Australian Government

Department of Health

Office of the Gene Technology Regulator

Annual Report 2017–18

Australian Government

Department of Health

Office of the Gene Technology Regulator

Annual Report 2017–18

Title: *Operations of the Gene Technology Regulator Annual Report 2017–18*

ISSN: 1833-6264

Online ISSN: 2205-4502

Publications Number: 11569

Contacts

Office of the Gene Technology Regulator
MDP 54
GPO Box 9848
Canberra ACT 2601 Australia

Level 11 Scarborough House
Atlantic Street
Woden ACT 2606

Telephone: 1800 181 030
Fax: (02) 6113 8303
Email: ogtr@health.gov.au
Website: www.ogtr.gov.au

ABN 15 862 053 538

Annual report webpage: www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1

Direct enquiries about the content of this report to the Regulatory Support Unit, Regulatory Practice and Compliance Branch, Office of the Gene Technology Regulator.

Australian Government

Department of Health

Office of the Gene Technology Regulator

The Senator the Hon. Bridget McKenzie
Minister for Regional Services, Minister for Sport,
Minister for Local Government and Decentralisation
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 2017 to 30 June 2018.

The annual report details the operations of the Gene Technology Regulator (the Regulator) as per the reporting requirements in section 136 (1A) of the *Gene Technology Act 2000* (the Act) and against the performance indicators in Outcome 5 (Regulation, Safety and Protection) of the Department of Health Portfolio Budget Statements for 1 July 2017 to 30 June 2018.

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

R. Bhula

Dr Raj Bhula
Gene Technology Regulator
2 October 2018

Contents

Chapter 4

Chapter 5

Appendix

Glossary

Indexes

About this report

The report describes the roles and responsibilities of the Gene Technology Regulator (the Regulator) and the Office of the Gene Technology Regulator (OGTR). It is a formal accountability document that summarises the OGTR's performance against deliverables and key performance indicators in Outcome 5 (Regulation, Safety and Protection) of the 2017–18 Department of Health Portfolio Budget Statements[1].

In accordance with the annual reporting requirements set out in section 136 of the *Gene Technology Act 2000* (the Act), this report as prescribed under subsection 136 (1A) of the Act includes information on[2]:

- genetically modified organism (GMO) licences issued during the financial year
- breaches of conditions of a GMO licence that have come to the Regulator's attention during the financial year
- Emergency Dealing Determinations (EDDs) 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.

The report contains five chapters:

- **Chapter 1: Gene Technology Regulator's overview**—summarises the OGTR's activities over the past year, including major achievements, and the outlook for the coming year.
- **Chapter 2: Office of the Gene Technology Regulator**—describes the Regulator's corporate and regulatory governance arrangements, including the structure of the OGTR and functions of its advisory committees.
- **Chapter 3: Operational activities**—describes the OGTR's functions, regulatory processes and operational performance, as well as achievements against priorities during 2017–18. It summarises the types of GMO dealings, the processes for authorisations, and statutory timeframes. The chapter reports deliverables and performance targets achieved for assessments and approvals, as well as for monitoring and compliance activities. It concludes with a summary of performance against the reporting structure published in the 2017–18 Portfolio Budget Statements.
- **Chapter 4: Engaging with stakeholders**—provides information on other activities relating to the Regulator's statutory functions, including the technical review of the Regulations, various consultations with stakeholders, and international engagements.
- **Chapter 5: Management and accountability**—provides an overview of the OGTR's resource management practices and reporting against Australian Government accountability principles.

1 The 2017–18 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.

2 Unless otherwise stated, all information provided in this report is sourced from the OGTR.

Chapter 1

Gene Technology Regulator's overview

In my second year as Regulator, I have spent time understanding the gene technology scheme's foundations, history and successful operations. At the same time, in this environment of fast-paced change, I am looking ahead to determine the best means for the OGTR to continue to be a best practice regulator.

The OGTR continues to meet the overarching objective of Australia's national gene technology scheme, to protect the health and safety of people and the environment.

Keeping pace with technology and achieving risk-based outcomes have been the drivers of our technical review of the gene technology regulations which continued during the year. Stakeholder consultation throughout this process has been essential to better understand the technology pathways important for Australia, as well as to ensure the drafted legal amendments adequately reflect the science.

We continue to look towards the future to ensure that regulating advancing technologies is commensurate with risk, while also providing the safeguards that the Australian community expects.

Our achievements against the Department of Health's Portfolio Budget Statements reflect how effectively and efficiently we have regulated these technologies. In 2017–18 we:

- met all our targets for preparing and consulting on Risk Assessment and Risk Management Plans (RARMPs) and issuing licences within statutory timeframes
- reported a high level of compliance from regulated stakeholders, with no adverse findings on human health or the environment from authorised GMOs
- strengthened our relations with state and commonwealth regulatory partners
- engaged actively in international activities to maintain best-practice regulation of gene technology while further progressing harmonisation in risk assessment methodologies.

Applications and licences: what's new

Licences for dealings involving intentional release into the environment (DIR) for research purposes continue to expand into different crop types and species. OGTR issued licences for conducting field trials in sorghum, buffalo grass and ryegrass as well as research trials for genetically modified (GM) vaccines for chickens and crocodiles.

Licences for dealings not involving intentional release into the environment (DNIR) included research and development of potential treatments for human diseases, including a number of clinical trials. Over the past two years, there has been an increase in the proportion of accreditation applications received from organisations that are involved in human clinical trials, highlighting the increased research interest in human therapeutics and treatments. The OGTR also received and processed a high number of variations to certifications, with over 600 applications being approved this year.

Monitoring and compliance activities

To better reflect our approach to cooperative compliance our Portfolio Budget Statement targets were changed from a numerical target to the qualitative target-regulated entities recording a high level of compliance with the gene technology legislation with no reported evidence adverse effects on human health or the environment from authorised GMOs. This target also supports our risk-based process for planning of inspection activities and education and communication outreach to focus on prevention of non-compliance.

In 2017–2018, OGTR inspected 41 per cent (39) field trial sites over a range of plant species such as banana, barley, canola, cotton, Indian mustard, safflower, sorghum, sugarcane, wheat and barley and white clover. Inspections were conducted in ACT, NSW, Qld, Vic and WA. In addition, we inspected 60 facilities across the country and monitored 15 licences for contained work with GMOs for compliance against licence conditions.

Stakeholder engagement: transparency in what we do

An acknowledged strength of the gene technology scheme is our consultation with the public, scientific experts, our committees, regulated entities, Commonwealth, state and territory government agencies. We consult on new applications for the release of GMOs, our RARMPs and licences issued, as well as changes to our guidelines and forms.

During this financial year we introduced newsletters to improve our communication with people working with GMOs. Three newsletters were published, which included articles on low level physical containment (Physical Containment 1 and Physical Containment 2) facility certification processes, Notifiable Low Risk Dealings (NLRD) and preparing for an OGTR monitoring and compliance inspection.

A number of new and revised OGTR factsheets were also published in June 2018 to provide information and factual resources to the public on various functions and activities of the OGTR in an easy to read format. Topics included: what is gene technology, genetically modified organisms in Australia and GM kits in schools.

Efficient and effective regulation

In March 2018, we began the online forms project to improve the efficiency of application processes and to make better use of digital services for the submission of applications. This project included the development, user acceptance testing and launch of two forms: the Notifiable Low Risk Dealing (NLRD) Reporting form and the Application for Certification of a Physical Containment Facility form. Stakeholders were engaged during the development and testing phases, and feedback was incorporated into further refinement of the forms. The OGTR receives a high volume of these forms each year, and the introduction of the online forms is expected to support greater processing efficiency for all involved.

Technical review of the gene technology regulations

During 2017–18, the technical review of the gene technology regulations continued, with the publication of proposed amendments and a call for submissions (from 30 November 2017 to 21 February 2018) on a Consultation Regulation Impact Statement. It was pleasing to see submissions from a broad range of stakeholders including members of the public, research organisations and individuals working with GMOs, companies in Australia and overseas, Commonwealth and state and territory government agencies, and GM interest groups. Agreement to the amendments will be sought from the Legislative and Governance Forum on Gene Technology in the next year.

International harmonisation and capacity building: sharing our knowledge

OGTR staff attended various regulatory harmonisation meetings during the year, with regular contributions to ongoing programs of work under the OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology and its Steering Group on Environmental Considerations. In addition, Australian presenters were invited to speak at a special OECD conference on genome editing in June.

The OGTR continues to support both the Department of Environment at UNEP Convention on Biological Diversity and its associated protocol meetings, and the Department of Agriculture and Water Resources on international activities associated with trade and Low Level Presence of GMOs.

Our people: an important resource now and into the future

OGTR would not be able to undertake its regulatory functions without the hard work, dedication and commitment of its staff. We are into the second year of our People Plan, which includes various initiatives for training, development and job retention.

In 2018, the office moved from Barton, where it had been since the OGTR commenced in 2001, to Woden to join the rest of the Department of Health. To acknowledge the planning, hard work and effort associated with the operation, Toni Cuthbertson from our Regulatory Support Unit was presented with the Regulators Achievement Award. Karina Dennis from our Application Entry Point was also acknowledged for her oversight in assisting staff to transition to a new records management interface, while managing the movement of important records. In both instances, the high level skills in negotiation, communication and leadership were clearly in action.

In support of the Department of Health's graduate program, four graduates spent three months each at the OGTR as part of their 12-month rotation. The OGTR also signed a Memorandum of Understanding with the University of Canberra to facilitate short-term student placements for 3rd and 4th year students completing their degrees in science. This is another initiative to attract young recruits to the department to work in a science-based regulatory agency.

Challenges ahead

While we are in the middle of the 3rd review of the Gene Technology scheme and anticipating the completion of the technical review of the regulations, there will be many challenges ahead to remain contemporary and forward-looking in the fast evolving area of gene technology. Decisions of our international regulatory counterparts will no doubt influence and contest our thinking, as well as our various stakeholders' views about the Australian system. However, our sound science-based approach, based on a foundation of international best practice, will ensure we continue to meet our challenges now and in the future.

Chapter 2

Office of the Gene Technology Regulator

This chapter provides an overview of the regulatory and corporate governance arrangements for the Gene Technology Regulator (the Regulator), a description of the organisational structure of the OGTR and its advisory committees.

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.

Regulatory governance arrangements

The *Gene Technology Act 2000*, the Gene Technology Regulations 2001, and corresponding state and territory laws (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/state-territory-legislation) provide a nationally consistent system to regulate the development and use of gene technology in Australia. The legislation establishes the Regulator as an independent statutory office holder to administer the national scheme. Overarching responsibility for the scheme is held at Ministerial level by the Legislative and Governance Forum on Gene Technology. 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 (available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/governance-1.)

The Regulator must consider risks to both human health and safety, and the environment, relating to dealings with GMOs. Other agencies, however, have responsibility for regulating GMOs or genetically modified (GM) products as part of a broader or different legislative mandate. Under gene technology legislation, the Regulator's activities form part of an integrated legislative framework that includes a number of other existing regulatory authorities with complementary responsibilities and expertise (available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/governance-1)

Conducting 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, such as a live GM vaccine, requires a licence from the Regulator as well as registration by the Therapeutic Goods Administration, which authorises administration of vaccines to people.

Similarly, while the Regulator is responsible for approving release of GM insect resistant or herbicide-tolerant plants into the environment, the Australian Pesticides and Veterinary Medicines Authority – which is responsible for regulating all agricultural and veterinary chemicals – must register the insecticide produced in the GM plant. It also approves the application of herbicides to GM herbicide-tolerant plants.

Although these other agencies have a different focus and responsibility from those of the Regulator, the Regulator has a policy of aligning its decision-making processes to the extent that is practicable within the limits of the relevant legislation.

Corporate governance arrangements

The Regulator is a statutory office holder with specific powers and functions under the Act (available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/about-regulator-1). In exercising these functions, the Regulator is directly responsible to the Australian Parliament.

Dr David Gillespie, formerly the Assistant Minister for Rural Health, was the minister responsible for regulating gene technology until late December 2017. The Minister for Regional Services Senator Bridget McKenzie, formerly the Minister for Rural Health, has held the portfolio since then. Under section 133 of the *Gene Technology Act 2000,* the Secretary of the Australian Government Department of Health supports the Regulator with administrative and scientific staff. For administrative purposes, staff and the Regulator are collectively referred to as the Office of the Gene Technology Regulator (OGTR). They are administered as a separate division of the Department of Health and the Gene Technology Special Account funds OGTR.

OGTR accesses a range of business management and reporting services directly through the Shared Services Centre of the Department of Health. These include information technology, financial reporting and accounting, human resources management, ministerial support and property management. The department reviews the cost of these services annually.

The *Public Governance, Performance and Accountability Act 2013* sets out the financial framework for OGTR's governance. We maintain integrity in financial reporting through internal audit arrangements as part of the agreement. OGTR complies with the Commonwealth Fraud Control Guidelines 2011, as the department requires. More information is available in the 2017–18 Department of Health Annual Report. We maintain our own business risk management plan, against which senior OGTR staff report periodically.

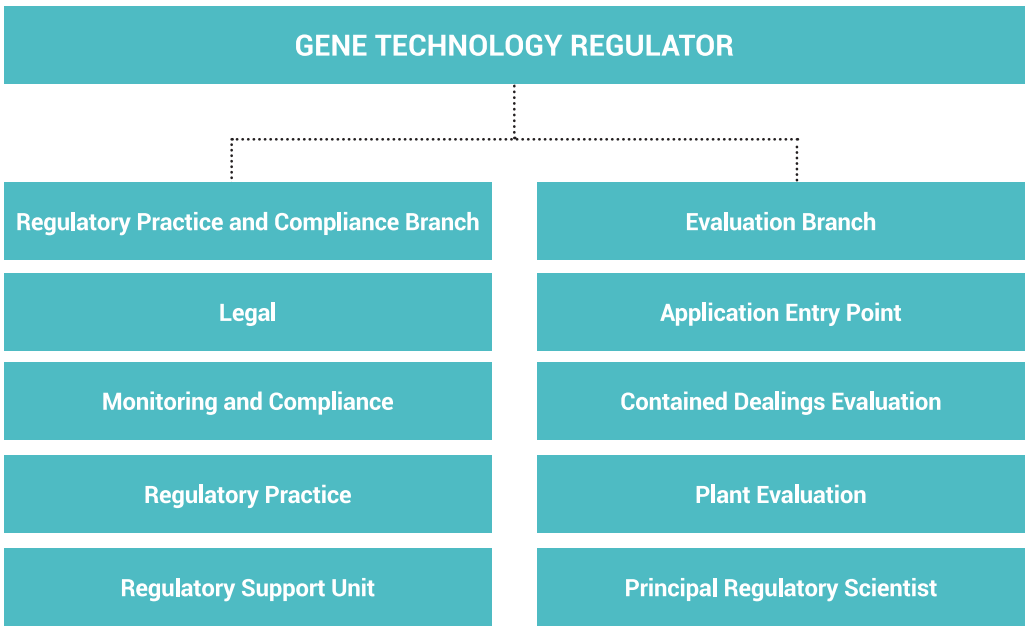
The employment framework for the OGTR is the *Public Service Act 1999*. The department's enterprise agreement, governance policies and practices cover OGTR staff. These include application of appropriate ethical standards under the Australian Public Service Values and Code of Conduct; compliance with Australian Government freedom of information (FOI), privacy, and work health and safety legislation; and compliance with the National Disability Strategy and the Australian Government's Workplace Diversity Policy.

