations structure generally

Currently

- Some regulations do not appear in the same order as their empowering provisions in the *Gene Technology Act 2000* (GT Act). For example, regulations relating to the Gene Technology Technical Advisory Committee (GTTAC) are contained in Part 4 of the GT Regulations, but Part 8 of the GT Act.
- This is not consistent with modern legislation.

Proposed amendments

- To ensure that the GT Act reflects modern standards of legislative drafting, the proposed changes to the GT Regulations should mirror the structure of the proposed changes to the GT Act. For example, Part 2 of the draft Bill should have a corresponding Part 2 in the GT Amendment Regulations.
- It is therefore anticipated that some parts of the GT Regulations would be renumbered and some existing regulations relocated without substantive amendment.

Question 1: Do you have any comments or concerns with regards to the proposed changes to the structure of the Regulations generally?

Part 1 – Preliminary

Currently

- Part 1 of the current GT Regulations provides definitions for significant terms used throughout the GT Regulations.

Proposed amendments

- Some amendments to existing definitions are needed, and new definitions will be added as a result of the proposed changes to the GT Act and GT Regulations.
- Definitions, among other aspects of the proposed changes, are subject to change as part of legislative processes, to effectively support legislative and regulatory requirements.
- Changed definitions will include:
    - limited and controlled release
    - inspector
    - physical containment level
    - therapeutic dealing
- New definitions include:
    - contained dealing
    - field trial
    - gene drive dealing
    - novel dealing
    - Record of Assessment
    - specified entities

Limited and controlled release

Under the current GT Act, section 50A applies to 'limited and controlled release' applications. The draft Bill proposes to repeal section 50A, however it is intended that the concept of 'limited and controlled release' should be retained in the proposed Amendment Regulations. It is proposed that the new definition should incorporate the test in paragraph 50A(1)(b) of the current Act only and should also adopt the definitions of the terms 'controls' and 'limits' as defined in the draft Bill.

Inspector

Under the proposed amendments to the GT Act, the term inspector is referred to as 'authorised inspector'. It is proposed that the GT Regulations would be amended accordingly.

Physical containment level

It is proposed that the definition of 'physical containment level' will refer to rules made by the Regulator under section 193A of the GT Act as required by section 90(a) of the GT Act as amended. Section 90(a) states that for a decision to be made on applications for certification, the rules must specify the containment requirements for the certification of a facility to a particular containment level. The rules may also specify other criteria the facility or applicant must comply with for certification to a particular containment level.

Therapeutic dealing

The term 'therapeutic dealing' will now mean a dealing that involves using the GMO:

- by administering it into a human for therapeutic purposes, or
- to produce therapeutic goods (within the meaning of the *Therapeutic Goods Act 1989)*.

Contained dealing

It is proposed that the term 'contained dealing' would mean a dealing that is:

- conducted in a facility certified under Division 2 Part 7; or
- conducted in accordance with rules made for the purposes of section 27A (rules for transport, storage and disposal of GMOs); or
- a dealing undertaken in a facility agreed in writing by the Regulator.

Field trial

It is proposed that 'field trials' will be defined as experiments with a GMO that are plants and are conducted otherwise than in a certified facility and:

- in a manner that controls the dissemination or persistence of the GMO and its genetic material in the environment; and
- in a manner that limits the proposed release of the GMO.

For the purposes of this definition, the term 'controls' is proposed to include, in relation to a GMO and its genetic material, the following:

- methods to restrict the dissemination or persistence of the GMO or its genetic material in the environment;
- methods for disposal of the GMO or its genetic material;
- the geographic area in which the dealings with the GMO or its genetic material may occur.

For the purposes of this definition, the term 'limits' is proposed to describe, in relation to the release of a GMO, limits on any of the following:

- the scope of the dealings with the GMO;
- the scale of the dealings with the GMO;
- the locations of the dealings with the GMO;
- the duration of the dealings with the GMO;
- the persons with appropriate skills and experience who are to be permitted to conduct the dealings with the GMO.

Gene drive dealing

Under the Amendment Regulations, the term 'gene drive dealing' is proposed to mean a dealing involving a GMO capable of sexual reproduction, the sexual progeny of which are, as a result of modification to the organism by gene technology, more likely to inherit a particular nucleotide or nucleotide sequence (when compared to inheritance from a parent organism that has not been modified by gene technology).

