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Department of Health

Office of the Gene Technology Regulator

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

LETTER OF TRANSMITTAL

Australian Government

Department of Health

Office of the Gene Technology Regulator

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 2019 to 30 June 2020.

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 2019 to 30 June 2020.

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
11 September 2020

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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 2019–20 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.

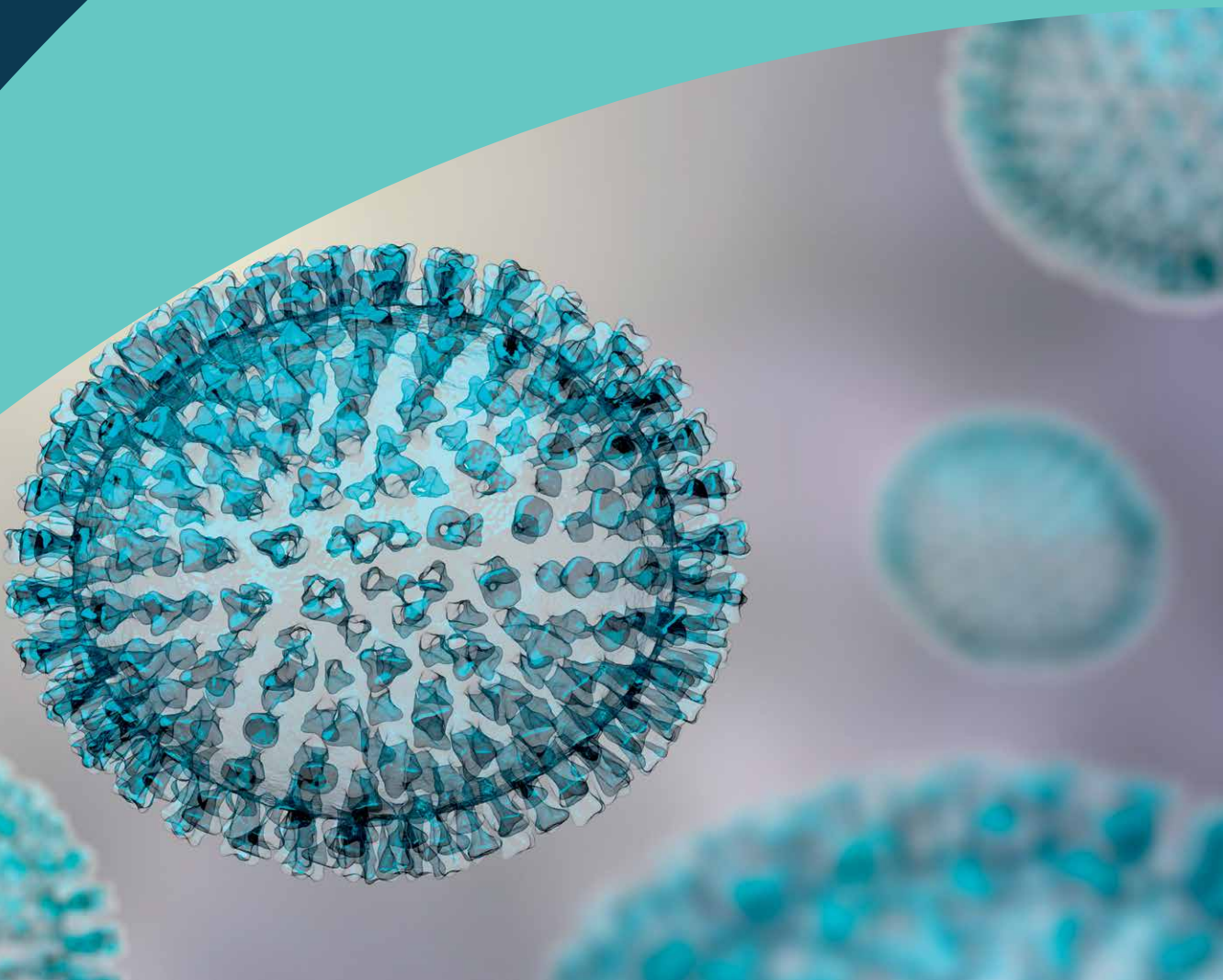
The report contains five chapters:

- **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 2019–20. 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 2019–20 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.
- **Chapter 5: Management and accountability**—provides an overview of the OGTR's resource management practices and reporting against Australian Government accountability principles.

1 The 2019–20 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 1



GENE TECHNOLOGY REGULATOR'S OVERVIEW

This year's annual report is a tale of two times, pre-COVID-19 and during the COVID-19 pandemic. The OGTR like many organisations has been and continues to be impacted by the pandemic and the constant change associated with managing and eliminating the virus. This means that we have had to find ways to modify our work practices so that we continue to support researchers conducting clinical trials, those that are developing important vaccines and life-saving therapies, and those that have had to stop their activities due to destruction of facilities following extreme weather events or lockdowns leading to postponement of field trials.

Contingency planning within the Office started early with help from the department, so that OGTR staff could continue to work efficiently, respond to inquiries and provide assistance as needed. The strength of the OGTR is its staff, whose focus and attitude has not changed despite times of uncertainty and for that I thank them all.

New amendments to the Gene Technology Regulations 2001 commenced in October 2019, providing greater clarity on the regulation of organisms developed using gene editing techniques. This was a noteworthy milestone, as it not only sets direction for continued research in Australia, but presents our position on risk and scientific perspective on these new technologies to the rest of the world.

We completed another Community Attitudes Survey which was published in July 2019. The survey found that Australians in the 16 to 30 age group were more accepting of gene technology and genetically modified organisms (GMOs) than other age groups. Also the rejection or support of genetically modified foods is conditional and likely to move based on knowledge of regulation or scientific evidence of safety. These findings reinforce the need for clear information for the public on the regulation of GMOs in Australia.

We continued our work in supporting the Department to implement recommendations from the third review of the Gene Technology Scheme, and participated in state and territory workshops to inform next steps of implementation.

Throughout this annual report, you will see how the activities of the OGTR have been impacted by the COVID-19 pandemic, and how much of our work has continued in the regulation of genetically modified organisms.

Meeting our performance targets

The Department of Health Portfolio Budget Statements (the PBS), Outcome 5 describes the performance target of the OGTR to protect the health and safety of the Australian community through regulation, monitoring, assessment and/or awareness raising in relation to GMOs. This target is delivered by administering the National Gene Technology Scheme (the Scheme) by assessing applications and issuing approvals, and by conducting routine inspections of certified facilities and licensed activities with GMOs. In addition, this target is supported by a modern, flexible and innovative scheme, ensuring protection of humans and the environment through working with all Australian governments to implement the 27 recommendations outlined in the final report on the third review of the Scheme.

The PBS performance targets were met this year as follows:

- Risk assessments and risk management plans were prepared, and decisions were made within statutory timeframes for 100% of licensed dealings.
- Stakeholders, including the public, were consulted on all assessments for proposed releases 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 the environment from authorised GMOs.

To address the 2019–20 priorities set in the Forum Action Plan as endorsed by Ministers of the Legislative and Governance Forum on Gene Technology (LGFGT), the OGTR assisted the department in consultations conducted from September to November 2019. The consultations were based around an issues paper entitled *Implementing Recommendations of the Third Review of the National Gene Technology Scheme: Phase 1*. The main focus of the consultations were issues related to current definitions in the Act, a look at current risk tiers and changes to those as a means to achieve risk-proportionate regulation against a background of advancement in gene technology, and how to streamline regulatory requirements and processes to support any changes. Submissions to the consultation were considered by the department to further inform the Gene Technology Standing Committee on how to move forward.

Applications and licences: what's new

Our applications are categorised according to whether dealings with a GMO are intended to be released into the environment (DIR) or are contained and not released into the environment (DNIR). This year, only three licences were issued under the DIR category and these were for limited and controlled releases allowing research into Influenza Virus vaccine for humans, a Ross River virus vaccine for horses and use of algae to manufacture modified fatty acids. This is the first year since the start of the scheme that the DIR licence statistics have not included an agricultural crop use.

Under the DNIR category, 20 licences were issued and these included clinical trials for vaccines against infectious diseases, cancer treatments, and gene therapies. Of note were two expedited assessments: one to allow treatment of a resistant bacterial lung infection in a young patient with cystic fibrosis and the other to conduct clinical trials for an active vaccine to reduce the severity of COVID-19 infection in high-risk groups.

The data from this period very clearly show that the majority of work coming to the OGTR is medical-related and involves new applications of GM platforms to treat diseases and genetic conditions.

Monitoring and compliance activities

Due to the COVID-19 pandemic and border restrictions across Australian states and territories, our monitoring and compliance program was quite limited for almost four months as we were unable to have a physical presence while conducting our activities. This meant that more effort was placed on desk-top reviews and staying in regular communication with our regulated entities as their workplaces and situations also changed.

During the period July 2019 to March 2020, OGTR inspected 15 field trial sites for four plant species, namely chickpeas, cotton, sorghum and wheat. This period also saw the lowest number of active field trial sites in the past five years, being 9 out of a total of 56 operating licences. In addition, 96 certified facilities across the country were inspected and 18 DNIR licences were monitored for compliance against licence conditions. Also, 16 practice reviews were conducted mostly on request from the licence holder or the accredited organisations.

The Third Review of the Gene Technology Scheme: implementation phases

While continuing to assist the department in implementing the recommendations from the Third Review of the Gene Technology Scheme, the OGTR has focused efforts on digital service delivery for applications and the development of online forms. This year, seven new forms were released and several new forms are currently under development. It has been pleasing to see the large number of applicants and stakeholders involved in user acceptance testing and maintaining an active involvement in the development phases of this work, so that expectations are met in terms of usability.

International harmonisation and capacity building: sharing our knowledge

Despite the COVID-19 pandemic, the OGTR continued to engage in international fora mostly via online and electronic meetings. In the early part of the year, the OGTR received delegations from the Korean Ministry of Food and Drug Control and a Chinese delegation visiting under the Australia–China Agricultural Cooperation Agreement. Staff also presented at regulatory workshops in Myanmar, the Philippines, Malaysia and Singapore. Most of these workshops focused on regulation of gene-editing crops and our experiences associated with the regulation amendments in Australia. Regular contributions were also made to the work programs of the OECD, namely the OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology and its Steering Group on Environmental Considerations where much effort is put into the development of biology documents and risk assessment framework methodologies.

Our people: our most important resource now and into the future

During this time of change and uncertainty, the OGTR staff have remained focused on achieving outcomes and maintaining operations as effectively and efficiently as possible. The Regulator's Award this year recognised the efforts of our support staff that work hard to keep things going and an individual that organised others to achieve organisational objectives. Justine Smith and Katherine Zhang in the Regulatory Support Unit worked tirelessly to answer questions and manage changes to travel reporting systems while also educating others in new administrative processes. Maria Alonso was acknowledged by colleagues for her enthusiasm and efforts in keeping a team working on development of new guidelines and forms for the conduct of clinical trials.

Challenges ahead

For a regulator to remain pro-active, it is always a work in progress, which is the current status of our implementation activities and work supporting the department to address recommendations arising from the Third Review of the Gene Technology Scheme. While we must continue with our day-to-day work, we are also planning for the future and how to make changes to existing frameworks.

While we are all in this pandemic together, the challenges ahead are about meeting the expectations of government and the community while vaccines for COVID-19 are in various stages of research and development. The work of the OGTR and its risk assessment and compliance processes will continue as part of that effort of safeguarding the Australian people and the environment.

CHAPTER 2

OFFICE OF THE GENE TECHNOLOGY REGULATOR

This chapter provides an overview of the regulatory and corporate governance arrangements for the Gene Technology Regulator (the Regulator), and 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 (LGFGT). 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 pesticides 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 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 Richard Colbeck, Minister for Aged Care and Senior Australians and Minister for Youth and Sport, is the minister responsible for gene technology regulation. 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 Shared Services Agreement. OGTR complies with the Commonwealth Fraud Control Framework 2017, as the department requires. More information will be available in the 2019–20 Department of Health Annual Report. We maintain our own business and risk management plans, against which senior OGTR staff report periodically.

