Operations of the Gene Technology Regulator

Annual Report 2018–19

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Letter of Transmittal

Senator the Hon Richard Colbeck
Minister for Aged Care and Senior Australians
Minister for Youth and Sport
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 2018 to 30 June 2019.

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 2018 to 30 June 2019.

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

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

Yours sincerely

Dr Raj Bhula

Gene Technology Regulator

27 September 2019

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 2018–19 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:** Functions of the Gene Technology Regulator—describes the OGTR's operational performance, as well as achievements against priorities during 2018–19. 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 2018–19 Portfolio Budget Statements.
- **Chapter 4:** Other functions of the Gene Technology Regulator—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.

[1] The 2018–19 annual report of the Australian Government Department of Health prepared in accordance with the *Public Governance, Performance and Accountability Act 2013* 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 5: Management and accountability**—provides an overview of the OGTR's resource management practices and reporting against Australian Government accountability principles.

1 Gene Technology Regulator's overview

This has been a year of highlights that marked the culmination of years of preparation, consultation and collaboration. Attention was focused on supporting the Regulatory Policy Branch in the Department of Health during the third review of the Gene Technology Scheme. The review commenced in July 2017 and a final report was published in October 2018, following endorsement of all recommendations by the Legislative and Governance Forum on Gene Technology (LGFGT), the 'Ministerial Forum'. The report is an excellent collation of technical, regulatory, governance, social and ethical issues that are challenging the gene technology scheme at this time. It also provides a useful record of the status of technology after almost 20 years of operation of the scheme in Australia, and mechanisms to future-proof the scheme going forward.

The technical review of the gene technology regulations was completed this year, with amendments to the Regulations being made in April 2019 following a Ministerial Forum decision earlier in the year. The amendments provide legal clarity on the regulation of gene editing techniques and resulting organisms, something that a number of governments are currently grappling with internationally.

The 8th National Institutional Biosafety Committee Forum was held in March 2019. 'Looking Towards the Future' was the theme of the forum and invited speakers reflected on future directions and applications of biotechnology research.

Meeting our Performance Targets

As described in the Department of Health Portfolio Budget Statements (the PBS) Outcome 5, the Government through OGTR protects the health and safety of people and the environment by regulating activities with genetically modified organisms.

Delivery of effective and efficient regulation is reflected in the achievements against the PBS targets. This year:

- Risk assessment and risk management plans were prepared and decisions were made within statutory timeframes, for100% of licenced dealings
- Stakeholders including the public were consulted on all assessments for proposed release of GMOs into the environment
- There was a high level of compliance with gene technology legislation with no evidence of adverse effect on human health or the environment from authorised GMOs.

In addition, we continued to strengthen our relations with state and commonwealth regulatory partners and ensured that all risk assessments of GMOs are based on current scientific evidence and represent international best practice in regulation.

Applications and licences: what's new

Over the past 5 years, licences issued for dealings involving intentional release into the environment (DIR) for research purposes have included different crop types and species. This year, licences were issued for the conduct of field trials in chickpeas for drought and heat tolerance, wheat for rust disease resistance and canola for altered oil characteristics. At the end of 30 June 2019, 49 licences are current of which 38 are for agricultural uses.

Licences for dealings not involving intentional release (DNIR) include clinical trial approvals for research and development of potential treatments for human diseases. At the end of June 2019, 127 DNIR licences are current, of which 109 or 86% are for medical applications of gene technology. Almost half of these licences have been issued to universities, with another 30% issued to specialised research institutes or hospitals and health service facilities. This demonstrates an increasing use of biotechnology for research into human diseases, including genetic treatments.

Monitoring and compliance activities

To ensure regulated entities comply with gene technology legislation, OGTR inspectors undertake monitoring and compliance activities, together with general communication, education and outreach. This year, audits, practice reviews, inspections of certified facilities, inspections of field trial sites and clinical facilities were conducted.

In 2018–2019, OGTR inspected 43 (66%) field trial sites over a range of 7 plant species: banana, barley, cotton, perennial ryegrass, sugarcane, wheat and barley. Inspections were conducted in NSW, Qld, SA, VIC, WA and NT. In addition, 109 facilities across the country were inspected and 21 DNIR licences were monitored for compliance against licence conditions.

This year 10 practice reviews were undertaken mostly on request from accredited organisations that were keen to ensure that they were meeting licence conditions prior to undertaking any activities with GMOs.

Stakeholder engagement: transparency in what we do

One of the highlights of the year was the 8th National Institutional Biosafety Committee (IBC) Forum. Professor Brendan Murphy, Chief Medical Officer, opened the forum and spoke about the work of OGTR, government priorities and investment in research into genomic medicines. Professor Dan Tompkins bought together elements of conservation, environmental biodiversity and the role of biotechnology in species preservation, as he spoke about the work of the International Union for Conservation of Nature (IUCN).

The forum included sessions on our digital service delivery program, legislative activities, regulatory culture and the future of technology. Information sharing sessions included Q&As and 'Quick Chats', operational experiences of IBCs, setting up of field trials, GMO waste management and licence conditions for plant field trials. Reviews of a range of guidelines commenced this year, some of which involved workshops at the IBC forum itself, such as the review of physical containment PC3 guidelines.

Publication of the OGTR Newsletter continued, with information features on regulation amendments, the third review of the gene technology scheme and submission of CCI applications.

The technical review of the gene technology regulations

The technical review of the regulations concluded on 4th April 2019 when the regulation amendments were made, following an earlier LGFGT decision. These amendments are the result of more than three years of collaborative dialogue, publication of options papers and Regulation Impact Statements with rounds of extensive public consultation, stakeholder meetings and continued discussion with 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. All in all, the amendments reflect a measured step, while we contribute to the next stages of the third review of the gene technology scheme.

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, OGTR staff were invited to speak at a number of conferences and participate in expert group meeting on topics ranging from synthetic biology, genome editing and regulation, to innovative agricultural technologies.

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 on international activities associated with trade and Low Level Presence of GMOs.

Our people: an important resource now and into the future

The OGTR would not be able to undertake its regulatory functions without the hard work, dedication and commitment of its staff. The Regulator's Achievement Award recognised collaboration and innovation in what we do. This year, the Plant Evaluation Section was acknowledged for working closely with the Contained Dealings Section to ensure that timeframe pressures did not overwhelm staff and the workload was distributed across the whole Branch. Emma Collins received the award for innovation leading to business improvements for her contribution to the online forms project.

In addition, a number of OGTR staff received departmental Australia Day awards for building strong relationships and working collaboratively with the Regulatory Policy Branch in the Office of Health Protection during the review of the gene technology scheme. In all

instances, high level skills in communication, collaboration and leadership were clearly in action.

Challenges ahead

It is often said that regulation can never keep pace with technology especially in areas of rapid advancement such as gene technology. However a sound science-based approach and a flexible operational framework that can respond to new technologies will help to ensure that regulation of advancing technologies is commensurate with risk while providing the safeguards expected by the Australian community.

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 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.

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.

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. In exercising these functions, the Regulator is directly responsible to the Australian Parliament.

Senator the Hon Bridget McKenzie, formerly the Minister for Regional Services, Sport, Local Government and Decentralisation, was the minister responsible for gene technology regulation until May 2019. Since then, Senator the Hon Richard Colbeck, Minister for Aged Care and Senior Australians and Minister for Youth and Sport, has been the responsible Minister. 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 the 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 Framework 2017, as the department requires. More information is available in the 2018–19 Department of Health Annual Report. We maintain our own business and risk management plans, against which senior OGTR staff report periodically.

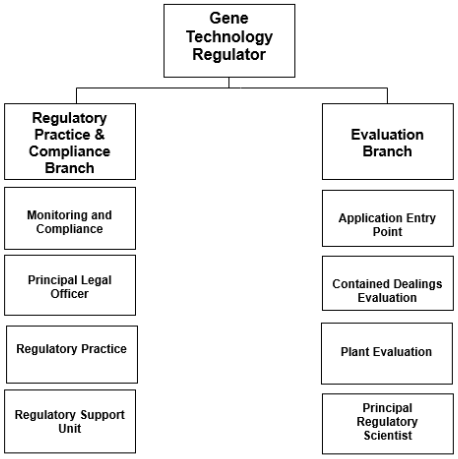
The employment framework for the OGTR is the *Public Service Act 1999*. The department's enterprise agreement, governance policies and practices cover OGTR staff. These include application of appropriate ethical standards under the Australian Public Service Values and Code of Conduct; compliance with 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, 2018–19



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 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.

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, provides advice in relation to FOI requests, and is the designated Privacy Officer for the Regulator for the purposes of the Australian Government Agencies Privacy Code[3].

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 technical reviews 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 overseeing the evaluation of licence applications and other authorisations relating to dealings with GMOs, as well as science-related projects that maintain and improve the technical capabilities of the OGTR.

Dr Heidi Mitchell has been acting as Assistant Secretary of the Evaluation Branch since April 2019 whilst Dr Michael Dornbusch was on leave.

[3]A legislative instrument made by the Australian Information Commissioner under the *Privacy Act 1988*

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 and administrative improvement 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 analysis 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 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. Current memberships expire 31 January 2020. On 10 May 2019, an appointment process for the 2020–23 memberships of both committees was initiated with a public call for nominations which included a notice on Twitter, the OGTR website and in several newspapers. Advice was also sent to subscribers to OGTR News and approximately 500 target organisations. The nominations closed on 28 June 2019.

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 three times during 2018–19: once in a face-to-face meeting 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.

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, Associate Professor Judith Jones, were reappointed for an interim term until 31 January 2020 by the then Minister for Regional Services, Minister for Sport and Minister for Local Government and Decentralisation, Senator the Hon Bridget McKenzie. The committee met once during 2018–19 in a face-to-face meeting held in Melbourne. Communiqués from committee meetings, which provide an overview of key matters discussed and resolutions, are published on the OGTR website.

3 Functions of the Gene Technology Regulator

This chapter describes the operational performance of the Regulator 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 2018–19 Department of Health Portfolio Budget Statements. 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 are described in Appendix 2.

Operational performance

This section describes the achievements and performance against Outcome 5 (Regulation, Safety and Protection) of the 2018–19 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.

Information on performance against deliverables and key performance indicators, as set out in the 2018–19 Department of Health portfolio budget statements, is summarised in the second part of this chapter.

Summary of approvals in 2018–19

The OGTR received 1656 applications and notifications, as defined under the Act (Table 1). 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 802 approvals over a range of various application types. There were no appeals associated with decisions made on applications under the gene technology legislation. As a result of the Regulator's decisions since the beginning of the scheme, there are currently 2072 certified facilities, 49 environmental release licences and 126 contained research licences (Table 2) at 30 June 2019.

Table 1: Applications and notifications, 2018–19

Application type	Received	Withdrawn	Approved[a]	Refused	Ceased consideration[b]	Under consideration[c]
Accreditation	8	0	8	0	0	0
Alternate facility request for an NLRD	2	0	1	0	0	1
Alternate transport, storage or disposal request for an NLRD	1	0	1	0	0	0
CCI declaration for DIR licence	8	0	6	0	0	8
CCI declaration for DNIR licence	7	0	2	0	0	13
CCI declaration for other information	2	0	2	0	0	1
Certification	110	2	114	0	0	10
DIR licence	5	2	6	0	0	1
DNIR licence	16	2	11	0	0	6
Lifting suspension of certification[d]	49	0	51	0	0	1
NLRD notification	848	n/a	n/a	n/a	n/a	n/a
Surrender of accreditation	4	0	4	0	0	1
Surrender of certification	63	0	63	0	0	0
Surrender of DIR licence	5	0	5	0	0	0
Surrender of DNIR licence	2	0	1	0	0	1
Suspension of certification[d]	74	2	73	0	0	0
Transfer of certification	1	0	1	0	0	0
Transfer of DIR licence	10	0	10	0	0	0
Transfer of DNIR licence	1	0	1	0	0	0
Variation of certification	392	10	395	0	1	67
Variation of DIR licence	7	0	5	0	0	2
Variation of DNIR licence	41	2	42	0	0	6
Total	1656	20	802	0	1	118

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 2018–19 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 2019.

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 2018–19 were all requested by the applicant.

Table 2: Status of primary applications and notifications from the start of the scheme till 30 June 2019 [a]

Application Type	Received	Withdrawn	Approved	Not Approved[b]	Under consideration	Current	Expired	Surrendered
Cert	4517	146	4356	5	10	2072	334	1824
DIR	169	17	146	5	1	49	1	96
DNIR	604	114	481	2	7	126	146	190
NLRD	10372	35	n/a	n/a	n/a	n/a	n/a	n/a
Total	15662	312	4983	12	18	2247	481	2110

[a] Categories and abbreviations as for Table 1 above.

[b] 'Not approved' includes 'refused', 'ceased consideration' and 'not considered' under section 42 of the *Gene Technology Act 2000*.

