Australian Government

National Gene Technology Scheme

An Australian, State and Territory Governments Collaboration

Public consultation on the Draft Gene Technology Amendment Bill

Acknowledgement of Country

In the spirit of reconciliation, the Department of Health and Aged Care acknowledges the Traditional 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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Public consultation on the Draft Gene Technology Amendment Bill

Sarah Syme
Assistant Secretary
Regulatory Engagement Branch
Australian Government Department of Health and Aged Care

Kirsteen Magee
Gene Technology Policy and Governance Section
Regulatory Engagement Branch
Australian Government Department of Health and Aged Care

The 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; and
  - 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.

Third Review of the Scheme

27 recommendations to future proof and modernise the Scheme

Legislative reforms to increase efficiency, flexibility and ensure regulatory capture of advancements in technology

Consultation and next steps

Public Consultation on the draft Bill

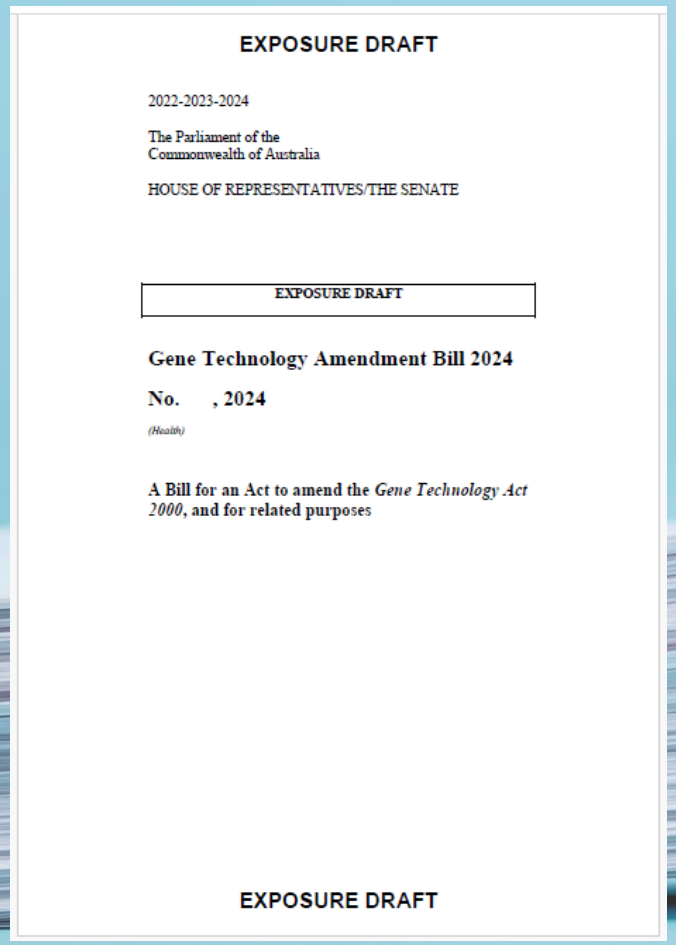
13 September 2024 – 8 November 2024

Gene Technology Ministers' Meeting (GTMM) approval

Introduction to Parliament

Navigating the consultation package

Exposure Draft



EXPOSURE DRAFT

2022-2023-2024

The Parliament of the
Commonwealth of Australia

HOUSE OF REPRESENTATIVES/THE SENATE

EXPOSURE DRAFT

Gene Technology Amendment Bill 2024

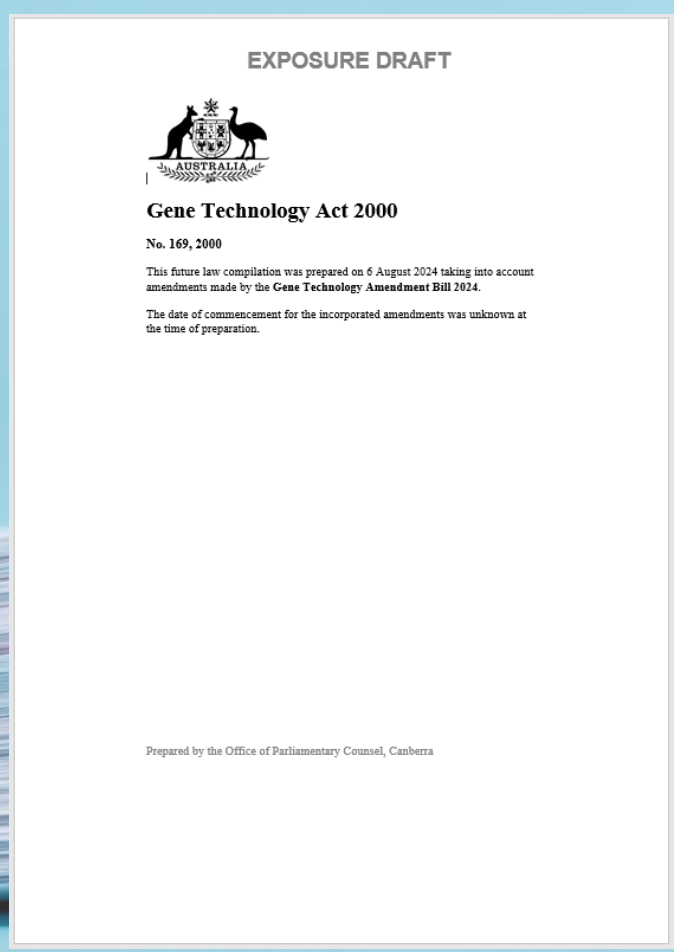
No. , 2024

(Health)

A Bill for an Act to amend the *Gene Technology Act 2000*, and for related purposes

EXPOSURE DRAFT

Future Law Compilation



EXPOSURE DRAFT

AUSTRALIA

Gene Technology Act 2000

No. 169, 2000

This future law compilation was prepared on 6 August 2024 taking into account amendments made by the **Gene Technology Amendment Bill 2024**.

The date of commencement for the incorporated amendments was unknown at the time of preparation.

