The Auditor-General
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Performance Audit

Regulation by the Office of the Gene Technology Regulator

Department of Health and Ageing

Australian National Audit Office

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Australian National
Audit Office

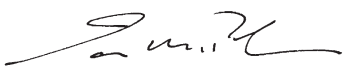
Canberra ACT
25 August 2005

Dear Mr President
Dear Mr Speaker

The Australian National Audit Office has undertaken a performance audit in the Office of the Gene Technology Regulator in accordance with the authority contained in the *Auditor-General Act 1997*. Pursuant to Senate Standing Order 166 relating to the presentation of documents when the Senate is not sitting, I present the report of this audit and the accompanying brochure. The report is titled Regulation by the Office of the Gene Technology Regulator.

Following its presentation and receipt, the report will be placed on the Australian National Audit Office's Homepage—http://www.anao.gov.au.

Yours sincerely



Ian McPhee
Auditor-General

The Honourable the President of the Senate
The Honourable the Speaker of the House of Representatives
Parliament House
Canberra ACT

AUDITING FOR AUSTRALIA

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For further information contact:
The Publications Manager
Australian National Audit Office
GPO Box 707
Canberra ACT 2601

Telephone: **(02) 6203 7505**
Fax: **(02) 6203 7519**
Email: **webmaster@anao.gov.au**

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Audit Team

David Nyskohus
Norman Newton
Paul Nicoll

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Abbreviations

ACT	Australian Capital Territory
the Act	*Gene Technology Act 2000* (Cth)
ALMS	Applications and Licence Management Section
ANAO	Australian National Audit Office
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
CCI	confidential commercial information
CDES	Contained Dealings Evaluation Section
DNA	deoxyribonucleic acid
DIR	dealing involving intentional release
DNIR	dealing not involving intentional release
FSANZ	Food Standards Australia New Zealand
GM	genetically modified
GMAC	Genetic Manipulation Advisory Committee
GMO	genetically modified organism
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
GTIMS	Gene Technology Information Management System
GTMC	Gene Technology Ministerial Council
GTTAC	Gene Technology Technical Advisory Committee
Health	Commonwealth Department of Health and Ageing
IBC	Institutional Biosafety Committee
IOGTR	Interim Office of the Gene Technology Regulator
NLRD	notifiable low risk dealing
NT	Northern Territory
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator

PC	physical containment
PHM	post-harvest monitoring
Qld	Queensland
RARMP	risk assessment and risk management plan
the Regulations	Gene Technology Regulations 2001 (Cth)
RNA	ribonucleic acid
TGA	Therapeutic Goods Administration
TTTPA	Trans-Tasman Therapeutic Products Agency
URL	uniform resource locator

Glossary

Accredited organisation[1]	An organisation that is accredited under section 92 of the *Gene Technology Act 2000* (Cth).
Biotechnology	The use of plants, animals and micro-organisms to create products or processes. Modern biotechnology also includes the use of gene technology. The term also refers to the production of genetically modified organisms or the manufacture of products from genetically modified organisms.
Certified facility	A facility that has been certified by the Regulator, in accordance with section 92 of the *Gene Technology Act 2000* (Cth), to a particular containment level.
Chromosome	The self-replicating genetic structures of cells containing the cellular DNA.
Containment level	In relation to a facility, means the degree of physical confinement of GMOs provided by the facility, having regard to the design of the facility, the equipment located or installed in the facility and the procedures generally used within the facility.
Deal with *or* dealing with (a GMO)	Section 10 of the *Gene Technology Act 2000* (Cth) provides that 'deal with' in relation to a GMO means the following: (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO; (d) propagate the GMO; (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO; and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (g).

[1] Note, the terms indicated in italics above are also defined by the *Gene Technology Act 2000* (Cth). Reference should be made to the Act to ascertain the particular meaning of a term in the context of the Act.

Dealing involving intentional release	Is a dealing involving a GMO where the GMO is intentionally released into the open environment, whether or not it is released with provision for limiting the dissemination or persistence of the GMO or its genetic material in the environment.
Gene	A sequence of DNA, located on a chromosome, which codes for the synthesis of a specific protein or has a specific regulatory function.
Gene technology	Any technique for the modification of genes or other genetic material.
Gene therapy	The use of gene technology to insert DNA into cells of an organism suffering from a genetic disease, in order to replace the defective gene and correct the genetic defect causing the disease.
Genetic modification	Any process that alters the genetic material of a living organism. Examples include the duplication, insertion, or deletion of genes from another species, in microbes, plants or animals (humans included). Where this is done in humans, it is gene therapy.
Genetically modified organism	An organism (plant, animal, bacteria, or virus) that has had its genetic material altered, either by the duplication, insertion or deletion of one or more new genes, or by changing the activities of an existing gene, in a way that does not occur naturally by mating or natural recombination.
Hazard	The capacity of a GMO to produce a particular type of adverse health or environmental effect, directly or indirectly; or an event, sequence of events or combination of circumstances that could potentially have adverse consequences
Herbicide	A substance that kills plants. Herbicides are used in agriculture, horticulture and gardening to control unwanted plants. Herbicides can be selective and kill selected species, or non-selective (broad spectrum) and kill all plants.
Insecticide	A chemical that kills insects.

Institutional biosafety committees	Specially constituted committees established by organisations to assist in internally reviewing and monitoring research proposals and activities within the organisation.
Notifiable low risk dealing	A dealing, prescribed by the Regulations, that has been assessed over time as posing minimal biosafety risks and thus may be conducted within contained facilities without the need to seek a licence from the Regulator.
Organism	A living thing that contains DNA and is capable of cell replication by itself.
Pesticide	A chemical that kills pests.
Recombination	Exchange of genetic material (DNA or RNA) between two individual organisms, resulting in a change in genetic makeup and properties. The exchange is heritable and permanent.
Risk	A function of the probability of an adverse effect and the severity of that effect.
Risk analysis	A process comprising three interconnected components: risk assessment, risk management and risk communication.
Risk assessment	A science-based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment, and risk characterisation.
Risk communication	The interactive exchange of information and opinions (throughout the risk analysis process) on hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.
Risk management	The process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and selecting appropriate prevention and control measures to minimise occurrence of the adverse event or its likely impacts.
Vector	The vehicle used to carry the cloned DNA segment for insertion into the recipient cell.

Summary and Recommendations

Summary and Key Findings

Background

Regulation of gene technology

1. 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.

2. 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 matter 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.

3. 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.

4. 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.

5. 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

6. 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.

7. 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

8. The audit focussed 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.

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

10. 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.

11. 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.

12. 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

13. 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.

14. 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.[2] 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.

15. 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.

16. 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.

17. Although OGTR policies and procedures dealing with evaluation and assessment activities are periodically assessed and reviewed, often no formal

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[2] There are four main types of dealings regulated under the Act, including dealings involving commercial release (DIRs) and dealings not involving commercial release (DNIRs) of a GMO.

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.

18. 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

19. 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.

20. 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.

21. 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.

22. 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

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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

29. 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.

30. 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.

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

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

Agency response

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

34. 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.

35. 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).

36. 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.

37. The OGTR is in the process of implementing Recommendation 5.

Recommendations

The ANAO considers that implementation of the Recommendations listed below will facilitate the efficient and effective performance by OGTR of its functions and will enhance regulation under the Act.

Recommendation No. 1
Para 2.19

The ANAO recommends that OGTR review and revise its forms and guidance documents in order to facilitate and ensure high level compliance with OGTR information requirements and to facilitate more efficient and effective regulation.

Health Response: *Agree.*

Recommendation No. 2
Para 2.37

In order to facilitate and enhance OGTR decision-making, the ANAO recommends that OGTR develop and publish clear guidance to applicants on the process and policies applied by OGTR in assessing applications for variation, cancellation, transfer and suspension.

Health Response: *Agree.*

Recommendation No. 3
Para 2.56

The ANAO recommends that OGTR adopt formal mechanisms for the review of its policy, procedure and guidance documents (and maintain records of such reviews), to ensure that they remain consistent and up-to-date.

Health Response: *Agree.*

Recommendation No. 4
Para 3.39

In order to provide better information on OGTR monitoring of licences and other instruments, the ANAO recommends that OGTR more fully explain its reported rates of monitoring, including maintaining and publishing information on the number of sites or organisations yet to be visited by OGTR. This will also enable any gaps in OGTR coverage of sites in its monitoring and inspection activities to be more readily identified.

Health Response: *Agree.*

Recommendation No. 5
Para 4.64

The ANAO recommends that OGTR seek clarification of its obligations (arising under the Act) to publicly report annual information on its operations. In order to facilitate better use of OGTR performance information and foster confidence in OGTR implementation of the Act, OGTR should assess the need for consolidated annual reporting (internal and/or external) of the performance information provided in its quarterly reports, as well as of other relevant information on its activities throughout the year.

Health Response: *Agree.*

Audit Findings and Conclusions

1. Audit Background

This chapter describes the audit, outlining the reasons for it and expected outcomes, as well as describing the audit objective, scope, and criteria.

The Gene Technology Regulator and the Office of the Gene Technology Regulator

1.1 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.[3]

1.2 The *Commonwealth Gene Technology Act 2000* (Cth) (the Act) came into force on 21 June 2001. The Act is part of a national regulatory framework for the regulation of gene technology. 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 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.[4] Instead, the Act establishes a regime that complements the work of existing regulators, ensuring that all aspects of the production, manufacture and sale of genetically modified organisms (GMOs) and genetically modified (GM) products are regulated and that there are no 'gaps' in regulatory coverage.[5]

1.3 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.

1.4 The regime for the regulation of gene technology is based upon identification and scientific assessment of the risks posed by various applications of gene technology, and the implementation and enforcement of measures designed to manage any such risks. The Office of the Gene

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3 See for example, *Gene Technology Act 2000* (Cth) s 10.

4 For example, the Therapeutic Goods Administration continues to regulate the sale or use of genetically modified pharmaceuticals, whilst Food Standards Australia New Zealand regulates genetically modified foods.

5 The majority of work currently regulated under the Act involves either research or commercial release of agricultural GMOs or GMOs used in laboratory research.

Technology Regulator (OGTR) supports the Regulator in the exercise of the functions provided for under the regulatory scheme.

1.5 The key roles of the OGTR are to support the Regulator by providing a process whereby: (i) applications for the use of gene technology are assessed consistently with the requirements of the Act; and (ii) any conditions imposed on the use of gene technology are complied with by users of the technology, and where non-compliance is found, appropriate measures are taken. In performing these roles, the OGTR thus ensures that the primary aim of the regime, that is, the protection of the health and safety of people and the environment, is met.

1.6 Further discussion of the regulatory regime is provided in Appendix 1.

Reasons for the audit

1.7 The audit was conducted for the following reasons:

- the OGTR has a vital national role in public health and environmental matters;
- the ANAO has not previously conducted a performance audit of OGTR;
- there has been significant debate and interest over the use and application of gene technology in recent years, particularly over field trials of genetically modified (GM) agricultural crops. The audit would examine whether the OGTR is efficiently and effectively discharging its important duties under the regulatory regime established by the Act, including establishing clear and transparent decision-making processes, and monitoring and enforcing compliance with regulatory conditions; and
- the conduct of an audit may also assist in informing the statutory review of the regime required to commence after the fourth anniversary of the commencement of the Act, that is, in the middle of 2005.

Audit scope

1.8 The audit focussed on the systems and processes the 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.

Audit objective and criteria

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

1.10 The audit assessed the practices of the 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.

1.11 The audit did not come to an opinion on the appropriateness of the regime for regulating gene technology or the merit of the scientific judgments involved.[6]

1.12 Details of the audit methodology are provided in Appendix 2. The audit was conducted in accordance with ANAO Auditing Standards at an estimated cost of $411 000.

Report structure

1.13 This report is structured as follows:

- **Chapter 1** provided a background to the audit, including a brief description of the national regime for the regulation of gene technology, and of the audit objective, scope and criteria.
- **Chapter 2** discusses the evaluation and assessment of applications and notifications made under the Act. It briefly describes the requirements prescribed by the Act for the processing of applications, before providing information on the numbers of such applications received and processed by OGTR over its first three years. OGTR policies and procedures for the submission and assessment of applications are then

[6] There are a number of matters that, although relevant to the regulation of gene technology, fall outside the scope of the Act or the scope of regulatory oversight fulfilled by OGTR. Although many of these matters are important in the context of the regulation of the applications and products of gene technology as a whole, they have not been explored throughout the course of this audit and thus the ANAO makes no findings on these matters. However, it should be noted that the forthcoming independent review of the Act may provide an avenue by which these can be addressed. A brief discussion of some of these matters is provided at paragraph 44 of Appendix 1.

analysed, with a final examination of OGTR policies for the protection of information provided during the application and evaluation processes.

- **Chapter 3** describes the monitoring and inspection activities undertaken by OGTR in seeking to secure compliance with the requirements of the Act, including compliance with licence conditions and risk management measures.
- **Chapter 4** discusses aspects of OGTR performance in discharging selected functions under the Act. The chapter first discusses OGTR budget and financial resources, before examining OGTR workforce planning and the external factors influencing, and risks associated with, OGTR deployment of its financial and human resources. The chapter then briefly describes training of OGTR staff, before examining OGTR performance measurement and reporting.

2. Evaluation and Assessment

This chapter discusses the evaluation and assessment of applications and notifications made under the Act. A brief background on the licensing regime established by the Act is first provided, followed by a description of the type of applications and notifications that may be made under the Act. OGTR processes and policies for the submission of applications (including guidance information provided by OGTR to applicants) are then discussed. This is followed by a consideration of the evaluation and assessment processes used by OGTR in evaluating and approving applications, with a final examination of OGTR policies for the protection of information provided during the application and evaluation process.

OGTR approval processes for regulated dealings

2.1 There are four main types of dealings with GMOs outlined in the Act:

- dealings involving intentional release into the environment (DIRs);
- dealings not involving intentional release into the environment (DNIRs);
- notifiable low risk dealings (NLRDs); and
- exempt dealings.

2.2 Figure 2.1 provides examples of the types of dealings with GMOs falling within each class. A fuller description of the licensing regime and the types of dealings regulated under the Act is provided in Appendix 1.

2.3 The Act provides for a number of different applications to be made to the Regulator for approval to conduct dealings with GMOs and other related matters. The Act also requires certain specified information to be provided to the Regulator by persons conducting such dealings. The main types of application and notification made under the Act are as follows:

- applications for DIR and DNIR licences;
- applications for variation, cancellation, transfer and suspension of licences;
- NLRD notifications;
- applications for accreditation;
- annual reports of accredited organisations;
- applications for certification of facilities; and
- applications for declaration of confidential commercial information (CCI).

Figure 2.1
Examples of types of dealings with GMOs

Dealings with GMOs involving intentional release into the environment

The following are examples of dealings with GMOs that have been considered by the Regulator and involve intentional release of the GMO into the environment:

- Commercial release of cotton varieties genetically modified to contain: a gene conferring resistance to the glyphosate herbicide Roundup®; and a gene producing an insect toxin that provides resistance to two caterpillar pests of cotton (DIR 023/2002).
- Commercial release of carnations genetically modified to produce novel coloured flowers (DIR 030/2002).
- Commercial release of a genetically modified oral cholera vaccine (DIR 033/2002).
- Field trial of pineapple plants genetically modified to contain a gene that delays flowering (DIR 027/2002).
- Field trial of papaya plants genetically modified to contain a gene that delays fruit ripening (DIR 026/2002).
- Field trial of grapevines genetically modified to contain genes affecting the browning of sultanas produced from the grapevines, grape colour and composition or flower and fruit development (DIR 031/2002).

Dealings with GMOs not involving intentional release into the environment

The following are examples of dealings with GMOs that have been considered by the Regulator and do not involve intentional release of the GMO into the environment:

- Development of novel gene therapy vectors for gene therapy of respiratory diseases and cancers (DNIR 323/2004).
- Development of a genetically modified non-toxic whooping cough vaccine (DNIR 132/2002).
- Investigation of the role of various proteins involved in apoptosis and cell survival in multiple myeloma cells and to identify potential targets for therapy (DNIR 309/2004).
- A study using recombinant adenovirus of the roles of newly identified genes in the development of diabetes and obesity (DNIR 112/2002).
- A study of the biology of the human immunodeficiency virus (HIV) as the basis for better drug and vaccine development (DNIR 086/2002).
- A clinical trial to assess the safety, tolerability and immunogenicity of a new formulation of vaccine, ChimeriVax™-JE, against Japanese Encephalitis (DNIR 320/2004).
- A clinical trial to assess the safety, tolerability and efficacy of a new therapy for prostate cancer (DNIR 298/2004).
- Importation of soybeans for processing into oil and stockfeed (DNIR 277/2004).
- Molecular breeding of grapevines for resistance to major root pests (DNIR 226/2003).

Notifiable low risk dealings with GMOs

The following are examples of dealings with GMOs that are considered to pose minimal biosafety risks and fall within the categories of notifiable low risk dealings specified by the Regulations. All these dealings are conducted in contained facilities and do not involve intentional release of the GMO into the environment:

- Storage of GMOs from past research projects (for example, NLRD 1402/2004).
- A study of sugar alcohol production in sugarcane (NLRD 1237/2004).
- Production of stem cells in the adult mouse ovary (NLRD 1388/2004).
- Generation and use of transgenic mice that express proteins in epithelial cells (NLRD 1383/2004).
- Generation of transgenic and knockout mice (NLRD 1360/2004).
- Importation of Bt cotton seed (NLRD 1162/2003).
- Animal trials of plant-based malarial vaccines (NLRD 941/2003).
- Genetic engineering of carrot and celery (NLRD 822/2003).
- Breeding low-allergen ryegrass (NLRD 517/2002).
- A study of mineral bio-processing (NLRD 222/2002).

Source: Adapted from information available on the OGTR GMO Record.

2.4 Further discussion of OGTR requirements in relation to each type of application is contained in Appendix 3.

Evaluation of applications by OGTR

2.5 OGTR is responsible for assisting the Regulator in the assessment of applications and related functions required under the Act.[7] As discussed earlier, there are a variety of applications made under the Act that are dealt with by OGTR. The numbers of applications received and processed are recorded in quarterly reports published by OGTR. Data has been analysed from 12 quarterly reports covering the period 1 July 2001 to 1 July 2004. In total, OGTR received 5 773 applications (or notifications), processing or finalising 3 248 of these, over that three-year period (see Figure 2.2).

Figure 2.2

Quarterly applications received and decisions made

Quarter ending	Sep 2001	Dec 2001	Mar 2002	Jun 2002	Sep 2002	Dec 2002	Mar 2003	Jun 2003	Sep 2003	Dec 2003	Mar 2004	Jun 2004	Total
New applications received[a]	155	180	112	472	451	690	589	615	179	155	116	184	**3 898**
New applications processed[a]	11	28	109	133	309	298	391	628	174	90	44	45	**2 260**
Other applications received[b]	51	33	50	83	74	119	86	59	72	189	270	789	**1 875**
Other applications processed[b]	26	23	5	7	33	155	72	76	89	63	116	323	**988**

Source: Adapted from OGTR.

Notes a Includes DIR and DNIR licence, certification and accreditation, and CCI applications and NLRD notifications.

b Includes applications for surrender, variation and transfer of licences, certifications and accreditations.

2.6 The majority of these applications related to the certification of facilities, the accreditation of organisations, or notification of NLRDs (including variations to such existing instruments). The number of applications for dealings requiring a licence (such as those involving field trials or commercial release of GM agricultural crops or the use of GMOs in a contained laboratory), were significantly fewer with only 52 DIR and 305 DNIR licence applications received.[8] Figure 2.3 shows the types of GMO involved in the 32 DIR licences thus far issued by the Regulator.

2.7 The *Evaluations Branch*, comprising the *Applications and Licence Management Section* (ALMS), the *DIR Evaluation Sections* and the *Contained*

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7 See Appendix 4 for further information on OGTR structure and staffing.

8 See Appendix 5 for further information on the numbers and types of applications received and processed by OGTR.

Dealings Evaluation Section (CDES), has responsibility for the assessment of the various applications made under the Act, as well as various other functions, as outlined below.

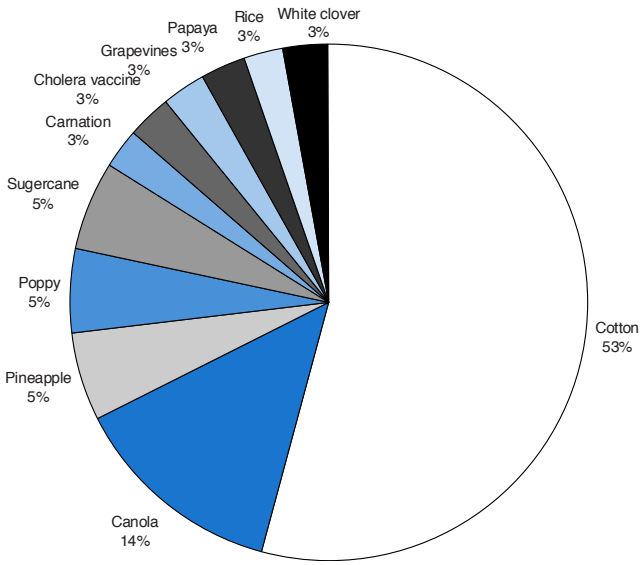
Submission of applications to OGTR

Guidance and information for applicants

2.8 All applications for licence and related correspondence must be submitted to OGTR for processing. 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. Such guidance also facilitates OGTR processing by helping to ensure that all necessary information is submitted by applicants and enables easy identification by OGTR of deficiencies in submitted information, as well as easy identification of the type of application that has been submitted.[9] Although available by contacting OGTR, all necessary forms and documents are also available via the Internet on OGTR's website (see paragraph 2.21 for further information).[10]

Figure 2.3

Types of genetically modified organism involved in issued DIR licences



Source: Data from OGTR.

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9 The Regulator is not required to consider an application for licence that does not contain all the required information: *Gene Technology Act 2000* (Cth) ss 40(2), 43(2)(a).

10 The URL or Internet address of the OGTR website is <http://www.ogtr.gov.au>.

2.9 A substantial package of material was developed by the (then) Interim Office of the Gene Technology Regulator (IOGTR) during consultation on and development of the Act. Although dated, this material provides useful background information on the regulatory regime in general, and on the rationale for the development of the regime. All these documents are available on the OGTR website. IOGTR also conducted extensive public consultations and information sessions during the development of the regulatory regime, providing information on the regulatory requirements upon commencement of the Act.

OGTR Handbook

2.10 The *Handbook on the Regulation of Gene Technology in Australia*, also available on the OGTR website, was developed by OGTR as a resource for applicants or users of the regulatory scheme.[11] The Handbook provides information on the key aspects of the regulatory regime, including the system of prohibitions and approvals for dealings with GMOs, the types of dealings and associated regulatory requirements and responsibilities of organisations undertaking dealings. The Handbook also provides an outline of other relevant OGTR activities and processes, including monitoring and enforcement activities. Each of the forms and guidelines issued by the Regulator is intended to be attached to the Handbook as an appendix. Although many organisations that the ANAO consulted during fieldwork indicated that the Handbook was a useful and comprehensive source of information, they noted, however, that, because of its large size, information on specific types of dealings and the OGTR processes and requirements was difficult to find. It was suggested that additional, specific and targeted guidance on the application process and requirements for each individual type of dealing would be useful, especially for those organisations that require information on only one type of dealing (for example, NLRDs or exempt dealings). A series of small, self-contained publications or fact-sheets for each type of dealing (that is, DIR, DNIR, NLRD and Exempt) would allow users to easily find information relevant to their circumstances. Information that could be provided would be similar to that already included in the Handbook, but instead specific to the dealing or application type, including:

- an outline of the criteria for determining whether the proposed dealing falls into the relevant category;

[11] OGTR, *Handbook on the Regulation of Gene Technology in Australia*, OGTR, Canberra, 2001.

- an outline of the processes to be followed by the applicant in conducting the dealing, including appropriate forms to be completed and approximate timeframes involved;
- ongoing obligations and responsibilities for the dealing, including reference to any relevant guidelines; and
- OGTR contact details and sources of further information.

2.11 A number of the guidelines and forms issued by the Regulator have been subject to revision during the first three years and new forms and guidelines have been issued since the Handbook's release. Although the Handbook is intended to incorporate these forms and guidelines as appendices (and hence act as a comprehensive source of all relevant OGTR guidance), there are now some forms and guidelines not referenced in the original Handbook. The ANAO suggests that OGTR review the Handbook to ensure that all relevant OGTR guidelines and forms are properly referenced, so that organisations can continue to rely on it as a comprehensive information tool for their dealings with OGTR. Such a review may also provide an opportunity for OGTR to revise other parts of the Handbook and to remove the (now spent) references to the transitional arrangements that remain throughout.

Other information material

2.12 OGTR has produced a number of other documents and guidelines that are also available on the OGTR website. For example, the following guidelines and policies have been published by the Regulator:

- *Guidelines for the Accreditation of Organisations*—Handbook Appendix 2.
- *Guidelines for the Certification of Facilities/Physical Containment Requirements*—Handbook Appendix 3.
- *Good Industrial Large Scale Practice (GILSP)*—Handbook Appendix 4.
- *Guidelines for the Transport of GMOs*—Handbook Appendix 5.
- *Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator*—Handbook Appendix 6.
- *Policy on storage of genetically modified organisms*.

2.13 As noted earlier, these guidelines and policies are intended to be incorporated within the Handbook as appendices. The *Guidelines for the Accreditation of Organisations* and the *Risk Analysis Framework* (which describes the detail of the risk analysis performed by OGTR in relation to the evaluation of applications for licence) have been recently revised and OGTR is seeking public comment on the revised documents.

2.14 The *Guidelines for the Certification of Facilities/Physical Containment Requirements* have recently been revised by the *Guidelines for Certification of PC2 Facilities/Physical Containment 2 Requirements*. Despite the title, the latter guidelines provide important information on general conditions of certification and are intended to apply to all types of facility (not merely PC2 level facilities), replacing much of the earlier guidelines. The newer guidelines do not presently apply to all types of facility, so that some facilities operate in accordance with the requirements of the earlier, and some the later, guidelines. It is intended that the newer guidelines will eventually completely replace the older guidelines and be applicable to all types of certified facility. The current situation leads to the possibility of confusion by organisations as to the applicable guidelines, further exacerbated by the need for cross-referencing between them to obtain a consolidated picture of all applicable requirements. Although OGTR is currently working towards finalising the newer guidelines (and completely withdrawing the earlier ones), the ANAO suggests that in the interim, OGTR examine its certification guidance to ensure that the applicable requirements are easily understood by organisations. For example, preparing revised, consolidated versions of both the earlier and newer guidelines, as well as more appropriately renaming the newer guidelines will increase the ease with which the complete certification requirements can be ascertained and will facilitate enhanced compliance by organisations with the conditions of accreditation.

OGTR forms and templates

2.15 There are a number of forms and templates that OGTR has produced to assist applicants in complying with the regulatory and OGTR administrative requirements. For example, available forms and templates include:

- application forms for regulated dealings (DIRs and DNIRs);
- NLRD notification form;
- IBC evaluation report form;
- exempt dealing evaluation report template;
- facilities inspection checklists;
- CCI declaration application form;
- accreditation and certification application forms; and
- accredited organisation annual report template.

2.16 All OGTR forms are available on the OGTR website and are available in Microsoft® Word or Adobe® Acrobat format (or both). The ANAO received a number of comments from users of OGTR forms offering suggestions to

improve their ease of use. Many users were pleased to be able to download an OGTR form and complete the application 'electronically', that is, being able (using the appropriate software) to fill in the form details and then print a copy of the completed form. ANAO received comments that this was much easier to achieve using the forms provided in Microsoft® Word format, since many users did not have the appropriate software to complete the forms provided in Adobe® Acrobat format otherwise than in a single sitting.[12] It was noted that, the forms for CCI declarations and accreditation, certification, and DIR applications were only available in Adobe® Acrobat format on the OGTR website. Since many users preferred to complete these applications electronically, yet were unable to practicably do so using the Adobe® Acrobat format (especially the DIR applications for which completion is usually particularly time-intensive), the ANAO suggests that OGTR provide all forms and templates in a format that allows users to more practicably complete the form electronically.

2.17 Many of the OGTR forms also contain instructions and guidance for completion within the form itself, as well as a range of other information, including contact details. The ANAO received a number of comments from organisations consulted during the audit that removing (and consolidating into a separate instruction booklet) the instructions and guidance currently provided within the forms would allow for easier completion of the forms. This was seen to be particularly so where, for example, in the case of NLRD notifications, organisations were submitting large numbers of similar forms, and did not require the instructions in each form and were looking to save on paper and printing costs in completing the forms. Organisations consulted by ANAO also commented that many of the forms seemed repetitive, requesting information already given in earlier parts of the form.

2.18 No forms had been produced for some types of application (for example, applications to vary, transfer, suspend or cancel existing instruments, requests for internal review of decisions, requests for review of NLRD and exempt dealings and requests for inclusion of a dealing on the GMO Record). This caused particular difficulties in relation to requests for variation to licences, since applicants were provided with little guidance on what information was required to be submitted with such requests. The lack of clear

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[12] Adobe® Acrobat forms are commonly read using the Adobe® Reader software package (which is made freely available by Adobe Systems Incorporated). Although Adobe® Reader will allow a user to electronically fill in the required form data, the software package does not allow users to save the completed form. This means that most users are required to complete the entire application form in a single sitting, printing out the completed application in hard copy. Users commented that since the form may take a number of hours to complete, use of the Adobe® Acrobat forms in this way was often inconvenient or impractical.

guidance or policies published by OGTR on requirements for applications for variation contributed further such difficulties.

Recommendation No. 1

2.19 The ANAO recommends that OGTR review and revise its forms and guidance documents in order to facilitate and ensure high level compliance with OGTR information requirements and to facilitate more efficient and effective regulation.

Health Response: *The OGTR agrees with this recommendation. All OGTR forms and guidance documents are subject to ongoing review and the OGTR is developing a schedule for, and will maintain a record of, the review of all such documents. The OGTR notes that the reviews that have been conducted to date have been initiated when confusion or operational problems were identified. This has demonstrated to users that the OGTR is concerned with their difficulties and has clarified requirements. Therefore the OGTR reserves the right to review its documents more frequently than indicated in a review schedule as the need arises.*

2.20 OGTR is in the process of implementing an electronic application lodgement system (the Gene Technology Information Management System—GTIMS—see Chapter 4 for further information). Although many organisations that the ANAO consulted during fieldwork indicated that they were aware of GTIMS and had received some information on its use, few organisations indicated that they were currently using GTIMS in order to lodge applications via the Internet or to manage their regulated dealings.

2.21 In addition to providing guidance and information for applicants and organisations, the OGTR website also provides a range of other information about the OGTR and the regulatory regime established by the Act.

Summary

2.22 OGTR has developed numerous policies, guidelines, forms and other information documents to assist applicants in dealing with OGTR. These documents were available to applicants in paper copy and on the OGTR website. Opportunity for consultation was also provided when key documents were undergoing revision. There were some minor format and useability issues that require attention, and also opportunities for provision of further information.

Assessment of applications by OGTR

OGTR policies and procedures

2.23 In order to assist in the assessment of applications, OGTR has developed policies and procedures for internal use by OGTR evaluators. These policies serve to facilitate processing of applications and consistency of decision-making by OGTR staff by providing detailed instructions on the steps to be followed in processing the respective application received. The various policies and processes employed for each type of application will now be discussed in further detail.

Receipt of applications and correspondence

2.24 The *Applications and Licence Management Section* has developed policies governing its work, and on the initial receipt and handling of applications received by OGTR.

2.25 The *Draft Standard Operating Procedures Manual* provides detailed instructions to ALMS staff on logging applications received and for creating the necessary files and forwarding the application to the relevant area for evaluation. All applications received are also recorded in the ALMS *Application Received Log* (a Microsoft® Excel spreadsheet), to track the status of applications. Information is also recorded in GTIMS. It is envisaged that once fully functional, GTIMS will replace the *Application Received Log* as the tool used for logging and tracking applications received. The ANAO notes that for this reason, there were a number of areas within the *Draft Standard Operating Procedures Manual* that were incomplete or required further updates. The ANAO suggests that OGTR ensure that its policies and procedures are reviewed to ensure that complete and up-to-date guidance is provided to ALMS staff on ALMS operations and requirements.

2.26 Upon initial processing of applications by ALMS, successful receipt of the application is acknowledged by way of either letter addressed to the applicant (in the case of DIRs) or email to the primary IBC contact (for all other applications).

