Australian Government
Department of Health
Office of the Gene Technology Regulator

OFFICE OF THE GENE TECHNOLOGY REGULATOR SCIENCE STRATEGY 2013-2018

Science forms the foundation for evidence based regulatory decision making that protects people and the environment from risks posed by gene technology. The Science Strategy outlines how the OGTR will maintain and enhance our scientific and risk analysis capabilities, and ensure their effective application to meet current and future gene technology regulatory needs.

INTRODUCTION

THE REGULATORY FRAMEWORK FOR GENE TECHNOLOGY

The development and use of genetically modified organisms (GMOs) in Australia is regulated through an integrated legislative framework which includes the Gene Technology Regulator (the Regulator) and a number of other regulatory authorities with complementary responsibilities and expertise.

The *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001*, in conjunction with corresponding State and Territory legislation, underpin the national scheme for the regulation of live and viable GMOs in Australia. The implementation of the scheme is overseen by the Legislative and Governance Forum on Gene Technology, which comprises ministerial representation from all Australian jurisdictions.

The object of the Act is "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".

The Regulator is an independent statutory office holder who administers the Act and has extensive powers to monitor and enforce the legislation. The Regulator is the sole decision maker for almost all approvals issued under the Act.

THE ROLE OF REGULATORY SCIENCE

Sound science and rigorous risk analysis underpin the Regulator's decisions under the Act, and are central to the regulatory activities undertaken by the Regulator. The staff of the Office of the Gene Technology Regulator (OGTR) support the Regulator by providing scientific and technical advice and conducting risk analyses.

The *Risk Analysis Framework* describes the principles of risk analysis used by the Regulator. It is a key document for guiding staff, informing applicants, stakeholders, the public and other domestic and international regulatory bodies about the rationale and approach adopted by the Regulator in undertaking risk analyses and arriving at risk management measures and licence conditions.

The Regulator must also seek scientific and technical advice from the Gene Technology Technical Advisory Committee (GTTAC) for all Risk Assessment and Risk Management Plans (RARMPs) for applications proposing intentional release of GMOs into the environment. GTTAC is an expert advisory committee appointed by the Minister with responsibility for gene technology regulation. It comprises eminent scientists with expertise in areas such as clinical medicine, molecular biology, toxicology, plant biotechnology, virology, immunology, ecology and risk assessment. Advice from GTTAC and from consultation with other experts, agencies and authorities are valuable contributors to regulatory science and risk analysis conducted by the OGTR.

PURPOSE OF THE SCIENCE STRATEGY 2013-2018

The OGTR is "Dedicated to ensuring that genetically modified organisms are safely managed in Australia" as stated in the OGTR Strategic Plan 2013-2016. Sound science, robust risk analysis and best practice regulation are critical for achieving our mission.

The Science Strategy 2013-2018 is guided by and complements the OGTR Strategic Plan 2013-2016 and the OGTR Communication Strategy (under development). The Science Strategy will be implemented through specific actions in OGTR annual business plans and people strategy action plans.

The purpose of the Science Strategy is to maintain the OGTR at the forefront of regulatory science for gene technology. It outlines how we will maintain and enhance our scientific and risk analysis capabilities, and ensure their effective application to meet current and future gene technology regulatory needs and challenges.