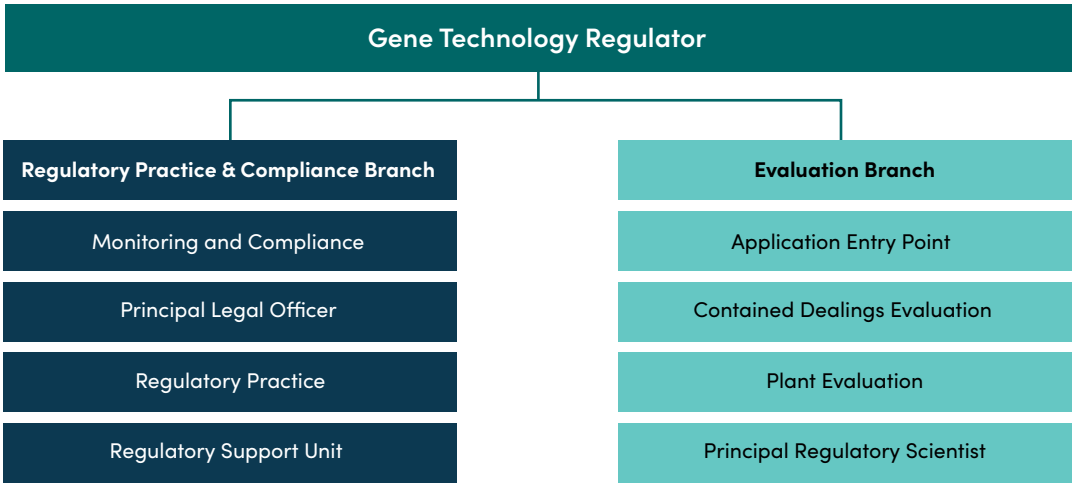
The employment framework for the OGTR is the *Public Service Act 1999*. The department's enterprise agreement, governance policies and practices cover OGTR staff. These include application of appropriate ethical standards under the Australian Public Service Values and Code of Conduct; compliance with 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, 2019–20



OGTR executive

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 Principal Legal Officer, the Monitoring and Compliance Section, the Regulatory Practice Section and the Regulatory Support Unit.

The OGTR's Principal Legal Officer advises the Regulator and the OGTR on how Commonwealth, state and territory laws affect their functions, including setting licence conditions and handling CCI. 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, clinical settings 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 provides technical and operational information to assist the Department of Health team leading implementation of recommendations from the Third Review of the National Gene Technology Scheme. 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 (GTECCC) and the Gene Technology Technical Advisory Committee (GTTAC), 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.

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

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, performance and risk reporting, 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.

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). These include clinical trials of live GMOs such as vaccines or gene therapies. The section also processes applications for certification of containment facilities. This includes inspecting high-level and large-scale facilities, 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 2023.

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 LGFGT, on:

- GMOs
- GM products
- applications made under the Act
- the biosafety aspects of gene technology
- the need for and content of:
  - » policy principles
  - » policy guidelines
  - » codes of practice
  - » 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 Minister Colbeck for a three-year term that commenced on 1 February 2020.

The committee met four times during 2019–20, once in a face-to-face meeting in Canberra and three times 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 LGFGT, on:

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

The current members of the committee, including the Chair, Associate Professor Judith Jones, were appointed by Minister Colbeck for a three-year term that commenced on 1 February 2020.

The committee met twice during 2019–20: once in a face-to-face meeting in Canberra, and once via videoconference. Communiqués from committee meetings, which provide an overview of key matters discussed and resolutions, are published on the OGTR website.

CHAPTER 3

FUNCTIONS OF THE GENE TECHNOLOGY REGULATOR

This chapter describes the operational performance of the Regulator in relation to the functions as required by subsection 136(1A) of the Act and against the performance indicators in Outcome 5 (Regulation, Safety and Protection) of the 2019–20 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 2019–20 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 2019–20 Department of Health Portfolio Budget Statements, is summarised in the second part of this chapter.

Summary of approvals in 2019–20

The OGTR received 1557 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 Regulator granted 710 approvals over a range of 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, currently there are 2079 certified facilities, 49 environmental release licences and 136 contained research licences (Table 2) at 30 June 2020.

Table 1: Applications and notifications, 2019–20

Application type	Received	Withdrawn	Approved[a]	Refused	Ceased consideration[b]	Under consideration[c]
Accreditation	10	–	10	–	–	–
Alternate facility request for an NLRD	1	–	1	–	–	1
Alternate transport, storage or disposal request for an NLRD	1	–	–	–	–	1
CCI declaration for DIR licence	5	–	2	–	–	9
CCI declaration for DNIR licence	10	–	1	–	–	21
CCI declaration for other information	–	–	1	–	–	–
Certification	97	–	100	–	–	6
DIR licence	6	1	3	–	–	3
DNIR licence	20	–	20	–	–	5
Lifting suspension of certification[d]	61	–	60	–	–	2
NLRD notification	829	–	–	–	–	–
GMO Register	1					1
Surrender of accreditation	1	–	2	–	–	–
Surrender of certification	63	–	63	–	–	–
Surrender of DIR licence	4	–	3	–	–	1
Surrender of DNIR licence	1	–	2	–	–	–
Suspension of certification[d]	95	–	96	–	–	–
Transfer of DNIR licence	2	–	1	–	–	1
Variation of certification	304	4	299	–	–	68
Variation of DIR licence	8	–	6	1	–	3
Variation of DNIR licence	38	–	40	–	1	3
Total	**1557**	**5**	**710**	**1**	**1**	**125**

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 2019–20 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 2020.

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 2019–20 were all requested by the applicant.

Table 2: Status of primary applications and notifications from the start of the scheme until 30 June 2020[a]

Application Type	Received	Withdrawn	Approved	Not Approved[b]	Under consideration[c]	Current	Expired	Surrendered
Cert	4614	146	4457	5	6	2082	335	1887
DIR	175	18	149	5	3	49	1	99
DNIR	624	114	483	2	5	136	155	192
NLRD	11202	35	n/a	n/a	n/a	n/a	7953	n/a
Total	**16615**	**313**	**5089**	**12**	**14**	**2267**	**8444**	**2178**

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*.

c Under consideration as at 30 June 2020.

Primary applications

Licences for dealings involving intentional release of GMOs

Dealings involving intentional release (DIR) of GMOs to the environment require authorisation by a licence. DIR licenses may contain specific conditions to manage any identified risks. The Regulator issued three DIR licences during 2019–20 (Table 3), with three further applications under consideration as at 30 June 2020.

Details of the traits introduced into the organisms for release are provided in Table 3. The three licences issued in 2019-20 were for the following limited and controlled releases:

- a field trial of GM microalgae
- a clinical trial of a live attenuated GM influenza vaccine
- a trial of a GM vaccines against Ross River virus infection in horses.

No DIR licences for commercial release of GMOs were issued in 2019–20. Of the three DIR licences issued in 2019–20, one was issued to a company, 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, 2019–20

DIR no.	Applicant	Parent organism	Introduced trait	Type of release	Received	Issued
DIR 171	Clinical Network Services (CNS) Pty Ltd	*Influenza virus*	Vaccine - Altered antigen expression; Attenuation	Limited and Controlled Release	21/10/2019	10/06/2020
DIR 170	The University of Queensland	*Ross River virus*	Resistance against Ross River virus infection	Limited and Controlled Release	02/07/2019	23/01/2020
DIR 169	The University of Queensland	*Nannochloropsis oceanica*	Modified fatty acid production; inability to use nitrate	Limited and Controlled Release	24/06/2019	16/01/2020

DIR = dealings involving intentional release of a GMO into the environment

The types of organisations to which DIR licences have been issued since commencement of the scheme are shown in Figure 2. Of the 149 DIR licences issued to date, 76 (51%) have been to companies, 5 (3%) to research institutes, 44 (30%) to government agencies and 24 (16%) to universities (Figure 2).

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

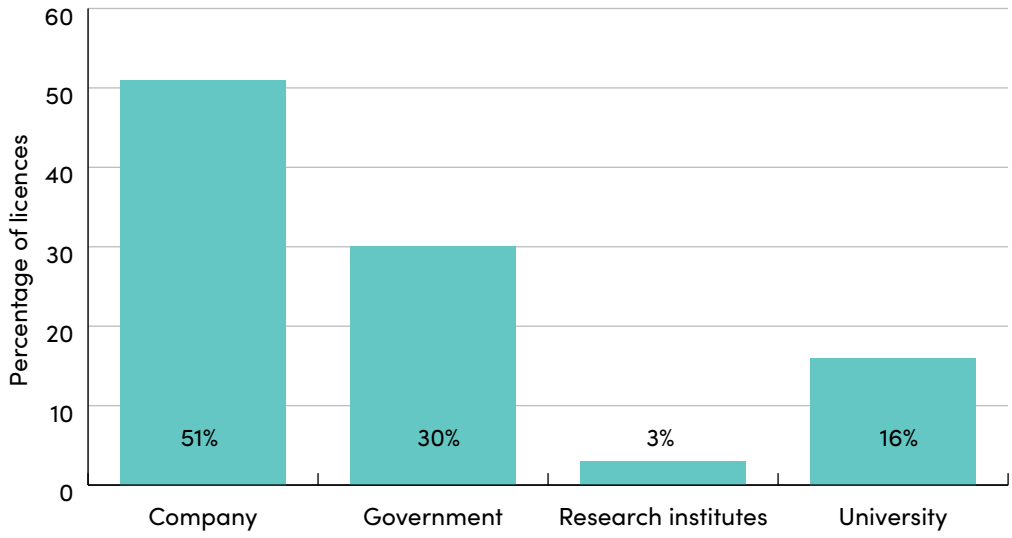
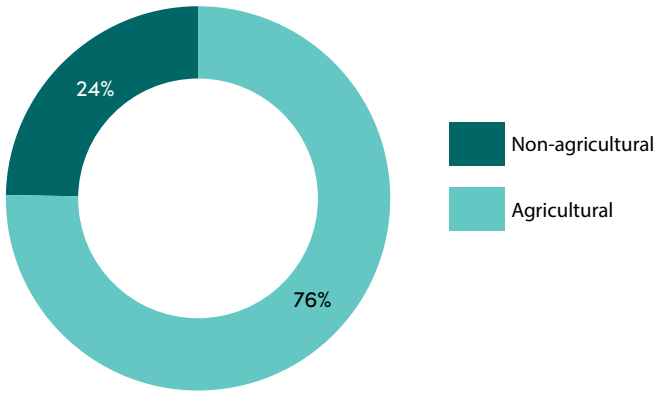


Figure 3: Agricultural vs non-agriculture purposes of DIR licences current as at 30 June 2020



One hundred and thirty one of the 149 DIR licences issued since the commencement of the scheme were for agricultural purposes including GM crops and algae. The remainder are for medicinal applications. Forty-nine of the 149 DIR licences issued since the beginning of the scheme were current at 30 June 2020. This consists of 37 agricultural licences and 12 non-agricultural (Figure 3).

Twenty nine of the current DIR licences 29 (59%) were issued to companies, five (10%) to government organisations, five (10%) to research institutes and ten (21%) to universities (Figure 4). Four (8%) of the DIR licences were held by organisations in the ACT, two (4%) in NSW, 16 (33%) in Qld, two (4%) in SA and 25 (51%) in Victoria (Figure 5).

Figure 4: Distribution of DIR licences current as at 30 June 2020, by organisation type

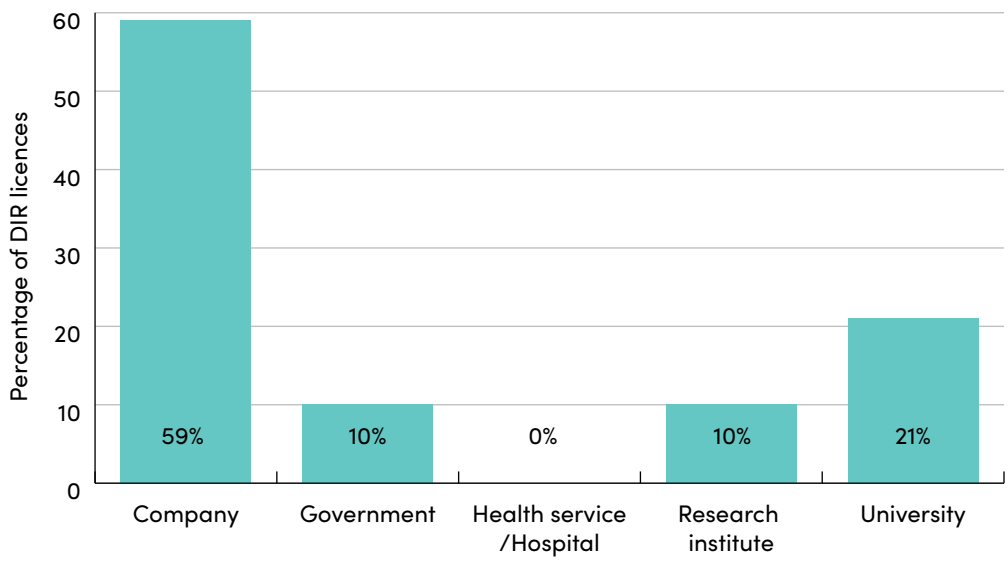


Figure 5: Distribution of DIR licences current as at 30 June 2020, by headquarters

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. DNIR licences include conditions that manage any identified risks. This category also includes clinical trials of live and viable GMOs that meet certain containment criteria.

In 2019–20, the Regulator issued 20 DNIR licences (see Table 4). All decisions were made within the statutory time limit of 90 days. The Regulator was considering a further five DNIR applications at 30 June 2020.