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

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, 2017–18



Gene Technology Regulator

The Regulator is an independent statutory office holder who administers the nationally consistent scheme for regulating gene technology, comprising the *Gene Technology Act 2000* and corresponding state and territory laws. In administering this 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
- managing those risks through regulating certain dealings with genetically modified organisms (GMOs).

Dr Raj Bhula commenced as the Gene Technology Regulator on 18 July 2016.

Dr Bhula has a background of over 20 years' experience in regulating pesticides in Australia. She was the Executive Director of Scientific Assessment and Chemical Review at the Australian Pesticides and Veterinary Medicines Authority and Program Manager, Pesticides at the authority for almost 10 years. Dr Bhula has represented Australia at international expert committees, such as the Codex Committee on Pesticide Residues, and contributed to technical groups of the Organisation for Economic Co-operation and Development (OECD) Working Group on Pesticides. Much of this work included developing 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.

Regulatory Practice and Compliance Branch

Mr Neil Ellis has been the Executive Director of the Regulatory Practice and Compliance Branch since December 2016. He is responsible for regulatory practice policy, oversight of monitoring and compliance activities, corporate business and regulatory support, performance reporting, coordinating expert advisory committees, stakeholder communication and international cooperation activities.

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

The OGTR's Legal Officer advises the Regulator and the OGTR on how Commonwealth, state and territory laws affect their functions, including setting licence conditions and handling confidential commercial information. The Legal Officer also trains OGTR staff on legal issues and helps respond to FOI requests.

The Monitoring and Compliance Section monitors and inspects dealings with GMOs conducted at field trial sites and within certified contained facilities. It ensures that dealings with GMOs comply with legislative obligations and are consistent with the object of the Act. The section monitors compliance with conditions of licences or other instruments and restrictions, and manages risks in relation to any potential breach of conditions. It conducts audits, reviews and investigations of organisations and individuals involved in GMO dealings (including self-reported incidents and allegations made by third parties) to ensure compliance with the Act.

The Regulatory Practice Section works collaboratively with the department's Regulatory Policy Branch. It delivers operational policies, provides technical support, liaises with state and territory officers and coordinates the technical review of the Regulations. It also provides secretariat services to the Gene Technology Ethics and Community Consultative Committee and the Gene Technology Technical Advisory Committee, coordinates ministerial correspondence and briefings, and contributes 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.

The Regulatory Support Unit advises and supports the OGTR's regulatory capacity. This includes whole-of-office strategic planning activities, managing the Gene Technology Special account, project design and management, and ensuring the office has access to the appropriate resources. The unit coordinates departmental engagement and interactions, and produces the annual report. It serves as the first point of contact for many external stakeholders by managing the freecall

number (1800 181 030), coordinating responses to general email inquiries (to ogtr@health.gov.au) and managing the OGTR website.

Evaluation Branch

Dr Michael Dornbusch has been Assistant Secretary of the Evaluation Branch since 2009. His responsibilities encompass evaluating licence applications and other relating to dealings with GMOs, as well as science-related projects that maintain and improve the technical capabilities of the OGTR.

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

The Application Entry Point receives and acknowledges all applications to the OGTR. Staff in this area also process accreditation applications, manage databases, provide trend and statistical analyses of application receipts and authorisations and report on workflows. Staff also manage or assist with business process reform and regulatory reform projects. The section also helps the Evaluation Branch source scientific literature, and it manages a range of journal subscriptions for the office library.

The Contained Dealings Evaluation Section prepares risk assessment and risk management plans 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 GM plants and prepares risk management plans for consultation with key stakeholders, including the public. The section gathers scientific data and publishes reference documents to inform the risk assessment process.

The Principal Regulatory Scientist provides advice on the risk assessment of GMOs, including the review and implementation of the OGTR's Risk Analysis Framework. The Principal Regulatory Scientist, together with other staff, is also engaged in national and international harmonisation activities in order to keep pace with developments in science and regulatory risk analysis.

Advisory committees

The Act establishes two statutory committees to provide advice to the Regulator and the Legislative and Governance Forum on Gene Technology. These are the:

- Gene Technology Technical Advisory Committee
- Gene Technology Ethics and Community Consultative Committee.

Membership of the statutory committees is listed in Appendix 1.

Gene Technology Technical Advisory Committee

The functions of the Gene Technology Technical Advisory Committee, as set out in section 101 of the Act, are to provide scientific and technical advice, at the request of the Regulator or the Legislative and Governance Forum on Gene Technology, on GMOs; GM products; applications made under the Act; the biosafety aspects of gene technology; and the need for and content of policy principles, policy guidelines, codes of practice, and technical and procedural guidelines in relation to GMOs and GM products.

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

The current members of the committee, including the Chair, Professor John Rasko AO, were appointed by the then Assistant Minister for Health, the Hon Dr David Gillespie MP, for a three-year term that commenced on 1 February 2017.

The committee met four times during 2017–18: twice in face-to-face meetings in Canberra and twice by video conference. Communiqués from committee meetings, which provide an overview of key matters discussed and resolutions, are published on the OGTR website (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gttaccomm-1).

Gene Technology Ethics and Community Consultative Committee

The functions of the Gene Technology Ethics and Community Consultative Committee are set out in section 107 of the Act. They are to provide advice, at the request of the Regulator or the Legislative and Governance Forum on Gene Technology, 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 and content of policy principles, policy guidelines, codes of practice, and technical and procedural guidelines relating to GMOs and GM products.

The current members of the committee, including the Chair, Ms Judith Jones, were appointed for the 2015–2018 triennium by the then Assistant Minister for Health, Senator the Hon Fiona Nash.

The committee met twice during 2017–18 in face-to-face meetings in Canberra. Communiqués from committee meetings, which provide an overview of key matters discussed and resolutions, are published on the OGTR website (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gteccc-comm-1).

Office accommodation

In December 2017, OGTR was relocated from Pharmacy Guild House in Barton, ACT to Scarborough House in Woden, ACT, co-locating with the rest of the Department of Health. This was the office's first move since it was created in 2001. The move has resulted in significant cost savings for accommodation, and co-location with Health has delivered improved efficiencies in our interaction with the rest of the department.

The OGTR can now be found at:

Level 11, Scarborough House
Atlantic Street
Woden ACT 2606

Staff phone numbers have also changed as a result of the move, but the freecall line (1800 181 030), and postal address (MDP 54, GPO Box 9848, Canberra ACT 2601) remain the same.

Work experience

The Regulator finalised a Memorandum of Understanding with the University of Canberra in April 2018. The MOU allows students undertaking relevant studies to gain work experience in a regulatory science environment, by spending a short period of time at the OGTR. Students engage with all sections of the office to gain an understanding of the range of job opportunities available and also to experience working within the public service. OGTR was able to host two students in June 2018 who, along with other tasks, produced factsheets on two GM crops during their time in the office.

Chapter 3

Functions of the Gene Technology Regulator

The first part of this chapter outlines the functions of the Regulator and the regulatory processes for authorising and monitoring dealings with genetically modified organisms (GMOs) that are defined by the Act, the Gene Technology Regulations 2001 (the Regulations), and corresponding state and territory laws. The second part of the chapter describes the operational performance in relation to the functions as required by the subsection 136(1A) of the Act and against the performance indicators in Outcome 5 (Regulation, Safety and Protection) of the 2017–18 Department of Health Portfolio Budget Statements.

Statutory functions and regulatory processes

Functions

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 GMOs.

Section 27 of the Act sets out the functions of the Regulator to:

- perform functions in relation to GMO licences, as set out in the Act (Part 5)
- develop draft policy principles, policy guidelines and codes of practice, as requested by the Legislative and Governance Forum on Gene Technology
- issue technical and procedural guidelines in relation to GMOs
- provide information and advice to other regulatory agencies about GMOs and GM products
- provide information and advice to the public about the regulation of GMOs
- provide advice to the LGFGT about the:
  - operations of the Regulator and the Gene Technology Technical Advisory committee
  - effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation
- undertake or commission research in relation to risk assessment and the biosafety of GMOs
- promote the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies
- maintain links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia
- perform such other functions as are conferred on the Regulator by the Act, the Regulations or any other law.

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 (the full definition is in section 10 of the Act).

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

(a) conduct experiments with the GMO

(b) make, develop, produce or manufacture the GMO

(c) breed the GMO

(d) propagate the GMO

(e) use the GMO in the course of manufacture of a thing that is not the GMO

(f) grow, raise or culture the GMO

(g) import the GMO

(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 the 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)
- licenced as:
  - a dealing not involving an intentional release (DNIR) of a GMO into the environment
  - a dealing involving an intentional release (DIR) of a GMO into the environment
- an inadvertent dealing
- included on the GMO Register
- specified in an emergency dealing determination (EDD).

More information is available on the OGTR website (http://www.ogtr.gov.au)

For both DNIRs and DIRs, the legislation requires the Regulator to prepare a risk assessment and risk management plan 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). 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.

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 dealings are minimal and that it is no longer necessary for people undertaking the dealings to be covered by a licence.

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

Table 1 summarises the categories of GMO authorisations, their authorisation requirements and the extent of containment required to conduct the dealings.

The Regulator may, directly or on application, vary an issued licence, GMO Register entry or other instrument. Variations may involve changes to conditions applied to a licence or to the GMO Register entry 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 dealings for intentional release of a GMO into the environment.

More information on the various categories of GMO authorisations and their assessment processes are available on the OGTR website (http://www.ogtr.gov.au).

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

Conditions of licences for GMO dealings include a requirement for the organisation conducting the dealings to maintain accreditation.

Table 1: Categories of authorisations for GMO dealings under the *Gene Technology Act 2000*

CATEGORY	AUTHORISATION REQUIREMENTS	CONTROLS
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	Controls 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	Controls 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	No intentional release to the environment Usually PC2 (or higher) certified physical containment 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 Legislative instrument	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 GMO dealings must have been previously licensed Review of relevant information by Regulator Legislative instrument	Controls may be required
Inadvertent dealings	Licence required Licence decision by Regulator only for the purposes of disposal of the GMO	Controls and/or disposal measures will apply
NLRD	Licence not required GMO dealings classified as NLRDs are scheduled in Regulations Conduct of NLRDs requires prior assessment by IBC to confirm proper classification Notified in annual report to Regulator	No intentional release to the environment Usually PC1- or PC2-certified physical containment 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(or 2) = physical containment level 1(or 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 2. They do not include periods when the Regulator has sought more information from the applicant and the decision-making process cannot proceed until the information is provided. In these instances, the statutory timeframe clock is regarded as stopped.

Operational performance

This section describes the achievements and performance against Outcome 5 (Regulation, Safety and Protection) of the 2017–18 Department of Health Portfolio Budget Statements. It provides details of achievements on deliverables and performance indicators in the key areas of:

- assessments and authorisations under the Act
- monitoring of GMO dealings
- compliance with the Act.

Summary of assessments and approvals

Information on performance against deliverables and key performance indicators, as set out in the 2017–18 Department of Health portfolio budget statements, is summarised in the second part of this chapter.

In 2017–18, the OGTR received 1,815 applications and notifications, as defined under the Act (Table 3). 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. The OGTR granted 1,084 approvals over a range of various application types. There were no appeals associated with decisions made on applications approved under the gene technology legislation.

Table 2: Prescribed timeframes for applications

CATEGORY	TIMEFRAME (WORKING DAYS)
Accreditation	90 (r. 16)
Certification	90 (r. 14)
DIR—limited and controlled, no significant risk	150 (r. 8)
DIR—limited and controlled, significant risk	170 (r. 8)
DIR—except for limited and controlled releases	255 (r. 8)
DNIR	90 (r. 8)
Licence variation	90 (r. 11A)

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

Table 3: Applications and notifications, 2017–18

APPLICATION TYPE	RECEIVED	WITHDRAWN	APPROVED[a]	REFUSED	CEASED CONSIDERATION[b]	UNDER CONSIDERATION[c]
Accreditation	7		9			
Alternate facility request for an NLRD	1					1
Alternate transport, storage or disposal request for an NLRD	1		1			
CCI declaration for DIR licence	6		4	1		6
CCI declaration for DNIR licence	4		1			8
CCI declaration for NLRD notification	4		4			
CCI declaration for other information	1					2
Certification	118	2	135			15
DIR licence	7		9			4
DNIR licence	11		9			3
Lifting suspension of certification[d]	57		58			3
NLRD notification	842					
Surrender of accreditation	6		5			1
Surrender of certification	108		110			
Surrender of DIR licence	10		10			
Surrender of DNIR licence	1	1	3			
Suspension of accreditation[d]	0					
Suspension of certification[d]	68		68			1
Transfer of certification	0		2			
Transfer of DIR licence	0					
Transfer of DNIR licence	2		2			
Variation of certification	521	9	610		2	81

APPLICATION TYPE	RECEIVED	WITHDRAWN	APPROVED[a]	REFUSED	CEASED CONSIDERATION[b]	UNDER CONSIDERATION[c]
Variation of DIR licence	5		5			
Variation of DNIR licence	35	2	39			9
Total	**1815**	**14**	**1084**	**1**	**2**	**134**

CCI = confidential commercial information; 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; NLRD = notifiable low risk dealing

a 'Approved' refers to the issuing of a new or varied licence or other instrument, consent to surrender an instrument, or a declaration in relation to a CCI application. Some applications reported as approved in 2017–18 were received in the previous financial year.

b Includes both 'ceased consideration' and 'not considered' under section 42 of the *Gene Technology Act 2000*.

c Under consideration at 30 June 2018.

d Suspension of accreditation or certification, as well as the lifting of a suspension, can include both those requested by the applicant and those initiated by the Regulator. Those reported in 2017–18 were all requested by the applicant.