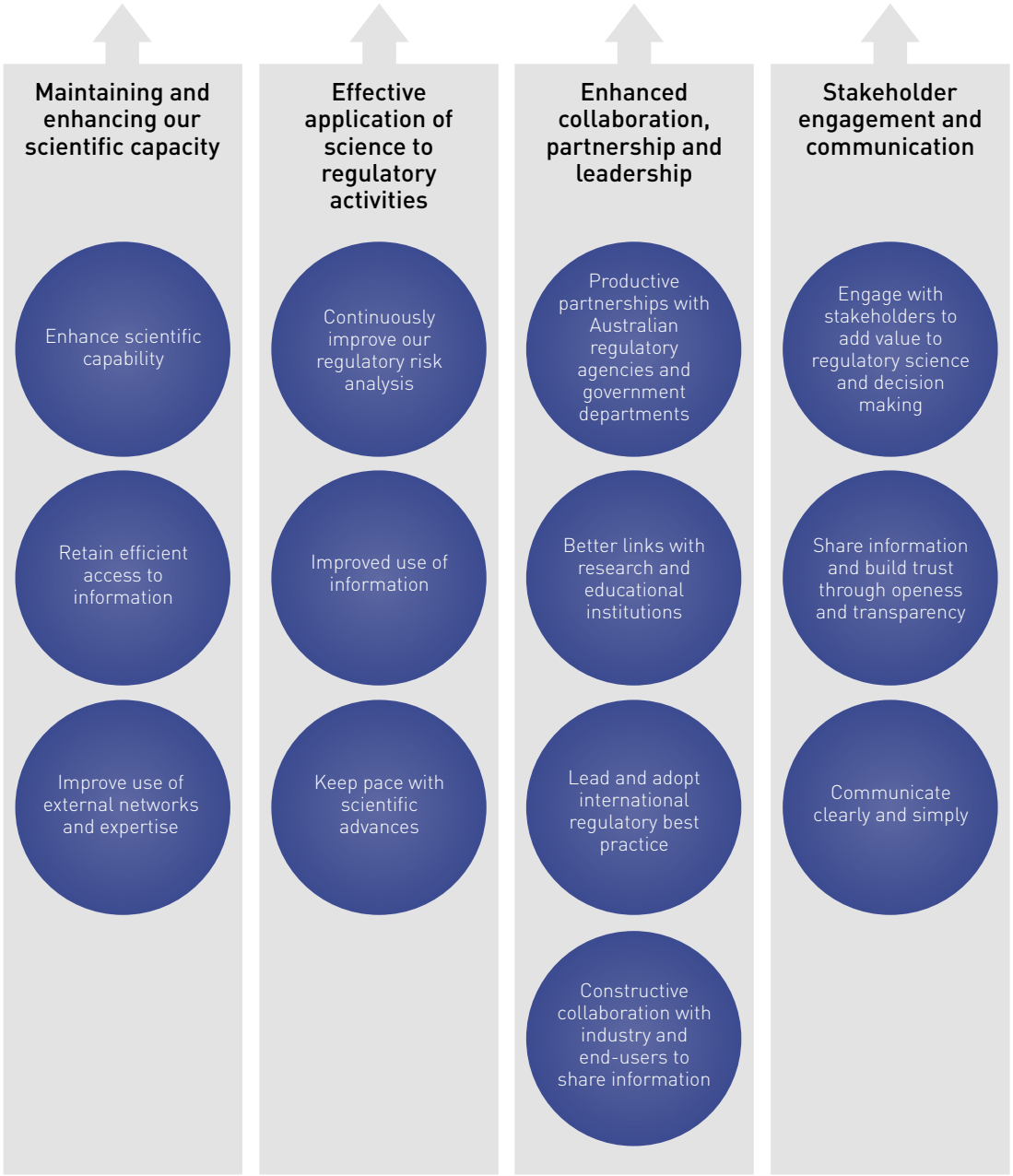
In the coming five years, the OGTR will focus on four key strategic areas, each contributing to the central aim of being recognised as leaders in regulatory science for gene technology:

1. Maintaining and enhancing our scientific capacity
2. Effective application of science to regulatory activities
3. Collaboration, partnership and leadership
4. Stakeholder engagement and communication

The following diagram provides an overview of the strategy and this document provides details for each of the key strategic areas.

AN OVERVIEW OF THE OGTR SCIENCE STRATEGY 2013-2018

LEADERS IN REGULATORY SCIENCE FOR GENE TECHNOLOGY



STRATEGIC AREA 1: MAINTAINING AND ENHANCING OUR SCIENTIFIC CAPACITY

ENHANCE SCIENTIFIC CAPABILITY

Biotechnologies, including gene technologies are among the most rapidly developing fields of science. Therefore, maintaining and expanding the scientific and technical skills of staff is critical to position the OGTR to meet the regulatory challenges posed by the rapid change in this complex area.

The OGTR currently has people with training, knowledge and experience in a range of scientific disciplines including molecular biology, biotechnology, ecology, virology, immunology, plant and animal biology, toxicology and risk analysis. A periodic skills audit as a part of workforce planning will assist in identifying any critical skills gaps which can then be addressed by targeted recruitment, skill acquisition by learning or by using external sources as required. It will also enhance the use of the existing skills.

A range of professional development activities will be important for maintaining and extending the scientific and technical skills of the OGTR. Supporting attendance and presentation at scientific and technical conferences, an active seminar program with internal and external expert speakers and attendance at relevant external seminars and other forums will provide professional development opportunities for staff.

Internal peer review, mentoring and in-house training activities will contribute to maintaining and enhancing the evaluation and risk analysis skills of staff. Continuing a program of providing work opportunities involving projects outside of individual areas of core expertise will help staff build a broader base of skills, knowledge and experience.

Collaboration and partnership (outlined in *Strategic area 3*) with researchers, technical experts, educators and other regulatory scientists will further support professional scientific development. As will taking advantage of opportunities to submit for publication key scientific and technical reference documents relevant to the work of the OGTR.

