



Australian Government

Department of Health and Ageing
Office of the Gene Technology Regulator

Office of the Gene Technology Regulator

STRATEGIC PLAN

2010 - 2013



Message from the Regulator

This Plan sets the strategic direction for the Office of the Gene Technology Regulator (OGTR) for the next three years, outlining our high-level objectives and priorities for the 2010 to 2013 period.

In the short time since the OGTR was established to implement Australia's regulatory scheme for genetically modified organisms (GMOs), we have earned national and international respect for the effectiveness with which we have fulfilled our responsibilities under the *Gene Technology Act 2000* and relevant state legislation. This respect is highly valued by OGTR staff and is based on a reputation for transparently applying sound science, robust and contemporary risk analysis, and efficient work practices. We will strive to enhance and build on this reputation as we continue our important role of regulating gene technology to protect the health and safety of people and the environment.

The science of gene technology and approaches to risk analysis are evolving rapidly. It is critical that the OGTR adapts and responds to the challenges posed by this ongoing change. Accordingly, we will give priority to ensuring that the risk assessment and risk management processes we use to deliver our legislated objectives remain contemporary, able to accommodate scientific advances, and consistent with the best practices employed around the world.

In doing this, we must continue to engage actively and positively with our various stakeholders. We will provide timely advice to the Gene Technology Ministerial Council to help ensure the national regulatory framework continues to reflect emerging needs. We will work closely with other Australian Government regulators, departments and the States and Territories to optimise the performance and integration of the overall regulatory system. We will use our engagement with counterpart regulators in other countries and in multilateral fora to remain abreast of, and contribute to, international best practice. Importantly, we will consult openly with the general public and the community we regulate to promote mutual understanding and timely resolution of issues of concern.

Through good governance, we will ensure that our resources are used efficiently and targeted appropriately. Central to this endeavour will be our efforts to continue to attract, develop and retain the very best people to help regulate gene technology for Australia.

A handwritten signature in blue ink that reads "Joe Smith". The signature is written in a cursive, flowing style.

Dr Joe Smith
Gene Technology Regulator

Vision

To be recognised as an international leader in gene technology regulation for a healthy and sustainable future.

Mission

To safeguard health and protect the environment through the application of good regulatory practice for gene technology.

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 to manage these risks through regulating certain dealings with GMOs.

The Gene Technology Regulator and the OGTR

The OGTR was established in June 2001 to support the Gene Technology Regulator (the Regulator). The Regulator is a statutory office holder with responsibilities for administering and making decisions under the *Gene Technology Act 2000* (the Act) and corresponding State law on behalf of the Australian and State and Territory Governments. The Act and associated *Gene Technology Regulations 2001* (the Regulations), together with corresponding State and Territory legislation, constitute a nationally consistent regulatory system. The Act operates in conjunction with other Commonwealth and State legislation that relates to the regulation of GMOs or GM products.

The Australian Government Parliamentary Secretary for Health has portfolio responsibility for matters relating to the OGTR, which resides within the Department of Health and Ageing.

To fulfill our role the Regulator, supported by the OGTR:

- evaluates applications for dealings with GMOs;
- licenses dealings with GMOs for environmental release or in contained facilities;
- accredits organisations and certifies facilities for work with GMOs;
- conducts monitoring and compliance activities to ensure compliance with regulatory requirements;
- issues guidelines and provides advice in relation to GMOs;
- advises the Gene Technology Ministerial Council on the operation of the regulatory scheme, including on possible amendments to legislation;
- promotes harmonisation of risk assessments with other regulatory agencies; and
- monitors international practices and interacts actively with international agencies involved in GMO regulation.

The OGTR has established comprehensive systems and procedures to support the performance of these functions. In doing so, we maintain productive relationships with stakeholders and consult widely on key decisions with our expert advisory committees (the Gene Technology Technical Advisory Committee, GTTAC, and the Gene Technology Ethics and Community Consultative Committee, GTECCC), State and Territory governments, the Australian Government Environment Minister, other regulatory authorities, the public and the regulated community. This consultation is critical to maintaining the effectiveness, transparency, credibility and responsiveness of the regulatory scheme.

Our objective

Our activities contribute to Outcome 1 (Population Health)¹ of the Health and Ageing *Portfolio Budget Statements*.

Through the Gene Technology Regulation component of Outcome 1, the Australian Government aims to protect the health and safety of people and the environment by regulating dealings with GMOs. The Regulator, supported by the OGTR, is to achieve this by administering a responsive, efficient, effective and science-based national scheme for the regulation of gene technology that revolves around a system of prohibitions and approvals.