Novel dealing
It is proposed that the definition of 'novel dealing' would include dealings covered by sections 49(1)(b)(i) or (ii) of the draft Bill:

- a GMO derived from a parent organism that is novel; or
- a GMO that displays a novel trait or traits that occurs because of gene technology.

Record of assessment
It is proposed that a 'record of assessment' will encompass 'a document produced by an Institutional Biosafety Committee when assessing a proposal to undertake a dealing' (see current regulation 13(1)(c)) and Guidance on making a Record of Assessment (www.ogtr.gov.au).

Specified entities
It is proposed that the Amendment Regulations will define 'specified entities' as the following:

- Food Standards Australia New Zealand;
- the Department administered by the Minister administering Chapter 1 of Part 8 of the *Biosecurity Act 2015*;
- the Department administered by the Minister administering the *Environment Protection and Biosecurity Conservation Act 1999*;
- the Executive Director of Australian Industrial Chemicals Introduction Scheme;
- the Australian Pesticides and Veterinary Medicines Authority;
- the Therapeutic Goods Administration; and
- the States.

Question 2: Do you consider that any other terms are unclear and require definition?

Part 2 – Interpretation and general operation

Currently

- Section 10 of the GT Act defines the terms 'deal with', 'gene technology' and 'genetically modified organism' for the purposes of the Scheme.
- The definition of 'gene technology' provides for the GT Regulations to prescribe techniques that are not taken to be gene technology. Regulation 4 provides that techniques set out in Schedule 1A to the GT Regulations are not 'gene technology' for the purposes of the GT Act.
- The definition of 'genetically modified organism' provides for the GT Regulations to prescribe organisms that are, or are not, 'genetically modified organisms'.
- Regulation 4A provides that things set out in Schedule 1B to the GT Regulations are 'genetically modified organisms' for the purposes of the GT Act, and regulation 5 provides that things set out in Schedule 1 to the GT Regulations are not 'genetically modified organisms'.

Proposed amendments

Definitions of 'deal with', 'gene technology' and 'genetically modified organism'

- The terms 'deal with', 'gene technology' and 'genetically modified organism' would be defined in sections 12A, 12B and 12C respectively of the draft Bill. Consequential amendments to the GT Regulations are required to refer to these new provisions.
- Section 12A of the draft Bill would enable the GT Regulations to prescribe further dealings for the definition of 'deal with'. It is not proposed that any additional dealings will be prescribed at this time.
- 'Gene technology' and 'GMO' would be defined in sections 12B (gene technology) and 12C (genetically modified organism) of the draft Bill. The GT Regulations will need to be amended to make reference to the new sections of the GT Act, and are intended to continue to refer to the current Schedules 1, 1A and 1B.
- Amendments to these schedules may be required to account for exclusion of human beings from the GMO definition.

Risks not required to be considered by the Regulator or minister

- To protect people and the environment from risks posed by gene technology, the draft Bill requires the minister and the Regulator to consider, or be satisfied in some way, about risks for particular decisions. For example, before issuing a GMO licence the Regulator must be satisfied that risks are able to be managed in such a way as to protect people and the environment. Under the draft Bill, and consistently with the Scheme's objectives, the minister or the Regulator may be required to take into account, be satisfied or give advice in relation to, matters related to risks before risk-tiering classes are specified in the GT Regulations and Rules.
- However, subsection 15A(2) of the draft Bill would provide that the Regulator and minister are not required to consider risks posed by dealings with GMOs if the risks are of a kind prescribed in the GT Regulations and are dealt with under the following Commonwealth Acts:
    - *Agricultural and Veterinary Chemicals Code Act 1994*
    - *Food Standards Australia New Zealand Act 1991*
    - *Therapeutic Goods Act 1989*
    - any other Act prescribed in the regulations.
- Proposed new regulations to supplement subsection 15A(2) seek to minimise regulatory overlap, and to address potential regulatory duplication resulting from changes to the definition of 'deal with'. Under that proposed change, the 'deal with' definition would expand to include any use of a GMO. Currently, use of a GMO is only a regulated dealing if it is in the course of another dealing.
- For example, the risks posed to patients by administration of a therapeutic good are managed by the Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act 1989*. TGA considers the quality, safety and efficacy of a medicine administered to

patients, before they are eligible for commercial supply in Australia. Regulations for the purpose of this proposed new section would seek to ensure that the Regulator would not be required to reconsider risks to patients.