Eleven of the DNIR licences issued in 2019–20 were for clinical trials of vaccines for protection against infectious diseases, cancer treatments or treatment for a bacterial infection; seven were for laboratory research into human diseases and potential treatments; and one was for supply of a gene therapy for inherited blindness. One of the clinical trials (DNIR-622) was for a live recombinant vaccine to reduce incidence and severity of COVID-19 infection in high risk groups. One of the licences authorised the use of a GMO to treat a young patient with cystic fibrosis who had acquired a bacterial lung infection that was resistant to other treatments (DNIR-620). Both of these licence applications required expedited assessment.

Table 4: DNIR licences issued, 2019–20

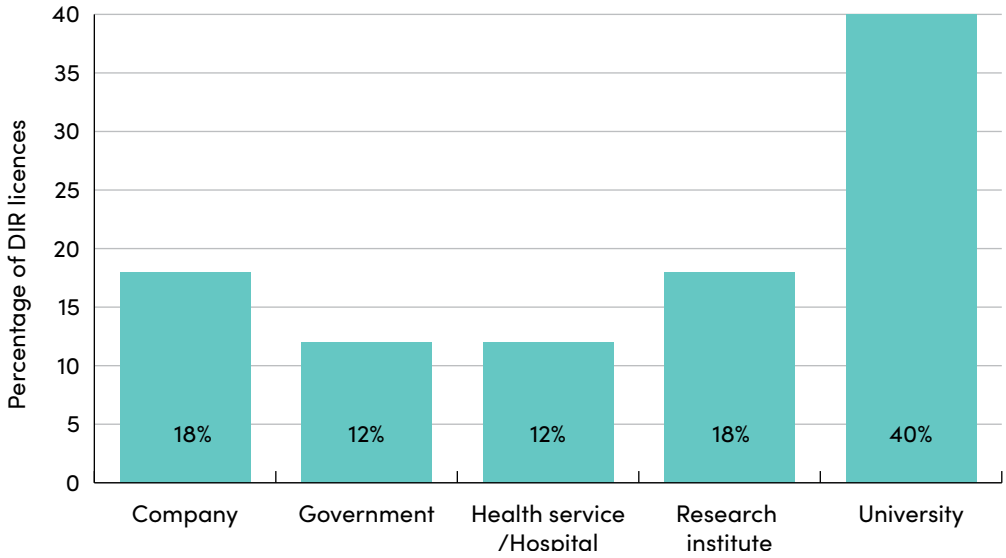
DNIR No.	Applicant	Title	Received	Issued
DNIR-622	Accelagen Pty Ltd	rBCG Vaccine to reduce incidence and severity of COVID-19 infection in high risk groups	2-6-2020	9-6-2020
DNIR-620	The Children's Hospital at Westmead	Therapeutic treatment of paediatric patient with cystic fibrosis and *Mycobacterium abscessus* pulmonary disease	15-4-2020	22-4-2020
DNIR-617	Griffith University	GM HIV that are more infectious than wild type HIV	13-2-2020	9-6-2020
DNIR-616	The University of Queensland	Understanding influenza virus pathogenesis	21-2-2020	11-6-2020
DNIR-615	Novartis Pharmaceuticals Australia Pty Limited	Supply of Luxturna (voretigene neparvovec) for the treatment of patients	13-2-2020	26-5-2020
DNIR-614	QIMR Berghofer Medical Research Institute	Manufacture and characterisation of a P. falciparum NF54 Inducible Gametocyte Producer (NF54/iGP3) Master Cell Bank for use in Phase I Clinical Trials utilising the Induced Blood Stage Malaria Infection Model	6-2-2020	18-5-2020
DNIR-613	The University of Queensland	Antibiotic resistance gene transfer in bacteria from water sludge	6-2-2020	28-5-2020
DNIR-612	University of New South Wales	Identification of protective anti-HCV antibodies in subjects that clear infection to inform vaccine design	10-1-2020	8-5-2020
DNIR-611	Monash University	Understanding how *Helicobacter pylori* causes disease	11-11-2019	11-3-2020
DNIR-610	Clinical Network Services (CNS) Pty Ltd	Clinical Trials with Zika Chikungunya Vaccine (SCV1002)	25-10-2019	2-3-2020
DNIR-609	Clinical Network Services (CNS) Pty Ltd	Clinical Trials with Hepatitis Treatment Vaccine (VTP-300)	21-10-2019	24-2-2020
DNIR-606	Peter MacCallum Cancer Centre	Clinical Study GO-004: An International Phase 1/2 Study of GRT-C901/GRT-R902, a Neoantigen Cancer Vaccine, in Combination with Immune Checkpoint Blockade for Patients with Advanced Solid Tumours	19-9-2019	15-1-2020
DNIR-605	Clinical Network Services (CNS) Pty Ltd	Clinical evaluation of GT005 in patients with age-related macular degeneration	6-9-2019	8-1-2020
DNIR-604	Clinical Network Services (CNS) Pty Ltd	An Immune Stimulating Oncolytic HSV-1 for use in Clinical Trials in Patients with Solid Tumours (VG161)	25-6-2019	22-10-2019
DNIR-603	Monash University	Limiting EAE through transplantation of HSCs	26-6-2019	21-10-2019
DNIR-602	TheraVir Pty Ltd	A clinical trial with a herpes simplex virus GMO (T3011) in patients with solid tumours	20-5-2019	26-9-2019
DNIR-601	IQVIA RDS Pty Ltd	BacTRL-IL-12 Phase 1 Trial in Humans with Various Cancers	3-5-2019	6-9-2019

DNIR No.	Applicant	Title	Received	Issued
DNIR-600	BioMarin Pharmaceutical Australia Pty Ltd	Studies to evaluate the efficacy and safety of BMN 270, an Adeno-Associated Virus vector-mediated gene transfer of human factor VIII in haemophilia A patients	17-4-2019	28-8-2019
DNIR-599	Medpace Australia Pty Ltd	A Phase 3, Open-Label, Randomized, Parallel Group Study to Evaluate the Efficacy and Safety of Intrapleural Administration of Adenovirus-Delivered Interferon Alpha-2b (rAd-IFN) in Combination with Celecoxib and Gemcitabine in Patients with Malignant Pleural Mesothelioma	25-3-2019	1-8-2019
DNIR-598	PPD Australia Pty Ltd	A Phase 1, double blind, randomized, placebo-controlled study to evaluate the safety and immunogenicity of Dengusiil in healthy adults	15-3-2019	13-8-2019

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

The types of organisations to which DNIR licences have been issued since commencement of the scheme are shown in Figure 6. Of the 483 DNIR licences issued to date, 191 (40%) have been to universities, 89 (18%) to research institutes, 86 (18%) to companies, 60 (12%) to health services/hospitals and 57 (12%) to government agencies.

Figure 6: Types of organisations issued with DNIR licences since commencement of the Act



One hundred and thirty six (136) of the 483 DNIR licences issued since the beginning of the scheme were current at 30 June 2020. Of these:

- 120 (88%) were medical, 16 (12%) were non-medical (Figure 7).
- 31 (23%) are held by companies, 11 (8%) by government organisations, seven (5%) by health services or hospitals, 28 (21%) by research institutes and 59 (43%) by universities (Figure 8).
- Four (3%) of the current DNIR licences were held by organisations in the ACT, 23 (17%) in NSW, 43 (32%) in Qld, 11 (8%) in SA, 49 (36%) in Victoria and six (4%) in WA (Figure 9).

Figure 7: Medical vs non-medical focus of DNIR licences current as at 30 June 2020

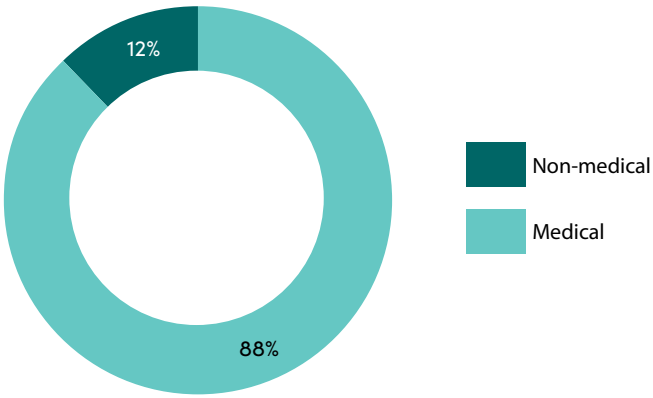


Figure 8: Distribution of DNIR licences current as at 30 June 2020, by organisation type

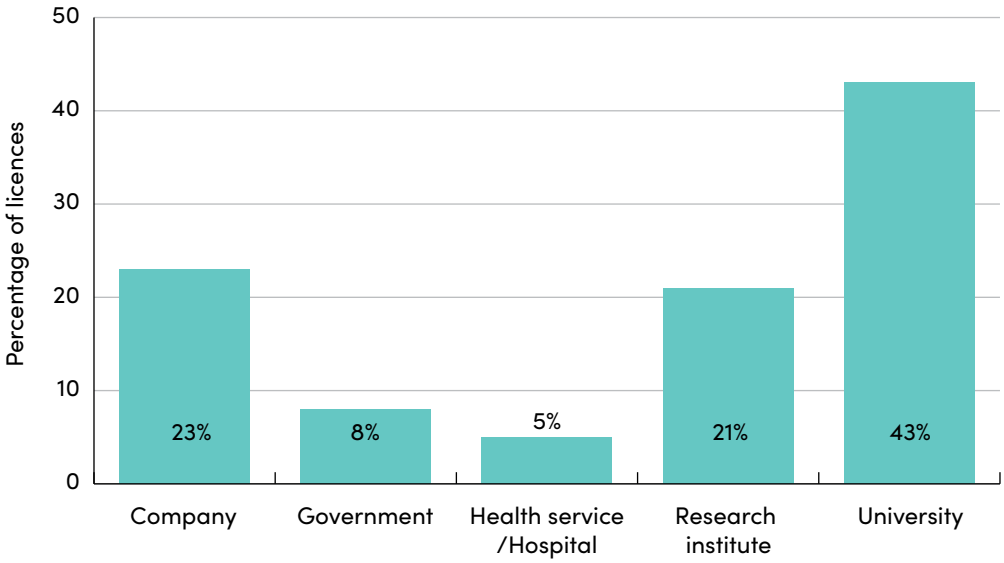


Figure 9: Distribution of DNIR licences current as at 30 June 2020, by headquarters

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. The criteria are published in Schedule 3, Parts 1 and 2 of the GT Regulations. NLRDs can be conducted for a maximum of five years after which they expire and a new NLRD must be assessed by an institutional biosafety committee (IBC) in order for the dealings to continue.

During 2019–20, 829 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 2019–20 are shown in Figure 10. The proportion of NLRDs notified by each organisation type which were current as at 30 June 2020 is shown in Figure 11. The proportion of NLRDs notified in each state or territory which were current as at 30 June 2020 is shown in Figure 12.

