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Inquiries about the content of this report may be directed to the Regulatory Support Unit, Regulatory Practice and Compliance Branch, Office of the Gene Technology Regulator.
Letter of Transmittal

Hon Dr David Gillespie MP
Assistant Minister for Rural Health
Parliament House
Canberra ACT 2600

Dear Minister

I am pleased to present to you the annual report on the Operations of the Gene Technology Regulator covering the period 1 July 2015 to 30 June 2016.

The annual report details the operations of the Gene Technology Regulator as per the reporting requirements in section 136(1A) of the *Gene Technology Act 2000* (the Act) and against the performance indicators contained in Outcome 7 (Health Infrastructure, Regulation, Safety and Quality) of the Department of Health Portfolio Budget Statements for the period 1 July 2015 to 30 June 2016.

The annual report has been prepared in accordance with section 136(1) of the Act, which requires that, as soon as practicable after the end of each financial year, an annual report on the operations of the Regulator during that year be prepared and given to the Minister.

Section 136(2) of the Act requires you to present this report to each house of parliament within 15 sitting days of that house after the day you are given the report.

Yours sincerely

Dr Raj Bhula
Gene Technology Regulator
30 September 2016
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OFFICE OF THE
GENE TECHNOLOGY
REGULATOR
OUR VISION
To be a trusted and respected regulator of gene technology safeguarding the Australian people and the environment.

OUR MISSION
Dedicated to ensuring that genetically modified organisms are safely managed in Australia.

OUR ROLE
To protect the health and safety of people and the environment by identifying risks posed by, or as a result of, gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms.
Strategic objectives

- To deliver efficient and effective regulation that protects people and the environment, and encompasses regulatory decisions and activities (science, compliance, performance) that are evidence based, outcome focused, transparent, and consistent and defensible.

- To provide a safe, respectful and inclusive workplace that is productive and professionally rewarding.

- To inform and engage effectively with our stakeholders so they understand and respect our decisions.

- To ensure our governance arrangements are robust, exemplify best practice and fulfill all legal obligations.

Enabling strategies

- Sound science
- Effective compliance
- Good governance
- Capable, qualified staff
- Clear communication

Outcomes

The Office of the Gene Technology Regulator contributes to Program 7.7 (Regulatory Policy) in Outcome 7 (Health Infrastructure, Regulation, Safety and Quality) of the 2015–16 Department of Health Portfolio Budget Statements.

Our agency outcomes, as set out in the Office of the Gene Technology Regulator Strategic Plan 2013–16, are as follows.

- A high-performing organisation that fulfils the requirements of the legislation, is respected as a regulator, can adapt to government imperatives, is responsive to stakeholders’ concerns, and anticipates change.

- Regulatory decisions that are transparent, consistent, defensible and evidence based.

- People that are skilled, productive and professional.

- A cooperative and compliant regulated community that engages with the regulatory system.
Our people

As at 30 June 2016, the Office of the Gene Technology Regulator comprised 50 scientific, legal, policy, professional and administrative staff. We value our people, and seek to attract and retain appropriately qualified and skilled people by providing an environment that builds capability, motivates, inspires and supports.

Our values

- Professional
- Transparent
- Accountable
- Proactive
- Collaborative
- Responsive
- Respectful
- Inclusive
- Ethical
About this report

This annual report is prepared in accordance with the annual reporting requirements in section 136 of the *Gene Technology Act 2000* (the Act). Subsection 136(1A) of the Act requires that the report include information on:

- Genetically modified organism (GMO) licences issued during the financial year
- Breaches of conditions of a GMO licence that have come to the attention of the Gene Technology Regulator (the Regulator) during the financial year
- Emergency dealing determinations (EDDs) made by the minister during the financial year
- Any breaches of conditions of an EDD that have come to the Regulator's attention during the financial year
- Auditing and monitoring of dealings with GMOs under the Act by the Regulator or an inspector during the financial year.

The report describes the roles and responsibilities of the Regulator and the OGTR. It provides a picture of the OGTR’s performance over the past 12 months. It is also a formal accountability document that summarises our performance against the deliverables and key performance indicators contained in Outcome 7 (Health Infrastructure, Regulation, Safety and Quality) of the 2015–16 Department of Health Portfolio Budget Statements (PBS).

Note: The 2015–16 annual report of the Australian Government Department of Health also contains information about the OGTR. This includes the OGTR financial statements, which are consolidated into the department's financial statements.
The report contains four chapters and a number of appendices. The chapters are organised as follows.

- Chapter 1, ‘Gene Technology Regulator’s review’, summarises the OGTR’s activities over the past year, including major achievements, and the outlook for the coming year.

- Chapter 2, ‘Corporate overview’, describes the OGTR’s corporate governance arrangements.

- Chapter 3, ‘Operational performance’, describes the OGTR’s achievements against the priorities for 2015–16. It discusses deliverables and performance targets achieved for assessments and approvals, monitoring and compliance, consultation with stakeholders, and international engagements. It also provides information on other activities relating to the Regulator’s statutory functions, as prescribed by the Act. It summarises the classes of dealings with GMOs, processes for authorisations, and statutory timeframes. Classes of dealings with GMOs are defined in the Act, the Gene Technology Regulations 2001, and corresponding state and territory laws. This chapter concludes with a summary of performance against the reporting structure set out in the 2015–16 PBS.

- Chapter 4, ‘Management and accountability’, provides an overview of the OGTR’s resource management practices and adherence to Australian Government accountability principles.

The appendices provide a range of statistical and other information, including information needed for compliance with annual reporting requirements. The appendices also contain detailed information on the history and structure of the gene technology regulatory system, types of GMO dealings and the assessment processes.

Note: Unless otherwise stated, all information provided in this report is sourced from the OGTR.
CHAPTER 1
Gene Technology
Regulator’s review
During 2015–16 the Office of the Gene Technology Regulator (OGTR) continued its effective and efficient delivery of Australia’s national gene technology regulatory system.

While the focus has been on successfully meeting all operational targets, staff have also laid the groundwork in preparation for future regulatory challenges associated with advancements in both gene technologies and the use of these technologies in diverse and new ways.
Applications and licences

Comprehensive risk assessments and risk management plans (RARMPs) were published, and stakeholders were consulted on nine licence approvals for release of genetically modified organisms (GMOs) into the environment. These were:

- three field trials of genetically modified (GM) crop plants (sugarcane, cotton and wheat)
- a clinical trial of a GM virus for cancer treatment
- three commercial releases of GM plants (two types of canola and importation of GM carnations as cut flowers)
- a commercial GM influenza vaccine for human use, and a commercial GM virus for cancer treatment.

Applications for human therapeutics reflect a very pertinent application of gene technology. Although the variety of application types has remained the same as last year, we have noted an increase in the number of human therapeutics that advanced from testing and clinical trial stages to commercialisation.

In addition, seven GMO licence applications for work in contained facilities based on RARMPs were approved. Of the GMO licences approved for work in contained facilities:

- five were for development or testing of potential vaccines or other treatments for human disease
- one was for research into pathogenesis and fungicide resistance in fungal plant pathogens
- one was for research into toxin gene/protein function.

The OGTR received 751 low risk dealing notifications during 2015–16. These were predominantly for research work.

At the close of the year, the OGTR was considering a number of applications:

- two for commercial release of GM cotton
- one for a clinical trial of a GM influenza vaccine
- five for work in contained facilities.
Monitoring activities

To ensure that any risks to human health and the environment associated with GMOs continue to be minimised, the OGTR has actively monitored licence holders for compliance with the requirements set out in their licences. In 2015–16, OGTR inspectors exceeded operational targets by inspecting 46% of field trial sites to monitor compliance with licence conditions. Sites were inspected in New South Wales, the Northern Territory, Queensland, Victoria and Western Australia. Crops inspected included GM canola, wheat, barley, cotton, sugarcane, banana and safflower. High levels of compliance by licence holders were reported.

The OGTR also inspected 21% of higher-level containment facilities to ensure compliance with certification conditions. These inspections focused on the integrity of the physical structure of the facility and on the general laboratory practices followed. Again, high levels of compliance by licence holders were found.

Stakeholder engagement

Openness and transparency are the hallmarks of the gene technology regulatory scheme. We continued to consult with the general public, scientific experts, regulated organisations, other government regulatory agencies, and the states and territories on all licence applications for release of GMOs into the environment. The Department of Health Twitter account was used to notify the public about new applications for release of GMOs, opportunities to comment on consultation RARMPs, and licences issued for release of GMOs. The OGTR maintains a comprehensive website that provides extensive information on the regulatory system and the decisions made by the Regulator. This information includes copies of the full RARMPs for each licensed release of a GMO into the environment, and a number of fact sheets on relevant issues.

Continued engagement through bilateral arrangements with other Australian Government agencies has again supported efficient and comprehensive assessment of GMOs and GM products. Regulatory harmonisation and the need to address regulation of new and emerging technologies has been a focus both nationally and internationally.

The OGTR actively participated in the Regulatory Science Network (RSN) and the Regulators Forum, which provided excellent opportunities for information exchange and collaboration between agencies. One of the highlights was the RSN annual event on ‘Assessing and determining risk, including that concerning new technologies, when there is uncertainty and incomplete data’. Staff also participated in an RSN co-sponsored symposium on risk governance (with the Society for Risk Analysis) and a workshop on gene drive technology (with CSIRO).
Efficient and effective regulation

A continued focus on reform has ensured that our regulatory practices remain risk-based—that is, the level of regulatory oversight is proportionate to the level of risk posed by the activity. We also continuously review our processes and guidance to regulated stakeholders to ensure our practices remain effective, efficient and timely.

The OGTR has participated in a number of meetings with the Department of Agriculture and Water Resources (DAWR) to explore opportunities to reduce the regulatory burden on stakeholders subject to joint oversight—that is, stakeholders who have facilities that are both certified by the OGTR and approved by DAWR. One of the outcomes of these meetings is a pilot project to assess potential benefits to stakeholders from joint inspections by the OGTR and DAWR. This pilot project is currently continuing between the two agencies.

This year, the regulated community was consulted on a streamlined new application form for commercial release of GMOs. This new form is the culmination of a significant amount of work in identifying relevant information required to underpin a rigorous risk assessment. It not only provides guidance for applicants on data requirements but also aims to improve the process and reduce regulatory impacts for applicants. The form will be made available on the OGTR website.

The Gene Technology Act Amendment Bill 2015 was passed in September 2015. This Bill gave effect to minor and technical amendments that were agreed to in the 2013 response by the Australian, state and territory governments to the 2011 review of the Act. The changes are expected to reduce regulatory burden for the regulated community.

Advances in genetic modification techniques have been rapid over the last few years, and the new techniques are often more specific, more targeted and cheaper than conventional genetic modification techniques. To address how these new technologies should be regulated, the OGTR has worked hard over the last year to develop a set of options for consultation in 2016–17.

International harmonisation and capacity building

Our active participation in international forums ensures that Australia’s GMO regulatory scheme takes account of new developments in regulation and science. International engagement also informs best practice based on Australia’s practical experience of administering efficient and effective GMO regulation. Our science-based approach to risk assessment is highly regarded internationally.

The OGTR actively participated in international efforts to harmonise regulatory oversight of work with GMOs. During the year, we were involved in a number of international meetings and provided ongoing input to the Organisation for Economic Co-operation and Development (OECD) Working Group on Harmonisation of Regulatory Oversight in Biotechnology and its Steering Group on Environmental Considerations. We also continued to contribute to Australia’s engagement in the United Nations Convention on Biological Diversity and the United Nations Cartagena Protocol on Biosafety through our involvement in an expert forum and in conjunction with the Department of Foreign Affairs and Trade and DAWR.
The OGTR was invited to present to government agencies responsible for gene technology in Malaysia, India, Japan and Korea on how we operate the gene technology regulatory scheme, including how we apply our process of risk analysis in the assessment of GMOs. Four visiting delegations were hosted by the OGTR this year. Members of the Ghanaian Ministry of Environment, Science and Technology and the Ugandan National Council for Science and Technology visited Australia to gain firsthand experience of the operation of the Australian gene technology scheme. Several officials from the Bangladeshi Department of Environment and the Philippine Department of Science and Technology visited the OGTR to understand the Australian gene technology regulatory scheme and its administration.

Our people

The ongoing commitment and dedication of OGTR staff has been essential in meeting our statutory timeframes and engaging effectively with our stakeholders. In recognition of this commitment, the Regulator’s Achievement Award was presented to the Application Entry Point team for their outstanding contribution to the work of the OGTR.

Staff have enthusiastically embraced the Department of Health’s Behaviours in Action policy, and this is reflected in staff survey results showing high levels of both participation and satisfaction. The OGTR also participated in communities of practice established jointly with the Therapeutic Goods Administration (TGA) and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which have increased collaboration and information sharing between the agencies.

Challenges ahead

A major challenge is maintaining efficient and effective regulation of new gene technologies, due to the rapid pace of science and innovation in this area. The technical review of the Gene Technology Regulations 2001, which commenced in 2015–16, is looking specifically at these new technologies. This review, together with the five-yearly review of the Act, will ensure the national regulatory scheme continues to be effective, risk-based and based on scientific principles.
CHAPTER 2
Corporate overview
This chapter provides an overview of the corporate governance arrangements for the Gene Technology Regulator (the Regulator) and a description of the organisational structure of the Office of the Gene Technology Regulator (OGTR).

It also describes the OGTR’s human resource management practices, and our financial reporting arrangements.
Corporate governance

The Regulator is a statutory office holder with specific powers and functions under the Act (see Appendix 1 for background information about the Act and its governance). In exercising these functions, the Regulator is directly responsible to the Australian Parliament. During 2015–16 the Assistant Minister for Health had portfolio responsibility for matters relating to the OGTR, which is part of the Australian Government Department of Health. The Secretary of the department provides staff to the OGTR under section 133 of the Act; these staff are funded by the Gene Technology Special Account to provide administrative and scientific support to the Regulator.

The OGTR has an ongoing head of agreement in place with the department to access a range of business management and reporting services directly through the Shared Services Centre. The services include information technology, financial reporting and accounting, human resources management, ministerial support, and property management. The cost of these services is reviewed annually.

The employment framework for the OGTR is the Public Service Act 1999. Staff are covered by the department’s enterprise agreement, governance policies and practices. These include application of appropriate ethical standards under the Australian Public Service Values and Code of Conduct; compliance with Australian Government freedom of information (FOI), privacy, and work health and safety legislation; and compliance with the National Disability Strategy and the Australian Government workplace diversity policy.

The Public Governance, Performance and Accountability Act 2013 sets out the financial framework for OGTR governance. Integrity in financial reporting is maintained through internal audit arrangements as part of the head of agreement with the department. The OGTR complies with the Commonwealth Fraud Control Guidelines 2011, as required by the department. More information is available in the 2015–16 Department of Health Annual Report.

OGTR internal policies and practices cover the physical security and protection of confidential commercial information received from applicants as required under the Act.

The OGTR maintains its own business risk management plan, against which senior OGTR staff report periodically.
Organisational structure

The OGTR comprises an Evaluation Branch and a Regulatory Practice and Compliance Branch. Sections in these branches focus on particular activities relating to regulation of gene technology (Figure 1).

Figure 1: Organisational structure of the OGTR, 2015–16

In April 2016 the Regulatory Practice and Compliance Branch was restructured: the Monitoring Section was combined with the Compliance and Investigation Section to form the Monitoring and Compliance Section.

The Legal Officer provides legal advice to the Regulator and the OGTR on the operation of Commonwealth, state and territory laws affecting their functions, including setting licence conditions and handling confidential commercial information. The Legal Officer is also responsible for training OGTR staff on legal issues and assists in responding to FOI requests.
Gene Technology Regulator

The Regulator is an independent statutory office holder who administers the nationally consistent scheme for regulating gene technology, comprising the Act and corresponding state and territory laws. In administering the gene technology regulatory system, the Regulator has specific responsibility 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 (GMOs).

Dr Jane Cook was the acting Regulator for most of the reporting period, from 23 November 2015 to 30 June 2016.

In June 2016 the department announced the appointment as Gene Technology Regulator of Dr Raj Bhula for a period of five years commencing on 18 July 2016.

Dr Bhula has a background of over 20 years experience in the regulation of pesticides in Australia. She was the Executive Director of Scientific Assessment and Chemical Review at the Australian Pesticides and Veterinary Medicines Authority (APVMA) and Program Manager Pesticides at APVMA for almost 10 years. Dr Bhula has represented Australia at international expert committees such as the Codex Committee for Pesticide Residues and contributed to technical groups of the OECD Working Group on Pesticides. Much of this work included the development of technical policy and risk assessment methodologies. Before joining the Australian Public Service, Dr Bhula was a research associate and part-time lecturer at the Australian Defence Force Academy, University of New South Wales, in Canberra.

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Regulatory Practice and Compliance Branch

Dr Vidya Jagadish has been the acting Assistant Secretary, Regulatory Practice and Compliance Branch since the transfer of Dr Robyn Cleland to the Department of Agriculture and Water Resources in mid-February 2016. Dr Jagadish joined the then interim Office of the Gene Technology Regulator in 2000, where she worked as an evaluator and from 2003 managed the Plant Evaluation Section. As acting Assistant Secretary she is responsible for regulatory practice policy, oversight of monitoring and compliance activities, corporate business and regulatory support, performance reporting, coordination of expert advisory committees, stakeholder communication and international cooperation activities.

The Regulatory Practice and Compliance Branch is made up of the Monitoring and Compliance Section, the Regulatory Practice Section and the Regulatory Support Unit.

The Monitoring and Compliance Section monitors and inspects dealings with GMOs conducted at field trial sites and within certified contained facilities. The aim of these activities is to ensure that dealings with GMOs comply with legislative obligations and are consistent with the object of the Act. Activities focus on monitoring compliance with conditions of licences or other instruments and restrictions, and managing risks in relation to any potential breach of conditions. Audits, reviews and investigations of organisations and individuals involved in GMO dealings (including self-reported incidents and allegations made by third parties) are conducted to ensure that any dealings are undertaken in accordance with the Act.

The branch’s Regulatory Practice Section works collaboratively with the Best Practice Regulation Branch of the department, it provides technical support and delivers operational policies. It supports the OGTR by providing secretariat services to the Gene Technology Ethics and Community Consultative Committee and the Gene Technology Technical Advisory Committee, coordinating ministerial correspondence and briefings and contributions to international regulatory harmonisation activities. It serves as the contact point for other Australian Government agencies and national and international organisations involved in regulating GMOs.

In partnership with the department, the Regulatory Support Unit undertakes corporate and administrative functions, including financial reporting, budget reporting, account processing, procurement, human resource management, staff training and coordination, accommodation, and property and asset management. It produces the annual report, staffs the freecall number (1800 181 030), coordinates responses to general email inquiries (to ogtr@health.gov.au) and manages the OGTR website. It has developed the Post Release Review Framework to guide ongoing oversight of GMOs that have been released commercially or as general releases.
Evaluation Branch

Dr Michael Dornbusch heads the Evaluation Branch. Dr Dornbusch first joined the OGTR in 2003 and managed the Plant Evaluation Section from December 2006 until his appointment as Assistant Secretary in September 2009. Dr Dornbusch’s responsibilities encompass management of the evaluation of licence applications and other authorisations relating to dealings with GMOs, as well as science-related projects that maintain and improve the technical capabilities of the OGTR.

The Evaluation Branch is made up of the Application Entry Point, the Contained Dealings Evaluation Section, the Plant Evaluation Section and the Principal Regulatory Scientist.

All applications are received and acknowledged through the Application Entry Point. Staff in this area also process accreditation applications, manage databases, provide trend and statistical analyses of application receipts and authorisations, report on workflows and undertake business improvement and efficiency initiatives.

The Contained Dealings Evaluation Section prepares risk assessment and risk management plans (RARMPs) in response to applications for dealings not involving intentional release of GMOs into the environment (DNIRs)—also known as ‘contained dealings’—and applications for non-plant dealings involving intentional release (DIRs). The section also processes applications for certification of containment facilities. This includes inspecting high-level and large-scale facilities, reviewing certification guidelines, and providing advice to accredited organisations and institutional biosafety committees on the classification of dealings with GMOs.

The Plant Evaluation Section assesses applications for DIRs for genetically modified (GM) plants and prepares RARMPs for the Regulator’s consideration and for consultation with key stakeholders, including the public. The section gathers scientific data and publishes reference documents to inform the risk assessment process. It also provides technical advice to the Regulator, other sections of the OGTR and stakeholders.

The Principal Regulatory Scientist develops and manages science-related projects, including ongoing review and implementation of the Risk Analysis Framework. The role includes providing scientific advice, training staff in risk analysis, and providing input to policies and processes associated with risk analysis, organising seminars, supporting contributions to national and international regulatory harmonisation programs, and overseeing the OGTR library.
Financial performance

The OGTR is funded through the Gene Technology Account, which is a Special Account for the purposes of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act). The Gene Technology Special Account receives all monies appropriated by the parliament and makes payments for expenses incurred in performing the Regulator’s functions. The executive and section managers are responsible for ensuring appropriate use of resources. The Regulatory Support Unit coordinates financial reporting and management.

The OGTR prepares accrual accounting financial statements in accordance with Department of Finance guidelines. The Australian National Audit Office audits these statements each year. The audited statements showing receipts and expenditure of the OGTR Special Account are then consolidated into the annual financial statements of the Department of Health for the year ended 30 June.

The 2015–16 federal budget measures for the OGTR are published in the 2015–16 Department of Health PBS and are summarised here in Table 1.

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CHAPTER 3
Operational performance
The first part of this chapter outlines the types of dealings with genetically modified organisms (GMOs) that are defined by the Act, the Gene Technology Regulations 2001, and corresponding state and territory laws. It summarises classes of dealings, the process for authorisations, and the statutory timeframe for consideration of each type of application. This chapter also reports on other statutory functions, such as certification and accreditation, that help the Gene Technology Regulator (the Regulator) manage risks to the health and safety of people and the environment.

The second part of the chapter describes the operational performance in relation to these activities as required by subsection 136(1A) of the Act and to the performance indicators in Outcome 7 (Health Infrastructure, Regulation, Safety and Quality) of the 2015–16 Department of Health Portfolio Budget Statements (PBS).
Statutory functions and regulatory processes

**GMOs, dealings and authorisations**

The Act defines a GMO as any organism that has been modified by gene technology, offspring derived from such an organism, or anything declared as a GMO in the Regulations.

Section 10 of the Act defines ‘deal with’, in relation to a GMO, as:

(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
(h) transport the GMO
(i) dispose of the GMO

and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).

The Act forms the basis of a prohibitory scheme that makes dealing with a GMO a criminal offence unless, as outlined in section 31, the dealing is:

- an exempt dealing
- a notifiable low risk dealing (NLRD)
- authorised by a licence
- included on the GMO Register
- specified in an emergency dealing determination (EDD).

Exempt dealings and NLRDs are defined in the Regulations. They are not considered to pose risks to either people or the environment that require detailed assessments by the Regulator. These kinds of dealings with GMOs involve routine laboratory techniques that have been used safely for many years and pose minimal risk when performed in accordance with the requirements of the Regulations.

Dealings authorised by a licence are further categorised into dealings not involving intentional release into the environment (DNIRs, which are conducted in contained facilities), dealings involving intentional release into the environment (DIRs) and inadvertent dealings.
For both DNIRs and DIRs, the legislation requires the Regulator to prepare a risk assessment and risk management plan (RARMP) as part of the process of making a decision on whether to issue or refuse a licence (sections 47 and 50 of the Act, respectively). Part 5 of the Act also allows the Regulator to grant a temporary licence (no longer than 12 months) to a person who finds that they are inadvertently dealing with an unlicensed GMO, so that they can safely dispose of the GMO.