DIR applications

2.27 OGTR has developed policies and procedures for the assessment of DIR applications (there were no internal policies or procedures dealing with the evaluation of variations, transfers, suspensions or cancellations of DIR licences).[13] There are six main steps that OGTR undertakes in the assessment of

[13] This finding is discussed further at paragraph 2.35.

DIR applications (Figure 2.4 and Figure 2.5). Further detail on assessment of applications under the Act is provided in Appendix 3.

2.28 Upon receipt and acceptance of an application, OGTR notifies the applicant of the process that will be followed in assessing the application, and the statutory deadline by which a decision on the application is due. OGTR also notifies those bodies that will be consulted on the application of its receipt (that is, State and Territory governments, GTTAC, the prescribed agencies, the Environment Minister and any relevant local councils), seeking advice on the application. Although not required by the Act, OGTR also publishes notification of receipt of the application on the OGTR website and sends an email notice to all subscribers to the OGTR contact list.

Figure 2.4

Outline of steps taken in evaluating DIR applications

Processing DIR Applications

Step 1—Whether the proposed dealings with the GMO poses significant risks to the environment or to the health and safety of people. OGTR must first consider the health and safety aspects of the GMO;

Step 2—Public consultation on the application. If the proposed dealings with the GMO do potentially pose significant risks to the environment or to the health and safety of people, OGTR must call for public submissions on the application, including consultation on the possible risks involved and the means of managing these risks;

Step 3—Consultation with prescribed agencies, the Environment Minister, States and Territories and GTTAC. This consultation process enables the Regulator to seek advice on possible risks posed by the application;

Step 4—Any other actions that OGTR considers necessary. For example, OGTR may call for public hearings, commission independent research, undertake literature reviews and consult with international experts;

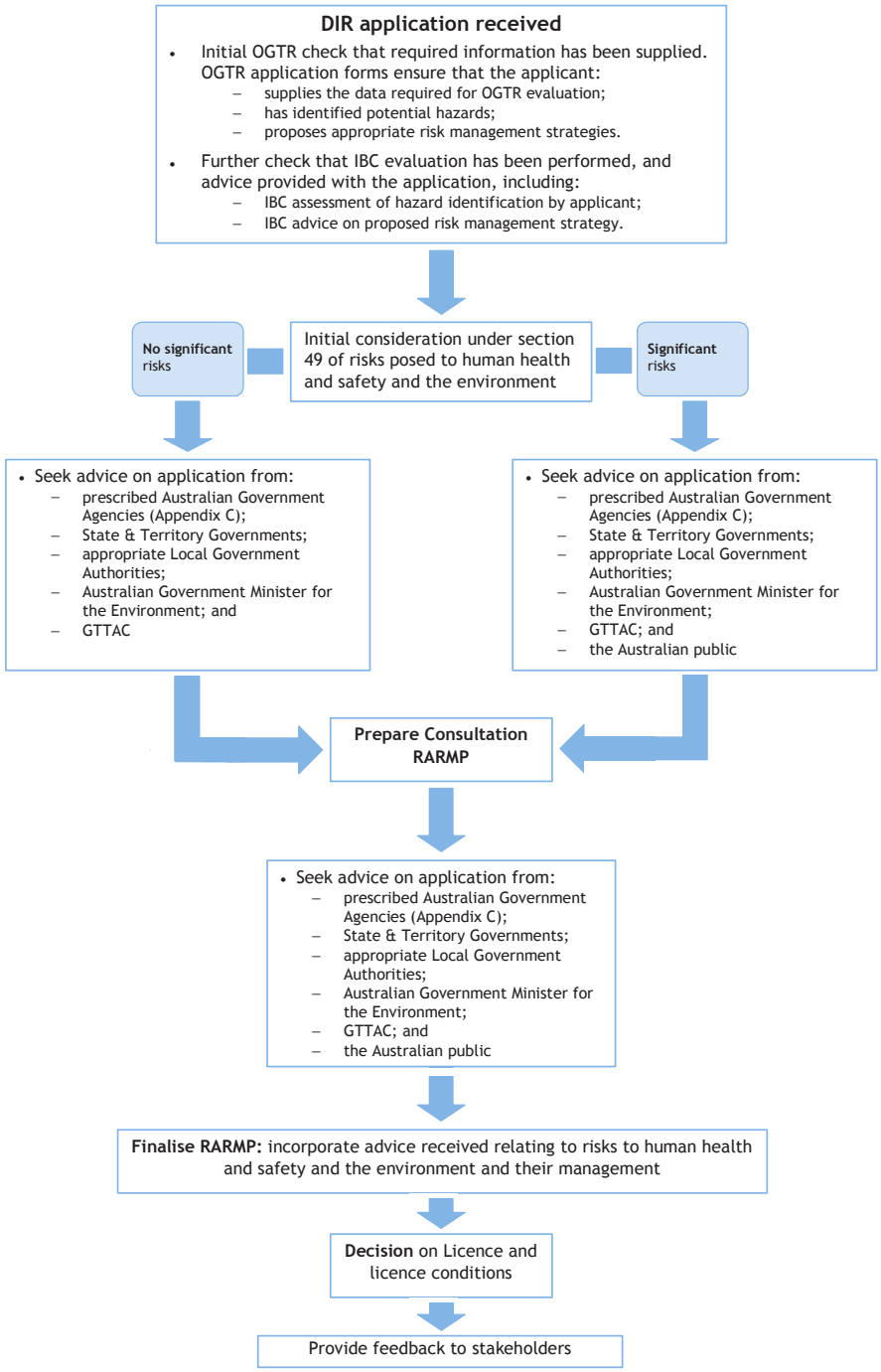
Step 5—Preparation of a risk assessment and risk management plan. This includes the identification of any hazards and the management of risks posed by the GMO; and

Step 6—Consultation on the draft risk assessment and risk management plan. OTGR must call for submissions on the assessment and the plan through advertisement in newspapers, the Government Gazette and on the OGTR website, as well as with the stakeholders identified in Step 3.

Source: OGTR.

Figure 2.5

Process involved in assessing DIR applications



Source: OGTR.

2.29 The Act requires the preparation of the *Risk Assessment and Risk Management Plan* (RARMP), taking into account any advice received from those bodies consulted. However, little guidance is given to OGTR evaluators on the preparation of the RARMP or the steps to be taken in conducting the risk analysis. For example, the relevant OGTR policy gives only the following guidance on preparation of the RARMP:

> **12. Preparation of Consultation RARMP and Biology and Ecology Document**
>
> 12.1 Evaluator to prepare Biology and Ecology document if it has not been previously prepared.
>
> 12.2 Evaluator to prepare consultation version of the RARMP—consult Risk Analysis Framework, contact TGA Library for literature search and database information.
>
> 12.3 Draft proposed licence conditions in liaison with Legal Unit.
>
> 12.4 Evaluator to incorporate/address relevant comments received from the 1st round consultation in the draft consultation RARMP.
>
> 12.5 Evaluator to submit the RARMP to Section Head, consider all comments/responses from Section Head and incorporate into RARMP.

and later:

> **15. Preparation for Licence Decision**
>
> …
>
> 15.4 Finalise RARMP as per templates.

2.30 Although the publicly available OGTR *Risk Analysis Framework* sets out the theory, rationale and components of risk analysis used by OGTR evaluators in assessing licence applications, it does not provide further guidance to evaluators on the deliberative steps to be taken in applying the *Risk Analysis Framework* in the preparation of the RARMP (see Appendix 6 for further information on the *Risk Analysis Framework*).

2.31 Once the RARMP has been prepared, advice is sought from those bodies prescribed by the Act. OGTR also makes copies of the RARMP available on the website and publicly advertises release of the consultation RARMP, seeking comments from interested persons. The Act prescribes that the Regulator must provide at least 30 days for the receipt of submissions, with OGTR usually providing 6 weeks (or 42 days).

2.32 At the close of the consultation period, the evaluator and the Regulator consider any submissions and advice received on the RARMP. A summary of

all issues raised in the submissions is included in the RARMP and a detailed summary of the public submissions is incorporated as an appendix. This appendix also indicates where the relevant issues have been addressed in the revised RARMP.

2.33 A decision on the licence is then made by the Regulator, on the advice of the evaluator, taking into consideration the issues identified in the RARMP. Other issues considered at this time include the compliance history of the applicant and its suitability to hold a licence. The applicant is alerted that a decision is pending and consulted on the proposed licence, including the conditions to be imposed.

2.34 Once a decision has been made on the licence, the applicant is notified as well as all those bodies consulted on the application. Details of the decision on the DIR application are made available on the OGTR website and if a licence has been issued, the dealing is entered onto the GMO Record.

Variations, transfers, cancellations and suspensions

2.35 As discussed earlier, the Act provides little further guidance on the steps that the Regulator (or licence holders) must take in varying (or seeking a variation to) a licence. Although providing some information to applicants, the OGTR *Handbook on the Regulation of Gene Technology in Australia* does not provide any advice on the policies that the Regulator applies in making a determination on applications for variation. The ANAO notes that on 29 September 2004 OGTR released the *Summary regarding the Policy on the variation of GMO licences*. The summary provides brief guidance to applicants on the OGTR's policy for determining whether a request to extend the authority of GMO licences should be considered as a variation or be considered as a new GMO licence application. However, the summary does not provide any further detail for applicants on the process used by OGTR in determining whether to accept an application for a variation, nor on the information required by OGTR in making such an assessment. There are currently no standard forms issued by OGTR for making applications for variation (or cancellation, transfer and suspension), of existing instruments issued by the Regulator. OGTR advises, however, that a single form that attempted to accommodate the range of diverse reasons for which variation requests are made would be cumbersome; and that the information required for surrenders or transfers can be readily conveyed in a letter—cancellation or suspension of instruments being solely at the discretion of the Regulator.

2.36 Guidance to applicants on the processes and policies applied by OGTR (as well as on information required by OGTR), in assessing applications for variation, cancellation, transfer and suspension will facilitate and enhance the submission and consideration of such applications as well as providing greater transparency of OGTR decision-making in relation to such applications.

Recommendation No. 2

2.37 In order to facilitate and enhance OGTR decision-making, the ANAO recommends that OGTR develop and publish guidance to applicants on the process and policies applied by OGTR in assessing applications for variation, cancellation, transfer and suspension.

Health Response: *The OGTR agrees with this recommendation. The OGTR notes that it has developed a policy on variations of licences and a guidance document is available on the website. The OGTR will develop similar guidance documents regarding its policies and processes for the variation of other instruments (such as certifications and accreditations), as well as their transfer and surrender. The OGTR would like to clarify that cancellations and suspensions are imposed by the Gene Technology Regulator – not applied for by an applicant. Guidance relating to the cancellation or suspension of instruments by the Gene Technology Regulator will also be developed by the OGTR.*

DNIR applications

2.38 Unlike DIR applications, DNIR applications are processed by CDES. There are detailed policies and procedures providing guidance to CDES staff on processing DNIR applications, and these deal with the receipt, processing and assessment of applications, and variation, cancellation or suspension and surrender of issued DNIR licences. Although not required by the Act, the policy requires that the evaluator consult on the licence application with relevant States and Territories. Once the RARMP has been prepared, the policy requires that (except in certain enumerated circumstances) the evaluator seek the advice of GTTAC on the application and on the RARMP. There is no further consultation required by the Act or by relevant OGTR DNIR policies and procedures.

2.39 The decision on the licence is made by the Regulator, on the advice of the evaluator and any other sources consulted, taking into consideration the issues identified in the RARMP. The applicant is notified once a decision has been made on the licence, and notification is also provided to any affected State or Territory Government. Details of the decision on the DNIR application are made available on the OGTR website.

NLRD notifications

2.40 The procedure to be followed by NLRD officers for processing NLRD notifications received by the Regulator is outlined in the CDES policy—*Procedure for processing NLRD notifications*. The policy requires that OGTR review a minimum of 20 per cent of the NLRD notifications received by the

Regulator each quarter.[14] The policy specifies criteria by which notifications will be selected for review, based on those NLRDs that pose potentially greater risks to human health and safety and the environment. For example, the policy states that notifications to be reviewed include:

- all notifications that are not being undertaken in facilities certified by the Regulator;
- all dealings involving the use of a viral vector;[15]
- all dealings involving the use of human pathogens as host, vector or source DNA;[16] and
- all dealings undertaken in PC1 facilities.

2.41 The policy also states that, '*where possible, additional (preferably all) notifications will be reviewed*'. Notifications are reviewed against a checklist. Upon completion, the checklist is either filed (if no further action is required), or the notifying organisation is requested to provide further information. All NLRD notifications are recorded on the OGTR website.

Accreditation and annual reporting

2.42 Responsibility for the assessment of applications for accreditation rests with ALMS. OGTR has developed policies and procedures providing guidance to ALMS staff on processing applications from organisations for accreditation. The policies deal with the receipt, processing and assessment of applications for accreditation, and variation, cancellation or suspension and surrender of accreditation.

2.43 In assessing applications for accreditation, the accreditation officer completes a checklist, directing the steps to be taken to confirm that the application indicates that all the accreditation criteria have been met. If the conditions appear to have been met, a minute is prepared recommending that the organisation be accredited, and upon accreditation being made, a letter of accreditation is then sent to the applicant. If the conditions do not appear to have been met, the applicant is advised by email or telephone and further information is requested.

2.44 Accredited organisations are also required to submit annual reports to OGTR, using the annual reporting template available on the OGTR website.

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[14] As indicated in Appendix 5 (see Table A5.6), on average, OGTR receives some 115 notifications per quarter. The NLRD policy thus requires that around 23 notifications be reviewed each quarter, although, OGTR advised that it currently reviews all NLRD notifications received.

[15] A viral vector is a virus (viral DNA) that has been modified for use as a vector.

[16] A human pathogen is any agent, especially a micro-organism, capable of causing disease in humans.

The report is then evaluated against an OGTR checklist to ensure that accreditation requirements are indicated as having been complied with (although there was no formal internal policy that had been developed dealing with the evaluation of accredited organisations' annual reports). It should be noted that information within an annual report may be subject to monitoring and auditing. The Act provides penalties (including imprisonment for up to a year) for making a false or misleading statement.[17]

Facility certifications

2.45 A number of policies and procedures have been developed for the processing of facility certifications by CDES.[18] These deal with the receipt, processing and assessment of applications for certification of facilities, and for the variation, cancellation or suspension and surrender of facility certification.

2.46 Certification applications are initially received by ALMS and forwarded to ALMS or CDES for assessment. Organisations are required to submit the relevant application form along with a report of the requisite inspection conducted by the IBC. The IBC inspection report is required to address all of the conditions set out in the relevant OGTR certification guidelines. OGTR has also produced a set of checklists for most, but not all, facility types to assist organisations carrying out facility inspections.

2.47 In assessing applications for certification, the CDES policies and procedures require the OGTR certification officer to complete a checklist, examining the information provided by the organisation to confirm that the application asserts that all the certification conditions have been met. Where the conditions appear to have been met, a minute is prepared recommending that certification is granted and a letter of certification is prepared for transmission to the applicant. Where the conditions do not appear to have been met, the applicant is advised by email or telephone and further information is requested. As noted earlier, in the case of certification of facilities above PC2 level, OGTR will also conduct an independent inspection of the facilities to ascertain compliance with the relevant conditions of certification. No such independent inspection is conducted for certifications to PC2 level and below (with the exception of PC2 large-scale facilities). However, all facilities certified to PC2 or below must be inspected annually by their organisation's IBC as a condition of their certification and are subject to random monitoring visits.

2.48 The CDES policies and procedures also provide guidance to certification officers on dealing with organisation requests for exemption from

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17 *Gene Technology Act 2000* (Cth) s 192.

18 As noted earlier, low-level certifications are processed by ALMS.

particular conditions of accreditation. Where such a request is received, the policies and procedures allow an exemption where, upon assessment of the alternative measures that are in place to meet the condition or an assessment of the relevant circumstances, any risks to human health and safety or to the environment that may result can be managed. Additional conditions of accreditation may also be imposed as an alternative to the prescribed condition. As noted earlier, OGTR has also released guidance documents on certification of facilities (see paragraph 2.14). Although OGTR has developed internal policies and procedures for dealing with requests for exemption, the publicly available guidelines do not make it clear to organisations that such requests may be made. A number of organisations consulted during fieldwork observed that it was only through direct contact with OGTR that such requests were discovered to be possible. In some cases, organisations had already expended resources to comply with the specific prescribed conditions, only to later become aware that an exemption could be sought to implement alternative measures that may not have required the same expenditure. The flexibility that is provided for in the internal policies and procedures does not appear to have been sufficiently communicated to organisations in the published guidance. Although the ANAO is aware of the benefits of ensuring standardised conditions of accreditation, the Act provides sufficient scope for variation of conditions in specific circumstances, and organisations may benefit from further guidance on the availability of seeking a variation to standard conditions, and the circumstances in which such a variation may be sought. This is consistent with the less prescriptive, outcomes-based approach contained in the new certification guidelines, and recognises that there may be a number of measures capable of achieving the appropriate level of containment and that overly prescriptive requirements may lead to unnecessary expenditure of resources. The ANAO suggests that OGTR provide further advice to organisations on procedures and requirements for requesting exemption from, or variation to, prescribed conditions of certification.

Confidential commercial information

2.49 As discussed in Appendix 1, the Act allows a person to apply to the Regulator seeking a declaration that specified information is confidential commercial information (CCI) for the purposes of the Act. Applications for CCI are decided by the Branch Head within the *Evaluations Branch*, acting on advice from the *Legal Unit* and evaluators. The *Confidential Commercial Information Manual* provides detailed advice to OGTR staff on the handling of CCI applications and of CCI. The CCI Manual is available to all OGTR staff, and describes:

- background information about Commonwealth laws governing handling of protected information by OGTR;
- the detailed practices and procedures that OGTR must adopt to ensure that CCI is properly protected from disclosure; and
- describes the policies and processes to be employed in making a determination on whether to declare specified information to be CCI.

2.50 Although providing some guidance to OGTR staff on procedures to follow when making CCI available to non-OGTR staff (for example, when seeking advice on DIR applications from prescribed agencies—see paragraph 3 of Appendix 3), there is little further instruction given to OGTR staff or to such non-OGTR staff on how this information should be handled or treated once outside OGTR. For example, although OGTR staff are instructed to use a standard form warning cover page that explains the significance of receipt of the CCI when sending CCI to external persons, the warning contains no guidance or instructions on appropriate storage or disposal or return of CCI. The ANAO suggests that OGTR review its policies and practices to ensure that those non-OGTR staff who are required to receive CCI are aware of, and receive adequate notice and training with regards to, their obligations for protecting CCI information.

Conclusion on OGTR policies and procedures

2.51 Overall, OGTR has developed policies and procedures dealing with evaluation and assessment activities—although further guidance could be published with respect to applications for variation, transfer, suspension and cancellation and surrender of instruments, as well as on handling of CCI by non-OGTR staff. These policies are available to relevant OGTR evaluation and assessment staff.

2.52 However, the ANAO found that these policies were not always complete and ease of use could often be improved through their better indexing and organisation. Given the complex and varied nature of the tasks performed by OGTR evaluation staff, the ANAO suggests that OGTR review its policies and procedures to ensure that they are (i) current; and (ii) formatted and presented to enhance access to relevant information and ease of use by OGTR staff.

Review of OGTR policies and procedures

2.53 Periodic and formal review of internal policies and procedures provides an opportunity to assess the effectiveness of those policies and procedures in describing and directing the systems and practices used to discharge the relevant functions, and also allows relevant revised information

to be incorporated. In an environment of advancing technology and a changing state of knowledge, periodic review becomes even more critical.

2.54 Recently, OGTR has revised a number of its publicly available policies and guidance documents and sought public comment on the revised versions (for example, the *Risk Analysis Framework*, the *Guidelines for Certification of PC2 Facilities* and the *Draft Guidelines for Accreditation of Organisations*).

2.55 Although OGTR internal policies and procedures were said to be continuously reviewed on an *ad hoc* basis, often no formal record of review was kept, nor timetables for future review. Given the pace of changes in technology and the types of applications OGTR can be expected to receive, formal mechanisms for the review of all 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.

Recommendation No. 3

2.56 The ANAO recommends that OGTR adopt formal mechanisms for the review of its policy, procedure and guidance documents (and maintain records of such reviews), to ensure that they remain consistent and up-to-date.

Health Response: *The OGTR agrees with this recommendation. All OGTR policies, procedures and guidance documents are subject to ongoing review. The OGTR is developing a formal mechanism, including the maintenance of records, for the review of all of its policy, procedure and guidance documents to ensure that they remain consistent and up-to-date. The OGTR notes that the reviews that have been conducted to date have been initiated when confusion or operational problems were identified. This has demonstrated to those regulated that the OGTR is concerned with their difficulties and is committed to clarifying and enhancing processes. Therefore the OGTR reserves the right to review its policies, procedures and guidance documents more frequently than indicated in a review schedule as the need arises.*

Applying OGTR policies and procedures

2.57 The ANAO analysed a sample of applications evaluated by OGTR and found that, overall, OGTR policies and procedures dealing with evaluation and assessment activities are applied by staff when performing evaluation and assessment functions.

2.58 However, when examining records relating to the assessment of DIR licence applications, there was little evidence recorded on application files relating to the development of the RARMP. Because of this, it was difficult for the ANAO to determine the steps taken by the responsible OGTR evaluator in

applying the OGTR *Risk Analysis Framework* and other relevant policies in considering the application, identifying the potential hazards, assessing potential risks and developing risk management measures. This was compounded by the little guidance given in the internal OGTR policies and procedures for DIR and DNIR applications on the steps to be taken in the preparation of the RARMP.

2.59 Although the RARMP prepared by OGTR evaluators represents the outcome of the complex risk analysis conducted in evaluation of the application, the absence of evidence documented on the application file on the development of the RARMP makes assessment of the steps taken by the evaluator and confirmation of the correct application of OGTR policies and procedures, particularly the application of the *Risk Analysis Framework*, difficult. The ANAO acknowledges the difficulty in recording the detailed deliberative steps involved in the development of the RARMP, particularly given that the science-based risk analysis is not always linear and easily amenable to stepwise documentation. However, in order to increase the transparency of decision-making, and to facilitate the conduct of quality assurance reviews on evaluator decisions, the ANAO suggests that OGTR improve documentation of the process leading to the development of the RARMP and of key evaluator decisions on hazard identification and risk assessment made during its development. Such records need not be lengthy, but should be fit for their purpose. That is, the level and standard of documentation needs to match the circumstances, with the standard expected increasing as the consequences of decisions and actions increases. At a minimum, OGTR records relating to the assessment of DIR licence applications should include evidence that the evaluator has applied the *Risk Analysis Framework* and undertaken the requisite key deliberative steps outlined therein.

2.60 In relation to other types of application, evidence of the assessment was recorded and filed, with the use of checklists and other templates by OGTR evaluators indicating that the relevant policies and procedures had been applied when undertaking the assessment. However, the ANAO noted that in some cases, relevant information relating to assessment decisions were not always recorded in chronological order on the file, hindering later review of the steps taken in the initial evaluation of the application.

Quality assurance review of OGTR decisions

2.61 OGTR policies and procedures for the assessment of applications incorporate a number of mechanisms for reviewing the quality of advice provided to the Regulator by OGTR evaluators. Quality assurance reviews are

important for ensuring consistency of decision-making and for facilitating accurate decision-making.

2.62 OGTR advised that the greatest level of scrutiny and quality assurance review is provided in relation to DIR and DNIR applications. The revised OGTR *Risk Analysis Framework* summarises the quality control measures in place in relation to the risk analysis as follows:

> **Quality Control and Review**
>
> Quality control operates at administrative, bureaucratic and legislative levels in the risk analysis process under the Act. There are a number of feedback mechanisms to maintain the effectiveness and efficiency of risk assessment and risk management, and which consider the concerns of all interested and affected stakeholders. These comprise both internal and external mechanisms.
>
> Internal processes of quality control include:
>
> - standard operating procedures for specific administrative processes;
> - internal peer review of RARMPs; and
> - merit based selection processes for OGTR staff.
>
> External processes of quality control include:
>
> - expert scrutiny by GTTAC of applications and RARMPs;
> - consultations with the Australian Government Environment Minister, State and Territory governments, prescribed agencies, interested parties and the public on all DIRs;
> - external scrutiny and review through the consultation processes;
> - input from State and Territory governments;
> - external, independent selection of the Regulator and advisory Committee members, and Ministerial Council agreement on these appointments;
> - provision of advice from the Ministerial Council; and
> - accountability to Parliament through the provision of quarterly reports.
>
> A critical aspect of this overall quality assurance is that the Regulator and OGTR maintain the expertise and capacity to undertake the risk analysis of GMOs.

2.63 The advice and risk assessments prepared by evaluators are subject to peer review by superior officers within OGTR, in accordance with the relevant

policies and procedures and in a manner commensurate with the risks posed by the particular type of dealing or decision.

2.64 Commensurate with the possible risks posed by DIRs and DNIRs, preparation of the RARMP and related advice by primary evaluators in assessing applications for DIR and DNIR licences are subject to internal peer review and clearance processes. The final decision on whether or not to issue DIR and DNIR licences is made by the Regulator in person.

2.65 The final decision on certification of high-level facilities is made by the Regulator or a delegate on the advice of the evaluator, whilst low-level facilities are certified by the delegate.[19] The Regulator, acting on the advice of the evaluator, makes decisions on the accreditation of organisations. There is no formal quality assurance review of assessments of NLRD notifications or accredited organisation annual reports. NLRD assessments are undertaken by IBCs, with CDES reviewing NLRDs notifications. ALMS reviews accredited organisation annual reports, identifying and investigating anomalies, reporting this work to the OGTR Executive.

2.66 Thus, OGTR policies and procedures incorporate internal quality assurance of evaluator advice through a system of approvals by senior officers, with most decisions being made ultimately by the Regulator in person. Given the importance to decision-making of OGTR evaluators' advice, and the need to ensure consistency and accuracy of decision-making, the ANAO suggests that OGTR should continue to ensure that the advice of evaluators is subject to formal quality assurance review.

Statutory timeframes for processing of applications

2.67 The Regulations specify times within which OGTR must process applications made under the Act. The times for processing licences are as follows:[20]

- DIR—170 working days;
- DNIR—90 working days;
- Accreditation—90 working days; and
- Certification—90 working days.

2.68 For DIR and DNIR applications, the above timeframes may be suspended when the Regulator cannot proceed with the decision making process or a related function because the Regulator:[21]

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[19] OGTR defines high-level facilities as those certified as PC4, PC3 or large-scale PC2 facilities, whilst low-level facilities are those certified to PC2 level or below.

[20] Regulation 8, Gene Technology Regulations 2001 (Cth) regs 8, 14, 16.

- is waiting for further information which has been requested in writing from the applicant; or
- has called a public hearing; or
- is considering a request from the applicant that the information provided by the applicant is confidential commercial information; or
- is seeking advice from the Gene Technology Ethics Committee (GTEC) on a relevant issue.

2.69 The timeframes will only be suspended for accreditation and certification applications if OGTR is waiting for further information that has been requested in writing from the applicant.[22] There are no legislated timeframes within which other applications (for example, variations, transfers, NLRD notifications, accredited organisation annual reports) must be processed by OGTR.

2.70 To-date, OGTR has processed all applications within the required statutory timeframes and ANAO analysis of OGTR processing data supports this assertion. Although OGTR monitors whether or not processing of applications is completed within the statutory timeframes, OGTR did not regularly report on the total elapsed time taken to process applications. OGTR advised that for most DIR applications, requests are usually made to the applicant for further information. As noted above, during this period and until the requested information is received, the timeframe for processing is suspended unless other application-related work can continue. ANAO received advice from organisations consulted during fieldwork that, although formal notification of suspension of the processing timeframe is provided to the applicant when the OGTR request for information is made, formal advice of the resumption of the processing timeframe is seldom provided to the applicant. Relevant OGTR policies and procedures do not require the evaluator to provide notice to the applicant that processing has resumed. Since it is not always clear to organisations when the OGTR information requirements have been satisfied and processing has resumed, it is difficult for such organisations to estimate when a decision on the application could be expected. Advice provided to the ANAO by applicants on a small sample of DIR applications indicated that, although the applications were processed within the 170-day statutory timeframe, elapsed time to process the applications averaged 223

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[21] Regulation 8, Gene Technology Regulations 2001 (Cth) reg 8.

[22] Regulation 8, Gene Technology Regulations 2001 (Cth) regs 14, 16.

days.[23] Monitoring the elapsed time taken to process applications and by recording and analysing the reasons for timeframe suspensions, may enable OGTR to better understand the average length of (elapsed) processing time and use this information for improved resource management planning and decision-making. Such monitoring and analysis may also enable OGTR to identify whether there are common causes for suspension of processing timeframes and whether any OGTR process improvements could be made to facilitate processing of applications.

Notification of decisions

2.71 Once a decision has been made on a particular application, OGTR writes to the applicant advising of the outcome of the evaluation and of the final decision. Decisions made in relation to applications are documented, filed and retained by OGTR. In the case of DIR licences, notification of issue of such a licence is also made via the OGTR website and notice of decisions on DIR applications is given to organisations and individuals registered on the OGTR mailing list, as well as to those bodies involved in consultations during the consideration of the application. Information about approved DIRs, DNIRs and NLRDs are placed on the GMO Record, also accessible through the OGTR website. Notice of decisions is given at the same time, or shortly after, the decision is made.

2.72 In the case of decisions relating to CCI applications, no immediate notice is given other than to the applicant. A summary of CCI declarations is provided in the OGTR quarterly reports and OGTR also indicates in the RARMP if CCI has been used in its preparation. However, in both cases, the notification that is provided by these two sources occurs some time after the CCI declaration was actually made. Also, in the case of the OGTR quarterly reports, no information is provided giving details of to which application a CCI declaration relates. In order to increase the transparency of CCI declarations and decision-making by OGTR, the ANAO suggests that OGTR consider providing more timely notification of CCI decisions (for example, through notification on the OGTR website), and provide details as to which application the CCI declaration relates).

Maintaining security of OGTR information and assets

2.73 In order to ensure that confidential commercial information is not disclosed otherwise than in accordance with the Act, OGTR must ensure that

[23] References to days here are references to calculable working days—for the purposes of the Act, Saturdays, Sundays and public holidays in the ACT are not included in calculating the statutory timeframe. As an indication, the 170-day statutory timeframe would correspond to around 238 calendar days, whilst 223 working days would correspond to around 312 calendar days.

such information is adequately protected. OGTR policies and procedures, including the *Confidential Commercial Information Manual*, provide guidance to staff on protecting such information. In addition, the OGTR *Risk Management Plan* identifies a number of security risks, defined in the plan as either '*a failure to protect physical assets and entry to the building or failure to protect information*'. The plan provides a number of risk management strategies for each identified security risk, including on the protection of CCI.

2.74 Although the CCI Manual provides detailed guidance to OGTR staff on handling CCI, (including, for example, standard templates to be used to inform those non-receiving CCI in performing functions under the Act) there is little guidance provided to such persons on appropriate storage or return of CCI. As noted earlier, the ANAO suggests that OGTR review its policies and practices to ensure that those non-OGTR staff who are required to receive CCI receive are aware of, and receive adequate notice and training in their obligations to protect CCI information.

Overall conclusion

2.75 OGTR has established systems and procedures for the management and assessment of applications under the Act. These procedures are applied by OGTR evaluators to facilitate decision-making that is transparent and consistent with relevant legislative requirements. OGTR has developed a large number of forms, templates and guidance documents to assist organisations in making applications to OGTR and to communicate OGTR requirements to stakeholders.

2.76 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.

2.77 The ANAO has made a number of recommendations and suggestions to improve OGTR evaluation and assessment systems and procedures in order to improve regulation under the Act.

3. Monitoring and Compliance

This chapter describes monitoring and inspection activities undertaken by the Office of the Gene Technology Regulator in seeking to secure compliance with the requirements of the Act, including compliance with licence conditions and risk management measures. The chapter firstly provides a background to tools and mechanisms provided by the Act for monitoring and enforcing compliance. The chapter then outlines the policies and procedures developed by OGTR for conducting monitoring activities and their application. Finally, the chapter discusses OGTR compliance and investigative activities, and the policies and procedures developed by OGTR for enforcing the requirements of the Act.

Background

3.1 As was described earlier, the *Gene Technology Act 2000* (Cth) provides a regime for regulating dealings with GMOs, requiring that such dealings be only undertaken in accordance with the provisions of the Act.[24] The Act contains two main types of provision to facilitate management of risk and achievement of the overall objects of the Act.