Licences for dealings involving intentional release of GMOs

The Regulator issued nine DIR licences during 2017–18 (Table 4) with a further four licence applications in progress as at 30 June 2018. Six of the DIR licences issued related to applications received before 1 July 2017.

Details of the traits introduced into the organisms for release are provided in Table 4.

All of the licence decisions were made within statutory timeframes (see 'Timeframes', Chapter 3).

Six of the DIR licences issued in 2017–18 were for field trial (limited and controlled release) and three were for commercial releases.

The field trial licences were issued for GM wheat and barley, buffalo grass, ryegrass and sorghum with a variety of introduced traits, and for GM vaccines for chickens and crocodiles. The commercial release licences were for GM cotton, GM canola and GM safflower.

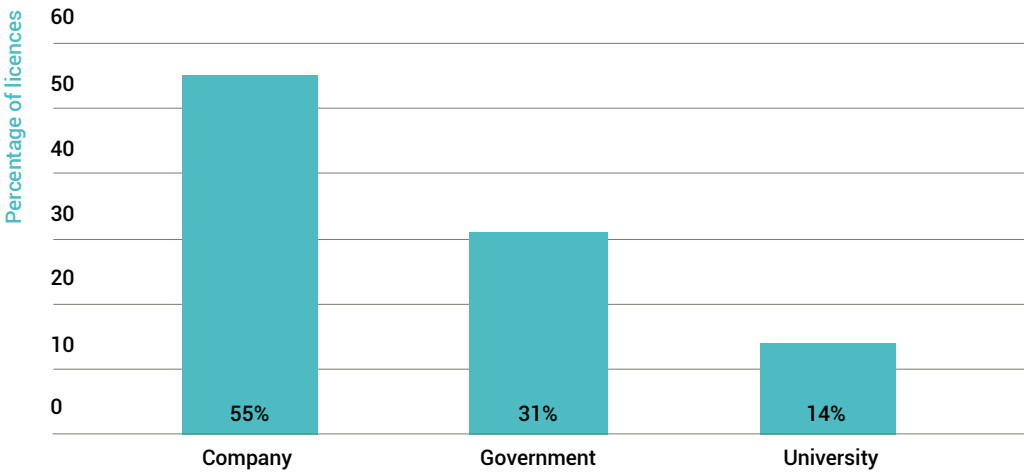
Of the nine DIR licences issued in 2017–18, four were issued to companies, one to a government agency and four to universities (Table 4). Of the 140 DIR licences issued since commencement of the Act, 77 (55%) have been to companies, 43 (31%) to government agencies and 20 (14%) to universities (Figure 2).

Table 4: DIR licences issued, 2017–18

DIR NO.	APPLICANT	PARENT ORGANISM	INTRODUCED TRAIT	TYPE OF RELEASE	RECEIVED	ISSUED
DIR 160	Department of Economic Development, Jobs, Transport and Resources	Ryegrass	Fructan biosynthesis	Limited and Controlled Release	18/8/2017	6/3/2018
DIR 159	The University of Queensland	Insect-Specific Virus	Vaccine – Altered antigen expression	Limited and Controlled Release	11/8/2017	9/5/2018
DIR 158	GO Resources Pty Ltd	Safflower	High oleic acid composition in seeds	General and Commercial Release	28/7/2017	27/6/2018
DIR 157	Syngenta Australia Pty Ltd	Cotton	Insect resistance	General and Commercial Release	28/6/2017	14/2/2018
DIR 156	RMIT University	Buffalo grass	Herbicide resistance, dwarf phenotype	Limited and Controlled Release	5/6/2017	11/4/2018
DIR 155	Nuseed Pty Ltd	Canola	Altered oil profile	General and Commercial Release	10/2/2017	14/2/2018
DIR 154	Bioproperties Pty Ltd	*Infectious Laryngotracheitis Virus*	Vaccine – Attenuation of pathogenicity	Limited and Controlled Release	21/12/2016	1/8/2017
DIR 153	The University of Queensland	Sorghum	Grain quality traits	Limited and Controlled Release	16/12/2016	25/7/2017
DIR 152	The University of Adelaide	Wheat and Barley	Abiotic stress tolerance and yield improvement	Limited and Controlled Release	13/12/2016	17/7/2017

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

Figure 2: Types of organisations issued with DIR licences since commencement of the *Gene Technology Act 2000*



Licences for dealings not involving intentional release of GMOs

Dealings not involving intentional release (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 2017–18, the Regulator issued nine DNIR licences (see Table 5). All approvals were made within the statutory time limit. The Regulator was considering a further three DNIR applications at 30 June 2018.

All of the nine DNIR licences issued in 2017–18 were for research, development and/or testing of potential treatments for human diseases (including three clinical trials). This is similar to previous years, with research into human disease and disease treatment predominating in DNIR licences, with other licences relating to either plant- or animal-disease research or production of therapeutic products using GMOs.

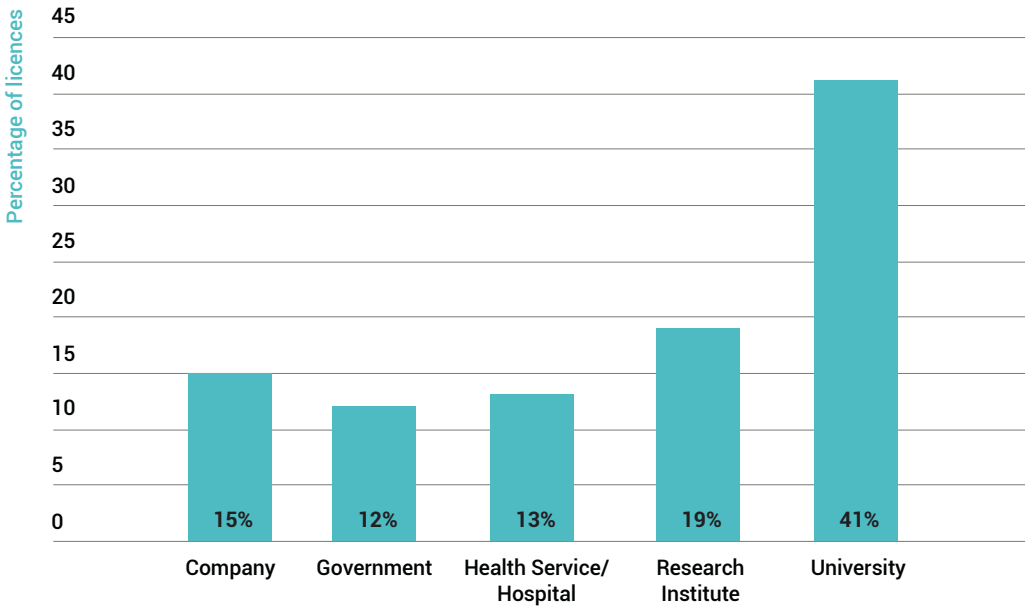
Table 5: DNIR licences issued, 2017–18

DNIR NO.	APPLICANT	TITLE	RECEIVED	ISSUED
DNIR-584	CSIRO	Large-scale fermentation of SCV vaccines.	22/1/2018	1/6/2018
DNIR-583	Novotech (Australia) Pty Ltd	Phase 3 Study of ADXS11-001 Administered Following Chemoradiation as Adjuvant Treatment for high risk Locally Advanced Cervical Cancer: AIM2CERV.	3/1/2018	16/5/2018
DNIR-582	Monash University	Genetic manipulation of cells by viral transduction using *in vivo* models	1/1/2018	10/5/2018
DNIR-581	Murdoch Children's Research Institute	Cardiac regeneration	29/11/2017	13/4/2018
DNIR-580	Clinical Network Services (CNS) Pty Ltd	MVA-NP+M1: a new Influenza vaccine for use in human clinical trials	22/9/2017	23/1/2018
DNIR-579	Griffith University	Investigating the mode of action of novel drug leads against *Giardia duodenalis*	10/8/2017	13/12/2017
DNIR-578	University of South Australia	A recombinant viral vaccine vector platform to produce polyclonal antibodies in milk and egg.	25/7/2017	20/12/2017
DNIR-577	PSI CRO Australia Pty Ltd	Gene-transfer, open-label, dose-escalation study of SPK-8011 [adeno-associated viral vector with B-domain deleted human factor VIII gene] in individuals with haemophilia A	18/7/2017	17/11/2017
DNIR-576	James Cook University	New strategies for improved tuberculosis vaccines	29/6/2017	3/11/2017

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

The types of organisations to which DNIR licences have been issued since commencement of the Act are shown in Figure 3. Of the 452 DNIR licences issued since commencement of the Act, 184 (41%) have been to universities, 84 (19%) to research institutes, 69 (15%) to companies, 58 (13%) to health services/hospitals and 57 (12%) to government agencies.

Figure 3: Types of organisations issued with DNIR licences since commencement of the Act



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

Notifiable low risk dealings

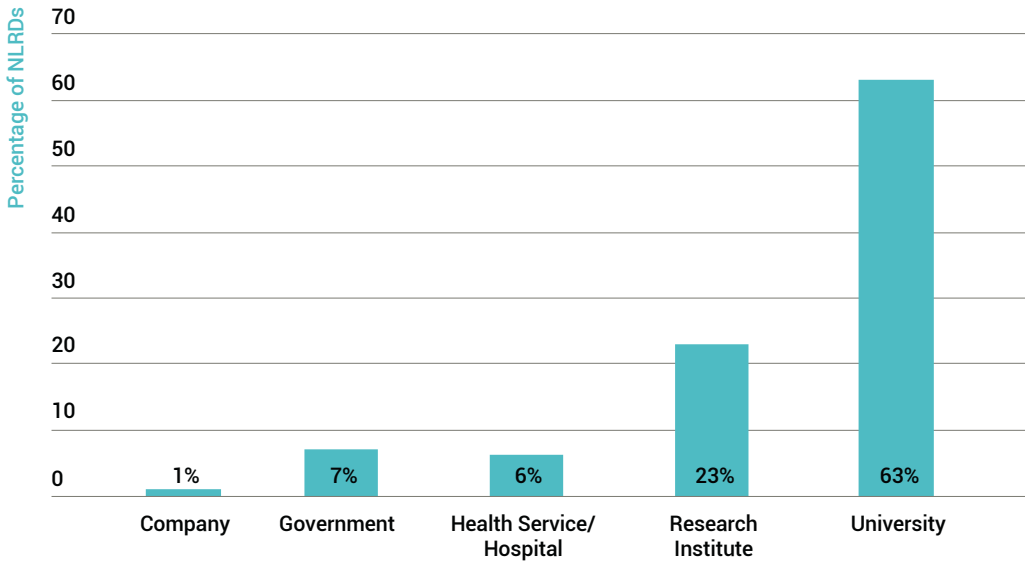
Notifiable low risk dealings (NLRDs) are GMO dealings that have been assessed, based on previous experience and current scientific knowledge, as posing low risk, provided certain criteria and risk management conditions are met. Dealings with GMOs classified as NLRDs are listed in the Regulations under 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).

Conducting NLRDs does not require prior authorisation from the Regulator, but the dealings must have been assessed by an institutional biosafety committee as meeting the NLRD classification, must be conducted in appropriate containment facilities (usually facilities certified by the Regulator) 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.

During 2017–18, 842 NLRD notifications were received. As in past years, these were predominantly for research work. The types of organisations that notified NLRDs to the OGTR in 2017–18 are shown in Figure 4.

The Regulations require NLRDs to be conducted in facilities certified by the Regulator to an appropriate type and containment level relevant to the dealing, or alternate facilities agreed by the Regulator (paragraph 13(2)(c)). Transport, storage and disposal of GMOs in the course of NLRDs may happen outside of approved facilities if it is conducted according to guidelines issued by the Regulator, or alternate requirements agreed by the Regulator (sub-paragraph 13(3)(b)(ii)).

Figure 4: Types of organisations that notified NLRDs in 2017–18



NLRD = notifiable low risk dealing

During 2017–18, the Regulator approved one alternate transport, storage and disposal request. The Regulator did not approve any alternate facility requests but one request was under consideration at the end of the period. Since these provisions were introduced in September 2011, six alternate facility requests and seven alternate transport, storage and disposal requests have been approved.

A certified PC2 laboratory in Queensland

Inspection of a current safflower field trial site in NSW

Dealings placed on the GMO Register

Dealings with GMOs may be placed 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 2017–18, there were no new listings on the register, and no applications were received to place dealings on the register.

Emergency dealing determinations

An emergency dealing determination is a legislative instrument made by the Minister under section 72 of 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 determination, including monitoring for compliance with any conditions.

During 2017–18, the OGTR did not receive any requests for advice in relation to making emergency dealing determinations. No determinations were made, and none were in effect.

Licences for inadvertent dealings

Part 5 of the Act allows the Regulator to grant inadvertent dealings licences (a temporary licence of no longer than 12 months) to a person who has inadvertently come into possession of an unauthorised GMO so that they can safely dispose of the GMO.

During 2017–18, there were no new inadvertent dealings licences issued and no applications were received.

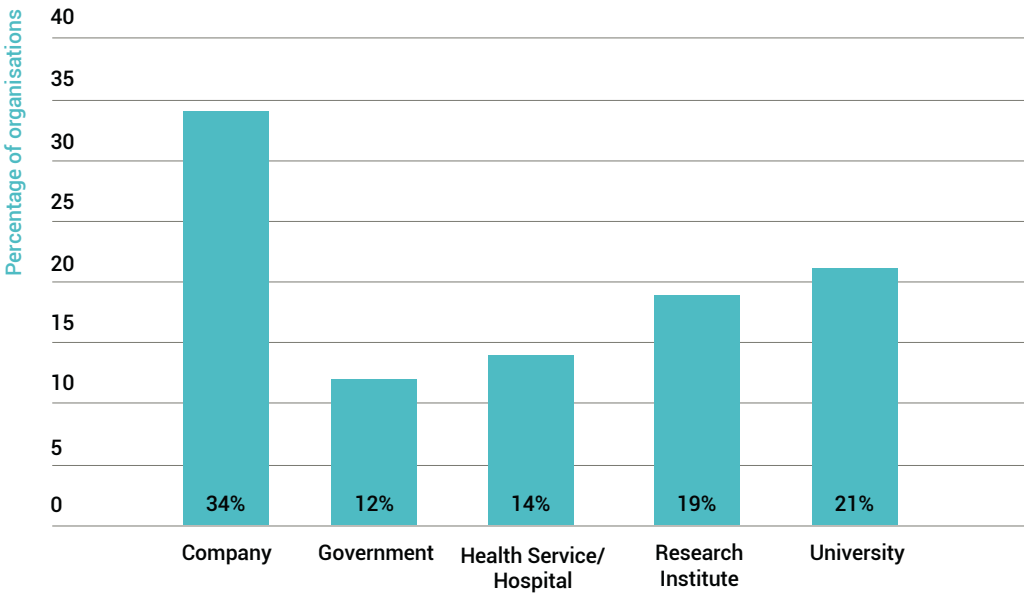
Accreditation of organisations

Organisations may apply to the OGTR for accreditation under section 91 of the Act and organisations conducting licensed dealings with GMOs must remain accredited. To achieve and retain accreditation, the organisation must have access to a properly constituted and resourced institutional biosafety committee, and must comply with other requirements of the Regulator's Guidelines for accreditation of organisations.