To be included on the GMO Register, the dealings with the GMO must first have been licensed by the Regulator. The Regulator must be satisfied that the risks associated with the dealing are minimal and that it is no longer necessary for people undertaking the dealings to be covered by a licence.

The provision for emergency dealing determinations (EDDs) in Part 5A of the Act gives the minister the power to expedite an approval of dealings with a GMO in an emergency.

Table 2 summarises the classes of dealings, their authorisation requirements and the extent of containment required to conduct the dealing.

The licensing system is centred on a rigorous process of risk assessment based on scientific evidence. For DIRs, the legislation requires consultation with a wide range of experts, agencies and authorities, as well as the public. These include the Gene Technology Technical Advisory Committee, state and territory governments, Australian Government agencies prescribed in the Regulations, the Minister for the Environment and Energy, and relevant local councils.

The Regulator may, directly or on application, vary an issued licence or other instrument. Variations involve changes to conditions applied to a licence or other instrument. The Regulator must not vary a licence unless satisfied that any risks posed by the dealings to be varied are able to be managed to protect the health and safety of people and the environment. The Regulator cannot vary a DNIR licence to authorise intentional release of a GMO into the environment.

More information on the various classes of GMO dealings and their assessment processes is in Appendix 2.\(^2\)

An organisation undertaking dealings with GMOs authorised under a licence must be accredited by the Regulator. Accreditation of organisations and certification of individual physical containment facilities helps to manage risks that may be associated with dealings involving GMOs (see Appendix 2).

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\(^2\) See also the OGTR website at www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmorec-index-1
<table>
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<th>Category</th>
<th>Authorisation requirements</th>
<th>Containment</th>
</tr>
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</table>
| DIR (except for limited and controlled releases) | Licence required  
Review of applications by IBC  
Consultation on application  
Preparation of RARMP  
Consultation on RARMP and licence decision by Regulator | Containment measures may be required, determined case by case, and other licence conditions will apply |
| DIR (limited and controlled releases) | Licence required  
Review of applications by IBC  
Preparation of RARMP  
Consultation on RARMP and licence decision by Regulator | Containment measures will be required, based on size and scope of release sought by applicant, and other licence conditions will apply |
| DNIR                             | Licence required  
Review of applications by IBC  
Preparation of RARMP  
Licence decision by Regulator | Usually PC2 (or higher) certified facilities |
| EDD                              | Licence not required  
Determination by minister, subject to advice of threat and utility of GMO from competent authorities, and risk assessment advice from Regulator | Containment measures may be included in EDD conditions |
| Exempt                           | Licence not required  
Dealings classified as exempt are scheduled in the Regulations | No intentional release to the environment |
| GMO Register                     | Licence not required  
Dealings must have been previously licensed  
Review of relevant information by Regulator | Containment measures may be required |
| Inadvertent dealing              | Licence required  
Licence decision by Regulator only for the purposes of disposal of the GMO | Containment and/or disposal measures will apply |
| NLRD                             | Licence not required  
Dealings classified as NLRDs are scheduled in Regulations  
Conduct of NLRDs requires prior assessment by IBC to confirm proper classification  
Notified in annual report | Usually PC1- or PC2-certified facilities |

DIR = dealing involving intentional release of a genetically modified organism into the environment; DNIR = contained dealing with a genetically modified organism not involving intentional release into the environment; EDD = emergency dealing determination; GMO = genetically modified organism; IBC = institutional biosafety committee; NLRD = notifiable low risk dealing; PC1(2) = physical containment level 1(2); RARMP = risk assessment and risk management plan.
**Timeframes**

Under section 43(3) of the Act, the Regulator must issue, or refuse to issue, a licence within a time limit prescribed by the Regulations. The Regulations also prescribe a timeframe for consideration of applications to accredit organisations and to certify facilities. These statutory timeframes are shown in Table 3. They do not include weekends or public holidays in the Australian Capital Territory. They also do not include periods when the Regulator has sought more information from the applicant. The decision-making process cannot proceed until the information is provided. In these instances, the statutory timeframe clock is regarded as stopped.

<table>
<thead>
<tr>
<th>Category</th>
<th>Timeframe (working days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accreditation</td>
<td>90 (r. 16)</td>
</tr>
<tr>
<td>Certification</td>
<td>90 (r. 14)</td>
</tr>
<tr>
<td>DIR—limited and controlled, no significant risk</td>
<td>150 (r. 8)</td>
</tr>
<tr>
<td>DIR—limited and controlled, significant risk</td>
<td>170 (r. 8)</td>
</tr>
<tr>
<td>DIR—except for limited and controlled releases</td>
<td>255 (r. 8)</td>
</tr>
<tr>
<td>DNIR</td>
<td>90 (r. 8)</td>
</tr>
<tr>
<td>Licence variation</td>
<td>90 (r. 11A)</td>
</tr>
</tbody>
</table>

DIR = dealing involving intentional release of a genetically modified organism into the environment; DNIR = contained dealing with a genetically modified organism not involving intentional release into the environment; r = regulation

**Operational achievements**

This section describes the achievements of delivering national gene technology regulation and performance against Outcome 7 (Health Infrastructure, Regulation, Safety and Quality) of the 2015–16 Department of Health PBS. It provides details of achievements on deliverables and performance indicators in the key areas of:

- assessments and authorisations under the Act
- monitoring of GMOs
- compliance with the Act
- consultation with stakeholders
- cooperation with relevant regulatory agencies
- operational changes arising from the 2013 response by all Australian governments to the 2011 review of the Act.
**Assessments and approvals**

Information on performance against deliverables and key performance indicators, as set out in the 2015–16 Department of Health PBS, is summarised in the second part of this chapter.

In 2015–16, the OGTR received 1571 applications and notifications, as defined under the Act (Table 4). The timing and volume of applications each year can be influenced by a range of factors, including research grant funding cycles, seasonal agricultural factors and changes to legislation.

**Table 4: Applications and notifications, 2015–16**

<table>
<thead>
<tr>
<th>Application type</th>
<th>Received</th>
<th>Withdrawn</th>
<th>Approved</th>
<th>Refused</th>
<th>Ceased consideration</th>
<th>Under consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accreditation</td>
<td>3</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>CCI declaration for DIR licence</td>
<td>7</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>CCI declaration for DNIR licence</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>CCI declaration for NLRD notification</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>CCI declaration for other information</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Certification</td>
<td>150</td>
<td>4</td>
<td>125</td>
<td>0</td>
<td>0</td>
<td>42</td>
</tr>
<tr>
<td>DIR licence</td>
<td>8</td>
<td>1</td>
<td>9</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>DNIR licence</td>
<td>9</td>
<td>0</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Lifting suspension of certification</td>
<td>25</td>
<td>1</td>
<td>23</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>NLRD notification</td>
<td>751</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Surrender of accreditation</td>
<td>5</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Surrender of certification</td>
<td>100</td>
<td>1</td>
<td>95</td>
<td>0</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Surrender of DIR licence</td>
<td>13</td>
<td>0</td>
<td>11</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Surrender of DNIR licence</td>
<td>11</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Suspension of certification</td>
<td>73</td>
<td>1</td>
<td>72</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Licences for dealings involving intentional release of GMOs

Decisions on DIR licence applications have a statutory time limit of 255 working days, unless the application is for a limited and controlled release. The statutory time limit for decisions on applications for limited and controlled release is 150 working days, or 170 working days if the proposed dealings may pose a significant risk to the health and safety of people or to the environment.

The Regulator issued nine DIR licences during 2015–16 (Table 5) and was considering a further five licence applications at 30 June 2016. Seven of the DIR licences issued related to applications received before 1 July 2015.

All of the licence decisions were made within statutory timeframes (see ‘Timeframes’ above). There were no appeals of decisions made under the gene technology legislation.

Four of the DIR licences issued in 2015–16 were for limited and controlled release (e.g. field trials or clinical trials), and five were for commercial releases. Three of the limited and controlled release licences and three of the commercial release licences related to crop plants with a variety of introduced traits. The other limited and controlled release was for a clinical trial of a GM virus for cancer treatment. The other two commercial release licences were for an influenza vaccine and a GM virus for cancer therapy. Details of the traits introduced into the organisms for release are provided in Table 5.
Of the nine DIR licences issued in 2015–16, six were issued to private companies, two to government agencies and one to a university (Table 5). Of the 122 DIR licences issued since commencement of the Act, 66 (54%) have been to private companies, 42 (34%) to government agencies and 14 (12%) to universities (Figure 2).

Table 5: DIR licences issued, 2015–16

<table>
<thead>
<tr>
<th>DIR no.</th>
<th>Applicant</th>
<th>Parent organism</th>
<th>Introduced trait</th>
<th>Type of release</th>
<th>Received</th>
<th>Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIR-132</td>
<td>Amgen Australia Pty Ltd</td>
<td>Herpes simplex virus</td>
<td>Attenuation; enhanced immune response</td>
<td>Commercial</td>
<td>8-8-2014</td>
<td>10-8-2015</td>
</tr>
<tr>
<td>DIR-134</td>
<td>International Flower Developments Pty Ltd</td>
<td>Carnation</td>
<td>Flower colour</td>
<td>Commercial</td>
<td>30-10-2014</td>
<td>5-10-2015</td>
</tr>
<tr>
<td>DIR-135</td>
<td>The University of Queensland</td>
<td>Sugarcane</td>
<td>Enhanced sugar content</td>
<td>Limited and controlled</td>
<td>5-1-2015</td>
<td>3-8-2015</td>
</tr>
<tr>
<td>DIR-136</td>
<td>CSIRO</td>
<td>Cotton</td>
<td>Fibre quality</td>
<td>Limited and controlled</td>
<td>5-2-2015</td>
<td>2-9-2015</td>
</tr>
<tr>
<td>DIR-137</td>
<td>AstraZeneca Pty Ltd</td>
<td>Influenza virus</td>
<td>Antigen expression; attenuation</td>
<td>Commercial</td>
<td>3-2-2015</td>
<td>14-1-2016</td>
</tr>
<tr>
<td>DIR-138</td>
<td>Bayer CropScience Pty Ltd</td>
<td>Canola</td>
<td>Herbicide tolerance; hybrid breeding system</td>
<td>Commercial</td>
<td>30-3-2015</td>
<td>16-3-2016</td>
</tr>
<tr>
<td>DIR-139</td>
<td>Pioneer Hi-Bred Australia Pty Ltd</td>
<td>Canola</td>
<td>Herbicide tolerance</td>
<td>Commercial</td>
<td>18-5-2015</td>
<td>18-3-2016</td>
</tr>
<tr>
<td>DIR-140</td>
<td>Clinical Network Services Pty Ltd</td>
<td>Vaccinia virus</td>
<td>Attenuation; enhanced immune response</td>
<td>Limited and controlled</td>
<td>23-7-2015</td>
<td>10-3-2016</td>
</tr>
</tbody>
</table>

DIR = dealing involving intentional release of a genetically modified organism into the environment
Licences for dealings not involving intentional release of GMOs

DNIR licences authorise dealings with GMOs that are conducted in laboratories and other physical containment facilities and may pose risks that require management through specific licence conditions. For DNIR licence applications, the Regulator must make a decision within the statutory timeframe of 90 working days.

In 2015–16, the Regulator issued seven DNIR licences (see Table 6). All approvals were made within the statutory time limit. The Regulator was considering a further five DNIR applications at 30 June 2016.
Table 6: DNIR licences issued, 2015–16

<table>
<thead>
<tr>
<th>DNIR no.</th>
<th>Applicant</th>
<th>Title</th>
<th>Received</th>
<th>Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>DNIR-557</td>
<td>Monash University</td>
<td>An investigation of a single intranasal administration of the interferon alpha compound ‘DEF201’ in longtail macaques</td>
<td>2-3-2015</td>
<td>3-7-2015</td>
</tr>
<tr>
<td>DNIR-558</td>
<td>St Vincent’s Institute of Medical Research</td>
<td>Generation of protein for structural studies of membrane-bound pore forming toxins</td>
<td>26-3-2015</td>
<td>31-7-2015</td>
</tr>
<tr>
<td>DNIR-559</td>
<td>Amgen Australia Pty Ltd</td>
<td>Evaluation of the efficacy and safety in the treatment of solid tumours with talimogene laherparepvec</td>
<td>29-6-2015</td>
<td>4-11-2015</td>
</tr>
<tr>
<td>DNIR-560</td>
<td>RMIT University</td>
<td>Generation of recombinant toxin molecules</td>
<td>5-8-2015</td>
<td>10-12-2015</td>
</tr>
<tr>
<td>DNIR-561</td>
<td>Griffith University</td>
<td>Development of an alphaviral vector to deliver bioactive factors to bone</td>
<td>6-8-2015</td>
<td>21-12-2015</td>
</tr>
<tr>
<td>DNIR-564</td>
<td>IDT Australia Limited</td>
<td>Phase l/lla study of DVC1-0101 in subjects with intermittent claudication secondary to peripheral artery disease</td>
<td>15-12-2015</td>
<td>29-4-2016</td>
</tr>
<tr>
<td>DNIR-563</td>
<td>Curtin University of Technology</td>
<td>Expression of genes from plant pathogenic fungi into a model fungus, Parastagonospora nodorum</td>
<td>28-10-2015</td>
<td>24-6-2016</td>
</tr>
</tbody>
</table>

DNIR = contained dealing with a genetically modified organism not involving intentional release into the environment

The types of GMO dealings authorised by DNIR licences issued in 2015–16 are research applications, the focus of which is shown in Figure 3.
Of the seven DNIR licences issued in 2015–16, five authorised the development or testing of potential vaccines or other treatments for human disease, one authorised research into pathogenesis and fungicide resistance in fungal plant pathogens, and one authorised research into toxin gene/protein function.

Two of the DNIR licences issued in 2015–16 were issued to private companies, one to a research institute and four to universities.

The types of organisations to which DNIR licences have been issued since commencement of the Act are shown in Figure 4.
**Notifiable low risk dealings**

NLRDs are dealings that have been assessed, based on previous experience and current scientific knowledge, as posing low risk. Dealings with GMOs classified as NLRDs are listed in the Regulations under Schedule 3, Part 1 (NLRDs appropriate for PC1 facilities) and Schedule 3, Part 2 (NLRDs appropriate for PC2 [Part 2.1] and PC3 [Part 2.2] facilities). Conduct of NLRDs does not require prior authorisation from the Regulator, but the dealings must have been assessed by an institutional biosafety committee (IBC) as meeting the NLRD classification, must be conducted in appropriate containment facilities and must comply with other requirements specified in the Regulations. NLRDs must be notified to the Regulator annually. Authority to conduct an NLRD has a five-year time limit.

The Regulator received 751 NLRD notifications during 2015–16. As in past years, notified NLRDs were predominantly for research work. The types of organisations that notified NLRDs to the Regulator in 2015–16 are shown in Figure 5.

*Figure 5: Types of organisations that notified NLRDs in 2015–16*

![Figure 5: Types of organisations that notified NLRDs in 2015–16](image)

NLRD = notifiable low risk dealing

**Dealings placed on GMO Register**

The GMO Register is a list of dealings with GMOs that the Regulator is satisfied pose minimal risk to human health and safety or the environment and can therefore be undertaken by anyone, subject to any specified conditions, without oversight of a licence holder. Sections 78 and 79 of the Act allow the Regulator to place dealings with GMOs on the GMO Register provided they have previously been licensed, pose minimal risks to people or the environment, and are safe for anyone to undertake without the need for a licence. Such determinations are disallowable legislative instruments and must be tabled in parliament.

During 2015–16, the Regulator entered no new listings on the register, received no applications to place dealings on the register and had no applications under consideration.
Emergency dealing determinations

An EDD is a legislative instrument made by the minister under section 72 of the Act to expedite approval of dealings with a GMO in an emergency. The Regulator provides risk assessment and risk management advice to the minister, and administers the EDD, including monitoring for compliance with any EDD conditions.

Before making an EDD, the minister must be satisfied that:

- there is an actual or imminent threat to the health and safety of people or the environment
- the dealings proposed to be specified in the EDD would, or would be likely to, adequately address the threat
- any risks posed by the proposed dealings can be managed to protect the health and safety of people, and the environment.

In relation to the first two points (the threat and addressing the threat), the minister must receive advice from the Commonwealth Chief Medical Officer, Chief Veterinary Officer or Chief Plant Protection Officer. In relation to the third point (management of risks), the minister must receive advice from the Regulator. The states and territories must also be consulted. EDDs have effect for up to six months but may be extended by the minister for additional periods of up to six months at a time, subject to similar requirements to those applying when the EDD is made.

Under the Act, the Regulator has powers to monitor compliance with the conditions of the EDD.

Appendix 2 provides further information about the process for making EDDs, and about EDDs issued under the Act.

During 2015–16, the Regulator did not receive any requests for advice in relation to making EDDs. No EDDs were made, and none were in effect.

To date, one EDD has been issued. This was for the temporary authorisation of equine influenza vaccine. It was issued in September 2007, was extended once and expired in September 2008.

Accreditation of organisations

Organisations may apply to the Regulator for accreditation under section 91 of the Act. The Regulator requires organisations authorised to work with GMOs to remain accredited. To achieve and retain accreditation, the organisation must satisfy the Regulator that it has, or has access to, a properly constituted and resourced IBC, and complies with other requirements of the Regulator’s Guidelines for accreditation of organisations. The Regulator must make a decision on accreditation applications within the statutory timeframe of 90 working days.

At 30 June 2016, 165 organisations were accredited. Accredited organisations are located in all Australian jurisdictions and one is based in the United States (Figure 6).
The profile of the types of organisations accredited by the Regulator has not changed significantly: a large proportion (68%) are primarily publicly funded (Figure 7).

**Figure 6: Organisations accredited at 30 June 2016, by location of headquarters**

**Figure 7: Organisations accredited at 30 June 2016, by type of organisation**
Certification of physical containment facilities

The Regulator may certify facilities to particular containment levels under section 84 of the Act. In accordance with the Regulations, the Regulator must make a decision about applications for certification of physical containment facilities within the statutory timeframe of 90 working days.

Physical containment facilities are classified according to how stringent the measures are for containing GMOs. The classifications relate to the structural integrity of buildings and equipment, and to the handling practices used by people working in the facility. Physical containment level 1 (PC1) facilities are used to contain organisms posing the lowest risk to human health and the environment. PC level 4 (PC4) facilities provide the most secure and stringent containment conditions. The number of facilities certified at 30 June 2016 is listed in Table 7 by facility type and containment level.

During 2015–16, 125 certifications for physical containment facilities were approved (Table 4).

The types of organisations issued with certifications in 2015–16 were predominantly universities (54%), research institutes (19%) and government agencies (14%). This distribution supports the research focus of these types of organisations, where most dealings require physical containment (NLRDs and DNIRs). OGTR-certified physical containment facilities are located in all Australian jurisdictions (Figure 8).

Table 7: Number of facilities certified at 30 June 2016

<table>
<thead>
<tr>
<th>Facility type</th>
<th>PC1</th>
<th>PC2</th>
<th>PC3</th>
<th>PC4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal</td>
<td>242</td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Aquatic</td>
<td>24</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant temperature room</td>
<td>41</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facilitya</td>
<td>288</td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Invertebrate</td>
<td>52</td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Laboratory</td>
<td>1079</td>
<td></td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>Large grazing animal</td>
<td>6</td>
<td>42</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Large scale</td>
<td>18</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plant</td>
<td>163</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>294</td>
<td>1661</td>
<td>33</td>
<td>5</td>
</tr>
</tbody>
</table>

PC = physical containment

* PC1 and PC4 facilities are not categorised into types.

Note: This table excludes facilities for which the certifications were suspended (at the request of the certification holders) as at 30 June 2016.
Figure 8: Physical containment facilities certified at 30 June 2016, by location

Trend data for approval of main types of applications

Fewer than half of the number of accreditations were issued in 2015–16 compared to the previous year (Table 8).

The total number of accredited organisations at 30 June 2016 was 165, slightly down from 168 on 30 June 2015.

The number of certification approvals rose to 125, more than in 2014–15 but fewer than in any other previous year. Even though there was an increase in new applications this reporting period, the number of overall current certifications dropped by 14. This reflects a continuing trend for organisations to consolidate their certified facilities into larger multi-room certifications.

The number of DIRs approved was higher than in any of the previous six years, while DNIR applications were lower. These trends in part reflect progress in development of therapeutic GMOs, with a movement from early stage research and development (conducted under DNIR licences) to clinical trials and commercial release of products containing such GMOs (conducted under DIR licence). Three of the DIR licences approved in 2015–16 were for GMO therapeutics, compared to only one veterinary vaccine and no human therapeutics in 2014–15.
Table 8: Trend data for approval of main types of applications, 2011–12 to 2015–16

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Accreditation</td>
<td>5</td>
<td>8</td>
<td>4</td>
<td>10</td>
<td>4</td>
</tr>
<tr>
<td>Certification</td>
<td>207</td>
<td>199</td>
<td>183</td>
<td>89</td>
<td>125</td>
</tr>
<tr>
<td>DIR</td>
<td>6</td>
<td>4</td>
<td>7</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>DNIR(^a)</td>
<td>11</td>
<td>8(^b)</td>
<td>10(^c)</td>
<td>10(^c)</td>
<td>7</td>
</tr>
<tr>
<td>NLRD</td>
<td>553</td>
<td>677</td>
<td>828</td>
<td>842</td>
<td>751</td>
</tr>
</tbody>
</table>

DIR = dealing involving intentional release of a genetically modified organism (GMO) into the environment; DNIR = contained dealing with a GMO not involving intentional release into the environment; NLRD = notifiable low risk dealing

\(^a\) ‘Approval’ for DNIR refers to the number of licences issued. This can differ from the total number of applications approved when two or more applications are integrated into a single licence.

\(^b\) Correction to the number (10) reported in the 2013–14 report. Three applications were approved and incorporated into a single licence.

\(^c\) Two applications were approved and incorporated into a single licence.
Secondary applications

Confidential commercial information
Applications can be made to the Regulator under section 184 of the Act for specified information that has not previously been made public to be declared CCI. The extent of CCI claims can be the subject of considerable discussion with the applicant and may require the OGTR to independently verify what information is already in the public domain. The Act does not assign a statutory timeframe for the Regulator’s decision on CCI applications, and the evaluation of a licence application may be paused if significant CCI claims need to be resolved.

In 2015–16, the Regulator made four CCI declarations. Decisions on eight CCI applications were pending at 30 June 2016.

Surrenders
Surrender of licences and certifications usually occurs when dealings have concluded. Before surrender is approved, the Regulator must be satisfied that all conditions (such as post-harvest monitoring) have been met, and that any required cleaning and decommissioning of facilities has taken place.

The OGTR received 129 surrender requests in 2015–16 and approved 95 for surrender of certifications of facilities, 11 for surrender of DIR licences, six for surrender of DNIR licences and six for surrender of accreditations.

Variations
The Regulator may initiate variations to instruments issued under the Act (licence, certification or accreditation), and instrument holders may also apply to the Regulator for variations. Variations to licences range from minor administrative changes (such as a change to contact details) to significant changes to dealings (such as a request to grow the GM crop at an additional or new site). Variations may also include evaluation of changes arising from renovations to a certified facility or new methods for handling GMOs.