Primary applications

Licences for dealings involving intentional release of GMOs

Dealings involving intentional release (DIR) licences authorise dealings with GMOs outside of containment that may pose risks that require management through specific licence conditions. The Regulator issued six DIR licences during 2018–19 (Table 3) with one further licence application in progress as at 30 June 2019.

Details of the traits introduced into the organisms for release are provided in Table 3. Five of the DIR licences issued in 2018–19 were for field trials (limited and controlled releases) of GM crops (canola, chickpea and wheat) with a variety of introduced traits. One DIR licence was issued for clinical trial of a live attenuated GM respiratory syncytial virus (RSV) vaccine. No commercial release licences were issued. Of the six DIR licences issued in 2018–19, three were issued to companies, one to a government agency and two to universities (Table 3). All of the licence decisions were made within statutory timeframes (see 'Timeframes', Appendix 2).

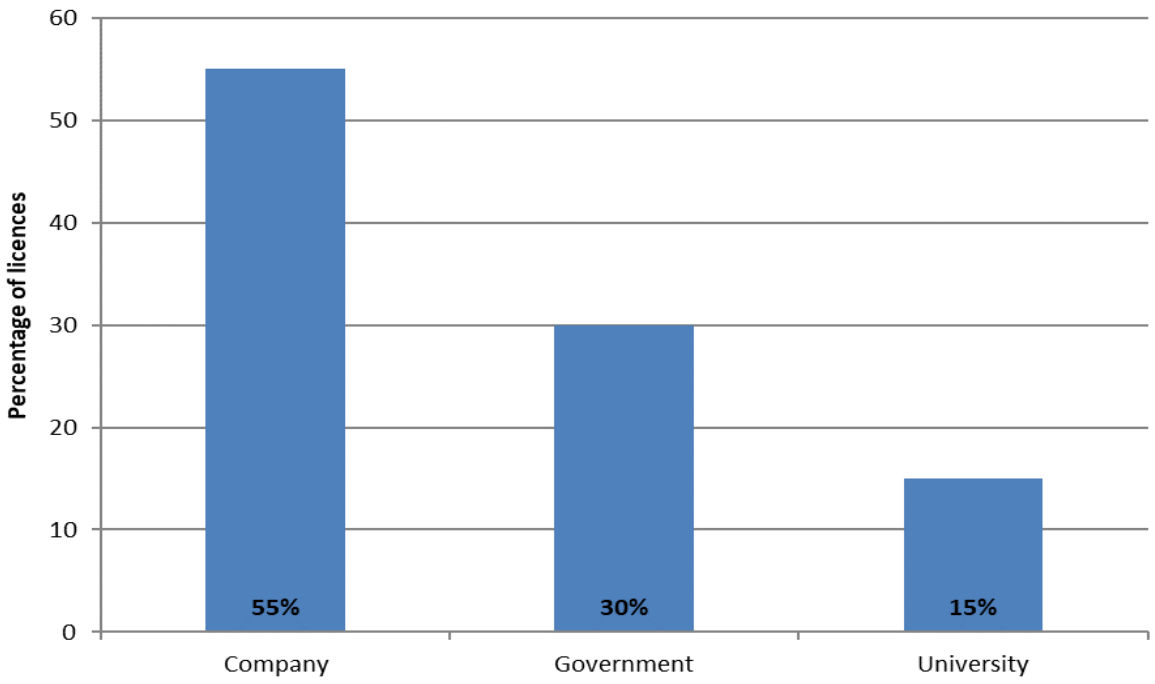
Table 3: DIR licences issued, 2018–19

DIR no.	Applicant	Parent organism	Introduced trait	Type of release	Received	Issued
DIR 166	Queensland University of Technology	Chickpea	Drought and heat tolerance	Limited and Controlled Release	29/10/2018	28/05/2019
DIR 165	The University of Melbourne	Wheat	Improved iron uptake, transport and bioavailability	Limited and Controlled Release	18/09/2018	17/04/2019
DIR 164	Monsanto Australia Pty Ltd	Canola	Herbicide tolerance	Limited and Controlled Release	24/04/2018	21/11/2018
DIR 163	Nuseed Pty Ltd	Canola	Altered oil content	Limited and Controlled Release	08/02/2018	06/09/2018
DIR 162	CSIRO	Wheat	Rust disease resistance	Limited and Controlled Release	02/01/2018	11/07/2018
DIR 161	Clinical Network Services (CNS) Pty Ltd	Respiratory syncytial virus	Attenuation, for use as vaccine	Limited and Controlled Release	11/12/2017	16/07/2018

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

Of the 140 DIR licences issued since commencement of the Act, 77 (55%) have been to companies, 43 (30%) to government agencies and 20 (15%) to universities (Figure 2).

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



Forty nine of the 140 DIR licences issued since the beginning of the scheme were current at 30 June 2019. Of these:

- 38 (78%) were Agricultural, 11 (22%) Non- Agricultural (Figure 3);
- 28 (57%) were issued to companies, six (12%) to government organisations, five (10%) to research institutes and ten (21%) to Universities (Figure 4); and
- Five (10%) of the DIR licences were held by organisations in the ACT, two (4%) in NSW, 15 (31%) in Qld, two (4%) in SA and 25 (51%) in Victoria (Figure 5).

Figure 3: Agricultural vs non-agriculture of DIR licences current as at 30 June 2019

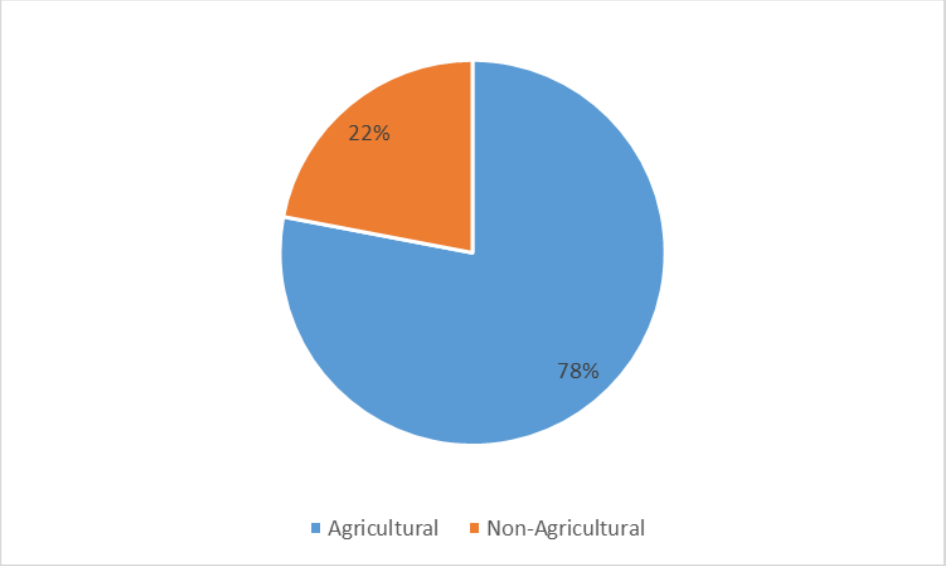


Figure 4: Distribution of DIR licences current as at 30 June 2019, by organisation type

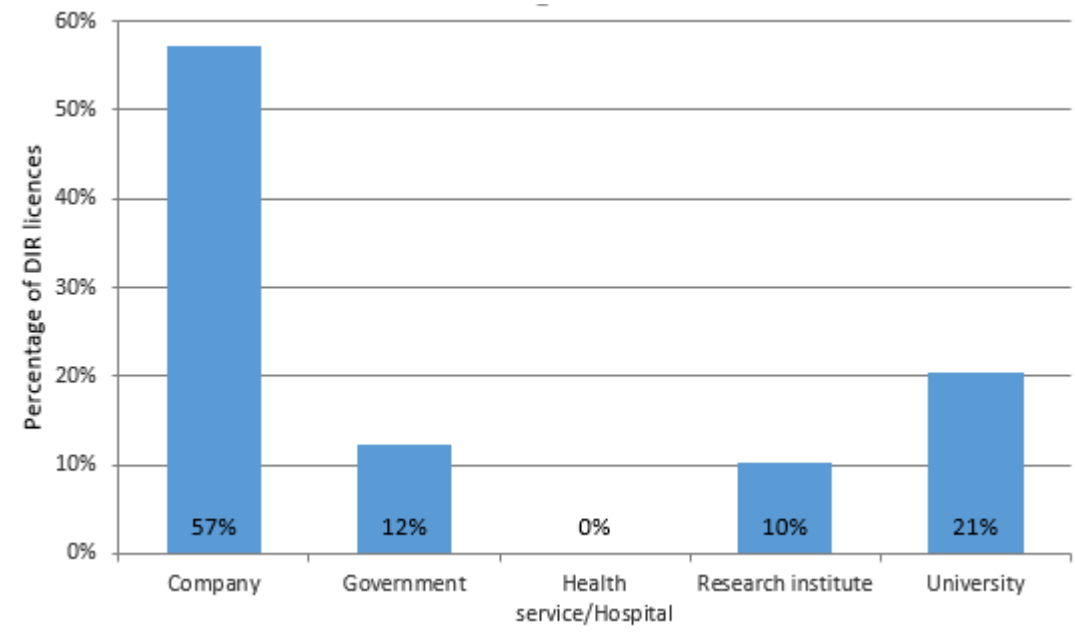
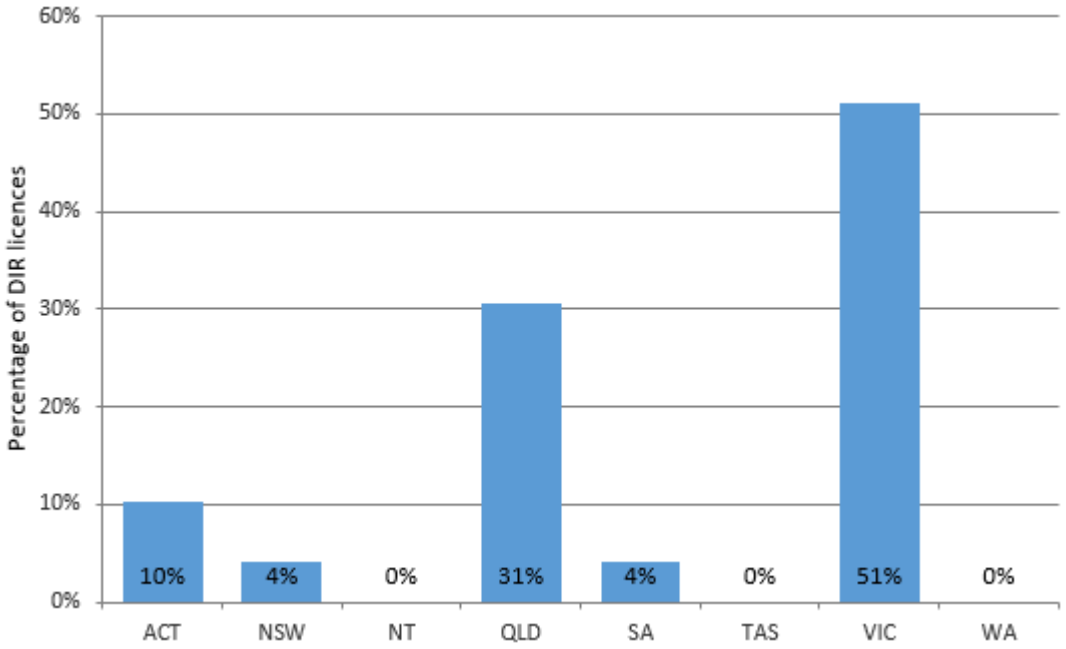


Figure 5: Distribution of DIR licences current as at 30 June 2019, by headquarters



Licences for dealings not involving intentional release of GMOs

Dealings not involving intentional release (DNIR) licences authorise dealings with GMOs in laboratories and other physical containment facilities and that may pose risks that require management through specific licence conditions. The Regulator must make a decision on DNIR licence applications within the statutory timeframe of 90 working days.

In 2018–19, the Regulator issued 11 DNIR licences (see Table 4). All decisions were made within the statutory time limit. The Regulator was considering a further six DNIR applications at 30 June 2019.

Six of the DNIR licences issued in 2018–19 were for clinical trials of vaccines for protection against infectious diseases, cancer treatments or treatment for a genetic disorder; three were for other research into human diseases and potential treatments; and two were for bulk import of GM grain for processing into stockfeed.

