Australian Government
Department of Health
Office of the Gene Technology Regulator

Gene Technology Regulator - Statement of Intent 2020–2023

Purpose

This Statement of Intent outlines the activities of the Gene Technology Regulator (the Regulator) and the Office of the Gene Technology Regulator (OGTR) over the next 3 years. It should be read in conjunction with the *OGTR Stakeholder Engagement Framework*, the *OGTR Science Strategy* and the *OGTR Monitoring and Compliance Framework*.

Introduction

Commonwealth and State and Territory governments regulate activities with Genetically Modified Organisms (GMOs) through a nationally consistent scheme led by the Legislative and Governance Forum on Gene Technology[1] (LGFGT) and centred on the *Gene Technology Act 2000* (the Act) and corresponding state and territory legislation. The functions and responsibilities of the decision-maker that administers the national system, the Gene Technology Regulator, are set out in the Act. The purpose of the scheme is described in the Object of the Act which is '*to protect the health and safety of people and 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*'.

The OGTR is within the Department of Health and staff at the OGTR assist the Regulator in performing functions as prescribed in the Act.

Mission, Role and Values of OGTR

The Government's vision for the OGTR is that it continues to be a high-performing organisation that supports the Regulator to achieve the important Object of the Act. The aim, mission, role and values and operational objectives of the Regulator and OGTR underpin that vision.

Aim	To be a trusted and respected regulator of gene technology safeguarding the Australian people and environment
Mission	Dedicated to ensuring that genetically modified organisms are safely managed in Australia
Role	To protect the health and safety of people and 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.
Values	Professional, transparent, accountable, proactive, collaborative, responsive, respectful, inclusive and ethical

[1] Expected to be known as the Gene Technology Ministers Meeting from 2021

Operational Objectives	To deliver efficient and effective regulation that protects people and the environment	To provide a safe, respectful and inclusive workplace that is productive and professionally rewarding	To inform and engage effectively with our stakeholders so that they understand and respect our decisions	To ensure our governance arrangements are robust, illustrate best practice and fulfil all legal obligations
How will we achieve these objectives	*Science Strategy* *Risk Analysis Framework* Sound science	*People Action Strategy* Capable qualified staff	*Stakeholder Engagement Framework* Clear communication	*Monitoring and Compliance Framework* Good governance Effective compliance
Outcome	Regulatory decision-making that is evidence-based, outcome-focused, transparent, consistent, defensible and consistent with LGFGT policy principles	People that are skilled, productive and professional	Stakeholders that understand and respect our decisions	A cooperative regulated community that complies with the regulatory system Highest practical compliance with legislative and reporting requirements
	A high-performing organisation that fulfils the requirements of the legislation, is respected as a regulator, can adapt to government directives, responds to stakeholders' concerns, and anticipates change			

Addressing the Minister's Expectations

I, as the Regulator, will diligently exercise my functions as prescribed by the Act and will progress the following priorities as requested by the Minister and government:

- Contribute to maintaining the National Gene Technology Scheme by setting a high standard of regulation of GMOs in Australia by providing advice and regulating dealings with GMOs.
- Maintaining best practice regulation of gene technology
- Providing technical and regulatory input into the implementation of recommendations arising from the third review of the Gene Technology Scheme.
- Maintaining productive and collaborative working relationships with the Minister, the Secretary and the Department of Health and stakeholders
- Be transparent and accountable and fulfil all reporting obligations as set out in Accountable Authority Instructions set by the Secretary of the Department of Health and under the PGPA Act 2013 to achieve effective performance and governance of the OGTR.

Dr Rajumati Bhula

Gene technology in Australia

Gene technology (also known as genetic engineering or genetic modification) provides ways to make changes to genes – the sets of instructions in the cells of all living organisms. There is a large amount of overlap between 'gene technology' and the newer term 'synthetic biology'. Gene technology can be used in agriculture, environmental management, and pharmaceutical development. It also refers to the production of GMOs and the manufacture of products from them. The largest application of gene technology in Australia involves human health, including both understanding disease and pathogens, and the development of drugs and other therapeutics to aid in their treatment. Other major areas are agricultural applications, and diagnostics. Newer areas under research and development include environmental management, the control of introduced pest species, bioremediation activities and the large scale production of industrially useful substances such as biofuels or bioplastics.