The Regulator approved 415 variations in 2015–16.

Monitoring genetically modified organisms
This section provides information on the OGTR’s range of inspection activities during 2015–16.
**Inspections of DIR licences**

The OGTR strategy for field trial monitoring draws on accumulated operational experience of compliance risk profiling.²³

During 2015–16, 21 accredited organisations held the 56 DIR licences in force—16 for commercial release of GMOs (12 for crops and four for vaccines), and 40 for limited and controlled release of GMOs (37 for crops and three for vaccines). None of the commercial release licences imposed conditions that necessitated monitoring. The OGTR inspected 15 of the 37 licences for limited and controlled trials of GM crop varieties (which might include a number of trial sites for each licence). No limited and controlled vaccine trials were inspected.

**Outcome of inspection activities**

The OGTR’s operational objective is to monitor at least 20% of all field trial locations of limited and controlled releases each year. A further target within this operational benchmark is to inspect a minimum of 5% of all field trial sites for limited and controlled releases during each quarter of the year.

In 2015–16, the OGTR exceeded both its operational benchmark and its quarterly objective. At the beginning of 2015–16, 102 licensed field trial sites were operating, 39 of which were current and 63 of which were subject to post-harvest monitoring conditions. The OGTR inspected 47 sites in 2015–16 (28 current and 19 post-harvest monitoring sites), representing 46% of total sites as of 1 July 2015, thereby exceeding the target of 20% of field trial sites each year. A breakdown of the number and proportion of sites inspected in 2015–16 is in Table 9.

The numbers of current sites and of sites inspected over the past five years (2011–2016) are in Figure 9.

**Table 9: Number and proportion of DIR field trial site inspections in each quarter of 2015–16**

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Current sites</th>
<th>Post-harvest monitoring sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>July–September 2015</td>
<td>4/39 (10%)</td>
<td>6/63 (10%)</td>
</tr>
<tr>
<td>October–December 2015</td>
<td>5/44 (11%)</td>
<td>4/58 (7%)</td>
</tr>
<tr>
<td>January–March 2016</td>
<td>6/40 (15%)</td>
<td>4/73 (5%)</td>
</tr>
<tr>
<td>April–June 2016</td>
<td>13/32 (41%)</td>
<td>5/77 (6%)</td>
</tr>
</tbody>
</table>

Chapter 3 Operational performance

Figure 9: Number of DIR field trial sites and number inspected each year, 2011–16

![Figure 9: Number of DIR field trial sites and number inspected each year, 2011–16](image)

DIR = dealing involving intentional release of a genetically modified organism into the environment

Types of GM crops inspected

DIR licences in force authorised the limited and controlled release of a range of GM crop and plant types: banana, barley, canola, cotton, Indian mustard, narrow-leafed lupin, perennial ryegrass, safflower, sugarcane, wheat and white clover. Although licences were in force, planting has not occurred in all cases. Canola was the most prevalent GM crop, trialled at 46 sites.

The OGTR inspected 47 field trial sites across seven crop types during 2015–16 (Table 10).

Table 10: Number of licensed DIR trial sites at beginning and end of 2015–16, and number inspected in 2015–16, by crop type

<table>
<thead>
<tr>
<th>Crop type (parent organism)</th>
<th>Trial sites on 1 July 2015</th>
<th>Trial sites on 30 June 2016</th>
<th>Trial sites inspected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Banana</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Canola</td>
<td>34</td>
<td>27</td>
<td>12</td>
</tr>
<tr>
<td>Canola, Indian mustard</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cotton</td>
<td>23</td>
<td>30</td>
<td>10</td>
</tr>
<tr>
<td>Perennial ryegrass</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Safflower</td>
<td>2</td>
<td>9</td>
<td>4</td>
</tr>
<tr>
<td>Sugarcane</td>
<td>20</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>Wheat</td>
<td>2</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Wheat, barley</td>
<td>13</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>White clover</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>102</strong></td>
<td><strong>109</strong></td>
<td><strong>47</strong></td>
</tr>
</tbody>
</table>

DIR = dealing involving intentional release of a genetically modified organism into the environment

Note: Some DIR licences authorise trials with two similar crop species. In this table, trial sites authorised under such licences are listed separately from trial sites authorised under a licence for a single crop species.
**Cycle and status of field trial sites**

During each year, field trials of GM crops undergo significant changes in status. When new trials are planted, they become subject to licence conditions to manage dissemination of the GMO from the trial site. Other trials are harvested and enter a post-harvest monitoring period. Monitoring of trial sites continues until the OGTR is satisfied that no further inspections are required to manage persistence of the GMO. The OGTR then signs off the site as having completed all necessary licence obligations.

Figure 10 shows the change during 2015–16 in the numbers of current field trial sites and of field trial sites subject to post-harvest monitoring.

**Figure 10: Number of DIR field trial sites and their status during 2015–16**

DIR = dealing involving intentional release of a genetically modified organism into the environment;  
PHM = post-harvest monitoring
Locations of field trial site inspections

In 2015–16, the OGTR inspected field trial sites in all states and territories where field trials were undertaken (Table 11).

Table 11: Number of DIR field trial sites and OGTR inspections in 2015–16, by state and territory

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Field trial sites at 1 July 2015</th>
<th>Field trial site inspections in 2015–16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australian Capital Territory</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>New South Wales</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td>Northern Territory</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Queensland</td>
<td>30</td>
<td>13</td>
</tr>
<tr>
<td>South Australia</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Tasmania</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Victoria</td>
<td>28</td>
<td>12</td>
</tr>
<tr>
<td>Western Australia</td>
<td>13</td>
<td>14&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100</strong></td>
<td><strong>47</strong></td>
</tr>
</tbody>
</table>

DIR = dealing involving intentional release of a genetically modified organism into the environment

<sup>a</sup> As new sites are planted in the course of each year, the number of inspections during the year may be greater than the initial number of sites.
**Inspections of contained dealings**

The monitoring program also encompasses dealings conducted in certified containment facilities under DNIR licences and NLRDs. For monitoring purposes, certified facilities are grouped into higher and lower containment types. PC4, PC3 and PC2 large-scale laboratories are categorised as higher-level containment facilities and the remaining facility types are categorised as lower-level containment facilities. At least 20% of higher-level physical containment facilities are monitored annually. As well as examining the integrity of the physical structure of the facility, inspections cover the general work practices used in handling GMOs.

At 30 June 2016, 144 organisations held 1993 certification instruments for containment facilities. During 2015–16, the OGTR inspected 93 facilities across the range of facility types (Table 12). Of the 61 higher-level containment facilities that had certification instruments in force at the beginning of 2015–16, 13 were inspected. This figure represents 21% of higher-level containment facilities and exceeds the minimum target of inspecting 20% of such facilities each year.

In addition, seven DNIR licences in force during 2015–16 were monitored.

**Table 12: Number of inspections of certified facilities conducted during 2015–16, by type**

<table>
<thead>
<tr>
<th>Containment type</th>
<th>PC level and facility type</th>
<th>Inspections</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower level</td>
<td>PC2 Animal</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>PC2 Aquatic</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>PC2 Constant temperature room</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>PC2 Invertebrate</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>PC2 Laboratory</td>
<td>47</td>
</tr>
<tr>
<td></td>
<td>PC2 Large grazing animal</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>PC2 Plant</td>
<td>6</td>
</tr>
<tr>
<td>Higher level</td>
<td>PC2 Large scale</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>PC3 Animal</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>PC3 Invertebrate</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>PC3 Laboratory</td>
<td>8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>93</strong></td>
</tr>
</tbody>
</table>

PC = physical containment
Locations of facility inspections

Certified facilities are located in all Australian states and territories (Figure 8). In 2015–16, monitoring activities took place in each state and territory except Tasmania and the ACT (Figure 11). The number of OGTR inspections of facilities reflects, as far as practicable, the number of facilities in each state and territory.

Figure 11: Number of certified facility inspections in 2015–16, by state and territory
**Types of organisations inspected**

Of the five OGTR categories of applicant organisations, universities held the largest number of certifications during 2015–16 (Figure 12). The number of OGTR inspections of facilities (Figure 13) reflects, as far as practicable, the number of facilities in each organisation category.

**Figure 12: Distribution of certified facilities at 30 June 2016, by organisation type**

**Figure 13: Number of certified facility inspections in 2015–16, by organisation type**
Compliance with the Act

The monitoring findings listed below indicate the monitoring activities of the OGTR with respect to dealings with GMOs, in accordance with section 136(1A) of the Act, and the Regulator’s response to those findings.

Findings by inspectors of inconsistencies between an event or state of affairs and the requirements imposed by licence or certification conditions are called non-compliances in this report. However, non-compliances are not regarded as breaches of licence conditions unless proven to be so after investigation. Non-compliances with licence conditions are assessed against a number of considerations before determining the OGTR response. Under the OGTR Compliance and Enforcement Policy the following aspects of the findings are taken into account as relevant:

- the extent of risk to the health and safety of people and the environment
- the severity of the issue or event involved in the finding
- the culpability of the licence holder or other relevant persons in bringing about the issue or event (e.g. whether there was a bona fide mistake involved)
- the types of mechanisms available to address the issue or event
- the compliance history of the licence holder or other relevant persons
- mitigating factors such as self-reporting or steps taken voluntarily by the licence holder to address the issue or event
- the need for deterrence.

After having regard to those matters, the Regulator has a range of options including additional investigation to determine whether further action is warranted—e.g. a recommendation of prosecution for an alleged breach of a licence condition or that a licence be suspended or cancelled. A proven breach of a licence condition will be reported in accordance with section 136(1A)(b) of the Act.

During 2015–16, the regulated community demonstrated a high level of compliance with the gene technology legislation.

---

Non-compliance findings for GMO dealings involving intentional release

In 2015–16, four DIR licences were found to be non-compliant. These findings are outlined below.

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<table>
<thead>
<tr>
<th>Organisation</th>
<th>Bayer CropScience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Licence number and site</td>
<td>DIR 133 Site 4</td>
</tr>
<tr>
<td>Summary of dealing</td>
<td>The purposes of the field trial are to assess the agronomic performance and pest resistance of the GM cotton grown under Australian field conditions, to evaluate crosses between the GM cotton and non-GM commercial cotton cultivars, and to produce seed for future releases, subject to further regulatory approvals.</td>
</tr>
<tr>
<td>Findings</td>
<td>Bayer CropScience self-reported that a small quantity (up to 280 g) of GM cotton seed spilled from planting equipment used at Site 4, Moree Plains, potentially onto private and public roads (up to 29 km, including the Newell Highway) during transport of the equipment. While the planting equipment had been cleaned and checked by trained persons prior to transport, an internal blockage resulted in the retention of GM seed within the equipment. Licence conditions require that equipment used in conjunction with the GMO be effectively cleaned before transport off site.</td>
</tr>
<tr>
<td>Assessment</td>
<td>Ephemeral populations of cotton can be found on roadsides where cotton seed is transported. However, cotton does not establish well in undisturbed sites, on roadsides and at low density. The hot, dry conditions present during the potential spill were unlikely to induce dormancy or be conducive to seed survival and germination. If the spilt GM cotton survived to flowering, its outcrossing to commercial cotton crops would be highly unlikely as cotton is predominantly a self-pollinating crop. Cotton plants approved under DIR 133 have been genetically modified with introduced genes conferring insect tolerance and/or herbicide resistance. Some plants also contain an introduced antibiotic resistant marker gene. The risk posed by this non-compliance to human health and safety of the environment has been assessed as negligible.</td>
</tr>
<tr>
<td>Compliance management</td>
<td>Bayer CropScience internal investigation concluded that the seed blockage occurred inside the planter tube of the equipment. This blockage was not apparent during operation or cleaning of the equipment. In consultation with the OGTR, Bayer CropScience has proposed additional monitoring of affected areas. Bayer CropScience has also proposed to revise the relevant equipment cleaning procedure and provide additional training to staff.</td>
</tr>
<tr>
<td>Organisation</td>
<td>Monsanto Australia Limited</td>
</tr>
<tr>
<td>-----------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>Licence number and site</td>
<td>DIR 120 Site 7</td>
</tr>
</tbody>
</table>

**Summary of dealing**
The purpose of the trial is to assess the agronomic performance of the GM cotton under Australian field conditions and generate data for possible future commercial release.

**Findings**
Monsanto self-reported the planting of an unapproved crop (soybeans) on Site 7 at Cecil Plains (Qld), a post-harvest site.

DIR 120 licence conditions state that no plants may be intentionally grown in the area unless the plants are:
- the GMOs, non-GM cotton, or commercially approved GM cotton planted in accordance with the conditions of DIR 120 licence; or
- listed as post-harvest crops permitted for GM cotton field trial sites in the OGTR Policy on Post-Harvest Crops as current at the time of planting; or
- agreed to in writing by the Regulator.

Planting soybeans is not in accordance with DIR 120 licence conditions.

As explanation of the incident Monsanto stated that the grower had lost approximately 60% of his commercial cotton crop in severe storms that passed through the region and had decided to plant soybeans to recover lost earnings. In his haste to take advantage of the rain received and the planting timing required for soybeans he went ahead with planting, thinking that soybeans were approved as a post-harvest crop for GM cotton.

**Assessment**
The planting of unapproved post-harvest plants (soybeans) on a post-harvest site can hinder the detection of volunteers. A list of approved post-harvest crops has been developed and the ability to seek the Regulator’s approval for a crop not on the list is also available.

Monsanto has now been granted approval by the Regulator to allow the planting of a soybean crop on this site only.

The OGTR is currently reviewing the current list of approved crops for post-harvest cotton sites, and management of this site will inform that review.

The risk posed by this non-compliance to human health and safety of the environment has been assessed as negligible.

**Compliance management**
In consultation with the OGTR, Monsanto has implemented the following strategies at the site:
- Inspections to occur every two weeks until harvest of the soybean crop
- Row-by-row inspection of the site, by people trained to recognise volunteers
- Retrain the grower at Site 7 to ensure that the grower is fully aware of their obligations under the licence
- Continue to ensure that all volunteers are destroyed prior to flowering
- Continue to ensure that all inspectors are adequately trained to recognise cotton volunteers
- The six-month volunteer-free period required prior to application for sign-off of a site will not commence until after the soybeans are harvested.
<table>
<thead>
<tr>
<th>Organisation</th>
<th>Nuseed Pty Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Licence number and site</td>
<td>DIR 123 Site 15</td>
</tr>
<tr>
<td><strong>Summary of dealing</strong></td>
<td>The primary purpose of the field trial is to evaluate the agronomic characteristics, oil content and genetic stability of the GM canola under field conditions. GM material generated from this field trial may be used in small-scale animal nutrition studies.</td>
</tr>
<tr>
<td><strong>Findings</strong></td>
<td>Nuseed self-reported the unintentional grazing of sheep on this site. A small number of sheep were able to access the planting area due to an unplanned drop in water levels in a dam which had previously acted as a natural barrier to the sheep. Licence conditions prohibit grazing on the site. Due to the unplanned need to change gene flow control measures from that of a pollen trap plus 400 m isolation zone to a 1 km isolation zone, Nuseed did not obtain access to the entirety of the isolation zone prior to commencement of GMO flowering. Licence conditions require that the licence holder be able to access and control all areas to the extent necessary to comply with licence conditions.</td>
</tr>
<tr>
<td><strong>Assessment</strong></td>
<td>It is unlikely that any viable GMOs would have been moved from the trial site by the sheep as there was no sign that the plants had been consumed or damaged. The canola plants were at an early developmental stage and so would not have had any seed present. There was no evidence that gene flow control measures were compromised in the isolation zone. There is a negligible risk posed to the health and safety of people and the environment by these non-compliances.</td>
</tr>
<tr>
<td><strong>Compliance management</strong></td>
<td>Nuseed, in consultation with the OGTR, voluntarily implemented a compliance management plan which included removal of sheep from the site and installation of additional fencing. Nuseed has obtained access to all parts of the site isolation zone and is undertaking inspection activities as required by licence conditions. No additional actions are required.</td>
</tr>
<tr>
<td>Organisation</td>
<td>Victorian Department of Economic Development, Jobs, Transport and Resources (DEDJTR)</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Licence number and site</td>
<td>DIR 103 Site 1</td>
</tr>
<tr>
<td>Summary of dealing</td>
<td>The purpose of this limited and controlled field trial is to conduct experiments to evaluate agronomic performance, including seed yield, of the GM canola lines under field conditions.</td>
</tr>
<tr>
<td>Findings</td>
<td>The DEDJTR self-reported the occurrence of four flowering canola volunteers on the post-harvest trial site. All four plants were uprooted at the time and transported, under double containment, to an approved facility for further molecular analysis. Allowing volunteers on a post-harvest trial site to reach flowering stage is not in accordance with licence condition 65 of DIR 103. The DEDJTR attributed this incident to the prevailing weather conditions of warmer temperatures and good rainfall in the period between two scheduled monitoring inspections. DEDJTR has since implemented inspections on a more frequent basis than required under DIR 103 licence to avoid a similar occurrence.</td>
</tr>
<tr>
<td>Assessment</td>
<td>The risk arising from flowering volunteer canola plants would be outcrossing from the GM canola to other canola or sexually compatible plants growing in the vicinity. The DEDJTR confirmed that the other non-GM canola planting around the trial site is located more than 1 km away and was not synchronously flowering at that time. The DEDJTR further confirmed that molecular analysis performed on the four flowering volunteers has since been completed and found them to be non-GM. The OGTR RARMP prepared for this licence considered factors such as asynchronous flowering times and isolation distances in its determination that the risk of gene transfer was negligible. The risk posed by this non-compliance to human health and safety of the environment has been assessed as negligible.</td>
</tr>
<tr>
<td>Compliance management</td>
<td>In consultation with the OGTR, the DEDJTR has proposed increased frequency of monitoring not only of this trial site but also of all other trial sites under the various licences it holds.</td>
</tr>
</tbody>
</table>
Non-compliance findings for GMO dealings not involving intentional release

In 2015–16 one DNIR licence was found to be non-compliant, as outlined below.

<table>
<thead>
<tr>
<th>Organisation</th>
<th>University of South Australia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Licence number</td>
<td>DNIR 529</td>
</tr>
<tr>
<td>Summary of dealing</td>
<td>The aim of this dealing is to generate GM vaccinia virus and GM lentiviral vectors and evaluate their efficacy as vaccine candidates against target antigens.</td>
</tr>
<tr>
<td>Findings</td>
<td>At the time of inspection, the licence holder had not obtained signed statements from autoclave staff undertaking dealings indicating that they understood and agreed to be bound by licence conditions or variations to those conditions. The University of South Australia did not ensure that a copy of licence DNIR 529 was available in all of the certified facilities listed on the licence. Staff had not undertaken specific sharps training and did not wear sharp/needle-proof undergloves when undertaking dealings with sharps as required by the licence. GM material being transported outside the facility was not labelled in a way to notify any handlers that the material being transported was or contained a GMO.</td>
</tr>
<tr>
<td>Assessment</td>
<td>Although signed statements were not obtained from autoclave staff, those staff were experienced and trained in autoclave procedures and operations. The risks to human health and safety and the environment have been assessed as negligible. A copy of the licence was kept in some of the laboratories listed on the licence; however, it was not accessible in all of the facilities. This was assessed as an administrative issue. Risks to human health, safety and the environment were assessed as negligible. Persons conducting dealings with the GMO who are not fully trained in licence conditions are at risk if exposed to the GM organism. There is no evidence, however, to suggest this issue has resulted in any harm to human health and safety at this stage. Transport of GMOs is conducted by authorised persons and is double-contained. Risks to human health, safety and the environment were assessed as negligible.</td>
</tr>
<tr>
<td>Compliance management</td>
<td>The University of South Australia is reminded that it must:</td>
</tr>
<tr>
<td></td>
<td>• Inform all persons covered by a licence of the conditions that apply to them and obtain a signed statement from each person covered by the licence acknowledging that the licence holder has informed the person of the conditions of the licence, or variations to those conditions, that apply to that person</td>
</tr>
<tr>
<td></td>
<td>• Ensure that a copy of the licence is available in each of the facilities listed on the licence</td>
</tr>
<tr>
<td></td>
<td>• Ensure that any person undertaking dealings with sharps is trained in the use of sharps and that a record of that training is kept. Sharp/needle-proof undergloves must also be worn when undertaking such dealings</td>
</tr>
<tr>
<td></td>
<td>• Label any GM material being transported appropriately in a way that indicates to any handler that the material is or contains a GMO.</td>
</tr>
</tbody>
</table>
Non-compliance findings for physical containment facilities
In 2015–16, 12 certified physical containment facilities were found to be non-compliant with 14 certification conditions. These findings are summarised in Table 13.

**Table 13: Number of minor non-compliances identified in certified facilities during 2015–16, by non-compliance type**

<table>
<thead>
<tr>
<th>Nature of non-compliance</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment</td>
<td>2</td>
</tr>
<tr>
<td>Personal protective equipment</td>
<td>0</td>
</tr>
<tr>
<td>Structure</td>
<td>1</td>
</tr>
<tr>
<td>Transport</td>
<td>2</td>
</tr>
<tr>
<td>Waste disposal</td>
<td>0</td>
</tr>
<tr>
<td>Work practices$^1$</td>
<td>9</td>
</tr>
</tbody>
</table>

$^1$ Work practices include personnel training, record keeping, or other actions affecting compliance with certification instruments.

Each incident of non-compliance was assessed according to established OGTR protocols and found to present negligible risk to human health and safety or to the environment, to be minor in nature, and to involve negligible or zero culpability. The non-compliances were resolved by reminders, education and/or cooperative compliance.
Compliance and enforcement mechanisms

Practice reviews
The OGTR may initiate practice reviews in response to observations made during monitoring activities, or to follow up incident reports that may relate to non-compliance with licence conditions by accredited organisations. The objective of practice reviews is to determine whether licence conditions can be, and are being, effectively implemented.

An accredited organisation may request a practice review to assess the effectiveness of systems used by its IBC(s) to ensure that dealings are being conducted in accordance with the Act.

The primary focus of the review process is to determine whether practices being used pose potential human health or environmental risks that require implementation of any management actions. In certain instances, where a suspected non-compliance with the Act is identified, the issue may be referred for investigation.

There were no practice reviews completed during this reporting period.

Audits
Audits can be initiated by the OGTR or at the request of an accredited organisation. An audit can entail:

- documentary evidence
- observations
- assessments of procedures and practices.

These activities are conducted to:

- verify that an accredited organisation has relevant and effective management procedures and practices to meet requirements under the Act, including accreditation requirements, guidelines and any licence conditions applicable to a dealing under the Act
- assess whether procedures and practices provide mechanisms to identify and resolve emerging risks
- where appropriate, suggest improvements to procedures and practices.

Audits are an opportunity for accredited organisations and the OGTR to share information to improve the risk management of dealings with GMOs under the Act. Audits may focus on a single dealing, a range of dealings (e.g. dealings with a common host organism or dealings within a common climatic zone), the activity of an organisation across a range of dealings, or an activity common to a range of organisations.
In 2015–16, two audits were completed. Their findings are outlined below.