¹ Outcome 1 Statement: *A reduction in the incidence of preventable mortality and morbidity in Australia, including through regulation and national initiatives that support healthy lifestyles and disease prevention.*

Our priorities

In pursuing this objective through our ongoing regulatory activities, we will seek to enhance our performance as an effective and efficient regulator by paying particular attention to:

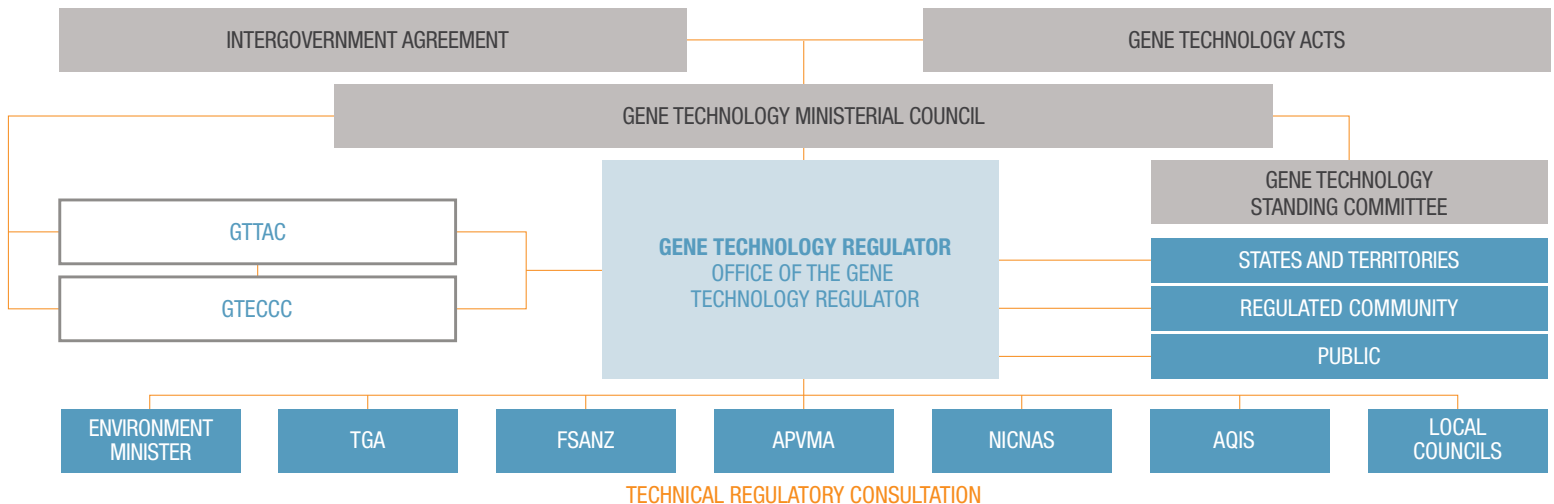
- ensuring our scientific awareness, risk assessment methodology and regulatory practices remain, and contribute to, state-of-the-art approaches through active and targeted engagement with national and international agencies and organisations involved in gene technology regulation;
- leveraging these advances through incorporation into our *Risk Analysis Framework* and its application to regulatory activities across the OGTR;
- working with regulatory agencies in our region and elsewhere through bilateral cooperation and participation in international fora;

- enhancing our external communications, guided by examination of the efficacy of our existing consultation processes;
- ensuring optimal use of our resources, informed by review of our operations, processes and structures; and
- maintaining the motivated and skilled staff we need into the future, supported by review of our workforce needs and preparation of a staff development charter to guide our efforts.

Two major scheduled activities will also be priorities in this period:

- completing the current review of the Regulations, and implementing the revised Regulations; and
- providing input to, and assisting with, the next review of the legislative framework for gene technology regulation in Australia, and implementing changes that arise from it.

The National Gene Technology Regulatory System:



Our people and values

The OGTR comprises some 50 scientific, legal, policy, professional and administrative staff.

We value our people and seek to attract and retain appropriately qualified and skilled people by providing an environment that builds capability, motivates, inspires and supports them. As part of the Commonwealth Health and Ageing portfolio, we are also guided by the Department's *People Strategy – Performance through People 2010-2015*.

We are committed to the *Australian Public Service Values* and *Code of Conduct* in all aspects of our business. We value:

- professionalism: through integrity, objectivity, excellence, commitment and consistency;
- accountability: through open and transparent processes;
- achievement: through effective, efficient and flexible work practices which are focused on delivering timely outcomes; and
- respect for each other and our stakeholders: through open and effective communication and quality service.