- This proposed change may lead to reduced data requirements for applications, or some dealings where other regulators manage substantial risks being authorised through lower risk-tiers.
- It is important to note that while the effect of section 15A of the draft Bill and corresponding GT Regulations amendments would provide that the Regulator and minister are not required to consider certain risks, it is not intended that this would preclude those risks from being considered by the Regulator or minister if deemed necessary or appropriate.
- The proposed new section 15A would also allow for the GT Regulations to prescribe additional Acts for the purpose of this section. This allows for the Scheme to be able to respond to additional risks, and for these risks to be appropriately managed in the future as needed.

Question 3: Are you satisfied with the proposal of certain risks being excluded from the requirement of ministerial and Regulator consideration if they are already considered under another scheme?

Part 2A – Gene Technology Regulator

Currently

- This part contains a single regulation made for the purposes of section 27 of the GT Act which provides for the GT Regulations to confer additional functions on the Regulator (Regulation 5A).

Proposed amendments

- No changes to this part of the GT Regulations are anticipated as a result of these reforms.

Part 3 – Dealings with GMOs

Currently

- Part 3 of the current GT Regulations prescribes the following matters:
  - dealings that are exempt from licensing
  - time limits for deciding applications
  - authorities that the Regulator must consult for certain licence applications and risk assessment and risk management plan (RARMP)
  - matters the Regulator must take into account when preparing a RARMP
  - dealings that are notifiable low risk dealings (NLRDs) and requirements for undertaking NLRDs.

Proposed amendments

Authorisation pathways

- It is proposed that the entirety of Part 3 of the GT Regulations, and Schedules 2 and 3, would be revoked and replaced with regulations to give effect to GMO licences and the new authorisation pathways set out in the draft Bill: that is GMO permits, notifiable dealings (NDs) and non-notifiable dealings (NNDs).
- The draft Bill would enable the GT Regulations to specify classes of GMO dealings that are designated dealings, permit dealings, NDs and NNDs. It is intended that it will be clear which authorisation pathway a dealing will be conducted under.
- The current GT Regulations list dealings that are not NLRDs (Part 3 of Schedule 3). This concept would be adapted to the new risk-tiering framework. It is proposed that the GT Regulations will prescribe 'designated dealings' that are not permit dealings, NDs or NNDs, and these dealings would be required to be authorised by GMO licences (see further information below).
- As noted in the consultation paper for the draft Bill, the policy intention is that the Regulator will make rules to specify further requirements to restrict classes of GMO dealings prescribed in the GT Regulations. The draft Bill would enable this rule making.
- This legislative structure would improve flexibility in the Scheme by enabling the Regulator to adjust technical details set out in rules in response to changes in technology or understanding of risk, but only within the constraints provided for by the GT Act and GT Regulations.

GMO licences

When a GMO licence is required

- The GMO licence pathway will continue to be the default authorisation pathway under the revised Scheme. A proponent would need a GMO licence to undertake a GMO dealing that is not a permit dealing, ND or NND (described below); is not included in the GMO Register; and is not authorised through an emergency dealing determination.
- GMO licences could also authorise GMO dealings that are permit dealings or NDs when the proponent is not able to meet the conditions specified in the rules for the dealings. For instance, if the rules specify that it is a condition of the permit that a field trial of GM wheat must be harvested in a particular manner and the proponent wishes to harvest in a different manner, then the proponent could apply for a licence.

Designated dealings

- The policy intent is that designated dealings would be excluded from classes of permit dealings, NDs or NNDs, regardless of class descriptions in regulations or matters specified by the Regulator in rules. For example, a dealing with a GM animal that is able to give rise to infectious agents as a result of the genetic modification will be a designated dealing and will not be a ND even if the class description seems to capture this dealing. Dealings with a genetically modified gene drive organism will also be designated dealings.

- Designated dealings will broadly correspond to paragraphs 3.1(1)(a), (i), (k), (o), (p), (r) and (s) and 3.1(2) of current Part 3 of Schedule 3 to the GT Regulations. The remaining paragraphs in current Part 3 of Schedule 3 will be addressed in regulations and rules for different classes, as appropriate.