<table>
<thead>
<tr>
<th>Audit</th>
<th>Queensland University of Technology and Royal Melbourne Institute of Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim</td>
<td>This audit is part of the OGTR’s ongoing audit program and was conducted to:</td>
</tr>
<tr>
<td></td>
<td>• trace, assess and reinforce QUT’s and RMIT’s compliance management arrangements for meeting compliance obligations under the national regulatory system for gene technology</td>
</tr>
<tr>
<td></td>
<td>• examine the potential for emerging compliance risks to arise from new operations on agricultural research stations.</td>
</tr>
<tr>
<td></td>
<td>Determination</td>
</tr>
<tr>
<td></td>
<td>The audit found that:</td>
</tr>
<tr>
<td></td>
<td>• there were no non-compliances or breaches evident</td>
</tr>
<tr>
<td></td>
<td>• QUT and RMIT have effective arrangements to meet national gene technology regulatory requirements.</td>
</tr>
<tr>
<td></td>
<td>Action</td>
</tr>
<tr>
<td></td>
<td>The audit team proposed a number of compliance risk management techniques to be considered as part of ongoing development of QUT’s and RMIT’s compliance arrangements. The audit promoted:</td>
</tr>
<tr>
<td></td>
<td>• the benefits of internal risk management and auditing in compliance and containment arrangements</td>
</tr>
<tr>
<td></td>
<td>• organisational arrangements to link risk management and internal auditing expertise with scientific and biosafety expertise.</td>
</tr>
</tbody>
</table>

QUT = Queensland University of Technology; RMIT = Royal Melbourne Institute of Technology

**Investigations**

An investigation is an inquiry into a suspected non-compliance with the Act and corresponding state laws with the aim of gathering evidence. An investigation may be initiated as a consequence of monitoring by the OGTR, self-reporting by an accredited organisation, or third-party reporting.

There were no investigations completed in this reporting period.

**National strategy for unintended presence of unapproved GMOs**

The OGTR is responsible for implementing a risk-based national strategy to manage the unintended presence of unapproved GMOs in seeds imported for sowing in Australia. The strategy was proposed and developed in 2005 under the then Australian Government Biotechnology Ministerial Council.

The strategy has six components (Table 14). It uses a risk management approach, with resources dedicated to the areas posing the highest likelihood of unintended presence of GMOs.
The OGTR has worked with the Australian Seed Federation to develop a voluntary auditing and testing program of existing industry quality assurance measures. In 2015–16, the OGTR continued to engage with other government departments, including the Australian Government Department of Agriculture and Water Resources, regarding low-level presence of unapproved GMOs. The OGTR also continued to liaise with the Australian Seed Federation and the seed industry to raise awareness of management of potential incidents involving low-level presence of GMOs, and to ensure their ongoing voluntary cooperation and action regarding this issue. No incidents involving low-level presence of unapproved GMOs have been identified in Australia.

Table 14: Components of national strategy for unintended presence of unapproved GMOs

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk profiling—identifying seed imports posing the highest likelihood of unintended presence</td>
<td>The OGTR has established a memorandum of understanding with the Department of Agriculture and Water Resources to access data on imports. Data on seeds imported for sowing, together with information on overseas commercial production of GMOs, and input from the Department of the Environment and other relevant agencies, were used to identify 12 priority crops.</td>
</tr>
<tr>
<td>Quality assurance and identity preservation</td>
<td>Industry uses quality assurance and identity preservation systems for seed quality purposes. The OGTR has developed a program for auditing and testing industry quality assurance systems that industry has agreed to and adopted.</td>
</tr>
<tr>
<td>Industry laboratory testing</td>
<td>The voluntary code of conduct (see below) refers to testing programs. Industry needs to be able to assure itself that it is managing the risk of importing unapproved seeds.</td>
</tr>
<tr>
<td>Approvals and advance risk assessments for Australia’s regulatory agencies</td>
<td>The OGTR has prepared GMO incident response documents for 12 crops identified through risk profiling as having the highest likelihood of unintended presence in imports of seeds for sowing. These are canola, cotton, maize, potato, tomato, papaya, soybean, squash, alfalfa, grasses, rice and wheat. The documents will provide a basis for rapid risk assessment and management actions should an unintended presence of an unapproved GMO be detected.</td>
</tr>
<tr>
<td>Post-market detection</td>
<td>The OGTR recognises the limitations of legislation in preventing unintended imports of unapproved GMOs and has worked cooperatively with industry to develop a voluntary code of conduct. The code aims to identify risks as early as possible in the commercial seed supply chain. This is supported by the standard OGTR practice of investigating information about potential and possible incidents.</td>
</tr>
<tr>
<td>Enforcement action</td>
<td>In the event of detection of unapproved GMOs, appropriate responses would be determined on a case-by-case risk management basis. The OGTR engages with Australian Government agencies, relevant industry organisations, and states and territories on this issue.</td>
</tr>
</tbody>
</table>

GMO = genetically modified organism; OGTR = Office of the Gene Technology Regulator
Consultation and provision of advice to stakeholders

The Regulator’s functions, as prescribed by section 27 of the Act, include:

- issuing technical and procedural guidelines in relation to GMOs
- providing advice to the Legislative and Governance Forum on Gene Technology (LGFGT)\(^5\) about
  - the operations of the Regulator and the Gene Technology Technical Advisory Committee
  - the effectiveness of the legislative framework for regulating GMOs, including in relation to possible amendments of the legislation
- providing information and advice to other regulatory agencies about GMOs and GM products
- providing information and advice to the public about regulating GMOs.

Security Sensitive Biological Agents Regulatory Scheme

The National Health Security Act 2007, which is administered by the department’s Office of Health Protection (OHP), provides for a scheme for regulating security sensitive biological agents (SSBAs). The SSBA Regulatory Scheme effects recommendations agreed by the Council of Australian Governments (COAG).

Regulation 5A of the Gene Technology Regulations 2001 provides for OGTR inspectors to also be appointed as inspectors under the National Health Security Act, in line with COAG recommendations regarding the similarities between monitoring for compliance under the gene technology and SSBA schemes. The OGTR has worked with the OHP to develop operational monitoring requirements. Under a service level agreement between the OGTR and the OHP, SSBA inspection activities commenced early in 2009–10. These activities continued during 2015–16.

Certification guidelines

The Regulator did not consult on, or issue, any revised guidelines in 2015–16. However, the Regulator has discussed with the Department of Agriculture and Water Resources (DAWR) the potential for further harmonisation between their respective certification schemes. This includes the potential for further alignment of the Regulator’s guidelines with DAWR’s requirements for quarantine facilities, and with the relevant Australian standard.

OGTR staff have also jointly inspected facilities with DAWR auditors to learn more about each other’s practices and processes, to determine whether this could also be an area of harmonisation.

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\(^5\) The Act refers to the Ministerial Council. As part of reforms by the Council of Australian Governments, on 11 February 2011, the former Gene Technology Ministerial Council became the Legislative and Governance Forum on Gene Technology.
**DIR application form**

The Regulator consulted on a new draft DIR application form for commercial release of GMOs. The new streamlined application form provides guidance for applicants and clarifies data requirements, with the aim of improving the application process and reducing regulatory impacts for DIR applicants.

**Legislative and Governance Forum on Gene Technology**

In 2015–16, the OGTR continued to implement recommendations agreed by the LGFGT in 2013 from its 2011 independent review of the Act. *The Gene Technology Amendment Act 2015*, which implements five agreed minor and technical recommendations from the 2011 review, was passed on 10 September 2015 and commenced on 11 March 2016. The changes do not alter the policy intent of the regulatory scheme but are expected to reduce regulatory burden for the regulated community. The OGTR has informed regulated stakeholders of the amendments and updated the OGTR website. The OGTR has been supporting jurisdictions that now need to update their gene technology legislation to ensure consistent provisions.

**Other forums**

During 2015–16, the Regulator and the OGTR participated in a range of presentations and meetings on gene technology to inform users, the Australian community and stakeholders about the regulatory system.

The OGTR participated in the following meetings:

- Regulatory Science Network meetings (Canberra)
- Regulators' Forum meeting (Canberra, August 2015)
- Workshop on the Social and Ethical, Environmental and Economic Impacts of Emerging Technologies (Melbourne, September 2015)
- Regulatory Science Network annual event, ‘Assessing and determining risk’ (Canberra, November 2015)
- Commonwealth Regulators Community of Practice meeting (Canberra, December 2015).

Appendix 3 lists OGTR activities at Australian meetings, forums and conferences.

**Advice on GMOs and GM products**

During 2015–16, the OGTR provided advice on the regulation of GMOs and GM products to other regulatory agencies and the public.
Advice to other regulatory agencies

To facilitate reciprocal exchange of information with other product regulatory agencies on assessment and approval of GMOs and GM products, the OGTR has developed memorandums of understanding (MOUs) with Food Standards Australia New Zealand (FSANZ), the Therapeutic Goods Administration, the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Australian Quarantine and Inspection Service (now the Department of Agriculture and Water Resources). In 2015–16, the OGTR progressed development of an annex to the overarching MOU between the Department of Health and the Department of Agriculture and Water Resources. The OGTR also has an MOU with the Department of the Environment and Energy in relation to consultation with the Minister for the Environment and Energy on DIR licence applications, as prescribed by the Gene Technology Act.

In line with recommendations from the 2006 statutory review of the Act, a Regulators’ Forum was established to facilitate information sharing between these other regulatory agencies and the Regulator. The forum met once in 2015–16, discussing a work program for improving overall regulatory effectiveness through greater cross-agency collaboration.

In 2011 the Regulatory Science Network (RSN) was established to help forge closer ties between the nine government agencies and departments responsible for the regulation of chemicals and biological agents in Australia. The RSN provides a forum for scientists and technical staff to discuss regulatory scientific issues and improve interagency cooperation. Its overarching objective is to help improve the performance of regulatory agencies by strengthening evidence-based decision-making. The RSN met throughout the year, and the OGTR participated in its annual event on ‘Assessing and determining risk, including that concerning new technologies, when there is uncertainty and incomplete data’. The OGTR contributed to an RSN co-sponsored symposium on risk governance (with the Society for Risk Analysis) and a workshop on gene drive technology (with CSIRO).

Advice to the public

The Act requires the Regulator to maintain a record of approvals for GMO dealings (the GMO Record), which can be accessed by the public. The GMO Record contains information on licences issued, NLRDs, GMO dealings included on the GMO Register, and EDDs. Until 11 March 2016 the Regulator was also required to include on the GMO Record GM product approvals notified by other Australian regulatory authorities. Amendments to remove GM products from the GMO Record, recommended by an independent review of the Act in 2011, were passed on 10 September 2015 and commenced on 11 March 2016. During 2015–16 the GMO Record was maintained and updated with new authorisations.

The OGTR maintains the GMO Record as a source of public information on such approvals on its website. The Gene Technology Consequential Amendments Act 2000 provides for product regulators—FSANZ, the Therapeutic Goods Administration, the National Industrial Chemicals Notification and Assessment Scheme, and the APVMA—to seek advice from the Regulator on GM products.
OGTR website and contact points

The OGTR maintains a comprehensive website\(^7\) that provides extensive information on the regulatory system and decisions made by the Regulator. This information includes copies of the full RARMPs for each licensed release of a GMO into the environment and a number of fact sheets on relevant issues.

Appendix 4 provides statistics on website use.

The OGTR has a 1800 freecall number and an email address\(^8\) that provide points of contact for members of the public and other interested parties. Assistance with specific questions and other mechanisms for public feedback are among the services provided.

The OGTR maintains a client register: a list of individuals and organisations that have registered their interest in regulation of gene technology. Members receive notifications of new applications for GMOs, licences issued for release of GMOs into the environment, and significant changes to gene technology legislation. They are also invited to comment on consultation RARMPs for applications to release GMOs into the environment. The OGTR client register has 413 individuals and organisations listed. To be included on the OGTR client register and receive notifications, interested people should contact the OGTR.

The OGTR also sends out tweets through the Department of Health Twitter account to notify the public about new applications for intentional release of GMOs, opportunities to comment on consultation RARMPs, and licences issued for release of GMOs.

International regulatory liaison

Under section 27 of the Act, the Regulator’s functions include:

- monitoring international practice in relation to regulation of GMOs
- maintaining links with international organisations that regulate GMOs
- promoting harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies.

\(^7\) www.ogtr.gov.au
\(^8\) Freecall number: 1800 181 030; email: ogtr@health.gov.au
Active participation in international forums ensures that Australia’s regulatory scheme takes account of developments in GMO regulation and science. Feedback from meetings continues to indicate that the Australian gene technology regulatory system is highly regarded. International engagement also enables Australia to inform international best practice based on its practical experience of administering efficient and effective GMO regulation.

In 2015–16, OGTR engagement included participation in multilateral forums, including the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology (WGHROB) and the United Nations Cartagena Protocol on Biosafety (Biosafety Protocol), and bilateral engagement with regulatory officials from other countries.

The OGTR provides input and advice on GMO regulation to other Australian agencies to support their international engagement—for example, responses to notifications by other countries about changes to regulation (including GMO regulation) under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures, and engagement in the UN Convention on Biological Diversity.

The OGTR continued to engage in international forums on harmonising the risk assessment and regulation of GMOs. The OGTR leads Australian representation on, and coordinates Australian input to, the OECD WGHROB. The WGHROB develops scientific guidance to support risk assessment of GMOs.

The OGTR is responsible for entering Australian commercial approvals of GMOs into the OECD BioTrack Product Database and the UN Biosafety Clearing-House. The OGTR provides technical advice to support Australian engagement in activities under the protocol, such as submissions on particular issues.

The OGTR is the national focal point for the UN Biosafety Protocol and for the Biosafety Clearing-House and disseminates information to other agencies. The OGTR also provided technical support for Australia’s engagement in the UN Convention on Biological Diversity, including for the delegation to the April 2016 meeting of the convention’s Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA).

An OGTR officer, Dr Paul Keese, continued to serve on the Biosafety Protocol’s Ad Hoc Technical Expert Group on Risk Assessment and Risk Management. OGTR officers also participated in the open-ended online expert forums on risk assessment and risk management (Biosafety Protocol) and synthetic biology (Convention on Biological Diversity). The OGTR contributed to an Australian submission to the Biosafety Protocol on contained use of living modified organisms.

In 2012, the OGTR entered into an MOU with the UN International Centre for Genetic Engineering and Biotechnology (ICGEB) to provide input to a training program for officials from sub-Saharan Africa about biosafety regulation. In 2015–16, the OGTR continued to provide input to ICGEB activities. This included hosting regulatory officials from Ghana and Uganda, and participating in a symposium organised by ICGEB and hosted by the Italian Embassy in Canberra.

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9 The BioTrack Product Database is on the OECD website at [www2.oecd.org/biotech/](http://www2.oecd.org/biotech/)
10 The Biosafety Clearing-House is online at [https://bch.cbd.int](https://bch.cbd.int)
The OGTR interacted with key regulatory counterparts in other countries through participation in international forums in 2015–16, including:

- GMO risk assessment training for the Malaysian Genetic Modification Advisory Committee (Kuala Lumpur, August 2015)
- ICGEB symposium, ‘Science and technology for development: the role of biotechnology’ (Canberra, September 2015)
- OECD WGHRB Steering Group on Environmental Considerations for the Risk/Safety Assessment of Transgenic Crop Plants (Washington DC, September 2015)
- International Life Sciences Institute, Workshop on Genome Editing in Agricultural Area (Tokyo, September 2015)
- Biosafety Protocol Ad Hoc Technical Experts Group on Risk Assessment and Risk Management meeting (Brazil, November 2015)
- Global Low Level Presence Initiative meeting (Rome, February 2016)
- Risk assessment training on GMOs for the Biosafety Unit (New Delhi, March 2016)
- International Seed Federation, 2nd Plant Breeding Innovation Meeting (Paris, 5–6 April 2016)
- Bilateral meeting with UK Department for Environment, Food and Rural Affairs (London, 7 April 2016)
- 20th meeting of the Convention on Biological Diversity’s SBSTTA (Montreal, Canada, April 2016)
- GMO risk assessment workshops, examining environment risk analysis for genetically modified organisms (South Korea and Tokyo, May 2016).

In 2015–16, the OGTR continued to receive requests from regulators in other countries to visit Australia and learn about the Australian approach to GMO regulation. This represents continuation of a trend over the past few years. Feedback from these visits indicates that the OGTR’s approach to risk analysis and regulation is held in high regard as scientifically rigorous, practical and effective.

Visits by international delegations to the OGTR regarding GMO regulation in 2015–16 were:

- Uganda, National Council for Science and Technology, November 2015
- Bangladesh, Department of Environment, March 2016
- Philippines, Biosafety Committee, Department of Science and Technology, May 2016.
Other functions of the Gene Technology Regulator

Under section 27 of the Act, functions of the Regulator include:

- undertaking or commissioning research in relation to risk assessment and the biosafety of GMOs
- promoting harmonisation of risk assessment relating to GMOs and GM products by regulatory agencies.

These functions maintain the OGTR’s capacity to conduct high-quality assessments based on regulatory best practice and relevant scientific data.

Promoting harmonisation

The OGTR has continued to liaise with other regulatory agencies and other Australian Government agencies on relevant issues. Regulatory harmonisation, and the need to address regulation of new and emerging technologies, has been a focus both nationally and internationally.

The OGTR has participated in a number of meetings with DAWR to explore opportunities to reduce the regulatory burden on stakeholders subject to joint oversight (i.e. stakeholders who have facilities that are both certified by the OGTR and approved by DAWR). One of the outcomes of these meetings is a pilot project to assess potential benefits to stakeholders from joint inspections by the OGTR and DAWR. This pilot project is currently being conducted by the two agencies.

Submissions to inquiries

In 2015–16 the Regulator made the following submissions:

- Submission to the House of Representatives Standing Committee on Agriculture and Industry inquiry into agricultural innovation (October 2015). The committee was asked to inquire into and report on the role of technology in increasing agricultural productivity in Australia. The Regulator’s submission discussed the regulatory scheme for gene technology, including the types of commercial and research activities regulated by the scheme, their relevance to agriculture, and the challenges of emerging and new technologies to all regulators globally. The Regulator also appeared at the committee’s public hearing in March 2016.

- Submission to the Senate Community Affairs Legislation Committee inquiry into the Food Standards Australia New Zealand Amendment (Forum on Food Regulation and Other Measures) Bill 2015 (November 2015). The Regulator’s submission provided support for the proposed amendments.

- Submission to the Productivity Commission’s inquiry into the regulation of agriculture (March 2016). The Productivity Commission has been undertaking a public inquiry into the regulatory burden on farm businesses. The final inquiry report is expected to be handed to the Australian Government by November 2016. The Regulator’s submission in March 2016 (prior to the release of the draft report in July 2016) described the regulatory scheme for gene technology and regulatory coverage between the Regulator and other product regulators, and discussed the OGTR’s international engagement activities and the challenges of regulating new and emerging technologies.
Performance against PBS targets

The OGTR’s activities for 2015–16 are described under Program 7.7 (Regulatory Policy) in Outcome 7 (Health Infrastructure, Regulation, Safety and Quality) of the 2015–16 Department of Health PBS. The key objective of the subprogram relating to gene technology regulation is:

*Protect the health and safety of people and the environment by regulating work with genetically modified organisms.*

The OGTR’s performance against the deliverables and key performance indicators set out in the PBS, which is also reported in the department’s 2015–16 annual report, is summarised below.

**Qualitative deliverable: Commence technical review of the Gene Technology Regulations 2001**

<table>
<thead>
<tr>
<th>2015–16 target</th>
<th>2015–16 result: Substantially met</th>
</tr>
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</table>

In 2015–16, a technical review of the Gene Technology Regulations 2001 commenced. Due to the complexity of new technologies, a discussion paper was prepared on options for the review of the regulations. During this period, the OGTR liaised with other regulatory agency stakeholders. A full consultation with all stakeholders will commence in 2016–17.

**Qualitative deliverable: Provide open, effective and transparent regulation of GMOs**

<table>
<thead>
<tr>
<th>2015–16 target</th>
<th>2015–16 result: Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk assessments and risk management plans prepared for 100% of applications for licensed dealings and made publicly available. Stakeholders, including the public, consulted on all assessments for proposed release of GMOs into the environment. Record of GMO dealings and maps of all field trial sites maintained and made publicly available on the OGTR website.</td>
<td>Prepared risk assessments and risk management plans for 100% of licence applications for release of GMOs into the environment. Consulted stakeholders, including the public, on all assessments of these applications. Maintained the Record of GMO Dealings and maps of all field trial sites and made them publicly available on the OGTR website.</td>
</tr>
</tbody>
</table>

The Gene Technology Regulator prepared comprehensive risk assessments and risk management plans and consulted with stakeholders, including the public, on nine GMO licence applications for intentional release into the environment (three field trials, two clinical trials, two commercial GM canola releases, one commercial GM cut flower release and a commercial GM cancer treatment). The Regulator also prepared risk assessments and risk management plans for six licence applications for work

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in contained facilities. The record of approved GMOs and maps of all field trial sites were made available on the OGTR website.\(^\text{12}\)

**Quantitative deliverable: Percentage of field trial sites and higher level containment facilities inspected**

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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>≥20%</td>
<td>46% of field trial sites</td>
<td>44%</td>
<td>40%</td>
<td>42%</td>
<td>44%</td>
</tr>
<tr>
<td></td>
<td>21% of higher level containment facilities</td>
<td>29%</td>
<td>25%</td>
<td>25%</td>
<td>33%</td>
</tr>
</tbody>
</table>

In 2015–16, 46% of GM field trial sites across the country were inspected to monitor compliance with licence conditions ensuring risks to human health and the environment are minimised. Sites were inspected in New South Wales, the Northern Territory, Queensland, Victoria and Western Australia. Inspections included GM banana, barley, canola, cotton, safflower, sugarcane and wheat.

The OGTR also inspected 21% of higher level containment facilities to ensure compliance with certification conditions. These inspections focused on the integrity of the physical structure of the facility and on the general laboratory practices followed.

**Qualitative indicator: Protect people and the environment through identification and management of risks from GMOs**

<table>
<thead>
<tr>
<th>2015–16 target</th>
<th>2015–16 result: Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comprehensive and effective risk assessment and risk management of GMOs.</td>
<td>Carried out comprehensive and effective risk assessment and risk management activities.</td>
</tr>
<tr>
<td>High level of compliance with the gene technology legislation and no adverse effect on human health or environment from authorised GMOs.</td>
<td>Assessed compliance level as high. Found no adverse effects on human health or the environment from authorised GMOs.</td>
</tr>
</tbody>
</table>

Routine monitoring of the regulated community found a high level of compliance with the gene technology legislation.

**Qualitative indicator: Facilitate cooperation and provision of advice between relevant regulatory agencies with responsibilities for GMOs and/or genetically modified products**

<table>
<thead>
<tr>
<th>2015–16 target</th>
<th>2015–16 result: Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>High degree of cooperation with relevant regulatory agencies and provision of timely advice.</td>
<td>Maintained high degree of cooperation with relevant regulatory agencies. Provided timely advice as required.</td>
</tr>
</tbody>
</table>

In 2015–16 the Regulator continued cooperative arrangements with other Australian Government regulators to enhance coordinated decision-making and avoid duplication in the regulation of GMOs and genetically modified products.

The OGTR engaged with international fora relevant to GMO regulation including the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology. Regulators from other countries continued to seek input from the OGTR because the Australian scheme is considered a model for robust, practical and efficient regulation of GMOs. The OGTR also provided technical support to Australian engagement in meetings under the United Nations Convention on Biological Diversity and Cartagena Protocol on Biosafety.