RETAIN EFFICIENT ACCESS TO INFORMATION

The information used by the OGTR for risk analysis comes from a variety of sources, including peer reviewed papers, other published literature and data from experiments conducted by applicants. Access to scientific and technical information in books, journals and other publications is critical to the capacity of the scientific staff to undertake independent risk analysis. The OGTR is committed to maintaining access to the information resources required for the highest quality risk analysis and science based regulatory decision making. Periodic review of information access requirements will be undertaken to make the most efficient use of resources available to the OGTR.

IMPROVE USE OF EXTERNAL NETWORKS AND EXPERTISE

The relatively small number of staff in the OGTR cannot cover the vast scope of scientific knowledge relevant to gene technology and its applications. It is therefore essential that staff have access to external scientific and technical expertise. In addition to the scientific and technical advice provided by GTTAC under the committee's statutory function, the individual experts may provide a useful means of obtaining additional scientific and technical advice on specific matters. Building relationships with scientists, researchers and technical experts as a part of the activities outlined in *Strategic area 3* will also be an important adjunct to advice from experts on GTTAC.

STRATEGIC AREA 2: EFFECTIVE APPLICATION OF SCIENCE TO REGULATORY ACTIVITIES

CONTINUOUSLY IMPROVE OUR REGULATORY RISK ANALYSIS

The Regulator's approach to risk analysis of GMOs is outlined in the *Risk Analysis Framework* (RAF). It explains why and how the Regulator undertakes risk analysis by describing the legislative context for risk analysis, the Regulator's approach to risk analysis and its application to the preparation of RARMPs for licence applications. It also discusses the Regulator's approach to risk communication.

Periodic review of the RAF will ensure that the Regulator's approach continues to reflect best practice regulatory risk analysis. A review was completed during 2012-13 with a particular focus on risk communication. The revised RAF will be applied to our regulatory work in conjunction with in-house training for our scientific staff. Another review of the RAF will occur during this period and will include reinforcing the review and feedback elements of risk analysis.

Risk analysis relies on scientific and technical information to evaluate the level of risk that may be posed by activities conducted with GMOs and to prepare RARMPs which are used as the basis for regulatory decision making on licence applications. It is therefore critical that this information is effectively incorporated into risk analyses and applied to the job of regulating activities with GMOs. Internal peer review will play a critical role in continuing to produce high quality risk assessment documents that draw appropriately on up-to-date scientific and technical information. External review of our risk assessments by government agencies, other regulatory authorities, experts, including GTTAC and the public will also continue.

IMPROVED USE OF INFORMATION

The OGTR has an active program of inspecting field trials with GM crops and work with GMOs conducted in contained facilities. Audits and practice reviews examine procedures and practices used by regulated organisations to manage compliance with the regulatory system. These and other post-approval activities collect information which can be valuable for informing regulatory risk analyses. Making better use of information collected from these activities and the experience gathered over the last decade of administering the regulatory system will help reinforce the review and feedback element of risk analysis, inform current and future RARMPs and help to identify areas for regulatory change.

KEEP PACE WITH SCIENTIFIC ADVANCES

Keeping up to date with developments in gene technology is critical for ensuring that regulatory science and the regulatory system are able to anticipate and respond to change. The application of new plant breeding techniques and applications of new technologies in areas such as human and veterinary medicine will pose some challenges for the current regulatory framework. The way in which research and development activities are conducted is also changing. New scientific information may shed new light on the possible risks associated with some work with GMOs. It is important that the OGTR continues to interrogate the scientific literature and interact with stakeholders involved in research, development and commercialisation activities to identify scientific advances and other developments that may impact on our regulatory science, current approvals and future risk assessments. Identifying and assessing scientific advances will also inform the need to recommend changes to regulations and legislation where warranted.

STRATEGIC AREA 3: ENHANCED COLLABORATION, PARTNERSHIP AND LEADERSHIP

PRODUCTIVE PARTNERSHIPS WITH AUSTRALIAN REGULATORY AGENCIES AND GOVERNMENT DEPARTMENTS

The OGTR operates within an integrated regulatory framework for gene technology which includes the regulatory agencies TGA, FSANZ, APVMA, NICNAS and the Department of Agriculture. Enhanced collaboration and information sharing with these regulatory partners will further strengthen the regulatory framework for gene technology. To underpin this, the OGTR will continue to have Memoranda of Understanding with these agencies. We will continue to build strong linkages through information exchange activities such as the Regulators' Forum –a regular meeting of the heads of regulatory agencies to discuss issues of mutual interest and work on collaborative projects - and the Regulatory Science Network, a meeting of regulatory scientists which aims to promote and strengthen regulatory science amongst Australian government regulatory agencies.