GMO licence application assessment

- The draft Bill would no longer specify assessment processes for GMO licences that differ according to whether or not the licence would authorise GMO dealings that involve intentional release of GMOs to the environment. Instead, GT Regulations as proposed to be amended would set out required consultations using risk-based criteria.
- Section 48 of the draft Bill would allow for regulations to prescribe matters that the Regulator must take into account when preparing a RARMP for GMO licence applications. It is proposed that regulations for the purposes of this section will broadly replicate the existing terms of regulations 9A and 10 of the GT Regulations.
- Section 49 of the draft Bill would specify when the Regulator must consult the public on a RARMP and would allow for regulations to prescribe who must be consulted on in developing a RARMP. Consistent with the Third Review recommendation to streamline application processes (recommendation 10) and make regulation risk proportionate (recommendation 12), consultations would be only undertaken when it adds value such as applications where GMOs are novel or high risk, or where the dealings are outside certified facilities or are general releases.
- Novel dealings would be defined as GMO that is derived from a parent organism that is novel; or a GMO that displays a novel trait that occurs because of gene technology.
- Public consultation would be required when the licence would authorise dealings with a GMO that is novel as defined in the draft Bill, provided the dealings are not contained and the GMO is not a therapeutic good. Regulations made for the purposes of section 49 of the draft Bill will describe different classes of GMO licence applications and the bodies the Regulator must consult, including states and territories and the GTTAC. Table 1 outlines the consultation requirements proposed to be specified in regulations.

Table 1: Licence class descriptions and proposed consultation requirements

Public consultation undertaken?	**Licence class description for the purpose of Section 49 of the draft Bill**	**Bodies to consult**
No*	Dealings in certified facilities involving novel and/or high risk GMOs	GTTAC
No*	Dealings outside containment that are limited and controlled, with some exceptions not requiring any consultation (e.g. plant field trials)	GTTAC
No*	Dealings outside containment that are not limited and controlled, with some exceptions not requiring any consultation (e.g. therapeutic GMOs where the parent is not novel or high risk, and the trait is not novel)**	States, GTTAC, specified authorities and agencies
Yes	N/A	In addition to the public: States, GTTAC, specified authorities and agencies

* These classes do not include dealings with novel GMOs outside containment, unless the GMO is to be used as a therapeutic good.

** Clinical trials that do not involve a novel or high-risk parent organism or a novel trait would also not require GTTAC consultation.

- Section 51 of the draft Bill would enable regulations to prescribe matters to be included in a notice the Regulator publishes on the internet, when consulting the public on a RARMP. No regulations are intended to be prescribed for the purposes of this section at this time.

Consideration periods for licence applications

- Consideration periods for all application types are in section 178F of the draft Bill. This section would also enable the GT Regulations to prescribe alternate consideration periods for applications as necessary. The policy intention is to specify alternate consideration periods for licences only, and these timeframes would generally be the same as or shorter than current licence application timeframes. Table 2 outlines proposed licence application timeframes; where an alternative consideration period is specified it overrides the default consideration period.
- In two cases the proposed timeframe is longer than the current timeframe:
    - The Regulator currently consults GTTAC on DNIR licence applications with novel or high-risk GMOs, however this is very challenging to accommodate in the 90 business day decision timeframe. It is proposed that these licences would have a 120 business day timeframe.
    - A timeframe of 400 business days is proposed for dealings with GM gene drive organisms that include release to the environment.

Table 2: Proposed alternative licence application consideration periods, in business days

Consultation required	**Default consideration period (section 178F of draft Bill)**	**Alternative consideration period to be specified in regulations**
No consultation required	(150 days)	90 days
GTTAC only	(150 days)	120 days
States, GTTAC, specified authorities and agencies	150 days	N/A
Public, States, GTTAC, specified authorities and agencies	200 days	• 400 days for GM gene drive organisms outside containment • 150 days if limited and controlled • N/A for other applications

Question 4 – Do you consider concept of designated dealing clear?
Question 5 – Do you have any concerns with the proposed consultation process for RARMPs?
Question 6 – Do you have any concerns with revised timeframes?
Question 7 – Do you have any concerns around the proposed range of dealings that will be required to be licenced?

GMO permits

- The draft Bill would establish the new authorisation pathway for GMO permits. GMO permits would be an alternative to licences where standard conditions are well established and known to manage risks effectively, and applicant suitability must be assessed. A GMO permit may authorise one or more permit dealings.
- It is proposed that the GT Regulations would prescribe classes of permit dealings by reference to such matters as:
    - the type or types of GMOs
    - the type or types of dealings which may be undertaken
    - the location where dealings may be undertaken (including physical containment)
    - matters the rules may specify for permit classes.
- Conditions for GMO permits will be prescribed in the draft Bill and rules to be made by the Regulator.
- Permit classes are being developed for plant field trials, clinical trials and GMO therapeutics accessed under TGA's Special Access Scheme. Table 3 sets out the types of matters currently intended to be specified in regulations and rules for all permit classes.