In 2017–18, nine accreditations were issued, with a total of 168 organisations holding accreditation at 30 June 2018. Accredited organisations are located in all Australian states and territories (Figure 5). The profile of the types of organisations accredited by the Regulator has not changed significantly: a large proportion (66%) are primarily publicly funded (Figure 6).

Figure 5: Organisations accredited as at 30 June 2018, by location of headquarters

Figure 6: Organisations accredited as at 30 June 2018



Certification of physical containment facilities

Facilities may be certified by the Regulator to particular containment levels under section 84 of the Act (known colloquially as 'OGTR-certified' facilities).

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.

During 2017–18, 135 certifications for physical containment facilities were issued (Table 6). The number of OGTR-certified facilities at 30 June 2018 is listed by facility type and containment level.

Table 6: Number of OGTR-certified facilities as at 30 June 2018

FACILITY TYPE	PC1[a]	PC2	PC3	PC4[a]	TOTAL
Animal		239	4		243
Aquatic		31			31
Constant temperature room		45			45
Facility	310			4	314
Invertebrate		53	2		55
Laboratory		1103	24		1127
Large grazing animal		54			54
Large scale facility		19			19
Plant		158			158
Total	310	1702	30	4	2046

PC = physical containment

a 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 2018.

The types of organisations issued with certifications in 2017–18 were predominantly universities (71%) and research institutes (14%). The types of organisations that held certifications as at 30 June 2018 were predominantly universities (57%), research institutes (18%) and government agencies (14%) (Figure 7). This distribution reflects 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 states and territories (Figure 8).

Figure 7: Distribution of OGTR-certified facilities as at 30 June 2018, by organisation type

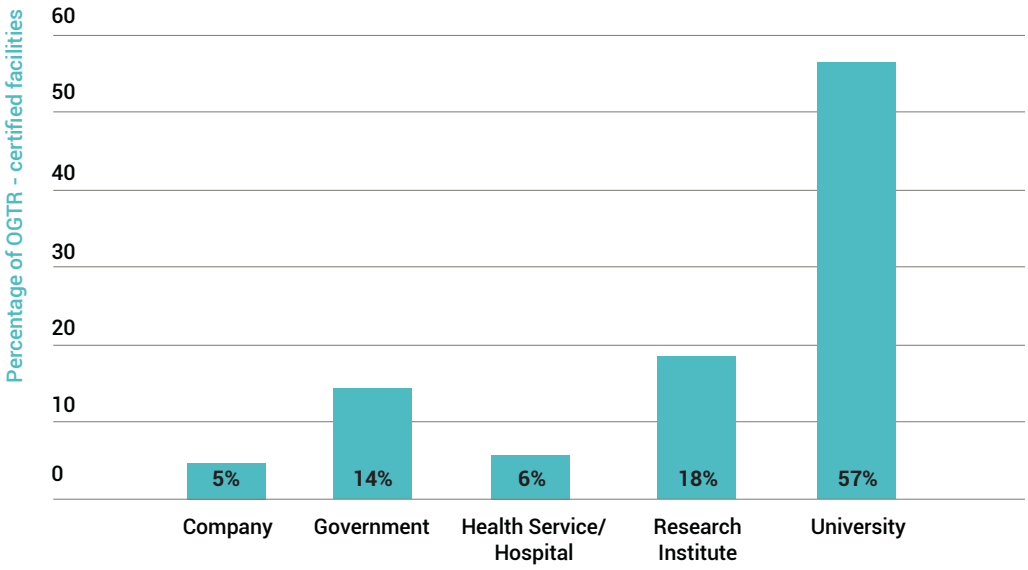
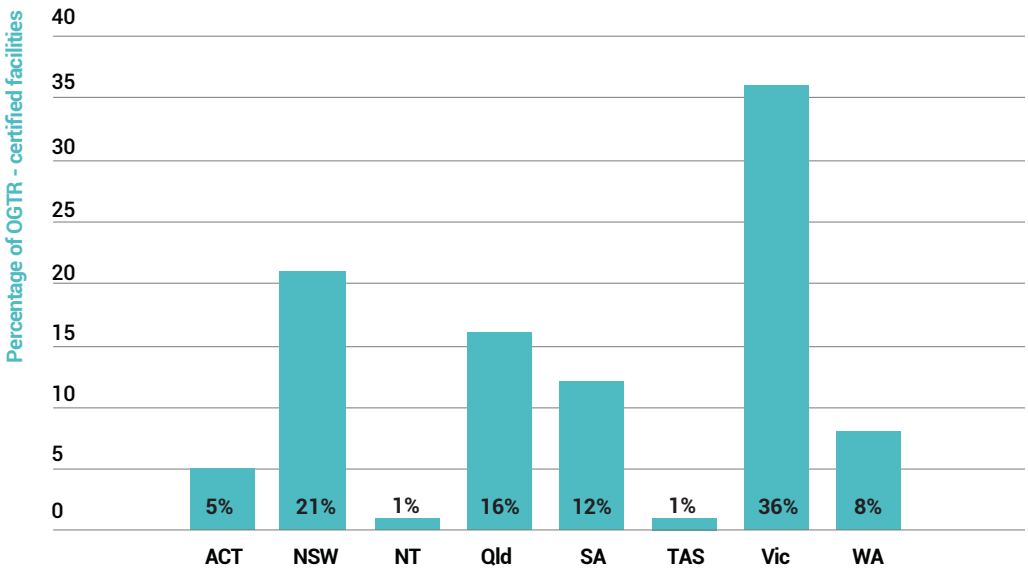


Figure 8: Distribution of OGTR-certified facilities as at 30 June 2018, by location



Application trends

The numbers of main authorisations issued during 2017–18 were similar to those in previous years (Table 7).

Table 7: Data for approval of main types of applications, 2013–14 to 2017–18

APPLICATION TYPE	2013–14	2014–15	2015–16	2016–17	2017–18
Accreditation	4	10	4	3	9
Certification	183	89	125	162	135
DIR	7	7	9	9	9
DNIR[a]	10[b]	10[b]	7	10	9
NLRD	827	842	767[c]	820[c]	842

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 Two applications were approved and incorporated into a single licence.

c Correction to the number (750) reported in the 2015–16 report and number (817) reported in the 2016–17 report. The complete set of data was not available at the time of the reports.

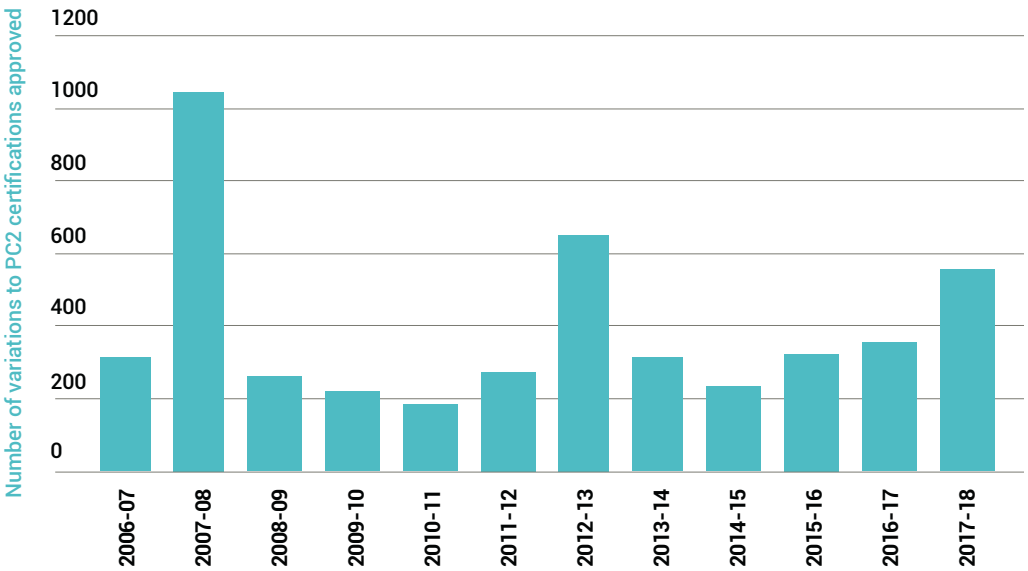
While there are no clear trends in numbers of licence applications, there has been a change in the character of DNIR licence applications received in 2017–18. There were more DNIR applications for human clinical trials of therapeutic GMOs than at any time in the previous four years (see Table 8). Over the last two years, there has also been an increase in the proportion of accreditation applications received from organisations involved in human clinical trials/and or human therapeutic GMO research and development (Table 8). This suggests increased research interest and activity in the area of human therapeutic GMOs.

Table 8: DNIR licence applications and accreditation application related to human therapeutic GMOs

	2013–14	2014–15	2015–16	2016–17	2017–18
Clinical trial DNIRs	0	2	2	1	6
Proportion of accreditation applications received from companies involved in clinical trials or human therapeutic GMO development.	25%	10%	0%	60%	57%

Since the regulatory scheme commenced in 2001, facilities certified at PC Level 2 have had a 5 year expiry date imposed. This has led to a peak in applications to vary certifications to extend the period of certification every 5 years. The 5-yearly peak in the approval of variation applications occurred in the 2017–18 period (Figure 9). Over time there has been a gradual reduction in the size of this 5-yearly peak due to both attrition (as older facilities are replaced) and proactive management processes in the office.

Figure 9: Variations to PC2 certifications approved, 2006–07 to 2017–18



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 commercial confidential information. The extent of these 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 commercial confidential information applications, and the evaluation of a licence application may be paused if significant claims need to be resolved.

In 2017–18, the Regulator made nine commercial confidential information declarations. Decisions on a further sixteen applications were pending as at 30 June 2018.

Surrenders

The surrender of licences and certifications usually occurs when GMO 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 facility decommissioning has taken place.

The OGTR received 128 surrender requests in 2017–18 and approved 110 for surrender of certifications of facilities, 10 for surrender of DIR licences, three for surrender of DNIR licences and five for surrender of accreditation.

Variations

Approval holders may apply to the Regulator for variations to instruments issued under the Act (licence, certification or accreditation), and the Regulator may also initiate 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 a 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 654 variations in 2017–18 (see Table 3).

Monitoring dealings with genetically modified organisms

This section provides information on the OGTR's inspection activities during 2017–18.

Inspections of DIR licences

The OGTR strategy for field trial monitoring draws on accumulated experience based on risk profiling and sampling of a range of dealings, locations where dealings are undertaken, and organisations who are conducting dealings.[3]

During 2017–18, there were 58 DIR licences in force held by 24 accredited organisations. These comprised:

- 22 commercial release licences (17 for crops, four for vaccines and one for a therapeutic); and
- 36 limited and controlled release licences (31 for crops, four for clinical trials of vaccines and one for a clinical trial of a therapeutic).

None of the commercial release licences imposed conditions that necessitated site inspections.

The OGTR inspected 13 of the 31 limited and controlled crop licences (which may have comprised multiple site visits per licence). One limited and controlled therapeutic clinical trial was inspected.

Outcome of inspection activities

The OGTR implements a risk-based selection process to identify limited and controlled release field sites for inspection. This process includes consideration of:

- the nature of the genetic modification and whether a site has reached a licence-specific milestone (i.e. flowering, harvest or sign-off)
- reports of incidents of potential non-compliances at sites, or after adverse weather events such as storms, floods or cyclones
- the level of experience of the licence holder and the potential for inspection activities to assist in preventing the occurrence of non-compliance.

At the beginning of 2017–18, 96 licensed field trial sites were operating, 37 of which were current and 59 were subject to post-harvest monitoring conditions. Thirty-nine of the field trial sites were inspected in the year (41%). In one instance a site was inspected twice in 2017–18 (discussed below). A breakdown of the number and proportion of sites inspected in 2017–18 is provided in Table 9.

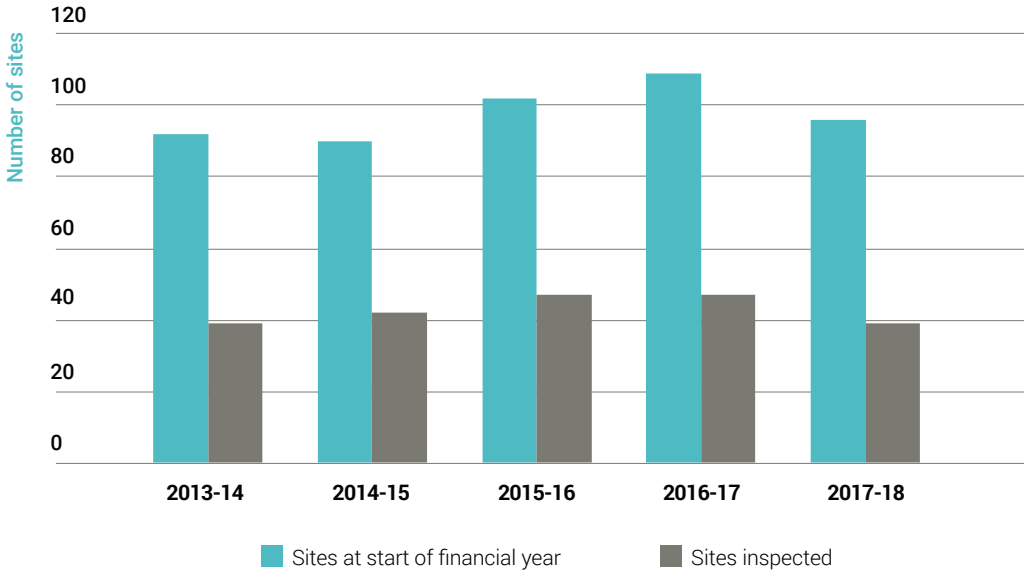
3 Details are in the Monitoring Protocol on the OGTR website at www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mc-protocols-1

Table 9: Number and proportion of DIR field trial site inspections in each quarter of 2017–18

REPORTING PERIOD	CURRENT SITES	POST-HARVEST MONITORING SITES
Annual	19/37 (51%)	20/59 (34%)
July–September 17	3/37 (8%)	4/59 (7%)
October–December 17	7/40 (18%)	8/56 (14%)
January–March 18	3/38 (8%)	5/63 (8%)
April–June 18	6/24 (25%)	3/57 (5%)

The number of active field-trial sites and inspections has remained consistent over the last five years (Figure 10).