Performance framework

We operate within a framework that guides our planning and resource management and assists us to meet our obligations as an Australian Government agency. This framework:

- is consistent with the Act and the Regulations, relevant policies and the Regulator's Statement of Intent;
- sets out key strategic directions for each financial year in the Portfolio Budget Statements, which guide our corporate and business plans;
- uses the Department's Capability Map and Performance Development Scheme to align individual, team and OGTR goals;
- provides people with the systems, tools and information needed to achieve these goals;
- reflects broader government policies and reforms and promotes the Australian Public Service Values and Code of Conduct;

- follows Australian Government financial management policies, and the Department's Chief Executive Instructions and Procedural Rules;
- anticipates opportunities and challenges, and manages risk; and
- evaluates and reports our performance to measure our success.

We promote continuous improvement of our performance through:

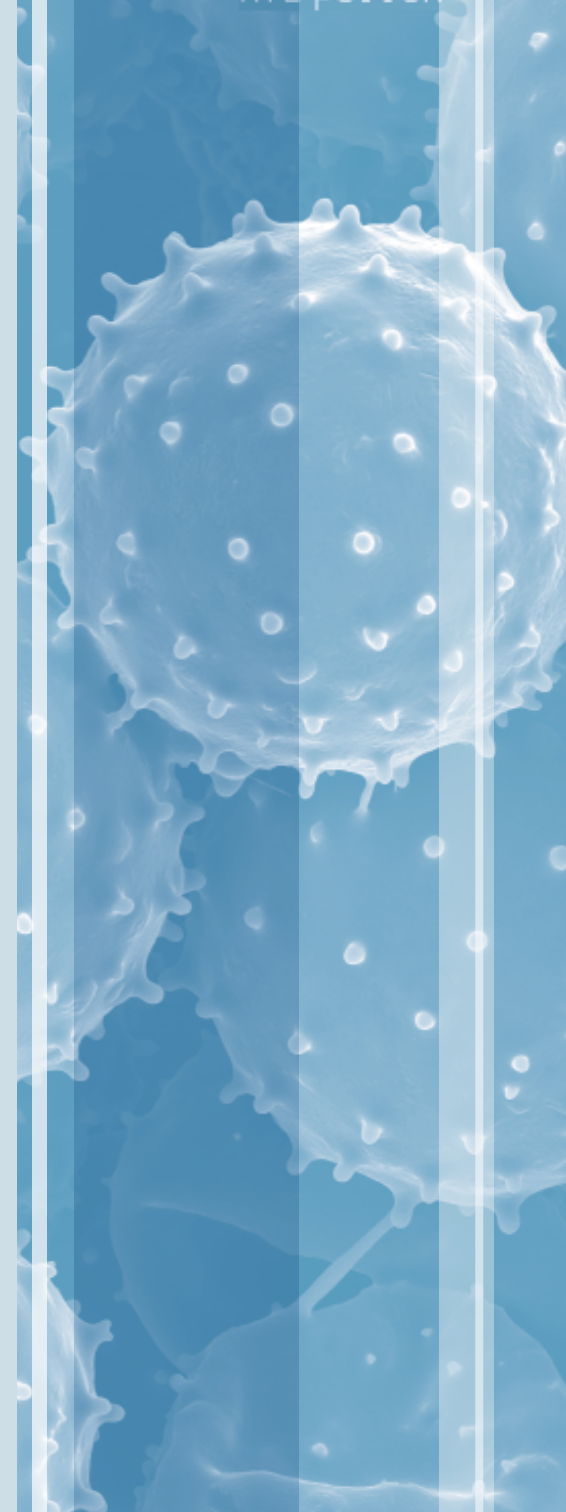
- ongoing reporting, monitoring and review of our processes;
- seeking and acting on feedback from stakeholders;
- remaining aware of scientific advances and regulatory best practice through engagement with other regulators and expert groups; and
- pursuing strategies to attract, develop and retain highly skilled and motivated staff.

□ ADVICE – PROVIDED UPON REQUEST FROM THE MINISTERIAL COUNCIL OR THE REGULATOR

■ CONSULTATION

■ GOVERNANCE





Contact

Office of the Gene
Technology Regulator
MDP 54 GPO Box 9848
Canberra ACT 2601
Australia

Level 1
Pharmacy Guild House
15 National Circuit
Barton ACT 2600

Telephone
1800 181 030

Fax
(02) 6271 4202

Email
ogtr@health.gov.au

Website
www.ogtr.gov.au