



**PERFORMANCE AUDIT
BROCHURE**

**Regulation by the Office of the Gene
Technology Regulator**

Department of Health and Ageing

UNDER EMBARGO
until Tabled 25 August 2005

**The Auditor-General
Audit Report No.7
2005–2006**

Background

Regulation of gene technology

The *Gene Technology Act 2000* came into force on 21 June 2001. The Act is part of a national regulatory framework for the regulation of gene technology. Gene technology refers to *'the transfer of DNA between living cells to produce a certain outcome'*. The use of gene technology is thus any technique employed for the modification of genes or other genetic material.

There are currently three main applications of gene technology: (i) the modification of biologically useful proteins to be used in the treatment of human medical conditions and in industrial processes; (ii) the modification of plants, primarily to provide resistance to herbicides and pests; and (iii) the modification of animals to introduce new traits. The majority of work currently regulated under the Act involves either research or commercial release of plant genetically modified organisms (GMOs) in agriculture, or GMOs used in laboratory research.

The Act establishes a statutory officer, the Gene Technology Regulator (the Regulator), to administer a licensing regime regulating the use of certain gene technologies not already regulated by other agencies. The Act regulates all *'dealings'* (which includes research, manufacture, production, propagation, commercial release and import) with live viable GMOs, requiring that any dealings with GMOs must occur with authorisation from the Regulator. Its objective 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 managing those risks by regulating certain dealings with GMOs, through a process involving expert scientific analysis.

However, the Act does not aim to replace existing regulatory schemes, and other regulatory agencies continue to have primary responsibility for the regulation of gene technology in their areas of activity. For example, the Therapeutic Goods Administration continues to regulate the sale or use of genetically modified (GM) pharmaceuticals, and Food Standards Australia New Zealand regulates genetically modified foods.

Instead, the Act establishes a regime that complements the work of existing regulators, ensuring that all aspects of the production, manufacture and sale of GMOs and GM products are regulated and that there are no 'gaps' in regulatory coverage. Existing regulators are required to seek advice from the Regulator in relation to applications for approval of GM products they are considering, and to inform the Regulator of decisions made in relation to GM products. The system thus aims to ensure that the Regulator either directly regulates, or provides advice to other regulators, on all GMOs and GM products.

Office of the Gene Technology Regulator

The Office of the Gene Technology Regulator (OGTR) supports the Regulator in the exercise of functions provided for under the regulatory scheme. OGTR is part of the Therapeutic Goods Administration within the Commonwealth Department of Health and Ageing (Health). OGTR is funded through budget appropriations to the Commonwealth Health portfolio.

In 2004–05 the Office was allocated \$8.35 million for its operations, with \$7.84 million budgeted for 2005–06. OGTR is located in Canberra and comprises some 55 scientific, legal, policy, professional and administrative staff.

Audit objective and methodology

The audit focused on the systems and processes OGTR has established for both receiving and assessing applications under the Act, and also for ensuring compliance with the statutory requirements through monitoring and inspection.

The audit objective was to form an opinion on the discharge by OGTR of selected functions entrusted to it under the Act.

The audit assessed the practices of OGTR against the following principal criteria:

- (a) Assessment of applications under the Act: Whether OGTR has established systems and procedures for the management and assessment of applications under the Act.
- (b) Ensuring compliance—monitoring, inspection and enforcement activities: Whether OGTR has

established systems and procedures for ensuring compliance with the requirements of the Act.

- (c) Performance management: Whether OGTR manages selected aspects of its work efficiently and effectively.

The audit did not seek to form an opinion on the appropriateness of the chosen structure of the regime for regulating gene technology or the merit of the scientific judgments involved.

The audit methodology included discussions with representatives from agencies that co-ordinate aspects of the co-operative regulatory regime for gene technology across Australian jurisdictions, with various other stakeholders and users of the regime, as well as with officers of OGTR, along with examination of OGTR documents and files.

Key Findings

Evaluation and assessment of applications

OGTR is responsible for assisting the Regulator in the assessment of applications for licences to deal with GMOs and related functions under the Act. Overall, OGTR has established systems and procedures for the management and assessment of applications under the Act and these procedures are applied by OGTR evaluators.

In its first three years of operation, OGTR received 5 773 applications or notifications made pursuant to the Act. The Regulations specify times within which OGTR must process certain applications made under the Act—170 days for DIR and 90 days for DNIR licence applications. OGTR advise that it has processed all applications within the required statutory timeframe and ANAO analysis of OGTR processing data supports this assertion. However, improved monitoring and reporting by OGTR of the elapsed time taken to process applications, including days not counted in calculating the statutory processing time, would enable OGTR to better know the average length of (elapsed) processing time and use this information for improved resource management planning and decision-making.

OGTR has developed a package of forms, templates and guidance documents to assist organisations in making applications to OGTR and in complying with the other requirements of the Act. These documents were made available on the OGTR website. Opportunity for consultation was provided when key guidance documents had been revised. There were some minor format and useability issues that may require attention, and also opportunities for the provision of further information.

OGTR has also developed comprehensive policies and procedures for staff in performing evaluation and assessment activities. These policies are available to and applied by relevant OGTR evaluation and assessment staff. Information on OGTR systems and procedures (including administrative requirements) dealing with evaluation and assessment activities are also available and communicated to stakeholders.

Although OGTR policies and procedures dealing with evaluation and assessment activities are periodically assessed and reviewed, often no formal record of review was kept, nor timetables for future reviews. Given the pace of changes in technology and the types of applications OGTR can be expected to receive, formal mechanisms for the review of OGTR policy, procedure and guidance documents (including maintaining records of the details of such reviews), will ensure that they remain relevant and up-to-date, helping to facilitate effective assessment of applications made under the Act.