Prepared by the Office of Parliamentary Counsel, Canberra

Consultation Paper

Australian Government
Department of Health and Aged Care

Consultation Paper

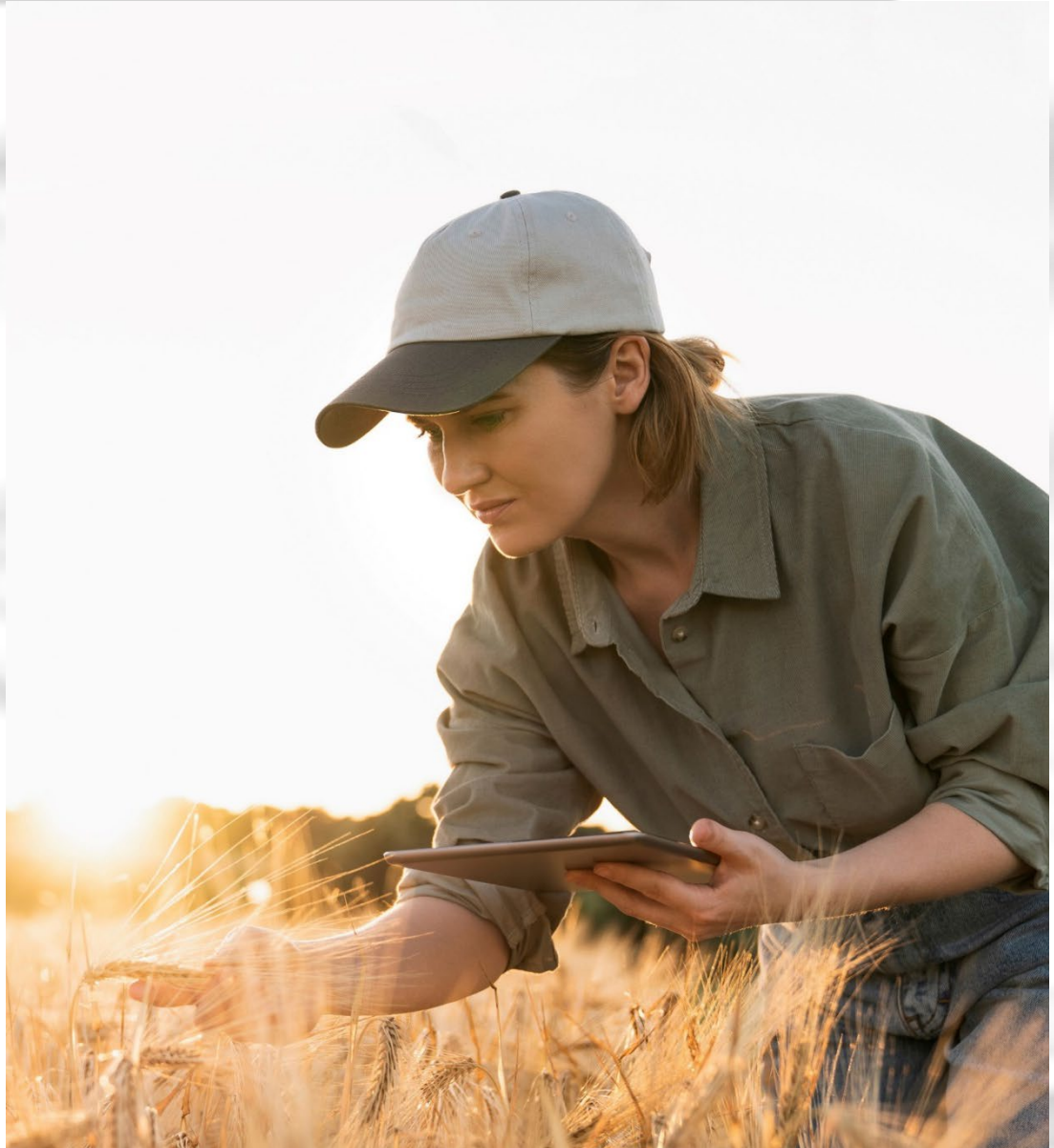
Draft Gene Technology Amendment Bill

Benefits of the reforms

1. Maintain overarching protection goals in line with the object of the Scheme – to protect human health and safety and the environment
2. Foster innovation and increase the competitiveness of the Australian biotechnology sector by providing clarity and certainty in the regulatory framework
3. 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
4. Reduce regulatory burden through streamlining processes and current regulatory requirements, where appropriate

Regulatory intersections with the Scheme

1. Agriculture
2. Health
3. Industry
4. Environment



Chapter 1: Scope of Regulation

Review recommendations 4 & 6

- Updating existing definitions to clarify the scope of regulation in light of ongoing advances;
- Amending the definition of ‘genetically modified organism’ to clarify that humans are not considered to be GMOs.

Proposed amendments to key definitions

‘deal with’; ‘gene technology’

and ‘genetically modified organism’

Changes are proposed to the definitions to recognise advances in technology since the Scheme commenced.

We are seeking your views on whether the proposed definitions provide enough clarity while remaining broad enough to prevent regulatory gaps.

Chapter 2: Risks considered under the Scheme

Review recommendation 21

- Clarify the intersection between the Gene Technology Regulator, other Commonwealth regulators and their legislation, including identifying any emerging areas where legislative or administrative changes can be made to reduce any unnecessary duplication

Proposed amendments

- address duplication in the assessment of risks posed by GMO dealings under different regulatory schemes; and
- clarify that the Minister and Regulator are not required to consider intended negative effects of a GMO on a specific weed, pest or pathogen.