3.2 Firstly, the Act imposes requirements in relation to the conduct of the dealing itself (for example, by restricting the location in which the dealing may take place or by requiring dealings only be undertaken by certain persons or under certain conditions). Secondly, the Act imposes requirements that facilitate ongoing monitoring of dealings by the Regulator (for example, by requiring the submission of annual reports or by requiring licence holders to give the Regulator access to premises on which dealings are being conducted).[25]

3.3 The Act also arms the Regulator with specific powers to enforce compliance with the various requirements of the regulatory regime (for example, by allowing the Regulator to give directions to licence holders or to seek injunctions from the Federal Court).[26]

3.4 Monitoring and compliance activities of OGTR enable an assurance that dealings are being conducted in accordance with the requirements of the Act,

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[24] In this chapter, except where the context otherwise provides, a reference to the Act includes a reference to the Regulations and any other statutory instruments (for example, guidelines or other documents issued by the Regulator) that together comprise the overall regulatory framework for the regulation of dealings with GMOs.

[25] In relation to the former, see, for example, ss 94, 98 and the *Guidelines for Accreditation of Organisations* issued by the Regulator in accordance with these provisions, in particular, Condition C1 of these guidelines. In relation to the latter, see, for example, s 64.

[26] See, for example, *Gene Technology Act 2000* (Cth) ss 146, 147.

including any licence conditions imposed by the Regulator. Such activities should be aimed not only at monitoring those dealings already under the oversight of OGTR (for example, a DIR that has been evaluated by OGTR and licensed to proceed), but also detecting potential dealings that have not been authorised (for example, the importation of viable GM seed that has not been evaluated by OGTR). Monitoring and compliance by OGTR ensures that the risk management measures identified in OGTR risk analyses are being properly implemented, so that risks to human health and safety and the environment are managed.

3.5 In addition, compliance activities serve to ensure that where instances of non-compliance are identified, appropriate corrective measures are taken. This also facilitates compliance by creating incentives for compliant behaviour through the threat of penalty where appropriate.

3.6 Before discussing specific policies and procedures governing OGTR monitoring and compliance activities, a brief outline of the legislative tools available to the Regulator for ensuring compliance will be provided, with a fuller summary in Appendix 7.

Monitoring and compliance under the Act

3.7 All licences for dealings with GMOs are subject to three main types of conditions:

- statutory conditions set out in the Act;
- conditions prescribed by the Regulations; and
- any conditions imposed by the Regulator (either at the time of issuing the licence or subsequently).

3.8 A wide variety of conditions may be prescribed or imposed on licences. The Act also imposes certain conditions on monitoring and auditing by the Regulator. For example, the Act provides that a person authorised by the licence to deal with a GMO must allow the Regulator (or a person authorised by the Regulator) to enter the premises where the dealing is being undertaken for the purpose of auditing or monitoring the dealing.[27]

3.9 In addition, there may also be conditions attached to other dealings regulated under the Act (for example, relating to NLRDs or exempt dealings).[28]

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[27] *Gene Technology Act 2000* (Cth) s 64.

[28] See Appendix 7 for further information.

Monitoring inspection and enforcement powers

3.10 The Act provides the Regulator with a number of monitoring and enforcement powers, in order to ensure that dealings regulated by the Act are conducted in accordance with any conditions imposed on such dealings, and to ensure that the provisions of the Act are enforced. For example, the Act provides a number of powers relating to access and entry to premises for the purpose of monitoring and auditing dealings with GMOs, as well as in order to investigate and collect evidence in cases where it is suspected that an offence against the Act has been or will be committed.[29]

Penalties for non-compliance with the Act

3.11 The Act also creates a number of different types of offences in relation to unauthorised dealings with GMOs, to breaches of conditions associated with authorised dealings, as well as a number of other accompanying offences.[30]

Monitoring and compliance section

3.12 The *Monitoring and Compliance Section* supports the Regulator by undertaking various monitoring, inspection, compliance and investigative activities on dealings conducted under the Act. The Section is divided into two units, the *Monitoring Team* and the *Compliance and Investigations Team* (see Figure 3.1).

3.13 Monitoring is conducted to ensure that dealings with GMOs are conducted in accordance with any conditions associated with the dealing, for example, licence conditions, requirements in relation to NLRDs and conditions of certification and accreditation. Compliance activities involve the further investigation of potential breaches of dealing conditions in order to establish whether there has been the commission of offences under the Act.

3.14 The Monitoring and Compliance Framework, issued by the OGTR, lists the mission and vision statements for the Section as follows:

> **Mission Statement**
>
> To protect the health and safety of people and the environment by providing effective, efficient and thorough monitoring and compliance oversight of accredited organisations dealing with genetically modified organisms.

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29 A fuller discussion of these powers is contained in Appendix 7.

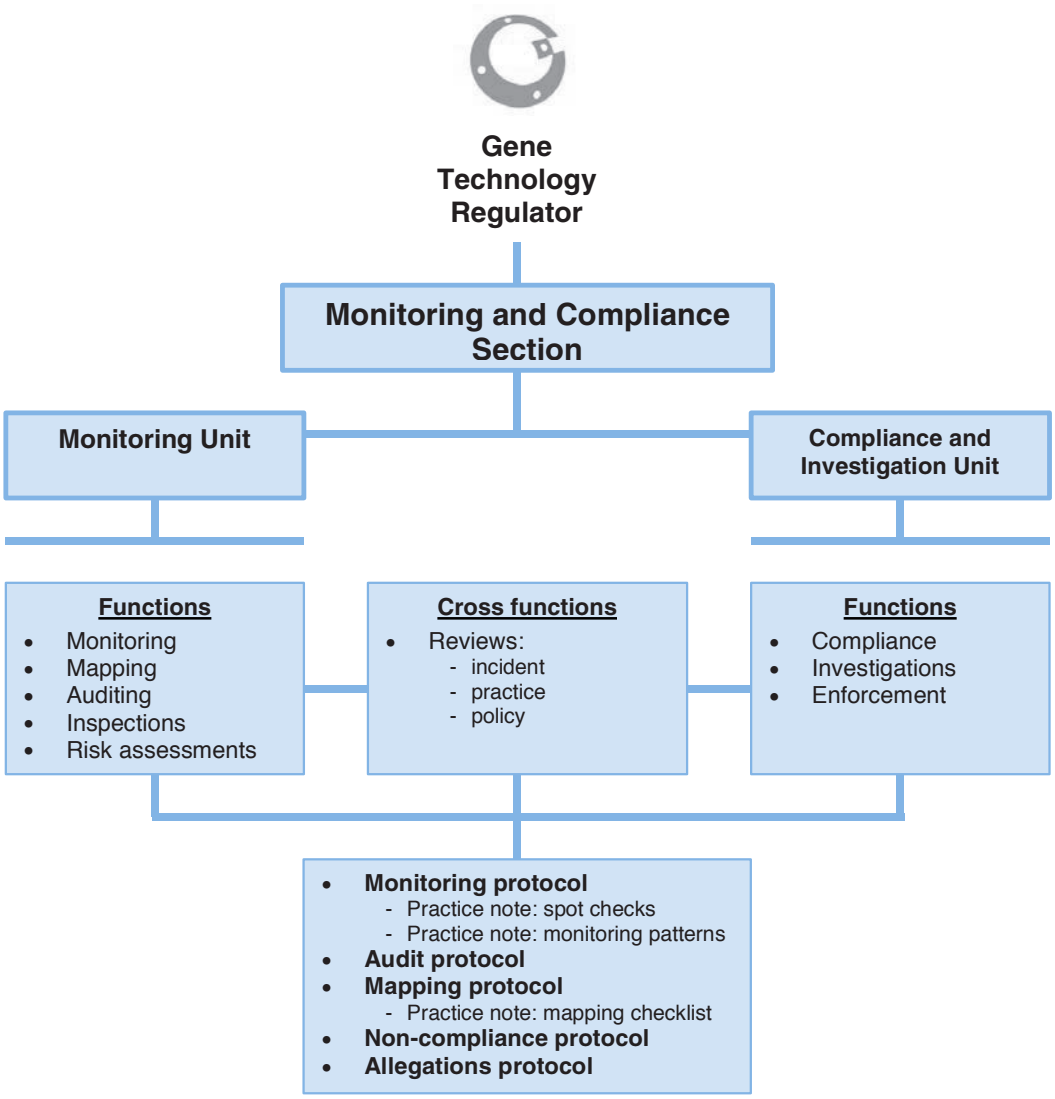
30 See Appendix 7 for further information.

Vision Statement

To set world's best practice in monitoring and compliance oversight of an accredited organisation's dealing with genetically modified organisms.

Figure 3.1

OGTR monitoring and compliance section—division of functions



Source: Adapted from OGTR.

3.15 The Section currently comprises some eight staff, of which seven form part of the *Monitoring Team*, with the remaining one forming the *Compliance and Investigation Team*. Further detail on the functions and activities of each team will be discussed in turn below.

Monitoring

3.16 OGTR conducts monitoring and inspection of field trial sites and certified facilities to ascertain compliance with the requirements of the Act and, where applicable, any conditions of licence. For example, this may involve a visit to a farm site where a GM crop is being grown to ensure that conditions of licence (such as maintenance of buffer zones or conditions relating to harvesting of the GMO) are being complied with. Alternatively, it may involve a visit to a research laboratory to ensure conditions of certification (such as maintenance of staff training records or requirements regarding the physical layout of the facility) are being met.

3.17 OGTR conducts various different types of monitoring activities, including:

- Routine monitoring visits and unannounced spot-checks—involving the visiting of premises where dealings are undertaken to ensure compliance with regulatory requirements; and
- Follow-up visits—undertaken to follow-up on issues or to check the implementation of any required remedial action.

3.18 Routine monitoring visits may be either 'announced', where the licence holder is given prior warning of the visit, or 'unannounced', where no such warning is given. Although the primary purpose of monitoring visits are to ascertain compliance with the requirements of the Act, monitoring also allows OGTR to raise awareness of the regulatory regime and requirements through further education of organisations and individuals dealing with GMOs.

Monitoring frequency and identification of premises

3.19 OGTR utilises a risk-based approach to selecting the number and identity of premises to be the subject of monitoring visits. In determining when to monitor, a risk profile is prepared that takes into account factors such as:

- the type(s) of GMO(s) dealt with and its/their relevant biological properties;
- the type(s) of facilities within which the dealing(s) is/are conducted, including OGTR knowledge of the procedures of the organisation conducting the dealing (including any previous history of compliance/non-compliance by the organisation); and

- in the case of field trial sites, seasonal, geographic and ecological risk factors.

3.20 OGTR has set monitoring targets for the various types of dealing and premises regulated under the Act (see Figure 3.2 and Figure 3.4 for statistics on monitoring activities).

3.21 The timing of monitoring will depend upon the premises to be visited and the type of dealing being conducted on the premises. Monitoring of DIR field trial sites is usually conducted at high-risk stages of the field trial, for example, at flowering or harvest time. OGTR has identified the key stages for field trials include planting, flowering, seed production/fruiting and harvesting. As indicated in Figure 3.2, OGTR also conducts post-trial monitoring of sites that were formerly used for DIR field trials.[31]

3.22 Although OGTR aims to ensure that all sites are inspected at least once during the course of their currency, OGTR was not able to readily identify those sites that had not yet been subject to OGTR monitoring and inspection visits. Although OGTR planning processes aim to ensure priority sites are inspected in a given quarter, the lack of readily available data on monitored sites inhibits fully informed planning and decision-making. OGTR has been implementing improved recordkeeping that will facilitate tracking of monitoring and inspection activity for particular sites.

Figure 3.2

OGTR monitoring targets

Dealing type	Monitoring Target (1)	Number of premises to be visited (2)
GM Field Trials—current	20%	5 (23)
GM Field Trials—post harvest monitoring	20%	35 (176)
Contained facilities—Higher risk dealings (3)	20%	23 (114)
Contained facilities—Lower risk dealings (4)	random sample	n.a. (1574)

Source: Adapted from OGTR.

Notes
1 Expressed as a percentage of total premises of that type, per annum.
2 Estimated total number of premises to be visited. Based on the total premises of the respective type as at 30 June 2004 (indicated in parentheses).
3 Comprising PC4, PC3 and large-scale PC2 facilities.
4 Comprising PC2 and PC1 facilities.

[31] The number and frequency of monitoring visits conducted by OGTR is discussed below at paragraphs 3.32–3.39.

3.23 OGTR is also currently considering acquiring software for more effective management of inspection activities, which will enable more ready access to timely and consolidated data on site information, monitoring and inspection activity and compliance history.

Conduct of the monitoring visit

OGTR monitoring policies and procedures

3.24 Monitoring visits are undertaken by inspectors, or authorised persons, appointed by the Regulator under the Act.[32] An independent expert relevant to the particular monitoring activity may also assist inspectors.[33]

3.25 OGTR has developed detailed policies and procedures detailing how monitoring visits will be conducted. For example, the *Monitoring Protocol* and standard operating procedures for routine DIR inspections detail the procedures to be followed in the case of an inspection of a current field trial site. The conduct of the monitoring visit will be tailored to the type of dealing and/or premises being inspected and the conditions attached to the dealing.

3.26 As noted earlier, it is a condition of licence that the Regulator (or an authorised person) be granted access to premises where a dealing is being undertaken, and, in the case of a monitoring visit of premises occupied by a licence holder or a person covered by a licence, there is no requirement that OGTR make contact prior to conducting the inspection. Despite this, in the case of routine monitoring, OGTR will make prior contact and arrange for the visit to be conducted at a mutually convenient time, in order to ensure continuing co-operation and to facilitate effective monitoring. Where the monitoring is conducted as part of an 'unannounced spot-check', however, no prior warning will be given by OGTR.

3.27 As noted earlier, monitoring is undertaken by the *Monitoring Team*, made up of personnel with technical expertise in agriculture, environmental management and microbiology. The monitoring team also provides advice on the application of risk management strategies in operational situations and gathers information on possible adverse effects from release of GMOs.

3.28 The team has developed policies and standard operating procedures to guide its work. These policies are available to team members in both paper and electronic formats. Many of the policies are also publicly available on the OGTR website.

3.29 Although, together, these policies comprehensively deal with the monitoring activities undertaken under the Act, the ANAO found that there

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[32] *Gene Technology Act 2000* (Cth) ss 64(1), 150.

[33] *Gene Technology Act 2000* (Cth) s 157.

were some inconsistencies between policies, particularly in relation to the powers of inspectors to gain access to premises when undertaking monitoring activities authorised by the Act. The ANAO suggests that OGTR review its monitoring policies to ensure that they provide consistent advice and guidance on the monitoring functions and activities provided by, and undertaken in accordance with, the Act.

Review of monitoring policies and procedures

3.30 OGTR internal policies and procedures were said to be continuously reviewed on an *ad hoc* basis, although often no formal record of review was kept, nor timetables for future review. Formal mechanisms for the review of all 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 monitoring and inspection of dealings conducted in accordance with the Act.

3.31 The ANAO has made a recommendation aimed at facilitating formal review of all OGTR policies, procedures and guidelines (see paragraph 2.56).

Applying OGTR monitoring policies and procedures

3.32 An outline of the procedures followed during a typical routine monitoring visit to a field trial site is shown in Figure 3.3.

Figure 3.3

Outline of pre-inspection and inspection procedures for routine DIR monitoring

Pre-inspection

- Identify site(s) to be inspected and obtain copies of site plans and documentation.
- Obtain any documentation relating to the site, including (where applicable) licence and/or certification instruments, previous inspection reports, compliance history.
- Contact accredited organisation and/or licence holder to advise of planned visit and proposed timing and to arrange convenient access and entry.

Inspection

- Interview the representatives of the licence holder or other personnel on the premise.
- Observe the GM field trial site and related activities, seeking objective evidence of compliance.
- Take measurements of buffer zones and calculate isolation distances, including measurement of mapping co-ordinates.
- Identify any closely related weeds/species within a GM field trial site and isolation zones, including making inquiries into waste disposal methods.
- Record findings, by either taking photographic and video images, audio recordings, making sketches, obtaining copies of relevant records, or taking samples for testing.

Post-inspection

- Conduct an exit meeting (if appropriate and/or necessary) discussing issues identified during the inspection, including any findings of non-compliance and necessary corrective action, and the probable contents, and timing for completion, of the OGTR monitoring report.

Source: Adapted from OGTR.

3.33 At the conclusion of a site inspection, OGTR prepares a report outlining the results of the visit.[34] Where non-compliance with licence conditions or other requirements is identified, the monitoring report will include an outline of any appropriate corrective actions required, including timeframes for implementation of that action. Findings from monitoring and compliance activities are reported in the OGTR quarterly reports. In cases of non-compliance, an incident review will be performed by the *Compliance and Investigation Team*. Following the incident review, a further investigation may be conducted in order to ascertain whether any further action should be taken, including prosecution under the offence provisions contained within the Act.

3.34 Figure 3.4 shows the monitoring activities of the team from commencement until the quarter ending December 2003. In total, 122 current DIR sites have been inspected, and a further 553 sites have been subject to post-harvest monitoring. Figure 3.5 shows the number of current DIR sites monitored each quarter, expressed as a percentage of total sites in the quarter. Figure 3.6 shows the number of post-harvest monitoring–DIR (PHM–DIR) sites each quarter, expressed as a percentage of total PHM sites in the quarter.

3.35 As shown by Figure 3.5, the number of current DIR sites inspected each quarter has ranged between 14 per cent in December 2001 and 48 per cent in December 2003. The number of such sites has dropped from a total of 105 in the September 2001 quarter, to 23 in the December 2003 quarter. On average, 22 per cent of current DIR sites have been subject to monitoring each quarter.[35]

3.36 A similar decline in the total number of PHM–DIR sites over the period is shown by Figure 3.6. Total number of PHM–DIR sites has fallen from 518 to 176 over the period. The proportion of PHM–DIR sites inspected has remained steady over the period, with, on average, 11 per cent of PHM–DIR sites subject to monitoring each quarter.

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[34] A copy of this report is provided to the licence-holder or accredited organisation.

[35] As discussed in Appendix 5, the decrease in DIR sites can be explained by the current moratoria on commercial release of GMOs implemented by most State and Territory governments (which has consequently led to a slowing of DIR applications) along with the lapsing of deemed licenses at the end of the transitional period provided for by the Act.

Figure 3.4

Monitoring activities and total number of current dealings, by quarter

Quarter ending	Sep 01	Dec 01	Mar 02	Jun 02	Sep 02	Dec 02	Mar 03	Jun 03	Sep 03	Dec 03	Total
Dealing type: (1, 2)											
DIR Licences											
Licences monitored (a)	18 (109)	40 (109)	23 (112)	22 (112)	22 (116)	19 (120)	18 (121)	12 (120)	8 (21)	9 (21)	**191**
Current sites	16 (105)	15 (105)	10 (53)	14 (53)	21 (72)	12 (66)	6 (25)	9 (26)	8 (31)	11 (23)	**122**
PHM sites	68 (518)	69 (518)	67 (508)	53 (508)	66 (578)	67 (602)	55 (546)	33 (520)	46 (450)	29 (176)	**553**
Total sites	84 (623)	74 (623)	87 (561)	67 (561)	87 (650)	79 (668)	61 (571)	42 (546)	54 (481)	40 (199)	**675**
Non-compliant	*0*	*6 (b)*	*2*	*0*	*0*	*0*	*2*	*2*	*2*	*6*	***20***
DNIR Licences											
Licences monitored (c)	0 (0)	0 (0)	0 (9)	0 (21)	0 (57)	0 (81)	0 (117)	0 (181)	7 (207)	6 (224)	**13**
Non-compliant	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Certified facilities											
PC4 (d)	0 (0)	3 (0)	0 (0)	0 (3)	0 (3)	0 (3)	0 (3)	0 (3)	0 (3)	0 (3)	**3**
PC3 (e)	0 (0)	7 (1)	4 (2)	0 (30)	0 (37)	0 (39)	0 (41)	1 (46)	1 (50)	0 (50)	**13**
PC2 (large scale) (f)	0 (0)	1 (0)	1 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**2**
PC2 (g)	0 (11)	10 (38)	5 (131)	10 (214)	19 (454)	21 (669)	20 (985)	22 (1462)	24 (1574)	33 (1616)	**164**
PC1	0 (0)	1 (0)	2 (0)	4 (0)	0 (3)	1 (11)	0 (15)	0 (19)	0 (19)	0 (21)	**8**
Total facilities	0 (11)	22 (39)	12 (133)	14 (247)	19 (497)	22 (722)	20 (1044)	23 (1530)	25 (1646)	33 (1690)	**190**
Non-compliant	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*

Source: Data from OGTR.

Notes to Figure 3.4 (opposite page)

1 Figures in parentheses indicate the total type of dealing or site regulated under the Act for that quarter, but do not include approvals under the GMAC system that carried over into the legislative system.

2 Each DIR licence may authorise GMO dealings on a number of different sites.

a Figures in parentheses for Licences monitored include 109 Planned Releases approved by GMAC which became Deemed DIR licences at the commencement of the Act on 21 June 2001. Two years after the commencement of the Act (20 June 2003) a number of administrative changes occurred to subsume these Deemed Licences into new or existing DIR Licences. 11 were renewed as 7 new DIR licences (several included on one licence), 38 which were still subject to post harvest monitoring conditions were included in existing DIR licences, 58 had completed their post harvest monitoring conditions prior to 20 June 2003 and were not continued as DIR Licences, 2 deemed licences were surrendered.

b Includes a finding of non-compliance reported in the subsequent quarter.

c Deemed DNIR licences active at 21 June 2001 until 20 June 2003, total number 419.

d Deemed PC4 certifications active 21 June 2001 until 20 June 2003, total number 4.

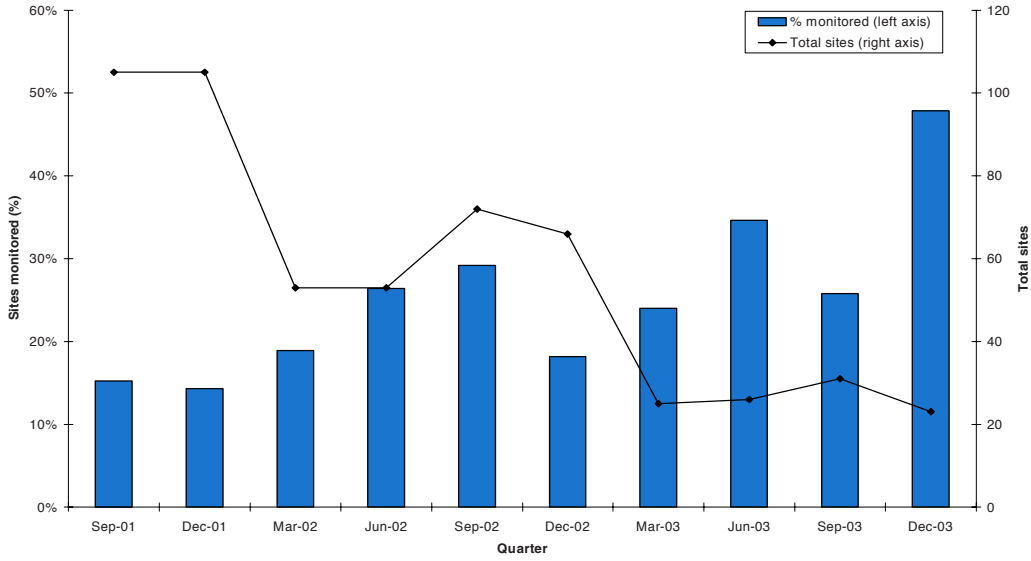
e Deemed PC3 certifications active 21 June 2001 until 20 June 2003, total number 38.

f Deemed PC2 large scale certification active 21 June 2001 until 20 June 2003, total number 14.

g Deemed PC2 certifications active21 June 2001 until 20 June 2003, total number 1617.

Figure 3.5

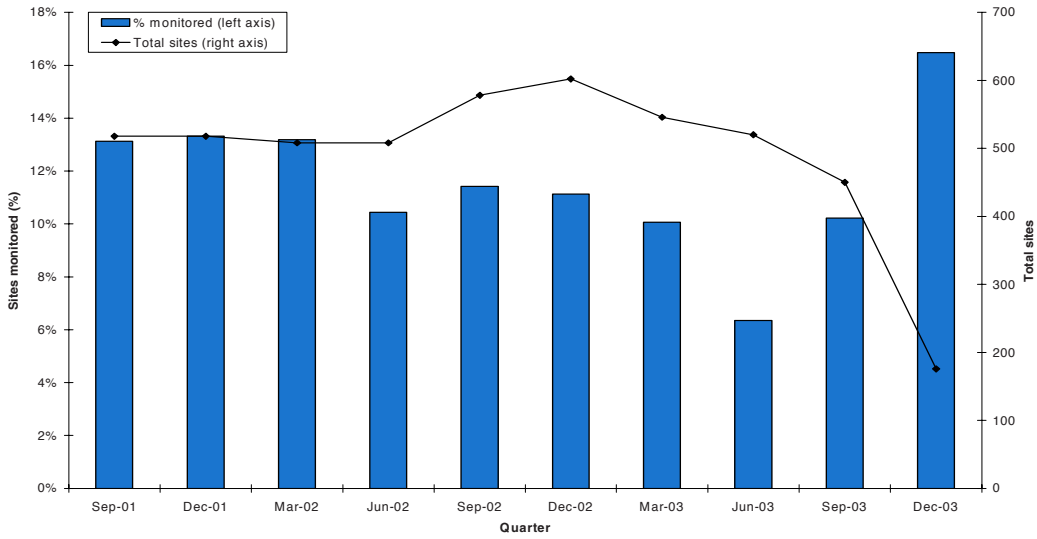
Number of current DIR sites monitored as a percentage of total number of sites, by quarter



Source: Data from OGTR.

Figure 3.6

Number of PHM–DIR sites monitored as a percentage of total number of sites, by quarter



Source: Data from OGTR.

3.37 Thus, annualised rates of monitoring of DIR sites are around 87 per cent of current sites and around 44 per cent of PHM–DIR sites. This far exceeds the OGTR target of 20 per cent of total sites (both current and PHM–DIR) per annum.

3.38 However, it should be noted that particular sites may be subject to multiple visits over time, so annualised rates of monitoring do not necessarily provide an indication of the proportion of total current sites visited. As noted earlier (see paragraph 3.22), OGTR does not maintain information on the number of current sites yet to be visited at any given time, so it is difficult to ascertain whether there remain gaps in OGTR's coverage of sites in its monitoring and inspection activities.

Recommendation No. 4

3.39 In order to provide better information on OGTR monitoring of licences and other instruments, the ANAO recommends that OGTR more fully explain its reported rates of monitoring, including maintaining and publishing information on the number of sites or organisations yet to be visited by OGTR. This will also enable any gaps in OGTR coverage of sites in its monitoring and inspection activities to be more readily identified.

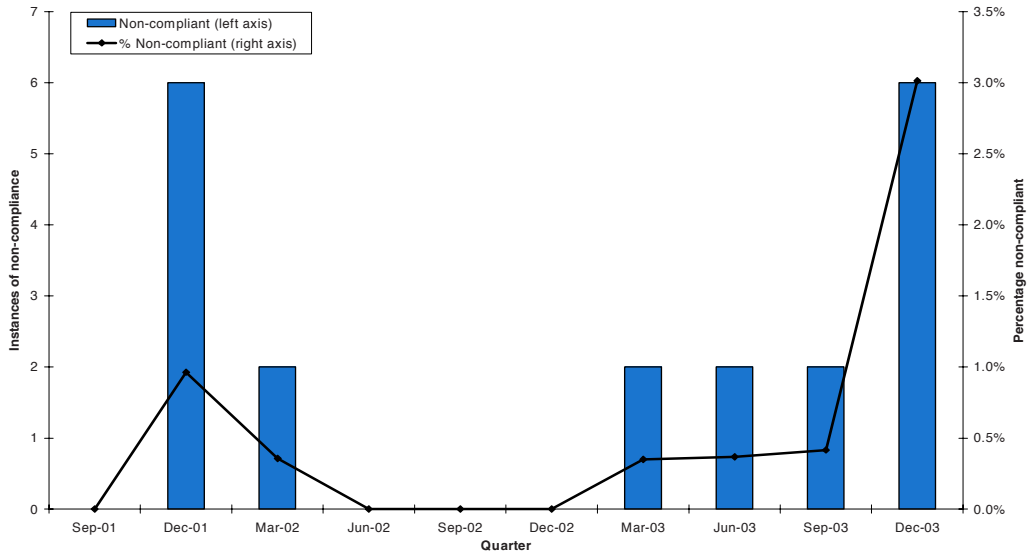
Health Response: *The OGTR agrees with this recommendation. The OGTR has this information available (internally) on an organisation by organisation and licence by*

licence basis. The OGTR is undertaking steps to consolidate this data in order to provide better information on monitoring of licences and other instruments. The OGTR anticipates this process will be complete by the end of 2005 and will incorporate this information in subsequent Quarterly Reports of the Gene Technology Regulator.

3.40 Over the period, there have been 20 findings of non-compliance in relation to DIR sites (as will be discussed, these have been assessed by OGTR as being minor in nature, posing no significant risks to either human health or the environment). Apart from in the December 2003 quarter, identified instances of non-compliance have represented a small proportion of total sites, averaging around 0.36 per cent (Figure 3.7). Expressed as a proportion of sites monitored, however, non-compliance was identified in 20 sites (or around three per cent), with a total of 675 sites inspected over the period (Figure 3.8).[36]

Figure 3.7

Number of findings of non-compliance on current and post-harvest monitoring sites and number of non-compliant sites as a percentage of total number of sites, by quarter



Source: Data from OGTR.

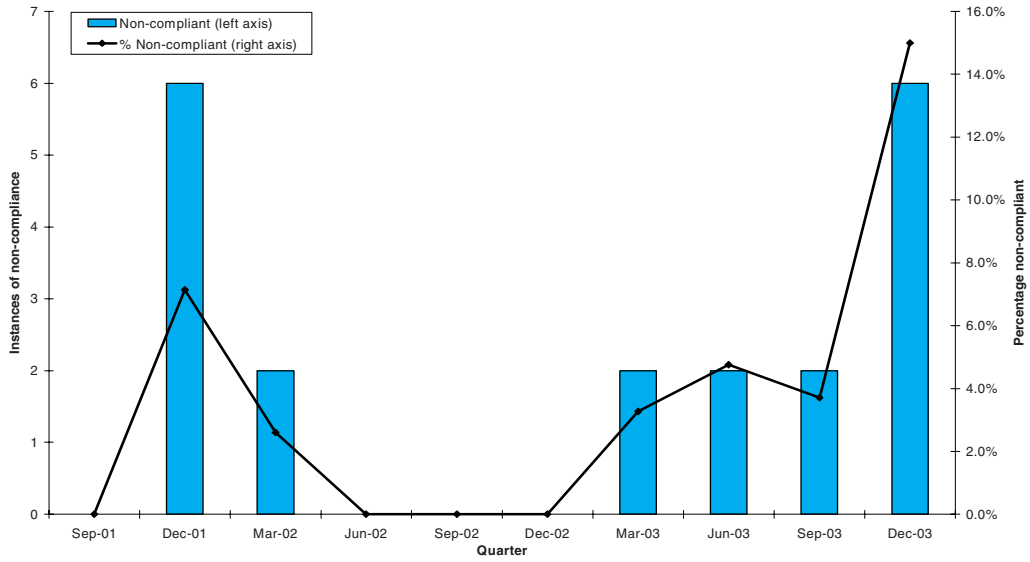
3.41 That is, although non-compliance is low when expressed as a proportion of total sites, when expressed as a percentage of sites actually

[36] In December 2003, six sites out of a total of 40 inspected (or 15 per cent) were found to be non-compliant.

visited, non-compliance is much higher. In the December 2003 quarter, out of 40 sites visited, six (or 15 per cent of sites visited) were non-compliant.

Figure 3.8

Number of findings of non-compliance on current and post-harvest monitoring sites and number of non-compliant sites as a percentage of sites monitored, by quarter.



Source: Data from OGTR.

Managing non-compliance

3.42 As noted earlier, if, during a monitoring visit, an inspector identifies a non-compliance issue on site, the inspector may request the representative of the licence holder to immediately take any corrective action considered appropriate to ensure the site is brought back into compliance with the licence conditions and/or to ensure the safety of persons and the environment.

