Proposed amendments to the Gene Technology Regulations 2001

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

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Guest speaker

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Acknowledgment of Country

In the spirit of reconciliation, the Department of Health, Disability and Ageing acknowledges the Traditional Owners and Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today.

Welcome

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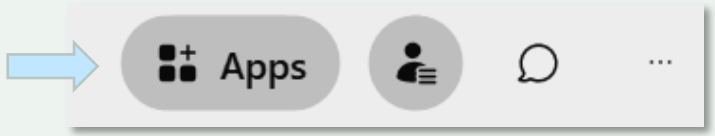

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Our team

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National Gene Technology Scheme

- The **National Gene Technology Scheme** (the Scheme) was established in 2000.
- The Scheme is authorised through the **Gene Technology Agreement 2001**, and is comprised of Commonwealth, state and territory legislation, including the:

Gene Technology Act 2000 (the Act)

Gene Technology Regulations 2001

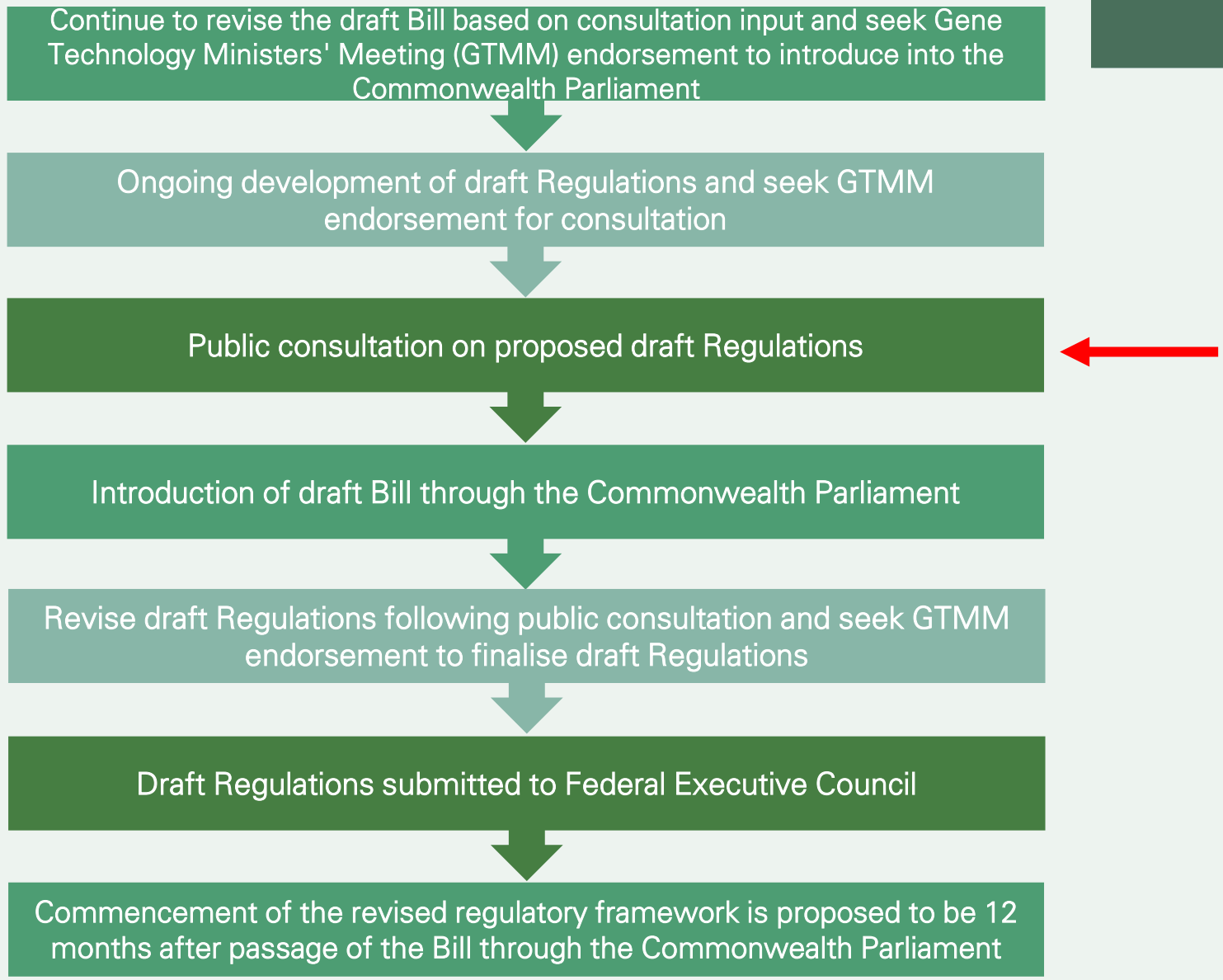
Corresponding state and territory legislation

- The object of the **Act** 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 genetically modified organisms (GMOs).