Figure 10: Types of organisations that notified NLRDs in 2019–20

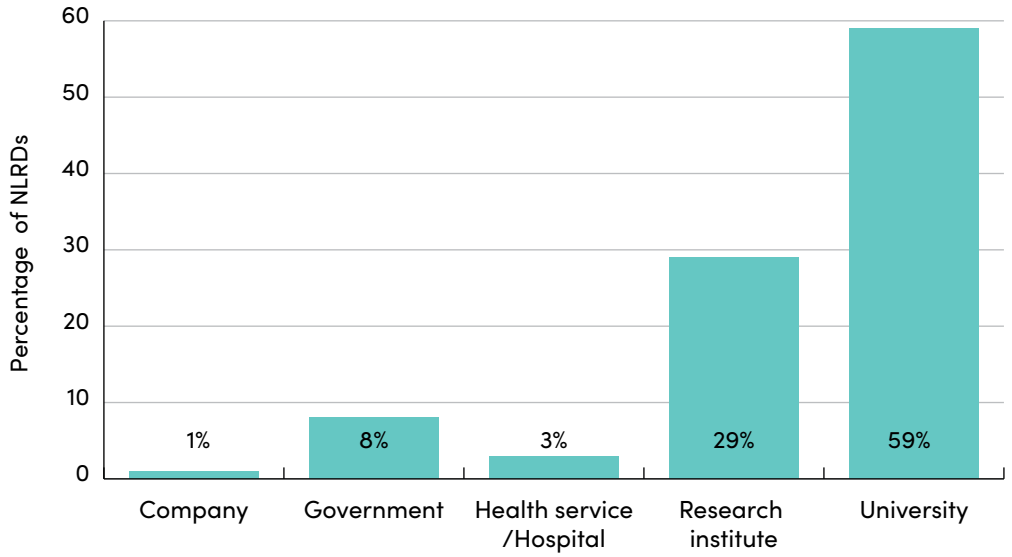
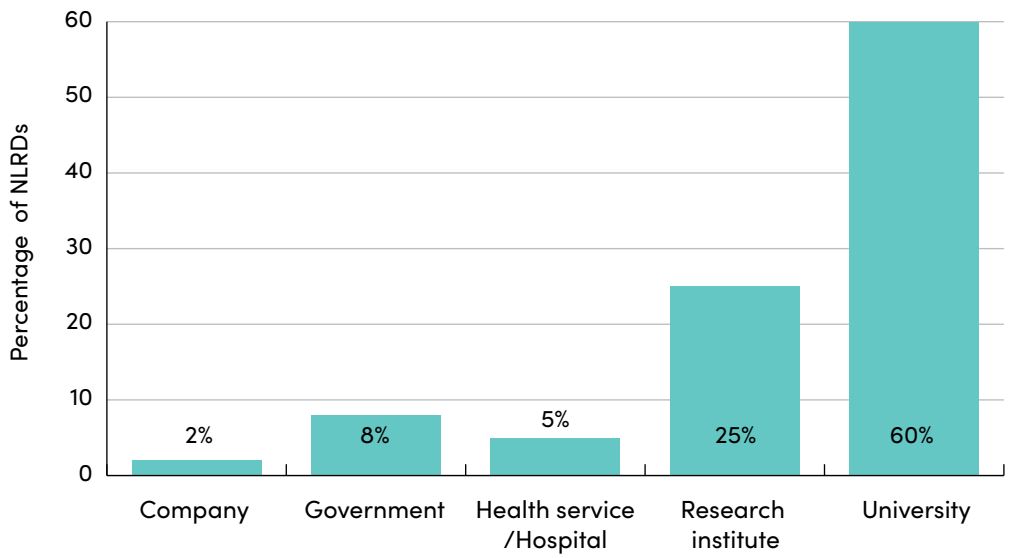


Figure 11: Types of organisations, holding current NLRDs as at 30 June 2020*



*NLRDs are current for five years after assessment

Figure 12: Distribution of all current NLRDs as at 30 June 2020, by state or territory

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 (Regulation 13(2)). Transport, storage and disposal of GMOs in the course of NLRDs may happen outside of approved facilities if conducted according to the Regulator's *Guidelines for Transport, Storage & Disposal of GMOs*, or alternate requirements agreed by the Regulator (Regulation 13(3).

During 2019–20, the Regulator received one request for alternate transport, storage and disposal of GMOs in connection with an NLRD which was still under consideration at the end of the period. The Regulator approved one alternate facility request with one request still under consideration at the end of the period. Eight alternate facility requests and eight alternate transport, storage and disposal requests have been approved since the relevant provisions in Regulation 13 were introduced (September 2011).

Dealings placed on the GMO Register

The Regulator may determine that dealings with GMOs be included 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. The determinations are legislative instruments that are not subject to disallowance but the instrument must still be tabled in parliament.

During 2019–20, there were no new listings on the GMO Register. One application was received, to place dealings with three GM carnations on the GMO Register; this was still under consideration at the end of the reporting period.

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 2019–20, 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 2019–20, there were no new inadvertent dealings licences issued, no applications were received and none were in effect.

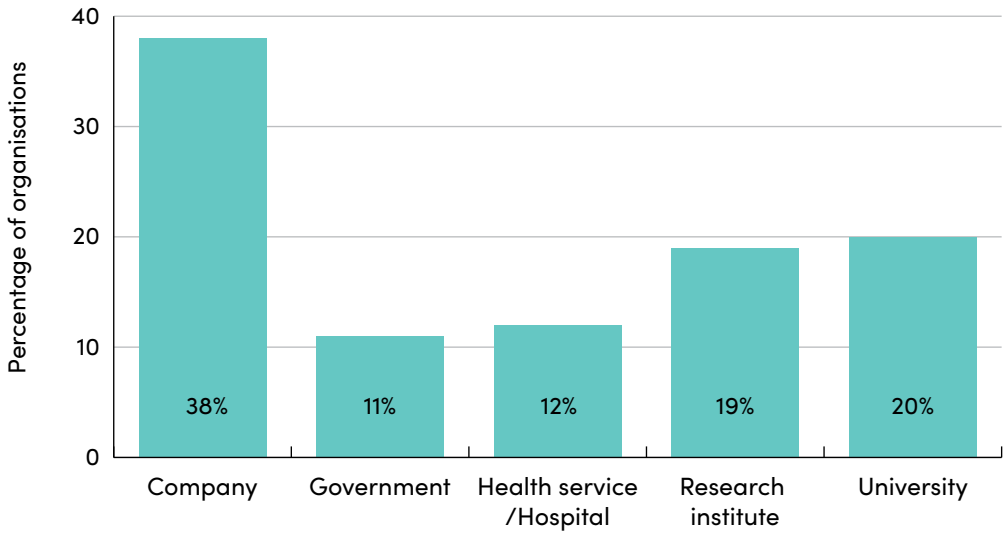
Accreditation of organisations

Organisations may apply to the OGTR for accreditation under section 91 of the Act and the Regulator requires that 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 2019–20, 10 accreditations were issued, with a total of 180 organisations holding accreditation at 30 June 2020 (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 (63%) are primarily publicly funded, i.e. government, hospital or health service university or research institute. (Figure 14).

Figure 13: Organisations accredited as at 30 June 2020, by location of headquarters

Figure 14: Types of organisations accredited as at 30 June 2020



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, and the type of organisms they are intended to contain. The classifications relate to the structural integrity of buildings and equipment, and to the handling practices used by people working in the facility. Physical containment level 1 (PC1) facilities are used to contain organisms posing the lowest risk to human health and the environment. PC level 4 (PC4) facilities provide the most secure and stringent containment conditions. The Regulator has issued guidelines for certification for the common types of facility as represented in Table 5. The guidelines are informed by the Australian standard AS/NZS 2243.4:2010, and by international best practice.

During 2019–20, 100 new certifications for physical containment facilities were issued. There was one new high level facility (PC3 laboratory) certified in 2019–20 which was inspected by OGTR staff prior to certification.

The number of OGTR-certified facilities at 30 June 2020 is listed by facility type and containment level in Table 5. PC2 laboratories are the most common type of facility certified by the Regulator (1146 PC2 laboratories).

Table 5: Number of OGTR-certified facilities as at 30 June 2020

Facility type	PC1[a]	PC2	PC3	PC4a	Total
Animal	–	239	5	–	244
Aquatic	–	33	–	–	33
Constant Temperature Room	–	41	–	–	41
Facility	326	–	–	4	330
Invertebrate	–	54	2	–	56
Laboratory	–	1146	25	–	1171
Large Grazing Animal	–	57	–	–	57
Large Scale Facility	–	19	–	–	19
Plant	–	131	–	–	131
Total	**326**	**1720**	**32**	**4**	**2082**

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 2020.

The types of organisations issued with certifications in 2019–20 were predominantly universities (67%), companies (16%) and research institutes (11%). The types of organisations holding certifications as at 30 June 2020 were predominantly universities (58%), research institutes (18%) and government agencies (13%) (Figure 15). This distribution corresponds with the high number of authorisations for dealings requiring containment (NLRDs and DNIRs) held by universities and research institutes (see Figures 8 and 11). 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 2020, by organisation type

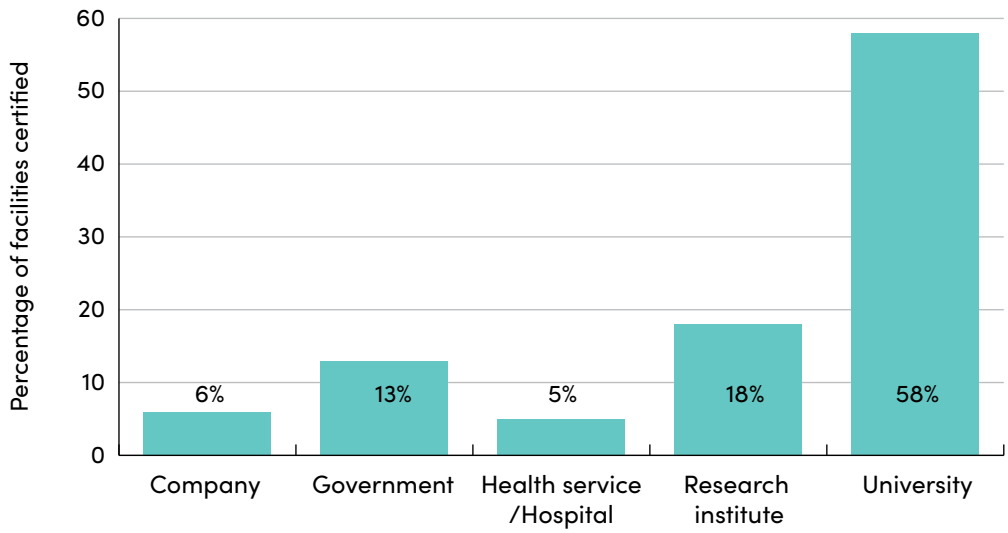


Figure 16: Distribution of OGTR-certified facilities as at 30 June 2020, by location

Application trends

The numbers of most authorisation types issued during 2019–20 were similar to those in previous years (Table 6). However, there was a large increase in the number of DNIRs authorising clinical trials of vaccines and gene therapies compared to previous years. Two of the three DIR licences were also for trials of a human and an animal vaccine.

Table 6: Data for approval of main types of applications, 2015–16 to 2019–20

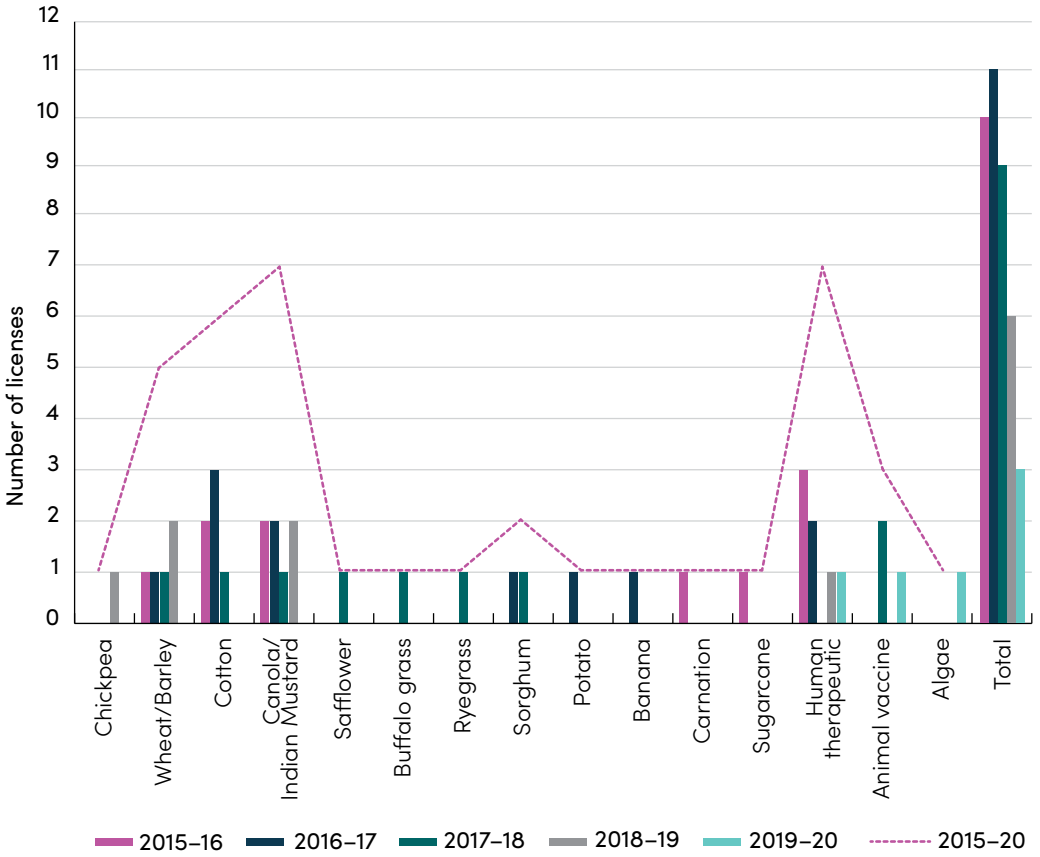
Application type	2015–16	2016–17	2017–18	2018–19	2019–20
Accreditation	4	3	9	8	10
Certification	125	162	135	114[a]	100
DIR	9	9	9	6	3
DNIR	7	10	9	11	20
NLRD	769[a]	820[a]	845[a]	849[a]	829

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 Some figures which were accurate at the time they were originally reported have been updated to reflect information received after the cut off period

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. New crop licences in the last five years include trials of sorghum, chickpea, potato and buffalo grass. There was a marked drop in the number of applications and licences for GM crops in 2019–20 with no new licences (limited and controlled or commercial release) for agricultural crops issued this period for the first time since the beginning of the scheme.

