Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

28 July 2023

The Hon Ged Kearney MP
Assistant Minister for Health and Aged Care
PO Box 6022
Parliament House
Canberra ACT 2600

Dear Minister

I am writing in response to your letter of expectations of 20 July 2023 to outline to you and the government, how I as the Gene Technology Regulator (Regulator), supported by the Office of the Gene Technology Regulator (OGTR), intend to achieve regulatory objectives, carry out regulatory functions, and exercise powers to protect the health and safety of people and the environment from risks posed by gene technology.

I appreciate your recognition of the independent role of the Regulator in administering the national scheme for the regulation of Genetically Modified Organisms (GMOs) in Australia. The scheme is governed by the Gene Technology Ministers' Meeting (GTMM) and centred on the *Gene Technology Act 2000* (GT Act) and corresponding state and territory legislation.

I am pleased to provide you with this Statement of Intent, which sets out how the expectations you have outlined contribute to the Government's policy priorities and objectives.

Regulatory Reform Agenda

As the Regulator, I will diligently exercise my functions as prescribed by the GT Act. I will contribute to the Regulatory Reform Agenda, including by:

- maintaining best practice regulation of gene technology
- applying the Resource Management Guide 128 Regulator Performance (available at https://www.finance.gov.au/government/managing-commonwealth-resources/regulator-performance-rmg-128) to regulatory functions to assess performance and engagement with stakeholders
- being transparent and accountable and supporting the reporting obligations of the Secretary of the Department of Health and Aged Care (the Secretary) as the Accountable Authority under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act) to achieve effective performance and governance of the OGTR.

I will, as a matter of priority, continue to support the GTMM and the department in implementing the legislative reforms agreed by GTMM, by providing technical and regulatory advice to ensure regulations remain commensurate with risk. The OGTR will also continue its program of work including streamlining processes to improve efficiency and exploring the feasibility of cost recovery arrangements.

Principles of regulator best practice

I will exercise my functions and powers in accordance with the principles of regulator best practice, particularly by:

- encouraging and supporting innovation and continuous improvement
- making decisions based on sound scientific evidence and within the legal considerations prescribed by the GT Act
- communicating clearly and consistently to maintain trust in the gene technology regulatory scheme and allow the OGTR to improve the way it operates
- engaging openly and transparently with OGTR's stakeholders.

Innovation and regulatory change

The OGTR continually monitors the operational environment including international practice and advancements in the regulation of GMOs to inform Australian policy and practice. Together with our engagement with other regulators and agencies involved in the regulation of GMOs and GM products, this allows the OGTR to respond flexibly to changes in the scientific and regulatory landscape and ensure regulatory burden remains commensurate with risk.

The OGTR provides high quality advice on the operation of the scheme. Guidelines, application forms and other guidance documents are available on the OGTR website and are subject to a regular review program to ensure they continue to set the best practice standards for safe work with GMOs.

Relationship with Minister, the Secretary and portfolio

Maintaining a productive working relationship with the department and the Minister responsible for gene technology is an important function of the Regulator. I will provide accurate and timely advice on significant issues relating to the regulation of GMOs and on other important matters for which the Government is accountable in parliament, including any relevant budgetary or operational issues. I will report to the Deputy Secretary, Health Products Regulation Group, on administrative matters, to support the Secretary in meeting obligations under the PGPA Act. Close collaboration with the department will also continue by providing scientific and regulatory advice during the development of policies relevant to gene technology.

I look forward to a collaborative and productive working relationship to achieve these expectations.

Yours sincerely

Dr Raj Bhula
Gene Technology Regulator

cc: The Hon Mark Butler MP, Minister for Health and Aged Care