OGTR Stakeholders

The wide range of possible applications of gene technology means there is an equally wide range of stakeholders interested in the work of the OGTR. Public attitudes are important and help to shape both industry uptake of emerging technologies and the underlying regulatory framework for them.

If the Australian community is concerned about a particular use of technology and its application, research and development in this area may be constrained and a host of potential benefits are likely to be missed. This could result in a lost opportunity for individuals, industry and the nation as a whole. The community is more likely to accept products of gene technology if reassured that the government has put in place a robust regulatory scheme with appropriate protection goals.

Therefore, up to date information from the Regulator can give the government and the community access to clear and accurate information about community attitudes, current uses of gene technology and the functioning of the gene technology regulatory scheme.

People conducting work with GMOs in Australia need certainty about regulations and what is required to be able to access gene technology in a safe and legal manner. It is therefore important that clear information is published by the OGTR about regulatory processes leading to both timely and predictable outcomes, which support research and innovation in Australia.

In order to make the best decisions, the Regulator needs to understand the expectations of all stakeholders. To facilitate continued stakeholder involvement, mechanisms are provided to receive input to inform decision making, especially about risks to people or the environment.

Senior officials from the States and Territories are important government stakeholders that promote a consistent national approach to gene technology regulation. Currently senior officials from the Commonwealth, States and Territories provide a national coordination role through the Gene Technology Standing Committee (GTSC). The Regulator is not a member of the GTSC, but attends as a participant. The Regulator and the OGTR will continue to engage with the GTSC to provide advice, when appropriate, to support the maintenance of the national regulatory scheme.

Our Stakeholders

General Public	– The wider community including members of the public and students with questions about or an interest in gene technology – People and organisations with concerns about the safety of gene technology – The media
Government	– Minister and Department of Health – LGFGT - National, state and territory ministers involved in gene technology regulation – Commonwealth and state government departments and agencies involved in gene technology regulation – Local councils in areas where GMOs are proposed to be released into the environment – International agencies with an interest in Australian gene technology regulation
People working with or wishing to work with GMOs	– Researchers, universities and research organisations – Companies seeking to commercialise GMOs, including human therapeutics – Farmers and agricultural organisations – Community scientists / biohackers

Independence, Transparency & Accountability

Every decision requires judgement and has an impact. It is the responsibility of the Regulator to analyse whether specific activities with GMOs can be undertaken safely, and to reduce possible risks to human health and safety and the environment.

Therefore, decisions by the Regulator must be:

- robust enough to withstand challenge;
- transparent so as to encourage trust and confidence; and
- be clearly communicated so they are understood.

To maintain the trust of both regulated stakeholders and the public it is important that all decisions are based on sound scientific evidence, are free from bias or external influence and are within the legal considerations prescribed by the Act. A range of information and views must be considered in a fair and transparent manner to make an informed, independent decision.

Information and advice relevant to a decision is sought from:

- the applicant via the application form, data and specific requests for further information;
- OGTR staff during their risk analysis advice; and
- the public, advisory committees, all Australian governments and relevant prescribed agencies through consultation on draft Risk Assessment Risk Management Plans (RARMPs).

Advisory committees are required to provide independent advice based on prescribed areas of expertise. Members are required to declare any potential conflicts of interest at the time of their appointment and prior to every meeting in which they are asked to provide advice to the Regulator. Procedures are in place to manage any conflict of interest when declared.

Information and advice provided during the assessment process, including advice from the independent advisory committees, informs the Regulator's decision. Decisions made the Regulator must also be consistent with any policy principles issued by the LGFGT.

An important part of the decision-making process involves consideration of possible negative impacts and how they can be managed or prevented through specific licence conditions. Licences or other authorisations are only issued if any identified risks posed by the proposed work with GMOs can be managed in accordance with the object of the GT Act.