Table 4: DNIR licences issued, 2018–19

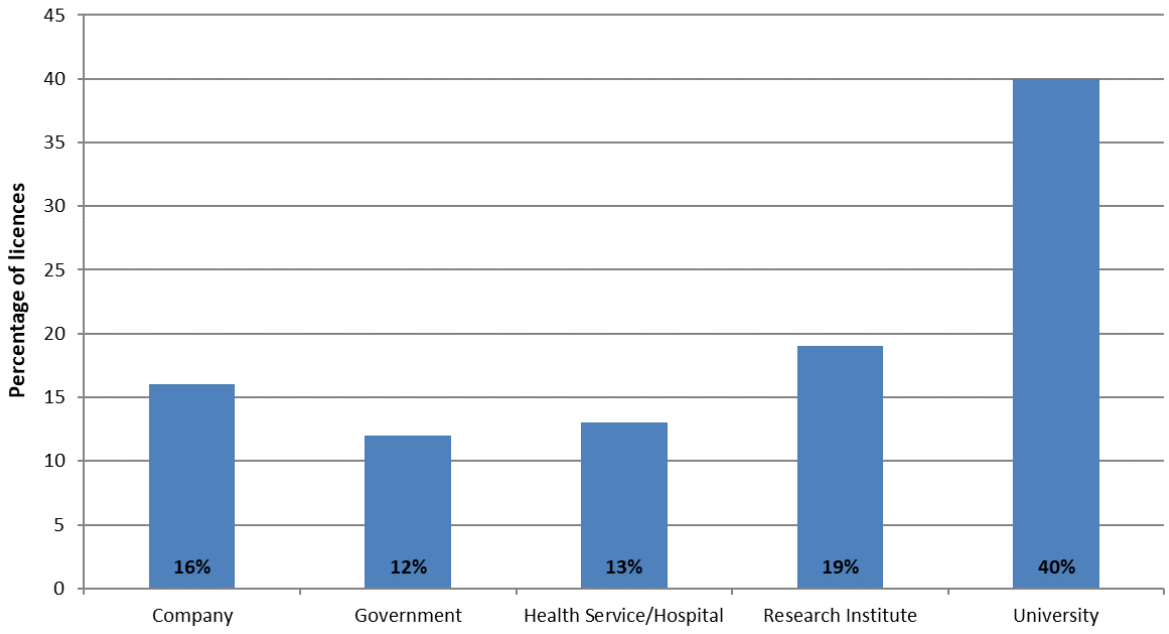
DNIR No.	Applicant	Title	Received	Issued
DNIR-596	Ridley Corporation Limited	US corn importation for Ridley to produce stockfeed	7/02/2019	31/05/2019
DNIR-595	Inghams Group Limited	US corn importation for Inghams to produce poultry feed	24/01/2019	23/05/2019
DNIR-594	Merck Sharp & Dohme (Australia) Pty Ltd	A cytomegalovirus prophylactic vaccine (V160) for use in clinical trials	21/11/2018	1/04/2019
DNIR-593	Hudson Institute of Medical Research	Endometrial MSC as a cell-based therapy for pelvic organ prolapse (POP) in an ovine model	20/11/2018	25/03/2019

DNIR No.	Applicant	Title	Received	Issued
DNIR-592	Clinical Network Services (CNS) Pty Ltd	An Oncolytic Immunotherapy Product for use in Clinical Trials	21/09/2018	23/01/2019
DNIR-591	QIMR Berghofer Medical Research Institute	Virus-mediated approaches to examine cardiovascular disease in vitro and in vivo	12/09/2018	16/01/2019
DNIR-589	The University of Melbourne	Using adeno-associated viral vectors to study striated musculature and related tissues in vitro and in vivo	31/07/2018	3/12/2018
DNIR-588	Janssen-Cilag Pty Ltd	Recombinant Respiratory Syncytial Viral Vaccine (Ad26.RSV.preF) for Clinical Studies	16/07/2018	20/11/2018
DNIR-587	GlaxoSmithKline Australia Pty Ltd	Clinical Trials with Respiratory Syncytial Virus (RSV) lnvestigational Vaccine ChAd155-RSV	31/05/2018	25/09/2018
DNIR-586	The Children's Hospital at Westmead	A global study of a single one-time dose of AVXS-101 delivered to infants with genetically diagnosed and pre-symptomatic Spinal Muscular Atrophy with multiple copies of SMN2.	1/05/2018	3/08/2018
DNIR-585	Clinical Network Services (CNS) Pty Ltd	Clinical Trial of an oncolytic vaccine for the treatment of cancers caused by the human papilloma virus (HPV)	4/04/2018	23/10/2018

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

Of the 463 DNIR licences issued since commencement of the Act, 185 (40%) have been to universities, 88 (19%) to research institutes, 74 (16%) to companies, 60 (13%) to health services/hospitals and 56 (12%) to government agencies (Figure 6)

Figure 6: 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

One hundred and twenty seven of the 463 DNIR licences issued since the beginning of the scheme were current at 30 June 2019. Of these:

- 109 (86%) Medical, 18 (14%) were Non-Medical, (Figure 7);
- 21 (17%) are held by companies, 12 (9%) by government organisations, six (5%) by health services or hospitals, 32 (25%) by research institutes and 56 (44%) by Universities (Figure 8).
- Four (3%) of the current DNIR licences were held by organisations in the ACT, 23 (18%) in NSW, 35 (28%) in Qld, 9 (7%) in SA, 49 (39%) in Victoria and seven (5%) in WA (Figure 9).

Figure 7: Medical vs non-medical focus of DNIR licences current as at 30 June 2019

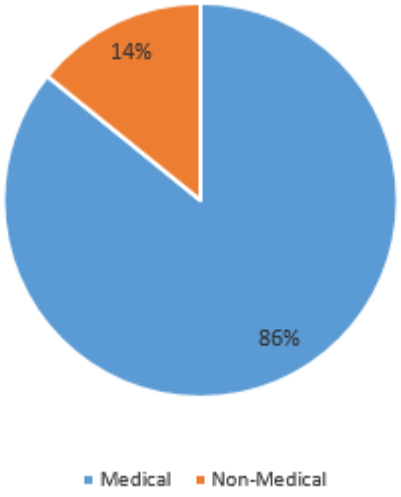


Figure 8: Distribution of DNIR licences current as at 30 June 2019, by organisation type

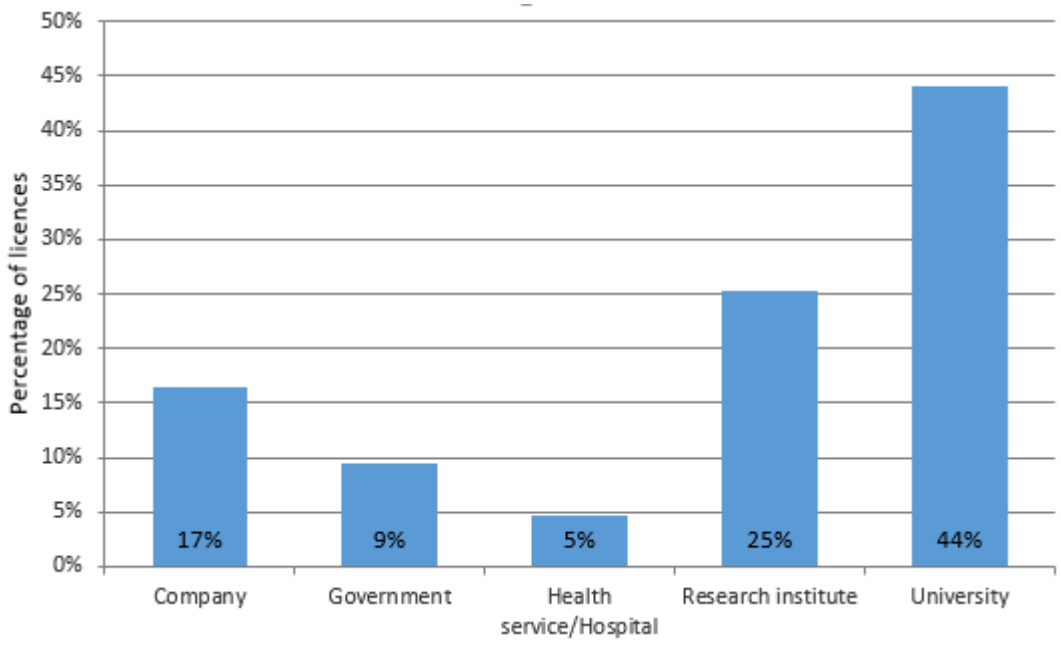
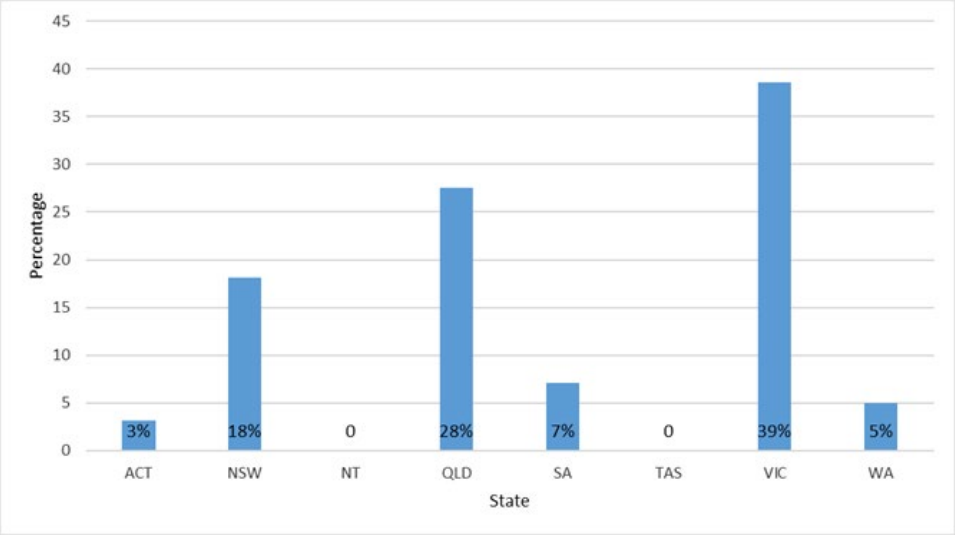


Figure 9: Distribution of DNIR licences current as at 30 June 2019, by headquarters

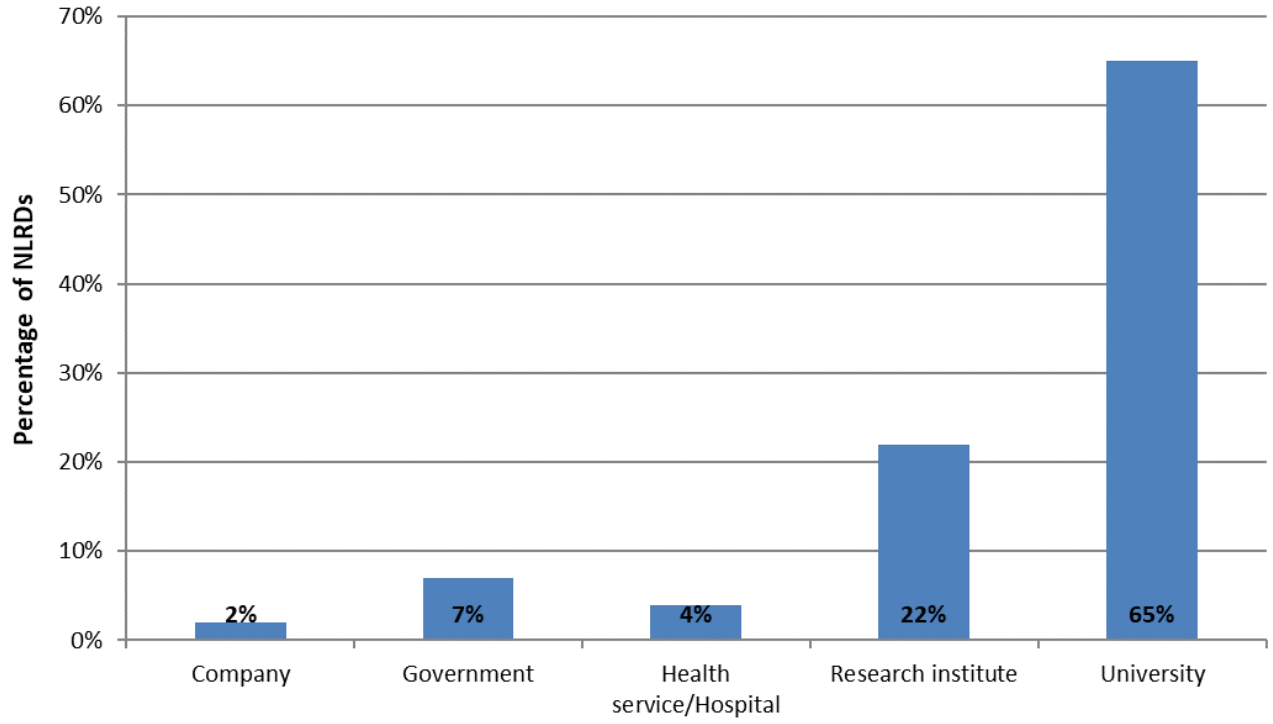


Notifiable low risk dealings

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.