In addition, there are a number of other Australian government departments and agencies in portfolio areas such as environment, industry and innovation, agriculture and foreign affairs which have an interest in gene technology. It is important that the OGTR continues to liaise productively with these organisations to communicate clearly the role of sound science in regulatory decision making and to contribute to whole of government approaches to gene technology matters.

The States and Territories play an integral role in the governance and operation of the regulatory system for gene technology in Australia. Consultation with them is a valuable, prescribed input into regulatory decision making for all applications involving intentional release into the environment. The OGTR has established a State and Territory Technical Contact Group for gene technology to enhance scientific and technical liaison.

BETTER LINKS WITH RESEARCH AND EDUCATIONAL INSTITUTIONS

Because the OGTR is a small agency, some areas of scientific expertise may not be available within the agency. Building better links with research and educational institutions helps us to access external scientific and technical expertise. Collaborating on projects relevant to our work, contributing to teaching, honorary positions, attending research seminars and conferences and inviting researchers and teachers to participate in our activities will build links with these institutions. Publication of key reference documents in peer reviewed journals, books and other publications will also assist engagement with the research and educational community.

LEAD AND ADOPT INTERNATIONAL REGULATORY BEST PRACTICE

Research, development and commercialisation and regulation of gene technology are all global activities. The OGTR and the Regulator's approach to risk analysis are highly regarded internationally. To maintain our position at the forefront of regulatory science for gene technology, effective international engagement is essential. The OGTR has an active program of international engagement, participating in a range of multilateral and bilateral forums and meetings. We will continue to participate in the activities of the OECD, WHO and in other relevant multilateral forums, taking opportunities to both influence and adopt international best practice risk analysis. We will also continue to engage with our counterparts in other countries to exchange information and promote consistent approaches to regulatory risk analysis for gene technology.

CONSTRUCTIVE COLLABORATION WITH INDUSTRY AND END-USERS TO SHARE INFORMATION

The commercial application of gene technology is an endpoint of years of research and development. Data for regulatory and other purposes is generated by industry during this process. Practical experience and other valuable information may also be gained from those industry sectors and end-users that use commercialised GMOs. Engaging broadly with these groups is important as their experience and information are valuable inputs for regulatory risk analysis. Sharing information on developments in the application of gene technology and reviewing practical experiences will help the OGTR anticipate needs for scientific and technical expertise and/or regulatory change. It will also assist with mutual understanding of regulatory requirements.

STRATEGIC AREA 4: STAKEHOLDER ENGAGEMENT AND COMMUNICATION

ENGAGE WITH STAKEHOLDERS TO ADD VALUE TO REGULATORY SCIENCE AND DECISION MAKING

It is important that we engage with and listen to the views and opinions of our stakeholders because they make valuable contributions to our regulatory science and decision making. The OGTR has a diverse range of stakeholders and we engage with them in various ways.

We will continue to engage constructively with our stakeholders by consulting with them during the development of key regulatory requirements and as a part of the risk analysis process for applications. We will participate in conferences and seminars, contribute to the development of regulatory science nationally and internationally and meet with stakeholders to discuss scientific, technical and regulatory matters.

A major stakeholder engagement activity undertaken by the OGTR is the Institutional Biosafety Committee (IBC) forum. Representatives from accredited organisations and IBC members from across the country meet with the OGTR to share information about the operation of the regulatory scheme.

SHARE INFORMATION AND BUILD TRUST THROUGH OPENNESS AND TRANSPARENCY

The legislative framework for gene technology was built on the values of openness and transparency. We provide many scientific and other documents on our website including the *Risk Analysis Framework*, RARMPs for all DIR applications, risk assessment references such as biology documents, guidelines and other documents outlining our requirements for applications and documents describing how the regulatory framework is constructed and the processes we follow for regulatory decision making. The OGTR will continue to be open and transparent by providing clear, accessible information on our assessment processes and regulatory decisions and being responsive to stakeholder feedback.

COMMUNICATE CLEARLY AND SIMPLY

Scientific and technical information can be complicated and confusing. Clearly communicating our science in a manner accessible to everyone is critical for maintaining and building trust, confidence and understanding of the regulation of gene technology. We aim to promote our regulatory science and provide information that is easy to understand for scientists and non-scientists alike. The OGTR will develop a Communications Strategy to guide our communication activities in an environment characterised by a rapidly expanding array of communication tools and increasing stakeholder expectations.