Providing Safeguards through Monitoring and Compliance

The OGTR monitoring and compliance team conducts regular inspections of approved facilities, trial sites and other licenced dealings to ensure that licence conditions are being met and that work with GMOs is being carried out in a manner which protects human health and safety and the environment.

OGTR inspectors provide advice to authorisation holders on how best to meet requirements, and their observations and findings are used to inform future decisions and refinement of conditions to ensure they are fit for purpose.

The GT Act allows the Regulator to respond to identified non-compliance with conditions. The Regulator can direct resources to the greatest areas of risk and negative impact and, taking into account the available information and evidence, can determine the right intervention for a particular set of circumstances. When considering decisions involving compliance activities and action, there is a range of interventions, from education through to prosecution. Enforcement action is taken when it is required.

Generally, the risk approach of the OGTR is to work cooperatively with regulated entities to encourage compliance, to ensure any risk is not realised and appropriate measures are put into place and maintained. The Monitoring and Compliance Framework articulates OGTR's approach.

Our monitoring activities are published on the OGTR website each quarter to provide information on current priorities. Monitoring outcomes are detailed in the Annual Report to demonstrate wide understanding of the level of compliance with regulatory requirements, so that interested stakeholders can be assured of the effectiveness of the scheme.

Accountability through Reporting

The Regulator, although independent in decision making under the Act, is accountable to the government and the Australian people. Each year a report must be presented to the Parliament detailing the activities of the OGTR for that year. Questions or requests for information from the Minister responsible for gene technology and the government as a whole must be addressed. Information about regulatory decisions and monitoring activities are published on the OGTR website. This includes the risk assessment and risk management plans (RARMP), licence conditions and supporting documents for all licences which involve an intentional environmental release of GMOs, an up to date list of all other licences issued, notifications received and GMOs placed on the GMO register.

Functions of the Regulator

As well as issuing authorisations for activities with GMOs, Section 27 of the GT Act sets out other functions of the Regulator.

The Regulator with the aid of OGTR staff (and where relevant, the Gene Technology Policy section in the Department of Health), can develop and maintain policy principles and policy guidelines, as requested by the LGFGT; codes of practice for those working with GMOs; and issue technical and procedural guidelines in relation to GMOs. In addition, the Act allows the Regulator to undertake or commission research in relation to risk assessment and the biosafety of GMOs to inform decision making and to ensure the best quality advice is provided to government.

To ensure that Australia develops and maintains best practice gene technology regulation, the OGTR works with other government agencies to promote the harmonisation of risk assessments relating to GMOs and GM products. International practice and advancements in the regulation of GMOs are monitored to inform Australian policy and practice by maintaining links with international organisations that deal with gene technology and with agencies that regulate GMOs in countries outside Australia.

Organisational capability

To maintain a high-performing organisation, and continue to be acknowledged as a best practice regulator, the OGTR and its staff must maintain a high level of competence, scientific expertise and integrity to best support the Regulator in achieving functions under the Act. The skills of OGTR staff include plant and agricultural science, chemistry, microbiology, immunology, environmental science, risk analysis, compliance and enforcement, regulatory practice, accountancy and law. With rapid changes in technology, it is important that the skills of staff remain relevant and contemporary through participation in training and development programs.