Question 8 – Do you have any concerns with dealings that are proposed to be authorised by a GMO permit?

Table 3: Matters to be specified in the GT Act, GT Regulations and rules for permit dealings

Draft Bill	GT Regulations	Rules
• Regulations may specify classes of permit dealings [subsection 72AB(1)] • Regulations may provide for the rules to specify a matter in relation to the class [subsection 72AB(4)] • A permit dealing is subject to any conditions specified in rules [paragraph 72AE(1)(b)] • Permits are subject to statutory conditions [sections 72AN-72AQ].	**Class P1** – Field trials with plants that have been modified by gene technology, where: 1. The dealing is for the purpose of conducting a plant field trial (as defined) 2. The plant species is one where the parent organism has previously been authorised by the Regulator A dealing is not a P1 dealing if: • it is a designated dealing • the species is not specified in rules • the characteristic is of a kind specified in the rules	Class P1 rules would specify: • parent species (may include cotton, canola, wheat and banana) • characteristics in relation to the parent species that are not included in the class Class P1 Conditions would include general conditions for all plants, as well as specific conditions for each plant species. These would be based upon standard conditions for previously issued field trial licences. For example, isolation distances, prohibiting use of GM products in food, post-harvest monitoring practices.
	Class P2 – Clinical trials involving a GMO for therapeutic use, where: 1. administration to the trial participant is undertaken in a clinical setting, and 2. the GMO is of a form or type that has previously been authorised for a clinical trial by the Regulator, and 3. the GMO is replication defective or unable to form a virion, and 4. the genetic modifications do not increase the capacity of the GMO to cause harm (as defined). A dealing is not a P2 dealing if it is a designated dealing	Class P2 rules would specify: • permitted GMO forms or types, e.g. Adenovirus, Adeno-associated virus, self-amplifying mRNA • that class P2 does not include certain GMOs of a form or type with specified genetic modifications P2 conditions would be based upon standard conditions for previously issued clinical trial licences. For example, requirements for dispensing the GMO, PPE needs and disposing of waste.

Draft Bill	GT Regulations	Rules
	Class P3 – Administering a GMO for therapeutic use to a patient, if: 1. the dealing is subject to an authority under the Therapeutic Goods Administration's Special Access Scheme Category A or B, and 2. the parent species is not Risk Group 3 or 4 in the AS/NZ Standard 2243.3.2010 and does not pose a biosecurity risk in Australia. A dealing is not a P3 dealing if it is a designated dealing	Rules would prescribe conditions. Class P3 conditions would be outcomes-focused to cover the potential range of GMO therapeutics. This could include requirement for Record of Assessment from an Institutional Biosafety Committee.
	Class P4 – Introducing genetically modified somatic cells into a human, where: 1. The dealing involves introduction of a GM human cell into a human; and 2. The GM cells contain residual infectious viral vector. A dealing is not a P4 dealing if it is a designated dealing	Rules would prescribe conditions: Class P4 conditions would be based upon standard conditions for previously issued clinical trial licences. For example, requirements for dispensing the GMO, PPE needs and disposing of waste.

Notifiable dealings

- The draft Bill would establish the new notifiable dealing (ND) authorisation pathway to replace NLRDs. NDs are GMO dealings that would require notification to the Regulator, and where authorisation requirements and standard conditions can manage risks.
- It is proposed the GT Regulations would prescribe classes of NDs by reference to matters such as:
    - the type or types of GMOs
    - the type or types of dealings
    - circumstances such as the purpose or location of the dealings (including physical containment), or the training and expertise required of persons undertaking the dealings
    - matters the rules may specify for ND classes.
- The GT Regulations as proposed to be amended would prescribe authorisation requirements for NDs. Dealings would only be authorised NDs if the authorisation requirements are met.
- The policy intent is that there will be two groups of NDs:
    - those that must be notified to the Regulator prior to the dealing commencing, 'pre-notified notifiable dealings', and
    - those that do not have an authorisation requirement of pre-notification but must be notified to the Regulator within a specified timeframe after the proponent has received an Institutional Biosafety Committee (IBC) Record of Assessment, 'post-notified notifiable dealings'.
- Similarly to permits, conditions for all NDs would be prescribed in the draft Bill and rules to be made by the Regulator.