**Quantitative indicator: Percentage of licence decisions made within statutory timeframes**

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<tbody>
<tr>
<td>100%</td>
<td>100%</td>
<td>95%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

During 2015–16 the Regulator made 15 licence decisions, all within statutory timeframes.
CHAPTER 4
Management and accountability
The management and accountability practices of the Office of the Gene Technology Regulator encompass human resources, work health and safety, and the Commonwealth Disability Strategy. The OGTR adheres to Australian Government policies for purchasing and assets management, contracting and consultancy, advertising and market research, and ecologically sustainable development. The Gene Technology Regulator reports to parliament annually, as required by legislation.
Human resources

The OGTR has a workforce of 50 employees. Of these, 48 are ongoing employees and two are non-ongoing employees (Appendix 5).

The terms and conditions for non–Senior Executive Service staff at the OGTR are covered by the Department of Health Enterprise Agreement 2016–19, which was made under section 172 of the Fair Work Act 2009. This is a principles-based agreement, with most of the detail on operation of conditions provided in supporting guidelines. It offers a range of non-salary benefits, listed in Table 15.

**Table 15: Non-salary benefits**

<table>
<thead>
<tr>
<th>Agreement</th>
<th>Benefits</th>
</tr>
</thead>
</table>
| Enterprise Agreement | Access to negotiated discount registration or membership fees to join a fitness or health club  
                     | Access to the employee assistance program  
                     | Award scheme  
                     | Access to extended purchased leave  
                     | Flexible working hours  
                     | Flexible working locations, including, where appropriate, access to laptop computers, dial-in facilities and mobile phones  
                     | Flex time  
                     | Influenza and hepatitis B vaccinations for staff who are required to come into regular contact with members of the community who have increased risk of exposure to influenza  
                     | Leave for compelling reasons and exceptional circumstances  
                     | Maternity and adoption leave  
                     | Parental leave  
                     | Pay-out of additional duty in certain circumstances  
                     | Recognition of travel time  
                     | Reimbursement of eyesight testing and eyewear costs prescribed specifically for use with screen-based equipment  
                     | Study assistance  
                     | Support for professional and personal development |

| SES                      | All of the above benefits except flex time  
|                          | Airport lounge membership  
|                          | Car parking  
|                          | Home office equipment  
|                          | Private use of motor vehicles or an allowance in lieu (not all officers)  |

SES = Senior Executive Service

The OGTR continued to build a strong team culture in its 15th year of operation. A weekly all-staff Friday morning tea was a successful way of keeping staff up to date on major issues, and provided opportunities for input, participation and feedback.
Friday was also promoted as casual dress day, and staff who took up this option were encouraged to contribute a gold coin for donations to:

- the Australian Paralympic Committee
- CanTeen
- Give Me 5 For Kids.

The OGTR implemented measures to maintain staff skills and motivation through appropriate training and development, and to ensure that recruitment occurred in a timely manner.

**Regulator’s Achievement Award**

This year the Regulator’s Achievement Award was given to the Application Entry Point team. This award recognises both the team as a whole and the contribution of individual team members.

This team provides one of the many foundations for the work of the OGTR. Its members’ innovation, learning of new skills, and forward thinking to increase the efficiency of their work has put the whole of the OGTR in a very sound position for the future.

The Application Entry Point team has contributed to the OGTR’s achievements for the past several years by delivering high-quality coordination, information and applications management. The high level of teamwork it has demonstrated by accurately logging data and efficiently tracking applications (most with statutory deadlines) has been critical to the OGTR’s achievement of 100% success rate in meeting statutory deadlines. As gatekeepers for applications received, the team’s work is pivotal to the functions of the Regulator and has direct flow-on relevance to virtually all other sections of the OGTR.

The team is also recognised for expertise in areas outside of its core functions, such as laboratory facility accreditation and management of confidential commercial information. It has ensured efficient database backups to minimise data loss and has demonstrated excellent ACCESS database skills.

![Regulator’s Achievement Award recipients](image-url)
Training

OGTR staff undertook 98 days of formal training during the year (compared with 100 days in 2014–15 and 120 days in 2013–14). This was in addition to orientation and induction training for all new starters.

OGTR staff can access professional development opportunities through the department’s performance development scheme. At the beginning of each 12-month cycle, all employees and their managers agree on key commitments for the employee’s professional development, and the associated performance measures and development requirements.

In 2015–16, refresher training was given to the emergency control team, which comprises a floor warden and two fire wardens. Members of the emergency control team are self-nominated. On completion of the required training, they receive an allowance in accordance with the Enterprise Agreement.

Supportive working environment

In keeping with the OGTR’s objective of providing a supportive working environment, staff have access to departmental assistance measures. These include financial support for eyesight testing, workstation assessments, problem resolution procedures and an employee assistance program. The employee assistance program is a free, short-term, professional and confidential counselling and advice service provided by Converge International. OGTR staff and their immediate family members can use the program.

As a family-friendly organisation, the OGTR has endeavoured to be responsive to employee needs and circumstances by providing flexible working arrangements, in recognition of the importance of work–life balance. The OGTR has a high proportion of part-time employees. Staff have accessed extended maternity leave on half pay, and the 48/52 provision, which provides additional unpaid leave while averaging salary payments during the year.

Feedback from the department’s annual staff survey again indicated high overall job satisfaction among OGTR staff. Survey feedback was used to inform the OGTR People Strategy Action Plan for 2015–16.

Work health and safety

The OGTR is committed to ensuring a safe and healthy work environment for all workers, including contractors and visitors, consistent with the legislative requirements of the Work Health and Safety Act 2011 and the Safety, Rehabilitation and Compensation Act 1988.

The OGTR actively supports injured and ill employees in their return to work, and provides appropriate reasonable adjustment to working environments to achieve this, including flexible working arrangements. The commitment to providing rehabilitation assistance to injured and ill employees is supported by medical examinations to determine fitness for duty and the need for workplace rehabilitation assistance.
Initiatives to ensure workers' health, safety and welfare

The department’s Improving Wellness and Motivation in the Workplace: Reducing Unplanned Leave initiative supports a commitment to:

- creating, promoting and maintaining a safe and healthy working environment
- encouraging productive working relationships
- promoting and encouraging behaviours in staff and managers to assist in the management and reduction of levels of unscheduled absence.

The initiative complements existing OGTR strategies and action plans aimed at promoting a positive work environment, increasing the health and wellbeing of staff, reducing rates of illness and injury, optimising performance, and managing workloads and work–life balance.

The OGTR provided the option of influenza vaccinations, at no cost, to all staff as part of the People Strategy Action Plan and the Enterprise Agreement.

The OGTR has implemented changes resulting from the introduction of the Work Health and Safety Act 2001 on 1 January 2012. In 2015–16, training was conducted for 'officers', 'workers', health and safety representatives, and a harassment contact officer. An e-learning module is available for all staff, including contractors and consultants, and an overview of the Work Health and Safety Act is available on the department’s intranet site. Strategies for identification and management of work health and safety risks have been incorporated into business planning processes.

Staff from the Monitoring Section and the Compliance and Investigation Section (which were combined during the year to form the Monitoring and Compliance Section) were issued with branded uniforms appropriate to the types of inspections—field sites or contained facilities—being conducted.

Other work health and safety support included provision of training in first aid, emergency evacuation systems and fire safety systems.

Health and safety outcomes

Information on health and safety outcomes (including impacts on injury rates of workers) related to the initiatives mentioned above or to previous initiatives is incorporated into the department’s annual report.

Notifiable incidents

Statistics relating to any notifiable incidents that arose from the conduct of business or undertakings by the OGTR of which the OGTR became aware during the year are incorporated into the department’s annual report figures.

Investigations under Part 10 of the Work Health and Safety Act

No directions, notices or enforceable undertakings under the Occupational Health and Safety (Commonwealth Employment) Amendment Act 2006 or the Work Health and Safety Act were served on the OGTR during the year.

Regular work health and safety inspections were undertaken at the OGTR premises in Barton during 2015–16. No major health or safety issues were identified.
Freedom of information

Entities subject to the *Freedom of Information Act 1982* (FOI Act) are required to publish information to the public as part of the Information Publication Scheme (IPS). This requirement is in Part II of the FOI Act and has replaced the former requirement to publish a section 8 statement in an annual report. Each agency must display on its website a plan showing what information it publishes in accordance with the IPS requirements.\(^{13}\)

**Freedom of information procedures**

From 1 November 2010, a number of changes arising from the *Australian Information Commissioner Act 2010* and the *Freedom of Information Amendment (Reform) Act 2010* were implemented, including removal of an application fee, and no cost for the first hour of decision-making.

To enable a prompt response and to help the OGTR meet its obligations under the FOI Act, applicants should provide as much information as possible about the documents they are seeking. A telephone number or an email address should also be included, in case OGTR officers need clarification.

**Freedom of information contact details**

Inquiries about submitting a formal request under the FOI Act should initially be directed to the Freedom of Information Coordinator on (freecall) 1800 181 030.

Formal requests should be sent to:

Freedom of Information Coordinator  
Office of the Gene Technology Regulator  
MDP 54  
GPO Box 9848  
Canberra ACT 2601

In accordance with the *Electronic Transactions Act 1999*, freedom of information requests may be emailed to ogtr@health.gov.au.

The OGTR received five requests for access under freedom of information legislation during the reporting period. The requests were finalised within the statutory timeframes.

The Regulator is required by the FOI Act (section 11C) to publish on the OGTR website a disclosure log listing information that has been released in response to a freedom of information request.\(^{14}\)

\(^{13}\) The OGTR’s Information Publication Scheme Agency Plan is on our website at www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ips-plan  
\(^{14}\) The OGTR’s Freedom of Information Disclosure Log is on our website at www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/foi-disclosure2-htm
Purchasing
In 2015–16, the OGTR complied with the Australian Government’s purchasing policies, as articulated in the Commonwealth Procurement Rules.

Assets management
The OGTR applies a whole-of-life asset management strategy that is consistent with the department’s asset management program. In April 2016, the OGTR undertook a stocktake of fixed and intangible assets, in accordance with section 41 of the Public Governance, Performance and Accountability Act 2013 (PGPA Act); section 17 of the PGPA Financial Reporting Rule 2015; and the department’s own Finance Business Rule 5.1—Accounting for Property-related Assets. This confirmed the location and condition of the OGTR’s assets, and ensured that the assets are carried at a value above the recoverable amount.

Exempt contracts
No exempt contracts were awarded in 2015–16.

Consultancies
The OGTR contracts consultancy services to ensure the achievement of more efficient and effective delivery of regulation and related outputs. The OGTR incurred $16 880 in consulting costs during 2015–16 (nil in 2014–15).

Table 16: Consultancies engaged, 2015–16

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Service provided</th>
<th>Paid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Management Solutions</td>
<td>Procurement of coaching services for OGTR executive staff</td>
<td>$16 880</td>
</tr>
</tbody>
</table>

Note: Amount listed includes goods and services tax.

The OGTR’s policy on selecting and engaging consultants accords with the Commonwealth Procurement Rules. Value for money is the core principle for selection, underpinned by a focus on encouraging competition, efficiency and effectiveness, ethical practices, and accountability and transparency.

The department’s Accountable Authority Instructions and Procedural Rules supports the core principles in the Commonwealth Procurement Rules.
Advertising and market research

The OGTR incurred $29,783 in advertising costs during 2015–16 ($18,073 in 2014–15) (Table 17). Advertising was used primarily to invite the public to comment on risk assessment and risk management plans for licence applications involving intentional release of genetically modified organisms (GMOs) into the environment, as required under section 52 of the Act.

Table 17: Media advertising organisations engaged, 2015–16

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Service provided</th>
<th>Paid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dentsu Mitchell Media Australia Pty Ltd</td>
<td>Placing advertisements regarding regulatory activities</td>
<td>$20,210</td>
</tr>
<tr>
<td>Dentsu Mitchell Media Australia Pty Ltd</td>
<td>Placing advertisements regarding nominations for the appointment of members to the Gene Technology Technical Advisory committee</td>
<td>$9,573</td>
</tr>
</tbody>
</table>

Note: Amount listed includes goods and services tax.

Annual reporting requirements

Section 136 of the Act requires the Regulator to prepare and provide an annual report to the minister on the Regulator’s operations during the year, for tabling in the Australian Parliament. The Act requires the report to include information on:

- GMO licences issued during the financial year
- any breaches of conditions of a GMO licence that have come to the Regulator’s attention during the financial year
- emergency dealing determinations made by the minister during the financial year
- any breaches of conditions of an emergency dealing determination that have come to the Regulator’s attention during the financial year
- auditing and monitoring of dealings with GMOs under the Act by the Regulator or an inspector during the financial year.


¹⁵ The report is available from the OGTR Information Officer or on the OGTR website at www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1
Quarterly reporting requirements

On 11 March 2015, the Gene Technology Amendment Act 2015 implemented the recommendations of the 2011 review of the Act, as agreed by all governments in 2013. Amendment to section 136 was made to require that information previously provided in quarterly reports be included in annual reports. Requirements that the Regulator prepare quarterly reports and provide them to the responsible minister, and that the minister table the reports in the parliament, were repealed. As a result of the implementation of these amendments, the last quarterly report prepared by the Regulator was the report for July to September 2015, which was tabled in the parliament in January 2016. However, the Regulator later prepared quarterly monitoring and compliance activity reports and made them available on the OGTR website to maintain transparency of the regulatory system.

Appendix 6 lists the quarterly reports the OGTR published in 2015–16.16

National Disability Strategy

Since 1994, non-corporate Commonwealth entities have reported on their performance as policy adviser, purchaser, employer, regulator and provider under the Commonwealth Disability Strategy. In 2007–08, reporting on the employer role was transferred to the Australian Public Service Commission’s State of the Service reports and the APS Statistical Bulletin. These reports are available at www.apsc.gov.au. From 2010–11, entities have no longer been required to report on these functions.

The Commonwealth Disability Strategy has been overtaken by the National Disability Strategy 2010–2020, which sets out a 10-year national policy framework to improve the lives of people with disability, promote participation and create a more inclusive society. A high-level, two-yearly report tracks progress against each of the six outcome areas of the strategy and presents a picture of how people with disability are faring. The first of these progress reports was published in 2014, and can be found at www.dss.gov.au.17

Ecologically sustainable development and environmental performance

The OGTR supports the Australian Government’s commitment to ecologically sustainable development principles, and reports here on its operations during 2015–16 against section 516A of the Environment Protection and Biodiversity Conservation Act 1999.

16 These reports are available from the OGTR Information Officer or on the OGTR website at www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1

17 The National Disability Strategy 2010–2020 report is on the Department of Social Services website at www.dss.gov.au
Section 516A(6)(a)—Legislation administered by the Regulator during 2015–16 that accords with ecologically sustainable development principles

The Regulator administers the Act, which aims to protect the health and safety of people and the environment by identifying risks posed by gene technology and managing those risks through regulating dealings with GMOs.

Section 516(6)(b)—How OGTR outcomes have contributed to ecologically sustainable development during 2015–16

In 2015–16, the OGTR continued to support the Regulator in regulating activities involving live and viable GMOs. These activities ranged from contained work in certified laboratories to releases of GMOs into the environment. The Regulator imposed licence conditions to protect the environment, and used extensive powers to monitor and enforce those conditions.

In 2015–16, the Regulator received 17 licence applications; eight were for dealings involving intentional release of a GMO into the environment (DIRs) and nine were for dealings not involving intentional release of a GMO into the environment (DNIRs). The Regulator issued 16 licences to deal with GMOs, comprising nine DIRs and seven DNIRs (see Chapter 3).

The OGTR submits a nil response to subsections 516A(6)(c), (d) and (e).
APPENDIX 1
History and structure of the gene technology regulatory system
This appendix briefly describes the development of the *Gene Technology Act 2000*, governance arrangements for the regulatory system and how gene technology is regulated in Australia.
Development of the Act

Voluntary oversight of gene technology in Australia began in the mid-1970s, primarily on the initiative of the Australian Academy of Sciences, and later that of the Australian Government. Significant advances in applications of gene technology and resulting elevated community concern about genetically modified organisms (GMOs) led, in November 1998, to a cooperative process between the state and territory governments and the Australian Government to establish a uniform national approach to regulating gene technology. After wide consultation, the Act and the Gene Technology Regulations 2001 came into effect on 21 June 2001.

In establishing the regulatory scheme, governments sought to recognise and reach a balance between the potential of gene technology to contribute to society, against community concerns over its development and deployment. Extensive consultation during development of the regulatory scheme reflected the emphasis placed on community input and participation in the decision-making process, and generated strong agreement about what should be included and excluded from the scope of the legislation. Broad consensus was reached that the Gene Technology Regulator (the Regulator) should consider only gene technology, and that other forms of genetic manipulation used in conventional breeding should be excluded from assessments. Other matters considered to be out of scope included trade and marketability, cost–benefit considerations, comparisons with alternative technologies, intellectual property and human cloning.

This led to the object of the Act being defined as:

*to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.*

The national regulatory system is underpinned by the intergovernmental Gene Technology Agreement. This agreement, signed by all Australian jurisdictions, sets out the understanding between governments of the nationally consistent regulatory system, and commits the states and territories to pass corresponding laws.
Governance arrangements

The Act, the Gene Technology Regulations, and corresponding state and territory laws (Table 18) provide a nationally consistent system to regulate development and use of gene technology in Australia. The legislation establishes the Regulator as an independent statutory office holder to administer the national scheme. Under the intergovernmental Gene Technology Agreement, the states and territories have committed to maintaining corresponding legislation with the Commonwealth. The Regulator is charged with performing functions and exercising powers under the Act and corresponding legislation (Figure 14).

Although the Regulator must consider risks to human health and safety, and the environment, relating to dealings with GMOs, other agencies have responsibility for regulating GMOs or genetically modified (GM) products as part of a broader or different legislative mandate. During development of the gene technology legislation, it was determined that the Regulator’s activities should form part of an integrated legislative framework that includes a number of other regulatory authorities with complementary responsibilities and expertise (see Figure 14). This arrangement both supports coordinated decision-making and avoids duplication. The Act was accompanied by consequential amendments to other relevant Acts relating to requirements for reciprocal request and provision of advice, and exchange of information between the Regulator and other relevant regulatory agencies. These requirements include the following:

The Regulator must consult Australian Government regulatory agencies prescribed in the Regulations (see Table 21) on all licence applications for dealings involving the intentional release of GMOs into the environment.

Agencies\(^\text{18}\) regulating GM products\(^\text{19}\) are required to consult and/or notify the Regulator regarding applications for registration of products that are GM or contain GMOs.

These provisions support an adequate and timely flow of information between the agencies to inform assessments and decisions. As a result of the *Gene Technology Amendment Act 2015* coming into effect from 11 March 2016, the agencies regulating GM products are no longer required to notify the Regulator about their decisions for inclusion on the GMO Record.

\(^{18}\) Therapeutic Goods Administration, Australian Pesticides and Veterinary Medicines Authority, National Industrial Chemicals Notification and Assessment Scheme, Food Standards Australia New Zealand.

\(^{19}\) A GM product is a thing (other than a GMO) derived or produced from a GMO.
Appendix 1 History and structure of the gene technology regulatory system

Figure 14: Governance arrangements for the Gene Technology Regulator

APVMA = Australian Pesticides and Veterinary Medicines Authority; DAWR = Department of Agriculture and Water Resources; FSANZ = Food Standards Australia New Zealand; GTTAC = Gene Technology Technical Advisory Committee; GTECC = Gene Technology Ethics and Community Consultative Committee; LGFGT = Legislative and Governance Forum on Gene Technology; NICNAS = National Industrial Chemicals Notification and Assessment Scheme; TGA = Therapeutic Goods Administration
### Table 18: Legislation administered by the Gene Technology Regulator

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Acts and Regulations*</th>
</tr>
</thead>
</table>
| Australian Capital Territory | Gene Technology Act 2003  
Gene Technology Regulations 2004 |
| Commonwealth          | Gene Technology Act 2000  
Gene Technology Regulations 2001  
Guidelines for the Transport, Storage and Disposal of GMOs\(^b\) |
| Northern Territory    | Gene Technology (Northern Territory) Act 2004                                              |
| Queensland            | Gene Technology Act 2001  
Gene Technology Regulation 2002 |
| South Australia       | Gene Technology Act 2001  
Gene Technology Regulations 2002 |
| Tasmania              | Gene Technology (Tasmania) Act 2012                                                       |
| Victoria              | Gene Technology Act 2001  
Gene Technology Regulations 2011 |

\(^a\) New South Wales, the Northern Territory and Tasmania do not have regulations, as their Acts automatically adopt any amendments to the Commonwealth Act and Regulations.  

\(^b\) These guidelines are a legislative instrument issued by the Regulator under section 27(d) of the Gene Technology Act.

### Legislative and Governance Forum on Gene Technology

The Legislative and Governance Forum on Gene Technology (LGFGT)\(^{20}\) provides oversight of the national regulatory scheme for gene technology.

The LGFGT was established by the Council of Australian Governments under clause 20 of the intergovernmental Gene Technology Agreement. It comprises a representative minister from each state and territory. Its role is to provide policy guidance for the operation of the Act. In addition, the LGFGT approves appointment of the Regulator and the chairs of the statutory advisory committees (see Appendix 7), and provides advice to the Australian Government minister responsible for gene technology regulation (the Assistant Minister for Health) on appointment of committee members.

Section 21 of the Act provides for the LGFGT to issue policy principles on ethical issues related to dealings with GMOs, and recognition of areas designated under state law for the purpose of preserving the identity of either GM crops or non-GM crops for marketing purposes. Policy principles are legislative instruments, and the Regulator must not issue a licence if it would be inconsistent with a policy principle. One policy principle has been issued to date (Table 19).

\(^{20}\) Referred to as the Ministerial Council in the *Gene Technology Act 2000.*
Table 19: Policy principles issued at 30 June 2016

<table>
<thead>
<tr>
<th>Policy principle</th>
<th>Date issued</th>
<th>Date effective</th>
</tr>
</thead>
</table>

The LGFGT is supported by the Gene Technology Standing Committee, which comprises officials (with relevant technical expertise) representing each state and territory.

The Department of Health provides the secretariat for the LGFGT and the standing committee. This makes clear the separation of the Regulator’s responsibility for administering the Act from responsibility for policy direction and development of the gene technology regulatory scheme.

Changes to gene technology legislation

One of the Regulator’s prescribed functions is to advise the LGFGT about the effectiveness of the legislative framework for regulating GMOs, including possible amendments to legislation. Since their inception, the Act and the Regulations have been amended (Table 20) to:

- improve the effectiveness and efficiency of the Regulations. Three sets of amendments to the Regulations have been made:
  - Amendment Regulations 2006 (as a result of the 2004–06 Regulator’s review)
  - Amendment Regulations 2007 (consequential amendments following the review of the Act)
  - Amendment Regulations 2011 (as a result of the 2008–11 Regulator’s review)

The Regulator’s reviews of the Regulations have focused on technical aspects, particularly ensuring that the classification of and requirements for the conduct of GMO dealings are commensurate with risk and up to date with current scientific knowledge.