Why legislative reforms?

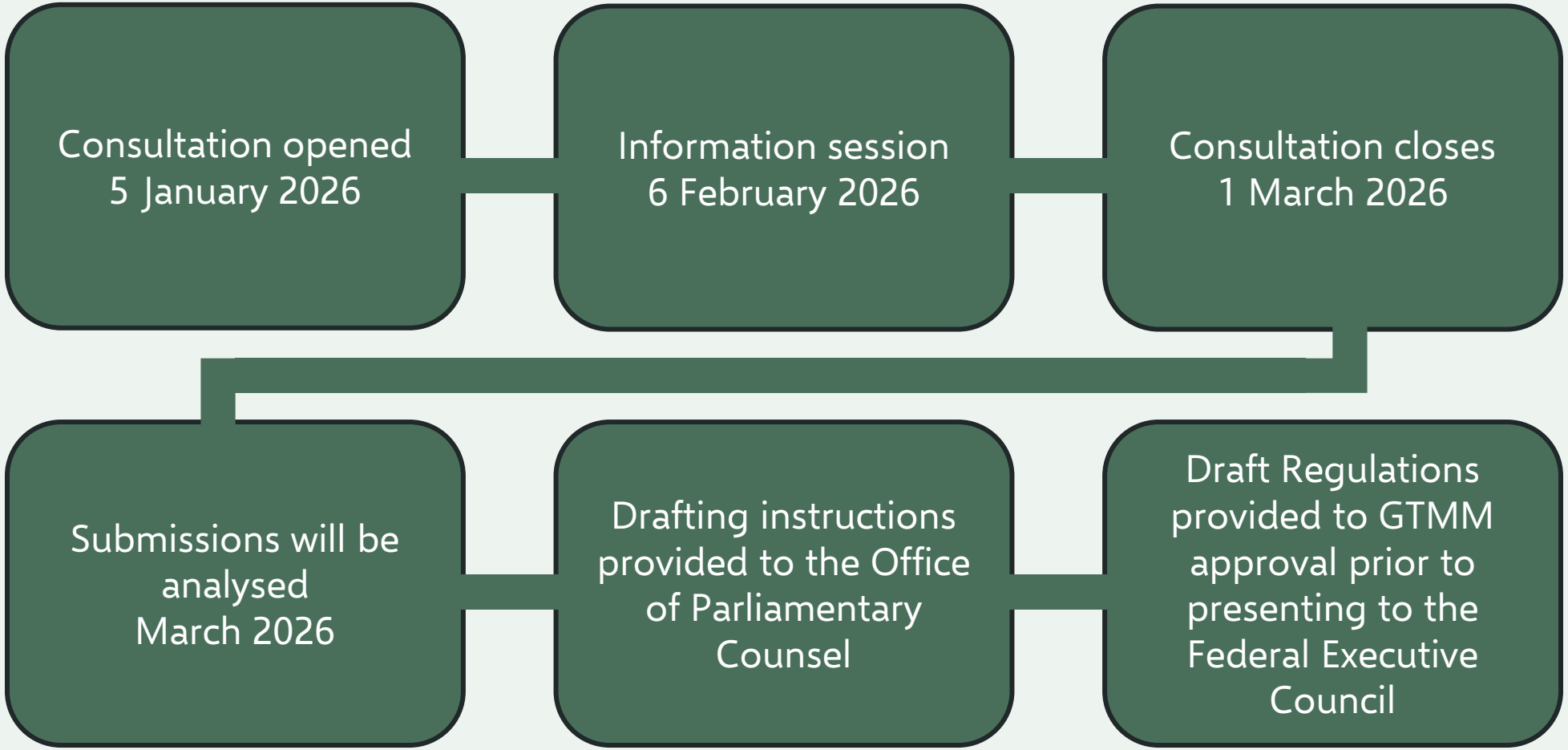
1. Reduce regulatory burden through streamlining processes and current regulatory requirements, where appropriate.
2. Maintain overarching protection goals in line with the object of the Scheme – to protect human health and safety and the environment.
3. Foster innovation and increase the competitiveness of the Australian biotechnology sector by providing clarity and certainty in the regulatory framework.
4. Introduce a new system of authorisations that allow treatment of GMOs according to their level of risk and introduce flexibility to respond to rapidly evolving advances in the field of gene technology and its application.