Areas of ongoing staff development

Leadership	Team leaders are trained to be effective in managing staff performance, as well as communicating and implementing change. They encourage innovation and look proactively for ways to improve OGTR processes. Leaders are encouraged to develop and maintain an awareness of relevant government policy and consider how it may affect our day to day work.	*Strategic direction and organisational resilience*
Regulatory and technical expertise	Staff maintain an understanding of current regulatory theory, practice and performance. This allows OGTR to respond flexibly to changes in the scientific landscape and ensure regulatory burden remains commensurate with risk. OGTR fosters and supports positive compliance and regulatory culture within stakeholder organisations. This reduces the likelihood of regulatory failure.	*Proactive Regulation*
Compliance capability	The *OGTR Monitoring and Compliance Framework* outlines OGTR monitoring activities and responses to non-compliance. OGTR staff are encouraged to provide experienced based advice into subsequent risk assessments and risk management plans.	*Effective risk management*
Science expertise	OGTR scientists are supported to maintain their knowledge through attendance of scientific conferences and meetings. Science discourse and sharing expertise is achieved through the sharing of relevant papers and regular scientific seminars. Staff maintain an active awareness of new technologies, new scientific research and regulatory developments.	*Evidence-based, independent decision making*
Risk analysis expertise	The Regulator's *Risk Analysis Framework* outlines our approach to science based risk assessment and is regularly reviewed against current national and international best practice. OGTR staff are encouraged to actively participate in the Australian Regulatory Science Network to build capacity and share expertise in science based risk analysis.	*Production of best practice, science based risk analysis to support licence decisions*
Policy expertise	OGTR staff are encouraged to maintain, build and apply knowledge of the government's health, agriculture, environmental and industry policies and objectives.	*Responsive Regulation*

OGTR staff adhere to the Australian Public Service (APS) Code of Conduct and uphold the APS Values and adhere to Department of Health policies.

Good employer obligations, health and safety, and resilience

The Regulator and the OGTR are committed to the principles and practice of equal opportunity, a diverse workplace and inclusive culture, and an environment that enables each person to safely share their views, and perform to the best of their ability.

We are committed to protecting all workers and visitors by providing and maintaining a safe working environment, and by taking all reasonably practicable steps to prevent illness, injury or damage from work carried out by, and on behalf of, the OGTR. Staff are supported to work remotely, either partially or full time.

Priorities 2020–2023

Contribute to maintenance of the scheme

Part of the role of the Regulator involves the provision of high quality advice to the public and to other regulatory agencies on the operation of the gene technology scheme. The OGTR website describes the requirements for seeking approvals to conduct dealings with GMOs in Australia. This includes guidelines, application forms and other guidance documents. These documents are subject to a regular review process to ensure they continue to set the best practice standards for safe work with GMOs.

Over the past two years, there has been an ongoing program of improvement in digital service delivery, which involves transitioning existing application forms to online forms to better meet stakeholders' needs and expectations.

A major review of the website is about to commence to ensure that accurate and appropriate information is published as part of the Australian Government's Digital Transformation Strategy.