Pre-notified notifiable dealings

- These proposed classes of NDs differ from the current NLRDs. Pre- notified notifiable dealings would cover some GMO dealings that are currently authorised by licences, but for which standard conditions are suitable to manage risk and there is no need to assess applicant suitability. Table 4 outlines the classes currently under consideration.
- It is proposed that the GT Regulations would prescribe the authorisation requirement that the Regulator must be notified before these dealings are undertaken. The GT Regulations would prescribe:
    - who must notify
    - the period in which they must notify
    - the form of notification which could be a form approved by the Regulator
    - any documents that must be included as part of the notification.
- An IBC Record of Assessment is not required for these types of dealings as these dealings are assessed by another regulator or agency.

Post-notified notifiable dealings

- It is proposed that in broad terms dealings that are currently NLRDs will become classes of 'post-notified notifiable dealings'.
- Similar to current NLRDs, post-notified notifiable dealing classes currently being considered include contained dealings and these dealings would be required to be assessed by an IBC. The GT Regulations as proposed to be amended would specify any actions the IBC is required to undertake.
- A condition in the draft Bill would require notification of these classes of dealings to the Regulator, with further details specified in the rules published by the Regulator.
- ND classes are being developed for post-notifiable dealings equivalent to current NLRDs and for two classes of pre-notified notifiable dealings. Table 4 sets out the types of matters currently intended to be specified in regulations and rules for all ND classes. This detail is subject to change during further development and legislative drafting.

Question 9 – Do you have concerns in relation to the proposed notifiable dealings classes?

Table 4: Matters to be specified in the GT Act, GT Regulations and rules for notifiable dealings

Draft Bill	GT Regulations	Rules

• Regulations may specify classes of NDs [subsection 74(1)]
• Regulations may provide for the rules to specify a matter in relation to the class [subsection 74(4)]
• Regulations may prescribe authorisation requirements [section 75]
• NDs are subject to conditions specified in rules [paragraph 75A(1)(b)]
• NDs are subject to statutory conditions [section 75B and, for post-notifiable dealings, section 75C]
	Post-notified notifiable dealings
	Classes ND1-3 would cover contained GMO dealings directly equivalent to current NLRDs:
	• **Class ND1** – plants and animals that do not contain a vector
	• This class is intended to correspond to the current 1.1 (a) and 2.1 (a), (aa) and (b) of Schedule 3.
	A dealing is not an ND1 dealing if it is a designated dealing
	• **Class ND2** – low risk host/vector systems with modifications that may increase capacity of the host or vector to cause harm, or with culture volumes above the relevant NND threshold (25L per vessel)
	• This class is intended to correspond to the current 2.1 (e), (f) and (h) of Schedule 3
	A dealing is not an ND2 dealing if it is a designated dealing
	ND2 would be limited to host vector/systems and genetic modifications specified in the rules.
	• **Class ND3** – other host/vector systems where any of the following apply:
	  ○ the host and the vector are non-pathogenic and very unlikely to cause harm, or
	  ○ the genetic modification carried by the host and/or the vector is unlikely to increase the ability of the host or the vector to cause harm, or
	  ○ the dealings involve virions of a replication defective vector, and the combined properties of
		For classes ND1-3 the rules would specify parameters such as:
		• host/vector systems considered low risk (if applicable)
		• genetic modifications considered low risk
		• minimum containment levels according to the type of organism (host), vector and genetic modification, or other containment requirements for transport, storage and disposal of GMOs.
		For the statutory condition in section 75C, the rules would specify notification requirements, including timing and information to be notified.
		Common conditions for ND1-3
		• Record-keeping obligations of the accredited organisation
		• Other notification obligations of the accredited organisation, e.g. reporting unintended effects of the GMO dealings.

Draft Bill	GT Regulations	Rules
	the host (if any), vector and donor nucleic acid are unlikely to cause harm. • This class is intended to correspond to 1.1 (c), 2.1 (c), (d), (g), (i)-(m) and 2.2 of Schedule 3 A dealing is not an ND3 dealing if it is a designated dealing **Authorisation requirements for ND1-3** • The person undertaking the dealing is an accredited organisation or a person engaged by the accredited organisation (e.g. waste management companies) • The dealings are covered by a Record of Assessment from the accredited organisation's Institutional Biosafety Committee (IBC) • The dealing is undertaken no later than 5 years after the date that the IBC makes its assessment.	
	Pre-notified notifiable dealings Classes ND4 and 5 would cover GMO dealings that currently must be licensed, but a lesser level of oversight is warranted because they pose low risk and/or other regulators manage key risks: • **Class ND4** – Commercial supply of veterinary vaccines subject to an authorisation of the Australian Pesticides and Veterinary Medicines Authority. A dealing is not an ND4 dealing if it is a designated dealing	**Conditions for ND4-5** • ND4 – Conditions may be required to further restrict this class. • ND5 – conditions would primarily be related to Transport, Storage and Disposal • ND5 - Must comply with conditions of permit issued under the *Biosecurity Act 2015*