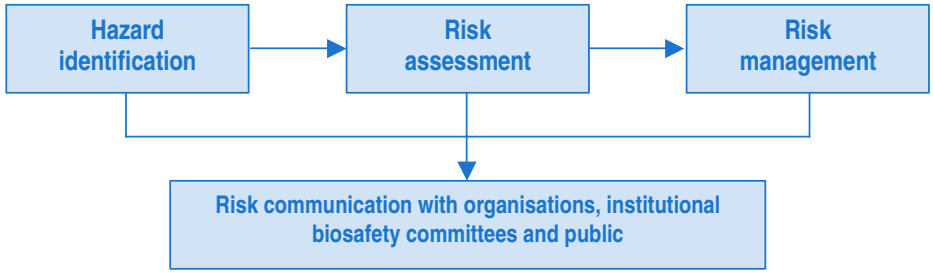
3.43 The *Monitoring and Compliance Risk Analysis Protocol* outlines the processes to be followed to ensure that any potential risks associated with non-compliance are properly identified and managed, and that appropriate action is taken to manage any such risks. The risk analyses conducted in accordance with the protocol also take account of any analysis of relevant risks undertaken during the evaluation and assessment stages, including any risk management strategies that had been developed. Where necessary, monitoring and compliance staff will draw from the expertise of evaluation personnel in the further identification and analysis of risk, and in the development of any

proposed risk management strategies. This will particularly be the case where the monitoring team identifies hazards to human health and/or the environment that were not previously identified during consideration of the dealing at the application assessment stage.

3.44 The *Risk Analysis Protocol* provides a framework for OGTR monitoring staff in conducting an analysis of the risks posed by findings of non-compliance. As shown in Figure 3.9, the framework comprises four components: (i) hazard identification; (ii) risk assessment; (iii) risk management; and (iv) risk communication. OGTR identifies risk communication, particularly with persons conducting dealings, but also with other regulatory agencies, as an important component of ensuring that any risks are appropriately managed.

Figure 3.9

The basic components of OGTR risk analysis



Source: OGTR.

3.45 In conducting risk analysis and preparing risk management strategies in relation to dealings with GMOs, the *Risk Analysis Protocol* specifies that OGTR take account of the following:

- Hazards to human health and safety, taking into account effects on:
  - persons undertaking the dealings (from an occupational health and safety perspective);
  - the general public, should the GMO be unintentionally, accidentally or deliberately released into the environment; and
  - the intended application or use of the GMO, and any affects on persons thus likely to be exposed to the GMO.

- Hazards to the environment, taking into account direct and indirect effects on the receiving environment, including:
  - flora and fauna;
  - habitat;
  - biodiversity; and
  - soil, air and water.

3.46 The risk assessment will also take into consideration the:

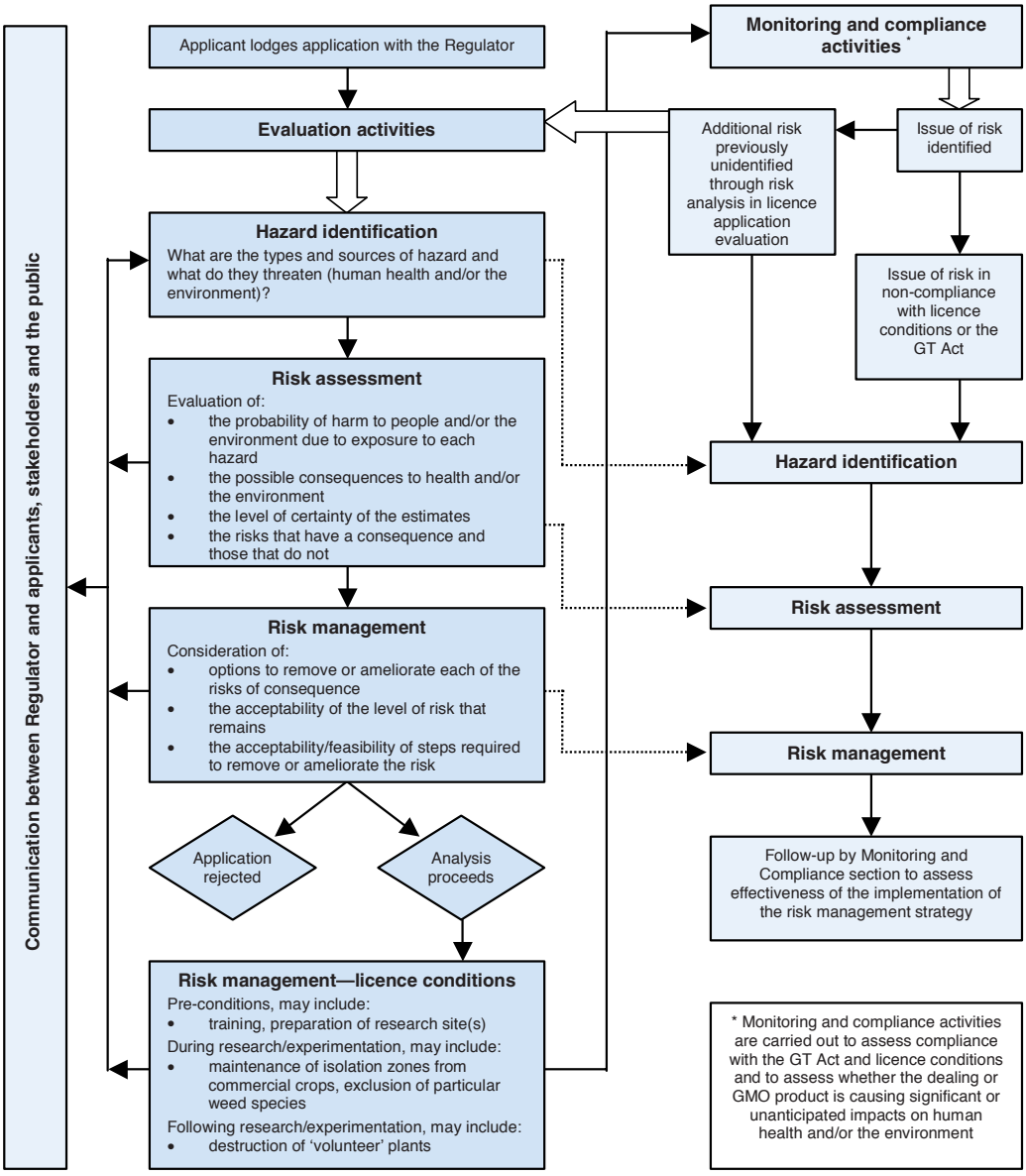
- GMO type;
- abundance and distribution of the GMO;
- biology and ecology of the GMO;
- specific environment in which the GMO has been detected;
- likely reaction of the GMO in that environment; and
- direct and indirect effects on human health and the environment.

3.47 As noted earlier, the risk analysis draws upon previous analyses and expertise gained during the evaluations and assessment processes. Thus, risk assessment and risk management occurs in an integrated manner drawing on expertise from all relevant parts of OGTR (see Figure 3.10). Once the risk has been assessed, a risk management strategy is prepared and implemented.

3.48 Upon conclusion of the risk analysis, the licence holder will be informed of the nature of the non-compliance or risk identified during monitoring, and any corrective action identified as required as outlined in the risk management strategy. The findings of all risk analyses are also included, in summary form, in the OGTR quarterly report.

Figure 3.10

OGTR Risk Analysis Framework and linkages between parts of OGTR in conducting risk analyses



Source: OGTR.

3.49 Instances of non-compliance may also lead to further investigation by the compliance and investigation team. Whether such an investigation will occur, and the consequences of any such investigation, including what sanctions may be applied, will be determined in accordance with the principles outlined in the OGTR *Monitoring and Compliance Model* (discussed below at paragraph 3.59).

3.50 ANAO observed application of monitoring and inspection policies and procedures whilst accompanying OGTR staff during a number of routine monitoring visits. The results of monitoring visits, along with details of any findings of non-compliance, are recorded on a database maintained by the *Monitoring Team*. This database is reviewed in order to ensure appropriate follow-up action is undertaken and completed by the organisation involved and by OGTR. However, (as noted briefly in paragraph 3.22), until recently, details of OGTR monitoring and inspection visits were filed in a manner that did not facilitate ready access to information associated with individual sites, licences or organisations. OGTR is currently reviewing and changing its recordkeeping practices to ensure that information on compliance history and monitoring activities is more readily available to OGTR staff, including to staff involved in the assessment of applications made under the Act, including in making determinations on applicant suitability.

3.51 Results of non-compliance are also recorded in the OGTR quarterly report, along with a summary of the risk assessment conducted in relation to the hazards posed by the non-compliance and of the risk management measures required in order to manage any such risks. To-date, all instances of non-compliance have been assessed to pose low or negligible risk, and thus have fallen towards the bottom of the *Monitoring and Compliance Model* (see paragraph 3.59).

3.52 The ANAO suggests that OGTR continue to ensure that information on the results of monitoring activities of individual sites is more readily accessible, in order to facilitate evaluation decision-making and planning of monitoring and inspection activities.

Compliance and investigation

The Compliance and Investigation Team

3.53 The *Compliance and Investigation Team* comprises personnel with extensive experience in law enforcement and compliance. The team states its role as being to '*maintain public confidence that the OGTR is dealing appropriately with those persons committing breaches against*' the Act. An outline of the roles and responsibilities of the Team is provided in Figure 3.11.

3.54 The team provides the Regulator with advice on, and implements strategies for, ensuring dealings are conducted in accordance with the requirements of the regulatory regime. In addition to conducting investigations into suspected offences against the Act, the team also undertakes a number of other activities aimed at ensuring compliance. The team draws upon the expertise of other OGTR staff, including members of the monitoring team and evaluation and assessment staff, where appropriate.

3.55 The team classifies its compliance activities into two main categories: (i) compliance assessment strategies; and (ii) compliance management strategies.

3.56 Compliance assessment strategies are aimed at identifying risks or instances of non-compliance and comprise the following activities:

- Analysis—the gathering and analysis of information in order to identify potential non-compliance or risks of non-compliance (see Figure 3.16);
- Audits and Practice Reviews—reviews in order to ensure that organisations conducting dealings have adequate processes, procedures and capabilities to meet and comply with regulatory requirements (see Figure 3.15);
- Incident Reviews—reviews of organisational practices and information gathering following self-reporting by organisations of instances of non-compliance; and
- Investigations—formal information collection and evidence gathering in relation to suspicions of offences against the Act (see below for further information).

Figure 3.11

Role and Responsibilities of the OGTR Compliance and Investigations Team

Role and Responsibilities of the OGTR Compliance and Investigations Team

The Compliance and Investigations Team will:

a. Maintain and expand our formal and informal networks in the community;
b. Conduct highly leveraged non-compliance investigations;
c. Provide community confidence in the OGTR's dealing with non-compliance;
d. Establish effective non-compliance detection approaches;
e. Maintain a non-compliance awareness program;
f. Influence and shape policy and legislative enhancements;
g. Invest in building skills and knowledge;
h. Promote and reward leadership and good management;
i. Ensure our administrative interpretation of legislation is consistent and professional;
j. Maintain overall compliance by engaging re-active and proactive non-compliance strategies;
k. Seek international benchmarks and learning synergies;
l. Set operational targets and implement a performance management and monitoring system for investigation activities; and
m. Provide cost effective solutions in delivering desired outcomes.

The Compliance and Investigation Team will engage in the prevention, detection and investigation of breaches committed against the *Gene Technology Act 2000* by the following strategies:

a. Through the use of strategic and operational intelligence identify non-compliance offences committed against the *Gene Technology Act 2000*;
b. Utilise tactical intelligence during the conduct of investigations;
c. Gather relevant evidence to support a prosecution case;
d. Prepare briefs of evidence for referral to the Commonwealth Director of Public Prosecutions (DPP) and State DPPs;
e. Provide further assistance to the DPP on prosecution matters;
f. Where considered appropriate by the Gene Technology Regulator, refer to the Australian Federal Police (AFP) potential serious non-compliance, and either assist in the investigation or conduct investigations where the AFP are unable to deal with a referral;
g. Liaise with the AFP in relation to specific joint investigations or case referrals;
h. Recovery of proceeds of non-compliance activity;
i. Provide executive briefings and reports;
j. Provide training to OGTR Investigators conforming to the standards set out by the Commonwealth Fraud Policy;
k. Provide advice and training to OGTR stakeholders on non-compliance matters; and
l. Provide support for other Government policies.

Source: OGTR.

3.57 Compliance management strategies are aimed at managing or preventing risks or instances of non-compliance. These strategies are often implemented in response to or in association with the team's compliance assessment strategies. They comprise education and awareness activities, in order to better inform individuals and organisations of their obligations and responsibilities under the Act (see Figure 3.11). Compliance management strategies may also involve seeking alternatives to formal prosecution under the Act, including administrative solutions and other alternatives to formal enforcement measures. OGTR has issued policies, for example the *Non-Compliance Protocol* and the *Monitoring and Compliance Model*, that provide

guidance to staff, as well as persons regulated by the Act, on OGTR compliance management strategies.

3.58 The team has developed numerous policies and procedures dealing with the various aspects of the team's activities. These policies are readily available to team members in both paper and electronic formats.

OGTR Monitoring and Compliance Model

3.59 OGTR has developed a *Monitoring and Compliance Model* that outlines its strategy for monitoring and compliance activities under the Act. The model applies to all dealings under the Act and allows for the assessment and management of risks to public health and safety of people and the environment, as well as non-compliance with the Act. A summary of the model is shown in Figure 3.12.

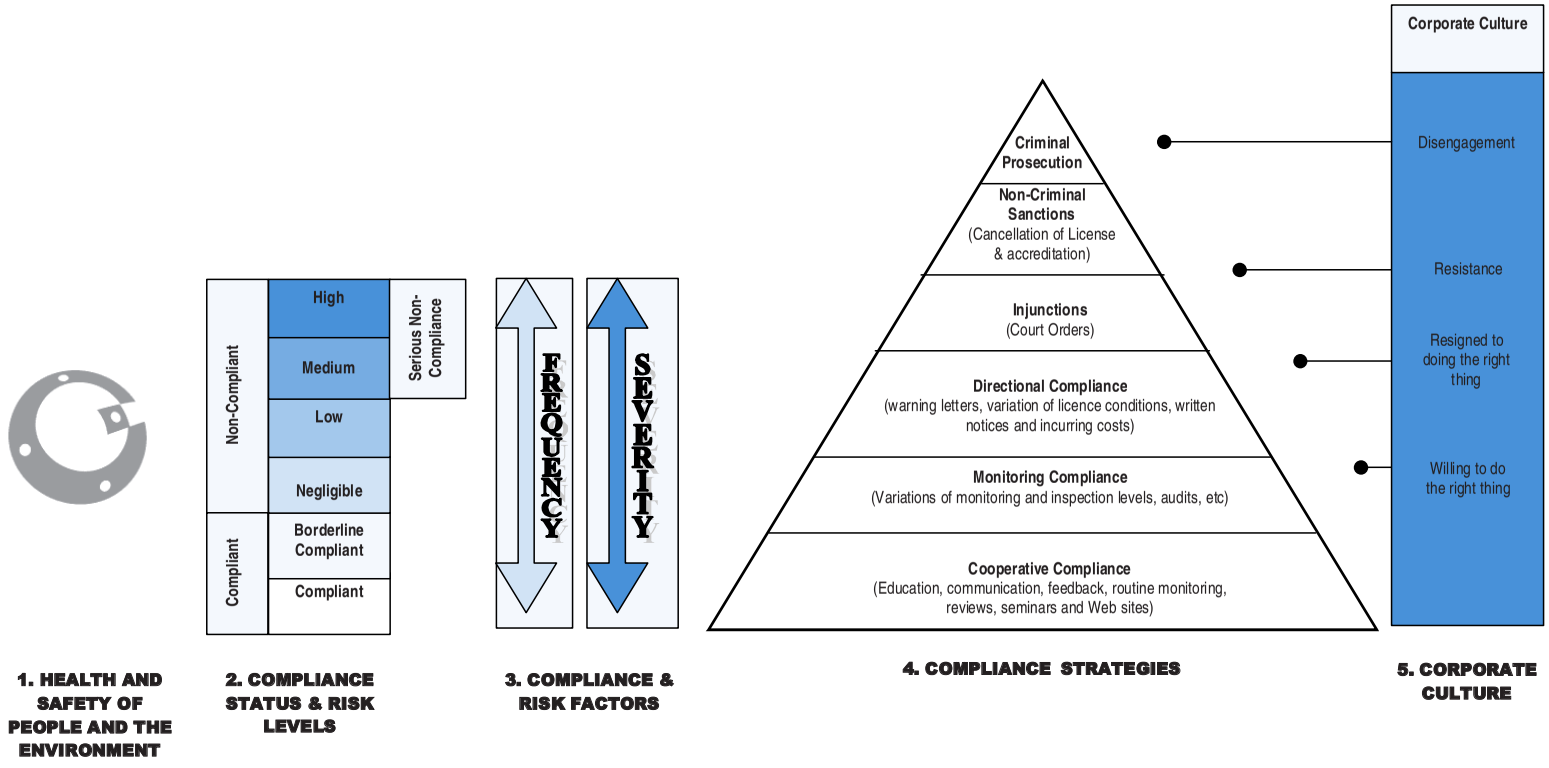
3.60 The model links the objective of protecting human health and safety of people and the environment with the prevention and management of risks associated with dealings with GMOs by ensuring that such dealings are undertaken in compliance with the regulatory regime established by the Act. The model outlines a range of strategies for securing compliance, seeking to balance enforcement measures with organisational behaviour and risks posed by non-compliant behaviour.

3.61 Thus, where the risks to human health and safety of people and the environment resulting from non-compliant behaviour are low, and such behaviour is infrequent or the non-compliance is of a minor nature, commensurate corrective measures will be taken by OGTR. Thus, the model provides for enforcement action of a co-operative nature for unintentional or technical non-compliance, where any risks associated with non-compliance are low or non-existent. Criminal prosecution is recognised as a measure appropriate in cases of severe non-compliance or where the associated risks are high.

3.62 The model thus recognises the need to educate organisations on regulatory requirements in a manner that elicits co-operative compliance, whilst also recognising the important deterrent and educatory effect of use of the mandatory penalty provisions in the Act, both in a context of an overall objective of protecting human health and safety of people and the environment.

Figure 3.12

Summary of the OGTR Monitoring and Compliance Model.



Source: OGTR.

Investigations

3.63 Where it is suspected that an offence has been committed against the Act, the team may conduct an investigation. An investigation may be initiated as a consequence of:

(i) a monitoring visit by the Monitoring Team;

(ii) a report or allegation made by a member of the public;

(iii) self-reporting by the responsible organisation; and

(iv) OGTR auditing of reports and records provided by organisations undertaking dealings.

3.64 An investigation aims to gather evidence to assist in determining whether an offence has been committed. As noted earlier, the Act provides specific powers to inspectors to enter premises and search for, and gather evidence of, possible offences.

3.65 The *Compliance and Investigations Team Procedural Guidelines* outlines the procedures to be followed in conducting non-compliance investigations. The Guidelines are designed to complement the *Australian Government Investigation Standards* and are designed to satisfy or exceed the requirements of the Commonwealth Investigations Technical Standards Committee.[37]

3.66 The Guidelines deal with all aspects of the OGTR investigation, including:

- functions, powers, and responsibilities of inspectors under the Act;
- relationships between OGTR and other agencies in relation to investigations of alleged offences against, and enforcement of, the Act;
- initial consideration of, and responding to, allegations of non-compliance, including subsequent action;
- investigation management methodologies and support;
- operational practices;
- investigation reporting, including preparation of briefs of evidence; and
- investigation results and reviews.

3.67 As noted earlier, licence holders can also voluntarily report potential breaches of their licence or other conditions to OGTR, and there is also scope

[37] The *Australian Government Investigation Standards* are developed by the Australian Federal Police under the Fraud Control Policy of the Commonwealth.

for reporting of suspected breaches by third parties. All such allegations are individually investigated by OGTR in accordance with the relevant OGTR protocol.

3.68 Where instances of non-compliance have been identified, the team makes recommendations to the Regulator on options for further action, including whether or not there is a need to exercise any of the enforcement powers provided for by the Act.

3.69 The Regulator is required to provide a quarterly report to the Minister outlining any breaches of conditions of licence that have come to the Regulator's attention and the activities of inspectors in auditing and monitoring dealings.[38] As at 30 June 2003, nine investigations had been conducted by OGTR since its inception. There have been no prosecutions commenced for offences against the Act. Figure 3.13 outlines the main compliance and investigation activities undertaken by OGTR over the past three years. This is reflective of the type of instances of non-compliance thus far identified by OGTR, and application of the *Monitoring and Compliance Model* to deal commensurately with the severity of the breaches identified.

Figure 3.13

Compliance and investigation activities, by quarter

Quarter ending	Sep 2001	Dec 2001	Mar 2002	Jun 2002	Sep 2002	Dec 2002	Mar 2003	Jun 2003	Sep 2003	Dec 2003	Mar 2004	Total
Activity type:												
Investigations	0	3	3	0	0	1	0	2	0	0	1	**10**
Audits	0	1	0	0	0	0	0	0	0	1	0	**2**
Practice	0	0	0	1	2	1	0	0	0	0	0	**4**
Incident reviews	0	0	1	1	0	2	2	1	2	2	0	**11**
Total	**0**	**4**	**4**	**2**	**2**	**4**	**2**	**3**	**2**	**3**	**1**	**27**

Source: Data from OGTR.

Audits, incident reviews and practice reviews

3.70 As noted earlier, in addition to conducting formal investigations into alleged offences against the Act, the team also undertakes a number of other activities aimed at securing compliance through both preventative and enforcement action.

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[38] *Gene Technology Act 2000* (Cth) s 136A. See also Chapter 5 for further discussion on reporting requirements under the Act.

Audits

3.71 OGTR defines an audit as a wide-ranging examination of an organisation's procedures, records and other relevant information in order to identify whether improvements can be made to an organisation's management of its dealings with GMOs, or in order to assess whether the organisation is in a position to comply with legislative requirements.

3.72 An audit may involve:

- a systematic paper-based examination of an organisation's records, standard operating procedures and other information relevant to the GMO dealing(s); and/or
- comprehensive on-site monitoring to verify compliance with organisational operating procedures and other information and records provided to OGTR.

3.73 At the conclusion of the audit, an audit report is prepared and provided to the organisation. An implementation plan is also prepared to define actions and strategies required to implement any recommendations arising from the audit. Both the audit report and the implementation plan are made publicly available on the OGTR website.

Incident reviews

3.74 Incident reviews are initiated when an organisation reports, or the monitoring team identifies, a particular incident that may present a potential risk to human health and/or the environment and that may be suspected to be non-compliant with the Act. Incident reviews are undertaken by both monitoring and compliance and investigation personnel. Incident reviews involve an assessment of the circumstances surrounding the incident to determine whether:

- the incident has resulted in a risk to public health or the environment; and
- any non-compliance with the Act ought to be referred for formal investigation.

3.75 The review aims to identify the risks associated with any uncontrolled exposure of the GMO to people or the environment, but also to analyse the events that led to the incident to ensure that management strategies are implemented to prevent any such future incidents.

3.76 In assessing whether there has been non-compliance with the Act and in determining whether the incident should be referred for formal investigation, OGTR takes the following matters into account:

- quality and reliability of information available;
- strength and clarity of technical provisions in licences and guidelines (as relevant);
- nature of the offence provisions within the Act, including the relevant elements comprising the particular offence provision; and
- types of compliance strategies available (see the OGTR *Monitoring and Compliance Model* at Figure 3.12, for further information).

Practice reviews

3.77 Practice reviews are initiated to determine if licence conditions can be, and are being, effectively implemented. They aim to identify any potentially adverse affects associated with dealings with GMOs and may be prompted by observations or a set of observations made during monitoring activities. Practice reviews aim to assess, in the practical environment of the laboratory and/or the field, whether the risk management strategies adopted by OGTR in its risk assessments and risk management plans, are able to effectively manage any risks associated with dealings with GMOs.

3.78 Practice reviews thus aim to inform OGTR risk assessment or risk management processes, by eliciting practical information about the effectiveness of proposed risk management strategies. They also aim to improve organisational management of dealings with GMOs by providing feedback to organisations on risk management strategies and practices and thus aim to prevent non-compliance or the occurrence of any potential hazards associated with particular types of dealings.

Other monitoring and compliance activities

3.79 In addition to the work described above, there are a number of other systems in place by which OGTR facilitates compliance and identifies non-compliant activities.

Review of organisational decision-making

3.80 The annual reporting required of accredited organisations assists in ensuring that organisations are kept aware of their responsibilities under the Act. The template annual report produced by OGTR requires organisations to make a number of assertions to the Regulator of compliance with the conditions of accreditation and other requirements of the Act.

3.81 Receipt of annual reports is monitored by ALMS (see Chapter 2 for further information) to ensure that all accredited organisations lodge the annual report. ALMS also review these annual reports to ensure that the

required information has been provided. Where information is incomplete, the organisation is requested to provide further detail to OGTR.

3.82 Accredited organisations are also required to provide a record of all exempt dealings conducted by the organisation. It is the organisation (acting on the advice of its IBC—see Figure 3.14 for further information on IBCs) that determines whether the dealing meets the criteria for classification as an exempt dealing. OGTR does not currently review the lists of exempt dealings submitted by accredited organisations to ascertain whether the dealing was correctly classified.

Figure 3.14

Institutional Biosafety Committees

Institutional Biosafety Committees

Institutional Biosafety Committees are specially constituted committees established by organisations to assist in internally reviewing and monitoring research proposals and activities within the organisation. They are usually comprised of relevant experts within the organisation and provide advice to the organisation and proponents on matters relevant to the proposed research. The precise composition, role and operating procedures of a particular IBC is a matter for the individual organisation, although, the conditions of accreditation prescribed by the Regulator specify certain requirements with which accredited organisations must comply. Institutional Biosafety Committees existed under the previous voluntary regimes (see paragraph 2.4) and continue to play an important advisory role under the regulatory regime established by the Act.

The accreditation requirements of the Act now formalise the role of IBCs, who assist the Regulator by:

- providing advice and assistance to proponents in relation to proposed dealings with GMOs, including assisting in the correct classification of dealings and in the preparation of relevant applications and notices to the Regulator; and
- performing annual inspections of certified facilities.

The Act envisages only an advisory role for IBCs: responsibility for complying with the requirements of the regime rests ultimately with the proponent; whilst responsibility for monitoring compliance with and for enforcing the Act rests with the Regulator:

> The IBC will never be responsible for performing the licensing functions of the [Regulator]. The [Regulator] will always be responsible for undertaking risk assessments, issuing licences, determining the classes of dealings with GMOs that are exempt or notifiable low risk dealings, and monitoring compliance with the legislation.[39]

However, in many cases, the organisation's IBC or IBCs will be closely involved in, or have organisational responsibility for, ensuring organisational compliance with the requirements of the Act.

Source: ANAO.

3.83 As mentioned in Chapter 2, organisations are also required to notify OGTR of all NLRDs being undertaken. OGTR conducts an assessment of each NLRD notification to check that the dealing has been correctly classified. OGTR advised that around one per cent of notifications are found to have been

[39] Interim Office of the Gene Technology Regulator, *Explanatory Guide to the Commonwealth Gene Technology Bill 2000*, IOGTR, July 2000.

misclassified by organisations (that is, the dealing should have been classified as exempt or as requiring a DNIR licence, instead of being classified as a NLRD). This was said to be attributable to ambiguities with the Regulations, which set out the classification criteria. OGTR is currently reviewing the Regulations with the aim of seeking amendment to remove these ambiguities.

3.84 Accredited organisations must also conduct an annual inspection of certified facilities to ensure continuing compliance with the conditions of certification, and confirm within the annual report that such inspections have been conducted.

3.85 OGTR review of organisational notifications and annual reports does not, however, verify the assertions made therein. Because organisations are required to determine the extent to which the dealing falls within the legislative regime (and its classification) as a first step to engaging with OGTR and the regulatory regime, poor understanding of the legislative requirements gives rise to a possibility of misclassification of the dealing. OGTR review of organisational notifications and annual reports provides one means by which misclassification can be identified. OGTR practice reviews and audits aim to validate organisational systems and processes and attempt to identify systemic problems with decision-making or organisational practice, and thus provide a more in depth examination of organisational practices and dealings. For example, the most recent practice review sought to evaluate IBC decision-making and risk management systems in accredited organisations (see Figure 3.15), finding that accredited organisations had well-developed and effective decision-making and risk management and compliance systems for their activities under the Act.

3.86 It is important that OGTR continues to ensure that organisations conducting dealings with GMOs maintain the systems and procedures appropriate to the management of risks associated with those dealings. In addition, given the important role that IBCs play in assisting organisational decision-making and classification of dealings, it is important that OGTR is satisfied that organisations understand the regulatory requirements and are applying these requirements in a way that leads to consistency in their application across all institutions. The review of the regulations to remove ambiguities will facilitate clear and consistent IBC advice and organisational decision-making. Although resource intensive in comparison to the desktop review of notifications and annual reports, practice reviews and audits are an important tool provided by the Act for detecting possible systemic problems and for facilitating consistency of decision-making and thus compliance with the Act.

Figure 3.15

Compliance management strategies—practice reviews

OGTR contained facilities practice review

The contained facilities practice review was conducted by OGTR during the first half of 2004 in order to:

- better understand and validate IBC decision-making processes, and risk and compliance management arrangements;
- co-operatively identify strategies to assist compliance with regulatory requirements; and
- provide input into the current review of the Gene Technology Regulations 2001 (Cth).

A total of 34 accredited organisations were visited during the review. The review established that:

> [A]ccredited organisations had well developed and effective decision-making and risk management and compliance systems for their activities under [the Act].

In addition to providing an assurance to OGTR on the systems and procedures in place in those organisations visited, participants provided useful suggestions that have been incorporated by OGTR in its review of the Regulations. The review also enabled OGTR to provide practical advice to participants on regulatory requirements. It is intended that the findings of the review will be presented at the National Institutional Biosafety Committee Forum, being held by OGTR in Canberra during April 2005.

Source: Adapted from OGTR.

Detection of non-compliance by others

3.87 The measures thus far discussed are directed at organisations already engaged with OGTR and known to OGTR. That is, they are aimed at examining compliance with conditions attached to dealings with GMOs, where the organisation has already brought itself within OGTR administrative oversight by seeking to fulfil the requirements of the regulatory regime (for example, by seeking licensing or accreditation or certification). However, these measures are not well suited to ready detection of instances of non-compliance by those organisations not familiar with or ignorant of OGTR requirements. For example, under normal circumstances, the importation of live viable genetically modified seed is prohibited by the Act and thus importation could only be conducted under licence granted by OGTR. However, where a person imported such seed without realising the seed to be genetically modified, then there would have been no OGTR licence sought, since it would not have been thought that there was any need for such licence.[40] In this example, if the seed was subsequently planted and used for agricultural production, the risks to human health and safety and to the environment posed by such use may not have been previously assessed by OGTR.

[40] Although the required AQIS permit application form asks for details on whether the material is genetically modified or contains genetically modified material, again, in this example the importer is not aware that the material is genetically modified and so would not have indicated as such on the application form.

Figure 3.16

Information gathering and analysis as a means of managing compliance

OGTR Analysis Function

OGTR undertakes surveillance activity on a daily basis, involving the collection and analysis of information on potential gene technology activity from a variety of sources, including:

- Australian and international media sources;
- Australian Stock Exchange announcements from companies involved in relevant biotechnology research and development;
- importation data sourced from the Australian Quarantine Inspection Service (AQIS) under an agreement for data sharing between the two agencies;
- published information on research projects funded by grants;
- Internet search engines; and
- other relevant sources.

This information is cross-referenced with existing OGTR information on approved dealings and accredited organisations, in order to identify potential unauthorised dealings.

The information gathered is also used to help inform the quarterly planning of monitoring activities.

Source: ANAO.

3.88 OGTR has developed processes for attempting to detect these instances of non-compliance. For example, the 'analysis' function of the *Compliance and Investigation Team* (see Figure 3.16) aims to gather intelligence in order to detect potential breaches of the regulatory requirements. In addition, OGTR has developed procedures for the handling of reports of potential breaches of the Act provided by members of the public. The OGTR website allows for anonymous reporting of suspected non-compliance over the Internet.

3.89 The nature of the regulatory regime, in particular the continued role of existing regulators in regulating genetically modified products within their area of regulatory responsibility, could also contribute to non-compliance through ignorance or misunderstanding of the multiple and different regulatory requirements. The requirement to seek such multiple regulatory approvals may not always be immediately apparent to those conducting the dealing. OGTR has also begun to formalise co-operative arrangements with other Commonwealth regulatory authorities in order to facilitate compliance and detect potential non-compliance (for example, see Figure 3.17).