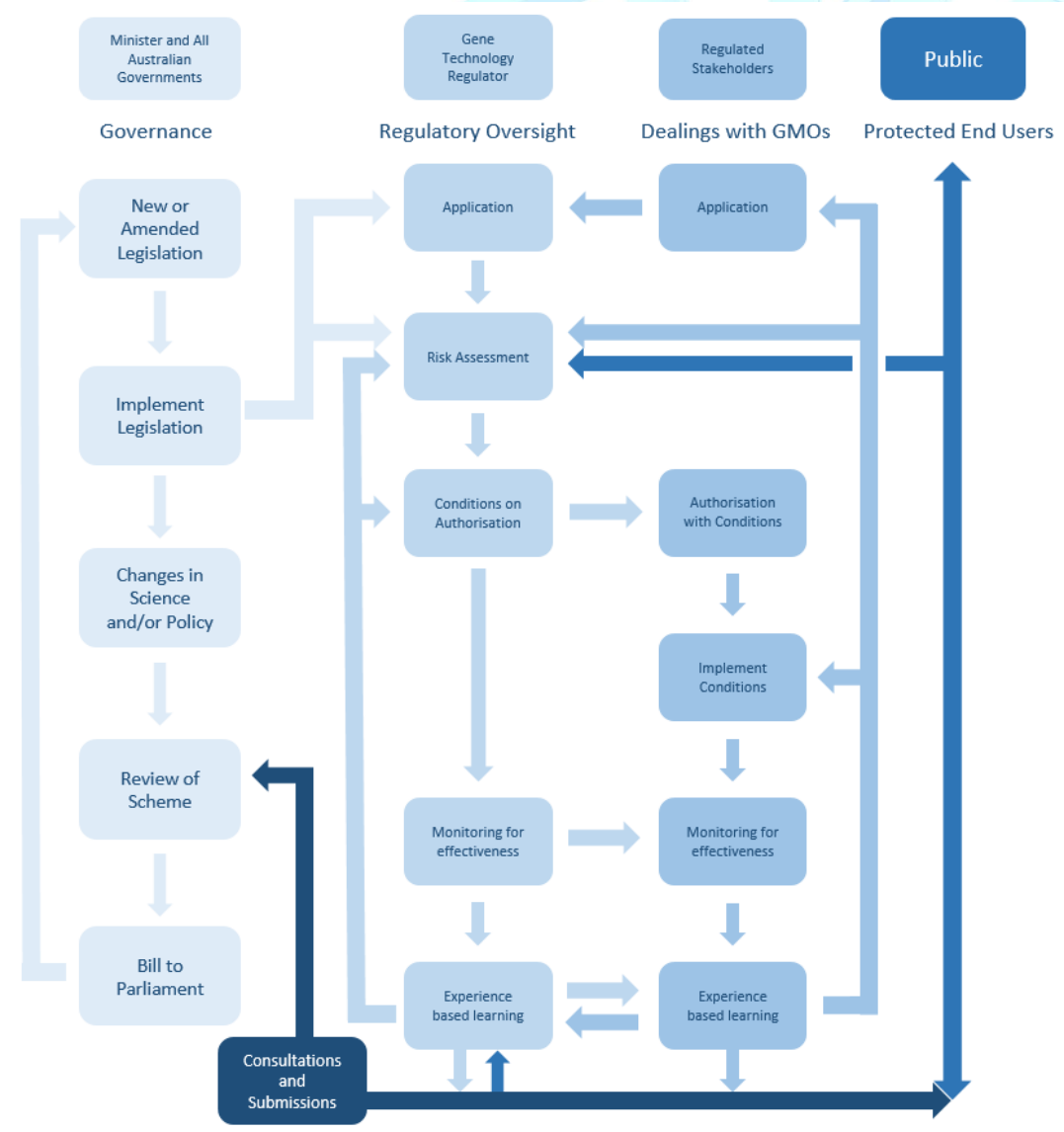
Maintain best practice regulation

Australia's gene technology scheme was designed to allow the level of regulation to be commensurate with the level of risk posed by each dealing or activity with a GMO. This ensures that regulated stakeholders are not subject to unnecessary regulation and are able to undertake research and innovation to the benefit of the Australian people.

Gene technology and related fields are advancing rapidly with new techniques and equipment being developed and trialled.

In order for gene technology regulation to remain relevant and appropriate, OGTR staff undertake risk assessments for new or novel GMOs, and GMOs produced by new technologies, as well as assessing whether they are appropriate for use in facilities that have been certified for the containment of dealings with GMOs.

Information and experience gained through the assessment of dealings, and from monitoring for compliance will be used to inform future assessments and ongoing review of practices. Feedback received from stakeholders and OGTR inspectors on the effectiveness of controls and licence conditions is used to inform and improve future risk analysis, approval conditions and revisions of guidelines (see figure below).



Regulated stakeholders can also use this information to improve their next applications and the implementation of any current and future approvals.

This experience based knowledge will also inform the advice provided to the Department, the Minister and Australian Governments during scheme reviews and other consultative processes.

Relationship with Minister and Portfolio

Maintaining a productive working relationship with the Department of Health and the Minister responsible for gene technology is an important function of the Regulator, particularly in the context of providing accurate and timely advice on significant issues in the field of gene technology and its regulation. The Regulator will continue to advise the Minister of other important matters for which the government is accountable in parliament, including any relevant budgetary or operational issues.

Close collaboration with the department will continue by providing scientific and regulatory advice during the development of policies relevant to GMOs, and the strengthening of GMO regulation in Australia. Close working relationships with the Chief Medical Officer and the Office of Health Protection will ensure they remain informed of new therapeutic GMOs and developments in gene technology relevant to their respective roles and responsibilities.