Where are the reforms up to?



Note, proposed Rules will be subject to a separate consultation process

Regulations consultation timeline



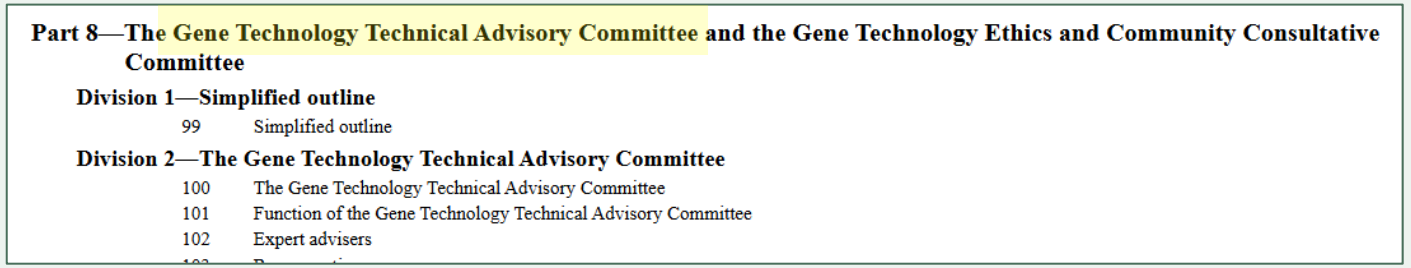
What are we proposing to change?

1. Structure of the Regulations
2. New and updated definitions
3. How are we reducing regulatory overlap?
4. Authorisation pathways
5. Other minor amendments

1. Proposed structure changes

- Currently, some regulations do not appear in the same order as their empowering provisions in the Act.
- The proposed changes intend for the Regulations to mirror the structure of the Act.
- For example, currently:

The Act (part 8)



Part 8—The Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee

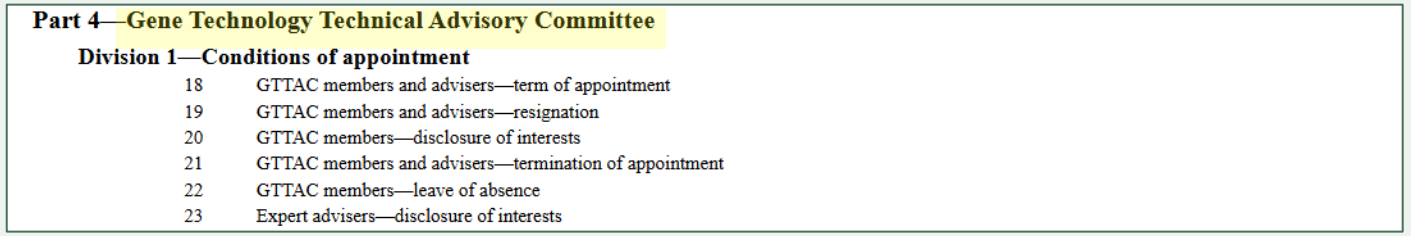
Division 1—Simplified outline

99 Simplified outline

Division 2—The Gene Technology Technical Advisory Committee

100 The Gene Technology Technical Advisory Committee
101 Function of the Gene Technology Technical Advisory Committee
102 Expert advisers

The Regulations (part 4)



Part 4—Gene Technology Technical Advisory Committee

Division 1—Conditions of appointment

18 GTTAC members and advisers—term of appointment
19 GTTAC members and advisers—resignation
20 GTTAC members—disclosure of interests
21 GTTAC members and advisers—termination of appointment
22 GTTAC members—leave of absence
23 Expert advisers—disclosure of interests

- Relocation and renumbering of the regulations will ensure consistency across legislation.