We are seeking your views on whether the proposed subsection 15A provides a suitable way to manage regulatory overlap where risks are already considered and assessed by other regulatory schemes.

Chapter 3: Authorisation Pathways

Review recommendations 9 & 11

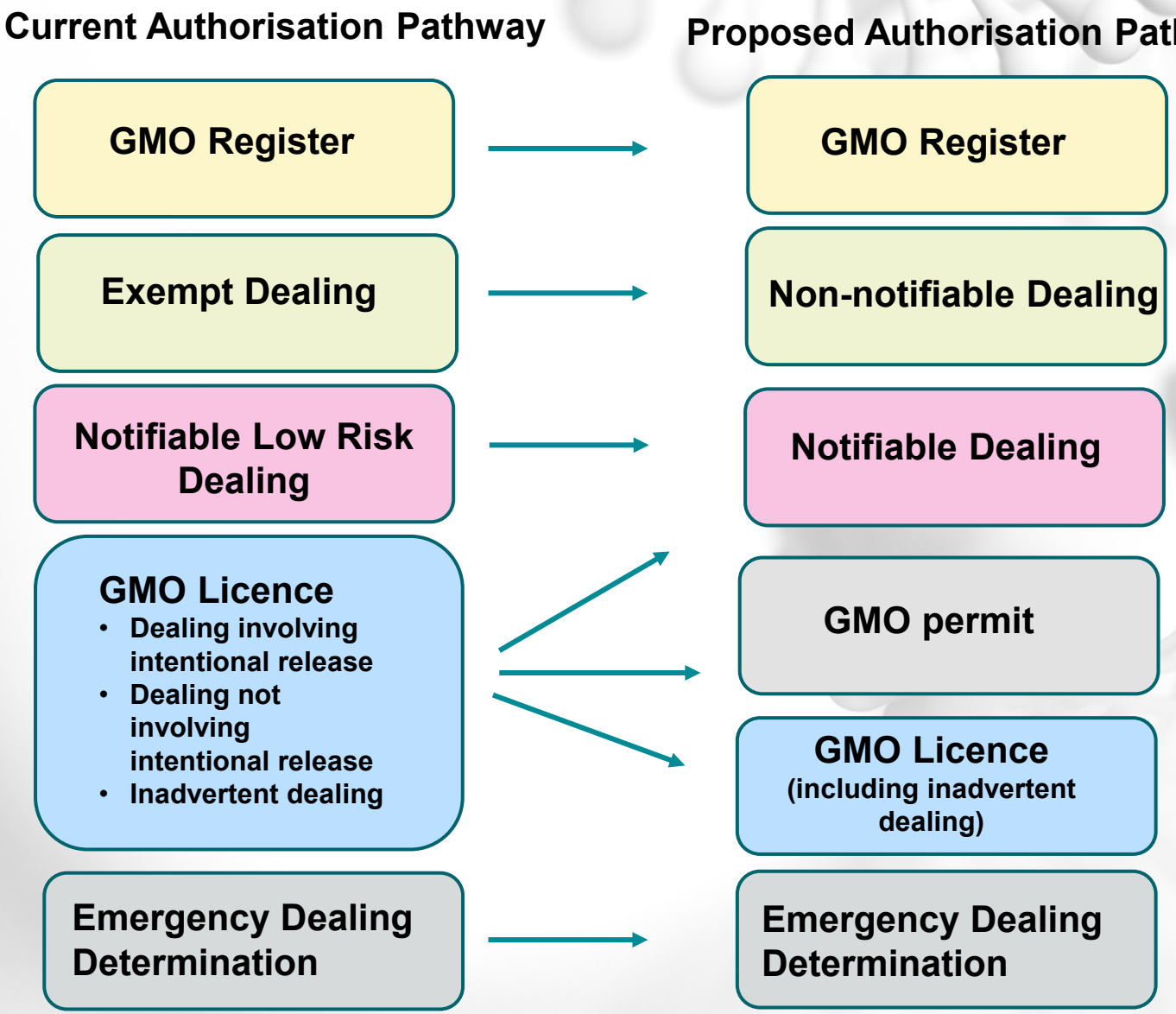
- Introducing additional risk tiering into the Scheme to facilitate flexibility and ensuring the level of regulation remains proportionate to risk;
- Making changes to better enable the GMO Register to be more effectively utilised within the Scheme.