Decisions on applications are clear, properly documented, and communicated to applicants in a timely manner. However, the ANAO has made some suggestions to improve documentation (particularly in relation to DIR applications and the development of the risk assessment and risk management plans) in order to facilitate transparency and consistency in decision-making, and to facilitate quality assurance review of decisions.

Monitoring and compliance

In order to facilitate and enforce compliance with the Act, OGTR supports the Regulator by undertaking various monitoring, inspection, compliance and

investigative activities on dealings conducted under the Act.

As at 30 June 2003, nine investigations had been conducted by OGTR since its inception. Although OGTR has identified a number of instances of non-compliance, in each case these have been assessed by OGTR to pose minimal or no additional risk to human health and safety or to the environment. There have been no prosecutions commenced for offences against the Act.

OGTR utilises a risk-based approach to selecting the number and identity of premises to be the subject of monitoring visits, setting and exceeding targets for annual monitoring rates for a number of dealing and premises type. However, the ANAO found that there was room for better use of information from OGTR's monitoring activities in planning.

OGTR has also developed comprehensive policies and procedures for monitoring and inspection of dealings with GMOs and for related compliance and investigation activities. These policies are available to, and followed by, relevant OGTR staff and guidance on these activities is also made available to stakeholders. Again, the ANAO has made some suggestions for a systematic approach to the review of policy, procedure and guidance documents to maintain relevance and consistency.

Managing performance within OGTR

OGTR has good information on its costs and current resource requirements, and has performed its regulatory functions within its annual appropriation. However, uncertainties over resources and requirements (influenced by external factors such as the recently resolved question of cost-recovery, as well as the impending establishment of the Trans-Tasman Therapeutic Products Agency—existing OGTR staff will be transferred to the new agency) have led to management strategies and decision-making that impact on the ability of OGTR to recruit and retain the highly-skilled staff it requires to perform its regulatory functions.

Staff training needs are identified and agreed between the individual and the relevant manager. In addition,

other training is provided in general aspects of OGTR operations, as well as opportunities for professional development and exchange through participation in relevant conferences and other training. However, the lack of a formal, documented training programme for the key areas of OGTR operations, leads to risks that the loss of key OGTR staff will place pressure on the ability of OGTR to adequately meet the training needs of future staff whilst continuing to meet its legislative obligations.

OGTR has performance measures on a number of key aspects of its assessment and monitoring activities. For example, OGTR has set as a measure of overall effectiveness of its implementation of the objective of the Act, 100 per cent compliance with the requirements of the Act for all licensed dealings, certifications and accreditations. However, compliance by licensees with conditions of licence will depend on a number of factors, some not directly associated with implementation of the Act's requirements by OGTR. OGTR reporting against this measure report does not provide any detailed analysis of the reasons for non-compliance or an analysis of trends in non-compliance that may enable an assessment of OGTR's effectiveness in managing the risks to human health and safety and to the environment posed by dealings with GMOs. In addition, although required by the measure, the annual report does not provide any information on instances of non-compliance found in monitoring of dealings other than for DIR and DNIR licences.

The ANAO has made a number of suggestions for improvement of OGTR's existing performance measures to provide greater information and transparency on OGTR regulatory performance to maintain public confidence in regulation.

Although OGTR reports a significant amount of operational information in its quarterly reports, the ANAO considers that there is room for much better reporting and use of performance information in assessing and improving OGTR systems, procedures and performance. For example, the ANAO found that generally there was a lack of long-term consolidated reporting within OGTR, with performance reporting mostly focused on provision of information to assist in

preparation of the quarterly reports. The delays in implementation and decreased functionality of OGTR's management information system (GTIMS) have contributed to this situation, with the necessity for ad hoc systems to be developed pending the implementation of GTIMS as a tool for recording and reporting on performance.

Consolidated annual (internal or external) reporting by OGTR on its activities over the year, will enable OGTR to use such information to analyse trends in workload and performance.

Overall conclusion

Overall, OGTR has developed and implemented policies and procedures for the efficient and effective discharge of selected functions entrusted to it under the *Gene Technology Act 2000*. OGTR has processed applications within the required timeframes and has exceeded targets for annual monitoring of DIR field trial sites.

OGTR has good information on its costs and resource requirements, although close monitoring of current staffing levels and the risks to attracting and retaining staff is necessary to ensure that it continues to have the staff necessary for it to effectively perform its regulatory functions.

Although OGTR reports a significant amount of operational information, there is room for better use of this information in measuring and improving performance.

The ANAO has made a number of recommendations and suggestions for improvement. Health has agreed to all recommendations.

Agency response

The Office of the Gene Technology Regulator (OGTR) accepts the five recommendations of the ANAO and has already undertaken steps towards their implementation.

With regard to Recommendations 1 and 3, all OGTR policies, procedures, forms and guidance documents are subject to ongoing review on an as needs basis. An

appropriate schedule and documentation process will be developed for future reviews.

In relation to Recommendation 2, the OGTR has guidance relating to licence variations available on its website. Similar guidance will be developed on the policies and processes pertaining to the variation of other instruments, and the transfer and surrender of instruments, as well as their cancellation or suspension by the Gene Technology Regulator (GTR).

The OGTR is in the process of implementing Recommendation 4 to improve the provision of information relating to its monitoring activities. It is anticipated that this will be fully actioned by the end of the year.

The OGTR is in the process of implementing Recommendation 5.



For more information please contact:

David Nyskohus
Dr Paul Nicoll

Tel: (02) 6203 7396
Tel: (02) 6203 7759

Or visit our website at

<http://www.anao.gov.au>