Proposed changes to definitions

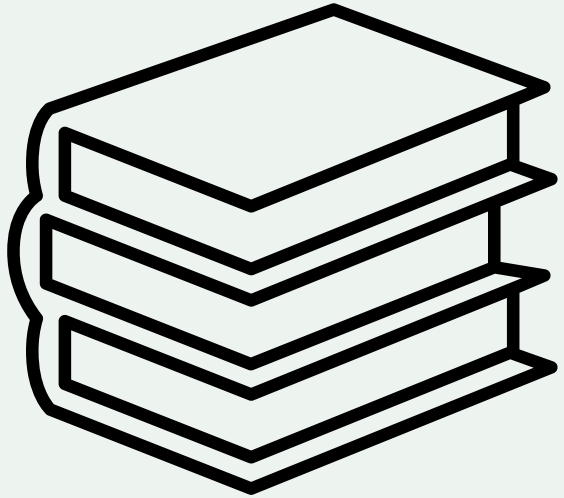
- The Regulations provide definitions for certain terms used throughout gene technology legislation.
- New and changed definitions have been added to reduce ambiguity and increase precision.

New definitions:

- Contained dealing
- Field trial
- Gene drive dealing
- Novel dealing
- Record of Assessment
- Specified entities.

Changed definitions:

- Limited and controlled release
- Inspector
- Physical containment level
- Therapeutic dealing.



How are we reducing regulatory overlap?

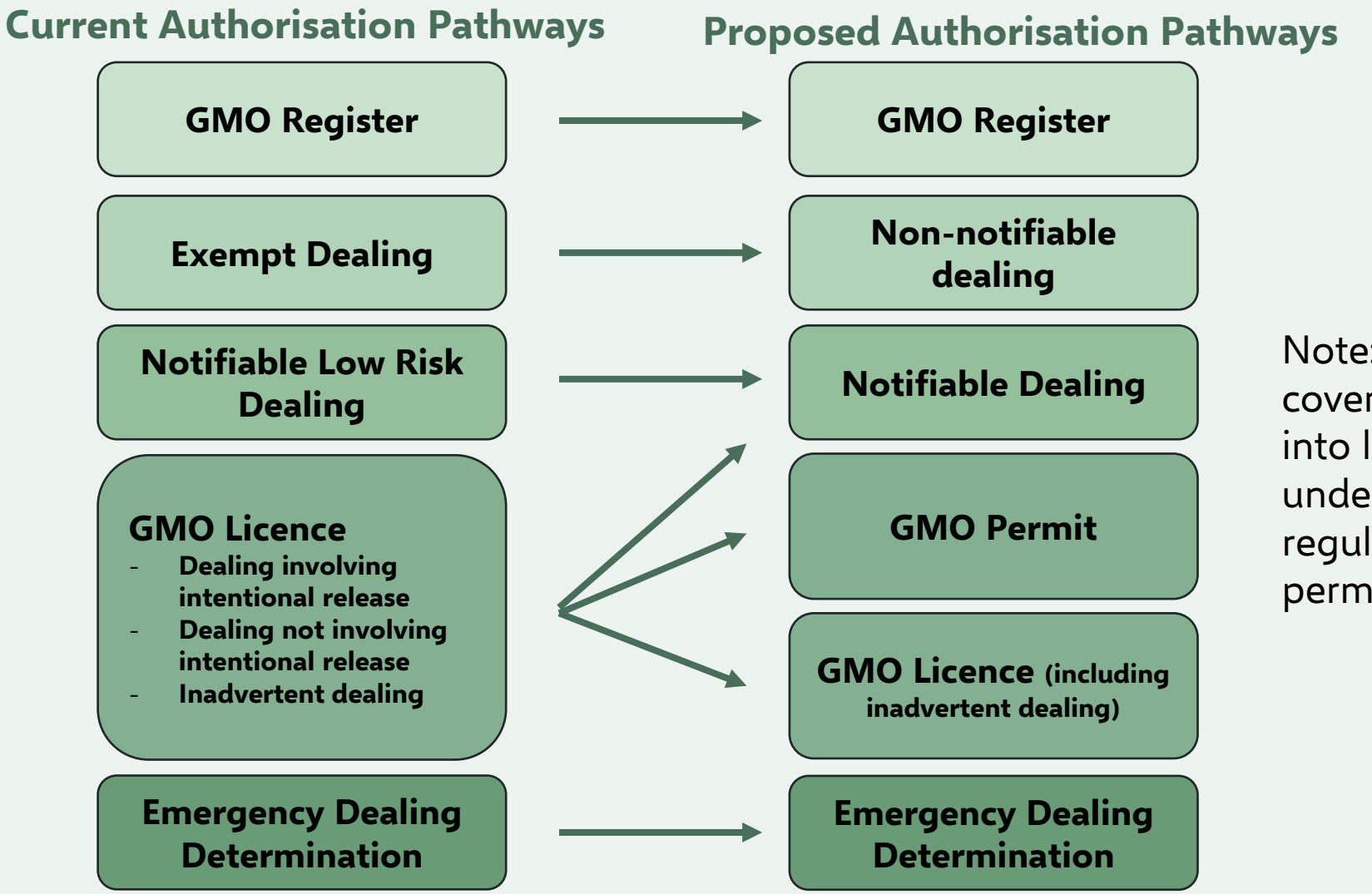
- The draft Bill requires the **Commonwealth Minister** and the **Gene Technology Regulator** to be satisfied about risks for particular decisions relating to GMOs.
- The Amendment Bill (subsection 15A(2)) poposes that this is not required, **if**, the risks are prescribed in the **Regulations** and 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.
- Importantly, risks not **required** to be assessed, does not preclude these risks from being considered if deemed necessary.