Proposed amendments

- Changes to authorisation pathways under the Scheme; and
- Proposed amendments to provisions governing the GMO Register.

We are seeking your views on the proposed new authorisation pathways and the use of rules for notifiable dealings to enable the Regulator to respond to technological changes in a timely way.

Proposed Changes to Authorisation Pathways



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).

Chapter 4: Compliance, monitoring and enforcement

Review recommendation 12

- To ensure the Scheme's current monitoring and enforcement activities remain adequate:
  a) Regular reviews of these activities are undertaken;
  b) Regulatory requirements for working with gene technologies are widely communicated and known; and
  c) The scope and associated risks of 'DIY biology' activity continue to be monitored.

Proposed amendments

- Adopting standard monitoring, investigation and enforcement powers of the *Regulatory; Powers (Standard Provisions) Act 2014* (Cth);
- Retaining additional monitoring, investigation and emergency powers where required

We are seeking your views on the scope of the proposed new enforcement powers to support the risk tiering framework.

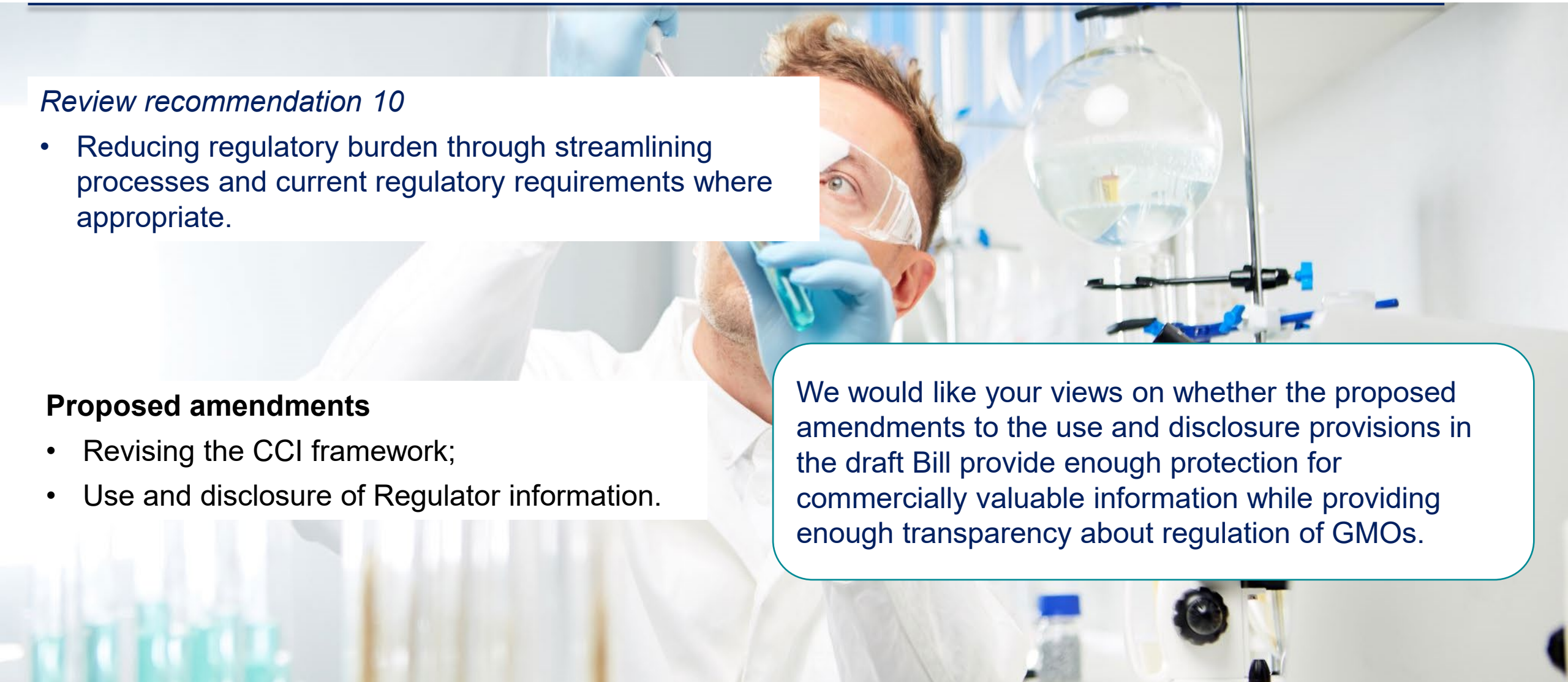
Chapter 5: Certification and Accreditation