3.90 Continued co-operation with other relevant agencies and other efforts by OGTR is important in ensuring that these types of non-compliance are detected in order to ensure that all dealings with GMOs are subject to the disciplines of risk analysis provided for by the Act so that its objectives of protecting human health and safety and the environment are achieved.

Figure 3.17

The importation of GMO seeds and border surveillance arrangements between OGTR and AQIS

Border surveillance

The Act prohibits all dealings with a GMO (including importing a GMO) unless authorised by the Act or Regulations or under licence issued by the Regulator. Common examples of GMOs that may be imported include GM seed or grain, GM live vaccines, or GMOs for use in research. OGTR is working closely with AQIS to identify strategies for managing the potential importation of GM seeds or grains.

Worldwide, approximately 80 different GM crops have been approved for commercialisation, with 17 countries growing commercially released crops in 2004. The four main crops commercially produced are canola, soybean, maize and cotton.

In 2002–03, 93 million tonnes of canola, soybean and corn were imported as seed into Australia. Imported seeds are used for a variety of purposes, including for use in sowing, for use as stock feed and for food production. The volume of seed imported depends on a number of factors, most importantly the prevailing environmental conditions and resulting volume of domestically produced seed and grain.

It is the responsibility of the importer to ensure it has complied with all applicable regulatory requirements prior to and after the importation of any seed. For example, agencies with specific responsibilities or requirements may include: the Australian Custom Service; the Australian Pesticides and Veterinary Medicines Authority (APVMA); AQIS; the Department of the Environment and Heritage; OGTR; TGA; and other relevant State government agencies such as Departments of Agriculture and Health and environmental protection authorities.

AQIS is responsible for implementing the *Quarantine Act 1908* (Cth), which prohibits the import of some products that may pose a pest and disease risk to human, animal and plant health and the environment. The importation of GM seed is prohibited under section 63(2) of the *Quarantine Proclamation 1998*, unless a valid AQIS '*Application for Permit to Import Quarantine Material*' form is completed.

Quarantine permit application forms now prompt the importer to indicate whether the product is genetically manipulated or contains genetically manipulated material. For the import of GMO seeds or grains, importers are required to obtain an authorisation number from OGTR and disclose it on the AQIS permit application form (AQIS may not issue a quarantine import permit unless an OGTR authorisation number has been provided). Quarantine permit application forms now include a statement indicating that information provided to AQIS may be passed to OGTR. OGTR and AQIS recently finalised a memorandum of understanding for the sharing of information to assist both agencies monitor compliance with their respective regulatory requirements. AQIS now provides OGTR with monthly data on declared GM seed and grain imports.

AQIS and OGTR are also working together to address the issue of unintended presence of genetically modified organisms in seed and grain imports.

Source: ANAO.

3.91 In order to continue to facilitate compliance with the requirements of the Act and to maximise detection of potential breaches, the ANAO suggests that OGTR ensure that appropriate resources are devoted across its monitoring and compliance activities, to ensure that the appropriate balance is struck between monitoring and inspection, assessment of annual reports and notifications, auditing and review of organisational practices and decision-making, as well as general surveillance and intelligence gathering activities.

Summary

3.92 OGTR policies and procedures ensure that decisions of OGTR staff in relation to assessment of applications are subject to quality assurance control and review. Organisational compliance with the requirements of the Act is facilitated through formal monitoring and inspection visits, as well as through assessment of annual reports and notifications. OGTR compliance and investigation staff follow relevant policies and procedures when performing compliance and investigation functions.

Overall conclusion

3.93 OGTR has developed detailed policies on monitoring of licences and certifications granted under the Act. These policies and guidelines also assist staff in performing the monitoring and compliance functions of the Act. There were some minor format and consistency issues that require attention. Policies were available to relevant OGTR staff.

3.94 It was evident from ANAO participation in monitoring and inspection visits that OGTR staff applied relevant policies. Although OGTR policies on monitoring and inspection require a risk-based approach to planning monitoring and inspection activities, OGTR does not publicly provide details on the rationale behind its choice of locations. There was room for better collection, use and recording of information on past monitoring activity and compliance history in informing planning decisions.

3.95 The ANAO also found that IBCs play an important advisory role in the regime. OGTR policies require a 20 per cent target for assessing NLRD notifications, however, OGTR does not publicly report on the outcomes of this quality assurance checking.

3.96 Although many policies are continuously reviewed, often no formal record of review was kept, nor timetables for future reviews.

3.97 OGTR has established systems and procedures for ensuring compliance with the Act. There have been as yet no prosecutions commenced for offences against the Act.

4. Performance Management

This chapter discusses aspects of OGTR performance in discharging selected functions under the Act. The chapter first describes OGTR budget and financial resources, before examining OGTR workforce planning and the external factors influencing, and risks associated with, OGTR deployment of its financial and human resources. The chapter then briefly describes training of OGTR staff, before examining OGTR performance measurement and reporting.

Background

4.1 Good financial management enables a regulatory organisation to ensure that it has enough resources to meet its regulatory demands and to plan for expected future demands on its resources. Good financial management also enables senior management to understand organisational resource requirements and to ensure that appropriate resources are provided to the assigned functions and activities.

Financing and OGTR budget

4.2 Currently, OGTR is funded through appropriations to the Commonwealth Health portfolio.[41] OGTR budget and expenditure since inception is shown in Figure 4.1.

Figure 4.1

OGTR budget and expenditure

Year	Budgeted appropriation ($m)	Actual expenditure ($m)	Surplus / (Deficit) ($m)
2001–02	8.6	6.8	1.8
2002–03	8.2	7.4	0.8
2003–04	8.1	7.9	0.2
2004–05	8.4	8.4	0.0
Total	**33.3**	**30.5**	**2.8**

Source: ANAO.

[41] Appropriations are paid into the Gene Technology Account established by the *Gene Technology Act 2000* (Cth) in accordance the *Financial Management and Accountability Act 1997*.

4.3 OGTR monitors its expenditure on a monthly basis, with monthly reporting of financial information to senior OGTR managers, highlighting material changes in expenditure from the previous month. A brief statement of OGTR budget and expenditure is provided in the annual report of the Department of Health and Ageing. Further information on public reporting by OGTR is provided at paragraph 4.30.

4.4 The early uncertainty surrounding the introduction of cost-recovery by OGTR (see below for further information), and the resultant three independent cost-recovery reviews, have given OGTR a sound understanding of the price of, and costs associated with, performing the various functions required of it under the Act. Processing of applications accounts for around 34 per cent of annual expenditure, whilst monitoring and compliance activities account for around 11 per cent (see Figure 4.2).

Figure 4.2

Actual costs incurred by OGTR budget from 1 July 2003 to 31 March 2004

Section/Area	9 months costs ($)	Annualised cost ($)	Proportion of total cost (%)
Evaluation Sections	966,578	1,288,771	18
Applications and Licence Management Section	311,743	415,657	6
Contained Dealings Evaluation Section	544,945	726,593	10
Monitoring and Compliance	580,736	774,315	11
Executive	500,444	667,259	9
Policy	345,053	460,071	6
Secretariat and Communications	444,538	592,717	8
Legal	205,330	273,773	4
Business Management	240,293	320,391	4
Corporate Overheads	992,056	1,322,741	18
Sub total	**5,131,716**	**6,842,288**	**95**
Depreciation of GTIMS	265,600	354,133	5
Total	**5,397,316**	**7,196,421**	**100**

Source: OGTR.

Summary

4.5 OGTR has good information on its costs and current resource requirements, and has thus far worked within its annual appropriation.

Workforce planning and recruitment

Managing workload

4.6 As shown in Appendix 5, OGTR has processed a large number of applications since its inception. There has also been great fluctuation in the total numbers of applications and notifications received and processed over the first three years, exacerbated by the applications received towards the end of the transitional period. However, OGTR advise that, nevertheless, all applications have been processed within the required statutory timeframes.

4.7 This variation causes difficulties in predicting future workload requirements, although analysis of the type and volume of applications and notifications received since the expiry of the transitional period would provide some indication of ongoing expected workload.[42]

4.8 Most of the DIR applications and licences received and issued by OGTR have, thus far, related to GM agricultural crops (see Figure 2.3). OGTR has developed particular expertise in dealing with these types of applications. However, OGTR advised that the number of DIR applications for this type has slowed, involving mainly limited release field trials rather than applications for commercial release.[43] The designation of GM-free areas in each State and Territory (with the exception of Qld and NT, where conditions are generally considered to be unsuitable for the commercial cultivation of the genetically modified crops so far approved for commercial release), has contributed to this slowing (see paragraph 44 of Appendix 1). It can be expected that the lifting of these moratoria will result in a resumption of related applications for DIR licence. However, the uncertainty over the expected duration of these moratoria make predicting the volume and timing of future DIR applications difficult.

4.9 In addition, because of its application to a wide range of fields, as the technology develops OGTR can expect to receive applications of other types, for example, in related to GM livestock or aquaculture or GM pharmaceutical or nutraceuticals.[44] Although such advances are difficult to plan for, OGTR will

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[42] For example, see paragraph 8 of Appendix 5 for a discussion of the large cyclical volume of accreditation applications/renewals that OGTR can expect to receive periodically.

[43] As noted in Chapter 2, there have only been a limited number of licences issued for commercial release, and no applications or licences issued since 2003: DIR 012/2002—BolgardII and BolgardII/ Roundup Ready® cotton; DIR 020/2002—Roundup Ready® canola; DIR 021/2002—InVigor® canola; DIR 022/2002—INGARD® cotton; DIR 023/2002—Roundup Ready®/INGARD® cotton; DIR 030/2002 GM carnation; DIR 033/2002—Orochol® cholera vaccine.

[44] A nutraceutical is ordinary food that has components or ingredients added to give it a specific medical or physiological benefit, other than a purely nutritional effect.

need to ensure that it can respond to these changes, maintaining appropriate expertise to effectively deal with all types of applications made under the Act.

4.10 Although the nature of the technology and other external factors influence the volume and type of application received by OGTR, making predicting future workload difficult, it is important that OGTR continue to monitor trends in application type and volume. This is important so that OGTR can ensure that it has sufficient expertise and resources to process future applications, and can develop and acquire the skills and expertise necessary to deal with the nature and type of future application.

Cost-recovery

4.11 The Government intended that the costs incurred by the Regulator as a result of performing the functions under the Act be 100 per cent cost-recovered from the users of the regulatory regime. IOGTR was initially budget funded for a period of two years, ending on 30 June 2001. However, following a review of cost-recovery released in September 2000, it was determined that it would not be practicable to implement cost-recovery within OGTR, and further budget funding was provided until 30 June 2003. In May 2003, following the release of a second report into cost-recovery within OGTR, the Government announced further budget funding for OGTR until 30 June 2005.

4.12 The funding uncertainty has now been resolved, with the recently completed third independent review into cost-recovery concluding that the gene technology industry and research community are currently unable to fund regulatory costs. The Government subsequently announced continued budget funding for OGTR, providing $32 million over four years to 2008–09.

4.13 However, the earlier uncertainty over the question of cost-recovery led to difficulties in effectively planning and making resource decisions within OGTR (exacerbated by the relatively short two-year funding horizon to which OGTR has been subject since its inception). This short-term uncertainty over OGTR budgets, also led to corresponding difficulties in decision-making on the future deployment and use of resources. This has had a particular impact on recruitment decisions, which will be further discussed below.

Attracting and retaining staff

4.14 The uncertainty over funding (caused by the prospect of cost-recovery and the resultant two-year timeframes for which OGTR is provided with budget certainty), affects decisions made by OGTR managers on engagement of resources, particularly the recruitment of new staff. The impending establishment of the Trans-Tasman Therapeutic Products Agency (existing OGTR staff will be transferred to the new agency—see Figure 4.3) also exerts an influence on decision-making.

Figure 4.3

The Trans-Tasman Therapeutic Products Agency

Trans-Tasman Therapeutic Products Agency

OGTR is part of the Therapeutic Goods Administration within the Commonwealth Department of Health and Ageing. OGTR staff are engaged under the *Public Service Act 1999*, and made available by the Department for the purpose assisting the Regulator.

On 10 December 2003, the Australian and New Zealand Governments concluded an agreement to establish a joint scheme for the regulation of therapeutic products. As part of this agreement, a new agency—the Trans-Tasman Therapeutic Products Agency (TTTPA)—will be established to replace the Therapeutic Goods Administration and the New Zealand Medicines and Medical Devices Safety Authority.

TTTPA will be incorporated under Australian law, and under the agreement, all employees of the existing bodies will be transferred to the new agency. Although it was intended that TTTPA would commence operation on 1 July 2005, this has now been delayed for 12 months. Existing arrangements for the provision of staff to OGTR will continue, and all OGTR staff will be transferred to TTTPA on or before 30 June 2006. Employees of the new agency will no longer be employed under the provisions of the Public Service Act, and OGTR has advised that an amendment to the Gene Technology Act is required in order for this arrangement to proceed.[45]

Source: ANAO.

4.15 As a result, OGTR has adopted a conservative approach to recruitment decisions until these matters are finalised and there is greater certainty over future OGTR budget and resources and operational structure. For example, OGTR advised that there was a reluctance to recruit additional permanent staff until these uncertainties were resolved, and the engagement of staff on temporary contract was used as a means of resolving staffing needs in the meantime.

4.16 Although such strategies are prudent in an environment of budget and workload uncertainty, they also have the potential to impact on the ability of OGTR to recruit and retain the highly skilled staff it requires to perform its functions.

4.17 For example, the impending transfer to the TTTPA, and the resultant move of staff outside of engagement under the Public Service Act (and corresponding potential loss of flexibility of staff to transfer within the Department and the public service generally), has had an impact on the retention of existing OGTR staff and on recruitment of new staff.

4.18 The employment of staff under contract, although providing flexibility to OGTR in terms of managing resources, also provides less control over the

[45] Section 133 of the *Gene Technology Act 2000* (Cth) requires that staff assisting the Regulator are to be persons employed under the Public Service Act.

retention of such staff and has contributed to corresponding difficulties in retaining staff. For example, of the four executive level officers in the monitoring unit, two were engaged under contract, due to expire on 30 June 2005 (when current budget funding comes to an end). Given the specialised skills required by OGTR, and the corresponding intensive training requirements (see paragraph 4.24), loss of such a great proportion of senior staff in that team could cause difficulties in replacing and training new staff.

4.19 In the eleven months to 31 May 2004, there were 12 staff departures, and in the 9 months to 1 March 2005, a further 9 departures (including the loss of several senior and experienced staff). In the latter case, total staffing at July 2004 was 64—the decrease in total staffing to 55 representing a loss of around 14 per cent of total staff. There are also a number of staff members within OGTR who have been performing higher duties for extended periods of time, and there remain a number of positions that have not been filled after the departure of existing staff.

4.20 The OGTR has developed a *Risk Management Plan* that deals with some of these issues. The Plan identifies, among others, the following human resource risks:

- inability to attract or retain suitably qualified staff;
- loss of quality staff due to funding constraints;
- loss of quality staff due to excessive workloads;
- loss of quality staff due to transition to TTTPA;
- inability to provide ongoing professional development; and
- failure to manage knowledge and ensure knowledge transfer.

4.21 Many of the factors contributing to the resource decisions made by OGTR managers are beyond OGTR's immediate control. However, such decisions contribute to a risk that OGTR is unable to attract and retain the staff necessary for it to effectively perform its regulatory functions. Close monitoring of current staffing levels and current and expected requirements is necessary to ensure that OGTR continues to have the staff necessary for it to effectively perform its regulatory functions. This may require the development of suitable staffing policies, including the implementation of measures to address the risks identified in its risk management plan, to ensure that OGTR decision-making does not contribute to the likelihood of these risks impacting upon OGTR's regulatory effectiveness.

Summary

4.22 OGTR has good information on its costs and current resource requirements, however, a number of external factors provide uncertainty with regards to future resource availability and requirements (for example, Trans-Tasman Authority, and State and Territory moratoria).

4.23 This uncertainty has impacted on the ability of OGTR to plan for and engage resources for future requirements and thus on related decision-making, which has in turn affected OGTR's ability to attract and retain staff. Coupled with the special expertise and intensive training requirements, this poses increased risks to regulatory effectiveness that must be carefully monitored.

Training

4.24 The nature and variety of the work performed by OGTR requires a highly skilled workforce. Coupled with the nature of gene technology itself—its application to a wide variety of fields and the varying pace of developments—mean that OGTR staff must not only have the necessary skills and knowledge to address the current types of applications and state of the technology, but must keep in step with developments in the technology to ensure that they have access to the information necessary to evaluate and monitor future applications.

4.25 In addition to the scientific and other expertise necessary to perform evaluation and monitoring functions, OGTR staff must understand the administrative and legislative framework within which those functions must be performed. For example, OGTR evaluators must understand the risk analysis framework within which decisions on applications must be made, and the application of scientific expertise in the deliberation and decision-making process involved as part of the risk analysis. In addition to an understanding of the scientific risks associated with particular dealings, OGTR monitoring staff must be aware of the practical implementation (and limitations) of OGTR licence conditions and other requirements in relation to particular dealings, all within the context of the legislative framework within which monitoring must be conducted and compliance must be measured.

4.26 As a result, in addition to requiring staff with specific skill and expertise requirements, a considerable amount of on-the-job training can be required before OGTR staff are fully proficient in undertaking the necessary OGTR function. OGTR advised that individual training needs are assessed for individual OGTR officers with reference to their duties. On the-job-training is provided to new staff by existing more experienced or senior OGTR officers. The duration and type of such training will vary according to the individual's training needs. OGTR advised that such training is usually time-intensive,

requiring a number of months before an evaluator or monitoring and compliance team member is ready to undertake independent duties with limited supervision.

4.27 OGTR also provides in-house training on relevant administrative aspects of OGTR operations. For example, formal training on matters specific to OGTR, such as on the legislative regime and OGTR's statutory roles and responsibilities, training on the handling of CCI, as well as on more general matters such as occupational health and safety, administrative law and decision-making. OGTR staff also participate in a number of conferences and other external training relevant to gene technology and regulation.

4.28 Although training is provided relative to the assessed needs of each individual, there was no formal, documented training programme outlining the general training requirements of the main functional areas of OGTR operations (that is, evaluation, monitoring and compliance, secretariat and policy support, and business management functions). A significant component of an individual's development involves on-the-job training, requiring existing OGTR officers to undertake such training over an extended period, diverting resources away from performing existing functions. The lack of a documented, formal training programme could pose risks in meeting required training needs if OGTR loses key experienced staff (see for example, paragraph 4.18), especially if this occurs during periods of unexpected high workload. The lack of documentation also leads to a risk that the level and content of training that is provided will be dependent on the officer providing the training, leading to potential inconsistency in training provided and staff expertise.

4.29 Development of documented, formal training programmes would ensure that OGTR staff are provided with consistent and appropriate training and would allow greater recording of and assurance that OGTR officers have been provided with adequate training. This will enable OGTR to ensure that it continues to meet its legislative obligations, and be better prepared to respond to changing workload pressures and requirements.

Performance reporting

4.30 An effective performance reporting and monitoring system is a key aspect of a well-governed agency.[46]

> Good governance requires that an agency have a structured and regular system of performance monitoring and review. This system should be aligned with the agency's outcomes and outputs framework and generate

[46] Australian National Audit Office and Commonwealth Department of Finance and Administration, *Better Practice in Annual Performance Reporting*, ANAO, Canberra, 2004, p. 1.

> information that is appropriate for both internal and external performance management needs and external reporting requirements…[emphasis added].

4.31 Performance reporting enables management to monitor current performance as well as enabling, through the publication of performance information, external scrutiny of agency activities and performance. Performance reports provide a foundation for planning and budgeting by providing succinct information on past results as a guide to priorities and changes required for the future. External reporting of performance provides an opportunity for agencies to demonstrate and promote their achievements and explain any variance from expectations or reference points.[47] Thus, performance reporting and performance management is an essential part of agency accountability.

4.32 A good performance reporting framework involves the development of clear and precise measures that address all key aspects of agency operations, which when reported, provide an indication of agency performance in those areas. OGTR has developed a number of indicators that it uses in reporting on its performance, which are discussed below.

Performance indicators

4.33 Two main types of performance information are reported by OGTR. Firstly, OGTR has developed a set of performance indicators that it includes in the Health annual report. Secondly, OGTR reports on a number of additional performance measures in its quarterly reports tabled in the Commonwealth Parliament (see paragraph 4.53 for further information).

4.34 Figure 4.4 shows the four main performance indicators reported annually by OGTR in the Health annual report (OGTR reporting against such indicators is discussed below, starting at paragraph 4.53).

[47] Australian National Audit Office and Commonwealth Department of Finance and Administration, *Better Practice in Annual Performance Reporting*, ANAO, Canberra, 2004, p. 4.

Figure 4.4

OGTR performance indicators for effectiveness

OGTR Performance Indicators	
Measure 1	Target:
Proportion of licensed dealings with GMOs that fail to meet licence conditions as identified through monitoring activities	100% compliance for all licensed dealings, certifications and accreditations.

Measure 2	Target:
A minimum of 20% of field trials inspected for compliance with conditions in licences to undertake dealings with GMOs.	A minimum of 20% of field trials.

Measure 3	Target:
Number of assessments of new applications and reviews of deemed licences processed within statutory timeframes.	100% of applications processed within statutory timeframes.

Measure 4	Target:
Publication and timely production of quarterly reports.	Four issues of OGTR quarterly reports.

Source: Health.

4.35 As shown in Figure 4.4, these indicators relate to the evaluation and monitoring activities of OGTR, as well as to the preparation and publication of performance information by OGTR. Although in compliance with the requirements for annual reporting, there are a number of limitations associated with these indicators.[48]

Measure 1—100% compliance for licensed dealings

4.36 Measure 1 (above) provides some indication on the overall effectiveness of OGTR implementation of the objective of the Act, however, the indicator is not a true indicator of OGTR performance. That is, compliance by licensees with conditions of licence will depend on a number of factors, some

[48] Department of the Prime Minister and Cabinet, *Requirements for Annual Reports for Government Departments, Executive Agencies and FMA Act Bodies*, Canberra, 2003.

not directly associated with implementation of the Act's requirements by OGTR. Indeed, where OGTR does detect instances of non-compliance, it will have failed to meet the target, even though the reasons for non-compliance by licence holders may not relate to OGTR's administration of the Act, and it is in fact an important function of OGTR to attempt to detect instances of non-compliance so that they can ensure that early remedial action is taken to manage any associated risks.

4.37 Information on performance against this measure is in the Health annual report. In addition, information on instances of non-compliance found is provided in the quarterly reports issued by OGTR. Although required by the measure, the annual report also does not provide any information on instances of non-compliance found in monitoring of dealings other than for DIR and DNIR licences. The measure sets a target of 100 per cent compliance for all certifications and accreditations as well as for licensed dealings, yet information on non-compliance found during such activities is not reported annually, or in detail in the quarterly reports.

4.38 The ANAO suggests that, in order to enable relevant assessment of OGTR effectiveness in implementing the requirements of the Act, OGTR ensure that all information required by Measure 1 (above) is reported and explained, including analysis or information on the types of non-compliance and the reasons for non-compliance, so that a fair picture of OGTR performance is provided.

Measure 2—Minimum inspection of 20% of field trials

4.39 OGTR reports against this measure in both its annual and quarterly reports, and the percentage of field trials visited by OGTR exceeds the 20 per cent target. However, clearer reporting against the measure could better explain OGTR performance and minimise the potential for the reporting to mislead.

4.40 For example, OGTR reporting against the measure does not specify whether the monitoring involved multiple visits to particular sites or only single visits to different sites. That is, although the target would tend to indicate that, over time, by monitoring 20 per cent of sites each site would eventually be visited once, OGTR reporting against the measure does not disclose that individual sites may be visited more than once. Disclosure of the percentage of sites yet to be subject to monitoring visits and/or the total number of sites not yet visited by OGTR, would provide a better indication of the scope of OGTR monitoring activities.

4.41 Although, where non-compliance is found, OGTR does indicate whether action was taken by the licensee to bring the dealing back into compliance, OGTR does not always provide an indication on whether such

actions were taken in a timely fashion, and what, if any, further action was undertaken by OGTR to ensure that these actions occurred. Reporting of such information would allow better understanding of OGTR measures taken to secure compliance with the Act.

4.42 In addition, although OGTR has set internal targets for its other types of monitoring activity (see Figure 3.2), information on such activities is not reported in the annual report. Information on the volume and scope of other OGTR activities (for example, facility inspections, accredited organisation reviews, NLRD notification assessments), including on activities as a proportion of total sites, facilities, or notifications, would further facilitate analysis of OGTR performance in discharging its monitoring responsibilities.

4.43 The ANAO suggests that OGTR review its performance indicators for its monitoring activities to include information on the volume and scope of other OGTR monitoring activities and for reporting its performance against these reviewing indicators.

Measure 3—100% of applications processed within statutory timeframes

4.44 Although OGTR reports in the annual report that 100 per cent of assessments and reviews of licences are conducted in accordance with the statutory timeframes, it does not provide any further detail on the actual time taken to process such applications in comparison to the statutory target. Also, given that the Act provides for a mechanism for calculation of timeframes, including the provision to not count certain days in calculating the processing time (that is, allowing the 'clock to stop'), information on processing time, including actual elapsed times and length of period during which the 'clock was stopped' would facilitate greater understanding of OGTR performance in assessing applications. Information on average actual elapsed time taken to process applications would also provide prospective applicants with indicative information on actual elapsed processing time required by OGTR in assessing applications. Finally, such information may also enable OGTR to identify areas for improvement in OGTR systems and processes, especially where information is provided on the length of various processing stages and also the reasons for any stopping of the statutory clock.

4.45 In addition, there are a number of other statutory targets that must be met by OGTR in performing functions under the Act. For example, the Regulations specify requirements in relation to processing of applications for certification and accreditation, although OGTR does not report on its performance in meeting these targets. In addition (as noted in Chapter 2), although the Act does not specify any requirements for the processing of variations to licences and other instruments, given the volume of such requests OGTR currently receives, information on the time taken to process variations

would facilitate a greater understanding of OGTR performance in dealing with variations of different types.

4.46 The ANAO suggests that OGTR review its measures of performance in processing timeframes across all application types and include information on total elapsed processing time.

Measure 4—Production of 4 quarterly reports per annum

4.47 As discussed below (see paragraph 4.53), the Act requires OGTR to produce quarterly reports on its operations. The performance measure developed by OGTR indicates merely that OGTR will produce four quarterly reports per year, but does not set any target as to the timeliness of such reports. Also, as discussed below, quarterly reports are not usually published by OGTR until at least the end of the following quarter. Timely preparation of quarterly reports is important in order that the performance information contained within remains relevant and gives a timely indication of current performance.

4.48 To ensure timely publication of information on OGTR performance to facilitate performance management and improvement, and to enhance transparency, the ANAO suggests that OGTR review its performance indicator on quarterly reporting to include a measure of timeliness of publication of quarterly reports.

Summary

4.49 Overall, OGTR has set performance measures on a number of key aspects of its assessment and monitoring activities. ANAO has made a number of suggestions for improvement of these measures to provide greater information and transparency on OGTR performance, thereby maintaining confidence in regulation by OGTR.

Performance data

4.50 Performance measurement and data management are important aspects of performance management. Especially for accountability purposes, stakeholders need to know the extent to which they can rely on the reported data that underpins the performance measures used for management and external reporting.

4.51 OGTR data on performance comes from a variety of sources. Although it was intended that the Gene Technology Information System (GTIMS) would provide a single source of OGTR performance information, each of the main functional areas of OGTR (that is, evaluation and monitoring and compliance areas) maintains its own internally-developed record of activities and other performance information (see Figure 4.5 for further discussion of GTIMS).

4.52 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 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. In addition, the maintenance of multiple systems for the recording of data and preparation of performance information leads to a risk of errors or duplication in such data, which could undermine the quality of performance information and resultant performance reports.

Performance reporting

Quarterly reports

4.53 The Regulator is required (as soon as practicable at the end of each quarter), to prepare and give to the Minister for Health and Ageing a quarterly report on the operations of the Regulator during that quarter.[49] The quarterly reports must include information about:

- licences issued during the quarter;
- any breaches of conditions of licences that have come to the Regulator's attention during the quarter; and
- auditing or monitoring activities during the quarter.

[49] *Gene Technology Act 2000* (Cth) s 136A.

Figure 4.5
Development of GTIMS

Gene Technology Information Management System

GTIMS is a database that is being developed by OGTR to assist in management and processing of applications, and in the preparation and publication of performance information.

It was intended that GTIMS also provide information (through the Internet) to the public on applications for dealings received and approved, and to accredited organisations on all dealings associated with the organisation. GTIMS was to also allow submission of applications electronically to OGTR through the OGTR website.

GTIMS was originally intended that GTIMS would be operational from the commencement of OGTR's operations in June 2001. The December 2000 quarterly report of the Interim Office of the Gene Technology Regulator noted:

> In 2000, the OGTR contracted an information technology company, Dialog Information Technology, to develop a database to underpin the new Regulatory System. The database is being developed using Lotus Notes technology.
>
> Users of the regulatory system will be able to maintain their own information online and track the progress of applications made to the OGTR. The general public will be able to access publicly available information, including the record of GMOs and GM product dealings, through the new database system.
>
> It is anticipated that training with clients of the OGTR will be held over the next two quarters. The system is to operate from 21 June 2001.

However, the development of GTIMS fell severely behind schedule and has not yet been fully released. There have been a number of reasons given for this delay, including the need to incorporate changes that were made to the Regulations and Guidelines during development of the regime into the system design, and the need for additional measures to safeguard applicant information, including CCI.

Differences in accounting for and recording the costs of development of GTIMS, means that a precise figure on the cumulative cost of GTIMS is not readily ascertainable, although between $1.3m and $2.3m has been spent on the system to-date. ANAO analysis of invoices filed by OGTR that related to GTIMS developed provided expenditure of $1.27m between June 2001 and November 2004. Thus, this figure does not include expenditure incurred prior to the commencement of OGTR. According to information reported under the Senate Order on Government Contracts, $2.32m has been spent on contracts associated with the development of GTIMS. In neither case does the expenditure figure include internal OGTR costs associated with development of GTIMS.

OGTR commenced a staged release of GTIMS in late October 2003 to accredited organisations and their IBCs, including the provision of training and instruction on the use of the system. OGTR is aiming to complete training and release to all accredited organisations by 30 June 2005.

Currently, information on all applications received by OGTR is entered onto GTIMS, as well as recorded on existing systems used by areas for data collection and production of performance information. The delayed implementation of GTIMS and decrease in functionality provided by the system has necessitated the maintenance of these separate systems for application tracking and management until GTIMS is fully operational. In addition, the delayed implementation of GTIMS has meant that the corresponding efficiency savings expected from electronic submission and management of applications have yet to be realised.

Source: ANAO.

4.54 Although not specifying any fixed timeframe within which quarterly reports must be issued, the Act does require such reports to be prepared as soon as practicable following the end of each quarter. As mentioned earlier, although OGTR has developed a performance indicator dealing with preparation and publication of quarterly reports, it does not specify any timeframes within which it must seek to issue such reports. Figure 4.6 shows the time taken to prepare and present the quarterly reports to the Minister.

Figure 4.6

Publication of OGTR quarterly reports

Quarter ending	Date presented to Minister	Time taken (months)
September 2001	25 January 2002	4 months
December 2001	13 May 2002	4.5 months
March 2002	26 September 2002	6 months
June 2002	27 September 2002	3 months
September 2002	29 November 2002	2 months
Dec 2002	2 April 2003	3 months
March 2003	27 June 2003	3 months
June 2003	2 September 2003	2 months
September 2003	15 December 2003	2.5 months
December 2003	16 March 2004	2.5 months
March 2004	30 July 2004	4 months
June 2004	8 December 2004	5 months
September 2004	27 January 2005	4 months
December 2004	29 April 2005	4 months
March 2005	12 July 2005	3.5 months

Source: ANAO.

4.55 On average, quarterly reports are presented to the Minister around four months after the end of the quarter for which they provide information (see Figure 4.6). There is often an even greater delay until the time the reports are then made publicly available on the OGTR website. As noted earlier, timely preparation of quarterly reports is important in order to ensure that the performance information contained within remains relevant and gives a timely indication of current performance. Publication of information on OGTR performance is an important component in OGTR accountability and it promotes confidence in its regulation. Timely access to information on OGTR operations is even more pertinent given the nature of the regulatory regime established by the Act, and its facilitation of public involvement and public access to information on, and decisions of, the Regulator and OGTR activities. Extensive delays in publication of performance information in the quarterly reports diminish the utility of such information in both assessing OGTR operations and activities and in improving performance.

