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The Hon Rebecca White MP
Assistant Minister for Health and Aged Care
Assistant Minister for Indigenous Health
Assistant Minister for Women

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Dr Raj Bhula
The Gene Technology Regulator
Office of the Gene Technology Regulator
Raj.Bhula@health.gov.au

Dear Dr Bhula

I am writing to set out my expectations for how the Gene Technology Regulator (Regulator) will achieve its regulatory objectives, carry out its regulatory functions and exercise its powers in line with the Australian Government's current policy objectives and directions.

This Statement of Expectations will assist with the Government's commitment to effective governance, performance and best practice regulation guided by the *Public Governance, Performance and Accountability Act 2013* (PGPA Act). It also supports initiatives to reduce unnecessary regulatory burden on business and the community, and to deliver productivity-enhancing reforms.

As the responsible Commonwealth Minister this Statement of Expectations sets out my expectations of the following regulatory functions undertaken within the Department of Health, Disability and Ageing.

The Government recognises and respects the independence of the Regulator and your responsibility for the regulatory oversight of genetically modified organisms (within Australia) the management of the Office of the Gene Technology Regulator and related functions, as provided by the *Gene Technology Act 2000* and Gene Technology Regulations 2001.

However, as a Commonwealth Regulator, I expect you to adopt the best practice principles of the Resource Management Guide 128 – Regulator Performance (RMG 128) and Regulatory Policy, Practice & Performance Framework, and follow good corporate governance guided by the PGPA Act. I also expect you to provide your perspective as the Regulator on delivery of my expectations and the Regulator's statutory objectives in a response Statement of Intent, guided by the Guidance Note attached to RMG 128. RMG 128 can be viewed at www.finance.gov.au using the search term 'Regulator Performance (RMG 128)'.

The Government expects that regulators should have a risk-based approach to compliance obligations, and 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.

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THE GOVERNMENT'S POLICY PRIORITIES AND OBJECTIVES

Regulatory Reform Agenda

The Regulatory Reform Agenda at www.finance.gov.au/government/regulatory-reform, seeks to improve Australia's productivity and reduce living costs by streamlining regulations. The Government aims for Commonwealth regulators to balance risk mitigation with efficiency, growth and dynamism. Regulators are expected to use risk-based, proportionate, data-driven methods to achieve these priorities.

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

- working with the broader department to progress legislative reforms to implement the recommendations of the Third Review of the Gene Technology Scheme in accordance with the Government's legislative priorities and making any related business process updates
- seeking ways to reduce duplication and streamline processes to improve efficiency and lift productivity, including ongoing monitoring of the global regulatory environment and engaging with relevant international regulatory bodies, to promote international harmonisation and alignment without compromising core regulatory protections
- acting in accordance with regulator best practice in decision-making, policies, processes and communications practices to maximise transparency and minimise compliance costs in alignment with the Regulatory Policy, Practice and Performance Framework where applicable
- applying 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's performance reporting processes and publication in the department's Annual Report, which supports greater transparency and accountability of regulator performance
- where appropriate, work with the Department of Finance to initiate, implement and report on any reform proposals to reduce unnecessary regulatory burden that may require legislative reform, or which have funding implications, including to consider cost recovery arrangements.

Principles of regulator best practice

In exercising your functions and powers I expect you and your office to display the following principles of regulator best practice:

1. Regulatory stewardship

In exercising its functions and powers in accordance with best practice principles set out under RMG 128, I expect the Regulator to foster continuous improvement and build trust by using data and analysis to assess and improve performance and proactively manage risks without creating unnecessary burden. I expect you and your office to engage openly with stakeholders, seek feedback, increase transparency and provide clear and accessible guidance to ensure compliance.

I also expect the Regulator to develop strong digital and data capabilities, with an agile and forward-looking approach to technology. This will enable the Regulator to respond to risk and continuously maintain regulatory systems throughout the regulatory life cycle. To achieve this, the Regulator should apply the 6 Regulatory Policy, Practice and Performance principles, found at www.finance.gov.au/government/regulatory-reform, to drive fit-for-purpose regulation in a digital era, protect against regulatory failures, and enhance productivity.

2. Risk-based and data-driven:

I expect the Regulator to proactively identify and minimise risks to manage regulatory functions without imposing unnecessary burdens on regulated entities. Additionally, I expect the Regulator to build organisational data capability and digital literacy to support secure and effective use of data and improve risk management.

3. Collaboration and engagement:

I expect the Regulator to ensure there is open, transparent and consistent engagement with stakeholders, including industry, other regulators, and the community. Collaboration is critical to the co-design of solutions where possible and the implementation of innovative regulatory practices.

Consequently, I expect the Regulator to:

- engage regularly and genuinely with stakeholders including regulated entities, other regulators and the community
- seek stakeholder feedback to inform regulatory decisions
- be transparent in decision-making and where possible provide reasons for regulatory decisions
- provide guidance and information that is clear, relevant and accessible to help regulated entities understand their obligations and responsibilities to encourage voluntary 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 and adapt to the operational environment to ensure regulatory approaches keep pace with changes in technology, industry practices, international regulation, and community expectations. Policies, protocols and operational procedures, should be regularly reviewed and, where necessary, adjusted as needed to respond to the changing social, technological and international regulatory environment and commercial context in which you operate.

Relationship with Minister and portfolio

You and your office play an essential role in ensuring that the Government is well placed to respond promptly to any policy changes and opportunities relating to gene technology and its regulation. Accordingly, the Regulator should provide accurate and timely advice on significant issues relating to your 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, Disability and Ageing

I expect that the Statement of Expectation is incorporated into the corporate documents and business processes to help the Secretary meet PGPA Act obligations, including annual performance reporting. I also expect you to coordinate administrative matters with the Deputy Secretary, Health Products Regulation Group, and keep in regular contact with the Secretary.

Statement of Intent

I look forward to your reply to this Statement of Expectations with a Statement of Intent outlining how you will implement my expectations. I ask that both the Statement of Expectations and the Statement of Intent be made publicly available on the Regulator's website and incorporated within your corporate documents.

Yours sincerely



Rebecca White

19 / 01 / 2026

cc: The Hon Mark Butler MP, Minister for Disability and the National Disability Insurance Scheme, Minister for Health and Ageing