Figure 10: Number of sites and number inspected each year, 2013–18



Types of GM crops inspected

OGTR inspected nine plant species across 39 field trial sites during 2017–18 (Table 10).

Table 10: Number of licensed DIR trial sites at beginning and end of 2017–18, and number inspected in 2017–18, by species

SPECIES	TRIAL SITES AS AT 1 JULY 2017	TRIAL SITES AS AT 30 JUNE 2018	TRIAL SITES INSPECTED DURING 2017–18
Banana	2	3	0
Barley	3	0	0
Canola	30	6	5
Cotton	3	6	1
Indian mustard	1	1	1
Safflower	13	2	8
Sorghum	0	1	1[4]
Sugarcane	19	19	7
Wheat	12	18	5
Wheat and barley	11	8	10
White clover	2	0	1

Note: Some limited and controlled field trial 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.

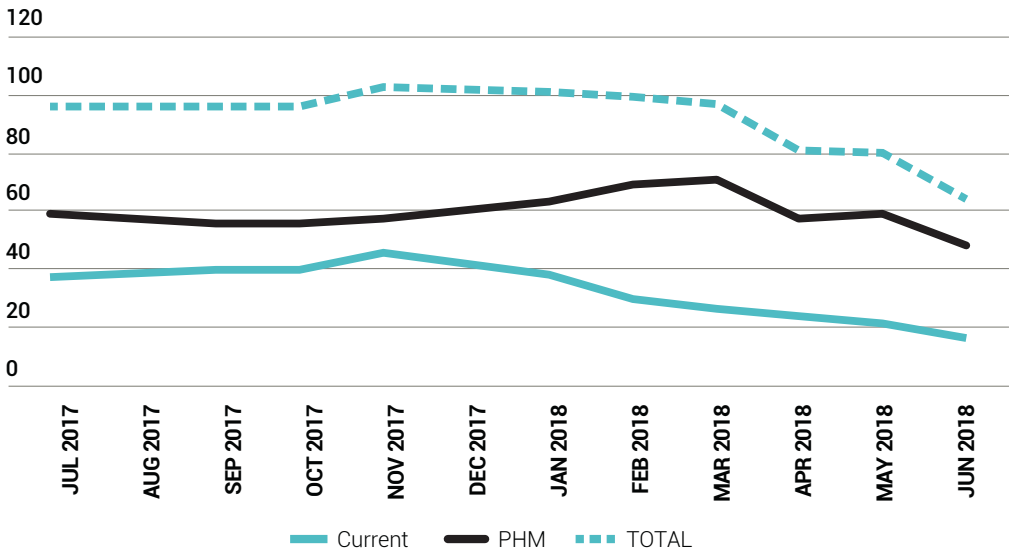
Cycle and status of field trial sites

During the course of each year, a significant number of GM crop field trials undergo changes in status (i.e. moving from 'current' to 'post-harvest', through to 'signed-off'). A newly planted (current) trial is subject to licence conditions to manage risks such as dissemination of the GMO from the trial site. These obligations continue until crop harvest and cleaning of the trial site is completed, changing the site status to post-harvest. Trial sites are then subject to different monitoring and reporting requirements, continuing until the OGTR is satisfied that no further inspections are required to manage persistence of the GMO. Sites may then become eligible for sign-off, subject to having completed all necessary licence obligations.

Figure 11 shows the change in the numbers of current field trial sites and of field trial sites subject to post-harvest monitoring during 2017–18.

4 This site was inspected twice in Quarter 4 of 2017–18

Figure 11: Number of DIR field trial sites and their status during 2017–18



PHM = post-harvest monitoring

Locations of field trial site inspections

In 2017–18, the OGTR inspected field trial sites in all states and territories where field trials were undertaken, except South Australia and the Northern Territory. No trials were undertaken in Tasmania (Table 11).

Wheat field trial site in the ACT

Table 11: Number of DIR field trial sites and OGTR inspections in 2017–18, by state and territory

JURISDICTION	TRIAL SITES AS AT 1 JULY 2017	TRIAL SITES AS AT 30 JUNE 2018	SITE INSPECTIONS
ACT	5	5	5
NSW	8	5	3
Qld	21	22	8[5]
SA	5	7	0
Vic	38	8	8
WA	19	15	15
NT	0	2	0
Tas	0	0	0
Total	96	64	39

Inspections of contained dealings

Our monitoring program includes dealings conducted in certified containment facilities under DNIR licences and NLRDs. For monitoring purposes, certified facilities are grouped into higher and lower containment types. These are designated by physical containment (PC) level. Accordingly, 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. 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 2018, 135 organisations held 2,046 approvals for the certification of containment facilities (11 organisations did not hold a facility). During 2017–18, 60 facilities were inspected across the range of facility types (Table 12); this includes 13 of the 57 higher-level containment facilities that had certification approvals in force at the beginning of 2017–18 (representing 23%).

In addition, 15 DNIR licences in force during 2017–18 were monitored.

5 One site was inspected twice in Quarter 4 of FY 2017–2018

Table 12: Number of inspections of certified facilities (by type) conducted during 2017–18

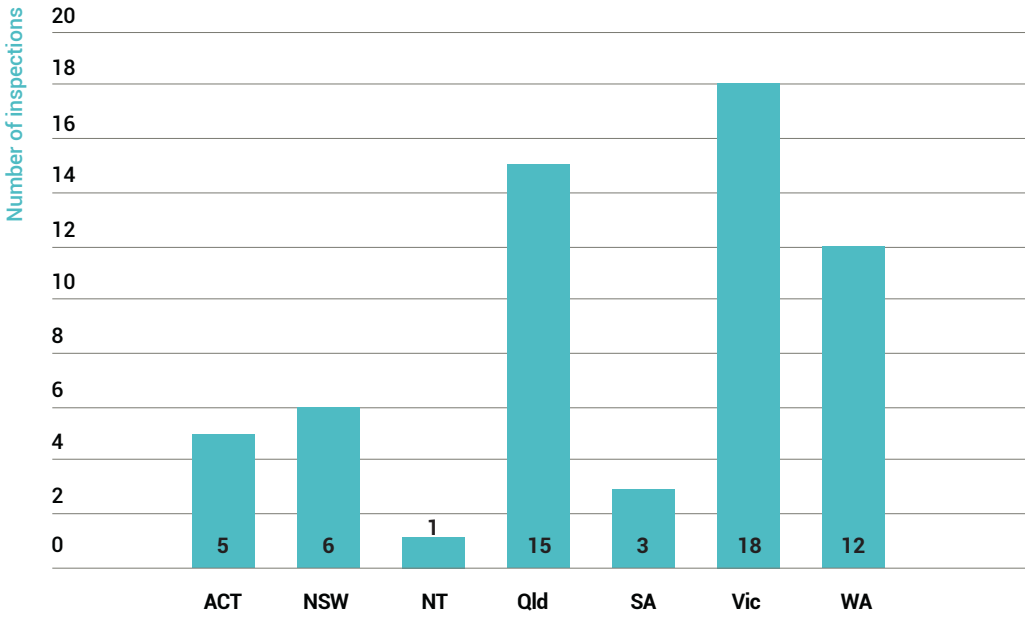
CONTAINMENT TYPE	PC LEVEL AND FACILITY TYPE	INSPECTIONS
Lower level	PC1 Facility	4
	PC2 Animal	12
	PC2 Laboratory	21
	PC2 Plant	6
	PC2 Aquatic	2
	PC2 Invertebrate	2
Higher level	PC2 Large scale	4
	PC3 Laboratory	5
	PC3 Invertebrate	1
	PC4 Facility	3
Total		60

PC = physical containment

Locations of facility inspections

Certified facilities are located in all Australian states and territories (Figure 8). In 2017–18, monitoring activities took place in each state and territory except Tasmania (Figure 12).

Figure 12: Number of certified facility inspections in 2017–18, by state and territory

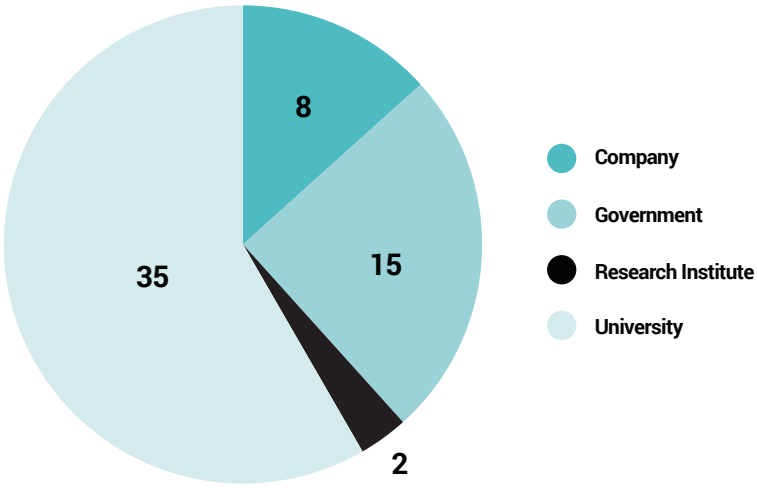


Inspection of air-handling systems for high level containment facilities in Victoria

Types of organisations inspected

Of the five categories of applicant organisations, universities held the largest number of certifications during 2017–18 (Figure 7). Figure 13 displays the distribution of inspections during 2017–18 by organisation type. Universities comprised the majority of inspections (35) followed by government (15), company (8) and research institutes (2).

Figure 13: Certified facility inspections in 2017–18, by organisation type



Compliance with the Act

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, are listed below.

Matters referred to as non-compliances in this report reflect situations where inspectors have found inconsistencies relating to requirements imposed by licence or certification conditions. Non-compliance is not regarded as a breach of the licence conditions unless proven to be so after investigation. Non-compliance with licence conditions is assessed against the OGTR Compliance and Enforcement Policy.[6]

During 2017–18, the regulated community demonstrated a high level of compliance with the gene technology legislation.

Non-compliance findings for GMO dealings involving intentional release

In 2017–18, two holders of DIR licences were found to be non-compliant. These findings are outlined below.

ORGANISATION	CLINICAL NETWORK SERVICES PTY LTD.
LICENCE NUMBER	DIR 140
SUMMARY OF DEALING	The purpose of the clinical trial is to assess the effectiveness and safety of the GMO as a treatment for advanced hepatocellular carcinoma when provided in conjunction with a standard treatment, compared with the standard treatment alone.
FINDINGS	• On 24 July 2017, Clinical Network Services Pty Ltd notified the OGTR of the commencement of a DIR 140 trial site; however, the first inoculation at this site was on 19 May 2017. Clinical Network Services Pty Ltd failed to notify the OGTR within seven days of the first inoculation. • Licence condition 50 requires the licence holder to notify the Regulator of the first inoculation of the first trial participant at each Study Site, within seven days of the event.
ASSESSMENT	This event was mainly caused by an administrative oversight. There was negligible risk to human health and to the environment.
COMPLIANCE MANAGEMENT	Clinical Network Services Pty Ltd has been reminded of their obligations as a licence holder under the *Gene Technology Act 2000*. Relevant staff were re-trained by the licence holder and made aware of their obligations under the licence conditions of DIR 140.

6 The Compliance and Enforcement Policy is on the OGTR website

ORGANISATION	THE UNIVERSITY OF QUEENSLAND
LICENCE NUMBER AND SITE	DIR 153 Site 1
SUMMARY OF DEALING	The purpose of the field trial is to assess the agronomic characteristics, yield and grain quality of the GM sorghum plants under field conditions.
FINDINGS	1. During a routine monitoring inspection of a current GM sorghum field trial conducted on 17 April 2018, OGTR inspectors were informed by The University of Queensland that their staff were unable to access a section of the monitoring zone that extended into an area that was leased by a third party, where a soybean crop was growing. Inspectors were unable to access the area on the day of inspection. Licence condition 11 requires the University of Queensland to have access and control of the monitoring zone for the duration of the licence. 2. Non-GM sorghum that was planted surrounding the GM sorghum was not treated as if it were GM sorghum, with flower heads not being bagged. Licence condition 28 requires that all non-GM sorghum grown in a planting area be handled as if it were the GMO. Licence condition 33 requires that GM Sorghum flower heads be enclosed in bags while flowering. 3. Prior to planting, the GM sorghum seed was transported from Brisbane to The University of Queensland's Gatton facility for seed treatment. At the time, the facility where the treatment was undertaken was neither OGTR certified, nor had been approved in writing by the Regulator. Licence condition 40 requires that any facilities used (under this licence) for threshing or processing of GM seed be approved by the Regulator. 4. At the time of the inspection, flowering related species were found in the planting area and the monitoring zone. Licence conditions 35 a and b require that any related species in the planting area and monitoring zone be destroyed prior to flowering.
ASSESSMENT	1. The ability to access and control an area is essential for adequate monitoring for related species. Monitoring for related species in a soybean crop from a distance without being in the crop is neither possible nor effective as a means of spotting flowering related species. The inability to access and control the monitoring zone may therefore increase the likelihood of spread and persistence of the GMOs. 2. Whilst the non-GM sorghum was not bagged, all GM sorghum flower heads were bagged during flowering, and all seed harvested from the GM and non-GM sorghum was treated as GM seed. This failure to bag all sorghum within the planting area has been assessed as causing negligible risks to human health and safety and the environment. 3. The seed treatment was undertaken in a shed and while it had not been approved in writing by the Regulator, it would have met the physical requirements of an approved facility. The GM sorghum seed was handled and transported to the site in accordance with the Transport, Storage and Disposal Guidelines. The incident posed negligible risk to human health and safety and the environment. 4. Following the inspection, all flowering related species were removed by hand, or mown and sprayed with herbicide. The likelihood of gene flow between the flowering related species and the GM sorghum was considered to be low, as all GM sorghum flower heads were bagged during flowering.