4.56 For instance, if an instance of non-compliance was identified by OGTR at the commencement of a given quarter, a four month delay in publication of the quarterly report detailing this breach could mean information is not given to the public about this breach until around six or seven months after it was

identified. Such a delay means that the opportunity for, and relevance of, public comment or other action with respect to breach is diminished.

4.57 Although, in order to facilitate ease of preparation, OGTR quarterly reports are prepared in a standard form, OGTR did not provide further advice regarding the reasons for such extensive delays in the preparation and publication of its quarterly reports.

4.58 In order to facilitate greater accountability and improve the utility of performance information provided in OGTR quarterly reports, the ANAO suggests that OGTR aim to provide such reports as soon as practicable, and investigate ways of ensuring more timely preparation and publication of its quarterly reports.

4.59 It is noteworthy that although the quarterly reports otherwise provide comprehensive information on OGTR activities for the quarter, no financial information is provided that may enable an assessment of the efficiency and cost effectiveness of OGTR operations, by establishing a link between financial and non-financial information contained in the report (this issue will be further discussed below at paragraph 4.63).

Annual reports

4.60 In addition to the quarterly reporting described above, the Act also requires the Regulator to prepare and provide to the Minister an annual report on the operations of the Regulator during that year.

4.61 Although the quarterly reports prepared by OGTR contain significant information on the operations of OGTR over each quarter, there is no consolidated annual reporting of such information by OGTR. The only annual reporting by OGTR is the information included on OGTR operations in the Health annual report. The information included on OGTR operations in the Health annual report is much more limited in scope and volume than that provided in the quarterly reports.

4.62 The preparation and publication of consolidated annual reports on its activities over the year will enable OGTR to use such information to analyse trends in workload and performance. Over-reliance on quarterly reports creates barriers to analysis of longer-term trends, by making consolidation of such information by interested external parties more difficult. Annual reporting would also provide a vehicle for implementing the ANAO's suggested improvements to OGTR performance indicators made earlier.

4.63 Although the Health annual report provides information on total OGTR budget and expenditure, there is no indication of the allocation of financial (and other) resources between the various OGTR functions. The ANAO considers that the provision of more detailed information on OGTR

budget and expenditure across its various functional areas would improve the transparency of OGTR operations, and enable an assessment of the efficiency and cost effectiveness of OGTR operations by establishing a link between financial and non-financial information contained in its performance reports. Such information could be included, at a minimum, in reports prepared annually by OGTR.

Recommendation No. 5

4.64 The ANAO recommends that OGTR seek clarification of its obligations (arising under the Act) to publicly report annual information on its operations. In order to facilitate better use of OGTR performance information and foster confidence in OGTR implementation of the Act, OGTR should assess the need for consolidated annual reporting (internal and/or external) of the performance information provided in its quarterly reports, as well as of other relevant information on its activities throughout the year.

Health Response: *The OGTR agrees with this recommendation and is in the process of implementing it.*

Summary

4.65 OGTR has developed a number of performance measures, which to-date it has met in all but its effectiveness measure (described as Measure 1 above). In this latter case, the lack of description and analysis of the instances of non-compliance found in the reporting against the measure, acts as a barrier to further understanding of the reasons for such non-compliance and the attribution of responsibility (if any) to OGTR for the non-compliance and hence failure to meet the target of 100 per cent compliance. Problems with timeliness of reporting undermine the effectiveness of these measures as tools for monitoring and improving performance and facilitating accountability and transparency of OGTR operations.

4.66 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, OGTR could prepare consolidated annual reports on its activities over the year, and use such information to analyse trends in workload and performance. This will ensure that there is a balanced focus on medium term trends and planning, instead of a relatively short-term focus on quarterly activities and performance. Improved reporting will also help foster public confidence in the effectiveness of regulation of gene technology by OGTR.

Overall conclusion

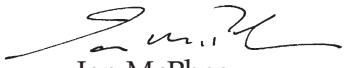
4.67 OGTR has good information on its costs and current resource requirements, however, a number of external factors provide uncertainty with regards to future resource availability and requirements (e.g. cost-recovery, Trans-Tasman Authority, State and Territory moratoria).

4.68 This uncertainty has impacted on the ability of OGTR to plan for and engage resources for future requirements and thus on related decision-making, which has in turn affected OGTR's ability to attract and retain staff. Coupled with the special expertise and intensive training requirements, this poses increased risks to regulatory effectiveness that must be carefully monitored.

4.69 Although OGTR has developed a number of performance measures, problems with timeliness of reporting reduce the effectiveness of these measures as tools for monitoring and improving performance (e.g. delays in quarterly reporting).

4.70 In addition, delays in the implementation of OGTR's information management tool, GTIMS, has impacted on OGTR's ability to easily generate and analyse performance information data. Implementation of GTIMS could also allow greater efficiency by allowing applications to be submitted via the Internet.

4.71 OGTR regularly monitors its financial position (or budget and expenditure) and tracks staff levels to workloads. The management information systems will improve with the full implementation of GTIMS. The ANAO has made some suggestions to improve the efficient and effective delivery of its statutory functions.



Ian McPhee
Auditor-General

Canberra ACT
25 August 2005

Appendices

Appendix 1—Regulation of Gene Technology

What is gene technology?

1. 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.[50]

2. 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.

3. Although there are numerous benefits associated with gene technology, there are also possible risks (both to human health and the environment) posed by its use.

Who regulates gene technology in Australia?

4. Various independent committees of scientific experts have overseen the development and use of gene technology in Australia since 1975. These committees were tasked with assessing the risks to human health and the environment that may be presented by the application of gene technology, and with providing advice on how those risks can be managed. However, these committees operated on a voluntary basis, and in the absence of statutory regulatory powers, there was little capacity for enforceable auditing or for monitoring of compliance with committee recommendations and advice, nor for the imposition of penalties in the event of non-compliance.

5. It is worthwhile noting that products derived from the use of gene technology, as opposed to the development or use of the technology itself, have been regulated under relevant existing regulatory regimes. For example, TGA regulates the sale or use of GM pharmaceuticals and Food Standards Australia New Zealand (FSANZ) regulates GM foods.[51]

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[50] See for example, *Gene Technology Act 2000* (Cth) s 10.

[51] The main regulatory authorities involved in the regulation of GM products (and the respective legislation under which they operate) are: **Food Standards Australia New Zealand** (*Australia New Zealand Food Authority Act 1991*); **National Industrial Chemicals Notification and Assessment Scheme** (*Industrial Chemicals (Notification and Assessment) Act 1989*); **Australian Pesticides & Veterinary Medicines Authority** formerly the **National Registration Authority** (*Agricultural and Veterinary Chemicals (Administration) Act 1992* and *Agricultural and Veterinary Chemicals (Code) Act 1994*); and the **Therapeutic Goods Administration** (*Therapeutic Goods Act 1989*). The Therapeutic Goods Administration and the National Health and Medical Research Council (the latter through the Gene and Related Therapies Research Advisory Panel and the Australian Health Ethics Committee) also play a role in overseeing human research involving gene therapy.

6. In 1997, community and industry perceptions and expectations, as well as the increasing use of gene technology, particularly in commercial applications, led to the resumption of efforts to establish a national statutory regulatory scheme for the development and use of gene technology. The increasing range of applications of gene technology meant that many GMOs and GM products were being developed that were not covered by existing regulatory bodies, including:

- the growing of GM agricultural crops;
- the growing or breeding of GM animals or fish; and
- stockfeed that may be produced from GM crops, for example, cotton.

7. Agreement between Commonwealth and State and Territory Governments was reached on a proposed national scheme in 1998, and consultation with community and industry on the proposed scheme was conducted in 1999. Legislation was introduced into the Commonwealth Parliament in 2000, with corresponding legislation introduced into the respective State and Territory Parliaments thereafter.[52]

8. The Commonwealth *Gene Technology Act 2000* (the Act) came into force on 21 June 2001. The Act is part of a national regulatory framework for the regulation of gene technology (Figure A1.1). The Act establishes a statutory officer, the Gene Technology Regulator (the Regulator) to administer a licensing regime regulating GMOs, research using certain gene technologies and GM products in coordination with other product regulators.

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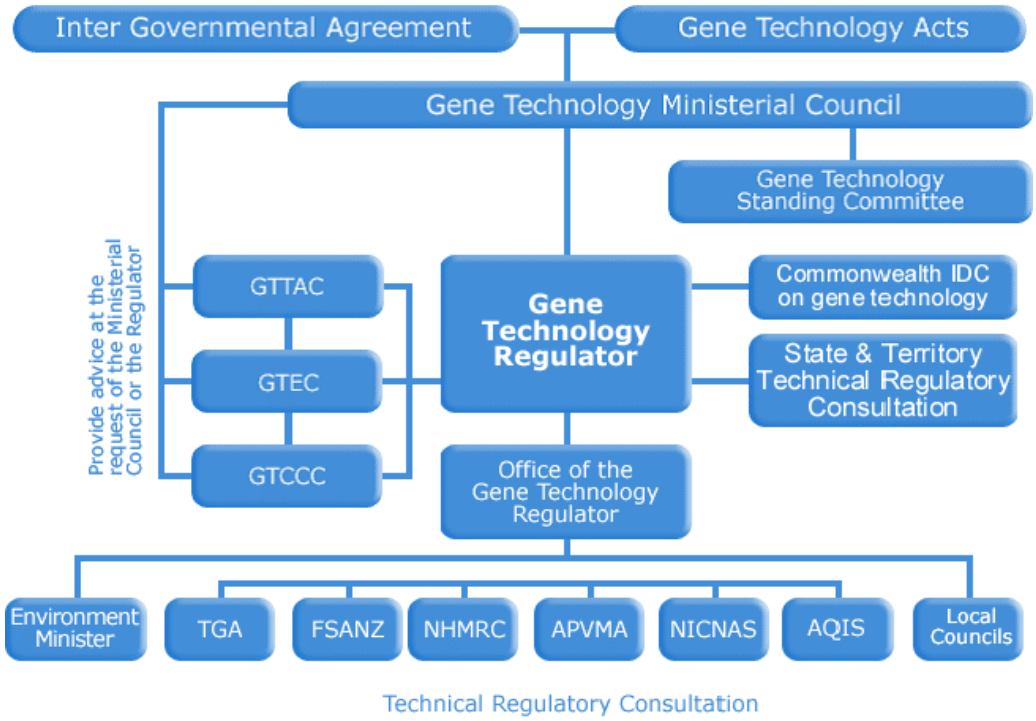
[52] The scheme is a co-operative scheme, in that it relies upon both Commonwealth and State legislative power for its operation. Thus far, corresponding State legislation has been declared in Queensland, South Australia and Victoria (the Act allows the Minister to declare similar State legislation to be "corresponding State law" for the purposes of the Act). The Australian Capital Territory, New South Wales and Tasmania have enacted compatible legislation but have not yet requested that it be declared corresponding legislation. Legislation has been passed by the Northern Territory but is not yet in force; and the Parliament of Western Australia is also considering enacting legislation.

Figure A1.1

National Gene Technology Regulatory System



Source: OGTR.

9. The object of the Act (as specified in s 3) 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 [genetically modified organisms].

10. Section 4 provides that this object is to be achieved through a regulatory framework that:

> …
>
> (a) provides an efficient and effective system for the application of gene technologies; and
>
> (b) operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products.

11. The Act does not aim to replace existing regulatory regimes, and the provisions of the Act operate in addition to, and not in substitution for, the requirements of any other Commonwealth law.[53]

12. 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 under licence granted by the Regulator. The Act also provides scope for the regulation of GM products not already regulated by existing regulatory regimes. While other regulatory authorities continue to have primary responsibility for the regulation of gene technology in their areas of responsibility, the Regulator plays an advisory role in relation to such GM products. Thus, the *Gene Technology (Consequential Amendments) Act 2001* (Cth), amends existing regulatory legislation, requiring existing regulators to:

- seek advice from the Regulator in relation to any application for approval for a GM product;
- take such advice into account in decision-making under the relevant legislation (although there is no requirement to comply with any such advice); and
- notify the Regulator of all decisions made in relation to GM products.

13. Thus, 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. The system also ensures that the Regulator either directly regulates, or provides advice to other regulators, on all GMOs and GM products.

The Gene Technology Regulator

14. Some of the tasks of the Regulator for which the Act provides include:

- functions in relation to the issuing of licences to deal with GMOs, including risk assessment of licence applications, the certification and accreditation of facilities and organisations, and monitoring and compliance activities;
- development of draft policy principles and policy guidelines;
- development of codes of practice;
- issuing technical and procedural guidelines;

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[53] *Gene Technology Act 2000* (Cth) s 15.

- providing information and advice to other regulatory agencies about GMOs and GM products;
- providing information and advice to the public about regulation of GMOs;
- undertaking or commissioning research in relation to risk assessment and the bio-safety of GMOs;
- promoting the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies;
- monitoring international practice in regulation of GMOs; and
- maintaining links with international organisations involved with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia.

The Office of the Gene Technology Regulator

15. The Office of the Gene Technology Regulator (OGTR) supports the Regulator in the exercise of the functions provided for under the regulatory scheme.[54]

The licensing regime

16. As noted earlier, the Act regulates all dealings with GMOs and prescribed GM products by requiring that all dealings with a GMO must be licensed.[55] Section 32 provides:

> **32 Person not to deal with a GMO without a licence**
>
> (1) A person is guilty of an offence if:
>
> (a) the person deals with a GMO, knowing that it is a GMO; and
>
> (b) the person knows that the dealing with the GMO by the person is not authorised by a GMO licence or is reckless as to whether or not the dealing is so authorised; and

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[54] See Appendix 2 for further information on OGTR structure and staffing.

[55] *Gene Technology Act 2000* (Cth) s 32. Note, that s 10 defines GMO, and includes anything declared by the Regulations to be a genetically modified organism. As at April 2004, although no GM products have been declared to be GMOs by the Regulations, it is noteworthy that the Regulations prescribe that for all dealings involving intentional release of a GMO into the environment, the applicant is required to give the Regulator details of proposed uses of the GMO or GMOs, or of things derived or produced from the GMO or GMOs, following release into the environment, including whether any GM products are to be given to animals as stockfeed.

(c) the person knows that the dealing is not a notifiable low risk dealing or is reckless as to whether or not the dealing is a notifiable low risk dealing; and

(d) the person knows that the dealing is not an exempt dealing or is reckless as to whether or not the dealing is an exempt dealing; and

(e) the person knows that the dealing is not included on the GMO Register or is reckless as to whether or not the dealing is included on the GMO Register.

(2) An offence under subsection (1) is punishable on conviction by whichever of the following applies:

(a) in the case of an aggravated offence—imprisonment for 5 years or 2,000 penalty units;

(b) in any other case— imprisonment for 2 years or 500 penalty units.

17. Four main types of dealings with GMOs are outlined in the Act:

- dealings involving intentional release into the environment (DIRs);
- dealings not involving intentional release into the environment (DNIRs);
- notifiable low risk dealings (NLRDs); and
- exempt dealings.

Dealings involving and not involving intentional release into the environment

18. The Act distinguishes between dealings that involve the intentional release of the GMO into the environment (for example, a field trial, or the release, for commercial sale and use, of a GM agricultural crop) and those not involving intentional release (for example, the use of a GMO in a laboratory — see Figure 2.1). Although in both cases the Regulator is required to prepare a risk assessment and risk management plan (RARMP) in relation to the dealings proposed to be authorised by the licence, in relation to DIRs, the Act specifies more onerous requirements with which the Regulator must comply in making a decision whether to grant a licence (see Part 5 of the Act and below for further information).

19. Although the Act does not require it, in the interests of transparency and clarity, DIR applications are described by OGTR as either involving commercial (general) release or involving only limited and controlled release (for example, the latter dealing may include field trials of a GM agricultural crop conducted prior to and in anticipation of future commercial release of the crop).

Notifiable low risk dealings

20. The Act provides that the Regulations may declare a dealing to be a NLRD for the purposes of the Act. The Regulations prescribe requirements that must be complied with in relation to NLRDs.[56] Persons engaging in NLRDs are thus not required to submit an application for a licence to engage in the specified dealing, but instead are required to notify the Regulator of such dealings and comply with specified conditions in relation to the conduct of those dealings. The Regulations classify five types of NLRD and the only dealings that have been included on the list are those that have been assessed over time as presenting minimal biosafety risks when conducted in accordance with the prescribed conditions.[57] Examples of the types of dealings that have been classified as NLRDs are shown in Figure 2.1.

Exempt dealings

21. The Act also allows the Regulations to declare certain dealings to be exempt from the requirements of the regulatory regime.[58] Section 10 of the Act allows the Regulations to declare certain organisms not to be GMOs for the purposes of the Act.[59]

The GMO Register

22. The Regulator may also enter certain dealings with GMOs on the GMO Register. The GMO Register is intended to enable those, previously licensed, dealings with GMOs to be undertaken without the requirement for a licence to be held by a named individual or organisation. This would occur where, for example, the dealings with the GMO have been undertaken for such period of time that they are held to be sufficiently safe that any person can undertake them in accordance with any conditions specified on the GMO Register.

23. Thus, unless the dealing has been declared notifiable low risk, has been declared to be an exempt dealing, or the dealing is included on the GMO Register, then it is an offence to deal with the GMO without a licence.

Dealings not regulated by the Act

24. The Act only regulates dealings with GMOs and prescribed GM products. The definition of GMO as provided by the Act limits the application of the regulatory regime (unless otherwise declared by the Regulations), to only those GMOs that are viable (that is, able to live and grow) or that are

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[56] See, for example, Gene Technology Regulations 2001 (Cth) Schedule 3.

[57] Office of the Gene Technology Regulator, *Handbook on the Regulation of Gene Technology in Australia, A user's guide to the* Gene Technology Act 2000 *and related legislation*, OGTR, 2001.

[58] See, for example, Gene Technology Regulations 2001 (Cth) Schedule 2.

[59] See, for example, Gene Technology Regulations 2001 (Cth) Schedule 1.

capable of reproduction or of transferring genetic material.[60] Thus, any dealings with GMOs that do not meet this definition (for example, GMOs that are no longer viable because of the application of some treatment process), will not be regulated by the Act and do not require licensing in accordance with the Act.

Licence conditions

25. The Act specifies a number of conditions with which licence holders must comply, and also allows additional conditions to be prescribed by the Regulations or imposed by the Regulator.

26. The Act also specifies that the holder of a GMO licence or a person covered by a GMO licence must not breach the conditions of the licence and creates offences for breach of licence conditions and conditions on the GMO Register or relating to NLRDs.

Consultation and communication with other regulators

27. The regime requires that other existing regulators involved in regulating the products of gene technology consult the Regulator and take that advice into account.[61] Similarly the Regulator is required to seek advice from these prescribed agencies.

Statutory committees

28. The Act establishes three key bodies that assist the Regulator in performing functions under the Act by providing advice on issues relating to gene technology:

- the Gene Technology Technical Advisory Committee (GTTAC);
- the Gene Technology Ethics Committee (GTEC); and
- the Gene Technology Community Consultative Committee (GTCCC).

Gene Technology Technical Advisory Committee

29. GTTAC provides scientific and technical advice to the Regulator on gene technology, GMOs, GM products and applications made under the Act. Section 101 of the Act outlines the functions of GTTAC.

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60 *Gene Technology Act 2000* (Cth) s 10.

61 For example, *Agricultural and Veterinary Chemicals (Administration) Act 1992* s 8A; *Australia New Zealand Food Authority Act 1991* s 11A; *Industrial Chemicals (Notification and Assessment) Act 1989* ss 10A, B and C; *Therapeutic Goods Act 1989* ss 30C, D and E.

101 Function of the Gene Technology Technical Advisory Committee

The function of the Gene Technology Technical Advisory Committee is to provide scientific and technical advice, on the request of the Regulator or the Ministerial Council, on the following:

(a) gene technology, GMOs and GM products;

(b) applications made under this Act;

(c) the biosafety aspects of gene technology;

(d) the need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products, and the content of such principles, guidelines and codes.

30. GTTAC is comprised of persons with skills or experience in science, medicine, public health, occupational health and safety or risk assessment.[62] GTTAC currently has 19 members.

31. Where a proposed dealing involves an intentional release of a GMO into the environment, ss 50 and 51 requires that the Regulator must seek advice from GTTAC and take that advice into account in preparing a risk management and risk assessment plan in relation to that dealing.

32. Section 52 also requires that, once prepared, the Regulator seek advice from GTTAC on the risk assessment and risk management plan.

Gene Technology Ethics Committee

33. GTEC provides advice to the Regulator on ethical issues relating to gene technology.[63] GTEC is comprised of persons with skills or experience in ethics, law, religious practices, population health, agricultural practices, animal health and welfare, consumer issues or environmental systems.[64] GTEC currently has 11 members and two expert advisors.

Gene Technology Community Consultative Committee

34. GTCCC provides advice to the Regulator on community concerns about gene technology.

35. GTCCC is a broadly based committee comprised of persons with skills or experience in environmental issues, consumer issues, the impact of gene

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62 *Gene Technology Act 2000* (Cth) s 100.

63 *Gene Technology Act 2000* (Cth) s 112.

64 *Gene Technology Act 2000* (Cth) s 111.

technology on the community, issues relevant to the biotechnology industry, issues relevant to gene technology research, public health issues, issues relevant to primary production, or issues relevant to local government. The membership of the Committee expired on 8 October 2004, the appointment process for the new Committee is still ongoing.

36. Although the Regulator is required to consult the GTTAC in relation to some dealings involving GMOs, the Act does not require the Regulator to consult either of GTEC and GTCCC in relation to any individual application under the Act.

Community consultation

37. The Act requires that, for dealings involving intentional release of a GMO, the Regulator call for public submissions on the application (if the dealing may pose significant risk to human health and safety or the environment) and then on the risk management and risk assessment plan prepared by the Regulator, including consultation on the possible risks involved and the means of managing those risks.[65] The Regulator must allow at least 30 days for receiving any such submissions.

38. The Regulator must advertise in newspapers and in the Commonwealth Gazette and place notices on the OGTR website.

39. If a licence is issued for a dealing involving a GMO, the Regulator must put certain details of the licence on the publicly available Record of GMOs and GM Product Dealings.[66] In addition, notifiable low risk dealings and any notifications provided to the Regulator regarding GM products approved by other regulators must also be recorded on the Record of GMOs and GM Product Dealings.[67] The Regulator must permit any person to inspect the Record.[68]

Review of the Act and regulatory regime

40. In the development of the draft Bill outlining the regulatory regime, the Government consulted extensively to seek comments and views on the proposed scheme. There was considerable stakeholder and community interest, and the proposed Bill was referred to the Senate Community Affairs References Committee, which reported on the proposed Bill in 2000.

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65 *Gene Technology Act 2000* (Cth) ss 49, 52.

66 *Gene Technology Act 2000* (Cth) s 138.

67 *Gene Technology Act 2000* (Cth) s 138.

68 *Gene Technology Act 2000* (Cth) s 139.

41. In addition, the Standing Committee on Environment and Public Affairs of the Western Australia Legislative Council has recently released its report into the proposed complementary legislation to be introduced into that State.

42. The Act itself contains provision for an independent review of the Act and OGTR after four years of operation. Section 194 of the Act provides:

> **194 Review of operation of Act**
>
> (1) The Ministerial Council must cause an independent review of the operation of this Act, including the structure of the Office of the Gene Technology Regulator, to be undertaken as soon as possible after the fourth anniversary of the commencement of this Act.
>
> (2) A person who undertakes such a review must give the Ministerial Council a written report of the review.
>
> (3) The Minister, on behalf of the Ministerial Council, must cause a copy of the report of the review to be tabled in each House of the Parliament within 12 months after the fourth anniversary of the commencement of this Act.
>
> (4) In this section:
>
> ***independent review*** means a review undertaken by persons who:
>
> (a) in the opinion of a majority of the Ministerial Council possess appropriate qualifications to undertake the review; and
>
> (a) include one or more persons who are not employed by the Commonwealth or a Commonwealth authority.

43. Terms of Reference for the independent review were endorsed by the Ministerial Council on 24 May 2005.

Matters outside the scope of the regulatory regime

44. There are a number of matters that, although relevant to the regulation of gene technology, fall outside the scope of the Act or the scope of regulatory oversight fulfilled by OGTR. Although many of these matters are important in the context of the regulation of the applications and products of gene technology as a whole, they have not been explored throughout the course of this audit and thus the ANAO makes no findings on these matters. However, it should be noted that the forthcoming independent review of the Act may provide an avenue by which these can be addressed. For the sake of completeness, some of these matters are mentioned below.

The 'gap-filling' policy behind the regulatory regime

45. As mentioned earlier, the Act operates in addition to, and not in substitution for, other regulatory regimes that may already regulate GMOs or GM products. Thus, the Gene Technology Regulator is said to perform a 'gap-filling' role, only regulating those GMOs and GM products not already regulated by other regulators. The Regulator does not duplicate the work of existing regulators where, for example, the application involves GMOs or GM products that may be used as or in foods, medicines and pharmaceuticals, pesticides and/or insecticides. The ANAO did not investigate the regulation of GMOs or GM products by these other relevant regulatory agencies, and so does not form any opinion on the adequacy of the regulation of gene technology across the board.

Consideration of socioeconomic issues

46. The Regulator must consider risks to human health and safety and to the environment in making decisions on authorising dealings under the Act. The Act defines 'environment' as:

> …ecosystems and their constituent parts, natural and physical resources and the qualities and characteristics of locations, places and areas.

47. It is noteworthy that this definition of the environment appears more limited than that provided, for example, by the *Environment Protection and Biodiversity Conservation Act 1999*, which, in addition to the above, includes social, economic and cultural aspects.[69]

48. OGTR has received legal advice from the Australian Government Solicitor on the scope of matters relevant in considering risks to the environment. This advice indicates that, consistent with the objects and of the Act and the regime it establishes, social, economic, and cultural matters are not relevant in consideration of risk to the environment by the Regulator. However, these are matters that may be considered through the Gene Technology Ministerial Council (GTMC) and addressed through the mechanism of policy principles provided for by the Act.

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[69] Section 528 of the *Environment Protection and Biodiversity Conservation Act 1999* defines environment as including:

(a) ecosystems and their constituent parts, including people and communities; and
(b) natural and physical resources; and
(c) the qualities and characteristics of locations, places and areas; and
(d) heritage values of places; and
(e) the social, economic and cultural aspects of a thing mentioned in paragraph (a), (b) or (c).

Consideration of marketability concerns and the role of the States and Territories

49. As noted above, although economic issues are outside the scope of the Regulator's consideration of risks during risk analysis under the Act, the GTMC issued a policy principle recognising States' rights to designate under State law special areas reserved for either GM or non-GM crops, for market purposes. All States and Territories (with the exception of Queensland and the Northern Territory) have imposed bans or moratoria on the commercial cultivation of all or certain GM crops. The Act prohibits the Regulator from issuing a licence, notwithstanding that the dealing poses no unmanageable risks to human health and safety or to the environment, if issuing the licence would be inconsistent with the policy principle.

Merit review of decision-making

50. Although the ANAO analysed the policies and procedures in place to guide decision-making within OGTR, and examined implementation of those policies and procedures in relation to selected applications, the ANAO did not undertake a review of the merits of the decisions themselves.

Appendix 2—The Audit Approach

Audit methodology

1. The audit methodology included:

- research, review and analysis of relevant literature, prior studies and policies and systems operating in State and Territory governments and overseas jurisdictions, including the experience of four OECD countries, related to the regulation of gene technology;
- discussions with representatives from agencies that co-ordinate aspects of the co-operative regulatory regime for gene technology across Australian jurisdictions;
- interviews with officers of OGTR;
- document and file examination within OGTR;
- anaylsis of data on OGTR operations under the Act; and
- interviews with various other stakeholders and users of the regime, including:
  - members of the various scientific and other advisory panels;
  - State and Territory government officers;
  - university and other proponents and users of the technology, including with members of organisations' IBCs; and
  - other relevant Commonwealth regulators.

Previous coverage

2. The ANAO has not conducted any audits directly of OGTR or of regulation under the Act.

3. However, the following previous ANAO audits are relevant in that they directly address or touch upon issues of regulation of consumer health and safety:

- Audit Report No. 12 of 1995–96, *Risk Management By Commonwealth Consumer Product Safety Regulators*.
- Audit Report No. 8 of 1996–97, *Drug Evaluation by the Therapeutic Goods Administration*.
- Audit Report No. 26 of 1997–98, *Strategic and Operational Management* [in the National Registration Authority].

- Audit Report No. 45 of 1998–99, *Food Safety Regulation in Australia—Follow up Audit*.
- Audit Report No. 24 of 1999–2000, *Commonwealth Management and Regulation of Plasma Fractionation*.
- Audit Report No. 2 of 2000–01, *Drug Evaluation by the Therapeutic Goods Administration—Follow-up Audit*.
- Audit Report No. 10 of 2000–01, *AQIS Cost-Recovery Systems*.
- Audit Report No. 47 of 2000–01, *Managing for Quarantine Effectiveness*.
- Audit Report No. 42 of 2002–03, *Managing Residential Aged Care Accreditation*.
- Audit Report No. 18 of 2004–05, *Regulation of Non-Prescription Medicinal Products*.

4. In addition, State or overseas audit offices have conducted the following audits relevant to regulation of gene technology:

- Report No. 55 of 2000, *Biotechnology: Information on Prices of Genetically Modified Seeds in the United States and Argentina*, General Accounting Office (US), January 2000.
- 2000 Report of the Auditor-General of Canada, Chapter 26, *Health Canada: Regulatory Regime of Biologics*, Office of the Auditor-General (Canada), December 2000.
- Report No. 727 of 2001, *International Trade: Concerns Over Biotechnology Challenge U.S. Agricultural Exports*, General Accounting Office (US), June 2001.
- Report No. 47T of 2001, *Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food*, General Accounting Office (US), October 2001.
- Report No. 566 of 2002, *Genetically Modified Foods: Experts View Regimen of Safety Tests as Adequate, but FDA's Evaluation Process Could be Enhanced*, General Accounting Office (US), May 2002.
- Report No. 255 of 2002–03, Safety, *Equality, Efficacy: Regulating medicines in the UK*, National Audit Office (UK), January 2003.
- 2004 Report of the Auditor-General of Canada, *Chapter 4, Canadian Food Inspection Agency—Regulation of Plants with Novel Traits*, Office of the Auditor-General (Canada), March 2004.

5. Finally, the following reports prepared during the passage of the Act and corresponding State legislation are of relevance to the audit and were consulted during preliminary audit work:

- *Work in progress: Proceed with caution—Primary producer access to Gene Technology*, Report by the House of Representatives Standing Committee on Primary Industries and Regional Services, June 2000.
- *A Cautionary Tale: Fish Don't Lay Tomatoes—A Report on the Gene Technology Bill 2000*, Report by the Senate Community Affairs References Committee, Australian Senate, Parliament of Australia, November 2000.
- *Inquiry into Biotechnology, Part II, Food Production*, Fifteenth Report of the Social Development Committee, Legislative Council, Parliament of South Australia, October 2001.
- *Select Committee on Genetically Modified Organisms—Final Report*, House of Assembly, Parliament of South Australia, July 2003.
- *Report of the Standing Committee on Environment and Public Affairs in Relation to the Gene Technology Bill 2001 and the Gene Technology Amendment Bill 2001*, Western Australia Legislative Council, July 2003.

Conduct of the Audit

6. The audit involved:

- examination of relevant Commonwealth policies and documents in relation to the scheme of gene technology regulation;
- examination of relevant State and overseas policies and documents in relation to the regulation of gene technology;
- examination of relevant legislation and legislative instruments, including State and Territory legislation implementing the national regulatory scheme as well as associated explanatory documentation;
- meetings with Commonwealth officers, including with officers of OGTR, the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Department of Agriculture, Fisheries and Forestry, the Department of the Environment and Heritage, Food Standards Australia New Zealand (FSANZ), the Therapeutic Goods Administration (TGA), and with the Gene Technology Regulator;
- interviews with relevant Commonwealth Parliamentary staff including the Secretary of the Senate References Committee for Community Affairs and staff of the Parliamentary Library;

- interviews with a selection of state government officers;
- interviews with a selection of state parliamentary staff;
- interviews with several licence holders and other organisations conducting dealings with GMOs in the Australian Capital Territory, Queensland, South Australia, Victoria and Western Australia, including visits to several sites at which GMO dealings were undertaken;
- discussions with various non-government organisations;
- discussions with members of the Gene Technology Community Consultative Committee, the Gene Technology Ethics Committee and the Gene Technology Technical Advisory Committee; and
- discussions with staff of the Canadian Audit Office about the Canadian Auditor-General's recent report on gene technology regulation.