Proposed amendments

- Introduce new offence provisions for breaches of conditions by accredited parties and holders of certification
- Including decision criteria for accreditation in the GT Act;
- Requirements for the holder of a certification

We are seeking your views on the underlying policy intent for amendments to certification and accreditation – noting that more detail on the criteria will be specified in the Rules and be part of a separate consultation process.

Chapter 6: Use and disclosure of information



Review recommendation 10

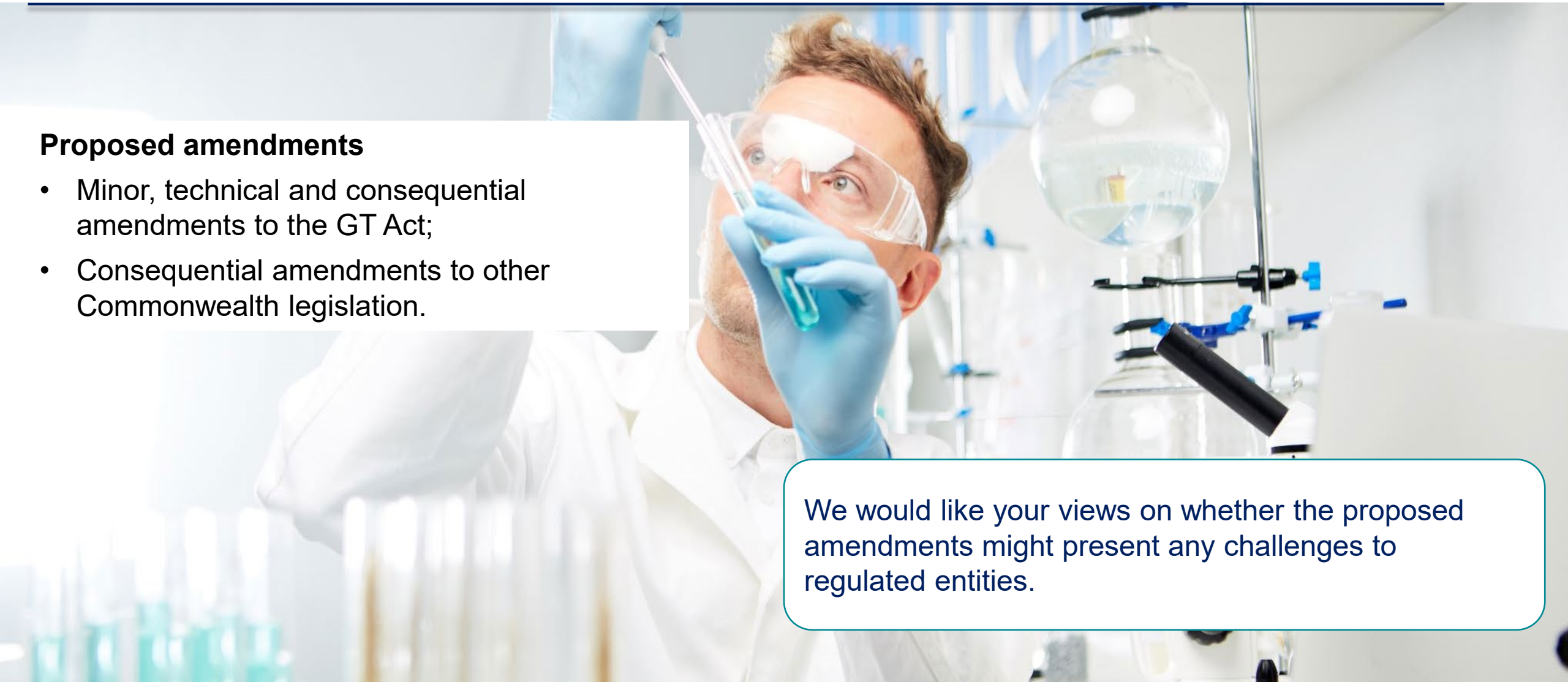
- Reducing regulatory burden through streamlining processes and current regulatory requirements where appropriate.