ORGANISATION	THE UNIVERSITY OF QUEENSLAND
COMPLIANCE MANAGEMENT	1. The University of Queensland subsequently engaged in discussions with the third party and have ensured ongoing access to the monitoring zone. In addition, third party staff have been trained in DIR-153 licence conditions. 2. At the time of the inspection, the non-GM sorghum surrounding the GM sorghum had already finished flowering. The University of Queensland was reminded of the need to treat the harvested seed and plant material as GM and to dispose of it accordingly. 3. The University of Queensland subsequently sought and obtained written approval from the Regulator for the facility onsite where the seed was treated. 4. The University of Queensland subsequently retrained all relevant staff in the licence conditions and volunteered to undertake inspections on a more frequent basis, in addition to regular post-harvest inspections of the site. The University of Queensland is also required to inspect the monitoring zone where flowering related species were found and destroy any volunteers prior to flowering.

Non-compliance findings for GMO dealings not involving intentional release

In 2017–18, no non-compliances were identified against DNIR licences.

Non-compliance findings for notifiable low risk dealings

In 2017–18, no non-compliances were identified against NLRDs requirements.

Non-compliance findings for physical containment facilities

In 2017–18, five certified physical containment facilities were found to be non-compliant with seven certification conditions. These findings are summarised in Table 13.

Table 13: Number of non-compliances identified in certified facilities during 2017–18, by non-compliance type

NATURE OF NON-COMPLIANCE	NUMBER
Equipment	0
Personal protective equipment	1
Structure	2
Transport	2
Waste disposal	0
Work practices[a]	2

a 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:

- to explore topics that could potentially pose compliance issues in the future
- in response to observations made during monitoring activities
- to follow up incident reports, such as those that may relate to non-compliance with licence and certification conditions.

The overarching objective of practice reviews is to determine whether organisations have the ongoing capacity to comply with the gene technology legislation. Practice reviews may also have more focused objectives, specific to a particular matter or condition of a licence or certification instrument. In addition, an accredited organisation may request a practice review to assess the effectiveness of systems used by its institutional biosafety committee/s to ensure that dealings are being conducted in accordance with the Act.

Practice reviews have a significant education and awareness raising component. In certain instances where a suspected non-compliance with the Act is identified, findings may be referred for investigation.

The OGTR undertook three practice reviews during this reporting period. These were initiated by organisations contacting the OGTR for advice on maintaining compliance in response to their changed practices or circumstances:

Transport, storage and waste disposal practice review

AIM	This is part of the OGTR's ongoing practice review program. We recognise that effective compliance is dependent on: • suitable arrangements to manage compliance for GMO dealings; • the appropriate use of specified equipment and service providers; and • the availability of appropriate services.
PARTICIPANTS	The review focused primarily on handling of GMOs within certified facilities along with the management of waste streams from these facilities. Included in the practice review were: the University of Adelaide, Baker Heart & Diabetes Institute, Animal Resources Centre and Ozgene Pty Ltd. The review assessed: • the operational practices for managing waste streams within facilities, along with transport, storage and disposal practices • the suitability of the organisations' arrangements to manage compliance risks, including training and oversight of staff and collaborating organisations • any industry or other regulatory issues which could impinge on the organisations' effective compliance performance.
FINDINGS	The review found that the participating accredited organisations had efficient tailored arrangements to comply and manage their obligations for transport, storage, and disposal of GMOs.
OUTCOMES	The OGTR practice review program continued to assess vulnerabilities to containment and compliance with the *Gene Technology Act 2000*. Information obtained under this program has contributed to: • an overall understanding of compliance performance and emerging barriers to effective compliance • the continual improvement of compliance management processes • the prevention of practices and arrangements that could lead to non-compliance • compliance management and awareness activities.

Preparedness of accredited organisations to undertake a limited and controlled release—practice review

AIM	This is part of the OGTR's ongoing practice review program. We recognise that effective compliance is dependent on: • suitable arrangements to manage compliance for GMO dealings; • suitable site selection and the appropriate use of containment measures; and • staff training and provision of resources necessary to manage compliance obligations.
PARTICIPANTS	The review focused primarily on the organisation's preparedness to undertake limited and controlled releases of two GM grasses or a GM animal vaccine. Organisations included in the practice review were: RMIT University, the Department of Economic Development, Jobs, Transport and Resources (Victoria), and Bioproperties Pty Ltd. The review assessed: • site selection and planning considerations for containment measures • the suitability of the organisations' arrangements to manage compliance risks, including training and oversight of staff, collaborating organisations and resourcing • any industry or other regulatory issues which could impinge on the organisations' effective compliance performance.
FINDINGS	The review found that the participating accredited organisations had considered and implemented effective measures in relation to site selection and planning for limited and controlled trials.
OUTCOMES	The OGTR practice review program continued to assess vulnerabilities to containment and compliance with the *Gene Technology Act 2000*. Such information contributed to: • an overall understanding of compliance performance and emerging barriers to effective compliance • the continual improvement of compliance management processes • the prevention of practices and arrangements that could lead to non-compliance • compliance management and awareness activities.

PC3 facility containment— practice review

AIM	This is part of the OGTR's ongoing practice review program. We recognise that effective compliance is dependent on: • suitable arrangements to manage compliance for GMO dealings, including the structure and operation of high containment facilities • staff training and provision of resources necessary to manage compliance obligations.
PARTICIPANTS	The review focused on suitability of facility structures, maintenance, contingency planning and governance at Griffith University and the University of Melbourne. The review assessed: • effectiveness of containment measures in accordance with OGTR containment guidelines • planning considerations for facility structure and ongoing maintenance • the suitability of the organisations' arrangements to manage compliance risks, including training and oversight of staff, collaborating organisations and resourcing • any industry or other regulatory issues which could impinge on the organisations' effective compliance performance.
FINDINGS	The review found that the participating accredited organisations had considered and implemented effective measures to ensure ongoing management of containment facilities.
OUTCOMES	The OGTR practice review program continued to assess vulnerabilities to containment and compliance with the *Gene Technology Act 2000*. Such information contributed to: • an overall understanding of compliance performance and emerging barriers to effective compliance • the continual improvement of compliance management processes • the prevention of practices and arrangements that could lead to non-compliance • compliance management and awareness activities.

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 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 or issue, 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 2017–18, an audit of Macfarlane Burnet Institute for Medical Research and Public Health was initiated by OGTR in response to ongoing inconsistencies with regards to facility maintenance and record keeping for a certified facility. The audit assessed these issues, along with the organisation's capacity to manage their ongoing obligations for this facility in the future.

These issues were found to be administrative in nature, not posing an immediate risk to containment.

In response to the audit, Macfarlane Burnet Institute for Medical Research and Public Health took significant steps towards improving their entire management system for facility maintenance, task tracking, record keeping and reporting. The organisation demonstrated a capacity to meet their existing and ongoing compliance obligations.

Audits are also undertaken as part of the National strategy for unintended presence of unapproved GMOs. 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 uses a risk management approach, with resources dedicated to the areas posing the highest likelihood of unintended presence of GMOs. We have worked with the Australian Seed Federation (ASF) to develop a voluntary testing program of existing industry quality assurance measures.

In 2017–18, we continued to liaise with the ASF and the seed industry, presenting at the annual ASF Convention to raise awareness amongst their membership about management of low-level presence of GMOs, and to ensure their ongoing voluntary cooperation and action regarding this issue. OGTR also visited two seed breeding organisations (South Australian Research and Development Institute, PGG Wrightson Seeds) to audit their quality assurance systems, and did not identify any issues of concern. We continued to engage with other government departments, including the Australian Government Department of Agriculture and Water Resources, regarding low-level presence of unapproved GMOs.

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 OGTR, self-reporting by an accredited organisation, or third party reporting.

No investigations were undertaken in this reporting period.

Monitoring of GM petunia inadvertent dealings licences

Throughout 2017–18, we worked with the horticulture industry to manage the possible inadvertent import of unapproved GM petunia varieties into Australia. This included gathering information about the industry as well as undertaking monitoring visits to ensure that importers destroyed any GM petunias in their possession in accordance with Inadvertent Dealings licences. This was complemented by a sampling and testing plan to confirm that no GM material remained in the domestic supply.

Testing was conducted in October 2017 and June 2018, screening a large proportion of material held by importing companies and having this material tested by the National Measurement Institute. All commercial petunia lines sampled were free of the GM traits.

Security Sensitive Biological Agents Regulatory Scheme

The *National Health Security Act 2007*, which is administered by the department's Office of Health Protection, provides for a scheme to regulate Security Sensitive Biological Agents. Regulation 5A of the *Gene Technology Regulations 2001* provides for OGTR inspectors to also be appointed as inspectors under the *National Health Security Act 2007*. We worked with the Office of Health Protection to develop operational monitoring requirements. Under a service level agreement, inspection activities commenced early in 2009–10. These activities continued during 2017–18.

Performance against Portfolio Budget Statements targets

Our performance against the deliverables and key performance indicators set out in the Portfolio Budget Statements, which is also reported in the department's 2017–18 annual report, is summarised below.

Our activities for 2017–18 are described under Program 5.1 in Outcome 5 (Regulation, Safety and Protection) of the 2017–18 Department of Health Portfolio Budget Statements.[7] The key objective of the subprogram relating to gene technology regulation is:

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

Progress against this objective is obtained through meeting targets in the following two areas:

Protect people and the environment through open, effective and transparent regulation of genetically modified organisms (GMOs).

2017–18 TARGET	2017–18 RESULT: MET
Risk assessments and risk management plans prepared for 100% of applications for licensed dealings. 100% of licence decisions made within statutory timeframes. High level of compliance with gene technology legislation and no adverse effect on human health or environment from authorised GMOs. Stakeholders, including the public, consulted on all assessments for proposed release of GMOs into the environment.	Risk assessments and risk management plans were prepared, and decisions made within statutory timeframes, for 100% of licensed dealings. There was a high level of compliance with gene technology legislation with no evidence of any adverse effect on human health or environment from authorised GMOs. Stakeholders, including the public, were consulted on all assessments for proposed release of GMOs into the environment.

OGTR has skilled technical staff to conduct science-based risk assessments. There are project management structures for all licence applications, including timeframe and quality assurance reporting, with public consultation procedures built in to relevant decision making processes.

Monitoring and compliance inspections have confirmed a high level of compliance with licence and certification requirements. Stakeholders are continuing to work with inspectors using a cooperative compliance approach.

Enhance harmonisation in the regulation of genetically modified organisms (GMOs) and genetically modified products.

2017–18 TARGET	2017–18 RESULT: MET
Maintained best practice regulation through participation in international harmonisation activities and collaboration with relevant national regulators.	The OGTR, and the Regulator, participated in a range of international and national activities that focused on best practice regulation of GMOs. New and emerging technologies and their regulation was a key topic of discussion for both national and international harmonisation.

The Regulator and her staff engage effectively in international forums and activities relevant to the regulation of GMOs. OGTR is invited to participate in international conferences and to host delegates due to our internationally acknowledged technical expertise and experience. The Australian gene technology regulatory system represents international best practice and has effectively protected people and the environment for 17 years.

7 The Portfolio Budget Statement is available at: http://www.health.gov.au/internet/budget/publishing.nsf/Content/2017-2018_Health_PBS

Chapter 4

Other functions of the Gene Technology Regulator

This chapter describes achievements on other functions of the Regulator.

Technical and procedural guidelines issued by the Regulator

During 2017–18, we continued to revise the Guidelines for Certification of a Physical Containment Level 2 Large Scale Facility. We released Version 3.1 of these guidelines on 28 February 2018. In the review, we aimed to capture current practice (including the use of liquid waste treatment systems and single-use equipment in facilities), provide clarity on existing requirements and, where possible, reduce regulatory burden. The revised guidelines are available on our website at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/cert-pc2-1.

OTGR also initiated a review of the Guidelines for Accreditation of Organisations in 2017–18.

Technical review of the Regulations

The Regulator periodically reviews the Regulations in order to advise the Legislative and Governance Forum on Gene Technology (LGFGT) about the effectiveness of the legislative framework, including in relation to possible amendments to the Regulations. These technical reviews address the interface between science and regulation, which needs to be kept up-to-date with current understanding and technology in this rapidly developing field. The Regulator's technical reviews of the Regulations are limited to issues that do not affect the policy settings of the regulatory scheme.

The field of gene technology has advanced significantly since the Regulator completed the last technical review of the Regulations in 2011—in particular, those techniques often referred to as genome editing. This includes site-directed nuclease techniques (for example, using CRISPR/Cas9) and oligonucleotide-directed mutagenesis. As a result, some of Australia's gene technology legislation do not provide clear and unambiguous requirements for those working with GMOs.

The Regulator initiated a technical review of the Regulations in 2015–16 to provide clarity about whether organisms developed using a range of new technologies are subject to regulation as GMOs and to ensure that new technologies are regulated in a manner commensurate with the risks they pose. We continued to progress this review in 2017–18.

Consultation on proposed amendments

Stakeholders raised a range of issues in response to our initial consultation in 2016–17. The Regulator considered these while developing draft amendments to the Regulations. The Regulator also considered the OGTR's experience, current scientific understanding, potential risks, regulatory burden implications for stakeholders, whether regulatory burden would be commensurate with risks and the policy intent of the Act.

From 30 November 2017 to 21 February 2018, the Regulator publicly sought submissions on proposed amendments to the Regulations, supported by a Consultation Regulation Impact Statement.

OGTR directly received 40 submissions from members of the public and 45 submissions from research organisations and individuals working with GMOs; companies working with GMOs in Australia and overseas; states, territories and relevant Australian Government agencies; and community and industry groups with an interest in gene technology regulation. We received an additional 365 submissions from members of the public and a community group through a

form initiated by Friends of the Earth Australia on the Do Gooder web platform. The consultation documents and submissions received are available on the OGTR website (http://www.ogtr.gov.au).

Next steps

In 2018–19, the Regulator will finalise the proposed amendments, and seek agreement to the amendments from the LGFGT. A special majority of states and territories must formally agree any amendments to the legislation – including the Commonwealth Regulations – through the LGFGT. If agreed by the LGFGT, the Commonwealth Minister would then seek to have the amendments made by the Governor-General and tabled in Parliament.

Advice on GMOs and GM products

During 2017–18, the OGTR advised other regulatory agencies and the public on the regulation of GMOs and GM products.

Advice to other regulatory agencies

To facilitate reciprocal exchange of information with other product regulatory agencies on assessing and approving GMOs and GM products, the OGTR has developed MOUs with Food Standards Australia New Zealand, the Therapeutic Goods Administration and the Australian Pesticides and Veterinary Medicines Authority. In 2017–18, the OGTR, in conjunction with the relevant agencies, finalised the MOU with Food Standards Australia New Zealand and commenced a review of the MOU with Australian Pesticides and Veterinary Medicines Authority.