Authorisation pathways

- Major changes to existing authorisation pathways were outlined during consultation on the draft Bill.
- It is proposed that entirety of Part 3 and Schedules 2 & 3 of the Regulations will be revoked.
- The Amendment Regulations will specify classes of GMO dealings using new risk proportionate **authorisation pathways**.

- Risk proportionate regulation is common in modern regulatory schemes, maintaining strong safeguards against high-risk dealings, whilst enabling efficiency for low-risk dealings.
- The Gene Technology Regulator will make rules to specify further requirements to restrict the GMO classes.

What are the new ‘risk-tiers’?



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

GMO licences

- A GMO licence is the **default authorisation pathway.**
- A dealing will require a **licence** if it is not:
    - a permit dealing
    - a notifiable dealing (ND)
    - a non-notifiable dealing
    - on the GMO register
    - authorised through an Emergency Dealing Determination
- **Designated dealings** are dealings that may appear to be captured within the above classes but will always require a licence.
- The GT Regulations will prescribe:
    - consultation and assessment requirements using risk-based criteria
    - alternate periods for applications as necessary (intended only for licences)

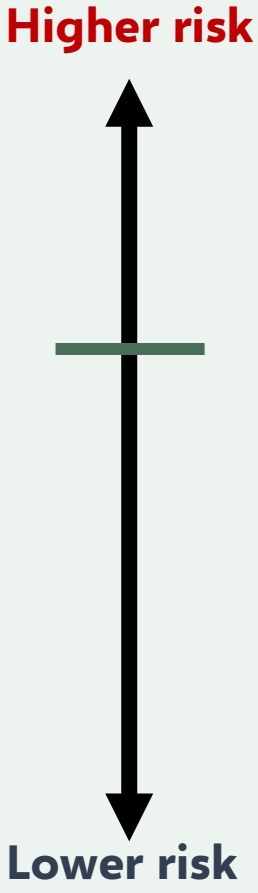
Permit Dealings

- Alternative pathway to GMO licences.
- Used when standard conditions are well established and known to manage risks effectively.
- Intends to provide streamlined assessment (30 business days) for well understood dealings.

Class P1	Class P2	Class P3	Class P4
Field trials with plants that have been modified by gene technology	Clinical trials involving a GMO for therapeutic use	Administering a GMO for therapeutic use to patients under TGAs Special Access Scheme	Introducing genetically modified somatic cells into a patient

*note – each of these classes have specific conditions that you can find in the consultation paper

- Remember, a dealing is not a **permit dealing** if it is a **designated dealing**.



Notifiable dealings (NDs)

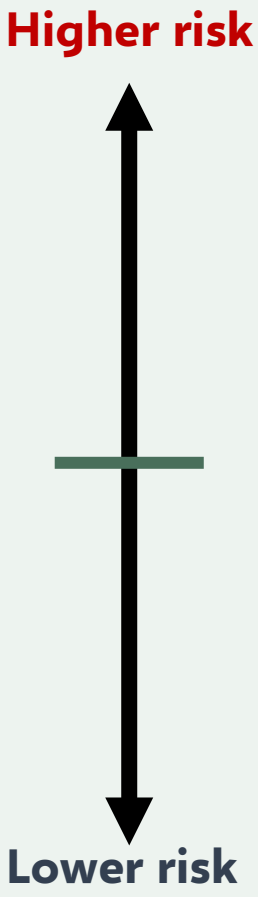
- Replacing the existing Notifiable Low Risk Dealings (NLRDs).
- Notification to the Gene Technology Regulator is **required.**
- Authorisation requirements and standard conditions manage risk.
- Proposed policy intent for 2 groups of notifiable dealings.