Appendix 3—OGTR Approval Processes for Regulated Dealings

Applying for a licence under the Act—DIR and DNIR licences

1. The Act allows a person to apply to the Regulator for a licence authorising otherwise prohibited dealings with a GMO or GMOs.[70] The Regulator must consider all applications made under s 40 (unless an exception applies[71]), and must issue or refuse to issue a licence within the period prescribed by the Regulations.[72] The Act and Regulations also require that certain specified information must be provided with applications.[73]

2. As noted earlier, the Act requires that the Regulator follow certain procedures when making a decision whether to grant a licence.[74] The process is dependent upon whether or not the dealing involves an intentional release of the GMO into the environment, and, if it does, whether or not the dealing poses significant risks to the health and safety of people or to the environment.[75] In all applications for licence, the Regulator is required to prepare a risk assessment and risk management plan (RARMP).[76]

Preparing a risk assessment and risk management plan

3. In relation to DIR applications, the Act and Regulations prescribe further requirements in relation to the preparation of the RARMP. The Regulator must, for example, seek advice on matters relevant to the preparation of the risk assessment and risk management plan from a number of prescribed bodies and take any such advice into account in preparing the RARMP:[77]

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70 *Gene Technology Act 2000* (Cth) s 40(1).

71 *Gene Technology Act 2000* (Cth) s 43(2) provides a list of circumstances (mostly relating to applications where required information has not been provided), where the Regulator is not required to consider an application.

72 *Gene Technology Act 2000* (Cth) s 43. The Regulations prescribe that a decision must be made within 170 days for DIR applications, and 90 days for DNIR applications: Gene Technology Regulations 2001 (Cth) regs 8(1)(a), (b).

73 *Gene Technology Act 2000* (Cth) ss 40(2)–(4) and Gene Technology Regulations 2001 (Cth) reg 7 and Schedule 4.

74 See for example, *Gene Technology Act 2000* (Cth) ss 47, 49–52, 55– 58.

75 *Gene Technology Act 2000* (Cth) ss 46, 48, 49.

76 *Gene Technology Act 2000* (Cth) ss 47(1), 50.

77 *Gene Technology Act 2000* (Cth) ss 50(3), 51(1)(b)–(f).

50 Regulator must prepare risk assessment and risk management plan

…

(3) The Regulator must seek advice on matters relevant to the preparation of the risk assessment and risk management plan from:

(a) the States; and

(b) the Gene Technology Technical Advisory Committee; and

(c) each Commonwealth authority or agency prescribed by the regulations for the purpose of this paragraph;[78] and

(d) the Environment Minister; and

(e) any local council that the Regulator considers appropriate.

4. The Regulator is also required to take into account specific matters related to the GMO and potential hazards posed by dealings with the GMO. For example, the Regulator must have regard to the matters outlined in s 49(2) of the Act (see paragraph 9).[79] In addition, the Regulations (reg 10) further prescribe other matters that must be taken into account:[80]

10 Risk assessment—matters to be taken into account

(1) For paragraphs 51(1)(g) and 51(2)(g) of the Act, other matters to be taken into account in relation to dealings proposed to be authorised by a licence include:

(a) any previous assessment, in Australia or overseas, in relation to allowing or approving dealings with the GMO; and

(b) the potential of the GMO concerned to:

(i) be harmful to other organisms; and

(ii) adversely affect any ecosystems; and

(iii) transfer genetic material to another organism; and

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78 Gene Technology Regulations 2001 (Cth) reg 9 prescribes the following Commonwealth authorities and agencies: Australian New Zealand Food Authority (now Food Standards Australia New Zealand); Australian Quarantine and Inspection Service; National Health and Medical Research Council; National Industrial Chemical Notification and Assessment Scheme; National Registration Authority for Agricultural and Veterinary Chemicals (now Australian Pesticides and Veterinary Medicines Authority) and Therapeutic Goods Administration.

79 *Gene Technology Act 2000* (Cth) s 51(1)(a) requires that the Regulator have regard to the matters mentioned in paragraphs 49(2)(a)–(f). This would appear to be the case whether or not the dealing is determined to pose significant risks to the health and safety of people or to the environment in accordance with s 49.

80 *Gene Technology Act 2000* (Cth) s 51(g) provides that the Regulator take into account any other matter prescribed by the Regulations.

(iv) spread, or persist, in the environment; and

(v) have, in comparison to related organisms, selective advantage in the environment; and

(vi) be toxic, allergenic or pathogenic to other organisms.

(2) In taking into account a risk mentioned in subsection 51(1) of the Act, or a potential capacity mentioned in subregulation (1), the Regulator must consider both the short term and the long term.

5. In relation to DNIR applications, however, the Act requires only that the RARMP take into account the risks posed by the proposed dealings, including any risks to the health and safety of people or to the environment, as well as the means of managing any such identified risks.[81] The Act does not prescribe any particular requirements or matters that must be followed in preparing the RARMP.

Consultation on applications and on the risk assessment and risk management plan

6. Having prepared a RARMP, for DIR applications the Regulator is required to publicly notify and seek written submissions on the RARMP, including from those prescribed bodies earlier consulted during the preparation of the RARMP (see paragraph 3).[82] The Regulator may also take any other action appropriate for the purpose of deciding the application, including holding a public hearing.[83]

7. In relation to DNIR applications, the Act does not require the Regulator to seek public or other comments on the application or on the RARMP.

Dealings that may pose significant risks

8. Where the Regulator is satisfied that a DIR application may pose significant risks to the health and safety of people or to the environment, the Act requires that the Regulator publish a notice in respect of the application and invite written submissions in relation to the preparation of a RARMP for the application.[84] The Regulator must take account of any such submissions made when preparing the RARMP.[85]

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81 *Gene Technology Act 2000* (Cth) s 47.

82 *Gene Technology Act 2000* (Cth) s 52.

83 *Gene Technology Act 2000* (Cth) s 53.

84 *Gene Technology Act 2000* (Cth) s 49.

85 *Gene Technology Act 2000* (Cth) s 51(1)(b).

9. In determining whether the dealings may pose significant risks, the Act requires the Regulator to have regard to the following:[86]

- the properties of the organism to which the dealings relate before it became, or will become, a GMO;
- the effect, or the expected effect, of genetic modification that has occurred, or will occur, on the properties of the organism;
- provisions for limiting the dissemination or persistence of the GMO or its genetic material in the environment;
- the potential for spread or persistence of the GMO or its genetic material in the environment;
- the extent or scale of the proposed dealings; and
- any likely impacts of the proposed dealings on the health and safety of people.

10. Thus, for DIR applications that may pose significant risks, the Regulator is required to hold two rounds of consultation: first in relation to the preparation of the RARMP; and then again on the proposed RARMP once it has been prepared.

Making a decision on whether or not to issue a licence

11. Having completed the requisite steps, the Act requires the Regulator to make a decision on whether to issue or refuse to issue a licence, and whether to impose any conditions to which the licence is subject.[87]

12. The Act provides that the Regulator must not issue a licence unless satisfied that any risks posed by the dealings can be managed in such a way as to protect the health and safety of people and the environment.[88] In reaching such a decision, the Regulator must have regard to the risk assessment and risk management plan contained in the RARMP, as well as any submissions received in relation to the application or the RARMP.[89] The Regulator is also required to take account of any policy guidelines or policy principles issued by the Gene Technology Ministerial Council (GTMC).[90]

13. A licence issued by the Regulator continues in force until the end of the period specified in the licence or until it is cancelled or surrendered,[91] and is

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86 *Gene Technology Act 2000* (Cth) s 49(2).

87 *Gene Technology Act 2000* (Cth) s 55.

88 *Gene Technology Act 2000* (Cth) s 56.

89 *Gene Technology Act 2000* (Cth) ss 56(2)(a)–(c).

90 *Gene Technology Act 2000* (Cth) ss 56(2)(d), 57(1). The Gene Technology Ministerial Council may issue policy principles or policy guidelines (under ss 21 and 23 of the Act, respectively).

91 *Gene Technology Act 2000* (Cth) s 60.

subject to a number of statutory conditions (see Chapter 3 for further discussion on licence conditions).[92]

Variations, cancellations and suspensions

14. The Act provides that the Regulator may, at any time, by notice in writing given to the licence holder, vary a licence.[93] Such a variation may extend or reduce the authority granted by the licence.[94] However, the Act provides little further guidance on the steps that the Regulator (or licence holders) must take in varying (or seeking a variation to) a licence. The Act requires only that, in varying a licence, the Regulator must not authorise dealings involving intentional release of a GMO into the environment if the application was originally considered a DNIR, and that the Regulator must be satisfied that any risks can be managed.[95] As discussed below, OGTR has issued further guidance for licence holders and applicants for determining whether a request to extend the authority of GMO licences will be considered by OGTR for processing as a variation to an existing licence or will be considered as new GMO licence application.

NLRD notifications

15. A person may undertake dealings prescribed by the Regulations as notifiable low risk dealings provided that the requirements prescribed by the Regulations are complied with.[96]

16. The Regulations require that a person undertaking an NLRD must first ensure that the dealing has been assessed by an Institutional Biosafety Committee (IBC) as being a dealing prescribed by the Regulations as an NLRD (see Figure 3.14 for further information on IBCs).[97] The IBC undertaking the assessment must also provide the Regulator, within 14 days after completion of the assessment, with the information specified by the Regulations (see Figure A3.1 for further description of the notification requirements).[98] A person must not undertake the NLRD until written notice has been received from the assessing IBC advising that the Regulator has been provided with the required information.[99]

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92 *Gene Technology Act 2000* (Cth) s 61.

93 *Gene Technology Act 2000* (Cth) s 71.

94 *Gene Technology Act 2000* (Cth) s 71(3)(c).

95 *Gene Technology Act 2000* (Cth) s 71.

96 *Gene Technology Act 2000* (Cth) s 71, Gene Technology Regulations (Cth) 2001 regs 12, 13.

97 Gene Technology Regulations (Cth) 2001 reg 13(1)(a).

98 Gene Technology Regulations (Cth) 2001 reg 13(1)(b).

99 Gene Technology Regulations (Cth) 2001 reg 13(1)(c).

Figure A3.1

Information required in NLRD notifications submitted to the Regulator

Information requirements for NLRD notifications

The Regulations require IBCs to include the following information when notifying the Regulator that an assessment of an NLRD has been undertaken:

Information about the proponent and proposed dealing

General Information

- information on the proponent;
- the project title
- description of the proposed dealing;
- description of the aim of or purpose for the dealing
- a description of the GMO(s) involved;
- the location(s) at which the dealing is to be undertaken; and
- the proposed date of commencement and duration of the dealing.

Genetics of the GMO

- the biological source of the donor DNA;
- the intended host organism; and
- the method of DNA transfer to be used.

Risk assessment information

- details of all risks that could arise from the genetic modification (including occupational health and safety risks for project personnel); and
- details of all risks that could arise from an unintentional release of the GMO(s) into the environment.

Risk management information

- details of the contained facility in which the detail will be undertaken (including OGTR certification information);
- details of transportation arrangements for the GMO(s);
- details of arrangements for the disposal of the GMO(s);
- details of actions proposed to be taken in the case of an unintentional release of the GMO(s) from containment;
- details of actions and precautions to minimise any risks posed by the proposed dealing; and
- details of the qualifications and experience of the project supervisor.

Supporting information from IBC for a proponent

– Confirmation that the information given to the Regulator has been checked by the IBC and is complete.
– Confirmation that the IBC considers that the personnel to be involved in the dealing have adequate training and experience for the task.
– A statement that the IBC has evaluated the proposed dealing and a copy of the evaluation report.
– A statement that the IBC has been established in accordance with the requirements of the Act.

Where the dealing involves a GMO that is a whole plant or is used in conjunction with a whole plant, additional information is also required.

Source: Gene Technology Regulations (Cth) 2001.

17. In addition to the above requirements, the Regulations specify other conditions with which the dealing must comply.[100] For example, unless otherwise determined by the Regulator, the NLRD must be undertaken in a facility that has been certified by the Regulator to at least physical containment (PC) level 2 and is of appropriate design for the type of dealing to be undertaken. The conduct of the dealing must also be properly supervised and records of the dealing must be kept. Any transportation of a GMO or GMOs must also be conducted in accordance with any relevant guidelines issued by the Regulator under s 27 of the Act.[101]

18. Provided the dealing can be conducted in accordance with these requirements, once a person has received written notice from the IBC that the Regulator has been properly notified, the proposed dealing can commence. However, upon receipt of the notification from the IBC, OGTR further examine such notifications to ensure that all requirements have been complied with and that the dealing has been correctly assessed by the IBC (see paragraph 2.40 for further discussion).

Accreditation and annual reporting

19. The Act provides for a system of accreditation of organisations undertaking, or proposing to undertake, dealings with GMOs. In many cases, accreditation is a precondition that an organisation must meet in order to conduct licensed dealings since, in most cases, the Regulator will require, as a condition of licence, that the licence holder be an accredited organisation. In the case of NLRDs, there is no strict requirement that the proponent be an accredited organisation. However, the conditions associated with conducting NLRDs (for example, that an IBC has assessed the dealing, that the dealing be properly supervised, and that it be conducted in certified facilities), will often mean that the proponent will in fact be accredited or will undertake the dealing in association with, or in facilities under the control of, an accredited organisation.

20. Essentially, accreditation acts as an assurance to the Regulator that the organisation proposing to undertake a dealing has (or has access to) a properly constituted IBC (see Figure 3.14 for further information on IBCs), and that the organisation has the necessary quality assurance systems in place essential to the conduct of dealings with GMOs.

21. In deciding whether to accredit an organisation, s 92 of the Act requires that the Regulator have regard to the following matters:

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[100] Gene Technology Regulations (Cth) 2001 reg 13(2).

[101] The *Guidelines for the Transport of GMOs*, issued by the Regulator in June 2001, outline the relevant transportation requirements.

92 Regulator may accredit organisations

(1) The Regulator may, by written instrument, accredit an organisation as an accredited organisation.

(2) In deciding whether to accredit an organisation, the Regulator must have regard to:

(a) whether the organisation has established, or proposes to establish, an Institutional Biosafety Committee in accordance with written guidelines issued by the Regulator under section 98; and

(b) whether the organisation will be able to maintain an Institutional Biosafety Committee in accordance with such guidelines; and

(c) whether the organisation has, or will have, appropriate indemnity arrangements for its Institutional Biosafety Committee members; and

(d) any other matters specified in such guidelines.

22. The *Guidelines for Accreditation of Organisations*, issued by the Regulator in June 2001, describe the criteria that the Regulator will apply in determining whether an organisation is suitable to be accredited. In making a decision whether to accredit an organisation under s 92 of the Act, the Regulator will take a range of matters into account, including whether the organisation meets the criteria for accreditation set out in the accreditation guidelines.[102] The accreditation guidelines require that an organisation must satisfy the Regulator that it meets the following criteria:[103]

- it is a suitable organisation to hold accreditation and is capable of meeting the conditions of accreditation;
- it has an IBC (or IBCs) and is committed to maintaining and appropriately resourcing the IBC(s) or it has arrangements in place to use an IBC managed by another organisation;[104]
- the relevant IBC is properly constituted;
- the IBC is capable of, and committed to, carrying out its functions;
- the organisation has appropriate arrangements in place for indemnifying IBC members; and

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[102] The Regulations prescribe that a decision must be made within 90 days: Gene Technology Regulations 2001 (Cth) reg 16.

[103] Office of the Gene Technology Regulator, *Guidelines for Accreditation of Organisations*, OGTR, June 2001, p. 16.

[104] Compare with the matters outlined in s 92 of the Act.

- the organisation has appropriate mechanisms in place to address conflicts of interest.

23. Once accredited, an organisation must comply with the conditions of accreditation imposed by the Regulator.[105] The *Guidelines for Accreditation of Organisations* state that the accreditation of an organisation is subject to a number of classes of conditions, relating to:[106]

- maintaining an IBC or maintaining access to an IBC;
- maintaining a register of dealings undertaken by the organisation and of personnel involved;
- reporting by the organisation to the Regulator;
- development of internal operating procedures and staff training;
- the function and operation of the IBC, including dealing with conflicts of interest, IBC membership and indemnification of IBC members; and
- the inspection of facilities.

24. The *Guidelines for Accreditation of Organisations* also state that the Regulator will regularly monitor all accredited organisations and IBCs to ensure that they are operating in accordance with the conditions of accreditation.

Facility certifications

25. The Act also provides for a system of certification of facilities within which certain dealings with GMOs are to be conducted.[107] Not all dealings with GMOs are required to be conducted in certified facilities—a dealing involving the release of a GMO into the environment (such as the commercial release of a genetically modified crop) would be one example. In such a case, the evaluation and assessment processes employed by the Regulator have been designed to address any risks that may be posed by the release of the particular GMO into the environment. However, for other types of dealings, particularly those not involving an intentional release of the GMO into the environment, the Regulator may require that the dealing be conducted and contained within appropriate facilities. The purpose of certification is to satisfy the Regulator that the facility in which the dealing will be conducted meets the Regulator's requirements for physical containment of the GMO and that

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[105] *Gene Technology Act 2000* (Cth) s 94.

[106] Office of the Gene Technology Regulator, *Guidelines for Accreditation of Organisations*, OGTR, June 2001, pp. 24–40.

[107] *Gene Technology Act 2000* (Cth) ss 83–90.

certain procedures will be observed to ensure the safety of those working with the GMO.[108]

26. There are a number of different types of facilities that may be certified by the Regulator, including, for example:

- laboratories;
- plant houses;
- insectaries;
- animal houses; and
- aquaria.

27. The type of facility within which dealings must be conducted and contained will depend upon a number of factors, including the type of GMO, the work to be conducted, and any particular risks that may be associated with such work with that GMO.

28. The Act provides that a person may, in writing, apply to the Regulator for certification of a facility.[109] The Regulator may certify the facility to a specified level of containment if the facility meets the containment requirements specified in guidelines issued by the Regulator.[110] Although there appears no such limitation in the Act or Regulations, the guidelines issued by the Regulator seem to require that applications for certification of facilities be made by, or on behalf of, accredited organisations.[111]

29. In order to obtain a certification, the applicant must satisfy the Regulator that the facilities meet the containment requirements set out in the certification guidelines.[112] The certification guidelines require that, for certification of facilities to PC2 level or below, the applicant arrange for inspection of the facility by a person with knowledge or experience in

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[108] Office of the Gene Technology Regulator, *Guidelines for Certification of Facilities/Physical Containment Requirements*, OGTR, June 2001, p. 10.

[109] *Gene Technology Act 2000* (Cth) s 83.

[110] *Gene Technology Act 2000* (Cth) s 84. The *Guidelines for Certification of Facilities/Physical Containment Requirements*, together with the *Guidelines for Certification of PC2 Facilities/Physical Containment 2 Requirements*—issued by the Regulator in June 2001 and August 2003, respectively—together outline the relevant requirements in relation to certification of facilities.

[111] Office of the Gene Technology Regulator, *Guidelines for Certification of PC2 Facilities/Physical Containment 2 Requirements*, OGTR, August 2003, p. 8.

[112] Office of the Gene Technology Regulator, *Guidelines for Certification of PC2 Facilities/Physical Containment 2 Requirements*, OGTR, August 2003, p. 7.

biocontainment.[113] The applicant must provide a copy of the inspection report arising from this inspection, along with the completed certification application form, to the Regulator. Based on this information, the Regulator may, by written instrument, certify the facility to a specified level of containment.[114]

30. Certification of a facility is subject to the conditions set out in the certification guidelines issued by the Regulator. The certification guidelines specify general requirements that must be complied with by the holder of any certification for a facility (irrespective of the type of facility or containment level) and additional specific requirements that will be applicable according to the type of facility or the containment level to which the facility is certified.[115] For example, the certification guidelines specify that all holders of a certification must:

- maintain control of GMO dealings in the facility through processes appropriate to the facility's containment level and type;
- prevent release of GMOs and organisms infected with GMOs from the facility unless specifically approved (in writing) by the Regulator;
- prevent the persistence of GMOs and organisms infected with GMOs within the facility other than those being stored or used in a dealing;
- comply, and ensure all people in the facility comply with, the specific conditions required by the certification guidelines; and
- ensure that the facility is inspected at least once per year and provide a copy of the inspection report, detailing the extent of compliance with the conditions of certification, if requested and to notify the Regulator of any instances of non-compliance as soon as practicable.

31. The Regulator may monitor compliance with conditions of accreditation (see Chapter 3 for further information).[116]

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[113] The guidelines provide for four levels of containment: PC1–PC4. The containment requirements differ according to the level of containment, with PC4 facilities providing for the most stringent level of containment. For certification greater than PC2, the Regulator will also arrange for an independent inspection of the facility by OGTR staff or contracted advisors.

[114] *Gene Technology Act 2000* (Cth) s 84. The Regulations prescribe that a decision must be made within 90 days: Gene Technology Regulations 2001 (Cth) reg 14.

[115] Office of the Gene Technology Regulator, *Guidelines for Certification of PC2 Facilities/Physical Containment 2 Requirements*, OGTR, August 2003, p. 12.

[116] *Gene Technology Act 2000* (Cth) s 152.

Other applications made under the Act

Confidential commercial information

32. The Act also allows a person to apply to the Regulator seeking a declaration that specified information provided to the Regulator is confidential commercial information (CCI) for the purposes of the Act.[117] Information declared by the Regulator to be CCI must not be disclosed by the Regulator except under the limited circumstances provided by the Act.[118] For example, although CCI is not permitted to be published in any proposed RARMP distributed to the public by the Regulator, such information is permitted to be disclosed to the Gene Technology Technical Advisory Committee, for example, in the course of carrying out the risk analysis functions under the Act.[119] However, the Regulator must not take information that has been declared CCI into account for the purposes of considering an application by another person for a GMO licence.[120]

33. The Act applies a two-step test in determining whether a declaration that information is CCI may be made. Firstly, where information meets the requirements outlined in s 185(1), then, subject to the next step in the test, the Regulator must declare that information to be CCI. Subsection (1) provides:

> **185 Regulator may declare that information is confidential commercial information**
>
> (1) Subject to subsection (2), if the person satisfies the Regulator that the information specified in the application is:
>
> (a) a trade secret; or
>
> (b) any other information that has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed; or
>
> (c) other information that:
>
> (i) concerns the lawful commercial or financial affairs of a person, organisation or undertaking; and
>
> (ii) if it were disclosed, could unreasonably affect the person, organisation or undertaking;
>
> the Regulator must declare that the information is confidential commercial information for the purposes of this Act.
>
> …

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[117] *Gene Technology Act 2000* (Cth) s 184. Neither the Act nor the Regulations prescribe any time frame within which a decision whether to declare information to be CCI must be made.

[118] *Gene Technology Act 2000* (Cth) s 187.

[119] *Gene Technology Act 2000* (Cth) s 187(1)(d)(iii).

[120] *Gene Technology Act 2000* (Cth) s 45.

34. However, in determining whether to make a declaration, the Act requires the Regulator to balance the prejudice that disclosure would cause, with the public interest in disclosure.[121] The Regulator must refuse to make a declaration where the public interest in disclosure outweighs the prejudice.[122]

35. The Regulator may at any time revoke a CCI declaration if satisfied that the specified information is no longer of a type provided by s 185(1) or that the public interest in disclosure outweighs the prejudice disclosure may cause.[123]

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[121] *Gene Technology Act 2000* (Cth) s 185.

[122] *Gene Technology Act 2000* (Cth) s 185(2). Where the information relates to the location at which field trials involving GMOs are occurring, the Act requires that the Regulator be satisfied that significant damage to the health and safety of people, the environment, or property would be likely to occur if the location was disclosed, before a declaration may be made.

[123] *Gene Technology Act 2000* (Cth) s 186.

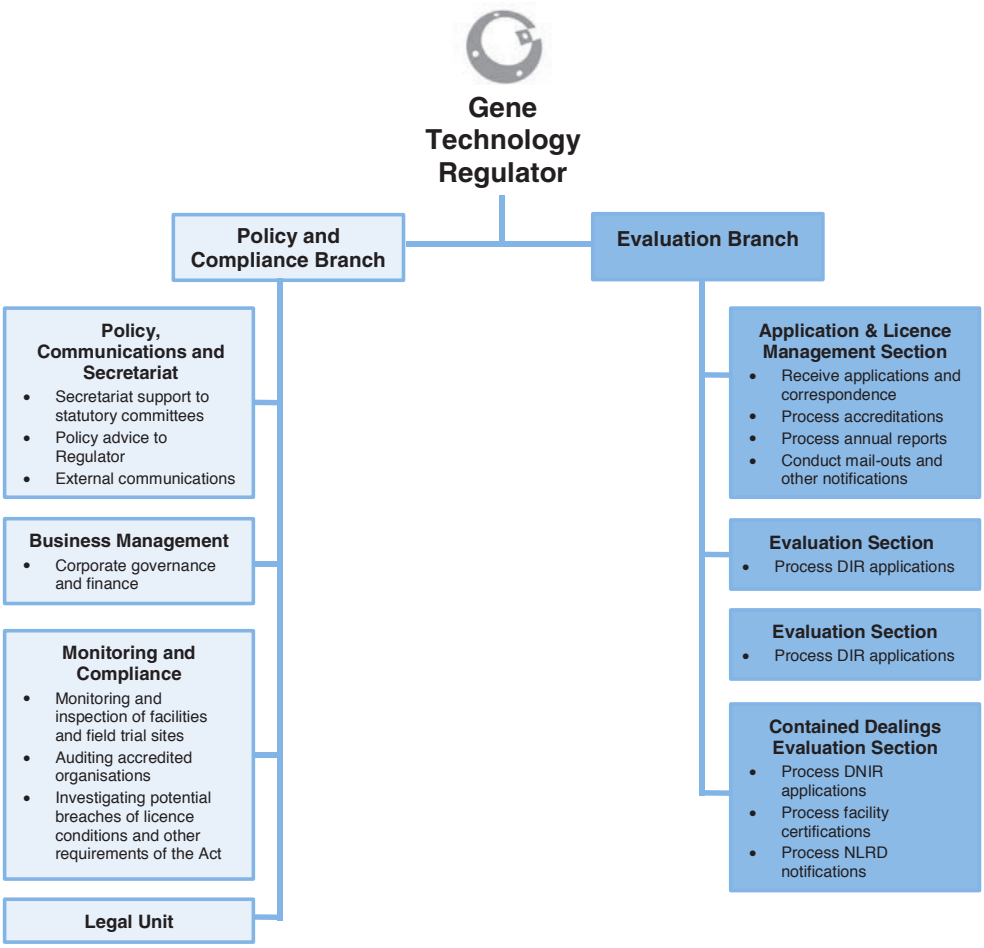
Appendix 4—Structure and organisation of OGTR

1. OGTR is responsible for assisting the Regulator in the assessment of applications and related functions required under the Act. As noted earlier, OGTR is staffed by some 55 officers, divided into two Branches—the *Policy and Compliance Branch*, and the *Evaluation Branch* (see Figure A4.1 and Figure A4.2 for OGTR structure and staffing). The *Policy and Compliance* Branch, with some 22 staff (or 40 per cent of OGTR total), is responsible for, among other things, monitoring and compliance activities, policy development and business management and support. Responsibility for the assessment of applications under the Act rests with the *Evaluation Branch*.

2. Comprised of some 33 staff (or 60 per cent of OGTR total), the *Evaluation Branch* is divided into four sections, the *Applications and Licence Management Section*, two *DIR Evaluations Sections*, and the *Contained Dealings Evaluation Section*. Each section has responsibility for the assessment of different types of applications made under the Act, as well as various other functions, as outlined below. Further detail on the number of applications received and processed by OGTR is provided in Appendix 5.

Figure A4.1

OGTR structure—division of functions



Source: ANAO.

Figure A4.2

OGTR staffing as at March 2005 (includes part-time and non-ongoing staff

Branch / Section	Staff	% of total staffing[a]
Policy and Compliance Branch	**22**	**40.0**
Policy, Communications and Secretariat	7	12.7
Business Management	4	7.3
Monitoring and Compliance	8	14.5
Legal Unit	1	1.8
Other[b]	2	3.6
Evaluation Branch	**33**	**60.0**
Evaluation Section 1	6	10.9
Evaluation Section 2	5	9.1
Contained Dealings Evaluation Section	6	10.9
Applications and Licence Management Section	11	20.0
Science Cohort	2	3.6
Other[c]	3	3.6
Total[d]	**55**	**100**

Source: Adapted from OGTR.

Notes
a Figures have been rounded to one decimal place and therefore do not total 100 per cent.
b Includes Branch Head and Executive Assistant for Branch.
c Includes Branch Head and two other staff.
d Total staffing also includes Executive Assistant to the Regulator (but does not include the Regulator).

Appendix 5—Volume of applications made to, and processed by, OGTR

1. As discussed earlier, there are a variety of applications made under the Act that are dealt with by OGTR. The numbers of applications received and processed are recorded in quarterly reports published by OGTR. Data has been analysed from 12 quarterly reports covering the period 1 July 2001 to 1 July 2004. In total, OGTR received 5 773 applications (or notifications), processing or finalising 3 248 of these, over that three-year period (see Figure A5.1).

Figure A5.1

Quarterly applications received and decisions made

Quarter ending	Sep 2001	Dec 2001	Mar 2002	Jun 2002	Sep 2002	Dec 2002	Mar 2003	Jun 2003	Sep 2003	Dec 2003	Mar 2004	Jun 2004	Total
New applications received[a]	155	180	112	472	451	690	589	615	179	155	116	184	**3 898**
New applications processed[a]	11	28	109	133	309	298	391	628	174	90	44	45	**2 260**
Other applications received[b]	51	33	50	83	74	119	86	59	72	189	270	789	**1 875**
Other applications processed[b]	26	23	5	7	33	155	72	76	89	63	116	323	**988**

Source: Adapted from OGTR.

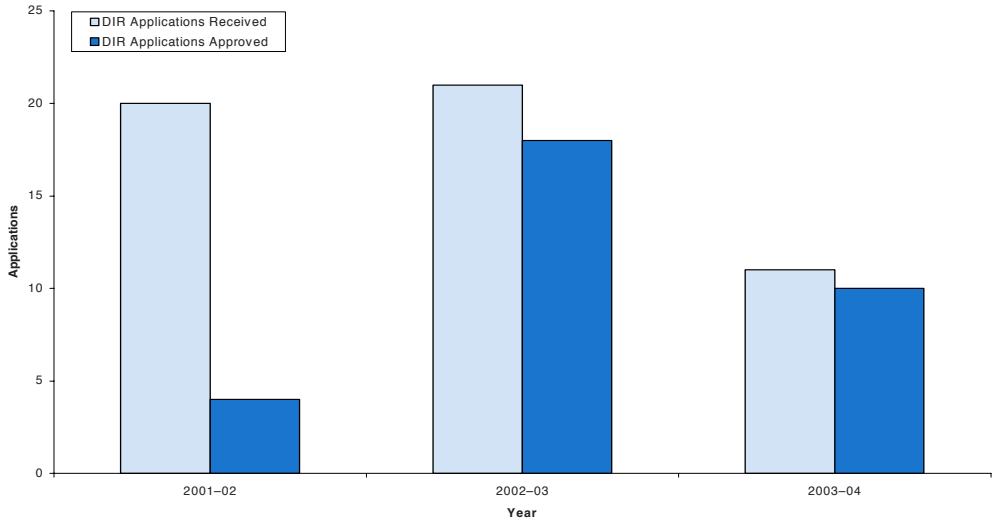
Notes a Includes DIR and DNIR licence, certification and accreditation, and CCI applications and NLRD notifications.

b Includes applications for surrender, variation and transfer of licences, certifications and accreditations.

2. Total annual applications received and processed by OGTR have increased significantly over the first three years (Figure A5.2). It should be noted that the Act provided for a two-year transition period within which existing dealings and facilities received deemed approval under the Act. The Act provided that these 'deemed' dealings and instruments remained in force until June 2003. Thus, OGTR received a large increase in applications during 2002–03 in response to the impending expiry of many of these deemed licences, certifications and accreditations.

Figure A5.2

Annual applications received and processed over the first three years of operation.



Source: Data from OGTR.

Note that a number of applications were withdrawn, cancelled, reclassified and/or suspended.