The OGTR also has an MOU with the Department of the Environment and Energy in relation to consulting with the Minister for the Environment and Energy on DIR licence applications, as prescribed by the *Gene Technology Act 2000*.

Inter-agency cooperation

The Regulatory Science Network is a network of Australian government agencies responsible for regulating chemicals and/or biological agents. It aims to strengthen the regulation of these across government agencies. It also provides a forum for discussing regulatory and technical issues, and enhancing interagency cooperation.

OGTR continued to participate in the network in 2017–18, including chairing it for the remainder of the 2017 calendar year. OGTR helped organise, and participated in, the network's Symposium on 13 November 2017, 'International harmonisation of regulation – the place of regulatory science: Standards; Work sharing; Use of overseas reports and evaluations.' OGTR hosted two network meetings (in September and December 2017).

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.[8] The GMO Record contains information on licences issued, NLRDs, GMO dealings included on the Register, and emergency dealing determinations. During 2017–18, we maintained the GMO Record and updated it with new authorisations.

Engagement with stakeholders

Digital service delivery for applications to the Regulator

As part of developing two online forms, the OGTR engaged with stakeholders in a variety of ways. Regulated stakeholders also participated in user acceptance testing, which provided valuable feedback that enabled OGTR to increase form usability and functionality.

In May 2018, as part of the engagement activities, OGTR staff visited 12 organisations in Vic, Qld and NSW. This helped us understand how organisations use their existing systems with application data related to OGTR matters. We used this feedback to finalise the current online forms and it will help us develop better online forms in the future.

8 The OGTR maintains the GMO Record as a source of public information on such approvals on its website available at: http://www.ogtr.gov.au.

At a pre-launch presentation for regulated stakeholders, OGTR gave a detailed overview of the online forms project. We also provided assistance documents to help stakeholders smoothly transition to the new online platform. Following the launch of the online forms, we held a live webinar to answer stakeholder questions and share any further suggestions for improvement. This comprehensive approach to stakeholder engagement throughout the process has resulted in online forms that are functional, fit-for-purpose and meet stakeholder needs and expectations.

OGTR newsletters

During 2017–18, the OGTR trialled a newsletter as part of our communication with the regulated community to advise of any key updates and to help clarify processes. The program aimed to:

- improve communication between the OGTR, applicant organisations and Institutional Biosafety Committees
- reduce the time taken to answer frequently asked questions
- inform and update the regulated community on changes that would impact them or their work.

We produced and distributed three newsletters in 2017–18. These included features on low-level (PC1 and PC2) facility certification processes, Notifiable Low Risks Dealings (NLRDs), as well as what to expect and how to prepare for an OGTR monitoring and compliance inspection.

Meeting and conference participation

During 2017–18, 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.

Staff from the OGTR participated in the following meetings:

- Australian Health Ethics Committee on 'Gene Editing Techniques – Regulatory Implications', Canberra, July 2017
- Australian Seed Federation convention, Adelaide, August 2017
- Australian Research Council Wheat Breeders Assembly, Sydney, August 2017
- International Life Sciences Institute (ILSI) and AACC International Symposium on sustainable food, Sydney, August 2017
- Association of Australian Cotton Scientists Conference, Canberra, September 2017
- CSIRO Synthetic Biology Future Science Platform meeting, Sydney, September 2017
- Synthetic Biology Australasia Conference, Sydney, September 2017
- 10th Australasian College of Toxicology and Risk Assessment Inc. Annual Scientific Meeting, Canberra, September 2017
- 2017 Australia cotton conference, Canberra, September 2017
- Combio2017, Adelaide, October 2017
- 19th NSW Weeds Conference, Armidale, October 2017
- CropLife 2017 National Members Forum, Canberra, October 2017
- 7th annual Association of Biosafety for Australia and New Zealand Biosafety and Biocontainment conference, Gold Coast, October to November 2017
- OGTR gave an overview talk on how were regulate GM cotton to a Brazilian Government delegation visiting Canberra, October 2017
- Regulatory Science Network Symposium on 'International harmonisation of regulation – the place of regulatory science: Standards; Work sharing; Use of overseas reports and evaluations', Canberra, November 2017
- TropAg 2017, Brisbane, November 2017
- CSIRO 'Gene Editing of Plants' workshop, Kiama, November 2017
- Australasian Society for Immunology Annual Conference, Brisbane, November 2017
- Refining Regulation to Strengthen Compliance conference, Canberra, February 2018
- Australasian Environmental Law Enforcement and Regulators neTwork (AELERT) Conference, Sydney, February 2018
- Agrifutures Australia Fodder Export Advisory Panel, Melbourne, April 2018
- National Health and Medical Research

Council workshop on 'Making evidence-based recommendations in public and environmental health', Sydney, April 2018

- CSIRO workshop on 'Advancing ecological modelling for the prediction of emerging infectious diseases', Canberra, May 2018
- Masterclass for professional regulators, Sydney, May 2018
- Several workshops in Australian capital cities as part of consultation on the Third Review of the National Gene Technology Scheme, as observers.

Research undertaken or commissioned by the Regulator

Documents to support the risk assessment of GMOs

During 2017–18, OGTR updated a number of biology documents with new information:

- Barley (*Hordeum vulgare* L.) (April 2017)
- Italian ryegrass, perennial ryegrass and tall fescue (*Lolium multiflorum, L. perenne, L. arundinaceum*) (November 2017)
- Safflower (*Carthamus tinctorius* L.) (March 2018)
- Sorghum (*Sorghum bicolor subsp bicolor*) – new biology document (July 2017)
- Wheat (*Triticum aestivum*) (July 2017).

These documents can be found, along with the rest of the Regulator's biology documents at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/biology-documents-1.

Promoting harmonisation

The OGTR continued to liaise with other regulatory agencies and other Australian Government agencies on relevant issues. A particular focus of discussion, both nationally and internationally, was regulatory harmonisation and regulation of new and emerging technologies.

International regulatory liaison

Actively participating in international forums helps OGTR keep Australia's regulatory scheme up-to-date with developments in GMO regulation and science. Feedback from meetings indicates a high regard for the Australian gene technology regulatory system. International engagement also enables Australia to contribute to international best practice based on its practical experience of administering efficient and effective GMO regulation.

The OGTR continued to engage in international fora about harmonising risk assessment and regulation of GMOs. The OGTR leads Australian representation on, and coordinates Australian input to, the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology. The working group develops scientific guidance to support the risk assessment of GMOs.

We provide input and advice on GMO regulation to other Australian government agencies to support their international engagement. This can include 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.

The OGTR provides technical advice to support Australian engagement in activities under the UN Convention on Biological Diversity and the UN Cartagena Protocol on Biosafety (the Protocol), such as submissions on regulating GMOs. We are the national focal point for the Protocol and for the Biosafety Clearing-House, and disseminate information to other agencies.

We are also responsible for entering Australian commercial approvals of GMOs into the OECD BioTrack Product Database[9] and the UN Biosafety Clearing-House[10].

By participating in and presenting at international forums, the OGTR continued to interact with key regulatory counterparts in other countries during 2017–18, including:

- UN Convention on Biological Diversity,

9 The BioTrack Product Database is on the OECD website http://www.oecd.org/science/biotrack/

10 The Biosafety Clearing-House is online https://bch.cbd.int/

Open-ended Online Forum on Synthetic Biology, 3 July to 2 October 2017

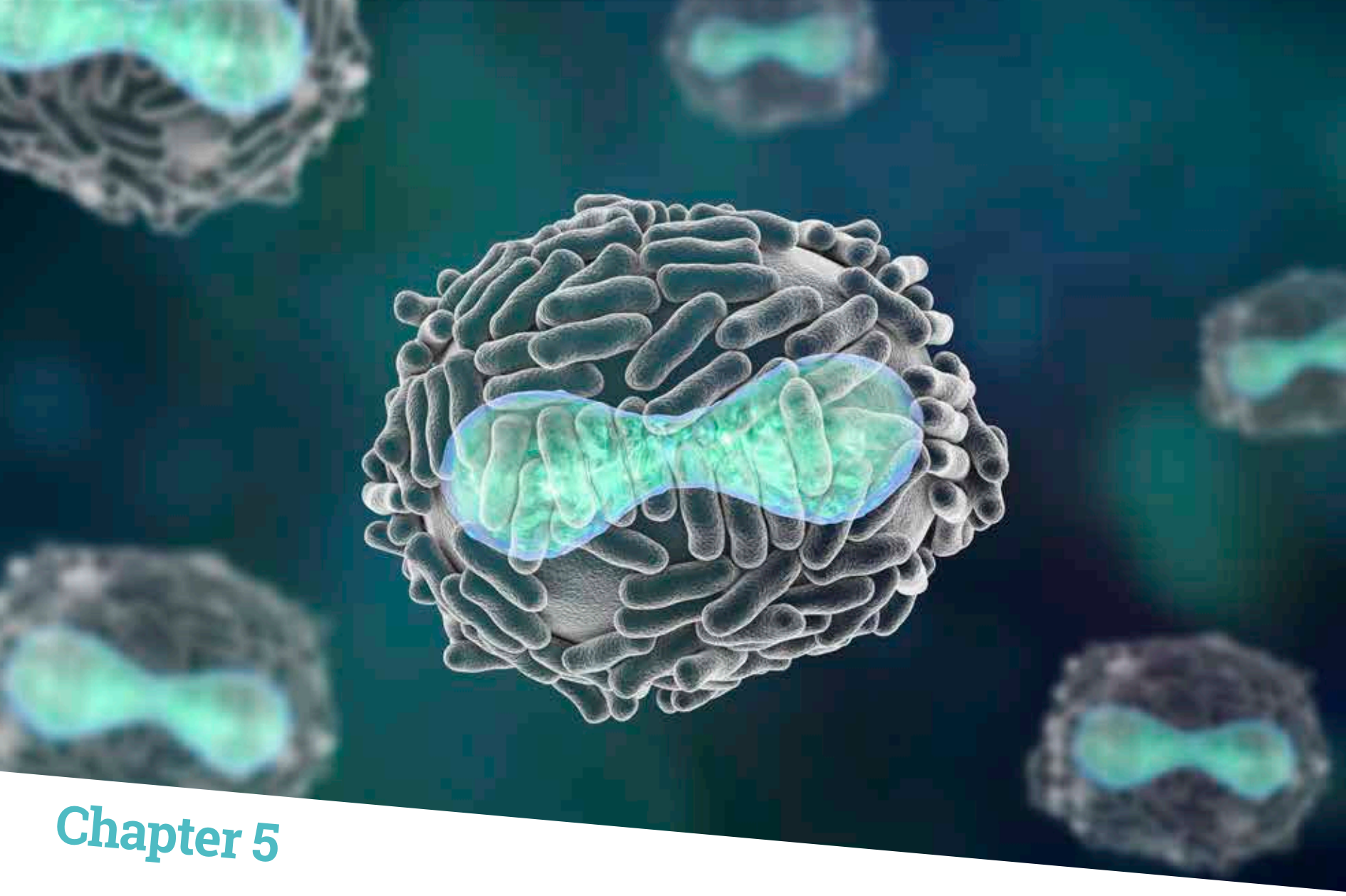
- Asia Forum on Risk Assessment and Risk Management in Jeju Island, Korea, November 2017
- International Symposium on Living Modified Organism Safety Management Systems and Environmental Release Cases, Seoul, December 2017
- UN Cartagena Protocol on Biosafety, Open-ended Online Forum on Risk Assessment and Risk Management, 29 January to 12 February 2018
- OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology (WGHROB) 8th, 9th meetings of the Steering Group on Environmental Considerations for Transgenic Plants, 12 to 14 September 2017, Berlin, Germany and 21 to 22 June 2018, Paris, France.
- OECD WGHROB 32nd meeting, 25 to 27 June Paris, France.
- OECD Conference on Genome Editing: Applications in Agriculture – Implications for Health, Environment and Regulation, 28 to 29 June 2018, Paris, France.

In 2017–18, the OGTR continued to receive requests from regulators in other countries to visit Australia and learn about our approach to GMO regulation. Feedback from these visits indicates a high regard for our approach to risk analysis and regulation, as scientifically rigorous, practical and effective.

Visits by international delegations to the OGTR regarding GMO regulation in 2017–18 were:

- Chinese delegation, November 2017.

Visiting Chinese delegation



Chapter 5

Management and accountability

The management and accountability practices of the OGTR include 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 53 employees. 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 14.

Table 14: Non-salary benefits

AGREEMENT	BENEFITS
Enterprise agreement	• access to negotiated discount registration or membership fees to join a fitness or health club • access to the employee assistance program • 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 vaccinations on an annual basis • 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 • 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 17th 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 following charities:

- Give me 5 for kids
- RSPCA ACT
- OzHarvest
- Jeans for Genes.

The OGTR implemented measures to maintain staff skills and motivation through appropriate training and development.

Regulator's Achievement Award

This year, we gave the Regulator's Achievement Award to two recipients. Karina Dennis for her persistence and stamina in managing OGTR's transition to a new records management interface, and Toni Cuthbertson for the planning, negotiations and hard work that made the move to the new office accommodation at Woden a very streamlined and stress-free event for the rest of the office.

Staff profile, training and development activities

This section provides information on Australian Public Service staff employed by the OGTR in 2017–18 under the *Public Service Act 1999*.

Training and development

OGTR staff undertook 56 days of formal training during the year. 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. Staff can also access financial assistance through the Department of Health's studybank program to undertake an approved course of study related to their work, or the work of the Department. Study provides employees with lifelong benefits and builds ongoing capability and knowledge in an area or discipline. Studybank has direct linkages to the employee's performance development scheme.

The OGTR also supports the Department of Health's graduate development program, providing placements for graduates during their second and third rotations. This allows graduates to gain experience working in a regulatory science environment. In return, we benefit from graduates' enthusiasm and fresh perspectives.

In 2017–18, 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.

During 2017–18, the OGTR Legal Officer provided introductory and ongoing training for OGTR staff on legal issues (Table 15).

Table 15: Internal training presentations on legal issues, 2017–18

DATE	TOPIC
September 2017	Confidential Commercial Information
October 2017	Offences under the *Gene Technology Act 2000*
October and November 2017	Freedom of Information
February 2018	National Gene Technology Scheme
February 2018	Confidential Commercial Information
June 2018	Code of Conduct, Confidential Commercial Information, Privacy and Freedom of Information

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 2017–18 (Table 16).