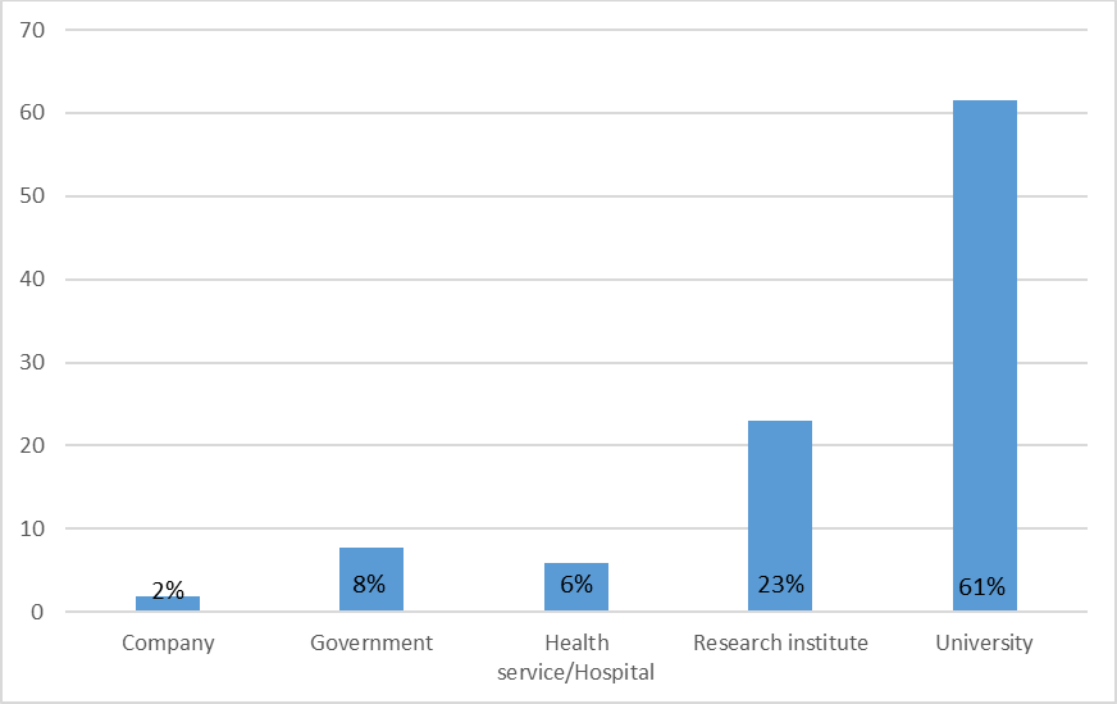
During 2018–19, 848 NLRD notifications were received. As in past years, these were predominantly for research work. The types of organisations that notified NLRDs to the OGTR in 2018–19 are shown in Figure 10. The proportion of NLRDs notified by each organisation type current as at 30 June 2019 is shown in Figure 11. The proportion of NLRDs notified in each state or territory current as at 30 June 2019 is shown in Figure 12.

Figure 10: Types of organisations that notified NLRDs in 2018–19



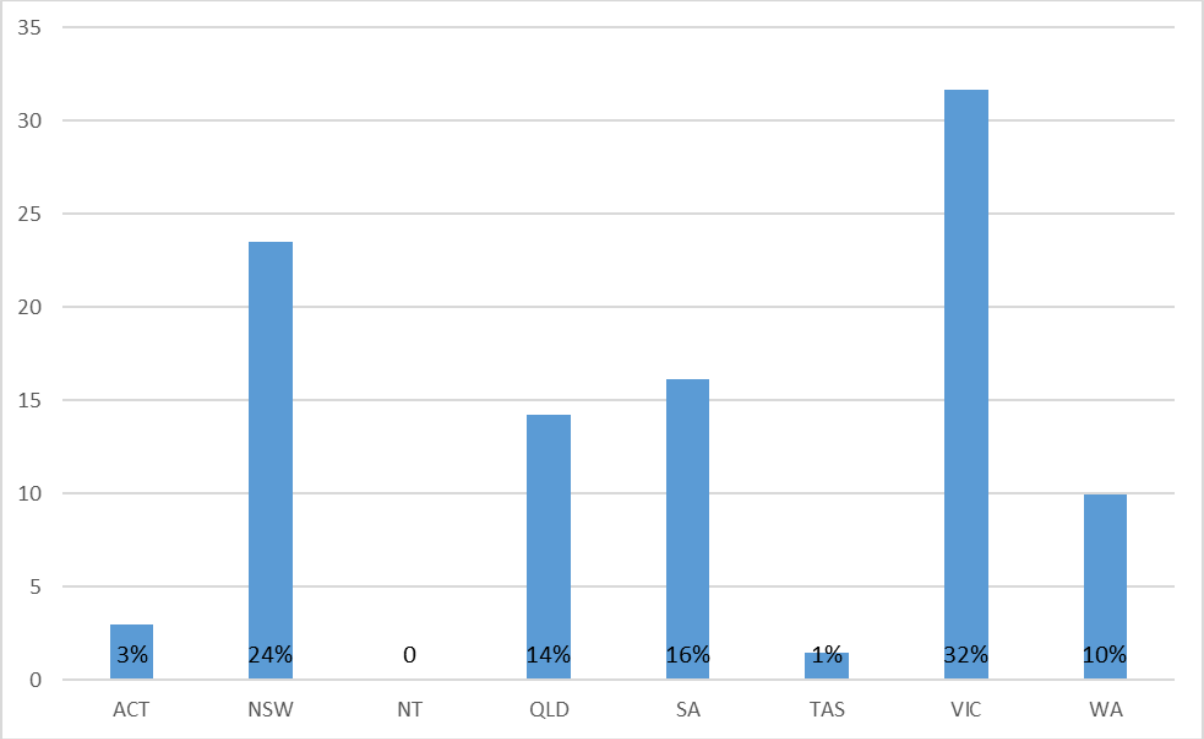
NLRD = notifiable low risk dealing

Figure 11: Types of organisations, holding current NLRDs as at 30 June 2019*



*NLRDs are current for five years after assessment.

Figure 12: Distribution of all current NLRDs as at 30 June 2019, by State



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. 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.

During 2018–19, the Regulator approved one alternate transport, storage and disposal request. The Regulator also approved one alternate facility request with one request still under consideration at the end of the period. Since these provisions were introduced in September 2011, seven alternate facility requests and eight alternate transport, storage and disposal requests have been approved.

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 2018–19, 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 2018–19, 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 2018–19, there were no new inadvertent dealings licences issued, no applications were received and none were in effect.

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 2018–19, eight accreditations were issued, with a total of 172 organisations holding accreditation at 30 June 2019 (this excludes four suspended at the organisations' request). Accredited organisations are located in all Australian states and territories (Figure 13). Over time, the profile of the types of organisations accredited by the Regulator has not changed significantly: a large proportion (64%) are primarily publicly funded (Figure 14).

Figure 13: Organisations accredited as at 30 June 2019, by location of headquarters

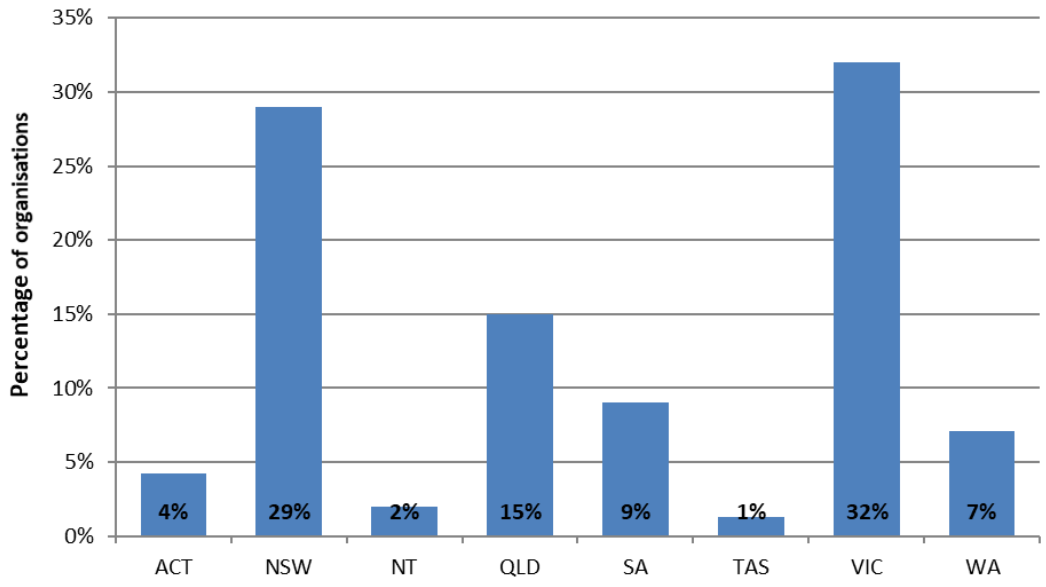
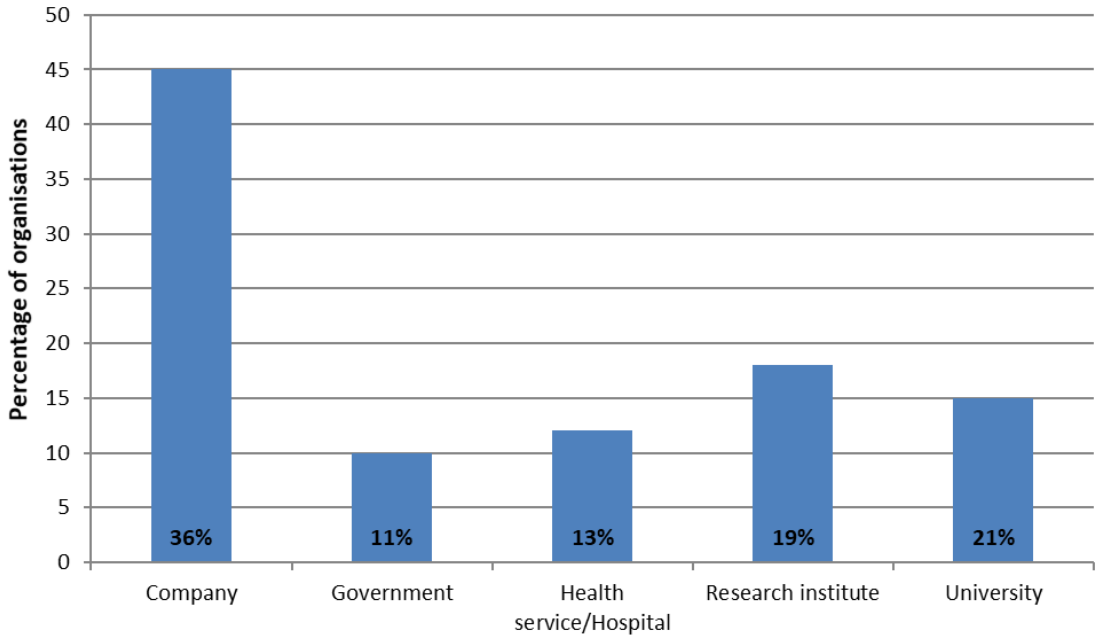


Figure 14: Types of organisations accredited as at 30 June 2019



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 2018–19, 114 new certifications for physical containment facilities were issued. The number of OGTR-certified facilities at 30 June 2019 is listed by facility type and containment level in Table 5.

Table 5: Number of OGTR-certified facilities as at 30 June 2019

Facility type	PC1[a]	PC2	PC3	PC4[a]	Total
Animal		238	5		243
Aquatic		32			32
Constant Temperature Room		43			43
Facility	323			4	327
Invertebrate		54	2		56
Laboratory		1116	24		1140
Large Grazing Animal		57			57
Large Scale Facility		19			19
Plant		155			155
Total	323	1714	31	4	2072

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 2019.

The types of organisations issued with certifications in 2018–19 were predominantly universities (66%) and research institutes (19%). The types of organisations holding certifications as at 30 June 2019 were predominantly universities (57%), research institutes (18%) and government agencies (14%) (Figure 15). This distribution corresponds with the high number of authorisations for dealings requiring containment (NLRDs and DNIRs) held by the universities and research institutes (see Figures 10 and 8). OGTR-certified physical containment facilities are located in all Australian states and territories (Figure 16).

