SENATOR THE HON. RICHARD COLBECK
Minister for Aged Care and Senior Australians
Minister for Youth and Sport

Ref No: MS20-000689

Dr Raj Bhula
The Gene Technology Regulator
Office of the Gene Technology Regulator
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21 JUL 2020

Dear Dr Bhula

I am writing to express my appreciation of the valuable and important work undertaken by the Gene Technology Regulator (Regulator) and the Office of the Gene Technology Regulator (OGTR), to protect the health and safety of people and to protect the environment through the regulation of genetically modified organisms (GMOs) within Australia. This letter also lays out my expectations of the Regulator, with a focus on the next 12 months. This Statement of Expectations will assist with the Australian Government's commitment to effective governance and performance of the OGTR, guided by the *Public Governance, Performance and Accountability Act 2013* (PGPA Act).

INTRODUCTION

The Government recognises and respects the independence of the Regulator and your responsibility for the regulation of GMOs within Australia, the management of the OGTR, and for related functions as provided by the *Gene Technology Act 2000* (GT Act).
To maintain confidence in the regulatory framework it is imperative that the Regulator acts, and is perceived to act, independently in performing functions and exercising powers as set out in the GT Act. This is an important role and I look forward to continuing to work with you to maintain the high international profile of the OGTR, while realising the Government's objectives.

Under section 27 of the GT Act, the Regulator - through the OGTR - carries out a number of other functions including:

- providing information and advice to the public about the regulation of GMOs;
- providing advice to the Ministerial level Legislative and Governance Forum on Gene Technology about the effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation;
- promoting the harmonisation of risk assessments relating to GMOs and genetically modified products by regulatory agencies;
- monitoring international practice in relation to the regulation of GMOs; and
- maintaining links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia.

The Regulator and the OGTR is expected to provide those functions with the highest level of integrity and based upon a firm understanding of gene technology and risks.

Accordingly, the OGTR should maintain a high level of competence and expertise in the fields in which it operates and an active awareness of new research, scientific and regulatory developments.

In addition, the Government expects that you and the OGTR should maintain a high level of awareness of the Government's health, industry, and environmental policy objectives and respond effectively to Government policy directions and objectives. The Government also expects that the OGTR, in fulfilling its role, will maintain productive working relationships with other relevant jurisdictional, Commonwealth regulatory, international research and standard setting bodies.

VISION

The Government's vision for the OGTR is that it continues to be a high performing organisation that supports you to achieve the important object of the GT Act: 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 GMOs; and the role of the Regulator and the OGTR in delivering the protection goals envisaged by the Act.

In undertaking your activities you should have regard to your responsibilities under the GT Act that, subject to the GT Act and to other laws of the Commonwealth, the Regulator has discretion in the performance or exercise of their functions or power. In particular, the Regulator is not subject to direction from anyone in relation to:

- whether or not a particular application for a GMO licence is issued or refused; or
- the conditions to which a particular GMO licence is subject.

In performing your role, I ask you to continue working closely and cooperatively with the Department of Health, which remains the primary source of policy development and advice to Government. The Department has strategic regulatory policy and national leadership responsibility for gene technology, with particular regard to the regulatory framework. This includes best practice regulation for health technologies related to gene technology.

PRIORITIES

The Government expects that you, and the OGTR, continue your contribution to maintaining the National Gene Technology Scheme (the Scheme) by setting a high standard of regulation of GMOs within Australia by providing advice, developing standards and regulating certain dealings with GMOs.

As you know, the objectives of the OGTR are specified in the Health *Portfolio Budget Statement 2019–20*: to protect the health and safety of the Australian community through regulation, monitoring, assessment and/or awareness-raising in relation to genetically modified organisms (GMOs), supported by the Office of the Gene Technology Regulator; and that the Australian Government, through the OGTR, administer the National Gene Technology Scheme by assessing and issuing approvals, and by conducting routine inspections of certified facilities and licensed activities with GMOs.

Maintaining best practice regulation of gene technology within the National Scheme

In exercising your responsibilities under the GT Act, you and the OGTR play a pivotal role in ensuring a nationally consistent regulatory scheme (Scheme) comprised of the Commonwealth Act, *Gene Technology Regulations 2001* (Regulations) and corresponding state and territory legislation. Your decisions on issuing licences must be consistent with policy principles issued by the Legislative and Governance Forum on Gene Technology (Forum).

As the Regulator of Australian research into the application and use of gene technology (in cooperation with other regulatory schemes intersecting with the national Scheme), the OGTR should continue to apply a risk informed approach to regulation.

To this end, I ask that you continue to identify and address specific risks to your regulatory processes to protect the public and the environment in the release of GMOs and delivery of services under the Act. Whilst doing this, it is important to take a forward looking view to address rapid changes in technology and to ensure that the degree of regulation is commensurate with risk.