Proposed amendments

- Revising the CCI framework;
- Use and disclosure of Regulator information.

We would like your views on whether the proposed amendments to the use and disclosure provisions in the draft Bill provide enough protection for commercially valuable information while providing enough transparency about regulation of GMOs.

Chapter 7: Minor, Technical and Consequential Amendments



Proposed amendments

- Minor, technical and consequential amendments to the GT Act;
- Consequential amendments to other Commonwealth legislation.

We would like your views on whether the proposed amendments might present any challenges to regulated entities.

Streamlining Applications

Review recommendation 10

- Reducing regulatory burden through streamlining processes and current regulatory requirements where appropriate. For example, this may include streamlining facility certifications and application processes.

Proposed amendments

- Streamlining applications;
- Setting out statutory consideration periods and enabling the Regulations to prescribe alternate consideration periods.

Questions are now open

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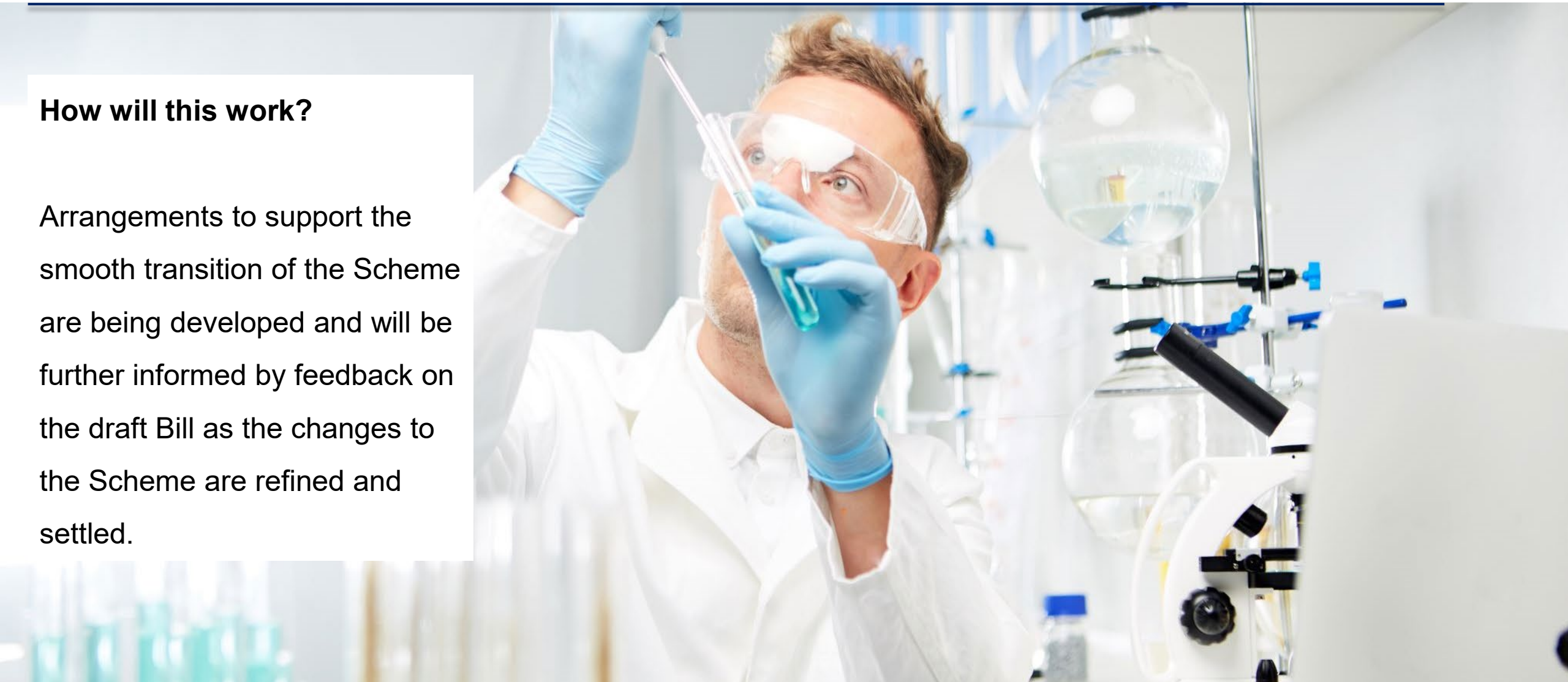
Chapter 8: Application, Savings and Transitional Provisions



How will this work?

Arrangements to support the smooth transition of the Scheme are being developed and will be further informed by feedback on the draft Bill as the changes to the Scheme are refined and settled.

Public consultation on the draft Bill