Collaborative working relationships and effective communication

The Gene technology scheme works best when there are high levels of trust between government and the community. Clear and consistent communication is a key part of building and maintaining that trust. Through almost 20 years of operation, the OGTR has built many productive and collaborative relationships. The Regulator will continue to build and maintain consistent, open, and respectful working relationships in accordance with the *OGTR Stakeholder Engagement Framework*. This framework is focussed on communication activities that:

- enable informed decision making;
- encourages compliance; and
- maintains government and community trust in the gene technology regulatory scheme.

Continued engagement activities will allow the OGTR to improve the way it operates. The framework will be updated from time to time to reflect best practice in government communications.

OGTR engagement principles

Purposeful	The OGTR begins every engagement with our stakeholders with a clear understanding of what we want to achieve and what we need to do to comply with the *Gene Technology Act 2000*.
Inclusive	The OGTR provides different ways for interested stakeholders to engage.
Timely	The OGTR consults our stakeholders in our decision making processes and provides timely opportunities for stakeholder input.
Transparent	The OGTR is open and honest in our engagement and sets clear expectations regarding the scope of the consultation, while also protecting privacy and other information required to be kept confidential.
Respectful	The OGTR acknowledges and respects the expertise, perspective, and needs of our stakeholders.

Provide Technical & Regulatory input into Review Implementation

The Third Review of the National Gene Technology Scheme was completed in October 2018 and Forum Ministers endorsed 27 recommendations which will '*enhance and strengthen the scheme so that it continues to be fit for purpose and is sufficiently agile to address future developments and challenges'.* The Regulator will as a matter of priority continue to support the LGFGT and the Department of Health in implementing these recommendations.

The majority of recommendations relate to the wider policy settings of the scheme and so are to be progressed by the LGFGT. However, some recommendations, such as those around the streamlining of processes and the review of monitoring and compliance activities are primarily the responsibility of the Regulator and the OGTR. Work has already commenced on developing IT infrastructure needed to support an online portal, which will enable faster and more efficient communication with regulated stakeholders and aid in quicker processing of applications by OGTR.

The Regulator will also aid the LGFGT by providing access to the scientific and regulatory experience based knowledge held by the OGTR, as well as advice from the two appointed committees, the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics and Community Consultative Committee (GTECCC).

In particular, close collaboration with the policy area of the Department of Health is required to provide information on operating costs and procedures to aid the development of a sustainable funding model for the OGTR.

The Regulator will also continue to provide advice on the risks posed by particular classes of dealings to ensure regulation will remain proportionate to risk. Collaboration with other regulators and agencies involved in the regulation of GMOs and GM products, as well as their policy areas will continue. Ongoing cooperation will ensure any changes resulting from other government reviews will lead to regulation that:

- remains effective and consistent;
- has the flexibility to respond to future developments in science and technology; and
- reduces unnecessary regulatory burden and
- supports innovation and research to the benefit of Australians.

OGTR's stakeholders will remain engaged in the implementation of the review recommendations through consultation processes and by providing information on progress on the OGTR website, as well as providing links to the LGFGTs review website. The 9th Institutional Biosafety Committee (IBC) forum will likely be held in 2021, and will provide an ideal opportunity to discuss the progress of the implementation of various review recommendations.

Organisation governance and financial management

The OGTR is staffed primarily by members of the APS and as such they will:

- apply the appropriate ethical standards under the APS Values and Code of Conduct;
- comply with Australian Government freedom of information (FOI), privacy, and work health and safety legislation; and
- comply with the National Disability Strategy and the Australian Government's Workplace Diversity Policy.

The OGTR is funded through the Gene Technology Special Account. The *Public Governance, Performance and Accountability Act 2013* (PGPA Act) sets out the financial framework for our governance. Integrity in financial reporting is maintained through internal audit arrangements as part of a Shared Services Agreement with the Department of Health. This agreement means that the OGTR participates in departmental processes to ensure compliance with the *Commonwealth Fraud Control Framework 2017*. By working closely with the finance areas of the department, the OGTR complies with the principles of the *Commonwealth Resource Management Framework* and *Enhanced Commonwealth Performance Framework* as specified in PGPA Act – and as described in Accountable Authority Instructions set by the Secretary of Health.