Figure 15: Distribution of OGTR-certified facilities as at 30 June 2019, by organisation type

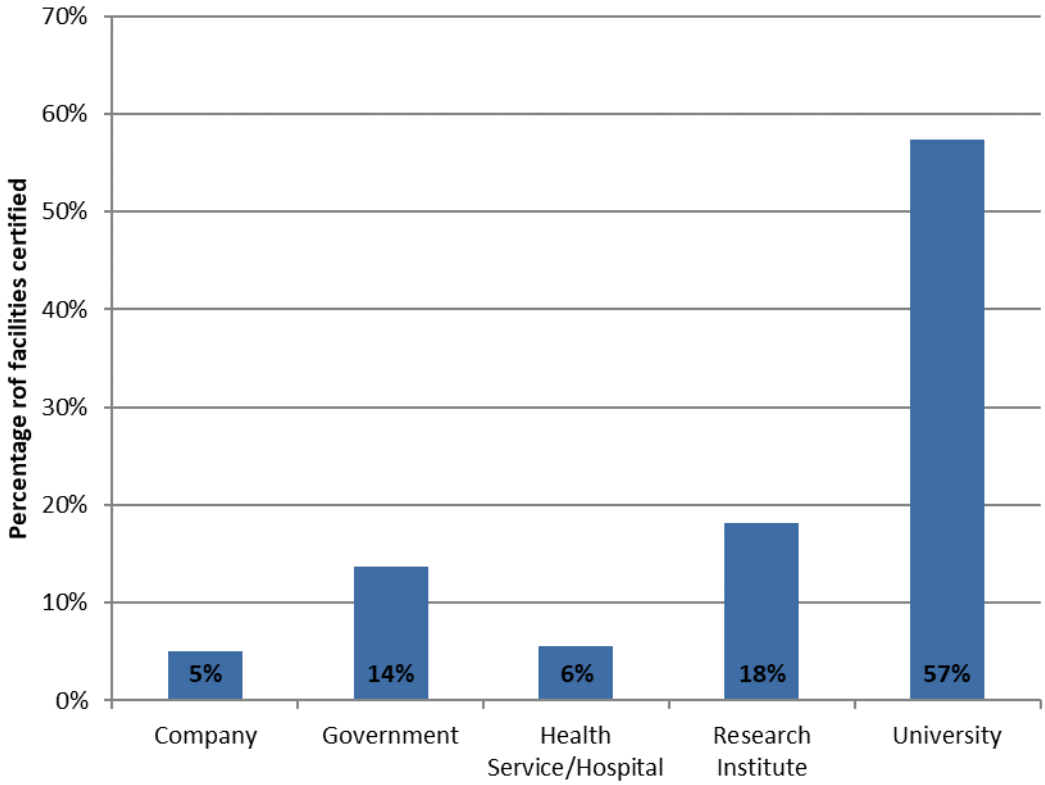
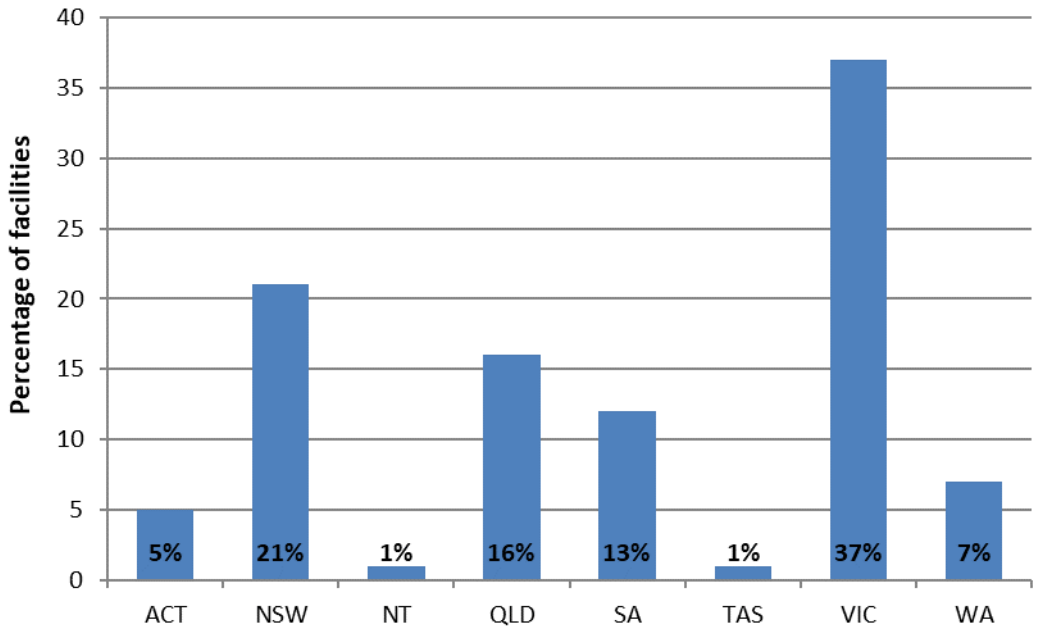


Figure 16: Distribution of OGTR certified facilities as at 30 June 2019, by location



Application trends

The numbers of main authorisations issued during 2018–19 were similar to those in previous years (Table 6).

Table 6: Data for approval of main types of applications, 2014–15 to 2018–19

Application type	2014–15	2015–16	2016–17	2017–18	2018–19
Accreditation	10	4	3	9	8
Certification	89	125	162	135	108
DIR	7	9	9	9	6
DNIR[a]	10[b]	7	10	9	11
NLRD	842	769[c]	820[c]	845[c]	848

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

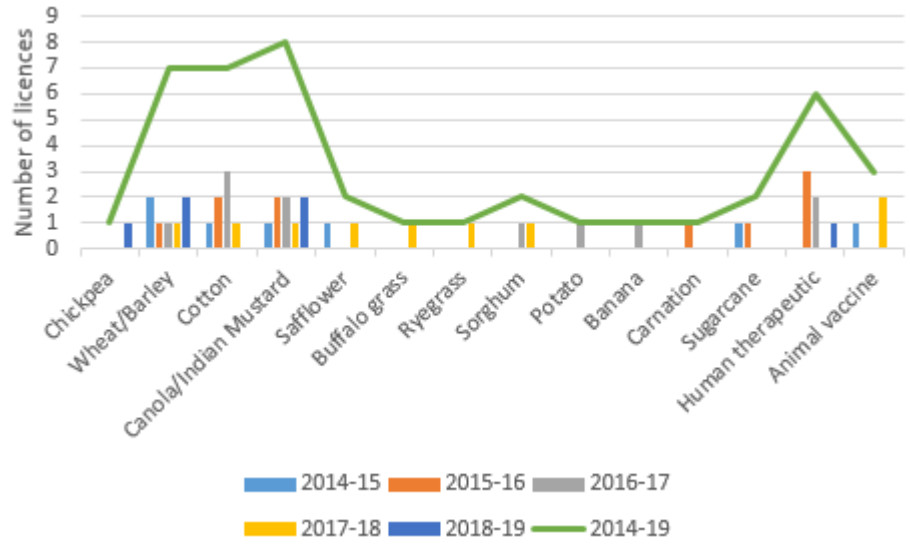
a 'Approval' for DNIR refers to the number of licences issued. This can differ from the total number of applications approved when two or more applications are integrated into a single licence.

b Two applications were approved and incorporated into a single licence.

c Correction to the number (750) reported in the 2015–16 report, number (817) reported in the 2016–17 report and number (842) reported in the 2018–19 report. The complete set of data was not available at the time of the reports.

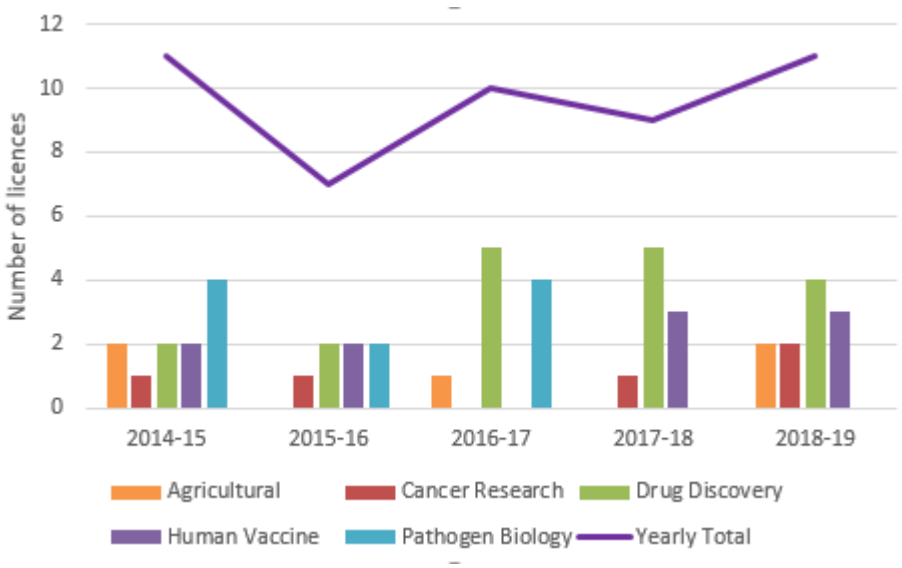
Cotton, canola (and Indian mustard) and wheat (and barley) have remained the most common crops for environmental release over the last five financial years (Figure 17). There has also been an increase in human vaccines and therapeutics being trialled and commercially released. The first GM animal vaccine commercially released was approved in 2014. New crop licences in the last five years include sorghum, potato and buffalo grass.

Figure 17: Focus of DIR licences, 2014–15 to 2018–19



DNIR licences issued for contained research continue to be dominated by medical research with only five licences out of the 48 issued in the last five financial years authorising agricultural work involving plants or animals (Figure 18). Drug discovery and testing is the most common type of research with 18 licences issued. Ten licences each were issued for vaccine development and testing, and for research into the biology of pathogens. Five licences were issued for research into cancer and its treatment.

Figure 18: Fields of research authorised under DNIR licences, 2014–15 to 2018–19



'Agricultural' includes animal vaccines, importing grain for food or feed use, and studying the biology of plant and animal pathogens

'Cancer research' includes studying cancer mechanisms as well as developing and testing potential treatments

'Drug discovery' includes identifying and testing possible new human therapeutics and delivery methods

'Human vaccines' includes the development and testing of vaccines to be used in humans

'Pathogen biology' includes the study of human pathogens and any toxins they may produce

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 confidential commercial information (CCI). 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 CCI applications, and the evaluation of a licence application may be paused if significant claims need to be resolved.

In 2018–19, the Regulator made 10 CCI declarations. Decisions on a further 22 applications were pending as at 30 June 2019.

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 Regulator received 74 surrender requests in 2018–19 and approved 63 for surrender of certifications of facilities, five for surrender of DIR licences, two for surrender of a DNIR licence and four 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 range from minor administrative changes (such as a change to contact details in a licence or room numbers in a certification) to significant changes (such as extending the period of authorisation, growing a GM crop at a new site, new procedures for handling GMOs or changes to the area of a certified facility). In February 2019, the Regulator introduced application forms for DIR and DNIR licence variations to provide licence holders guidance on the type of information to include in their application for a variation.

The Regulator approved 442 variations in 2018–19 (see Table 1). Of these, five were for DIR licences, 42 were for DNIR licences and 395 were for certifications. Around 70% of the variations to certifications were for extending the period of authorisation which has not differed greatly over the past 10 years. Twenty-three higher-level containment facilities (14 PC3, 1 PC4 and 8 PC2 large scale facilities) were inspected prior to extension of the certification period.

Monitoring dealings with genetically modified organisms

This section provides information on the OGTR's inspection activities during 2018–19.

Inspections of DIR licences

The Regulator's 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.[4]

During 2018–19, there were 54 DIR licences in force held by 24 accredited organisations. These comprised:

- 22 commercial release licences (17 for plant products, four for human clinical products and one animal vaccine product)
- 32 limited and controlled release licences (26 for plant field trials, four human clinical trials and two animal vaccine trials).

None of the commercial release licences imposed conditions that necessitated site inspections. Post-release reviews into the oversight of commercially approved GM crops were conducted against commercial release licences held by Monsanto and BASF. These reviews focused on what steps are undertaken by commercial crop licence holders to monitor the safety of commercial GM crops after approval in case any new information emerges. The OGTR inspected 11 of the 26 limited and controlled plant field trials (which may have comprised multiple site visits per licence). One limited and controlled therapeutic clinical trial was inspected.

Outcome of inspection activities

The Regulator 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 2018–19, 64 licensed field trial sites were operating, 16 of which were current and 48 were subject to post-harvest monitoring conditions. 66% of the field trial sites were inspected in the year. In two instances a site was inspected twice in 2018–19. A breakdown of the number and proportion of sites inspected in 2018–19 is provided in Table 7.

Table 7: Proportion of DIR field trial site inspected in each quarter of 2018–19

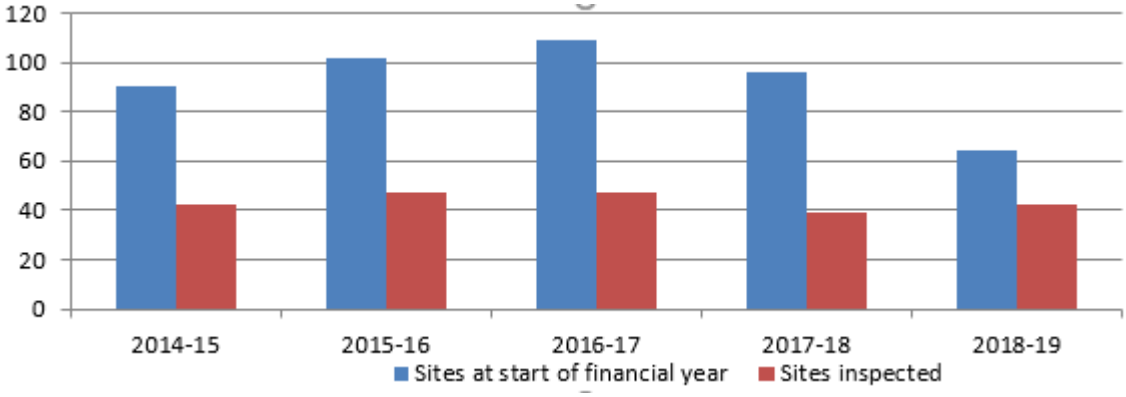
Reporting period	Current sites	Post-harvest monitoring sites
July–September 18	2/16	13/48
October–December 18	7/15	8/45

[4] Details are in the Monitoring Protocol on the OGTR website

January–March 19	3/15	2/48
April–June 19	4/10	2/48
Total Inspections	16	25

The number of active field-trials in 2018/19 was the lowest in the last five years. The number of inspections has remained relatively consistent over the same period (Figure 19).

