



Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

The Hon Mark Butler MP
Parliamentary Secretary for Health
Parliament House
Canberra ACT 2600

Dear Parliamentary Secretary

OFFICE OF THE GENE TECHNOLOGY REGULATOR
STATEMENT OF INTENT

I am pleased to provide you with my Statement of Intent (attached), which sets out my plan to achieve the expectations outlined for myself and the Office of the Gene Technology Regulator (OGTR) in your Statement of Expectations.

This Statement of Intent enables me to affirm my commitment to administering the *Gene Technology Act 2000* to safeguard human health and protect the environment through the application of good regulatory practice for gene technology. I will maintain the OGTR's established reputation as an internationally recognised, high performing agency and ensure that it operates in accordance with all relevant legislation, policies and principles.

Since coming to the position of Gene Technology Regulator earlier this year, the Statement of Intent also provides me with an opportunity to highlight the areas and initiatives which I believe will have the most significant impact in the coming year. In this vein, the review of the Gene Technology Regulations 2001, due to be completed in mid-2010, will result in a number of changes which will improve both the effectiveness and efficiency of the regulatory system. The review will involve extensive consultation and provide opportunities for stakeholder and public input to the process, in line with the OGTR's commitment to openness and transparency.

I look forward to working closely with you to deliver and continue to enhance Australia's gene technology regulatory system.

Yours sincerely

A handwritten signature in black ink, appearing to read 'J. Smith'.

Dr Joe Smith
Gene Technology Regulator
23 September 2009

OFFICE OF THE GENE TECHNOLOGY REGULATOR STATEMENT OF INTENT

Role

I will uphold my responsibility for implementing the national gene technology regulatory system on behalf of the Australian Government and the State and Territory Governments by administering the *Gene Technology Act 2000* (the GT Act), the Gene Technology Regulations 2001 (GT Regulations) and the corresponding legislation in other jurisdictions.

I acknowledge my responsibility for providing strong and effective leadership and management of the staff of the OGTR, provided to me by the Department of Health and Ageing. I will ensure that the OGTR maintains its culture of continuous improvement of its procedures and practices taking account of operational experience and the feedback of stakeholders.

Legislative framework

I will administer the GT Act, the GT Regulations and corresponding State and Territory legislation to achieve the mission of the OGTR – to safeguard human health and protect the environment through the application of good regulatory practice for gene technology.

Further to administering corresponding State and Territory gene technology legislation, I will continue to work with the States and Territories to progress the achievement of a nationally consistent scheme for gene technology.

I will also ensure that the OGTR operates in accordance with all relevant legislation, including the *Public Service Act 1999* and the *Financial Management and Accountability Act 1997*.

Short and long term priorities

I am committed to maintaining the reputation that the OGTR has gained as a high performing organisation in the regulation of genetically modified organisms. My primary concern is always to protect human health and safety, and the environment, by identifying and managing risks posed by or as a result of gene technology. I will achieve this by fulfilling my role as set out in Section 27 of the GT Act and by ensuring that my decisions are consistent with the policy principles issued by the Gene Technology Ministerial Council.

Internal reviews

A major short term priority for the OGTR is the completion of the review of the GT Regulations, which was commenced in October 2008. The scope of this review is limited to issues which do not affect the policy settings of the regulatory scheme and which are consistent with achieving the object of the GT Act. Following the analysis of submissions, which were sought from relevant stakeholders and Commonwealth and State and Territory Government contacts, five areas for potential amendment have been identified, however the main focus of the review is the classification of exempt and notifiable low risk dealings. The Gene Technology Ministerial Council and the Gene Technology Technical Advisory Committee have been consulted on the proposed amendments and we are now developing drafting instructions. I will undertake a public consultation on the draft Amendment

Regulations in line with the consultation requirements in the GT Act. My aim is to have the amendments made in mid-2010.

As part of an ongoing program of revision of the Regulator's *Guidelines for Certification of Physical Containment (PC) Facilities* (the Guidelines), the OGTR is currently revising the Guidelines for PC3 Animal Facilities and PC3 Arthropod (now Invertebrate) Facilities, both of which were issued on 1 June 2001. Draft revised guidelines were released for a targeted consultation in April 2009 to organisations with experience with PC3 animal and invertebrate facilities. Comments are currently being analysed by the OGTR.

I recently completed a review of the *Risk Analysis Framework*, a key guidance document for the OGTR, applicants and stakeholders. The revised document was launched on 30 April 2009. The revision resulted in a number of minor amendments to achieve greater alignment with the *Australian Standard/New Zealand Standard 4360:2004 Risk Management* and to provide a clearer explanation of the Regulator's current approach to risk analysis in Risk Analysis and Risk Management Plans (RARMPs), incorporating experience developed within the OGTR and reflecting recent changes in the legislation. The next review of the *Risk Analysis Framework* is due to commence in 2010.