Table 16: Presentations at the OGTR Forum, 2017–18

DATE	TOPIC AND PRESENTER
August 2017	Like Minded Group and Global Low Level Presence Initiative meetings — Rome, Italy: 13 to 15 June 2017 – Neil Ellis, OGTR
August 2017	30 years experience with regulated cotton trials – Dr Warwick Stiller, CSIRO Agriculture and Food
September 2017	Overview of Monsanto product pipeline and scientific advances – Dr Harvey Glick and Dr David Saltmiras, Monsanto Co., USA
November 2017	2017 study of community attitudes to gene technology – Dr Craig Cormick
December 2017	Genetically modified bananas for Australia, Africa and beyond – Prof James Dale, QUT
May 2018	OGTR Compliance: Engagement or Enforcement—Getting the right balance – Neil Ellis, OGTR
May 2018	Exploring biological engineering solutions to ensure a future for coral reefs – Professor Madeleine JH van Oppen
May 2018	Identifying and accounting for the regulatory, institutional and governance implications of reef restoration and adaptation interventions: A scoping study – Professor Karen Hussey

Supportive working environment

OGTR staff have access to a range of departmental assistance measures, as part of providing a supportive working environment. 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. We have the highest proportion of staff on flexible work arrangements, mostly part-time. 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.

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. We provide appropriate reasonable adjustment to working environments to achieve this, including flexible working arrangements. We support our commitment to providing rehabilitation assistance to injured and ill employees 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:

- create, promote and maintain a safe and healthy working environment
- encourage productive working relationships
- promote and encourage behaviours in staff and managers to help manage and reduce 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.

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

The OGTR has implemented changes resulting from the introduction of the *Work Health and Safety Act 2011* in 2012. In 2017–18, we conducted training 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 2011* is available on the department's intranet site. We have incorporated strategies for identifying and managing work health and safety risks into business planning processes.

Other work health and safety support included 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 OGTR business or undertakings, which the OGTR became aware of during the year, are incorporated into the department's annual report figures.

Investigations under Part 10 of the *Work Health and Safety Act 2011*

No directions, notices or enforceable undertakings under the *Occupational Health and Safety (Commonwealth Employment) Amendment Act 2006* or the *Work Health and Safety Act 2011* were served on the OGTR during the year.

We undertook regular work health and safety inspections at the OGTR premises in Barton during 2017. When the office moved to Woden in 2018, we inspected the new premises. 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.[11]

Freedom of information contact details and procedures

The OGTR received six requests for access under freedom of information legislation during the reporting period. Two of the requests were withdrawn, and OGTR finalised the remaining four requests within the statutory timeframes in 2017–18.

The FOI Act (section 11C) requires the Regulator to publish on the OGTR website a disclosure log listing information that has been released in response to a freedom of information request.[12]

Feedback received

The OGTR welcomes feedback on ways to improve provision of information about gene technology regulation.

During 2017–18, regulated stakeholders and other organisations provided positive feedback about OGTR's professionalism and responsiveness and expressed their appreciation of OGTR's stakeholder engagement activities.

> I am writing today to express our deep gratitude for the speedy processing of eleven applications for certification of new laboratories.
>
> Thanks for another great newsletter. It is very helpful to get these short informative updates. Really appreciate the way you are striving to simplify processes and streamline applications. Thank you.
>
> A quick email to thank Michael and the OGTR office for presenting at the ARCS webinar.

Presentations and meetings on gene technology in Australia

The Regulator and staff from the OGTR regularly attend and present papers to meetings, forums and conferences in Australia (Table 17).

11 The OGTR's Information Publication Scheme Agency Plan is available at: http://www.ogtr.gov.au

12 The OGTR's Freedom of Information Disclosure Log is available at: http://www.ogtr.gov.au

Table 17: Presentations and representations in Australia by the Regulator and OGTR staff, 2017–18

DATE	EVENT	LOCATION
July 2017	'Gene editing' techniques—regulatory implications? Australian Health Ethics Committee meeting	Canberra
August 2017	International Life Sciences Institute (ILSI) and AACC International Sustainable food supply meeting	Sydney
September 2017	2017 Australian Cotton conference	Canberra
September 2017	Australian Pesticides and Veterinary Medicines Authority industry sessions	Canberra
September 2017	CSIRO Future Science Platform Synthetic biology meeting	Sydney
September 2017	Synthetic Biology Australasia Conference	Sydney
September 2017	New biotechnology techniques: Challenges for regulation and risk analysis, Australian College of Toxicology and Risk Assessment Annual Scientific Meeting	Canberra
November 2017	CSIRO gene editing in plants workshop	Kiama
November 2017	Regulating the environmental release of GMOs—challenges for international harmonisation, RSN Symposium	Canberra
February 2018	OGTR Compliance: Engagement and Enforcement—getting the right balance, Refining Regulation to Strengthen Compliance Conference	Canberra
April 2018	National Health and Medical Research Council workshop—Making evidence-based recommendations in public and environmental health	Sydney

Stakeholder and public access to the OGTR

The OGTR helps accredited agencies, stakeholders and the public access its services through a website, an email address and a freecall 1800 number (1800 181 030).

Website usage

Table 18 tracks monthly usage numbers for the OGTR website. The most requested online information sheets and website pages are listed below.

Table 18: Website activity, 2017–18

MONTH	SESSIONS[a]	USERS[b]
July	5,289	3,863
August	5,747	3,941
September	5,751	4,062
October	6,091	4,427
November	6,483	4,616
December	4,639	3,413
January	5,210	3,811
February	6,573	4,894
March	6,593	4,708
April	5,004	3,666
May	6,535	4,631
June	5,720	4,171

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 2017–18 were, in descending order:

1. Technical Review of the Gene Technology Regulations 2001
2. Guidelines for Certification of Physical Containment 2 Facilities
3. Record of GMO Dealings
4. Table of applications and authorisations for Dealings involving Intentional Release (DIR) into the environment
5. Legislation
6. Application to certify facilities
7. Guidelines for Certification of a Physical Containment Level 2 Laboratory
8. Genetically Modified Product approvals
9. About the Regulator
10. What's new

The most popular downloaded documents in 2017–18 were:

1. Guidelines for Certification of a Physical Containment Level 2 Laboratory
2. Guidelines for the Transport, Storage and Disposal of GMOs
3. Guidelines for Certification of a Physical Containment Level 2 Animal Facility
4. Types of Dealings with GMOs classified as Notifiable Low Risk Dealings (NLRDs)
5. Final Report—2017 Community attitudes to gene technology
6. What Dealings with GMOs are Classified as Exempt Dealings?
7. Guidelines for Certification of a Physical Containment Level 1 Facility
8. Risk Analysis Framework 2013
9. Regulation impact statement for the Gene Technology Regulations 2001
10. Technical Review of the Gene Technology Regulations 2001 Discussion paper: Options for regulating new technologies

Email address and freecall number

The 1800 number (1800 181 030) and the OGTR email address (ogtr@health.gov.au) are points of contact for members of the public and other interested parties. Through these, we help with specific questions and advice on additional mechanisms for public feedback. During 2017–18, use of the email address declined compared with the previous year (Table 19).

Table 19: Email and freecall 1800 number activity, 2017–18 and 2016–17

MONTH	EMAILS		1800 NUMBER	
	2017–18	2016–17	2017–18	2016–17
July	70	39	61	63
August	50	30	62	65
September	62	35	51	75
October	68	240	42	60
November	40	98	51	67
December	52	590	52	59
January	43	68	64	63
February	410	110	57	35
March	50	120	55	81
April	42	140	46	75
May	45	125	59	64
June	52	81	38	63
Total	**984**	**1676**	**638**	**770**

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 OGTR 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 1,154 emails during 2017–18 (compared to 1,203 in 2016–17).

The Contained Dealings Evaluation Section maintains an email inbox to efficiently coordinate responses to queries on classifying GMO dealings, certification requirements and GMO licences. The inbox received 510 emails during 2017–18 (compared to 471 in 2016–17).

The Application Entry Point maintains an email inbox to provide a central, shared communication point, allowing us to efficiently coordinate responses to correspondence and queries about applications. The inbox received 2,842 emails during 2017–18 (compared to 1,658 in 2016–17).

The OGTR welcomes feedback on ways to improve provision of information about gene technology regulation.

Appendix

Appendix 1 Membership of statutory committees

Table 20: Gene Technology Technical Advisory Committee members 2017–20

MEMBER	POSITION
Professor John Rasko AO (Chair)	Director, Cell and Molecular Therapies, Royal Prince Alfred Hospital; Program Head, Centenary Institute (NSW)
Dr Graham Bonnett	Research Director, CSIRO Agriculture and Food (Qld)
Dr Orin Chisholm	Program Director, Pharmaceutical Medicine and Senior Lecturer, UNSW (NSW)
Ms Laura Fell	Egg Farmer, McLaren Vale (SA)
Dr Tessa Gargett	Research Scientist, Royal Adelaide Hospital (SA)
Dr Richard Gordon	Senior Research Fellow, School of Biomedical Sciences, University of Queensland (Qld)
Professor John Hayball	School of Pharmacy and Medical Sciences, University of South Australia (SA)
Professor Robert Henry	Professor of Innovation in Agriculture, and Director, Queensland Alliance for Agriculture and Food Innovation (Qld)
Dr TJ Higgins, AO	Honorary Fellow, CSIRO Agriculture and Food (ACT)
Dr Danny Llewellyn	Chief Research Scientist, CSIRO Agriculture and Food (ACT)
Dr Rebecca McCrackan	Senior Intellectual Property Advisor; Patent and Trade Marks Attorney (WA)
Dr Michael Michael	Laboratory Head, Flinders Centre for Innovation in Cancer, Flinders Medical Centre (SA)
Dr Gabrielle O'Sullivan (GTECCC cross-member)	Executive Officer and Member, Institutional Biosafety Committee, Royal Prince Alfred Hospital (NSW)
Associate Professor Jason Smythe	Senior Business Development Manager, Faculty of Medicine, Monash University; Adjunct Associate Professor, Faculty of Science and Engineering, La Trobe University (Vic)
Dr Robert Sward (GTECCC cross-member)	Director, BioBotanicals Consulting (Vic)
Professor Paul Young	Professor of Virology and Head of School, School of Chemistry and Molecular Biosciences, University of Queensland (Qld)

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.

Table 21: Gene Technology Ethics and Community Consultative Committee members 2015–18

MEMBER	POSITION
Ms Judith Jones (Chair)	Senior Lecturer, Australian National University College of Law (ACT)
Ms Paula Fitzgerald	Agricultural advocate and consultant (Vic)
Dr Vaughan Monamy	Associate Professor of Environmental Science and Environmental Ethics, Australian Catholic University (NSW)
Professor Dianne Nicol (AHEC cross-member)	Director, Centre for Law and Genetics; Professor of Law, University of Tasmania
Dr Rachel Nowak	Principal, Rachel Nowak and Associates (Vic)
Dr Gabrielle O'Sullivan (GTTAC cross-member)	Executive Officer, Institutional Biosafety Committee, Royal Prince Alfred Hospital (NSW)
Ms Meg Parkinson	Free range Egg Farmer (Vic)
Dr Gregory Pike	Founding Director of the Adelaide Centre for Bioethics and Culture (SA)
Dr Frances Shapter	Project Officer, School of Veterinary Science, University of Queensland (Qld)
Dr Robert Sward (GTTAC cross-member)	Director, BioBotanicals Consulting (Vic)
Mrs Emma Thomas	Farmer and agricultural consultant (NSW)
Mr Hugh Roberts AM	Farmer and a Director of the Australian Seed Authority and the Australian Crop Accreditation System (NSW)

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.

In memoriam – Mr Hugh Roberts AM, 1941–2018

In July 2018, we were saddened to hear of the passing of Gene Technology Ethics and Community Consultative Committee member Mr Roberts, and we extend our sympathies to his family and friends.

Mr Roberts made a significant contribution to the work of the committee since he was appointed in 2011. He was a dedicated committee member who always demonstrated respect and integrity. Mr Roberts' commitment and vast experience was of great value to the committee, the Regulator, and the gene technology regulatory scheme more broadly.

Glossary

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.

TERM	DESCRIPTION
Accredited organisation	An organisation that is accredited under section 92 of the *Gene Technology Act 2000*
Act	*Gene Technology Act 2000*
APVMA	Australian Pesticides and Veterinary Medicines Authority
CCI	Confidential commercial information declared under section 185 of the *Gene Technology Act 2000*
Contained dealing	See DNIR
CSIRO	Commonwealth Scientific and Industrial Research Organisation
Dealing	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.
DAWR	Department of Agriculture and Water Resources
Department	Australian Government Department of Health
DIR	A dealing involving intentional release of a GMO into the environment (e.g. field trial or commercial release)
DNIR	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)
EDD	Emergency dealing determination
FSANZ	Food Standards Australia New Zealand
Gene Technology Agreement	An intergovernmental agreement that all Australian jurisdictions signed in 2001, which underpins the nationally consistent regulatory framework for gene technology
GM	Genetically modified
GM product	A thing (other than a GMO) derived or produced from a GMO
GMO	Genetically modified organism
GMO Record	Record of GMO dealings
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional biosafety committee
Incident	A self-reported event that may constitute a non-compliance with regulatory requirements and a risk to public health or the environment
LGFGT	Legislative and Governance Forum on Gene Technology
MOU	Memorandum of understanding
NLRD	Notifiable low risk dealing (e.g. plant or tissue culture work undertaken in a certified physical containment facility)
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator

TERM	DESCRIPTION
PBS	Portfolio Budget Statements
PC1, PC2, PC3, PC4	Physical containment levels of facilities certified by the Regulator
Physical containment facility	A building or place certified by the Regulator to a specified containment level under section 84 of the *Gene Technology Act 2000*
RARMP	Risk assessment and risk management plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator
RSN	Regulatory Science Network
TGA	Therapeutic Goods Administration
UN	United Nations

Indexes

List of requirements

GENE TECHNOLOGY ACT 2000 REFERENCE	PART OF REPORT	DESCRIPTION
136(1A)(a)	21–24	GMO licences issued during the financial year
136(1A)(b)	40-42	Any breaches of conditions of a GMO licence that have come to the Regulator's attention during the financial year
136(1A)(c)	24	Emergency dealing determinations made by the Minister during the financial year
136(1A)(d)	27	Any breaches of conditions of an emergency dealing determination that have come to the Regulator's attention during the financial year
136(1A)(e)	33-37, 40-46	Auditing and monitoring of dealings with GMOs under this Act by the Regulator or an inspector during the financial year

Index