Figure 19: Number of sites and number inspected each year, 2014–19



Types of GM crops inspected

OGTR inspected seven plant species across 43 field trial sites during 2018–19 (Table 8).

Table 8: Number of licensed DIR trial sites at beginning and end of 2018–19, and number inspected in 2018–19, by type

Species	Trial sites as at 1 July 2018	Trial sites as at 30 June 2019	Trial sites inspected during 2018–19
Banana	3	2	3
Canola	6	1	0
Cotton	6	12	7
Indian mustard	1	1	0
Perennial ryegrass	0	1	1
Safflower	2	0	0
Sorghum	1	3	5*
Sugarcane	18	10	4
Wheat	18	19	13

Wheat and barley	8	7	8

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.

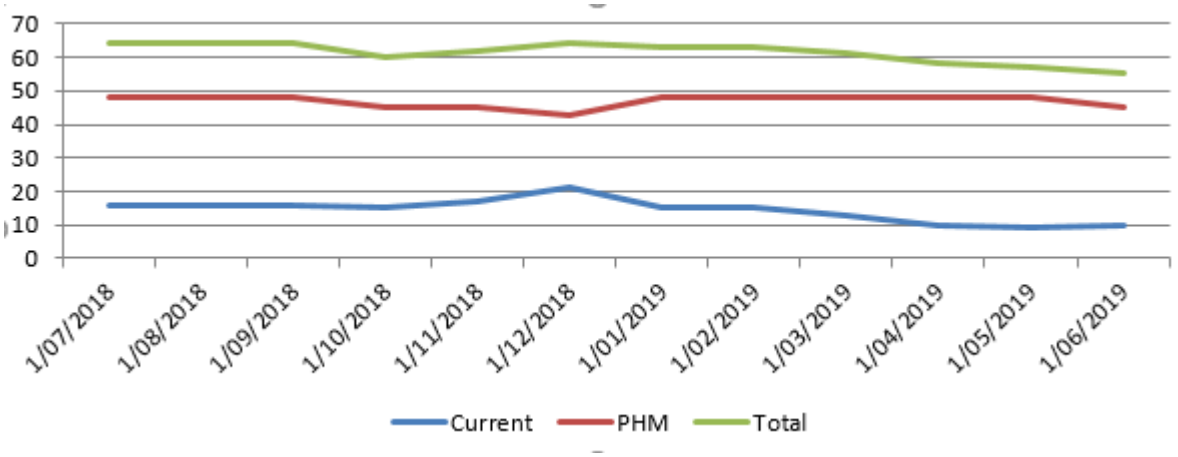
* Throughout the course of 2018–19 there were three sites for this licence, two of which were inspected multiple times.

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 the potential for harm occurring 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 Regulator 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 20 shows the change in the numbers of current field trial sites and of field trial sites subject to post-harvest monitoring during 2018–19.

Figure 20: Number of DIR field trial sites and their status during 2018–19



PHM = post-harvest monitoring

Locations of field trial site inspections

In 2018–19, the OGTR inspected field trial sites in all states and territories where field trials were being undertaken, except the Australian Capital Territory. No trials were undertaken in Tasmania (Table 9).

Table 9: Number of DIR field trial sites and OGTR inspections in 2018–19, by state and territory

Jurisdiction	Trial sites at 1 July 2018	Trial sites at 30 June 2019	Site inspections
ACT	5	6	0
NSW	5	6	4
Qld	22	17	11
SA	7	7	7
Vic	8	4	2
WA	15	14	15
NT	2	2	2
Tas.	0	0	0
Total	64	56	41

Inspections of contained dealings

Our monitoring program includes dealings conducted in clinical and 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.

During 2018–19, 109 certified facilities were inspected across the range of facility types (Table 10); this includes 17 of the 56 higher-level containment facilities that had certification approvals in force at the beginning of 2018–19 (representing 30%).

In addition, 21 DNIR licences in force during 2018–19 were monitored.

Table 10: Number of inspections of certified facilities (by type) conducted during 2018–19

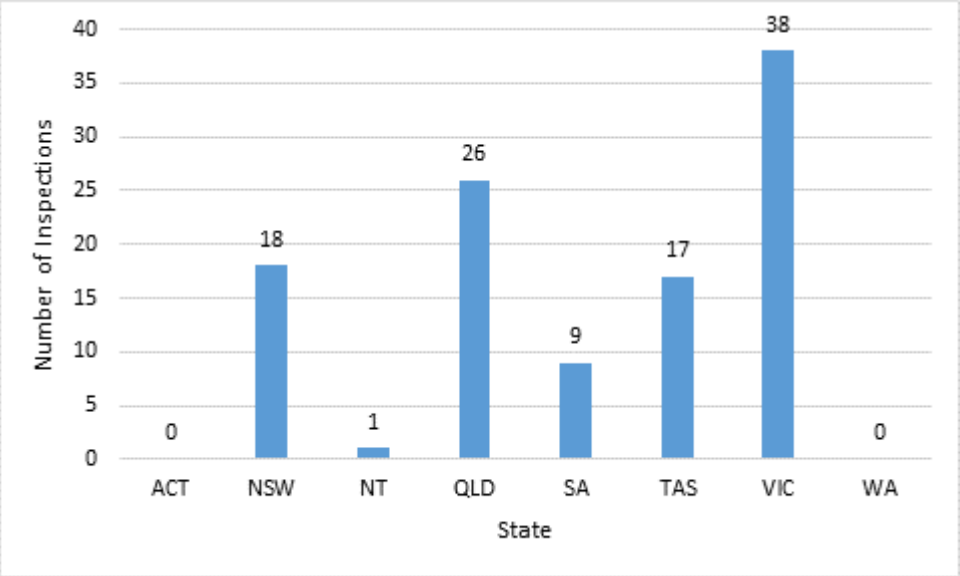
Containment type	PC level and facility type	Inspections
Lower level	PC1 Facility	5
	PC2 Animal	20
	PC2 Laboratory	55
	PC2 Plant	7
	PC2 Aquatic	3
	PC2 Constant Temperature	1
	PC2 Invertebrate	1
Higher level	PC2 Large scale	7
	PC3 Laboratory	9
	PC3 Animal	1
	PC4 Facility	0
Total		109

PC = physical containment

Locations of facility inspections

Certified facilities are located in all Australian states and territories (Figure 8). In 2018–19, monitoring activities took place in each state and territory except the Australian Capital Territory and Western Australia (Figure 21).

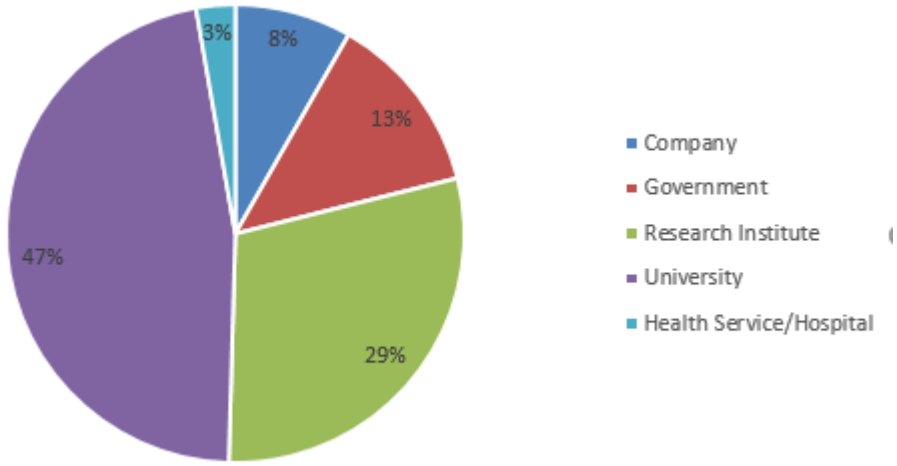
Figure 21: Number of certified facility inspections in 2018–19, by state and territory



Types of organisations inspected

Of the five categories of applicant organisations, universities held the largest number of certified facilities during 2018–19 (Figure 15). Figure 22 displays the distribution of inspections during 2018–19 by organisation type. Universities comprised the majority of inspections followed by research institutes, government, company and health services/hospitals.

Figure 22: Certified facility inspections in 2018–19, 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.[5]

During 2018–19, the regulated community continued to demonstrate a high level of compliance with the gene technology legislation.

Non-compliance findings for GMO dealings involving intentional release

In 2018–19, no holders of DIR licences were found to be non-compliant.

Non-compliance findings for GMO dealings not involving intentional release

In 2018–19, one non-compliance was identified against a DNIR licence. The finding is outlined below.

[5] The Compliance and Enforcement Policy is on the OGTR website

Organisation	The University of Queensland
Licence number	DNIR 518
Title of Project	Isolation, expression and characterization of the toxins expressed by the Australian paralysis tick (*Ixodes holocyclus*).
Summary of dealing	This study will use GM bacteria and yeast to express putative toxin proteins from the Australian paralysis tick, for the purpose of developing a vaccine against tick bite for companion animals.
Findings	1. Prior to undertaking dealings, The University of Queensland did not inform persons covered by the licence of relevant licence conditions that applied to them (Condition 9), or obtain signed statements from these persons confirming that they had been trained in and understood and agreed to be bound by licence conditions (Condition 14). 2. Licensed dealings were undertaken in a certified facility that was not listed on the licence as a permitted facility (Condition 16; Attachment B). 3. A condition of the licence listed a number of work practices and behavioural requirements that must be employed when conducting a dealing to ensure containment of the GMO and to not compromise the health and safety of people. The University of Queensland failed to train other users of the facility in relation to these work practices prior to dealings being undertaken, as required by condition 27(g).
Assessment	Persons conducting dealings with the GMO who are not fully trained in licence conditions are at risk if exposed to the GM organism. Likewise, persons who share a room or equipment with those working on dealings are also at increased risk having not been trained to recognise potential symptoms and treatment options. The unauthorised facility where researchers conducted licensed dealings was equivalent to and certified at the same containment level as those listed on the licence. There is no evidence of any harm to human health and safety. As such, no additional risks were identified.
Compliance management	In consultation with the OGTR, The University of Queensland has initiated the following: 1. Immediately ceased the licensed dealings in the unauthorised facility and destroyed all GM material that was produced. 2. Applied for and were granted a licence variation to include the unauthorised facility in the licence. 3. Conducted training for all persons undertaking licensed dealings, including obtaining signed statements from those persons. 4. Has ensured that all staff who share a room or equipment where experiments with the GMOs are conducted, will be trained in licence work practices, and made aware of potential symptoms and treatment options in the event of exposure to the GMOs.

Non-compliance findings for notifiable low risk dealings

In 2018–19, four NLRDs were identified to be non-compliant against the Regulations, in that dealings were being undertaken in non-certified facilities.

Non-compliance findings for physical containment facilities

In 2018–19, 21 certified physical containment facilities were found to be non-compliant with a total of 32 certification conditions. These findings are summarised in Table 11.

Table 11: Number of non-compliances identified in certified facilities during 2018–19, by non-compliance type

Nature of non-compliance	Number
Equipment	3
Personal protective equipment	1
Structure	8
Transport	5
Waste disposal	6
Work practices [a]	9

[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 practice reviews with 10 organisations during this reporting period.

	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 • 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 was Murdoch University. The review assessed: • the operational practices for managing waste streams within facilities, along with transport, storage and disposal practices • the suitability of the organisation's 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 organisation's effective compliance performance.
Findings	The review found that the participating accredited organisation 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.

	Facility structure and maintenance — practice review
Aim	This is part of the OGTR's ongoing practice review program. The OGTR recognises 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 the University of Western Australia. 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.

	Preparedness of accredited organisations to undertake licensed dealings involving intentional release – Practice Review
Aim	This is part of the OGTR's ongoing practice review program. The OGTR recognises that effective compliance is dependent on: • suitable arrangements to manage compliance for GMO dealings • suitable site selection and the appropriate use of containment measures • 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 a GM grass, GM grain crops or GM animal vaccines. Organisations included in the practice review were: the Department of Economic Development, Jobs, Transport and Resources (Victoria), Bioproperties Pty Ltd, the University of Queensland and the University of Melbourne. 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.