Licensed dealings

3. Over the first three years of operation, OGTR received 52 DIR applications and issued 32 DIR licences, and received 305 DNIR applications and issued 263 DNIR licences (see Figure A5.3).

Figure A5.3

Quarterly applications received and decisions made—new DIR and DNIR licences

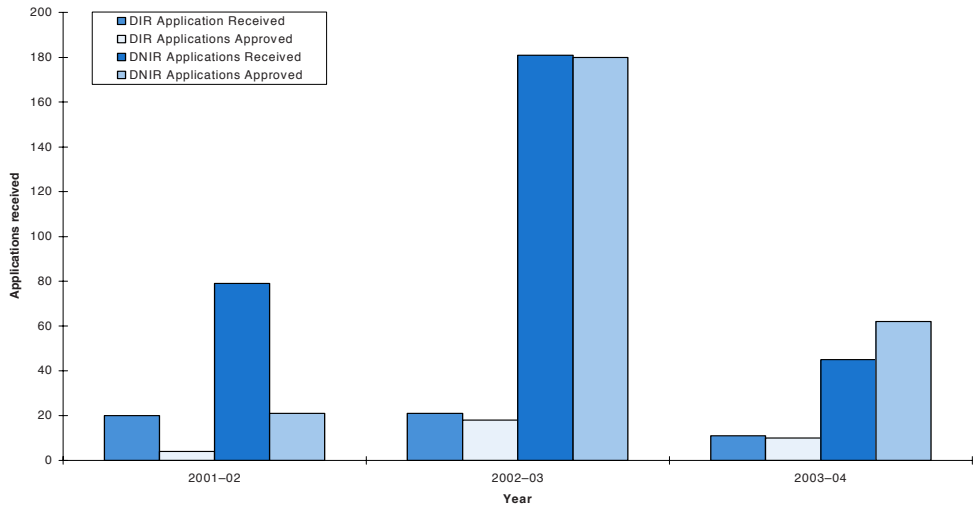
Quarter ending	Sep 2001	Dec 2001	Mar 2002	Jun 2002	Sep 2002	Dec 2002	Mar 2003	Jun 2003	Sep 2003	Dec 2003	Mar 2004	Jun 2004	Total
Applications for:													
DIRs													
Received	5	6	7	2	8	5	6	2	2	5	2	2	**52**
Approved	0	0	4	0	4	5	0	9	1	7	1	1	**32**
DNIRs													
Received	7	13	11	48	34	57	52	38	14	10	6	15	**305**
Approved	0	0	9	12	45	24	42	69	32	18	6	6	**263**

Source: Adapted from OGTR.

4. There has been great fluctuation in the numbers of DIR and DNIR applications received and approved over the first three years. In the first year of operation, there were 20 DIR and 79 DNIR applications received and 4 DIR and 21 DNIR licences issued. In the second year of operation, (coinciding with the end of the transition period), there were 21 DIR and 181 DNIR applications received and 18 DIR and 180 DNIR licences issued. In the third year of operation, applications received had declined to 11 DIR and 45 DNIR, and licences were issued to 10 DIR and 62 DNIR (see Figure A5.4).

Figure A5.4

Annual DIR and DNIR licence applications received and approved over the first three years of operation



Source: Data from OGTR.

Notes A number of applications were withdrawn, cancelled, reclassified and/or suspended.

5. Licences for DIRs usually remain in force until signed-off as having met all licence conditions and surrendered or cancelled. DNIR licences are usually issued for a limited period of five years. To date, most DIR applications have involved dealings with agricultural GMOs (20 out of the 37 licences involved genetically modified cotton—see Chapter 2, Figure 2.3). The current *de facto* and *de jure* moratoria on commercial release of GMOs implemented by most State and Territory governments has consequently led to a slowing of DIR applications, and OGTR expects this trend to continue whilst the moratoria remain in place. However, the OGTR has noted speculation that applications involving non-agricultural GMOs may increase over the coming years.

Certifications, accreditations and notifications

6. Although 135 applications for organisational accreditation were received over the first three years (see Figure A5.6), many of these applications were from organisations operating under the former voluntary regime and that received 'deemed' accreditation under the transitional arrangements and hence needed to seek re-accreditation upon the expiry of the deemed accreditation. Once accreditation has been granted, organisations remain accredited so long as they continue to meet the conditions of accreditation contained in the accreditation guidelines issued by the Regulator. Thus, the volume of new applications for organisational accreditation in future years is expected to remain low in comparison to that seen during the two-year transitional period. However, all accredited organisations are required to submit an annual report to the Regulator. Each of these reports is assessed by OGTR to ensure completeness of the information provided and compliance with the conditions of accreditation.

Figure A5.6

Applications received and decisions made, new accreditations, certifications and notifications

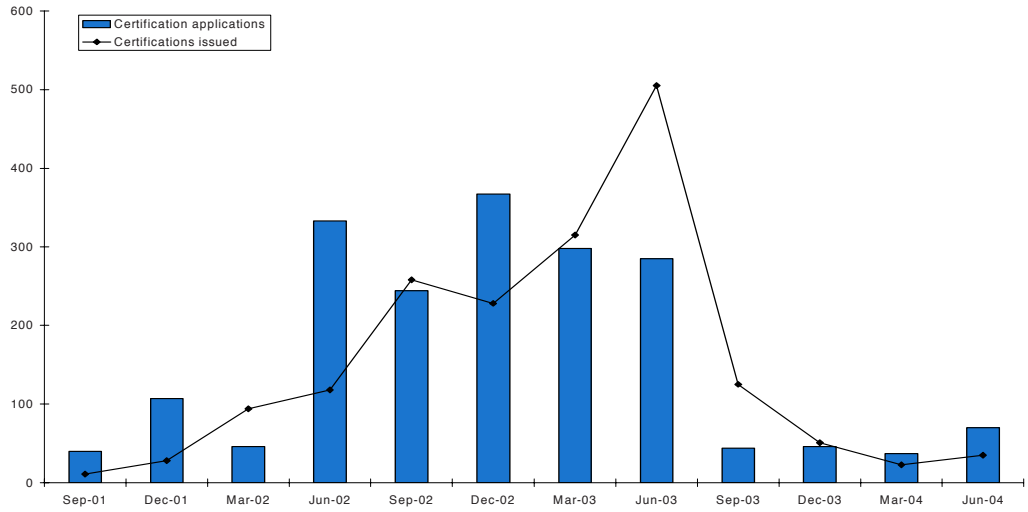
Quarter ending	Sep 2001	Dec 2001	Mar 2002	Jun 2002	Sep 2002	Dec 2002	Mar 2003	Jun 2003	Sep 2003	Dec 2003	Mar 2004	Jun 2004	Total
Applications for:													
Organisational accreditation													
Received	0	1	2	3	28	37	24	30	2	4	2	2	**135**
Approved	0	0	1	2	2	39	31	44	7	4	1	1	**132**
Contained facility certification													
Received	40	107	46	333	244	367	298	285	44	46	37	70	**1 917**
Approved	11	28	94	118	258	228	315	505	125	51	23	35	**1 791**
NLRD notifications													
Received	56	49	42	80	128	214	200	254	112	86	67	95	**1 383**

Source: Adapted from OGTR.

7. Similarly, applications for certification of facilities rose rapidly from the June 2002 quarter, peaking at 367 during the December 2002 quarter, before declining substantially by the September 2003 quarter (see Figure A5.7). Over that same period, certifications issued rose to 258 in the September 2002 quarter, peaking at 505 in the June 2003 quarter, before falling to 125 in the next quarter.

Figure A5.7

Applications for facility certification received and processed



Source: Data from OGTR.

8. It should be noted that, unlike organisational accreditations, facility certifications are issued for a limited duration, usually five years for PC2 facilities, and a maximum of two years for PC3 and above. Thus, many of the facilities receiving certification towards the expiry of the transitional period (that is, over the June 2002 to June 2003 quarters), can be expected to submit applications for renewal at the expiry of the certification. This is likely to result in a substantial increase in workload over the year commencing July 2007 and ending June 2008 (some 1 306 certifications were issued over the corresponding July 2002 to June 2003 period). This cyclical increase in certification applications and processing, a remnant of the transitional arrangements provided for by the Act, is a product of the standardised, limited duration for which similar facilities are certified. This is likely to continue to place heavy cyclical demand on OGTR resources to meet the processing requirements for these applications.

9. As Figure A5.6 shows, a total of 1 383 NLRD notifications were received over the first three years at an average of 115 notifications each quarter (or 38 notifications per month). These figures suggest that, taking into consideration the volume and nature of the applications dealt with during the transitional period, NLRD notifications will represent the main type of work (by volume) received by OGTR per annum. OGTR policy requires that 20 per cent of notifications received be reviewed each quarter. However, OGTR advised that it currently reviews all NLRD notifications received (see paragraph 3.83 for further information on NLRD notifications).

CCI applications

10. A total of 106 applications seeking CCI declarations were received over the first three years, with declarations being made on 42 of these applications (Figure A5.8). The majority of these declarations related to DIR applications (50 per cent), followed by DNIRs (36 per cent) and NLRDs (14 per cent).

11. As Figure A5.8 shows, 54 CCI applications were received for DIRs (two more than the 52 DIR licence applications themselves), with 21 CCI declarations made by the Regulator (compared with the 32 DIR licences issued over that same period).

Figure A5.8

Applications received and decisions made regarding CCI

Quarter ending	Sep 2001	Dec 2001	Mar 2002	Jun 2002	Sep 2002	Dec 2002	Mar 2003	Jun 2003	Sep 2003	Dec 2003	Mar 2004	Jun 2004	Total
CCI applications relating to:													
DIR													
Received	24	3	4	2	2	4	5	2	4	3	1	0	**54**
Finalised	0	0	1	0	0	1	2	1	8	3	4	1	**21**
DNIR													
Received	20	0	0	3	1	5	3	1	1	0	0	0	**34**
Finalised	0	0	0	1	0	1	1	0	1	6	4	1	**15**
NLRD													
Received	3	1	0	1	6	1	1	3	0	1	1	0	**18**
Finalised	0	0	0	0	0	0	0	0	0	1	5	0	**6**

Source: Adapted from OGTR.

Notes 1 In the December 2002 quarter, two applications were approved in relation to certification of facilities.

Variations, surrenders and transfers

12. A total of 1 875 applications were received (with 988 processed) relating to the variation, surrender, or transfer of existing licences or other instruments issued by the Regulator (see Figure A5.9). The majority of these were applications for variation (1 420 or 76 per cent), with 412 (22 per cent) applications for surrender and 43 (2.3 per cent) applications for transfer.

13. Of the applications for variation, the majority related to variations to facility certification (1 124 applications). There were 156 applications for variation to DIR licences (from a total of 32 DIR licences issued over the period) and 119 to DNIR licences (from a total of 263 issued DNIR licences).

Figure A5.9

Applications received and decisions made—existing licences and other instruments

Quarter ending	Sep 2001	Dec 2001	Mar 2002	Jun 2002	Sep 2002	Dec 2002	Mar 2003	Jun 2003	Sep 2003	Dec 2003	Mar 2004	Jun 2004	Total
Applications for:													
Surrender													
DIR licence	2 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (0)	3 (0)	0 (0)	0 (0)	0 (0)	1 (0)	1 (1)	**9 (1)**
DNIR licence	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	1 (5)	1 (2)	0 (0)	1 (0)	0 (1)	1 (1)	**5 (12)**
Certification	6 (1)	8 (0)	19 (0)	35 (0)	53 (19)	83	50 (43)	18 (44)	12 (54)	19 (21)	23 (18)	71 (45)	**397 (354)**
Accreditation	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (1)	**1 (1)**
Sub Total	**8 (1)**	**8 (0)**	**19 (0)**	**35 (0)**	**53 (19)**	**87 (112)**	**54 (48)**	**19 (46)**	**12 (54)**	**20 (21)**	**24 (19)**	**73 (48)**	**412 (368)**
Variation													
DIR licence	37 (23)	15 (19)	11 (3)	9 (1)	11 (2)	16 (3)	9 (3)	16 (3)	10 (4)	5 (3)	9 (6)	8 (10)	**156 (80)**
DNIR licence	5 (2)	3 (3)	6 (1)	2 (0)	5 (1)	7 (10)	10 (9)	7 (12)	17 (11)	9 (10)	21 (16)	27 (17)	**119 (92)**
Certification	1 (0)	5 (1)	4 (0)	4 (0)	1 (4)	8 (19)	10 (11)	15 (11)	31 (17)	150	214	681 (248)	**1124 (408)**
Accreditation	0 (0)	1 (0)	7 (0)	2 (6)	2 (4)	0 (0)	0 (0)	1 (1)	2 (3)	5 (4)	1 (2)	0 (0)	**21 (20)**
Sub Total	**43 (25)**	**24 (23)**	**28 (4)**	**17 (7)**	**19 (11)**	**31 (32)**	**29 (23)**	**39 (27)**	**60 (35)**	**169 (42)**	**245 (96)**	**716 (275)**	**1420 (600)**
Transfer													
Licence	0 (0)	1 (0)	3 (1)	8 (0)	2 (3)	1 (11)	3 (1)	1 (3)	0 (0)	0 (0)	1 (0)	0 (0)	**20 (19)**
Certification	0 (0)	0 (0)	0 (0)	23 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (1)	0 (0)	**23 (1)**
Sub Total	**0 (0)**	**1 (0)**	**3 (1)**	**31 (0)**	**2 (3)**	**1 (11)**	**3 (1)**	**1 (3)**	**0(0)**	**0 (0)**	**1 (1)**	**0 (0)**	**43 (20)**

Source: Adapted from OGTR.

Notes 1 Figures in parentheses indicate number processed.

Appendix 6—Risk Analysis and the OGTR Risk Analysis Framework

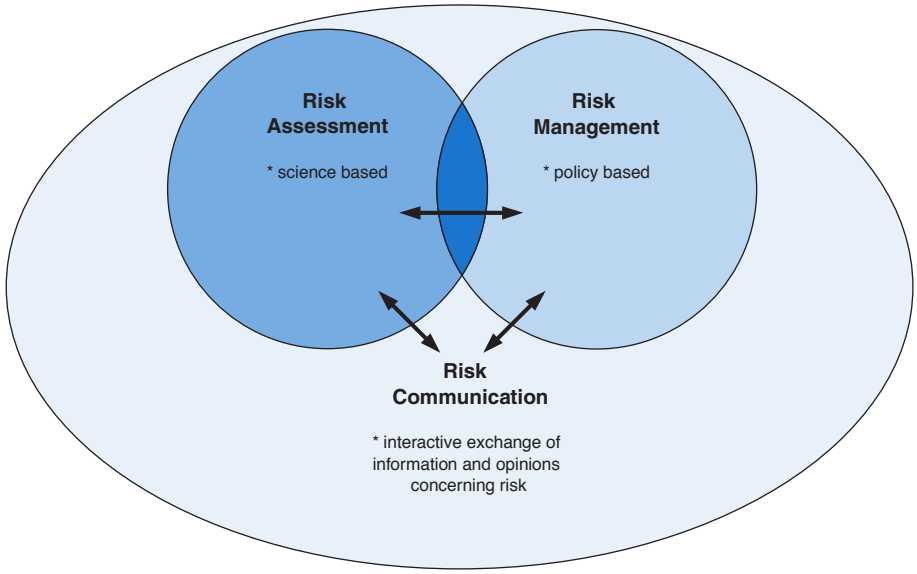
Risk analysis under the Act

1. The Act establishes a regime for science-based assessment of the risks associated with the use of gene technology, and for the management of those risks, by requiring the Regulator to conduct a risk analysis in relation to certain dealings with GMOs. The Act does not, however, define risk analysis nor does it provide any further guidance on the risk assessment or risk management approach to be employed by the Regulator. The Regulator has prepared a guidance document outlining the risk analysis approach to be taken in the assessment of licence applications made under the Act.[124]

2. Risk analysis is commonly defined as a process consisting of three interconnected components: risk assessment, risk management and risk communication (Figure A6.1).[125]

Figure A6.1

A risk analysis framework and key components



Source: ANAO.

[124] Office of the Gene Technology Regulator, *Risk Analysis Framework*, 2nd Ed., OGTR, Canberra, 2005. This replaces the earlier version published in January 2002.

[125] European Food Safety Authority, 'Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed', *EFSA Journal* (2004) 99, p. 7.

3. Risk assessment is generally acknowledged to involve four steps:[126]

- hazard identification;
- hazard characterisation;
- exposure assessment; and
- risk characterisation.

4. Risk management is the process of selecting and implementing appropriate risk management measures, involving the weighing of policy alternatives and consideration of the risk assessment, and other factors, including appropriate prevention and control options.[127]

5. Risk communication is the interactive exchange of information and opinions throughout the risk analysis process on hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.[128]

6. Together, these components work to ensure that the risks associated with particular dealings with GMOs can be identified and better understood, and potential measures for the management of such risks proposed, so that an informed decision can be made on whether or not the particular dealing should be allowed to proceed. In the context of the objectives of the Act, this requires the Regulator to determine, on the basis of the risk analysis (as well as taking other relevant information into account), that any risks posed by the proposed dealings are able to be managed in such a way as to protect the health and safety of people and the environment.

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[126] European Food Safety Authority, 'Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed', *EFSA Journal* (2004) 99, p. 7.

European Council, 'Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety', *Official Journal of the European Communities*, L 31:1–24.

[127] European Food Safety Authority, 'Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed', *EFSA Journal* (2004) 99, p. 7.

[128] European Council, 'Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety', *Official Journal of the European Communities*, L 31:1–24.

OGTR Risk Analysis Framework

7. As noted earlier, OGTR recently released a revised version of its *Risk Analysis Framework*, following a period of public consultation on the proposed revision. The *Risk Analysis Framework* provides guidance on how the Regulator and OGTR officers conduct the risk analysis when assessing applications to conduct dealings under the Act.

8. The stated purpose of the Risk Analysis Framework is to:[129]

- provide a guide to the rationale and approach to risk analysis used by the Regulator;
- enable the application of a consistent risk analysis approach to evaluating licence applications;
- provide a clear guide to the provisions of the legislation that relate to risk assessment and risk management; and
- ensure that the risk analysis and decision-making processes are transparent to both applicants and the broader community.

9. The *Risk Analysis Framework* provides background material on the regulatory regime established by the Act as well as providing information on the risk analysis required by the Act. The *Risk Analysis Framework* then introduces and discusses in further detail, the risk analysis model employed by OGTR in conducting risk analysis under the Act.

[129] Office of the Gene Technology Regulator, *Risk Analysis Framework*, OGTR, Canberra, 2005, p. ii.

Appendix 7—Monitoring and compliance

Conditions associated with dealings with GMOs

1. As was discussed in Chapter 2, all licences for dealings with GMOs (i.e. dealings involving, and dealings not involving, intentional release—DIRs and DNIRs, respectively) are subject to the statutory conditions set out in the Act. Section 61 of the Act outlines four main types of condition that may be imposed on such dealings:

> **61 Licence is subject to conditions**
>
> A GMO licence is subject to the following conditions:
>
> (a) the conditions set out in sections 63, 64 and 65;
>
> (b) any conditions prescribed by the regulations;
>
> (c) any conditions imposed by the Regulator at the time of issuing the licence;
>
> (d) any conditions imposed by the Regulator under section 71 after the licence is issued.

2. The Act provides wide scope on the types of conditions that may be prescribed or that the Regulator may impose on licences for dealings with GMOs. For example, s 62(2) of the Act provides that licence conditions may relate to, but are not limited to, the following matters:

> **62 Conditions that may be prescribed or imposed**
>
> …
>
> (a) the scope of the dealings authorised by the licence;
>
> (b) the purposes for which the dealings may be undertaken;
>
> (c) variations to the scope or purposes of the dealings;
>
> (d) documentation and record-keeping requirements;
>
> (e) the required level of containment in respect of the dealings, including requirements relating to the certification of facilities to specified containment levels;
>
> (f) waste disposal requirements;
>
> (g) measures to manage risks posed to the health and safety of people, or to the environment;
>
> (h) data collection, including studies to be conducted;
>
> (i) auditing and reporting;

(j) actions to be taken in case of the release of a GMO from a contained environment;

(k) the geographical area in which the dealings authorised by the licence may occur;

(l) requiring compliance with a code of practice issued under section 24, or a technical or procedural guideline issued under section 27;

(m) supervision by, and monitoring by, Institutional Biosafety Committees;

(n) contingency planning in respect of unintended effects of the dealings authorised by the licence;

(o) limiting the dissemination or persistence of the GMO or its genetic material in the environment.

3. Conditions may also be imposed that relate to GM products derived from a particular licensed dealing with a GMO.[130]

4. Sections 63–65 provide certain statutory conditions that apply to all licences. For example, s 63 provides that it is a condition of licence that the licence holder inform any person covered by the licence of relevant conditions attached to the licence, whilst s 65 requires that the licence holder inform the Regulator of certain additional information associated with the licensed dealing that may become available.

5. Section 64 imposes certain conditions in relation to monitoring and auditing by the Regulator. Section 64 provides:

64 Condition about monitoring and audits

(1) It is a condition of a licence that if:

(a) a person is authorised by the licence to deal with a GMO; and

(b) a particular condition of the licence applies to the dealing by the person;

the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

6. The monitoring and inspection powers of the Regulator will be discussed in further detail below.

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[130] *Gene Technology Act 2000* (Cth) s 62(1).

7. In addition, there may be conditions attached to dealings not requiring a licence, that is, NLRDs, exempt dealings or dealings on the GMO Register. For example, the Regulations impose a number of conditions on NLRDs, requiring, amongst other things; assessment of the proposed dealings by an Institutional Biosafety Committee; notification to the Regulator of the information required by the Regulations in relation to the proposed NLRD; that the dealing be conducted in facilities certified by the Regulator; and that the conduct of the dealing is properly supervised.[131]

8. The technical and procedural guidelines issued by the Regulator also specify additional conditions under which the various classes of dealings must be conducted.[132]

Monitoring, inspection and enforcement powers

9. As mentioned earlier, the Regulator has power to do all things necessary or convenient to be done in connection with the Regulator's functions.[133] In addition to the power to impose conditions on dealings with GMOs outlined earlier,[134] the Act provides the Regulator with a number of monitoring and enforcement powers. These powers are aimed at ensuring that dealings regulated by the Act are conducted in accordance with any conditions imposed on such dealings, and to ensure that the provisions of the Act are enforced.

Monitoring powers

10. The Act provides for two types of monitoring of dealings with GMOs. Firstly, as noted earlier, it is a condition of licence that a person authorised by the licence to deal with a GMO must allow the Regulator (or a person authorised by the Regulator) to enter premises where the dealing is being undertaken for the purposes of 'auditing or monitoring' the dealing.[135] Secondly, distinct from the powers under s 64, ss 152 and 153 provide specific monitoring powers available to inspectors for monitoring compliance. Section 152 provides:

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131 See for example, Gene Technology Regulations 2001 (Cth) reg 13.

132 As noted earlier, such guidelines are issued by the Regulator under s 27 in accordance with s 62. Some examples of guidelines issued by the Regulator include: *Guidelines for Accreditation of Organisations*, *Guidelines for the Transport of GMOs*, and the *Guidelines for Certification of PC2 Facilities / Physical Containment 2 Requirements*.

133 *Gene Technology Act 2000* (Cth) s 28.

134 See *Gene Technology Act 2000* (Cth) ss 61, 62.

135 *Gene Technology Act 2000* (Cth) s 64.

152 Powers available to inspectors for monitoring compliance

(1) For the purpose of finding out whether this Act or the regulations have been complied with, an inspector may:

(a) enter any premises; and

(b) exercise the monitoring powers set out in section 153.

(2) An inspector is not authorised to enter premises under subsection (1) unless:

(a) the occupier of the premises has consented to the entry; or

(b) the entry is made under a warrant under section 172; or

(c) the occupier of the premises is a licence holder, or a person covered by a licence, and the entry is at a reasonable time.

11. In contrast to the power under s 64, the monitoring powers available under ss 152 and 153 are exercisable only for the purpose of '*finding out whether this Act or the regulations have been complied with*'. In addition, these powers are only exercisable by '*inspectors*', appointed under s 150.

Auditing or monitoring under s 64

12. Section 64 does not define the activities that an authorised person may engage in when entering premises for the purposes of auditing or monitoring, nor does it define the meaning of the terms auditing or monitoring.

13. Legal advice provided to OGTR indicates that an audit may be carried out in order to establish the accuracy and integrity of the licence holder's records, including, in addition to financial records, records of policies and procedures and other records related to the dealing. Monitoring is seen to be generally concerned with the observation of a dealing under a licence.

14. Advice from OGTR also indicates that in conducting auditing or monitoring activities, an authorised person may:

(a) access premises;

(b) inspect books, records or documents;

(c) inspect and examine things;

(d) take notes, photographs, audio and video recordings; and

(e) ask questions.

15. In contrast to the powers under s 153, s 64 does not allow entry to premises without the consent of the occupier. However, refusal by a person covered by a licence to grant access to premises where a dealing is being undertaken would be a contravention of the statutory licence condition and would thus subject the person to possible sanctions under the Act. Once entry

is gained to premises, any action taken under s 64 is taken only with the consent of the occupier and is limited to acts of a non-coercive, routine and observational nature.

Monitoring under ss 152 and 153

16. In contrast to s 64, s 152 authorises entry to premises by authorised persons. Where the premises are occupied by a licence holder or a person covered by a licence, such entry may be without the consent of the person, provided entry is made at a reasonable time.[136] Entry is also authorised in relation to other premises with the consent of the occupier or under warrant issued under s 172.[137]

17. Section 153 outlines the powers that may be exercised by inspectors upon entering premises in accordance with s 152. Section 153 provides:

> **153 Monitoring powers**
>
> (1) The ***monitoring powers*** that an inspector may exercise under paragraph 152(1)(b) are as follows:
>
> (a) to search the premises and any thing on the premises;
>
> (b) to inspect, examine, take measurements of, conduct tests on, or take samples of, any thing on the premises that relates to a GMO;
>
> (c) to take photographs, make video or audio recordings or make sketches of the premises or any thing on the premises;
>
> (d) if the inspector was authorised to enter the premises by a warrant under section 172—to require any person in or on the premises to:
>
> (i) answer any questions put by the inspector; and
>
> (ii) produce any book, record or document requested by the inspector;
>
> (e) to inspect any book, record or document on the premises;
>
> (f) to take extracts from or make copies of any such book, record or document
>
> (g) to take onto the premises such equipment and materials as the inspector requires for the purpose of exercising powers in relation to the premises;

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[136] *Gene Technology Act 2000* (Cth) s 152(2)(c).

[137] *Gene Technology Act 2000* (Cth) ss 152(2)(a), (b).

(h) to secure a thing, until a warrant is obtained to seize it, being a thing:

(i) that the inspector finds during the exercise of monitoring powers on the premises; and

(ii) that the inspector believes on reasonable grounds is evidential material; and

(iii) that the inspector believes on reasonable grounds would be lost, destroyed or tampered with before the warrant can be obtained.

…

18. Although the range of activities that may be engaged in when monitoring under s 152 are wider than those permitted under s 64, these activities are only exercisable for the purpose of ensuring compliance with the Act. This is in contrast to s 64, which allows exercise of the activities under that provision for the broader purpose of auditing or monitoring the dealing.

Enforcement powers

19. In addition to the monitoring powers outlined above, the Act also provides offence-related powers allowing an inspector to enter premises and exercise specific powers where there is a suspicion that an offence against the Act has been or will be committed.[138] Section 154 provides:

154 Searches and seizures related to offences

(1) This section applies if an inspector has reasonable grounds for suspecting that there may be evidential material on any premises.

(2) The inspector may:

(a) enter the premises, with the consent of the occupier or under a warrant issued under section 173; and

(b) exercise the powers set out in subsection (3) and section 155; and

(c) if the entry is under a warrant—seize the evidential material, if the inspector finds it on the premises.

20. Evidential material is defined in s 10 of the Act as follows:

evidential material means any of the following:

(a) a thing with respect to which an offence against this Act or the regulations has been committed or is

[138] *Gene Technology Act 2000* (Cth) ss 154, 155.

suspected, on reasonable grounds, to have been committed;

(b) a thing that there are reasonable grounds for suspecting will afford evidence as to the commission of any such offence;

(c) a thing that there are reasonable grounds for suspecting is intended to be used for the purpose of committing any such offence.

21. In contrast to the monitoring powers under ss 152 and 153, an inspector is only authorised under s 154 to enter premises with the consent of the occupier or under warrant issued under s 173.[139]

22. Upon entering premises under s 154, an inspector may engage in the activities enumerated in s 155. Section 155 provides:

155 Offence-related powers of inspectors in relation to premises

The powers an inspector may exercise under paragraph 154(2)(b) are as follows:

(a) to search the premises and any thing on the premises for the evidential material;

(b) to inspect, examine, take measurements of, conduct tests on, or take samples of the evidential material;

(c) to take photographs, make video or audio recordings or make sketches of the premises or the evidential material;

(d) to take onto the premises such equipment and materials as the inspector requires for the purpose of exercising powers in relation to the premises.

23. It is noteworthy that an inspector may only seize such evidential material if entry has been obtained under a warrant.[140]

24. The Act also allows the Regulator to give directions to a licence holder or person covered by a licence, where the Regulator believes that the person is not complying with the requirements of the Act or Regulations, in order to protect the health and safety of people or to protect the environment.[141] Failure to comply with such directions is an offence under the Act.[142] Where a person fails to take the steps required, the Regulator may arrange for those steps to be

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139 *Gene Technology Act 2000* (Cth) ss 154.

140 *Gene Technology Act 2000* (Cth) s 154(2)(c).

141 *Gene Technology Act 2000* (Cth) s 146.

142 *Gene Technology Act 2000* (Cth) s 146(3).

taken, and any costs incurred by the Regulator may be recovered from the person.[143]

25. The Act also allows the Regulator to seek an injunction from the Federal Court restraining or requiring conduct, where engaging in the conduct or failure to engage in the conduct (respectively) is or would be an offence against the Act.[144]

Penalties for non-compliance with the Act

26. The regulatory regime is founded on the general prohibition on dealings with GMOs. A number of different types of offences are created by the Act. Firstly, the Act prohibits dealings with GMOs unless authorised by the Act.[145] That is, a person must not deal with a GMO unless the dealing has been licensed, is a notifiable low risk dealing, is on the GMO Register, or is an exempt dealing.

> **32 Person not to deal with a GMO without a licence**
>
> (1) A person is guilty of an offence if:
>
> (a) the person deals with a GMO, knowing that it is a GMO; and
>
> (b) the person knows that the dealing with the GMO by the person is not authorised by a GMO licence or is reckless as to whether or not the dealing is so authorised; and
>
> (c) the person knows that the dealing is not a notifiable low risk dealing or is reckless as to whether or not the dealing is a notifiable low risk dealing; and
>
> (d) the person knows that the dealing is not an exempt dealing or is reckless as to whether or not the dealing is an exempt dealing; and
>
> (e) the person knows that the dealing is not included on the GMO Register or is reckless as to whether or not the dealing is included on the GMO Register.
>
> (2) An offence under subsection (1) is punishable on conviction by whichever of the following applies:
>
> (a) in the case of an aggravated offence— imprisonment for 5 years or 2,000 penalty units;

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143 *Gene Technology Act 2000* (Cth) ss 146(4), (5).

144 *Gene Technology Act 2000* (Cth) s 147.

145 *Gene Technology Act 2000* (Cth) s 32.

(b) in any other case— imprisonment for 2 years or 500 penalty units.

27. The Act also creates a strict liability offence for unauthorised dealings with GMOs.[146]

28. In addition to the general prohibition on unauthorised dealings created by sections 33 and 34, the Act also establishes offences related to breach of conditions associated with authorised dealings. In relation to conditions attached to GMO licences, the Act provides that the holder of a GMO licence, or a person covered by a GMO licence, must not take an act or make an omission that would contravene a condition of the licence: ss 34, 35. The Act also creates offences for dealings with GMOs that are on the GMO Register or that are notifiable low risk dealings, where the dealing contravenes any conditions related to such dealings: ss 36, 37.

29. The Act also creates a number of other accompanying offences, for example prohibiting the disclosure of confidential commercial information (CCI);[147] prohibiting the giving of false or misleading information to the Regulator;[148] and prohibiting the interference with dealings with GMOs.[149]

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[146] *Gene Technology Act 2000* (Cth) s 33.

[147] *Gene Technology Act 2000* (Cth) s 187.

[148] *Gene Technology Act 2000* (Cth) s 192.

[149] *Gene Technology Act 2000* (Cth) s 192A.

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