Providing technical and regulatory input into Review implementation

The Third Review (Review) of the National Gene Technology Scheme (Scheme) identified 27 recommendations addressing technical, regulatory, governance, and social and ethical issues. Consistent with your responsibilities under the GT Act, I ask that you continue to provide high quality technical and regulatory advice to inform implementation of these recommendations, and that you progress those recommendations that specifically relate to your responsibilities. This will help to achieve a regulatory framework that can keep pace with technology. Your work should include reviewing the financial sustainability of the OGTR, including analysis to inform potential cost recovery options in a revised regulatory framework, and modernising systems and IT structures, including in collaboration with other regulators interfacing with the Scheme.

Maintaining productive and collaborative working relationships

The Scheme is complex and involves many government, industry, research, regulatory, peak body and community stakeholders. I expect you to maintain productive and collaborative working relationships with this diverse stakeholder group, including the provision of high quality technical and regulatory advice as required. I also expect you to provide information and advice to the public about the regulation of GMOs, and to maintain links with international organisations that deal with the regulation of gene technology and regulate GMOs in countries outside of Australia.

RELATIONSHIP WITH MINISTER AND PORTFOLIO

The OGTR plays an essential role in ensuring that I, as the Minister for Aged Care and Senior Australians and Minister for Youth and Sport, and the Government, are well placed to respond promptly to issues that may arise in the gene technology sector.

You, as the Regulator, should therefore provide Government with accurate and timely advice on significant issues relating to its core area of business. Significant issues might include: matters for which the Government is likely to be accountable in Parliament; and important operational or budgetary issues. I would also expect you work closely with the Department in contributing to ongoing policy advice and ideas to strengthen our vision that GMOs are safely managed in Australia.

In this context, I am looking forward to maintaining my close working relationship with you and the Office of the Chief Medical Officer. I request that I, and the Department, are consulted early in the development process for future work, and I will ensure you are fully informed of the Government's policy direction as specific initiatives and strategies are considered. The Government expects the OGTR and the Office of Health Protection will continue to maintain a close working relationship.

I also expect the Secretary of the Department of Health, as stipulated under section 133 of the GT Act, to provide staff to the OGTR and assist in building an effective working relationship and communications between the OGTR, the Department and Government.

ORGANISATIONAL GOVERNANCE AND FINANCIAL MANAGEMENT

As Regulator, I request that you continue to provide appropriate governance of OGTR's advisory bodies (the Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee), covered under Part 8 of the GT Act. In light of recent public scrutiny of the governance of some Commonwealth instrumentalities, we need to ensure we meet the requirements of the legislation and also remain cognisant of community expectations.

I expect you to continue to comply with all responsibilities under the PGPA and GT Act, and to operate in accordance with all relevant legislation, the principles of the Commonwealth Resource Management Framework and enhanced Commonwealth Performance Framework as specified in the PGPA Act - and as described in Accountable Authority Instructions set by the Secretary of the Department of Health.

Furthermore, my expectation is that the OGTR maintains the capacity to be flexible and responsive to emerging priorities and issues, which might arise throughout the year.

REGULATORY FRAMEWORK

As the Regulator, I expect you will exercise your regulatory functions appropriately with due diligence and according to the GT Act. In addition, I would ask that you ensure that the OGTR also acts in accordance with Government policies to minimise regulatory burden and maximise the clarity and transparency of your operations. I understand that a key mechanism to achieve this in relation to gene technology will be through continuing to encourage nationally consistent regulation through the Scheme.

TRANSPARENCY AND ACCOUNTABILITY

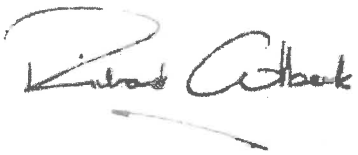
The OGTR is accountable to me, as the relevant Minister, and to the Parliament.

In accordance with the PGPA Act, I expect the OGTR to fulfil its reporting obligations under Part 9, division 5 of the GT Act, including to deliver an annual report (as soon as practicable after the end of each financial year) and report on the operation of the Regulator to Parliament (at any time required), and to provide these reports to me as the responsible portfolio Minister.

I would appreciate your response to this letter in the form of a Statement of Intent within three months. The Statement of Intent should outline how the OGTR proposes to meet the expectations outlined herein, and ensure that the Government's priorities are reflected in the Department's strategic and operational plans. The OGTR has a leadership role in advancing the Government's gene technology policy agenda and I am keen to continue working with OGTR to ensure that the current high standards continue into the future.

To enable greater transparency and accountability, information in this letter, along with your response, should be published and made publically available on your website in due course.

Yours sincerely



Richard Colbeck

cc: Minister Hunt, Minister for Health, Minister Assisting the Prime Minister for the Public Service and Cabinet