	Preparedness of accredited organisations to undertake licensed dealings not involving intentional release – human clinical trials
Aim	This is part of the OGTR's ongoing practice review program. The OGTR recognises that effective compliance is dependent on: • suitable arrangements to manage compliance for GMO dealings • suitable site selection and appropriate use of containment measures • staff training and provision of resources necessary to manage compliance obligations.
Participants	The review focused primarily on the organisation's preparedness to undertake licensed clinical trials in humans and included Janssen-Cilag Pty Ltd, PSI CRO Australia Pty Ltd, Clinical Network Services Pty Ltd and Merck Sharp & Dohme (Australia) 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 a licensed dealing not involving an intentional release.
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.

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 2018–19, we continued to liaise with the ASF and the seed industry, attending 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. 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, and no incidents were identified in Australia.

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.

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 2018–19.

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 2018–19 annual report, is summarised below.

Our activities for 2018–19 are described under Program 5.1 in Outcome 5 (Regulation, Safety and Protection) of the 2018–19 Department of Health Portfolio Budget Statements.[6] 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 area.

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

2018–19 target	2018–19 result: Met
Risk assessments and risk management plans prepared for licence applications and all decisions made within the statutory timeframes. Stakeholders, including the public, consulted on all assessments for proposed release of GMOs into the environment. High level of compliance with gene technology legislation and no adverse effect on human health or environment from authorised GMOs.	Risk assessments and risk management plans were prepared, and decisions made within statutory timeframes, for 100% of licensed dealings. Stakeholders, including the public, were consulted on all assessments for proposed release of GMOs into the environment. 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.

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.

6 The Portfolio Budget Statement is on the department's website

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.

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 18 years.

4 Other functions of the Gene Technology Regulator

This chapter describes achievements on other functions of the Regulator.

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

- developing draft policy principles and policy guidelines, as requested by the LGFGT
- developing codes of practice
- issuing technical and procedural guidelines in relation to GMOs
- providing information and advice about GMOs and GM products to other regulatory agencies
- providing information and advice to the public about the regulation of GMOs
- providing advice to the LGFGT about the:
    - operations of the Regulator and the GTTAC
    - effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation
- undertaking or commissioning research in relation to risk assessment and the biosafety of GMOs
- promoting the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies
- maintaining links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia
- performing such other functions as are conferred on the Regulator by the Act, the Regulations or any other law. These functions maintain the OGTR's capacity to conduct high-quality risk analysis based on regulatory best practice and relevant scientific data.

Technical and procedural guidelines issued by the Regulator

In 2018–19, OTGR has initiated reviews of the following Guidelines:

- Guidelines for Accreditation of Organisations
- Guidelines for Certification of a Physical Containment Level 3 Laboratory
- Guidelines for Certification of a Physical Containment Level 3 Animal Facility
- Guidelines for Certification of a Physical Containment Level 3 Invertebrate Facility.

These reviews are ongoing. As part of the review of Physical Containment Level 3 facility guidelines, workshops with certification holders were conducted in Brisbane, Melbourne and Sydney.

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 Regulator initiated a technical review of the Regulations in 2015–16 to clarify the regulatory status of organisms developed using a range of new technologies and ensure that the new technologies are regulated in a manner commensurate with the risks they pose. This included consideration of site-directed nuclease techniques (for example, using CRISPR/Cas9) and oligonucleotide-directed mutagenesis.

2019 Amendments to the Gene Technology Regulations 2001

After extensive consultation, the Technical Review has concluded with the LGFGT approving amendments to the Gene Technology Regulations 2001[7]. The Regulator provided a Decision Regulation Impact Statement to support the LGFGT's consideration of the proposed amendments[8].

On the 4th April 2019 the Governor-General made the Gene Technology Amendment (2019 Measures No. 1) Regulations 2019, which will commence from 8 October 2019[9]. The amendments are substantially the same as those put forward for public consultation on 30 November 2017, with minor changes to clarify the drafting and address a possible loophole, ensuring oversight of organisms intended to be regulated as GMOs.

The amendments will commence in three stages:

- 8 October 2019: the majority of amendments
- 1 July 2020: minor administrative amendments to Notifiable Low Risk Dealing assessment and reporting requirements
- 8 October 2020: repeal of an item on the list of organisms that are not GMOs (Schedule 1 item 1).

OGTR will provide information directly to regulated organisations and on the OGTR website in preparation for each commencement stage.

Third Review of the National Gene Technology Scheme

Commencing in 2017–18, the Third Review of the National Gene Technology Scheme was a broad-reaching policy review conducted by a collaboration of Commonwealth, state and territory officials on behalf of all Australian governments, independently of the Regulator. In

[7] LGFGT announcement available on their website
[8] The Decision Regulation Impact Statement is available on the OGTR website
[9] The amendments and an Explanatory Statement are available on the Federal Register of Legislation

October 2018 the Legislative and Governance Forum on Gene Technology endorsed the final report of the review, which included 27 recommendations to ensure the Scheme remains effective and fit for purpose into the future. Throughout the review OGTR provided technical and operational information on request, and the effectiveness of this collaboration with the review team in the Department of Health was recognised with an Australia Day award from the Department.

In 2018–19 OGTR began administrative implementation of the review recommendations. Streamlining initiatives to reduce regulatory burden included ongoing digital service delivery roll-out (online forms), and introducing application forms for DIR and DNIR licence variations. OGTR also assisted the Department of Health team leading implementation of review recommendations. This work will progress into 2019–20.

Advice on GMOs and GM products

During 2018–19, 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 (APVMA). In 2018–19, the OGTR and the APVMA continued a review of their MOU.

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 (RSN) 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 2018–19. OGTR participated in the Annual Symposium on 'Risk Communication for Regulatory Scientists' in November 2018. OGTR hosted a RSN committee meeting in May 2019.

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.[10] The GMO Record contains information on licences issued, NLRDs, GMO dealings included on the Register, and

[10] The OGTR maintains the GMO Record as a source of public information on such approvals on its website.

emergency dealing determinations. During 2018–19, we maintained the GMO Record and updated it with new authorisations.

Engagement with stakeholders

8th National IBC forum

The IBC Forum provides an important opportunity for feedback and exchange of information between IBCs and the OGTR, enhancing regulation of gene technology. The forum also allows IBCs to share experiences and learn from each other. IBCs are important partners in the regulatory scheme, providing in-house expertise and oversight within organisations. IBCs have consistently indicated that the forum helps them to share knowledge, regulatory approaches and strategies across organisations, which assists compliance with regulatory requirements.

The 8th National IBC Forum was held in Canberra on 28 and 29 March 2019 at the National Gallery of Australia. Representatives of IBCs and accredited organisations from most states and territories attended, with 166 delegates from 92 organisations. Professor Brendan Murphy, Chief Medical Officer and Deputy Secretary, Department of Health opened the forum. Professor Dan Tompkins from New Zealand Predator Free 2050 gave the keynote address on the International Union for Conservation of Nature's review of synthetic biology and the environment. Guest speakers and panel members from organisations and IBCs, together with OGTR staff, contributed to an engaging and well-received program. Major topics for discussion included regulatory culture, biohacking, an update on the technical review of the Regulations, and the 3rd National Review of the Gene Technology Scheme. There were also workshops on clinical trials, plant licence conditions and PC3 certification guidelines. The forum provided an important opportunity for feedback and exchange of information between IBCs and the OGTR, enhancing regulation of gene technology**.**

Digital service delivery for applications to the Regulator

As part of the ongoing development of digital service delivery, during 2018–19 the OGTR released two online forms – Application for the Certification of a Physical Containment Facility, and the NLRD Reporting Form.

Several forms are currently under development with the view to release them within the 2019–2020 financial year. These forms include the Accredited Organisation Annual Reporting Form, the Application for Accreditation of an Organisation form, the DIR/DNIR variation forms and the Modifications to Certifications form.

Information regarding the new online forms and ongoing work was presented at the OGTR IBC Forum held in March 2019. Forum participants were informed of the development of additional online forms and stakeholders were invited to take part in User Acceptance Testing (UAT) of these forms. A large number of stakeholders volunteered to participate in the UAT process and actively engaged in providing detailed feedback.

This comprehensive approach to stakeholder engagement and participation has resulted in online forms that are functional, fit for purpose and meet stakeholders' needs and expectations.

OGTR newsletters

The OGTR releases a newsletter to our regulated stakeholders via email and on the website as part of our communication with the regulated community to advise of any key updates and to help clarify processes. The newsletter aims to:

- Improve communication between the OGTR, applicant organisations and the 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.

In 2018–19 two newsletters were produced. These feature information on the Third Review of the National Gene Technology Scheme, The Technical Review of the Gene Technology Regulations as well as comprehensive information on the submission of Confidential Commercial Information (CCI) applications.

Meeting and conference attendance

During 2018–19, the Regulator and the OGTR participated in a range of conferences 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 and conferences:

- Australian Cotton Conference, Gold Coast, August 2018
- Presentation to Biosecurity Course students, Australian National University, Canberra, August 2018
- Presentation on OGTR regulation, LaTrobe University, Melbourne, August 2018
- Society of Invertebrate Pathology Workshop, Gold Coast, August 2018
- ComBio 2018, Sydney, September 2018
- AusCanola 2018 Conference, Perth, September 2018
- 21st Australasian Weeds Conference, Sydney, September 2018
- Reef restoration workshop, Brisbane, October 2018
- CSIRO, Island Conservation, Department of Biodiversity, Conservation and Attractions (DBCA), Western Australian Biodiversity Science Institute (WABSI). Stakeholder discussions on gene drives. Perth, November 2018
- Regulatory Science Network Annual Symposium. Risk Communication for Regulatory Scientists, Canberra, November 2018
- Fenner conference on the environment: the use of gene drive technology in conservation, Canberra, November 2018
- RSPCA Animal Welfare Seminar 2019, Canberra, February 2019
- Gene Editing in Agriculture Roundtable, Sydney, March 2019
- Regulation and Compliance for Commonwealth Regulators Seminar Series, Canberra, March 2019
- National Environmental Law Association conference, Canberra, March 2019

- CSIRO Agriculture and Food Seminar, Canberra, April 2019
- Australian Banana Industry Congress, Gold Coast, May 2019
- 2019 Australian Biosecurity Symposium, Gold Coast, June 2019
- Stakeholder consultation on the review of the Certification Guidelines for Physical Containment Level 3 facilities, Sydney, Brisbane and Melbourne, June 2019.

Research undertaken or commissioned by the Regulator

Documents to support the risk assessment of GMOs

During 2018–19, OGTR wrote a new biology document:

Chickpea (*Cicer arietinum* L.) (March 2019).

Community attitudes survey

As part of an ongoing information-gathering project on public attitudes towards GMOs, the OGTR commissioned Instinct and Reason to conduct a survey to:

- explore current awareness, attitudes and understanding towards general science and technology, specific biotechnology issues and specific applications and controllers of the technology
- explore differences in awareness, perceptions and attitudes according to key demographic variables, such as age, gender, location and education and, in terms of mindsets, to determine segments in the community.

The final report shows a movement towards a more neutral response to GMOs, with younger Australians (ages 16–30) being more accepting of gene technology and GMOs. Australians are still more in support of GMOs than opposed, although this depends on the application of the technology. For example, support is greater for medical and industrial uses than for using the technology in food and crops. The report found a low level of information and understanding of gene technology with an increase in the number of ‘don’t know’ responses. The report also shows that most support or rejection of genetically modified foods is conditional, and is likely to move based on knowledge of regulation or scientific evidence of safety.

Website discovery project

As part of the Australian government’s digital transformation agenda the OGTR commissioned Squiz Australia to undertake the discovery phase of the redevelopment of the OGTR website.

Squiz held workshops in Brisbane and Canberra to obtain stakeholder and public feedback on website usage and needs. They also assessed the website content against Digital Transformation Agency (DTA) requirements. The report has identified potential improvements, including the creation of general content to address community needs and changes to the layout and structure of the website.

IT systems modernisation discovery project

As part of a program of ongoing process improvement, and digital transformation, the OGTR instigated a discovery phase to identify and prioritise business requirements to develop IT solution options for the modernisation of data holdings. This work was also in response to ongoing feedback from our stakeholders relating to modernising the interface and communication channels between the OGTR and its stakeholders. The solution options provided cost estimates which may result in seeking additional funding to proceed with the preferred option. This work aligns with Australian government's digital transformation agenda and could contribute to the implementation of Recommendation 10 of the Final Report of the Review of the Nation Gene Technology Scheme. The Review identified under Recommendation 10 that application processes and IT solutions need to be modernised.

Promoting harmonisation

The Regulator and 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. The OGTR provided inputs and comments to the draft Australian and New Zealand Standards 2243.3:2019, Safety in laboratories, Part 3: Microbiological safety and containment.

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.

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.