- improve the operation of the Act. These generally minor amendments included addition of emergency powers to the Act that give the minister the ability to expedite approval of a GMO in emergencies. The amendments were made as a result of the 2005–06 statutory review of the Act and the Gene Technology Agreement (Gene Technology Amendment Act 2007 and Gene Technology Amendment Regulations 2007). The Gene Technology Amendment Act 2015 implemented five recommendations of the LGFGT’s 2011 independent review of the Act, agreed by the LGFGT in 2013. The amendments commenced on 11 March 2016.
<table>
<thead>
<tr>
<th>Amending legislation</th>
<th>Change informed by</th>
<th>Summary of changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gene Technology Amendment Regulations 2006</td>
<td>2004–06 Regulator’s review</td>
<td>• Changes to requirements for IBC assessment, notification and conduct of NLRDs&lt;br&gt;• Changes to classification of particular GMO dealings as exempt, NLRD or licensable&lt;br&gt;• Changes to classification of particular techniques as not gene technology, and particular organisms as not GMOs&lt;br&gt;• Licence application requirements detailed in forms issued by the Regulator</td>
</tr>
<tr>
<td>Gene Technology Amendment Act 2007</td>
<td>2005–06 independent statutory review of the Gene Technology Act 2000</td>
<td>• Capacity to authorise a GMO by an emergency dealing determination&lt;br&gt;• Capacity to authorise disposal of GMOs by an inadvertent dealings licence&lt;br&gt;• Specific requirements for assessment and consultation on limited and controlled release licence applications&lt;br&gt;• Changes to application timeframes&lt;br&gt;• Replacement of Gene Technology Ethics Committee and Gene Technology Community Consultative Committee by Gene Technology Ethics and Community Consultative Committee</td>
</tr>
<tr>
<td>Gene Technology Amendment Regulations 2007</td>
<td>2005–06 independent statutory review of the Gene Technology Act 2000</td>
<td>• Annual notification of NLRDs&lt;br&gt;• Changes to classification and containment requirements for NLRDs&lt;br&gt;• Changes to exempt dealing requirements</td>
</tr>
<tr>
<td>Gene Technology Amendment Regulations 2009</td>
<td>Council of Australian Governments’ recommendations</td>
<td>• Capacity for OGTR inspectors to be appointed as inspectors for Security Sensitive Biological Agents Regulatory Scheme</td>
</tr>
<tr>
<td>Gene Technology Amendment Regulations 2011</td>
<td>2008–11 Regulator’s review</td>
<td>• Clarification of requirements for IBC assessment, notification, containment and conduct of NLRDs, including transport, storage and disposal guidelines&lt;br&gt;• Changes to classification of particular GMO dealings as exempt, NLRD or licensable</td>
</tr>
</tbody>
</table>

GMO = genetically modified organism; IBC = Institutional Biosafety Committee; NLRD = notifiable low risk dealing; OGTR = Office of the Gene Technology Regulator
Coordination with prescribed agencies

Conduct of activities with a GMO sometimes requires approval from both the Regulator and another regulatory body—for example, dealings with a human medicine that is a GMO. Some human medicines (e.g. live GM vaccines) require both a licence from the Regulator and registration and assessment by the Therapeutic Goods Administration, which authorises administration of the vaccine to people. Similarly, while the Regulator is responsible for approving release of GM animal vaccines and GM insecticide or herbicide-tolerant plants into the environment, the Australian Pesticides and Veterinary Medicines Authority, which is responsible for regulating all agricultural and veterinary chemicals, registers the vaccine or the insecticide product produced in the GM plant and approves application of the herbicide to which the GM plants are tolerant.

Although these other agencies have different focuses and responsibilities from those of the Regulator, the Regulator has a policy of aligning the decision-making processes to the extent that it is practicable within the limits of the relevant legislation. The OGTR and other regulatory agencies work together to ensure that parallel applications are thoroughly assessed in a coordinated way and that, wherever possible, the timing of decisions by the agencies coincides.

In other instances, approval is required from one regulatory agency but not another. For example, Food Standards Australia New Zealand assesses the safety of a GM product that will be imported for sale as a human food, where no application has been (and may never be) submitted to the Regulator to grow in Australia the GMO from which the GM product is derived.

The respective roles of the various agencies that regulate GMOs or GM products, along with the relevant legislation, are listed in Table 21.

**Table 21: Regulatory agencies in Australia with a role in regulating gene technology**

<table>
<thead>
<tr>
<th>GMO, GM product or activity</th>
<th>Agency</th>
<th>Portfolio</th>
<th>Scope</th>
<th>Relevant legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td>GMO dealings</td>
<td>OGTR</td>
<td>Health</td>
<td>The OGTR underpins the national scheme for regulating GMOs in Australia. It aims to protect human health and safety, 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.</td>
<td>Gene Technology Act 2000</td>
</tr>
<tr>
<td>GMO, GM product or activity</td>
<td>Agency</td>
<td>Portfolio</td>
<td>Scope</td>
<td>Relevant legislation</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------</td>
<td>-----------</td>
<td>-------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Medicines, medical devices, blood and tissues</td>
<td>TGA&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Health</td>
<td>The TGA administers legislation that provides a national framework for regulating therapeutic products in Australia, and ensures their quality, safety and efficacy.</td>
<td>Therapeutic Goods Act 1989</td>
</tr>
<tr>
<td>Food</td>
<td>FSANZ&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Health</td>
<td>FSANZ is responsible for the Australia New Zealand Food Standards Code, which prohibits use of food products produced using gene technology in Australia unless there is specific approval for sale of these foods following a safety assessment. The code also contains provisions for labelling GM foods.</td>
<td>Food Standards Australia New Zealand Act 1991 Standard 1.5.2—Food produced using gene technology</td>
</tr>
<tr>
<td>Agricultural and veterinary chemicals</td>
<td>APVMA&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Agriculture</td>
<td>The APVMA operates the national system that evaluates, registers and regulates all agricultural chemicals (including those that are, or are used on, GM crops) and veterinary therapeutic products. Assessments consider human and environmental safety, product efficacy (including insecticide and herbicide resistance management) and trade issues relating to residues.</td>
<td>Agricultural and Veterinary Chemicals (Code) Act 1994 Agricultural and Veterinary Chemicals Act 1994 Agricultural and Veterinary Chemicals (Administration) Act 1992</td>
</tr>
<tr>
<td>Industrial chemicals</td>
<td>NICNAS</td>
<td>Health</td>
<td>NICNAS provides a national notification and assessment scheme to protect the health of the public, workers and the environment from the harmful effects of industrial chemicals.</td>
<td>Industrial Chemicals (Notification and Assessment) Act 1989</td>
</tr>
<tr>
<td>Quarantine</td>
<td>Department of Agriculture and Water Resources&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Agriculture</td>
<td>Department of Agriculture and Water Resources (Biosecurity) regulates importation into Australia of all animal, plant and biological products that may pose a quarantine pest or disease risk.</td>
<td>Biosecurity Act 2015 Imported Food Control Act 1992</td>
</tr>
</tbody>
</table>

APVMA = Australian Pesticides and Veterinary Medicines Authority; FSANZ = Food Standards Australia New Zealand; GM = genetically modified; GMO = genetically modified organism; NICNAS = National Industrial Chemicals Notification and Assessment Scheme; OGTR = Office of the Gene Technology Regulator; TGA = Therapeutic Goods Administration

<sup>a</sup> Prescribed agencies in the Gene Technology Regulations that the Regulator must consult on applications for a dealing involving intentional release of a GMO into the environment.
APPENDIX 2
Application types, authorisations, and monitoring and compliance
This appendix describes:

- the classes of dealings with genetically modified organisms (GMOs) that are defined by the Act, the Gene Technology Regulations 2001, and corresponding state and territory laws

- the procedures followed for each type of application and other instruments that help the Gene Technology Regulator (the Regulator) manage risks to the health and safety of people, and the environment

- activities that the Office of the Gene Technology Regulator (OGTR) undertakes to monitor dealings with GMOs for compliance with legislation, and actions it takes in response to non-compliances.
GMO Register

The GMO Register is provided for by Part 6, Division 3 of the Act. The Regulator may make a determination to include dealings with GMOs on the GMO Register according to section 78 of the Act. To be included on the GMO Register, the dealings must first have been authorised by a GMO licence. Dealings will not be entered on the GMO Register until the Regulator is satisfied that the risks they pose are minimal, and that it is not necessary for anyone conducting them to be covered by a licence to protect the health and safety of people or the environment. After inclusion on the GMO Register, the dealings no longer require authorisation by a licence from the Regulator but may still have conditions attached to their registration.

One GMO dealing (for a colour-modified carnation) is currently on the GMO Register.

Types of dealings

Exempt dealings

Exempt dealings are dealings with GMOs that have been assessed over time as posing negligible risks to people or the environment. They comprise basic molecular biology techniques that are used extensively in laboratories worldwide. The criteria for exempt dealings are specified in the Gene Technology Regulations (Schedule 2). Exempt dealings must not involve intentional release of a GMO into the environment but do not require a case-by-case risk assessment or a specified level of containment. Guidance on appropriate containment measures for exempt dealings is provided on the OGTR website.

Examples of exempt dealings are dealings with:

- an animal into which genetically modified (GM) somatic cells have been introduced, where the introduced somatic cells do not produce infectious agents
- small volumes (less than 25 litres) of an approved host–vector system into which low-risk genetic material has been introduced—for example, the introduced DNA must not encode an uncharacterised gene from a pathogen, an entire viral genome or a toxin.

Notifiable low risk dealings

Notifiable low risk dealings (NLRDs) are dealings with GMOs that have been assessed as posing negligible risks provided that certain management conditions are met. The Regulations specify the GMO dealings that are classified as NLRDs (Schedule 3, Part 1 and Part 2) and requirements for undertaking NLRDs (regulation 13). Such dealings may only be undertaken in a facility certified by the Regulator to a specified

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21 It is important to note the difference between the GMO Record and the GMO Register. The GMO Register lists GMOs that no longer require a licence and is a subset of dealings included on the GMO Record. The GMO Record is a comprehensive listing of all dealings with GMOs, including licensed dealings and NLRDs.

22 The term ‘negligible’ is defined in Chapter 3 of the Risk Analysis Framework and is used here for consistency.
physical containment level (usually PC1, PC2 or PC3) and of an appropriate design for the kind of dealing undertaken. Conducting NLRDs requires prior assessment by an Institutional Biosafety Committee (IBC) to confirm that the proposed dealings are properly classified as NLRDs, that the facilities are of the appropriate physical containment level and type, and that personnel have the appropriate training or experience. Organisations must keep a record of all current NLRDs and notify them in an annual report to the Regulator. NLRDs are included on the GMO Record (see below) but do not require case-by-case risk assessment by the Regulator.

An example of NLRDs that may be conducted in PC1 facilities is working with GM laboratory guinea pigs, mice, rabbits or rats where the genetic modification does not provide an advantage and has not made the animal infectious.

NLRDs that may be conducted in PC2 facilities include dealings with:

- a GM animal (other than a GM laboratory guinea pig, mouse, rabbit, rat or roundworm (*Caenorhabditis elegans*), including invertebrates
- a GM plant
- an approved host–vector system that does not meet the criteria for an exempt dealing (e.g. the introduced DNA may encode a pathogenic determinant or may be an uncharacterised gene from a pathogen).

NLRDs involving microorganisms classified as Risk Group 3 under Australian Standard AS/NZS 2243:3:2012 (Safety in laboratories—microbiological safety and containment) must be undertaken in facilities certified to at least PC3 level and appropriate to the dealings.

**Licensed dealings**

Any dealing with a GMO not classified as exempt, an NLRD, listed on the GMO Register, or authorised by an emergency dealing determination (EDD) must not be conducted unless licensed. The Regulator considers all licence applications case by case. The Regulator must consider whether the risks posed by the dealing can be managed in such a way as to protect human health and safety, and the environment. The Regulator must make a decision on whether to issue or refuse a licence to allow a dealing. If a licence is to be issued, the Regulator must decide on the management conditions to be imposed to manage any risks.

The legislation sets out a series of actions that the Regulator must take in considering applications for licences for contained dealings (DNIRs) and for intentional release of GMOs into the environment (DIRs). The Act details steps that must be taken in assessing licence applications, and application forms detail the information an applicant must provide.

For both DNIRs and DIRs, the Regulator requires an applicant to identify risks that the dealings may pose to human health and safety, and the environment, and any measures proposed to manage those risks. The organisation’s IBC must support the application.
The Act requires the Regulator to prepare a risk assessment and risk management plan (RARMP) for both DNIR and DIR applications. The risk assessment takes account of any risks to human health and safety, and the environment, posed by the dealing, and the risk management plan determines how these risks can be managed. The Regulator uses information provided in the application, as well as other relevant scientific and technical knowledge. The requirements of the legislation have been framed to place DIRs under greater scrutiny than DNIRs.

The Regulator may impose conditions on all licences. For example, for all DIRs determined to be limited and controlled releases, measures will be imposed to restrict the persistence and spread of the GMO and its genetic material.

For both DNIR and DIR applications, the applicant must provide information about their suitability to hold a licence. This includes any information on relevant convictions and on revocations or suspensions of licences under laws relating to human health and safety or the environment. The Regulator also assesses the applicant’s capacity to comply with licence conditions. Non-compliance with conditions placed on licences issued under the Act is a criminal offence.

Although the Act is highly prescriptive about the process to be followed in assessing licence applications, it is not explicit in directing how the Regulator should undertake risk analyses. The Risk Analysis Framework was therefore developed to provide guidance on how the Regulator and the OGTR should apply internationally recognised risk analysis practices in the context of the legislation. The framework was applied to all licence applications processed during 2015–16.\(^\text{23}\)

**Dealings not involving intentional release**

DNIRs usually take place under specified physical containment conditions in certified facilities that minimise risks to human health and the environment. The Act (section 47) requires preparation of an RARMP for DNIR applications. The application form specifies the information the Regulator requires.

The legislation provides that, in relation to DNIR licences, the Regulator may consult the Gene Technology Technical Advisory Committee (GTTAC), the states and territories, relevant Australian Government agencies and any person the Regulator considers appropriate.

The Regulator considers the RARMP in deciding whether to issue a licence and in determining the licence conditions that should be imposed. Typical licence conditions require the applicant to conduct the dealings in certified facilities, to follow particular handling requirements (such as avoiding use of ‘sharps’ and using biosafety cabinets), to train and supervise staff, to transport and dispose of the GMO appropriately, and to have, and if necessary implement, contingency plans.

The process for assessing DNIR applications is shown in Figure 15. The statutory timeframe for consideration of a DNIR application is 90 days.

Figure 15: DNIR assessment process

DNIR = contained dealing with a genetically modified organism not involving intentional release into the environment; RARMP = risk assessment and risk management plan.
The application process comprises five stages, as described below.

**Stage 1**
The applicant completes the DNIR application form and provides comprehensive information about the proposed dealings with the GMO, including possible risks posed by the dealings and ways in which each risk would be managed. The applicant must ensure that all responses to the Regulator's information requirements are supported by appropriate data and literature citations.

**Stage 2**
The IBC reviews the application and appends an evaluation report setting out its advice on the completeness of the application. The IBC’s role is to ensure the quality of applications submitted to the Regulator. If insufficient information has been provided, the application is rejected.

**Stage 3**
Section 47 of the Act requires the Regulator to prepare an RARMP. The information provided in the application is used to prepare the RARMP.

The actual risk assessment process is, to some extent, shaped by the data requirements set out in the DNIR application form; however, the Regulator can require submission of any data required to comprehensively identify and evaluate risks posed by the dealing. The Regulator is permitted by the legislation to seek and take into account any other relevant information, such as independent research, independent literature searches and the advice of any person or group. The Regulator may also request more information from the applicant.

Risk assessment involves developing risk scenarios that describe how risks that may be posed by dealings with the GMO could result in harm, identifying risks that require more detailed characterisation, and estimating the level of risk based on the likelihood of the event occurring and the likely consequences of that occurrence. Risks are then evaluated to determine which ones require treatment to protect people and the environment.

The risk management plan considers how risks to human health and safety or to the environment may be managed. This provides the basis for conditions that may be applied to the licence. Draft conditions are included in the consultation version of the RARMP.
Stage 4
The Regulator may consult experts, agencies or authorities about the RARMP. These include GTTAC, the states and territories, prescribed Australian Government agencies, the Minister for the Environment and Energy, and appropriate local government authorities. The Regulator finalises the RARMP, considering the advice provided.

Stage 5
The Regulator decides whether to issue a licence and, if so, any conditions to be imposed. This decision is based on the RARMP, having regard to any policy principles issued by the Legislative and Governance Forum on Gene Technology (LGFGT). The Regulator must notify the applicant in writing that a licence decision has been made. The Regulator also advises all experts, agencies and authorities that were consulted.

Dealings involving intentional release
The legislation defines two types of DIRs: limited and controlled DIRs, and other DIRs. Currently, two application forms are available: one for limited and controlled DIR applications involving GM plants, and another for all other applications. A specific application form for commercial release of GM plants is under development. The Regulator will, on a case-by-case basis, use information that the applicant has provided on the application form to determine whether the release should be assessed as a limited and controlled release. This decision will determine which consultation process and timeframe under the Act will apply for processing the application.

The Risk Analysis Framework outlines the approach taken to risk analysis and preparing RARMPs. The assessment process for DIR applications is shown in Figure 16. The statutory timeframe allowed for consideration of a DIR application, except for a limited and controlled release application, is 255 days. For a limited and controlled release application, this timeframe is either 170 days (for dealings that may pose a significant risk) or 150 days (for dealings that do not pose a significant risk).
Figure 16: DIR assessment process

Application for DIR licence

- Sufficient information? NO: Reject application
  YES: Is the release limited and controlled?
    NO: Seek advice
    YES: Prepare consultation RARMP

- Do the dealings pose a significant risk?
  NO: Consultation minimum 30 working days
  YES: Consultation minimum 50 working days

- Finalise RARMP

- Can the risks be managed to protect people and the environment?
  NO: Refuse to issue licence
  YES: Finalise licence conditions

Issue licence
The application process comprises eight stages, as described below.

**Stage 1**
The applicant completes the DIR application form and provides comprehensive information about the proposed dealings with the GMO, including possible risks posed by the dealings and ways in which each risk would be managed. The applicant must ensure that all responses to the Regulator’s information requirements are supported by appropriate data and literature citations. Wherever possible, quantitative data should be provided. It is expected that applicants will collect relevant data during contained work and early trials to support applications for dealings involving intentional releases of GMOs.

**Stage 2**
The IBC reviews the application and appends an evaluation report setting out its advice on the completeness of the application. The IBC’s role is to ensure the quality of applications submitted to the Regulator.

**Stage 3**
Section 50A of the Act allows the Regulator to determine whether the application is for a limited and controlled release, which follows a shorter process.

Section 50A(1) of the Act specifies that an application is a limited and controlled release application if the Regulator is satisfied that:

- the principal purpose of the application is to enable the licence holder, and people covered by the licence, to conduct experiments
- the application proposes
  - controls to restrict dissemination or persistence of the GMO and its genetic material in the environment
  - limits on the proposed release of the GMO
- the controls and limits are of such a kind that it is appropriate not to seek the advice referred to in section 50(3).

Section 50A(2) of the Act describes ‘controls’ as including:

- methods to restrict the dissemination or persistence of the GMO or its genetic material in the environment
- methods for disposal of the GMO or its genetic material
- data collection, including studies to be conducted about the GMO or its genetic material
- the geographic area in which the proposed dealings with the GMO or its genetic material may occur
- compliance with
  - a code of practice issued under section 24, or
  - a technical or procedural guideline issued under section 27.
Section 50A(3) describes ‘limits’ as including the:

- scope of the dealings
- scale of the dealings
- locations of the dealings
- duration of the dealings
- people who are permitted to conduct the dealings.

**Stage 4**
A notification of application is sent out to those on the OGTR mailing list and placed on the website, advising when the consultation RARMP is expected to be released for comment. This is not a requirement of the Act, but increases the transparency of the regulatory system and aims to increase participation in the consultation process.

The Regulator must provide a copy of the application to anyone who requests it (section 54). This excludes any information that has been declared by the Regulator as (or is under consideration as) confidential commercial information.

**Stage 5**
The Regulator must seek advice on the application regarding matters relevant to preparation of the RARMP from GTTAC, the states and territories, prescribed Australian Government agencies, the Minister for the Environment and Energy, and appropriate local government authorities (section 50). The Regulator usually consults local government authorities in the area where the release is proposed to occur. In addition, the Regulator routinely seeks advice from Australian Government agencies such as the Department of Agriculture and Water Resources and the Department of Foreign Affairs and Trade.

If the application is for a limited and controlled release, this consultation stage is not required.

**Stage 6**
Section 51 of the Act requires the Regulator to prepare an RARMP (consultation version) and to take account of submissions received during any consultation on the application under section 50.

The actual risk assessment process is, to some extent, shaped by the data requirements set out in the DIR application form; however, the Regulator can require submission of any data required to comprehensively identify and evaluate risks posed by the dealing. The Regulator is permitted by the legislation to seek and take into account any other relevant information, such as independent research, independent literature searches and the advice of any person or group. The Regulator may also request more information from the applicant or hold a public hearing.

Risk assessment involves developing risk scenarios that describe how risks that may be posed by the dealings with the GMO could result in harm, identifying risks that require more detailed characterisation, and estimating the level of risk based on the likelihood of the event occurring and the likely consequences of that occurrence.
Risks are then evaluated to determine which ones require treatment to protect people and the environment.

The risk management plan considers how risks to human health and safety or to the environment may be managed. This provides the basis for conditions that may be applied to the licence. Draft conditions are included in the consultation version of the RARMP.

**Stage 7**

Once the consultation version of the RARMP is prepared, the Regulator must determine whether any of the proposed dealings pose a significant risk to the health and safety of people or to the environment. The minimum consultation period specified in the Act is 50 days if the Regulator is satisfied that the dealings may pose a significant risk to the health and safety of people or to the environment. If the Regulator considers that the proposed dealings do not pose significant risks, a minimum 30-day consultation period is specified (section 52(2)).

The Regulator is required to seek public comment on the consultation RARMP through advertisements in relevant newspapers, the Australian Government Gazette and notices on the Regulator’s website. In practice, the Regulator advertises more broadly, including in metropolitan and regional newspapers, and special-interest publications. All people and organisations that have registered their interest in receiving such information are advised by mail or email. Under section 52(3) of the Act, the Regulator must also seek advice on the RARMP from the expert groups, agencies and authorities listed in Table 21 (for consultation on the application).

The Regulator is required to consult with the Australian Government Minister for the Environment and Energy on DIR licence applications.

**Stage 8**

The Regulator finalises the RARMP, considering advice provided in response to the consultation version of the RARMP, in accordance with section 56(2) of the Act. The Regulator decides whether to issue the licence and any conditions to be imposed, based on the finalised RARMP, having regard to any policy principles issued by the LGFGT (formerly the Gene Technology Ministerial Council).

The Regulator must notify the applicant in writing that a licence decision has been made. The Regulator also publishes the finalised RARMP on the OGTR website; advises all experts, agencies and authorities that were consulted, and people or organisations that made submissions; and notifies registered recipients on the OGTR mailing list.

**Inadvertent dealings**

Part 5 of the Act allows the Regulator to grant a temporary licence (for no longer than 12 months) to a person who finds that they are inadvertently dealing with an unlicensed GMO. The licence may be issued to the person for the purposes of disposing of the GMO. There is no requirement to prepare an RARMP or consult in relation to inadvertent dealing applications, but the Regulator must not issue a licence unless satisfied that the risks posed by the dealings can be managed to protect the health and safety of people, and the environment.
Emergency dealing determinations

The EDD provision in Part 5A (sections 72A–E) of the Act gives the minister the power to expedite approval of a dealing with a GMO in an emergency, when a rapid assessment of a proposed dealing with a GMO may be needed. An EDD can only be made for a limited period (up to six months), but this may be extended by the minister. Before making an EDD, the minister must be satisfied that:

- there is an actual or imminent threat to the health and safety of people or to the environment
- the proposed dealings would, or would be likely to, adequately address the threat
- any risks posed by the dealings can be managed to protect the health and safety of people, and the environment.