Figure 17: Focus of DIR licences, 2015–16 to 2019–20



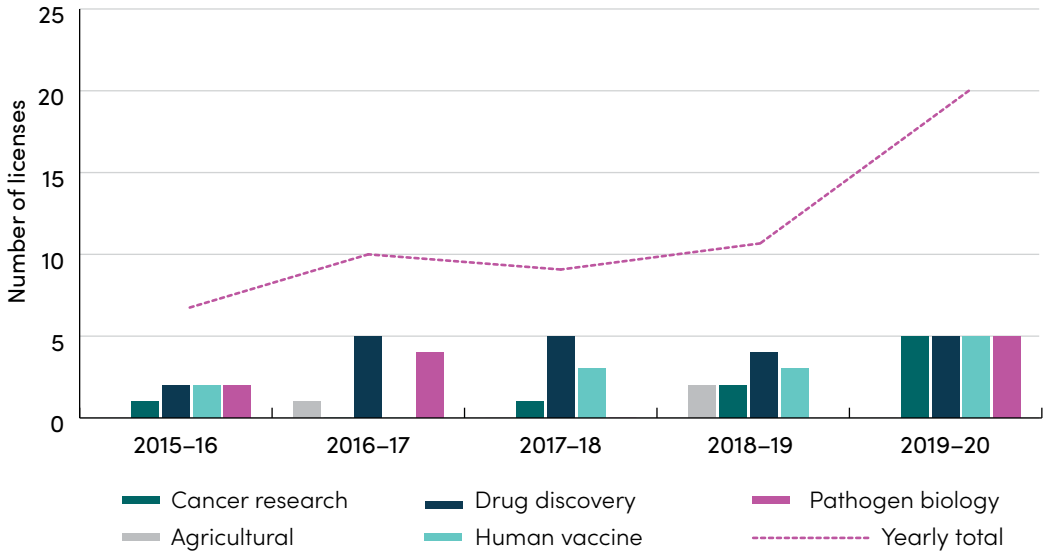
In 2019–20 there was a marked increase in the number of DNIR licence applications received. DNIR licences issued for contained research continue to be dominated by medical research with only three licences out of the 57 issued in the last five financial years authorising agricultural work involving plants or animals (Figure 18). Drug discovery and testing is the most common type of research with 21 licences issued. Thirteen licences were issued for vaccine development and testing, and 11 for research into the biology of pathogens. Nine licences were issued for research into cancer and its treatment.

There has also been an increase in the number of DNIRs issued for clinical trials. Since 2016-17, there has been an increase in the proportion of accreditation issued to organisations involved in human clinical trials/and or human therapeutic GMO research and development (Table 7). This suggests increased research interest and activity in the area of human therapeutic GMOs.

Table 7: DNIR licences issued and accreditation applications issued related to human therapeutic GMOs

	2015–16	2016–17	2017–18	2018–19	2019–20
Clinical trial DNIRs	2	2	3	6	11
Proportion of accreditation applications issued to organisations involved in clinical trials or human therapeutic GMO development.	0%	67%	56%	88%	80%

Figure 18: Fields of research authorised under DNIR licences, 2015–16 to 2019–20



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 2019–20, the Regulator made four CCI declarations. Decisions on a further 30 applications were pending as at 30 June 2020.

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 70 surrender requests in 2019–20 and approved 63 for surrender of certifications of facilities, three for surrender of DIR licences, two for surrender of a DNIR licence and two for surrender of accreditation.

Variations

Authorisation 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 with guidance on the type of information to include in their application for a variation.

The Regulator approved 350 variation requests in 2019–20 (see Table 1). Of these, 6 were for DIR licences, 40 were for DNIR licences and 299 were for certifications. Around 75% of the variations to certifications were for extending the period of authorisation which has not differed greatly over the past 10 years. Eight higher-level containment facilities (1 PC2-large scale, 1 PC3 Animal, 4 PC3 Laboratory and 2 PC4 Facilities) were inspected prior to extension of the certification period. These inspection activities were impacted by the implementation of COVID-19 response measures, including border closures, travel restrictions and physical distancing restrictions throughout February to June 2020. Two PC2-large scale facilities, 6 PC3 laboratories, 1 PC3 Invertebrate and 2 PC4 facilities were granted short term extensions to facility authorisations based on information from desk-top audits. The 2 PC4 facilities that were extended by audit had been inspected by OGTR staff 12 months earlier.

Monitoring dealings with genetically modified organisms

This section provides information on the OGTR's inspection activities during 2019–20. Due to the COVID-19 pandemic travel restrictions some of the monitoring and compliance activities were conducted in a desktop capacity between April and June 2020, comprising:

- one monitoring inspection of a DIR licence
- two monitoring inspections of DNIR licences
- three monitoring inspections of certified facilities
- four Practice Reviews of clinical trials and certified facilities.

Inspections of DIR licences

The Regulator's strategy for monitoring of trials for compliance with licence conditions 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 2019–20, there were 50 DIR licences in force held by 23 accredited organisations. These comprised:

- 22 commercial release licences (17 for plant crops, 4 for human clinical products and 1 animal vaccine product)
- 28 limited and controlled release licences (19 for plant field trials, 5 human clinical trials, 3 animal vaccine trials and 1 microalgae research licence).

None of the commercial release licences imposed conditions that necessitated site inspections. The OGTR inspected 6 of the 19 limited and controlled plant field trial licences (which may have comprised multiple site visits per licence), and one animal vaccine trial licence.

Outcome of inspection activities

The Regulator implements a risk-based selection process to identify limited and controlled release field sites and research or clinical trial 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 2019–20, 56 licensed field trial sites were operating, 9 of which were current and 47 were subject to post-harvest monitoring conditions. Twenty-seven per cent of the plant field trial sites were inspected in the year. A breakdown of the number and proportion of sites inspected in 2019–20 is provided in Table 8.

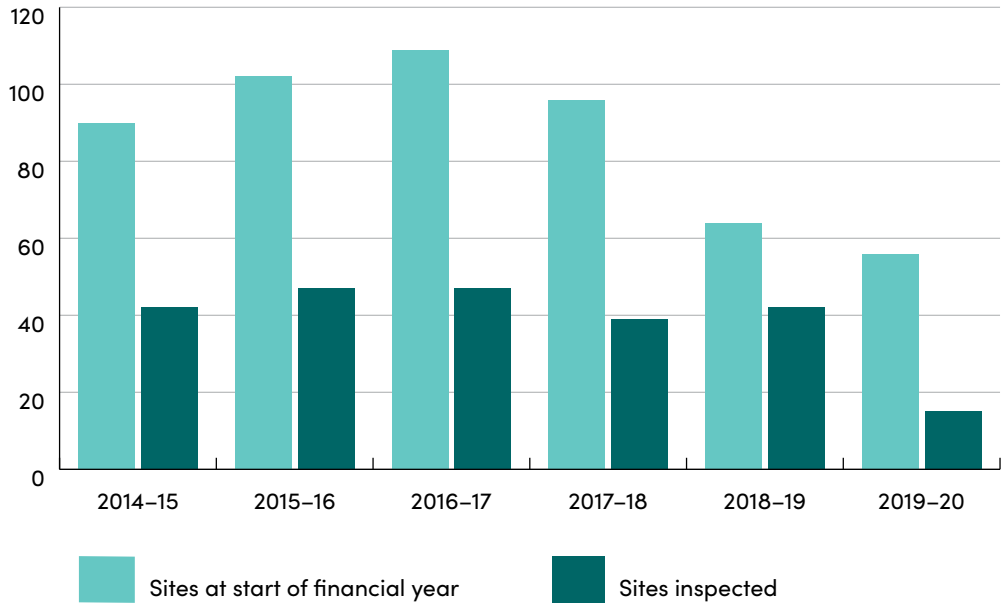
4 Details are in the Monitoring Protocol on the OGTR website

Table 8: Proportion of plant DIR field trial site inspected in each quarter of 2019–20

Reporting period	Current sites	Post-harvest monitoring sites
July–September 2019	1/9	3/47
October–December 2019	2/9	4/42
January–March 2020	1/11	3/39
April–June 2020	1/7	0/35
Total inspections	5	10

The number of active field-trials in 2019–20 was the lowest in the last five years. The number of inspections has remained reasonably consistent since 2014–15, with a significant reduction during the latter half of 2019–20 primarily due to travel restrictions imposed by the COVID-19 pandemic (Figure 19).

Figure 19: Number of sites and number inspected each year, 2014–20



A PC2 Plant Containment facility

A seed planter used on a field trial site in Queensland

Types of GM crops inspected

OGTR inspected four plant species across 56 field trial sites during 2019–20 (Table 9).

Table 9: Number of licensed GM plant DIR trial sites at beginning and end of 2019–20, and number inspected in 2019–20, by plant type

Species	Trial sites as at 1 July 2019	Trial sites as at 30 June 2020	Trial sites inspected during 2019–20
Banana	2	2	0
Canola	1	0	0
Cotton	12	12	3
Indian mustard	1	0	0
Perennial ryegrass	1	1	0
Sorghum	3	3	4*
Sugarcane	10	0	0
Wheat	19	15	7
Wheat and barley	7	4	0
Chickpea	0	1	1

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

* Throughout the course of 2019-20 there were four sites for this licence, including one planting and one site sign-off. All sites were inspected.

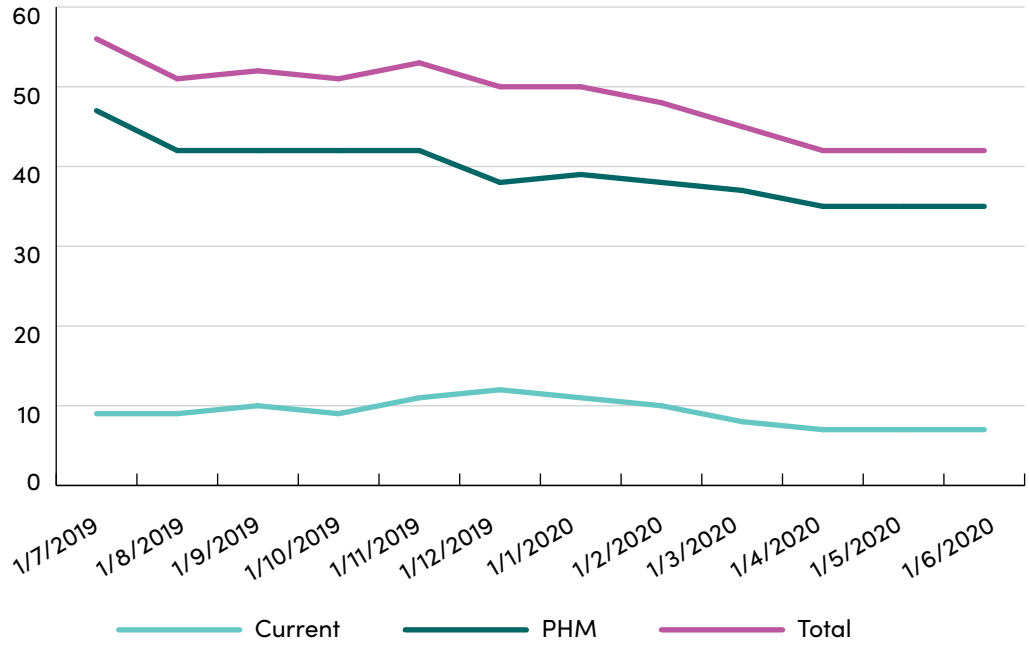
A post-harvest crop of wheat on a GM cotton site in New South Wales

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 are 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 2019–20.

Figure 20: Number of DIR field trial sites and their status during 2019–20



PHM = post-harvest monitoring

Locations of field trial site inspections

In 2019–20, the OGTR inspected field trial sites in all states and territories where field trials were being undertaken, except South Australia, Western Australia and Northern Territory. No trials were undertaken in Tasmania during 2019–20 (Table 10).

Table 10: Number of DIR plant field trial sites and OGTR inspections in 2019–20, by state and territory

Jurisdiction	Trial sites at 1 July 2019	Trial sites at 30 June 2020	Site inspections
ACT	6	4	6
NSW	6	6	3
NT	2	2	0
Qld	17	9	5
SA	7	7	0
Vic	4	3	1
WA	14	7	0
Tas	0	0	0
Total	**56**	**38**	**15**

Inspections of contained dealings

OGTRs monitoring program includes GMO dealings conducted in clinical facilities 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.

The OGTR has received an increasing number of clinical trial applications, and therefore Monitoring and Compliance activities are commensurately focused on these activities to ensure compliance and to assist licence holders new to the gene technology scheme in achieving best practice.

During 2019–20, 96 certified facilities were inspected across the range of facility types (Table 11); this includes 7 of the 54 higher-level containment facilities that had certification approvals in force at the beginning of 2019–20 (representing 13%).