Risk-derived regulatory goals and key performance

The OGTR has developed a reputation for high quality and scientifically robust risk assessments of genetically modified organisms (GMOs). OGTR scientific staff maintain a high level of competence and an active awareness of developments in research and regulation around the world. The OGTR's Business Risk Management Plan identifies the retention of highly qualified staff as a key issue and I will ensure that this high quality of scientific analysis is maintained and supported through recruiting highly qualified staff, providing ongoing staff development opportunities, and maintaining access to up to date scientific information.

The OGTR will apply a risk-informed approach to regulation and continually review the key performance indicators outlined in the Business Risk Management Plan to ensure that they are relevant and appropriate. These key performance indicators are monitored on a weekly basis as part of regular management meetings. The Portfolio Budget Statements also describe performance measures and targets for the OGTR. I will report progress against these measures in my Annual and Quarterly Reports.

The maintenance of high scientific and legal standards in the preparation of the Risk Assessment and Risk Management Plans (RARMPs) that form the basis of my licence decisions and conditions is integral to achieving the objective of the GT Act "to protect the health and safety of people and the environment". I will maintain the integrity of the regulatory system by ensuring that all relevant requirements of the GT Act are met in processing and deciding on licence applications.

Once licences have been issued, I will ensure that the requirements of the GT Act and the licence conditions are being complied with by continuing the OGTR's systematic program of monitoring GMO dealings. These activities will maintain focus on the areas of highest risk.

In consultation with other agencies and key industry stakeholders, I will continue the implementation of the Australian Government's strategy for dealing with the potential occurrence of the unintended presence of unapproved GMOs. I will also continue the development and implementation of a Post Release Review program for commercial scale releases.

Harmonisation and bilateral arrangements

I will strive to ensure that the OGTR operates in harmony with the Government's broader policy reform agenda and maintain a high level of awareness of the Government's health, industry and environmental policy objectives. This will be achieved through strong liaison between the OGTR and relevant areas of the Department and other Australian Government departments, including the Department of the Environment, Water, Heritage and the Arts and the Department of Agriculture, Fisheries and Forestry. In addition, the OGTR will continue to comply with the requirements of the Office of Best Practice Regulation and the Department of Finance and Deregulation in relation to any changes to specific aspects of the regulatory system such as forms and guidelines.

I remain committed to harmonising standards, as far as possible, with other regulatory agencies with complementary responsibilities and with Standards Australia. I will continue to give a high priority to liaison and cooperation with the Australian Quarantine Inspection Service (AQIS) and will ensure that the OGTR remains represented on the relevant committee of Standards Australia - Subcommittee CH-026-03, "Safety in Laboratories - Microbiology".

I will strengthen bilateral arrangements with the other agencies that also have a key role in Australia's integrated regulatory framework for gene technology, such as Food Standards Australia New Zealand, the Australian Pesticides and Veterinary Medicines Authority, the Therapeutic Goods Administration, and the National Industrial Chemicals Notification and Assessment Scheme, to exchange information and, as far as possible under the respective legislation, coordinate assessments and align decision making. I will also undertake a review of the memoranda of understanding between OGTR and other agencies and amend these where appropriate.

I will develop the OGTR's relationship with the Office of Health Protection within the Department, which has responsibility for the operation of the regulatory system for security sensitive biological agents (SSBAs) under the *National Health Security Act 2007*. In line with the new function conferred by the Gene Technology Amendment Regulations 2009, the OGTR will provide inspectors to carry out inspections under the SSBA scheme.

International engagement

The OGTR will continue to interact directly with key regulatory counterparts in many other countries through bilateral discussions and participation in international fora. In particular, the OGTR will participate in the Organisation for Economic Cooperation and Development (OECD) Working Group on Harmonisation of Regulatory Oversight in Biotechnology. This Working Group promotes international harmonisation of biotechnology regulation through a number of projects; most importantly by publishing science-based consensus documents that assist risk assessment of GMOs.

The OGTR provides support to the Department of Foreign Affairs and Trade (DFAT) as the lead agency in Australia's engagement in the UN Cartagena Protocol on Biosafety (Biosafety Protocol). The Protocol applies to the transboundary movement, transit, handling and use of all living modified organisms (LMOs) that may have adverse effects on the conservation and sustainable use of biological diversity. Although not a party to the protocol, Australia maintains active participation as a non-Party in negotiations. The OGTR will continue to provide technical advice and expertise, including through participation in technical expert groups.