The OGTR is also responsible for entering Australian commercial approvals of GMOs into the OECD BioTrack Product Database[11] and the UN Biosafety Clearing-House.[12]

By participating in and presenting at international forums, the OGTR continued to interact with key regulatory counterparts in other countries during 2018–19, including:

[11] The BioTrack Product Database is on the OECD website
[12] The Biosafety Clearing-House is online

- 22nd meeting of the UN Subsidiary Body on Scientific, Technical & Technological Advice, Montreal, Canada, July 2018
- Like-minded Group on Innovative Agricultural Technologies, Natal, Brazil, September 2018
- 6th Global Low Level Presence Initiative Meeting, Natal, Brazil, September 2018
- Association of Biosafety for Australia and New Zealand conference, Wellington, New Zealand, October-November 2018
- 2nd Asia forum on genome editing, Kangneung, Republic of Korea, November 2018
- OECD invasive species workshop, Tarragona, Spain, 31 March 2019
- International Society for Biosafety Research Symposium, Tarragona, Spain, 1–4 April 2019
- Government regulatory scientists workshop, Tarragona, Spain, 4 April 2019
- OECD WGHROB Steering Group on Environmental Considerations, Paris, France, 8 April 2019
- Joint Workshop of OECD WGHROB and Working Group for the Safety of Novel Foods & Feeds (WGSNFF), Paris, France, 8 April 2019
- OECD Conference on Regulation of Externally Applied dsRNA-based Products, Paris, France, 10–12 April
- Convention on Biological Diversity Ad hoc Technical Expert Group on Synthetic Biology, Canada, 4–7 June 2019

In 2018–19, 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.

A delegation from Vietnam's Ministry of Agriculture and Rural Development met with the OGTR in November 2018, as part of their visit to the Department of Agriculture and Water Resources.

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. All permanent employees other than the Regulator are Australian public service staff employed by the OGTR under the *Public Service Act 1999*.

The terms and conditions for non–Senior Executive Service staff at the OGTR are covered by the Department of Health Enterprise Agreement 2019–2022, 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 12.

Table 12: 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 • 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 18th 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:

- Hands Across Canberra
- Communities at Work in Canberra
- Canteen Canberra
- Jeans for Genes.

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

Regulator's Achievement Award

This year, the Regulator's Award recognised teamwork and collaboration as well as innovation in supporting administrative efficiency.

The Plant Evaluation Section (PES) staff received a team award for assessing and processing applications that were outside of their area of expertise. This required staff in the Contained Dealings Section (CDES) being patient and offering support to PES staff, while they dealt with issues outside of their 'technical comfort zone'. Everyone put forward their best efforts and worked together to ensure that application deadlines were met and licences were issued on time.

Emma Collins received an award for innovation and collaboration. In July 2018, the OGTR released new online forms for the first time. Emma Collins managed the project, starting from engagement of the Department of Industry, Innovation and Science through to the User Acceptance Testing, delivery and stakeholder engagement up to release and use. Into the project brief, Emma included training to allow OGTR staff to develop future online forms in-house and to enable maintenance and future enhancements to be made. A very thorough stakeholder engagement plan was developed where communication options were thoroughly explored to ensure value for money and clear messaging. Stakeholder engagement was innovative in that new ways of communication with our stakeholders were trialled, including the use of Vimeo presentations and a webinar. Emma exhibited extraordinary dedication to her team, the online forms project, the office's stakeholders, the Executive and the whole of the OGTR during several months.

Health's Australia Day Awards

The Health Department team involved in the 3rd Review of the National Gene Technology Scheme received a Highly Commended award in the category of Building Strong Relationships at Health's Australia Day awards. OGTR staff were recognised for their part in working collaboratively with the Health Department team, including providing technical input and responding to requests for information about the operation of the gene technology regulatory scheme.

Training and development

OGTR staff undertook 86 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 2018–19, refresher training was given to the emergency control team, which comprises three fire wardens and two first aid officers. 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 2018–19, the OGTR Legal Officer provided introductory and ongoing training for OGTR staff on legal issues (Table 13).

Table 13: Internal training presentations on legal issues, 2018–19

Date	Topic
22 October; 5 November; 22 November	Conflict of Interest
3 December; 13 December	Confidentiality Obligations
12 December; 20 December; 26 February	Licence Conditions
6 March; 19 March; 16 May	Privacy Awareness
12 April; 30 April	Confidential Commercial Information
23 May; 31 May	Administrative Law

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 2018–19 (Table 14).

Table 14: Presentations at the OGTR Forum, 2018–19

Date	Topic and presenter
21 Aug 2018	OECD WGHROB meetings June 2018 – issues and outcomes Dr Peter Thygesen, OGTR
21 Aug 2018	22nd meeting of the Subsidiary Body on Scientific, Technical and Technological Advice: an interesting negotiation Dr Heidi Mitchell, OGTR
28 Aug 2018	Reflections on the APEC agricultural biotechnology workshop Neil Ellis, OGTR
14 Sept 2018	Look at the birdie, and other tales of Australia's first GM sorghum field trial Prof Ian Godwin, University of Queensland
27 Sept 2018	Fruit fly management in Australia as a basis for international market access Dr Craig Hull, Department of Agriculture and Water Resources
23 Oct 2018	Precision medicine in immune disease Prof Carola Vinuesa, Centre for Personalised Immunology
13 Nov 2018	Regulation of Products Used in Vertebrates in the U.S. John Eisemann, USDA APHIS Wildlife Services
20 Nov 2018	GRDC perspectives on genetic technologies Dr Hugo Alonso Cantabrana, GRDC
27 Nov 2018	Like Minded Group and Global Low Level Presence Initiative meetings Neil Ellis, OGTR
04 Dec 2018	Feedback from 2nd Asia forum: gene editing Dr Heidi Mitchell, OGTR
04 Dec 2018	8th Annual ABSANZ Biosafety and Biocontainment Conference Dr Kylie Tattersall, OGTR
23 Jan 2019	The long road to the next banana Prof James Dale, Queensland University of Technology
27 Mar 2019	Predator free 2050 Prof Dan Tompkins, Predator Free 2050 Ltd
13 May 2019	Feedback on OECD meetings Dr Peter Thygesen, OGTR
13 May 2019	Three for the price of one: OECD invasive species workshop, International Society for Biosafety Research symposium, Government regulatory scientists workshop Dr Heidi Mitchell, OGTR
21 May 2019	CRISPR-Cas 9 gene editing technology - What CRISPR can and can't do? Dr Gaetan Burgio, JCSMR, ANU
18 Jun 2019	Understanding regulatee behaviour Dr Deborah Cleland, ANU

Date	Topic and presenter
27 Jun 2019	Identity crisis in water quality management -*Escherichia coli* – an indicator organism? Dr Angelin Samuel, OGTR

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 a high proportion of staff on flexible work arrangements, mostly part-time. Staff have accessed 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.

In 2018–19, 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.

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). Each agency must display on its website a plan showing what information it publishes in accordance with the IPS requirements.[13]

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 2018–19.

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.[14]

[13] The OGTR's Information Publication Scheme Agency Plan is on our website.
[14] The OGTR's Freedom of Information Disclosure Log is on our website.

Presentations 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 15).

Table 15: Presentations in Australia by the Regulator and OGTR staff, 2018–19

Date	Event	Location
June 2019	Australian Animal Health Laboratory staff forum	Geelong
June 2019	Translational Photosynthesis Conference 2019	Brisbane
June 2019	2019 Australian Biosecurity Symposium	Gold Coast
March 2019	Regulation and Compliance for Commonwealth Regulators: Licensing and other approvals: striking a balance between granting a 'ticket to play' and effectively managing risk	Canberra
February 2019	RSPCA Animal Welfare Seminar 2019 “Farm animal welfare & gene technology”	Canberra
November 2018	Practical Biocontainment Practices, CSIRO and ABSANZ	Geelong
November 2018	Regulatory Science Network, Annual Symposium 2018, presentation on Environmental Risk Assessment of Organisms, Harm vs Pathways to Harm - Challenges for Risk Communication	Canberra
October 2018	8th Annual ABSANZ Conference	Wellington
September 2018	2018 Croplife national Members Forum	Canberra
September 2018	Combio2018	Sydney
August 2018	AusCanola 2018 (presentation)	Perth
August 2018	Presentation to Biosecurity Course students	Australian National University, Canberra
August 2018	Presentation to LaTrobe Biotechnology students on OGTR regulation and risk communication	LaTrobe University, Melbourne

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

Table 16: Website activity, 2018–19

Month	Sessions[a]	Users[b]
July	5,289	3,863
August	5,747	3,961
September	5,699	4,016
October	5,661	3,850
November	5,669	4,120
December	3,838	2,857
January	4,327	3,117
February	5,404	4,007
March	6,671	4,735
April	7,474	5,039
May	7,790	5,545
June	5,194	3,599

[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 2018–19 were, in descending order:

1. Guidelines for Certification of Physical Containment 2 Facilities
2. Record of GMO Dealings
3. Technical Review of the Gene Technology Regulations 2001
4. Table of applications and authorisations for Dealings involving Intentional Release (DIR) into the environment
5. Legislation
6. Fact sheets
7. Application to certify facilities
8. Guidelines for Certification of a Physical Containment Level 3 Laboratory
9. Application forms to work with GMOs
10. What are Notifiable Low Risk Dealings (NLRDs)?

The most popular downloaded documents in 2018–19 were:

1. Guidelines for Certification of a Physical Containment Level 2 Laboratory
2. Guidelines for the Transport, Storage and Disposal of GMOs
3. Fact Sheet – Genetically modified organisms in Australia
4. Guidelines for Certification of a Physical Containment Level 2 Animal Facility
5. Types of Dealings with GMOs classified as Notifiable Low Risk Dealings (NLRDs)
6. What Dealings with GMOs are classified as Exempt Dealings?
7. Guidelines for Certification of a Physical Containment Level 1 facility
8. Questions and Answers on the Technical Review of the Gene Technology Regulations 2001
9. List of NLRDs as notified to the Gene Technology Regulator
10. Risk Analysis Framework 2013

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 2018–19, use of the email address declined compared with the previous year (Table 17).

Table 17: Email activity, 2018–19 and 2017–18

Month	Emails	
	2018–19	2017–18
July	35	70
August	48	50
September	43	62
October	48	68
November	117	40
December	30	52
January	45	43
February	185	410
March	55	50
April	49	42
May	33	45
June	42	52
Total	730	984

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 1162 emails during 2018–19 (compared to 1,154 in 2017–18).

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 617 emails during 2018–19 (compared to 510 in 2017–18).

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 1477 emails during 2018–19 (compared to 2,842 in 2017–18).

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

Appendix 1 Membership of statutory committees

Table 18: 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, University of Sydney (NSW)
Dr Graham Bonnett	Research Director, CSIRO Agriculture and Food (Qld)
Associate Professor Orin Chisholm	Program Director, Pharmaceutical Medicine, UNSW (NSW)
Ms Laura Fell	Free range egg farmer, McLaren Vale (SA)
Dr Tessa Gargett	Research Scientist, Royal Adelaide Hospital (SA)
Dr Richard Gordon	Group Leader in Clinical Neuroscience, Advance Queensland Mid-Career Fellow, Faculty of Medicine, 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	Principal Advisor Intellectual Property, Patents and Trade Marks Attorney (WA)
Associate Professor Michael Michael	Medical Scientist, Head, Gene Expression Laboratory, 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)
Dr Jason Smythe	Chief Operating Officer, Monash Institute of Medical Engineering, Monash 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 19: Gene Technology Ethics and Community Consultative Committee members 2018–20

Member	Position
Associate Professor Judith Jones (Chair)	Associate Professor, Australian National University College of Law (ACT)
Ms Paula Fitzgerald	Director and consultant (Vic)
Dr Vaughan Monamy	Retired Associate Professor of Environmental Science and Environmental Ethics, Australian Catholic University (NSW)
Dr Rachel Nowak	Director, Research Marketing and Communications, University of Melbourne (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	Director Adelaide Centre for Bioethics and Culture (SA)
Dr Frances Shapter	Clinical Skills Hub Coordinator and Lecturer in Veterinary Science, School of Veterinary Science, The University of Queensland (Qld)
Dr Robert Sward (GTTAC cross-member)	Director, BioBotanicals Consulting (Vic)
Mrs Emma Thomas	Farmer and agricultural consultant (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.

Appendix 2 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).

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 Environment Minister, 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 20 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.

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.

More information on the various categories of GMO authorisations and their assessment processes are available on the OGTR website.

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

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

Table 20: 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 GMO 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 21. 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.

Table 21: 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

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.

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
PBS	Portfolio Budget Statements

Accredited organisation	An organisation that is accredited under section 92 of the *Gene Technology Act 2000*
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

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)	42–44	Any breaches of conditions of a GMO licence that have come to the Regulator's attention during the financial year
136(1A)(c)	30	Emergency dealing determinations made by the Minister during the financial year
136(1A)(d)	30	Any breaches of conditions of an emergency dealing determination that have come to the Regulator's attention during the financial year
136(1A)(e)	36-49	Auditing and monitoring of dealings with GMOs under this Act by the Regulator or an inspector during the financial year