Draft Bill	GT Regulations	Rules

	• **Class ND5** – Import of bulk grain for processing (contained), where:
	  ○ the GMO has been approved in the country of origin, and
	  ○ import of the bulk grain is authorised under a permit issued by the Department of Agriculture, Fisheries and Forestry
	  ○ the grain is to be de-vitalised.
	Authorisation requirements
	• Notification of dealings to the Regulator prior to the dealings being undertaken, including timing and information to be notified.
	• Additional authorisation requirements may be prescribed for each pre-notified notifiable dealings class.	

Non-notifiable dealings

- The draft Bill would provide for the new authorisation pathway for NNDs. This pathway is intended to operate similarly to current exempt dealings (as set out in the current GT Regulations at Regulation 6), and it is proposed that dealings that are currently exempt dealings will fall into this authorisation pathway.
- The GT Regulations as proposed to be amended would prescribe classes of NNDs by reference to matters such as:
    - the type or types of GMOs
    - the type or types of dealings which may be undertaken
    - the location where dealings may be undertaken
    - training and expertise of persons undertaking the dealings
    - matters the rules may specify for NND classes.
- NND classes would only include dealings not intentionally released into the environment, similarly to the current exempt dealings.
- In contrast to other authorisation pathways, but consistent with current exempt dealings, there would not be any conditions for NNDs.
- Table 5 sets out the types of matters currently intended to be specified in regulations and rules for all NND classes.

Question 10 – Do you have concerns in relation to the proposed non-notifiable dealings classes?
Question 11 – Do you consider the language 'not involving intentional release into the environment' appropriate for NNDs?

Table 5: Matters to be specified in the GT Act, GT Regulations and rules for non-notifiable dealings

<table>
<tr><th>Act</th><th>Regulations</th><th>Rules</th></tr>
<tr><td rowspan="2">• Regulations may specify classes of non-notifiable dealings [subsection 75E(1)]
• Regulations may provide for the rules to specify a matter in relation to the class [subsection 75E(4)]</td><td colspan="2">For all NND classes
Classes NND1-4 would cover contained GMO dealings directly equivalent to current exempt dealings:</td></tr>
<tr><td>• Class NND1 – Dealings involving low risk host/vector systems with low risk modifications and less than 25L in each vessel
• Dealings do not involve the intentional release of a GMO into the environment
A dealing is not an NND1 dealing if it is a designated dealing
This class will correspond to Items 4 and 5 of Part 1 of Schedule 2</td><td rowspan="2">For classes NND1-3 the rules would specify parameters such as:
• Species or host/vector systems considered low risk (initial list would replicate current table at Part 2 of Schedule 2, with minor adjustments as needed)
• Genetic modifications considered low risk (those that meet the requirements of Items 4 and 5 of Part 1 of Schedule 2, with minor adjustments as needed).
NND1-4 will not have any conditions</td></tr>
<tr><td></td><td>• Class NND2 – Dealings with GM animals that have genetically modified somatic cells, or to introduce genetically modified somatic cells into an animal
• Dealings do not involve the intentional release of a GMO into the environment
A dealing is not an NND2 dealing if it is a designated dealing
This class is intended to correspond to Items 3 and 3A of Part 1 of Schedule 2, with an additional dealing of introducing GM somatic cells into animals (authorised as notifiable low risk dealings under the current Act)</td></tr>
</table>

Act	Regulations	Rules
	• **Class NND3** – Dealings with *C. elegans* with low risk modifications. • Dealings do not involve the intentional release of a GMO into the environment A dealing is not an NND3 dealing if it is a designated dealing **This class is intended to correspond to Item 2 of Part 1 of Schedule 2**	
	• **Class NND4** – Introducing genetically modified human somatic cells into a human for somatic cell therapies e.g. CAR-T. • Dealings do not involve the intentional release of a GMO into the environment • This is a new class • A dealing would not be an NND4 dealing if i. the somatic cells contain a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells (unless the only viral vector present in the somatic cell is the viral vector that was used to modify the somatic cell); or ii. the somatic cells could, as a result of the modification by gene technology, give rise to an infectious agent; or iii. the somatic cells contain residual infectious viral vector; or iv. It is a designated dealing **This is a new class**	Rules may be prescribed to restrict this class (for example the viral vectors which may be used to modify the somatic cells)