- Inform any required changes prior to presenting the final exposure draft to the Australian Parliament;
- Submit your views via the Consultation hub by **8 November 2024**, specifically considering:
    - Are additional amendments required to give effect to the decisions of the GTMM (and the intent of the Third Review recommendations)?

Questions?

Contact us by email at

gene.technology.implementation@health.gov.au

or telephone on +61 (2) 6289 2033

Information and resources

Department of Health and Aged Care website	https://www.health.gov.au/
National Gene Technology Scheme	https://www.genetechnology.gov.au/
Consultation hub	https://consultations.health.gov.au/best-practice-regulation/amendments-to-the-gene-technology-act-200
Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers	https://www.ag.gov.au/legal-system/publications/guide-framing-commonwealth-offences-infringement-notices-and-enforcement-powers.au)

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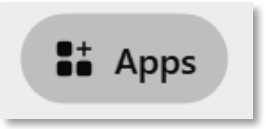

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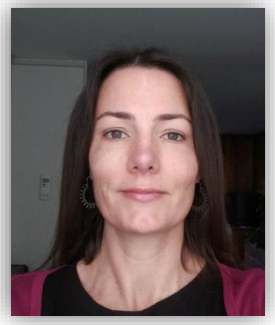
Sarah Syme
Assistant Secretary
Regulatory Engagement Branch
Department of Health and Aged Care

Kirsteen Magee
Gene Technology Policy and Governance Section
Department of Health and Aged Care

Dr Raj Bhula
Gene Technology Regulator

Neil Ellis
Assistant Secretary
Office of the Gene Technology Regulator



Dr Louisa Matthew
Director
Office of the Gene Technology Regulator

Contact us

Email

gene.technology.implementation@health.gov.au

Telephone:

- Ph: +61 (2) 6289 2033