Post-notified notifiable dealings

- Regulator notification **after** commencement
- Require Institutional Biosafety Committee (IBC) assessment
- Regulator rules will prescribe conditions:
  - who must notify
  - the period in which they must notify
  - form of notification
  - any documents required in notification

Pre-notified notifiable dealings

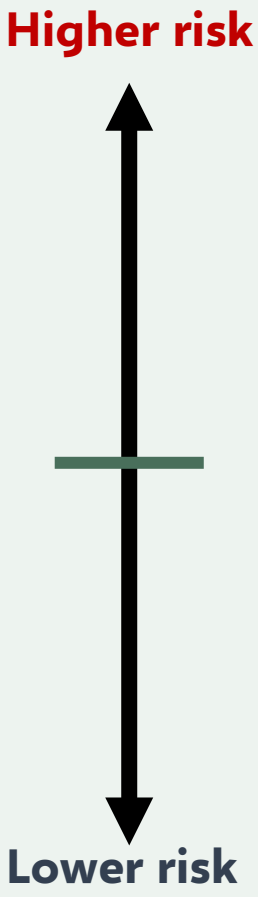
- Regulator notification **prior** to commencement
- Would cover some currently licenced dealings
- Regulations will prescribe:
  - who must notify
  - the period in which they must notify
  - form of notification
  - any documents required in notification



Post-notified notifiable dealings (ND1-3)

- GMO dealings equivalent to current **NLRDs.**
  - **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.
  - **ND2** – low risk host/vector systems with modifications that may increase the capacity of the host or vector to cause harm, or with culture volumes above the relevant threshold (25L per vessel).
    *This class is intended to correspond to the current 2.1 (e), (f) and (h) of Schedule 3
  - **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 GM is unlikely to increase the ability of the host and vector to cause harm, or
    - the dealings involve virions of a replication deficient vector, and the combined properties of the host (if any), vector and donor nucleic acid are unlikely to cause harm.

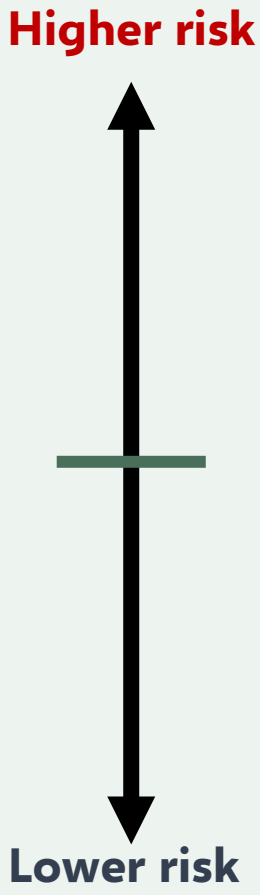
    *This class is intended to correspond to 1.1 (c), 2.1 (c), (d), (g), (i)-(m) and 2.2 of Schedule 3



- These dealings must be undertaken within 5 years of IBC assessment.

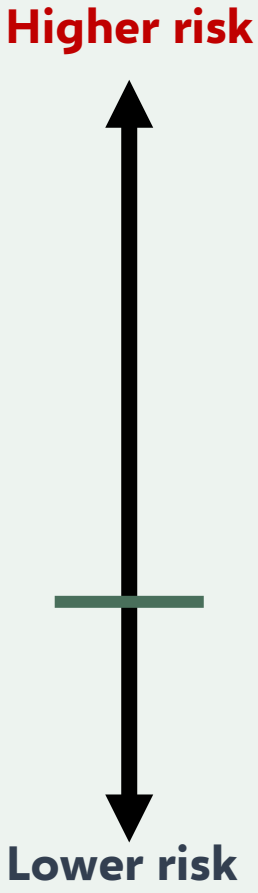
Pre-notified notifiable dealings (ND4-5)

- Contains GMO dealings that are **currently licensed** but have been identified as low risk and or other regulators manage key risks.
    - **ND4** – commercial supply of veterinary vaccines subject to an authorisation by the Australian Pesticides and Veterinary Medicines Authority.
    - **ND5** – import of bulk grain for processing (contained), where:
        - the GMO has been approved in the country of origin; and
        - import of bulk grain is authorised under a permit issued by the Australian Government Department of Agriculture, Fisheries and Forestry; and
        - the parent species of the grain is of a kind prescribed in the rules; and
        - the grain is devitalised.



