



**The Hon Ged Kearney MP**  
**Assistant Minister for Health and Aged Care**

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Dear Dr Bhula

As the responsible Minister, I am writing to outline my expectations of how you, as the Gene Technology Regulator (Regulator) through the Office of the Gene Technology Regulator (OGTR), will achieve your regulatory objectives, carry out your regulatory functions, and exercise your powers to protect the health and safety of people and protect the environment. This Statement of Expectations will assist the Australian Government's commitment to effective governance and performance of regulatory functions by the OGTR, guided by the *Public Governance, Performance and Accountability Act 2013* (PGPA Act). It forms part of the Government's commitment to good corporate governance of regulatory bodies and reducing burden on business and the community.

The Government recognises and respects the independence of the Regulator and your responsibility for the regulatory oversight of GMOs within Australia, the management of the OGTR, and related functions as provided by the *Gene Technology Act 2000* and *Gene Technology Regulations 2001*. To maintain confidence in the regulatory framework, it is important that the Regulator acts, and is perceived to act, independently.

The Government is of the view that regulators should have a risk-based approach to compliance obligations, engagement and enforcement that allows for proportionate responses appropriate to the nature and seriousness of identified risks. This allows regulators to achieve objectives more effectively while recognising that it is not possible to eliminate all risks.

## **THE GOVERNMENT'S POLICY PRIORITIES AND OBJECTIVES**

### **Regulatory Reform Agenda**

The Regulatory Reform Agenda is a key component of the Government's plan to boost Australia's productivity and lower the cost of living by ensuring a fit-for-purpose regulatory environment.

The Government is looking at ways to boost productivity through reducing unnecessary or duplicative regulatory costs. Working with state, territory and international partners will identify opportunities to improve the quality of regulation and lower the cost of living for Australians.

The Government is also improving regulator performance, capability and culture through regulatory stewardship. This supports the Government's commitment to Australian Public Service reform by building trust in Government and its institutions, and by putting business and community at the centre of policy and services.

I expect you and your office to contribute to the regulatory reform process by:

- seeking opportunities to reduce duplication and streamline processes to improve efficiency and lift productivity, including international harmonisation or alignment through appropriate engagement with relevant international regulators, organisations and Government agencies
- acting in accordance with regulator best practice in decision-making, policies, processes and communications practices, to maximise transparency and minimise compliance costs
- applying Resource Management Guide 128 Regulator Performance (available at [www.finance.gov.au/government/managing-commonwealth-resources/regulator-performance-rmg-128](http://www.finance.gov.au/government/managing-commonwealth-resources/regulator-performance-rmg-128)) to regulatory functions to assess performance and engagement with stakeholders
- supporting the performance reporting obligations of the Secretary as the Accountable Authority under the PGPA Act, by engaging with the Department of Health and Aged Care's performance reporting processes and publication in the department's Annual Report, which supports greater transparency and accountability of regulator performance
- where appropriate, giving consideration of cost recovery arrangements.

### **Principles of regulator best practice**

In exercising your functions and powers in accordance with these principles, I expect you and your office to display the following principles of regulator best practice.

- 1. Continuous improvement and building trust:**
  - Use qualitative and quantitative analysis as important tools for assessing and reporting on performance, and to support continuous improvement.
  - Promote a work culture that builds public confidence in the work of the OGTR and promotes trust in Government decision-making.
- 2. Risk-based and data-driven:**
  - Actively understand, engage with and effectively mitigate strategic risks to successfully manage regulatory functions without unnecessarily impeding the operations of regulated entities.
  - Use data sources that meet relevant data assurance standards for assessing and reporting on the quality of statistical information.
- 3. Collaboration and engagement:**
  - Open, transparent, and consistent engagement with stakeholders including industry, Government and the broader community is crucial to maintaining competent and innovative regulatory practices. Consequently, I expect you and your office to:
    - seek opportunities to engage and consult genuinely with stakeholders
    - be receptive to feedback and diverse stakeholder views
    - seek to increase transparency in decision-making processes
    - provide up-to-date, clear and accessible guidance and information to assist regulated entities with compliance

- maintain productive working relationships with other relevant jurisdictional and Commonwealth regulators and relevant international bodies.

### **Innovation and regulatory change**

I expect you and your office to continually monitor the operational environment to ensure regulatory approaches keep pace with changes in technology, industry practices, international regulation, and community expectations.

I also expect you and your office to regularly review and, where necessary, adjust policies, protocols, and operational procedures, to ensure responsiveness to the changing social, technology, international regulatory environment, and commercial context in which it operates.

### **Relationship with Minister and portfolio**

You and your office play an essential role in ensuring that the Government and I are well placed to respond promptly to any policy challenges and opportunities arising from the administration of these regulatory functions, as relating to the regulation of GMOs. Accordingly, I expect you as the Regulator, to provide accurate and timely advice on significant issues relating to these regulatory functions in accordance with the Government's policy priorities and objectives. I also expect you to work closely with the department in contributing to ongoing policy advice.

As the responsible Minister, I will provide an enabling environment for you and your office to consistently implement best practice by ensuring you are well informed of the Government's policy direction, as specific initiatives and strategies are being considered.

### **Relationship with Secretary of the Department of Health and Aged Care**

As the Executive Director of OGTR, you are primarily accountable to me as the responsible portfolio Minister. You also have a role in supporting the Secretary of the department in meeting their obligations with regards to the *Public Governance, Performance and Accountability Act 2013*, including annual performance reporting. You will report to the Deputy Secretary, Health Product Regulation Group on administrative matters and maintain an association with the Secretary of the department.

### **Statement of Intent**

I look forward to your reply to this Statement of Expectations, including your Statement of Intent, indicating how you will implement my expectations as outlined above.

Yours sincerely



Ged Kearney

20 / 07 / 2023

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