In addition, 18 DNIR licences in force during 2019–20 were subject to monitoring inspection or practice reviews.

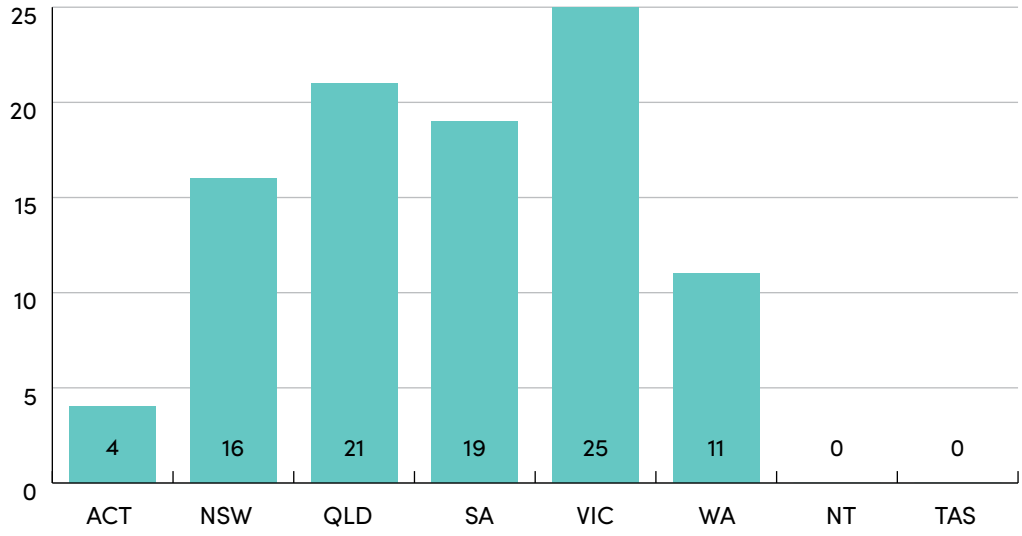
Table 11: Number of inspections of certified facilities (by type) conducted during 2019–20

Containment type	PC level and facility type	Inspections
Lower level	PC1 Facility	1
	PC2 Animal	8
	PC2 Laboratory	60
	PC2 Plant	5
	PC2 Aquatic	6
	PC2 Large Grazing Animal	8
	PC2 Constant Temperature	0
	PC2 Invertebrate	1
Higher level	PC2 Large scale	1
	PC3 Laboratory	3
	PC3 Animal	1
	PC4 Facility	2
Total		**96**

Locations of facility inspections

Certified facilities are located in all Australian states and territories (Figure 16). In 2019–20, monitoring activities took place in each state and territory except the Northern Territory and Tasmania (Figure 21).

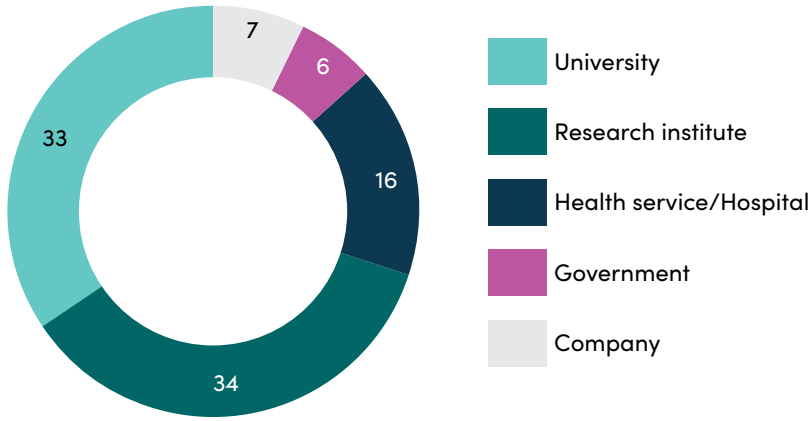
Figure 21: Number of certified facility inspections in 2019–20, by state and territory



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 2019–20 by organisation type. Research Institutes comprised the majority of inspections followed by universities, health services/hospitals, companies and government.

Figure 22: Certified facility inspections in 2019–20, 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 2019–20, 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 2019–20, no DIR licence holders were found to be non-compliant.

Non-compliance findings for GMO dealings not involving intentional release

In 2019–20, non-compliances were identified against two DNIR licences. The findings are outlined below.

Organisation	Griffith University
Licence number	DNIR-535
Title of Project	Investigation of malaria parasite proteins
Findings	Prior to undertaking disposal (decontamination of the GMO or waste containing GMO), Griffith University did not inform a person covered by the licence of relevant licence conditions that applied to them, or obtain signed statements from this person confirming that they had been trained in and understood and agreed to be bound by licence conditions.
Assessment	People and the environment face risks if exposed to incompletely decontaminated GMO. In this instance however information and records provided by the licence holder show that GMOs were treated in a manner as to render them non-viable. As such, no additional risks were identified.
Compliance management	OGTR has reminded Griffith University of their obligation to ensure that all people undertaking licensed dealings are trained in licence conditions and have provided signed statements.

5 The Compliance and Enforcement Policy is on the OGTR website

Organisation	Curtin University
Licence number	DNIR-563
Summary of dealing	The purpose of this dealing is to use GM *Parastagonospora nodorum* in *in vitro* and *in vivo* experiments to develop an understanding of fungal pathogenicity and fungicide resistance.
Findings	1. A small number of people undertook licensed dealings in a certified facility, unaware the facility was not authorised by licence; and 2. Curtin University did not obtain signed statements from several people confirming that they had been trained in, understood and agreed to be bound by licence conditions
Assessment	Persons conducting dealings with the GMO who are not fully trained in licence conditions pose risks to containment, as does the use of facilities which have not been assessed as appropriate to contain the GMOs. In this instance the unauthorised facility where researchers conducted licensed dealings was equivalent to and certified at the same containment level as those listed on the licence. With the exception of using an unauthorised facility, work practices imposed by the licence were followed appropriately and there is no evidence of any harm to human health or loss of containment of the GMO. As such, no additional risks were identified.
Compliance management	Upon becoming aware of the matter, Curtin University: 1. Immediately ceased the licensed dealings in the unauthorised facility, moved the GMOs to an authorised facility and notified the Regulator of the matter; and 2. Subsequently applied for and were granted a licence variation to include the unauthorised facility and conducted training for all persons undertaking licensed dealings, including obtaining signed statements from those persons. No additional actions are required from the licence holder.

Non-compliance findings for notifiable low risk dealings

In 2019–20, no 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 2019–20, 10 certified physical containment facilities were found to be non-compliant with a total of 12 certification conditions. These findings are summarised in Table 12.

Table 12: Number of non-compliances identified in certified facilities during 2019–20, by non-compliance type

Nature of non-compliance	Number
Equipment	0
Personal protective equipment	0
Structure	3
Transport	1
Waste disposal	6
Work practices [a]	2

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

Each incident of non-compliance was assessed according to established OGTR protocols and found to present negligible risk to human health and safety or to the environment, to be minor in nature, and to involve negligible or zero culpability. The OGTR takes a 'cooperative compliance' approach, with an emphasis on education, engagement and awareness-raising. Open communication by the OGTR, backed by strong regulation, has helped to create an environment in which cooperative compliance works from day to day, year to year.

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 GMO 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 16 practice reviews with 16 organisations during this reporting period. This year practice reviews covered five topic areas and the findings for 15 reviews are outlined below; one practice review is still under consideration and the findings thereof will be included in the next reporting period.

GM plants growing in a PC2 plant facility

Preparedness of accredited organisations to undertake licensed dealings involving intentional release of GMOs	
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 reviews focused primarily on the organisations' preparedness to undertake limited and controlled releases of GM wheat, GM chickpea and GM micro-algae. Organisations included in the practice reviews were: The University of Melbourne; Queensland University of Technology; and The University of Queensland. 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 Act. 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 an intentional release – human clinical trials	
Aim	This practice review 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 trial site selection and appropriate use of containment measures; and • staff training and provision of resources necessary to manage compliance obligations.
Participants	The review focused primarily on the organisations' preparedness to undertake licensed clinical trials in humans and included: Merck Sharp & Dohme (Australia) Pty Ltd; BioMarin Pharmaceutical Australia Ltd; GlaxoSmithKline Australia Pty Ltd, IQVIA RDS Pty Ltd; Medpace Australia Pty Ltd; and TheraVir 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 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 Act. 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 an intentional release	
Aim	This practice review 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 trial 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 organisations' preparedness to undertake licensed dealings not involving an intentional release for GM grain import, and for the mode of action of novel drug treatments against *Giardia duodenalis*. Organisations involved in these reviews included: Ridley Corporation Limited; Inghams Group Limited; and Griffith University. The review assessed: • 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 effective compliance performance.
Findings	The review found that: • Suitable arrangements had been implemented to reasonably ensure compliance with licence requirements. • Work practices and containment measures proposed by the licence holder were found to be appropriate to the requirements of the licence. • The licence holder has arrangements in place to ensure that authorised persons have received a high level of training in licence requirements and are sufficiently resourced to manage compliance obligations
Outcomes	The OGTR practice review program continued to assess vulnerabilities to containment and compliance with the Act. 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.

Facility structure and maintenance	
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 New South Wales. 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 organisation's 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 organisation's effective compliance performance.
Findings	The review found that the participating accredited organisation 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 Act. 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.

Response to serious weather event	
Aim	This is part of the OGTR's ongoing practice review program. The OGTR recognises that effective compliance is dependent on: • a demonstrated capacity to comply with the conditions of certification specified within the *Guidelines for Certification of a Physical Containment Level 2 Plant Facility* • suitable arrangements to manage compliance for GMO dealings • the appropriate use of specified equipment and service providers • the appropriate use of containment measures • staff training and provision of resources necessary to manage compliance obligations.
Participants	The review focused primarily on the demonstrated capacity of the CSIRO and the Australian National University (ANU) to comply with the conditions of certification specified within the *Guidelines for Certification of a Physical Containment Level 2 Plant Facility* and the *Guidelines for Transport, Storage and Disposal of GMOs* after a serious weather event caused extensive damage to various certified facilities. The review assessed: • consideration and planning of containment strategies after a serious weather event • arrangements to manage compliance risks, including supervision of staff, containment, transport, storage and disposal of GMOs after a serious weather event • any industry or other regulatory issues which impinged on the organisations' effective compliance performance.
Findings	The review found that both CSIRO and ANU had considered and implemented effective measures in managing work undertaken in certified facilities after a serious weather event caused extensive damage to various facilities.
Outcomes	The OGTR practice review program continued to assess vulnerabilities to containment and compliance with the Act. 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.

One audit of CSIRO was undertaken in 2019–20, which is ongoing. This will be further reported upon in 2020–21.

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 2019–20, we continued to liaise with the seed industry to raise awareness 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, Water and the Environment, 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*, administered by the department's Office of Health Protection and Response Division, provides for a scheme to regulate a List of 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*. Under a service level agreement, monitoring and compliance arrangements commenced early in 2009–10. During 2019–20, the OGTR continued to work with the Office of Health Protection to operationalise these monitoring arrangements, however these activities were impacted by the implementation of COVID-19 response measures, including border closures, travel restrictions and physical distancing restrictions throughout February to June 2020.

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 2019–20 annual report, is summarised below.

Our activities for 2019–20 are described under Program 5.1 in Outcome 5 (Regulation, Safety and Protection) of the 2019–20 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).

2019–20 target	2019–20 result: Met
Risk assessments and risk management plans prepared for licence applications and all decisions are made within the statutory timeframes.	Risk assessments and risk management plans were prepared, and decisions made within statutory timeframes, for 100% of licenced dealings.
Stakeholders, including the public are consulted on all assessments for proposed release of GMOs into the environment.	Stakeholders, including the public, were 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.	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.