GMO Register

- Recommendation 11 of the Review suggested that changes be made to improve the utilisation of the GMO Register, as this reduced regulatory burden for low-risk dealings with a history of safe use.
- While the draft Bill retains current policy settings in so far as the GMO Register is a legislative instrument, the draft Bill proposes to improve the utility of the register by providing for additional criteria to be prescribed in the Regulations, which would allow the Regulator to add items on their own initiative.
- Based on consideration of risk, it is proposed that the authorisation of gene-edited plants will be via the GMO Register.
- The proposed intent is to limit gene-edited plants that may be included on the GMO Register to those with cisgenic modifications, deletions and introduction of naturally occurring transfer DNA (T-DNA) sequences from Agrobacterium spp. Modified genes do not need to be inserted at the native locus.
- Retaining the GMO Register as a legislative instrument provides for appropriate consultation and transparency on when these items are added to the GMO Register.

Certification and accreditation

- Existing Division 3 of Part 3 (regulations for certification and accreditation) would no longer be required, as these matters would be set out in the draft Bill and Rules to be issued by the Regulator.

Application fees

- The draft Bill would enable application fees to be specified in regulations. As noted in the consultation paper for the draft Bill, a separate consultation process would be undertaken should a decision be made to set in motion the introduction of cost recovery.

Part 4 – Gene Technology Technical Advisory Committee

Currently

- Division 1 of Part 4 of the GT Regulations prescribes conditions for appointment of GTTAC members and expert advisors. These include terms of appointment, resignation processes, disclosure of interests and leaves of absence.
- Division 2 of Part 4 of the GT Regulations prescribes committee procedures. These include governance and administration of meetings.
- Division 3 of Part 4 of the GT Regulations prescribes the operation of sub-committees.

Proposed amendments

- No changes are proposed to Part 4 as part of these reforms.

Part 5 – Gene Technology Ethics and Community Consultative Committee

Currently

- This part prescribes conditions for appointment of the Gene Technology Ethics and Community Consultative Committee members and expert advisors, committee procedures and the operation of sub-committees.

Proposed amendments

- Minor administrative amendments are proposed to ensure consistency between the draft Bill and the GT Regulations, for naming of the committee.

Part 7 – Miscellaneous

Currently

- This part currently contains 4 regulations relating to reviewable state decisions, review of decisions, the record of GMO dealings and inspector identity cards.

Proposed amendments

- No substantive amendments to the GT Regulations are proposed as part of these reforms regarding reviewable state decisions or reviewable decisions.
- The requirement for inspector identity cards to display a recent photograph will be repealed as this requirement will be contained in the draft Bill.
- Existing regulation 39 prescribes particulars of NLRDs that are part of the Record of GMO dealings. This will be repealed and replaced with a new regulation relating to NDs.

Part 8 – Transitional Provisions

Currently

- Transitional provisions relating to the technical regulation amendments made earlier in 2025 are currently included in the GT Regulations and will be retained unchanged.

Proposed amendments

- Transitional provisions for the amended Scheme would primarily be provided in the draft Bill, however it is possible some transitional matters would be addressed in regulations.

Schedules 1, 1A and 1B

Current

- For the purposes of the current GT Regulations 4, 4A and 5, these schedules prescribe techniques that are not gene technology, and organisms that are and are not GMOs.

Proposed amendments

- As described above, current GT Regulations 4, 4A and 5 will be replaced with new regulations for the purposes of sections 12B and 12C of the draft Bill.
- Minor amendments to these existing schedules may be required as a result of the proposed exclusion of human beings from the definition of a GMO.

Schedule 2 – Dealings exempt from licencing

Currently

- Schedule 2 prescribes dealings that are currently exempt from licencing, including specific host/vector systems that are exempt from licencing.

Proposed amendments

- As described above, it is proposed that schedule 2 will be revoked and replaced by regulations to describe classes of NNDs, and related rules made by the Regulator.

Schedule 3 – Notifiable low risk dealings

Current

- Schedule 3 currently described the containment requirements for NLRDs.

Proposed changes

- As previously highlighted, Schedule 3 will be revoked and replaced by regulations to describe the classes of NDs and related rules made by the Regulator.