The minister must receive advice from the Commonwealth’s Chief Medical Officer, Chief Veterinary Officer or Chief Plant Protection Officer that the proposed emergency dealing would address the threat, and from the Regulator about managing risks. The states and territories must also be consulted.

In developing the risk assessment advice for the minister, the Regulator will apply the principles embodied in the Risk Analysis Framework. Because of the emergency context and the need for a rapid assessment, there are no prescribed consultation requirements.

GMO Record

Section 138 of the Act requires the Regulator to maintain a Record of GMO Dealings (the GMO Record). The GMO Record contains information on licences issued (DNIRs, DIRs, inadvertent dealings), NLRDs, GMO dealings included on the GMO Register and EDDs.

The GMO Record is currently divided into separate sections:

- NLRDs
- contained dealings—DNIR licences
- intentional releases—DIR licences
- inadvertent dealing licences
- GMO Register
- EDDs.

24 The GMO Record is on the OGTR website at www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmorec-index-1
Accreditation and certification

Accreditation of organisations and certification of individual physical containment facilities help to manage risks that may be associated with dealings with GMOs.

The Regulator requires organisations undertaking certain dealings with GMOs to be accredited. The process of accreditation enables the Regulator to assess whether the organisation has the resources and internal processes to enable it to effectively oversee work with GMOs. Before an organisation can be accredited, it must have established, or have access to, an appropriately constituted IBC.

IBCs provide on-site scrutiny of low risk contained dealings that do not require case-by-case consideration by the Regulator, through independent assessment of NLRD proposals (under regulation 13B). On behalf of their organisation, they ensure compliance with legislative requirements. IBCs comprise a range of suitable experts and an independent person. They provide a quality assurance mechanism that reviews the information that applicants submit to the Regulator.

Certain dealings must only be undertaken in facilities that are certified by the Regulator. The legislation allows the Regulator to certify physical containment facilities to ensure that appropriate standards are met for containment of GMOs, and that trained and competent staff are carrying out procedures and practices. Under the legislation, the Regulator has issued guidelines specifying the requirements for certification of each type of facility (laboratory, plant, animal, etc.) to physical containment levels 1, 2, 3 or 4, which must be met before a facility can be certified. All certified facilities must be inspected before certification and annually thereafter (except PC1 facilities). The OGTR inspects all high-level facilities (PC3, PC4 and large-scale PC2) before certification and recertification.

Monitoring and compliance

The aim of OGTR monitoring and compliance activities is to ensure that dealings with GMOs comply with legislative obligations and are consistent with the object of the Act. Non-compliance with conditions placed on licences issued under the Act is a criminal offence. The OGTR has adopted an operational philosophy that places strong emphasis on helping accredited organisations and licence holders comply with their legislative obligations.

Monitoring activities focus on managing dealings at field trial sites and within certified physical containment facilities to ensure that:

- dissemination of a GMO and its genetic material is minimised
- persistence of a GMO in the environment is managed
- effective management of the GMO is maintained.

25 The guidelines for certification of physical containment facilities are on the OGTR website at www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/certifications-1
OGTR monitoring activities comprise routine monitoring (including spot checks), assessing monitoring findings and, where necessary, recommending corrective action and follow-up activities.

The OGTR makes routine monitoring visits to at least 20% of field trial sites each year. The OGTR strategy for field trial monitoring draws on accumulated operational experience of risk profiling in relation to compliance. For example, OGTR field trial monitoring coincides, where possible, with periods or circumstances when non-compliance with licence conditions designed to limit the spread and persistence of GMOs or their genetic material is more likely to occur (e.g. during flowering or harvesting of GM crops).

The monitoring program for contained dealings involves inspecting DNIRs and the facilities in which these dealings are conducted, as well as monitoring at least 20% of PC4, PC3 and large-scale PC2 facilities every year. These inspections focus on the integrity of the physical structure of the facility and on the general laboratory practices followed in the facility, including the practices followed for DNIRs and NLRDs.

OGTR compliance activities comprise reviews of potential compliance risks, audits, investigations and related enforcement activities.

The OGTR may initiate practice reviews in response to observations made during monitoring activities or to follow up incident reports relating to non-compliance with licence conditions by accredited organisations. The objective for practice reviews is to determine whether licence conditions can be, and are being, effectively implemented. An accredited organisation may seek a practice review to assess the effectiveness of systems that its IBCs use to ensure that dealings are being conducted in accordance with the Act.

The OGTR or an accredited organisation can initiate an audit, entailing documentary evidence, observations, and/or assessments of procedures and practices, to:

- verify that an accredited organisation has relevant and effective management procedures and practices to meet requirements under the Act, including accreditation requirements, guidelines and any licence conditions applicable to a dealing
- assess whether procedures and practices provide mechanisms to identify and resolve emerging risks
- suggest improvements to procedures and practices, where appropriate.

An investigation is an inquiry into a suspected non-compliance with the Act, and corresponding state or territory laws, with the aim of gathering evidence. Such investigations are not restricted to criminal aspects—in the wider context, they may include advice on detected flaws and vulnerabilities in policies, practices and procedures. An investigation may be initiated as a consequence of OGTR monitoring, self-reporting by an accredited organisation or third-party reporting.

Presentations made in 2015–16 are listed in Table 22.
APPENDIX 3
Presentations and meetings on gene technology in Australia
The Regulator and staff from the Office of the Gene Technology Regulator regularly attend and present papers to meetings, forums and conferences in Australia.
### Table 22: Presentations and representations in Australia by the Regulator and OGTR staff, 2015–16

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 2015</td>
<td>Australian Society for Microbiology—Annual Scientific meeting 2015</td>
<td>Canberra, ACT</td>
</tr>
<tr>
<td>August 2015</td>
<td>Australian Seed Federation annual meeting</td>
<td>Toowoomba, Queensland</td>
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<tr>
<td>August 2015</td>
<td>Crawford Fund 2015 Annual Conference—The Business of Food Security: Profitability, Sustainability and Risk</td>
<td>Canberra, ACT</td>
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<tr>
<td>September 2015</td>
<td>2015 Agricultural Bioscience International Conference</td>
<td>Melbourne, Victoria</td>
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<td>September 2015</td>
<td>Australian and New Zealand Laboratory Animal Association Conference</td>
<td>Adelaide, South Australia</td>
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<tr>
<td>September 2015</td>
<td>17th Australian Agronomy Conference</td>
<td>Hobart, Tasmania</td>
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<td>ComBio 2015a</td>
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<tr>
<td>October 2015</td>
<td>2015 Australasian Environmental Law Enforcement and Regulators Network Conference</td>
<td>Brisbane, Queensland</td>
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<td>November 2015</td>
<td>2015 Association of Biosafety for Australia and New Zealand (ABSANZ) Conference</td>
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<tr>
<td>November 2015</td>
<td>Regulatory Science Network annual event</td>
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<td>April 2016</td>
<td>CSIRO and Synthetic Biology Australasia: Synthetic Biology Cutting Edge Symposium</td>
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<td>April 2016</td>
<td>The Legislation Process</td>
<td>Canberra, ACT</td>
</tr>
<tr>
<td>June 2016</td>
<td>CSIRO—Regulatory Science Network symposium—The Use of Gene Drive Technology in Controlling Pests and Diseases</td>
<td>Canberra, ACT</td>
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</table>
APPENDIX 4
Stakeholder and public access to the OGTR
The Office of the Gene Technology Regulator (OGTR) facilitates access by accredited agencies, stakeholders and the public to its services through a website, an email address and a freecall 1800 number.
Website usage

Table 23 tracks usage numbers for the OGTR website month by month. The most requested online information sheets and website pages are listed below.

Table 23: Website activity 2015–16

<table>
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<tr>
<th>Month</th>
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<th>Users^b</th>
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</table>

^a A session is a period of active engagement with a website by a user.

^b Includes both new and returning users.

The most popular pages viewed on the OGTR website during 2015–16 were, in descending order:

- Genetically modified product approvals
- Application to certify facilities
- Record of GMO Dealings
- Table of applications and authorisations for dealings involving intentional release (DIR) into the environment
- Genetically modified organisms—field trial sites
- Legislation
- Guidelines for certification of Physical Containment Level 2 facilities
- About the Regulator
- DIR 126—Clinical trial of a genetically modified vaccine against Cholera—PaxVax Australia Pty Ltd
- Guidelines for the Transport, Storage and Disposal of GMOs.
The most popular downloaded documents in 2015–16 were:

- Guidelines for the Transport, Storage and Disposal of GMOs
- Guidelines for Certification of a Physical Containment Level 2 Laboratory
- Issue of licence DIR 126 to PaxVax Australia Pty Ltd for a clinical trial of a genetically modified vaccine against cholera
- Questions and answers on licence application DIR 126—Clinical trial of a genetically modified (GM) vaccine against cholera
- Types of dealings with GMOs classified as notifiable low risk dealings (NLRDs)
- Guidelines for Certification of a Physical Containment Level 2 Animal Facility
- What dealings with GMOs are classified as exempt dealings?
- Guidelines for Certification of a Physical Containment Level 1 Facility
- Guidelines for Certification of a Physical Containment Level 3 Laboratory
- Guidelines for Certification of a Physical Containment Level 2 Laboratory.

Email address and freecall number

The 1800 number and the OGTR email address (ogtr@health.gov.au) are points of contact for members of the public and other interested parties. Assistance with specific questions and advice on additional mechanisms for public feedback are among the services that the 1800 line and email facilities provide. Use of the email address declined compared with the previous year (Table 24).

### Table 24: Email and freecall 1800 number activity, 2015–16 and 2014–15

<table>
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<td>578</td>
<td>843</td>
<td>546</td>
<td>771</td>
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</tr>
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</table>
The Monitoring and Compliance Section maintains an email inbox to facilitate efficient communication with accredited organisations. The inbox provides a central point through which accredited organisations can contact the section with queries, legislative notifications and self-reporting of non-compliances. The inbox ensures that all communications are answered efficiently while staff are away from the office. The inbox received 1115 emails during 2015–16 (1044 in 2013–14).

The Regulatory Practice Section maintains an email inbox to facilitate efficient communication between advisory committee members and secretariat staff. The inbox ensures that secretariat staff answer all communications in a timely manner. The inbox received 790 emails during 2015–16 (1148 in 2013–14).

The Contained Dealings Evaluation Section maintains an email inbox to provide efficient coordination of responses to queries relating to classification of GMO dealings, certification requirements and GMO licences. The inbox received 578 emails during 2014–15 (330 in 2013–14).

The Application Entry Point maintains an email inbox to provide a central, shared communication point, allowing efficient coordination of responses to correspondence and queries about applications the section has received. The inbox received 1427 emails during 2015–16 (1881 in 2014–15).

The OGTR welcomes feedback on ways to improve provision of information about gene technology regulation.
APPENDIX 5
Staff profile, and training and development activities
This appendix provides information on Australian Public Service staff employed by the Office of the Gene Technology Regulator (OGTR) in 2015–16 under the Public Service Act 1999.

Tables 25 to 27 provide details on staff numbers, and aggregated information on salary, performance pay and non-salary benefits provided to staff during 2015–16 under the Department of Health Enterprise Agreement 2011–2014 and individual flexibility arrangements.

Tables 28 and 29 show the staff training and development activities conducted in 2015–16.
### Staff profile

**Table 25: OGTR staff numbers, by classification and contract type, 30 June 2016**

<table>
<thead>
<tr>
<th>Nominal classification</th>
<th>EA</th>
<th>IFA</th>
<th>Section 24 of Public Service Act</th>
<th>Remuneration Tribunal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holder of Public Office</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>SES1</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>EL2</td>
<td>2</td>
<td>6</td>
<td></td>
<td></td>
<td>8</td>
</tr>
<tr>
<td>EL1</td>
<td>17</td>
<td>1</td>
<td></td>
<td></td>
<td>18</td>
</tr>
<tr>
<td>Legal 2</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>APS6</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>APS5</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>APS4</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>39</td>
<td>8</td>
<td>2</td>
<td>1</td>
<td><strong>50</strong></td>
</tr>
</tbody>
</table>

APS = Australian Public Service; EA = Enterprise Agreement; EL = executive level; IFA = Individual Flexibility Arrangement; SES = Senior Executive Service

**Table 26: OGTR staff numbers by gender, 30 June 2016**

<table>
<thead>
<tr>
<th>Employee group</th>
<th>Female</th>
<th>Male</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>27</td>
<td>21</td>
<td>48</td>
</tr>
<tr>
<td>Non-ongoing</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>28</strong></td>
<td><strong>22</strong></td>
<td><strong>50</strong></td>
</tr>
</tbody>
</table>

**Table 27: Number of employee commencements and cessations in 2015–16**

<table>
<thead>
<tr>
<th>Action</th>
<th>Female</th>
<th>Male</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hiring</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Termination</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>5</strong></td>
<td><strong>5</strong></td>
<td><strong>10</strong></td>
</tr>
</tbody>
</table>

SES = Senior Executive Service
Training and development

During 2015–16, OGTR Legal Officer Alceo Turello conducted introductory and ongoing training for OGTR staff on legal issues (Table 28).

**Table 28: Internal training presentations on legal issues, 2015–16**

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 2015</td>
<td>Prosecution of a regulatory offence</td>
</tr>
<tr>
<td>September 2015</td>
<td>Amendment and corresponding state law</td>
</tr>
<tr>
<td>October 2015</td>
<td>Marsh v Baxter</td>
</tr>
<tr>
<td>January 2016</td>
<td>Introductory coverage of the main features of the legislation</td>
</tr>
<tr>
<td>February 2016</td>
<td>Legal status and jurisdiction</td>
</tr>
<tr>
<td>February 2016</td>
<td>Legal status and corresponding state law</td>
</tr>
<tr>
<td>February 2016</td>
<td>Information disclosure</td>
</tr>
</tbody>
</table>

The OGTR Forum provides a venue where presentations are made by visiting experts, and staff share current information on scientific and risk assessment issues, summaries of recent conferences, and feedback from international meetings. A range of OGTR staff and guest speakers made presentations at the OGTR Forum in 2015–16 (Table 29).

**Table 29: Presentations at the OGTR Forum, 2015–16**

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11 August 2015</td>
<td>Work in other government agencies</td>
<td>Nicole White, Sharon Ronald, Simeon Hui</td>
</tr>
<tr>
<td>1 September 2015</td>
<td>Overview of the Compliance Section activities along with some case examples</td>
<td>Andrew Radanovich</td>
</tr>
<tr>
<td>17 September 2015</td>
<td>Community attitudes to gene technology</td>
<td>Craig Cormick, Instinct and Reason</td>
</tr>
<tr>
<td>17 November 2015</td>
<td>Feedback from workshop on new plant breeding technologies</td>
<td>Michael Dornbusch</td>
</tr>
<tr>
<td>17 November 2015</td>
<td>Feedback from workshop on environmental considerations for risk assessment of transgenic plants</td>
<td>Peter Thygesen</td>
</tr>
<tr>
<td>1 December 2015</td>
<td>A genetic toolkit for modifying CO₂ fixation</td>
<td>Professor Spencer Whitney, Research School of Biology, Australian National University</td>
</tr>
<tr>
<td>8 December 2015</td>
<td>Biosafety and the gene revolution in Africa: Experiences from Uganda and lessons to learn from Australia</td>
<td>Dr Julius Ecuru, Uganda National Council for Science and Technology</td>
</tr>
<tr>
<td>2 February 2016</td>
<td>Findings of facility monitoring 2010–2015</td>
<td>Andrew Berry</td>
</tr>
<tr>
<td>7 March 2016</td>
<td>Environmental risk assessments at the Department of the Environment and Energy</td>
<td>Caitriona Dowd</td>
</tr>
<tr>
<td>Date</td>
<td>Topic</td>
<td>Speaker(s)</td>
</tr>
<tr>
<td>-----------</td>
<td>-----------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>15 March 2016</td>
<td>Feedback from Like Minded Meeting; FAO Symposium on Biotechnology; and Global Low Level Presence Initiative meeting</td>
<td>Greg Barber</td>
</tr>
<tr>
<td>23 March 2016</td>
<td>Developments on biosafety regulatory regime in Bangladesh</td>
<td>Mohammed Solaiman Haider, Department of Environment, Bangladesh</td>
</tr>
<tr>
<td>29 March 2016</td>
<td>Risk analysis workshop in New Delhi</td>
<td>Michael Dornbusch, Heidi Mitchell</td>
</tr>
<tr>
<td>16 May 2016</td>
<td>Philippines biosafety regulatory system</td>
<td>Julieta Fe L. Estacio, Department of Science and Technology, the Philippines</td>
</tr>
<tr>
<td>26 May 2016</td>
<td>A generic risk analysis framework for organisms</td>
<td>Peter Thygesen</td>
</tr>
<tr>
<td>14 June 2016</td>
<td>CRISPR genome editing: a new revolution in biotechnology</td>
<td>Sergey Kurdyukov</td>
</tr>
<tr>
<td>21 June 2016</td>
<td>A glimpse into international negotiations—feedback from the 20th SBSTTA meeting under the Convention on Biological Diversity</td>
<td>Heidi Mitchell</td>
</tr>
<tr>
<td>21 June 2016</td>
<td>Feedback from Plant Breeding Innovation and OECD Biotechnology Working Group meetings</td>
<td>Peter Thygesen</td>
</tr>
<tr>
<td>28 June 2016</td>
<td>‘Information capture’ in risk regulation: the perspective from the United States</td>
<td>Judith Jones, Senior Lecturer, College of Law, Australian National University</td>
</tr>
</tbody>
</table>

APVMA = Australian Pesticides and Veterinary Medicines Authority; GM = genetically modified; GMO = genetically modified organism
APPENDIX 6
Publications
Documents published during 2015–16\(^1\) were:

*Operations of the Gene Technology Regulator Quarterly Report 1 April to 30 June 2015*

*Operations of the Gene Technology Regulator Quarterly Report 1 July to 30 September 2015*

\(^1\) Copies are available from the OGTR website at www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1

Paper copies of some publications are also available from the OGTR Information Officer.
APPENDIX 7
Membership of statutory committees and attendance at meetings
The Act establishes two statutory committees to provide advice to the Gene Technology Regulator (the Regulator) and the Legislative and Governance Forum on Gene Technology (LGFGT). These are the:

- Gene Technology Technical Advisory Committee (GTTAC)
- Gene Technology Ethics and Community Consultative Committee (GTECCC).
Gene Technology Technical Advisory Committee

GTTAC’s functions, as set out in section 101 of the Act, are to provide scientific and technical advice, at the request of the Regulator or the LGFGT, on genetically modified organisms (GMOs); genetically modified (GM) products; applications made under the Act; the biosafety aspects of gene technology; and 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 and codes.

The Regulator must seek GTTAC’s advice on the risk assessment and risk management plan (RARMP) for all licence applications for dealings involving intentional release (DIR) and may seek advice on other applications. The Regulator must also seek GTTAC’s advice during the preparation of the RARMP for all DIR applications that are not assessed as limited and controlled under section 50A of the Act.

In 2015–16, the Regulator sought advice from GTTAC on 10 DIR applications, including for the limited and controlled release of GM cotton and GM wheat; two limited and controlled release applications for clinical trials of GM viruses for therapeutic uses; and the commercial release of GM carnation, GM influenza vaccine, GM canola and GM cotton.

GTTAC met six times during 2015–16: twice in face-to-face meetings and four times by videoconference (Table 30).

Communiqués from GTTAC meetings, which provide an overview of key matters discussed and resolutions, are published on the Office of the Gene Technology Regulator (OGTR) website.26

Table 30: Attendance at GTTAC meetings, 2015–16

<table>
<thead>
<tr>
<th>Meeting date</th>
<th>Number of GTTAC members attending</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 August 2015</td>
<td>15</td>
</tr>
<tr>
<td>13 October 2015</td>
<td>14</td>
</tr>
<tr>
<td>21 December 2015</td>
<td>16</td>
</tr>
<tr>
<td>9 March 2016</td>
<td>16</td>
</tr>
<tr>
<td>14 April 2016</td>
<td>13</td>
</tr>
<tr>
<td>6 June 2016</td>
<td>17</td>
</tr>
</tbody>
</table>

26 Communiqués from GTTAC meetings are on the OGTR website at www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gttaccomm-1
**GTTAC chair**

GTTAC is chaired by Professor John Rasko AO, BSc (Med), MBBS (Hons), PhD, MAICD, FFSc (RCPA), FAHMS, FRCPA, FRACP.

Professor Rasko has relevant skills and experience in molecular biology, virology, risk assessment, clinical medicine, biochemistry, animal biology and immunology.

Professor Rasko directs the Department of Cell and Molecular Therapies at Royal Prince Alfred Hospital, and heads the Gene and Stem Cell Therapy Program at the Centenary Institute, University of Sydney. Professor Rasko is a clinical haematologist, pathologist and scientist with a productive track record in gene and stem cell therapy, experimental haematology and molecular biology. He is an Australian pioneer in the application of adult stem cells and genetic therapy. In more than 150 publications, he has contributed to the understanding of stem cells and blood cells, gene-transfer technologies, cancer, human genetic disorders and non coding RNAs.

Professor Rasko’s contributions to scientific organisations include being co-founder (2000) and past president (2003–05) of the Australasian Gene Therapy Society, vice-president (2008–12) and president elect (2016–17) of the International Society for Cellular Therapy (ISCT); immediate past chair of the Advisory Committee on Biologicals (Therapeutic Goods Administration); a member of scientific advisory committees; a board member for philanthropic foundations; and a member of several ethics committees. He is the recipient of national awards (Distinguished Fellow Award of the Royal College of Pathologists of Australasia, Eric Susman Prize for 2011 from the Royal Australasian College of Physicians, Roche Medal from the Australian Society for Biochemistry and Molecular Biology) and international awards in recognition of his commitment to excellence in medical research. Professor Rasko was appointed as an Officer of the Order of Australia in June 2012 for distinguished service to biomedical research in the field of gene and cell therapy as a clinician.

## GTTAC members 2014–17

The current members of GTTAC (Table 31) were appointed in February 2014 by the then Assistant Minister for Health, Senator the Hon Fiona Nash.