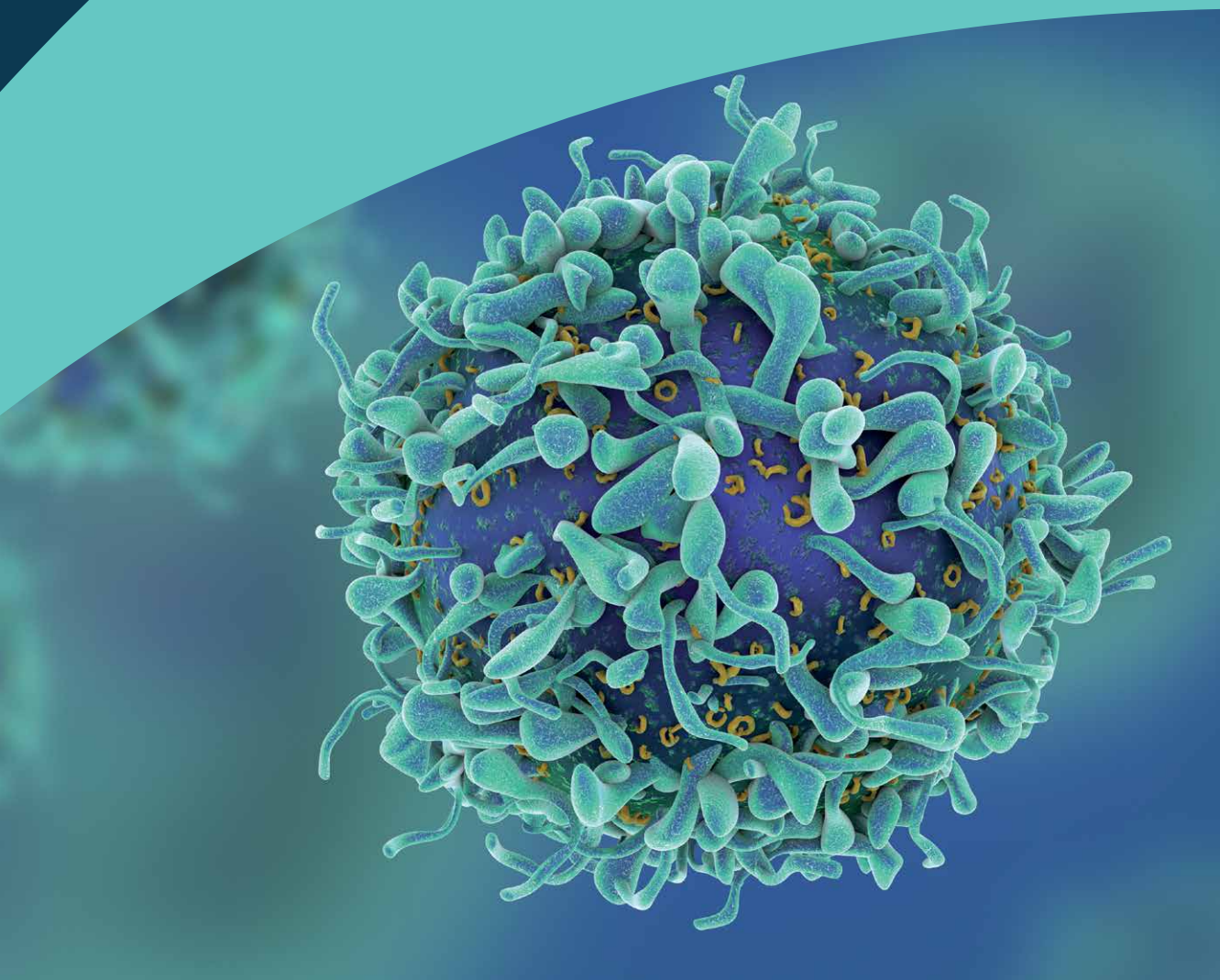
Monitoring and compliance inspections have confirmed a high level of compliance with licence and certification requirements. Stakeholders are continuing to work with inspectors using a cooperative compliance approach.

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 19 years.

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

CHAPTER 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 2019–20, OGTR has continued reviewing the PC3 Certification Guidelines. This built on regulated stakeholder workshops held in 2018–19 in Melbourne, Sydney and Brisbane, and at the 2019 IBC Forum. Work in 2019–20 has focused on seeking advice from technical experts and further internal OGTR discussion of consultation on issues including key technical issues, the interaction with draft AS/NZS Standards and analysis of data collected during Monitoring visits.

2019 amendments to the Regulations

The Regulator periodically reviews the Regulations in order to advise the LGFGT about the effectiveness of the legislative framework, including in relation to possible amendments to the Regulations. The Regulator's technical reviews of the Regulations are limited to issues that do not affect the policy settings of the regulatory scheme.

The Technical Review that concluded in 2018–19 resulted in amendments to the Regulations, the majority of which came into effect on 8 October 2019. In 2019–20 the OGTR has assisted regulated organisations to implement the amendments through regular correspondence, responding directly to stakeholder queries and updates to its website.

Further amendments commence as follows:

- 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).

Implementing recommendations from the Third Review of the National Gene Technology Scheme

In October 2018, the Legislative and Governance Forum on Gene Technology endorsed the final report of the Third Review of the National Gene Technology Scheme, which included 27 recommendations to ensure the Scheme remains effective and fit for purpose into the future. The Third Review was a broad-ranging policy review conducted by a collaboration of Commonwealth, state and territory officials on behalf of all Australian governments, independently of the Regulator.

In 2019–20, OGTR continued administrative implementation of the review recommendations. Streamlining initiatives to reduce regulatory burden included ongoing digital service delivery roll-out (online forms). OGTR has continued to provide technical and operational information to assist the Department of Health team leading the implementation of review recommendations. This work will continue into 2020–21.

Advice on GMOs and GM products

During 2019–20, 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).

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

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. In 2019–20 the RSN moved to using GovTeams to share information. OGTR's contributions to the 2019 RSN Annual Symposium on 'Transcending the Regulatory Interface' included a presentation by Dr Kylie Tattersall, and sessions chaired by Dr Heidi Mitchell and Dr Peter Thygesen. The symposium was well-attended by OGTR staff. OGTR continues to be active in the RSN.

Dr Peter Thygesen presenting at the RSN

Dr Kylie Tattersall and Gill Shaw at the RSN

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.[7] The GMO Record contains information on licences issued, NLRDs notified, GMO dealings included on the Register, and emergency dealing determinations. During 2019–20, OGTR maintained the GMO Record and updated it with new authorisations.

Engagement with stakeholders

Digital service delivery for applications to the Regulator

As part of the ongoing development of digital service delivery, during 2019–20 the OGTR released seven online forms:

- Accredited Organisation Annual Reporting Form
- Application to vary DIR & DNIR licence forms
- Application for the Modifications to Certifications form
- Application for a licence for importation and processing of bulk grain form
- Application for a licence for inadvertent dealings with a GMO form
- Notification of Change in Contacts for Organisations form.

Several forms are currently under development with the view to release these within the 2020–21 financial year. These forms include:

- Application for Accreditation of an Organisation form
- Application to transfer Certifications and licences form
- some specific DIR and DNIR licence applications forms
- Application for Declaration that specified information is confidential commercial information (CCI).

A large number of stakeholders participated in user acceptance testing processes and actively engaged in providing detailed feedback. As part of the form development process, a survey was completed by key stakeholders in relation to DIR and related CCI forms. This was part of our comprehensive approach to stakeholder engagement, enabling the design of online forms that are functional, fit for purpose and meet the needs and expectations of our stakeholders.

Information on COVID-19

In April 2020 the OGTR provided advice to stakeholders in response to the COVID-19 pandemic and associated border closures, travel restrictions and physical distancing restrictions. Two new web pages were also added to the website which provided information about changes to how the OGTR would be engaging with stakeholders, and suggestions for how to manage certified facilities and licences during COVID-19 restrictions.

Meeting and conference attendance

During 2019–20, the Regulator and the OGTR staff 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:

- ARCS Australia conference, Sydney, 6–8 August 2019
- 19th Australian Agronomy Conference, Wagga Wagga, 26–29 August 2019
- Enhancing Investigations and Enforcement Outcomes, Canberra, 24–25 September 2019
- Synthetic Biology Australasia 2019 conference, Brisbane, 14–16 October 2019
- 9th Annual Association of Biosafety for Australia & New Zealand 'Biosafety and Biocontainment' conference, Melbourne, 28–31 October 2019

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

- AusBiotech 2019 conference, Melbourne, 30 October–1 November 2019
- Regulatory Science Network Annual Symposium 'Transcending the Regulatory Interface', Canberra, 7 November 2019
- 2019 Joint Scientific Meeting, Australasian Society for Stem Cell Research/Australasian Gene and Cell Therapy Society/International Society for Cell & Gene Therapy, Brisbane 13–15 November 2019
- Australia and New Zealand Society for Immunology conference, Adelaide, 8–10 December 2019
- International Conference on the Regulation of AgVet Chemicals and Technologies, Armidale, 16–20 February 2020
- Conservation gene drive governance workshop, University of Queensland Centre for Policy Futures, Brisbane, March 2020
- International Society for Cell & Gene Therapy 2020 Paris Virtual Annual Meeting, 28-29 May 2020
- In July 2019, the proceedings of the June 2019 OECD Conference 'Genome Editing: Applications in Agriculture—Implications for Health, Environment and Regulation' was published in the journal Transgenic Research (Volume 28). The proceedings included a paper prepared by an OGTR staff member:

  Thygesen, P. (2019). Clarifying the regulation of genome editing in Australia: situation for genetically modified organisms. *Transgenic Research* 28: 151–159.

Research undertaken or commissioned by the Regulator

Documents to support the risk assessment of GMOs

OGTR publishes documents, including on the biology of organisms that may be genetically modified, to inform and support risk assessment of GMOs.

During 2019–20, OGTR published two new documents:

- A Generic Risk Assessment Framework for Organisms
- The Biology of *Nannochloropsis oceanica* Suda & Miyashita (a microalga).

During 2019–20, OGTR updated two biology documents:

- The Biology of *Carthamus tinctorius* L. (safflower)
- The Biology of *Dianthus caryophyllus* L. (carnation).

These, and other biology and risk assessment documents, are available on the OGTR website.

Community attitudes survey

The Regulator commissions reports to help track community attitudes and behaviours to gene technology.

A report produced by Instinct and Reason was finalised in July 2019 and 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. The report can be viewed on the OGTR website.[8]

8 The Community Attitudes Survey can be found on the OGTR website

IT systems modernisation project

This project is part of a program of ongoing process improvement, digital transformation, and is in response to ongoing feedback from our stakeholders relating to modernising the interface and communication channels between the OGTR and its stakeholders. The OGTR put forward an Investment Proposal to acquire funding to progress the preferred solution option identified in the 2018–19 discovery phase for the modernisation of data holdings. The bid resulted in an allocation of funding to first look at remediation of current data management software being used across the department. The remediation work is almost complete, which may lead into the submission of further bids for additional funding to proceed with a larger scale upgrade.

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, but in a somewhat different format to usual during the latter quarter of 2020.

Dr Heidi Mitchell with workshop attendees in Myanmar

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. 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. Feedback from meetings indicates a high regard for the Australian gene technology regulatory system.

The OGTR provides technical advice to support Australian engagement in activities under the UN Convention on Biological Diversity (CBD) 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[9] and the UN Biosafety Clearing-House.[10]

By participating in and presenting at international forums, the OGTR continued to interact with key regulatory counterparts in other countries during 2019–20, including:

- workshop on the application for environmental release [of GMOs] in research and development, Myanmar, 28–30 July 2019
- APEC High Level Policy Dialogue on Agricultural Biotechnology workshop and meeting, Chile, 18–21 August 2019
- regulatory workshops on stacked GM products – safety assessment and regulatory update, Malaysia and Singapore, 21–23 August 2019
- Symposium and Workshop on Risk Assessment and Regulation of Genome Edited Plants, Philippines, 8–10 October 2019
- Global Community Bio-Summit 3.0 and meeting with community scientists, USA, 6–15 October 2019
- meeting with researchers from China and Japan undertaking a biotechnology course at CSIRO; discussion of GMO regulation in Australia, Canberra, 26 November 2019
- meeting with Chinese delegation visiting Australia under the Australia–China Agricultural Cooperation Agreement, Canberra, 27 November 2019
- meeting with delegation from the Korean Ministry of Food and Drug Control; discussion of GMO regulation in Australia, Canberra, 28 November, 2019
- 34th OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology online meeting 18–20 March 2020, and Steering Group on Environmental Considerations for Risk/Safety Assessment of Transgenic Plants online meeting 17 March 2020
- International Society of Cell and Gene Therapy (ISCT) 2020 virtual meeting, 28 & 29 May 2020
- various fora associated with the United Nations Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety, including online participation in the Open-ended Online Forum on Risk Assessment and Risk Management and the Ad Hoc Technical Expert Group on Risk Assessment from 2020.

In 2019–20, 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.

9 The BioTrack Product Database is on the OECD website
10 The Biosafety Clearing-House is online

CHAPTER 5

MANAGEMENT AND ACCOUNTABILITY

The management and accountability practices of the OGTR include human resources, work health and safety, and the Commonwealth Disability Strategy. The OGTR adheres to Australian Government policies for purchasing and assets management, contracting and consultancy, advertising and market research, and ecologically sustainable development. The Gene Technology Regulator reports to parliament annually, as required by legislation.

Human resources

The OGTR has a workforce of 46 employees. All permanent employees other than the Regulator are Australian public service staff employed by the Department of Health 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 13.

Table 13: Non-salary benefits

Agreement	Benefits
Enterprise Agreement	• 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 19th 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 morning tea had to be discontinued in late March 2020 due to COVID-19 restrictions. However, the OGTR explored other ways of staying in touch and informed using our online collaboration tools, as approved by the department. 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:

- MovemberCommunities at Work Canberra
- St John's Care Canberra.