I will seek opportunities to inform and influence developments in GMO regulation based on Australian experience and to ensure that the regulatory scheme takes account of international practice.

Stakeholder relationships

I note that the Secretary of the Department plays an important role in providing you with policy advice in your oversight of portfolio agencies. To help ensure that the Secretary and the Department can fulfil this advisory role, my staff and I will continue to foster a close working relationship with the Department so that the Secretary is apprised of issues and information regarding gene technology regulation affecting the portfolio. This will involve, but not be limited to, my attendance at Portfolio CEO meetings, and representation at regular meetings and ongoing liaison with the Regulatory Policy and Governance Division. I will continue to advise your office regarding public notifications, consultations and decisions on applications for the intentional release of GMOs. Information on key issues and events which may impact on Government operations will be provided with appropriate notice and in accordance with the ministerially endorsed Relationship and Appointment protocols.

Stakeholder confidence

Maintaining sound working relationships with our stakeholders is critical to maintaining the effectiveness, credibility and responsiveness of the regulatory scheme. My staff and I will continue to work closely with stakeholders at all levels: Australian Government; States and Territories; local governments; regulated organisations; business and community associations; and the general public.

The GT Act requires a high degree of transparency. Consistent with this objective, I have adopted a strongly consultative approach, embodied in the OGTR Service Charter, that seeks to provide stakeholders with a means of communicating their concerns or issues. I am committed to providing clear and accurate information in a timely manner to stakeholders and promoting stakeholder confidence that the gene technology legislation is administered competently, reasonably and objectively.

Consultation practices

I will aim to ensure that the requirements of the GT Act for consultation are exceeded. I will continue my practice of publishing notifications of licence applications and providing longer than the minimum required periods of consultation to facilitate provision of information and promote input to the decision-making process, particularly by the community. I will also continue my practice of seeking stakeholder feedback and input to the development and revision of guidance documents produced by the OGTR.

I will continue to seek the advice of the Gene Technology Technical Advisory Committee (GTTAC) in respect of all licence applications for dealings with GMOs involving intentional release into the environment, as required by the GT Act. I will also continue to seek advice from GTTAC on other matters including the classification of dealings under the GT Act and GT Regulations.

I will continue to seek advice from the Gene Technology Ethics and Community Consultative Committee (GTECCC) on ethical and community consultation issues which arise in relation to the operation of the regulatory system.

Compliance activities

I will ensure that the programs of the OGTR are delivered within its approved budget and provide value for money service delivery. I will support the Secretary by managing the OGTR's affairs in a way that promotes the efficient, effective and ethical use of resources. I will exercise prudence in the financial management of the OGTR Special Account and ensure compliance with the requirements of the *Financial Management and Accountability Act 1997* and the financial management policies of the Department. In the event that there are any breaches of these requirements, they will be reported through the OGTR's input to the Department's annual certificate of compliance.

I will discharge my obligations under the GT Act to report, through the Parliamentary Secretary for Health, to the Australian Parliament. This will include the Annual Report on the operations of the OGTR, and Quarterly Reports in relation to any GMO licences issued during the quarter; any breaches of conditions; the conduct of auditing and monitoring of dealings; details of any Emergency Dealing Determinations (EDDs) made; and any breach of EDD conditions.

I will ensure that my Annual Report is provided to all States and Territories and that both the Annual and Quarterly Reports are available to interested parties via the OGTR website and mailing list. I will provide progress reports on the operations of the OGTR and the effectiveness of the legislative framework to the Gene Technology Ministerial Council. I will ensure that relevant information, including financial and performance information, is provided for inclusion in the Annual Report of the Department of Health and Ageing.

The agency as an employer

I will aim to ensure that OGTR staff model the Australian Public Service (APS) standards and values, and I will continue the program of ongoing training for staff on their responsibilities as members of the APS. The OGTR will continue to comply with the provisions outlined in the Department's Collective Agreement and maintain its high level of human resource standards.

The OGTR strives to be a 'family friendly' organisation, is inclusive of the diverse community, and endeavours to be responsive to employee needs and circumstances through the provision of flexible working arrangements. The OGTR recognises the importance of work/life balance in maintaining qualified staff and morale and supports flexible working arrangements such as allowing staff to work part-time, extended maternity leave and access to the 48/52 provisions that allow for additional unpaid leave while averaging the salary payments over the year.

OGTR's internal management arrangements provide for regular meetings and feedback to ensure that issues are identified and addressed in a timely manner. The OGTR Business Risk Management Plan is a key reference in this regard. OGTR staff will continue to be provided with opportunities to provide input to decision making and to express concerns or aspirations. This input, together with the data provided by the Department's Annual Staff Survey, will be used by the OGTR management team to review our performance and procedures.