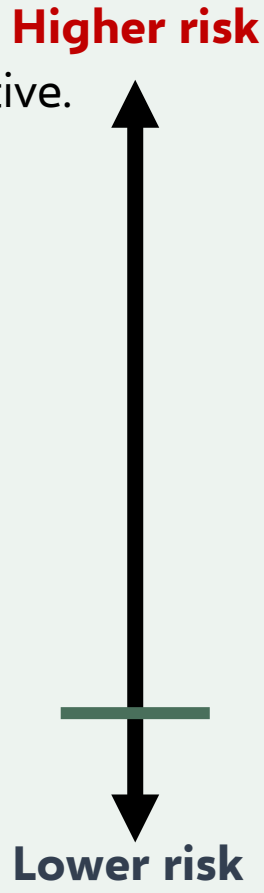
Non-notifiable dealings (NNDs)

- Intends to operate similarly to the current '**exempt dealings**'
- Will only include dealings not intentionally released into the environment.
- Unlike other authorisation pathways, there will be no conditions for NNDs.
    - **NND1 –** Dealings involving low risk host/vector systems with low-risk modifications and less than 25L in each vessel. *corresponds to Items 4 and 5 of Part 1 of Schedule 2
    - **NND2 –** Dealings with GM animals that have genetically modified somatic cells, or to introduce genetically modified somatic cells into an animal.
      * corresponds predominantly to Items 3 and 3A of Part 1 of schedule 2 as well as an NLRD dealing
    - **NND3 –** Dealings with *C. elegans* with low-risk modifications.
      * corresponds to Item 2 of Part 1 Schedule 2
    - **NND4 –** Introducing genetically modified human somatic cells into a human for somatic cell therapies such as CAR T-Cell therapy. * this is a new class
- A dealing is not a **non-notifiable dealing** if it is a **designated dealing**.



GMO Register

- Intended to be used to reduce regulatory burden for low-risk dealings.
- The Regulations to enable the Gene Technology Regulator to add items on their own initiative.
- New proposal for gene-edited plants to be included the **GMO Register**.
- Initially limited to gene-edited plants produced through:
    - cisgenic mutations
    - deletions
    - introduction of naturally occurring DNA (T-DNA) sequences from *Agrobacterium spp*.
- Note: Criteria may change over time.
- Supporting horticultural industries.

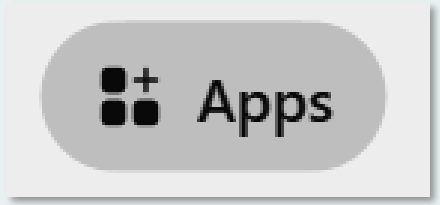


Other minor amendments

- Other minor administrative amendments are proposed to be made to Part 5 of the current Regulations.
- Transitional provisions will mostly be contained in the Amendment Bill; however, some transitional regulations may be required.
- Minor changes to Schedules 1, 1A and 1B may be required in response to the proposed exclusion of human beings from the definition of a GMO.
- Schedules 2 and 3 will be repealed and replaced with new regulations for the purpose of NDs and NNDs as earlier described.

How did we go?

Take a moment to complete our survey, and we'll be back with your shortly for Q&A



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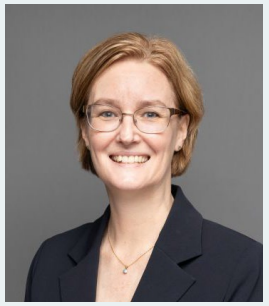

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Information and resources

Department of Health, Disability and Ageing website	https://www.health.gov.au/
National Gene Technology Scheme	https://www.genetechnology.gov.au/
Office of the Gene Technology Regulator	https://www.ogtr.gov.au/about-ogtr
Consultation hub	https://consultations.health.gov.au/best-practice-regulation/draft-amendments-to-the-gene-technology-regulation/
Gene Technology Regulations 2001	https://www.legislation.gov.au/F2001B00162/latest/text

Contact us

For any further queries please reach us by

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Australian Government
Department of Health, Disability and Ageing

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