### Table 31: Members of GTTAC at 30 June 2016

<table>
<thead>
<tr>
<th>Name</th>
<th>Position/Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Associate Professor Jason Able</td>
<td>Head, Department of Agricultural Science and Associate Professor in Plant Breeding, University of Adelaide; Southern Node Leader, Durum Breeding Australia (South Australia)</td>
</tr>
<tr>
<td>Emeritus Professor Craig Atkins</td>
<td>Senior Honorary Research Fellow, School of Plant Biology, University of Western Australia (Western Australia)</td>
</tr>
<tr>
<td>Professor Ross Barnard</td>
<td>Biotechnology Program Director, School of Chemistry and Molecular Biosciences, University of Queensland (Queensland)</td>
</tr>
<tr>
<td>Professor Jacqueline Batley</td>
<td>ARC Future Fellow, School of Plant Biology, University of Western Australia (Western Australia)</td>
</tr>
<tr>
<td>Professor Gabrielle Belz</td>
<td>Laboratory Head, Division of Molecular Immunology, Walter and Eliza Hall Institute of Medical Research, Melbourne (Victoria)</td>
</tr>
<tr>
<td>Dr Graham Bonnett</td>
<td>Research Director, CSIRO Agriculture and Food (Queensland)</td>
</tr>
<tr>
<td>Ms Laura Fell</td>
<td>Egg farmer, McLaren Vale (South Australia)</td>
</tr>
<tr>
<td>Professor Ian Godwin</td>
<td>Professor in Plant Molecular Genetics, School of Agriculture and Food Sciences, University of Queensland (Queensland)</td>
</tr>
<tr>
<td>Associate Professor John Hayball</td>
<td>School of Pharmacy and Medical Sciences, University of South Australia (South Australia)</td>
</tr>
<tr>
<td>Dr Rodney Mahon</td>
<td>Retired CSIRO entomologist (Australian Capital Territory)</td>
</tr>
<tr>
<td>Dr Michael Michael</td>
<td>Laboratory Head, Flinders Centre for Innovation in Cancer, Flinders Medical Centre (South Australia)</td>
</tr>
<tr>
<td>Dr Gabrielle O'Sullivan (GTECCC cross-member)</td>
<td>Executive officer and member, Institutional Biosafety Committee, Royal Prince Alfred Hospital (New South Wales)</td>
</tr>
<tr>
<td>Professor Marie Ranson</td>
<td>School of Biological Sciences, University of Wollongong; Illawarra Health and Medical Research Institute, University of Wollongong (New South Wales)</td>
</tr>
<tr>
<td>Professor John Rasko AO (chair)</td>
<td>Director, Cell and Molecular Therapies, Royal Prince Alfred Hospital; Program Head, Centenary Institute (New South Wales)</td>
</tr>
<tr>
<td>Dr Kelly Shaw</td>
<td>Senior consultant, KP Health (Tasmania)</td>
</tr>
<tr>
<td>Professor Kevin Smith</td>
<td>Professor of Plant Breeding, University of Melbourne (Victoria)</td>
</tr>
<tr>
<td>Associate Professor Jason Smythe</td>
<td>Senior Business Development Manager, Faculty of Medicine, Monash University; Adjunct Associate Professor, Faculty of Science and Engineering, La Trobe University (Victoria)</td>
</tr>
<tr>
<td>Dr Diane Webster</td>
<td>Chair, Swinburne Biosafety Committee; Executive Committee member, Women in Science Australia (Victoria)</td>
</tr>
<tr>
<td>Professor Paul Young</td>
<td>Professor of Virology and Head of School, School of Chemistry and Molecular Biosciences, University of Queensland (Queensland)</td>
</tr>
</tbody>
</table>

Note: Members are appointed as individuals, not as representatives of any organisation. Occupation and employment information is included to demonstrate experience and qualifications relevant to their appointment.
Gene Technology Ethics and Community Consultative Committee

GTECCC’s functions are set out in section 107 of the Act. They are to provide advice, at the request of the Regulator or the LGFGT, on:

- ethical issues relating to gene technology and matters of general concern relating to GMOs
- community consultation and risk communication regarding licence applications for DIRs
- the need for policy principles, policy guidelines, codes of practice, and technical and procedural guidelines relating to GMOs and GM products, and the content of such principles and codes.

Consultation of the Regulator with GTECCC on licence applications is not a statutory requirement.

Communiqués from GTECCC meetings, which provide an overview of key matters discussed and resolutions, are published on the OGTR website and in the Regulator’s quarterly reports to Parliament. No meetings were held in 2015–16.

**GTECCC chair**

GTECCC is chaired by Ms Judith Jones BSc, LLB, DipPracLegTraining, Solicitor NSW.

Ms Jones is a Senior Lecturer at the Australian National University (ANU) College of Law. Harnessing her dual background in both science and law, she began her research career as an environmental and planning lawyer by focusing on uncertainty, precaution and risk assessment. This included over a decade (1999–2014) of service, in different capacities, on the federal non-statutory and statutory bodies that provide advice to the Regulator on legal and ethical issues relating to risk assessment and the regulation of gene technology in Australia. Ms Jones has a range of scholarly publications in the areas of environmental impact assessment, risk regulation and precaution, with an emphasis on designing regulation in conditions of scientific and other uncertainty. She is also a member of the ANU Institutional Biosafety Committee.

More recently, Ms Jones’s research has taken a new direction, combining her environmental law research interests with her own rural background and Australian legal history to examine the impact of historical and current land-use practices on Australian soils, water and vegetation. This research focuses on the impact of colonial property law and culture on land-use practices and consequent environmental degradation. In terms of contemporary agricultural land use, this research focuses on law and culture relevant to encouraging sustainable land-use practices in regions of high agricultural value.

### Table 32: Members of GTECCC at 30 June 2016

<table>
<thead>
<tr>
<th>Name</th>
<th>Occupation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms Judith Jones</td>
<td>Senior Lecturer, Australian National University College of Law (Australian Capital Territory)</td>
</tr>
<tr>
<td>Ms Paula Fitzgerald</td>
<td>Agricultural advocate and consultant (Victoria)</td>
</tr>
<tr>
<td>Dr Vaughan Monamy</td>
<td>Associate Professor of Environmental Science and Environmental Ethics, Australian Catholic University (New South Wales)</td>
</tr>
<tr>
<td>Dr Rachel Nowak</td>
<td>Principal, Rachel Nowak and Associates (Victoria)</td>
</tr>
<tr>
<td>Dr Gabrielle O’Sullivan</td>
<td>Executive Officer, Institutional Biosafety Committee, Royal Prince Alfred Hospital (New South Wales)</td>
</tr>
<tr>
<td>(GTTAC cross-member)</td>
<td></td>
</tr>
<tr>
<td>Ms Meg Parkinson</td>
<td>Free-range egg farmer (Victoria)</td>
</tr>
<tr>
<td>Dr Gregory Pike</td>
<td>Founding Director of the Adelaide Centre for Bioethics and Culture (South Australia)</td>
</tr>
<tr>
<td>Mr Hugh Roberts</td>
<td>Farmer and a Director of the Australian Seed Authority and Australian Crop Accreditation System (New South Wales)</td>
</tr>
<tr>
<td>Dr Frances Shapter</td>
<td>Project Officer, School of Veterinary Science, University of Queensland (Queensland)</td>
</tr>
<tr>
<td>Dr Robert Sward</td>
<td>Director, BioBotanicals Consulting (Victoria)</td>
</tr>
<tr>
<td>Mrs Emma Thomas</td>
<td>Farmer and agricultural consultant (New South Wales)</td>
</tr>
</tbody>
</table>

Note: Members are appointed as individuals, not as representatives of any organisation. Occupation and employment information is included to demonstrate experience and qualifications relevant to their appointment.

### Remuneration and allowances for committee members

The Remuneration Tribunal is an independent statutory body that determines the remuneration and allowances for all members of OGTR committees. Committee members are part-time office holders for the purposes of the Remuneration Tribunal and are paid in accordance with the current determination for part-time office holders.27

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27 The Remuneration Tribunal website is at [www.remtribunal.gov.au](http://www.remtribunal.gov.au)
GLOSSARY AND SHORTENED FORMS
The terms described in this glossary are important to understanding this report; however, they do not substitute for the definitions of terms relevant to the operation of the gene technology regulatory system in section 10 of the Act.
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>accredited organisation</td>
<td>an organisation that is accredited under section 92 of the Gene Technology Act 2000</td>
</tr>
<tr>
<td>Act</td>
<td>Gene Technology Act 2000</td>
</tr>
<tr>
<td>APVMA</td>
<td>Australian Pesticides and Veterinary Medicines Authority</td>
</tr>
<tr>
<td>CCI</td>
<td>confidential commercial information declared under section 185 of the Gene Technology Act 2000</td>
</tr>
<tr>
<td>contained dealing</td>
<td>contained dealing. See DNIR</td>
</tr>
<tr>
<td>CSIRO</td>
<td>Commonwealth Scientific and Industrial Research Organisation</td>
</tr>
<tr>
<td>dealing</td>
<td>To ‘deal with’ a GMO is defined in section 10 of the Gene Technology Act 2000. It includes to experiment with, manufacture, breed, propagate, grow, culture, import, transport and dispose of a GMO, and to possess, supply or use a GMO in the course of any of these activities.</td>
</tr>
<tr>
<td>DAWR</td>
<td>Department of Agriculture and Water Resources</td>
</tr>
<tr>
<td>department</td>
<td>Australian Government Department of Health</td>
</tr>
<tr>
<td>DIR</td>
<td>a dealing involving intentional release of a GMO into the environment (e.g. field trial or commercial release)</td>
</tr>
<tr>
<td>DNIR</td>
<td>a contained dealing with a GMO not involving intentional release of the GMO into the environment (e.g. experiments in a certified facility such as a laboratory)</td>
</tr>
<tr>
<td>EDD</td>
<td>emergency dealing determination</td>
</tr>
<tr>
<td>FSANZ</td>
<td>Food Standards Australia New Zealand</td>
</tr>
<tr>
<td>Gene Technology Agreement</td>
<td>an intergovernmental agreement that all Australian jurisdictions signed in 2001, which underpins the nationally consistent regulatory framework for gene technology</td>
</tr>
<tr>
<td>GM</td>
<td>genetically modified</td>
</tr>
<tr>
<td>GM product</td>
<td>a thing (other than a GMO) derived or produced from a GMO</td>
</tr>
<tr>
<td>GMO</td>
<td>genetically modified organism</td>
</tr>
<tr>
<td>GMO Record</td>
<td>Record of GMO Dealings</td>
</tr>
<tr>
<td>GTECCC</td>
<td>Gene Technology Ethics and Community Consultative Committee</td>
</tr>
<tr>
<td>GTTAC</td>
<td>Gene Technology Technical Advisory Committee</td>
</tr>
<tr>
<td>IBC</td>
<td>institutional biosafety committee</td>
</tr>
<tr>
<td>incident</td>
<td>a self-reported event that may constitute a non-compliance with regulatory requirements and a risk to public health or the environment</td>
</tr>
<tr>
<td>LGFGT</td>
<td>Legislative and Governance Forum on Gene Technology</td>
</tr>
<tr>
<td>MOU</td>
<td>memorandum of understanding</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>NICNAS</td>
<td>National Industrial Chemicals Notification and Assessment Scheme</td>
</tr>
<tr>
<td>NLRD</td>
<td>notifiable low risk dealing (e.g. plant or tissue culture work undertaken in a certified physical containment facility)</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>OGTR</td>
<td>Office of the Gene Technology Regulator</td>
</tr>
<tr>
<td>PBS</td>
<td>Portfolio Budget Statements</td>
</tr>
<tr>
<td>PC1, PC2, PC3, PC4</td>
<td>physical containment levels of facilities certified by the Regulator</td>
</tr>
<tr>
<td>physical containment facility</td>
<td>a building or place certified by the Regulator to a specified containment level under section 84 of the Gene Technology Act 2000</td>
</tr>
<tr>
<td>RARMP</td>
<td>risk assessment and risk management plan</td>
</tr>
<tr>
<td>Regulations</td>
<td>Gene Technology Regulations 2001</td>
</tr>
<tr>
<td>Regulator</td>
<td>Gene Technology Regulator</td>
</tr>
<tr>
<td>RSN</td>
<td>Regulatory Science Network</td>
</tr>
<tr>
<td>SBSTTA</td>
<td>Subsidiary Body on Scientific, Technical and Technological Advice (United Nations Convention on Biological Diversity)</td>
</tr>
<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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<tr>
<td>UN</td>
<td>United Nations</td>
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<tr>
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<td>136(1A)(c)</td>
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<td>136(1A)(e)</td>
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<td>17AD(g)</td>
<td>iii</td>
<td>Letter of transmittal</td>
<td></td>
</tr>
<tr>
<td>17AI</td>
<td></td>
<td>A copy of the letter of transmittal signed and dated by accountable authority on date final text approved, with statement that the report has been prepared in accordance with section 46 of the Act and any enab</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AD(h)</td>
<td></td>
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<tr>
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<td>Mandatory</td>
</tr>
<tr>
<td>17AJ(c)</td>
<td>133–134</td>
<td>Glossary of abbreviations and acronyms.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AJ(d)</td>
<td>137–142</td>
<td>List of requirements.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AJ(e)</td>
<td>ii</td>
<td>Details of contact officer.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AJ(f)</td>
<td>ii</td>
<td>Entity’s website address.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AJ(g)</td>
<td>ii</td>
<td>Electronic address of report.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AD(a)</td>
<td>*</td>
<td>Review by accountable authority</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AD(a)</td>
<td>*</td>
<td>A review by the accountable authority of the entity.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AD(b)</td>
<td></td>
<td>Overview of the entity</td>
<td></td>
</tr>
<tr>
<td>17AE(1)(a)(i)</td>
<td>2, 15–20</td>
<td>A description of the role and functions of the entity.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AE(1)(a)(ii)</td>
<td>16</td>
<td>A description of the organisational structure of the entity.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AE(1)(a)(iii)</td>
<td>3, 64–66</td>
<td>A description of the outcomes and programmes administered by the entity.</td>
<td>Mandatory</td>
</tr>
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<td>17AE(1)(a)(iv)</td>
<td></td>
<td>A description of the purposes of the entity as included in corporate plan.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>PGPA Rule reference</td>
<td>Part of report</td>
<td>Description</td>
<td>Requirement</td>
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</tr>
<tr>
<td>17AE(1)(b)</td>
<td></td>
<td>An outline of the structure of the portfolio of the entity.</td>
<td>Portfolio departments—mandatory</td>
</tr>
<tr>
<td>17AE(2)</td>
<td></td>
<td>Where the outcomes and programs administered by the entity differ from any Portfolio Budget Statement, Portfolio Additional Estimates Statement or other portfolio estimates statement that was prepared for the entity for the period, include details of variation and reasons for change.</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td>17AD(c)</td>
<td></td>
<td>Report on the performance of the entity</td>
<td></td>
</tr>
<tr>
<td>17AD(c)(i): 16F</td>
<td>*</td>
<td>Annual performance statement in accordance with paragraph 39(1)(b) of the Act and section 16F of the Rule.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AD(c)(ii)</td>
<td></td>
<td>Report on financial performance</td>
<td></td>
</tr>
<tr>
<td>17AF(1)(a)</td>
<td>*</td>
<td>A discussion and analysis of the entity’s financial performance.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AF(1)(b)</td>
<td>*</td>
<td>A table summarising the total resources and total payments of the entity.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AF(2)</td>
<td>*</td>
<td>If there may be significant changes in the financial results during or after the previous or current reporting period, information on those changes, including: the cause of any operating loss of the entity; how the entity has responded to the loss and the actions that have been taken in relation to the loss; and any matter or circumstances that it can reasonably be anticipated will have a significant impact on the entity’s future operation or financial results.</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td>17AD(d)</td>
<td></td>
<td>Management and accountability</td>
<td></td>
</tr>
<tr>
<td>17AG(2)(a)</td>
<td>*</td>
<td>Information on compliance with section 10 (fraud systems).</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AG(2)(b)(i)</td>
<td>*</td>
<td>A certification by accountable authority that fraud risk assessments and fraud control plans have been prepared.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AG(2)(b)(ii)</td>
<td>*</td>
<td>A certification by accountable authority that appropriate mechanisms for preventing, detecting incidents of, investigating or otherwise dealing with, and recording or reporting fraud that meet the specific needs of the entity are in place.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AG(2)(b)(iii)</td>
<td>*</td>
<td>A certification by accountable authority that all reasonable measures have been taken to deal appropriately with fraud relating to the entity.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>PGPA Rule reference</td>
<td>Part of report</td>
<td>Description</td>
<td>Requirement</td>
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</tr>
<tr>
<td>17AG(2)(c)</td>
<td>*</td>
<td>An outline of structures and processes in place for the entity to implement principles and objectives of corporate governance.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AG(2)(d)–(e)</td>
<td>*</td>
<td>A statement of significant issues reported to Minister under paragraph 19(1)(e) of the Act that relates to non-compliance with Finance law and action taken to remedy non-compliance.</td>
<td>If applicable, mandatory</td>
</tr>
</tbody>
</table>

**External scrutiny**

| 17AG(3)             | *              | Information on the most significant developments in external scrutiny and the entity's response to the scrutiny. | Mandatory |
| 17AG(3)(a)          |                | Information on judicial decisions and decisions of administrative tribunals and by the Australian Information Commissioner that may have a significant effect on the operations of the entity. | If applicable, mandatory |
| 17AG(3)(b)          |                | Information on any reports on operations of the entity by the Auditor-General (other than report under section 43 of the Act), a Parliamentary Committee, or the Commonwealth Ombudsman. | If applicable, mandatory |
| 17AG(3)(c)          |                | Information on any capability reviews on the entity that were released during the period. | If applicable, mandatory |

**Management of human resources**

| 17AG(4)(a)          | 70             | An assessment of the entity's effectiveness in managing and developing employees to achieve entity objectives. | Mandatory |
| 17AG(4)(b)          | 117            | Statistics on the entity’s APS employees on an ongoing and non-ongoing basis; including the following:  
  • Statistics on staffing classification level;  
  • Statistics on full-time employees;  
  • Statistics on part-time employees;  
  • Statistics on gender;  
  • Statistics on staff location;  
  • Statistics on employees who identify as Indigenous. | Mandatory |
<p>| 17AG(4)(c)          | 15, 69         | Information on any enterprise agreements, individual flexibility arrangements, Australian workplace agreements, common law contracts and determinations under subsection 24(1) of the <em>Public Service Act 1999</em>. | Mandatory |
| 17AG(4)(c)(i)       | 117            | Information on the number of SES and non-SES employees covered by agreements etc. identified in paragraph 17AD(4)(c). | Mandatory |
| 17AG(4)(c)(ii)      | *              | The salary ranges available for APS employees by classification level. | Mandatory |</p>
<table>
<thead>
<tr>
<th>PGPA Rule reference</th>
<th>Part of report</th>
<th>Description</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>17AG(4)(c)(iii)</td>
<td>15, 69</td>
<td>A description of non-salary benefits provided to employees.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AG(4)(d)(i)</td>
<td></td>
<td>Information on the number of employees at each classification level who received performance pay.</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td>17AG(4)(d)(ii)</td>
<td></td>
<td>Information on aggregate amounts of performance pay at each classification level.</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td>17AG(4)(d)(iii)</td>
<td></td>
<td>Information on the average amount of performance payment, and range of such payments, at each classification level.</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td>17AG(4)(d)(iv)</td>
<td></td>
<td>Information on aggregate amount of performance payments.</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td></td>
<td>Assets management</td>
<td>An assessment of effectiveness of assets management where asset management is a significant part of the entity’s activities.</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td>17AG(5)</td>
<td></td>
<td>An assessment of entity performance against the Commonwealth Procurement Rules.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AG(6)</td>
<td>74</td>
<td>An assessment of entity performance against the Commonwealth Procurement Rules.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AG(7)(a)</td>
<td>*</td>
<td>A summary statement detailing the number of new contracts engaging consultants entered into during the period; the total actual expenditure on all new consultancy contracts entered into during the period (inclusive of GST); the number of ongoing consultancy contracts that were entered into during a previous reporting period; and the total actual expenditure in the reporting year on the ongoing consultancy contracts (inclusive of GST).</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AG(7)(b)</td>
<td>*</td>
<td>A statement that “During [reporting period], [specified number] new consultancy contracts were entered into involving total actual expenditure of $[specified million]. In addition, [specified number] ongoing consultancy contracts were active during the period, involving total actual expenditure of $[specified million].”</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AG(7)(c)</td>
<td>*</td>
<td>A summary of the policies and procedures for selecting and engaging consultants and the main categories of purposes for which consultants were selected and engaged.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AG(7)(d)</td>
<td></td>
<td>A statement that “Annual reports contain information about actual expenditure on contracts for consultancies. Information on the value of contracts and consultancies is available on the AusTender website.”</td>
<td>Mandatory</td>
</tr>
<tr>
<td>PGPA Rule reference</td>
<td>Part of report</td>
<td>Description</td>
<td>Requirement</td>
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</tr>
<tr>
<td>17AG(8)</td>
<td></td>
<td>Australian National Audit Office access clauses</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If an entity entered into a contract with a value of more than $100 000 (inclusive of GST) and the contract did not provide the Auditor-General with access to the contractor’s premises, the report must include the name of the contractor, purpose and value of the contract, and the reason why a clause allowing access was not included in the contract.</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exempt contracts</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td>17AG(9)</td>
<td></td>
<td>If an entity entered into a contract or there is a standing offer with a value greater than $10 000 (inclusive of GST) which has been exempted from being published in AusTender because it would disclose exempt matters under the FOI Act, the annual report must include a statement that the contract or standing offer has been exempted, and the value of the contract or standing offer, to the extent that doing so does not disclose the exempt matters.</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Small business</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td>17AG(10)(a)</td>
<td>*</td>
<td>A statement that “[Name of entity] supports small business participation in the Commonwealth Government procurement market. Small and Medium Enterprises (SME) participation statistics are available on the Department of Finance’s website.”</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AG(10)(b)</td>
<td>*</td>
<td>An outline of the ways in which the procurement practices of the entity support small and medium enterprises.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>17AG(10)(c)</td>
<td>*</td>
<td>If the entity is considered by the Department administered by the Finance Minister as material in nature—a statement that “[Name of entity] recognises the importance of ensuring that small businesses are paid on time. The results of the Survey of Australian Government Payments to Small Business are available on the Treasury’s website.”</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Financial statements</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td>17AD(e)</td>
<td>*</td>
<td>Inclusion of the annual financial statements in accordance with subsection 43(4) of the Act.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>PGPA Rule reference</td>
<td>Part of report</td>
<td>Description</td>
<td>Requirement</td>
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</tr>
<tr>
<td>17AD(f)</td>
<td>Other mandatory information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17AH(1)(a)(i)</td>
<td>*</td>
<td>If the entity conducted advertising campaigns, a statement that “During [reporting period], the [name of entity] conducted the following advertising campaigns: [name of advertising campaigns undertaken]. Further information on those advertising campaigns is available at [address of entity’s website] and in the reports on Australian Government advertising prepared by the Department of Finance. Those reports are available on the Department of Finance’s website.”</td>
<td>If applicable, mandatory</td>
</tr>
<tr>
<td>17AH(1)(a)(ii)</td>
<td>If the entity did not conduct advertising campaigns, a statement to that effect.</td>
<td>If applicable, mandatory</td>
<td></td>
</tr>
<tr>
<td>17AH(1)(b)</td>
<td>A statement that “Information on grants awarded to [name of entity] during [reporting period] is available at [address of entity’s website].”</td>
<td>If applicable, mandatory</td>
<td></td>
</tr>
<tr>
<td>17AH(1)(c)</td>
<td>Outline of mechanisms of disability reporting, including reference to website for further information.</td>
<td>Mandatory</td>
<td></td>
</tr>
<tr>
<td>17AH(1)(d)</td>
<td>73 Website reference to where the entity’s Information Publication Scheme statement pursuant to Part II of FOI Act can be found.</td>
<td>Mandatory</td>
<td></td>
</tr>
<tr>
<td>17AH(1)(e)</td>
<td>Correction of material errors in previous annual report</td>
<td>If applicable, mandatory</td>
<td></td>
</tr>
<tr>
<td>17AH(2)</td>
<td>Information required by other legislation</td>
<td>Mandatory</td>
<td></td>
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* The reference is to the location of the item in Schedule 2 of the PGPA Rule 2014.
* Refer to the Department of Health 2015–16 annual report.
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