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

Regulator's Achievement Award

During this time of change and uncertainty, OGTR staff have remained focused on achieving outcomes and maintaining operations as effectively and efficiently as possible. The recipients of the 2019 Regulator's Award were acknowledged for their leadership, teamwork, and persistence in meeting organisational objectives.

Justine Smith and Katherine Zhang in the Regulatory Support Unit were recognised for their efforts in training and supporting staff while the Department moved to a new travel and financial expenses reporting system.

Justine was acknowledged for her willingness to assist and provide training to Monitoring and Compliance staff, as well as the Executive, in a new financial expenses system. She was commended for her perseverance in resolving problems and in assisting the department in ironing out electronic issues. Her flexibility and responsiveness while there was a transition stage between systems was noticed, especially as staff required additional assistance during that time.

Katherine was recognised for her knowledge and collaboration while managing the finances and budget performance reporting for OGTR for an extended period. Her always pleasant nature and willingness to help others during times of high workload and uncertainty was acknowledged, particularly in taking inquiries on the 1800 call line, in addition to her designated duties.

Maria Alonso was acknowledged by colleagues for her leadership, persistence and enthusiasm in keeping a team working on development of new guidelines and forms for the conduct of clinical trials. Maria was able to drive the project from its inception, as a result of stakeholder interest at the 2019 IBC Forum, to a consultation draft. Without her oversight and team management, the project would not have progressed as quickly to electronic form development.

Recipients of the Regulators achievement award

Training and development

OGTR staff undertook 127 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 2019–20, 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 2019–20, the OGTR Principal Legal Officer provided introductory and ongoing training for OGTR staff on legal issues (Table 14). This training had to be put on hold due to the COVID-19 situation.

Table 14: Internal training presentations on legal issues, 2019–20

Date	Topic
9 and 19 September 2019	'Regulations amendments and the states'
25 September 2019	'Comcare v Banerji'
22 October 2019; 5 December 2019	'Who are the Regulators'
12 November 2019	'Confidential Commercial Information'

The OGTR Forum provides a venue where presentations are made by visiting experts, and staff share current information on scientific and risk assessment issues, summaries of recent conferences, and feedback from international meetings. A range of OGTR staff and guest speakers made presentations at the OGTR Forum in 2019–20 (Table 15). Due to the COVID19 pandemic, the number of presentations was lower than in previous years.

Table 15: Presentations at the OGTR Forum, 2019–20

Date	Topic
21 August 2019	Developing and optimising production of conditional male-only strains of Queensland fruit fly (*Bactrocera tryoni*) for Sterile Insect Technique Simon Baxter (University of Adelaide)
21 August 2019	Technologies for mosquito control Maciej Maselko (Macquarie University/CSIRO)
10 September 2019	Regulatory status of gene edited products in Japan and consumer's perceptions Masashi Tachikawa (Nagoya University, Japan)
17 September 2019	Risk analysis training in Myanmar Heidi Mitchell, OGTR
17 September 2019	APEC high level policy dialogue for agricultural biotechnology workshop (Chile, August 2019) Neil Ellis, OGTR
26 September 2019	2019 Community Attitudes presentation Craig Cormick, Instinct and Reason
10 December 2019	USA Biohacker community and Boston Global Community Bio Summit 3.0 Andrew Radanovich, 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.

COVID-19

OGTR had to significantly change the way staff were working as a result of the COVID-19 outbreak. We worked with the department to provide a COVID-19 safe workplace. This included an increase in the ability for staff to work from home, provision and expansion of online collaboration tools, flexible working hours and an increase in office cleaning. Staff were advised how best to remain safe while continuing to support the Regulator in carrying out her duties, and were offered online learning opportunities to replace face-to-face teaching. During April and May 2020 the majority of staff worked partially or wholly from home, and staff continue to access remote working flexibility. To enable safe remote working conditions the department provided access to online WHS workstation assessments and staff were permitted to take some IT and ergonomic equipment home. The department is transitioning all OGTR and health staff to laptops to aid in long-term flexibility.

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 2019–20, we conducted training for officers, workers, health and safety representatives, and an 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, as well as our performance reporting.

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.[11]

Freedom of information contact details and procedures

The OGTR received two requests for access under freedom of information legislation during the reporting period. One of the requests was withdrawn, and OGTR finalised the remaining request within the statutory timeframes in 2019–20.

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

11 The OGTR's Information Publication Scheme Agency Plan is on our website.
12 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 16).

Table 16: Presentations in Australia by the Regulator and OGTR staff, 2019–20

Date	Event	Location
30 June – 3 July 2019	ARC Centre of Excellence for Translational Photosynthesis Conference 2019 – Innovations in Agriculture for Food Security	Brisbane
9 August 2019	Lecture to ANU biotechnology students	Canberra
19 August 2019	Lecture to La Trobe University students	Melbourne
16 October 2019	CropLife Forum 2019 (CropLife National Members' Forum)	Canberra
19 February 2020	International Conference on the Regulation of AgVet Chemicals and Technologies	Armidale

Dr Raj Bhula presenting at a conference

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).

The OGTR website was updated with a message for our stakeholders about working with the Office and working with GMOs during the COVID-19 pandemic.

Website usage

Table 17 tracks monthly usage numbers for the OGTR website. The most requested online information sheets and website pages are listed below.

Table 17: Website activity, 2019–20

Month	Sessions[a]	Users[b]
July	5,912	4,241
August	6,720	4,636
September	6,262	4,302
October	7,622	5,298
November	6,477	4,481
December	4,803	3,608
January	6,341	5,057
February	9,222	7,142
March	7,247	5,465
April	6,155	4,466
May	6,792	4,849
June	6,805	4,909

[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 2019–20 were, in descending order:

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

The most popular downloaded documents in 2019–20 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. Types of Dealings with GMOs classified as exempt dealings – October 2019
5. Guidelines for Certification of a Physical Containment Level 2 Animal Facility
6. Guidelines for Certification of a Physical Containment Level 1 Facility
7. Types of Dealings with GMOs classified as Notifiable Low Risk Dealings (NLRDs) – October 2019
8. Overview of amendments to the Gene Technology Regulations 2001
9. Guidelines for Certification of a Physical Containment Level 3 Laboratory
10. Community attitudes to gene technology – Report of a 2019 survey conducted by Instinct and Reason.

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 2019–20, use of the email address declined compared with the previous year (Table 18).

Table 18: Email activity, 2019–20 and 2018–19

Month	Emails	
	2019–20	2018–19
July	48	35
August	30	48
September	41	43
October	48	48
November	43	117
December	31	30
January	41	45
February	34	185
March	43	55
April	48	49
May	35	33
June	39	42
Total	**481**	**730**

Due to COVID-19 pandemic measures across states and territories, a dedicated email inbox was created for organisations to contact the OGTR if their organisation was unable, or foresees that it may become unable, to meet its obligations under Australia's gene technology legislation. Stakeholders were advised to address their COVID-19 related queries to OGTR.Alerts@health.gov.au. The inbox has received 35 emails since its creation in March 2020.

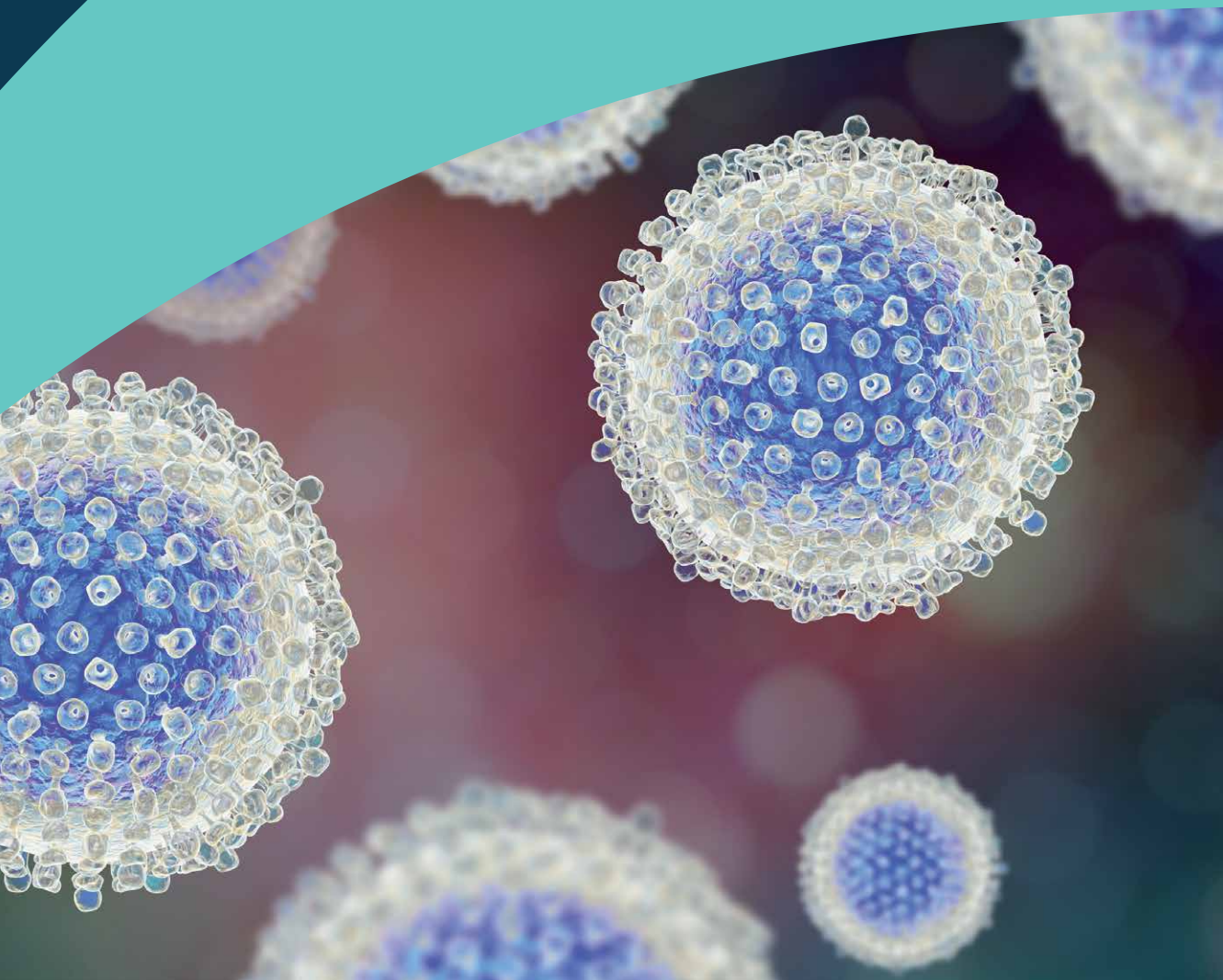
The Monitoring and Compliance Section maintains an email inbox to facilitate efficient communication with accredited organisations. The inbox provides a central point through which accredited organisations can contact OGTR with queries, legislative notifications and self-reporting of non-compliances. The inbox ensures that all communications are answered efficiently while staff are away from the office. The inbox received 804 emails during 2019–20 (compared to 1,162 in 2018–19).

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 644 emails during 2019–20 (compared to 617 in 2018–19).

The Application Entry Point maintains an email inbox to provide a central, shared communication point, allowing us to efficiently coordinate responses to correspondence and queries about applications. The inbox received 2,438 emails during 2019–20 (compared to 1,477 in 2018–19).

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

APPENDIX



APPENDIX 1—MEMBERSHIP OF STATUTORY COMMITTEES

Table 19: Gene Technology Technical Advisory Committee members 2020–23

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, Integrated Farming Systems program, CSIRO Agriculture and Food (QLD)
Honorary Professor Fiona Cameron	Honorary Professor, ANU College of Science (ACT)
Associate Professor Michael Considine	Australian Research Council Future Fellow, University of Western Australia (WA)
Dr Paul Downey	CEO/Principal Consultant – environmental management, Paul Downey Consulting (NSW)
Dr Tessa Gargett	Postdoctoral Research Officer, Royal Adelaide Hospital and Centre for Cancer Biology (SA)
Dr Grant Logan	Senior Scientist, Gene Therapy Research Unit, Children's Medical Research institute (NSW)
Associate Professor Michael Michael	Medical Scientist, Department of Gastroenterology and Hepatology, Flinders Medical Centre (SA)
Associate Professor Geraldine O'Neill	Deputy Head, Children's Cancer Research Unit, The Children's Hospital at Westmead (NSW)
Dr Gabrielle O'Sullivan (GTECCC cross-member)	Executive Officer and Member, Institutional Biosafety Committee, Royal Prince Alfred Hospital (NSW)
Dr Kelly Pearce (layperson)	Director and Founder, Wheatbelt Science Pty Ltd (WA)
Dr Jason Smythe	Chief Operating Officer, The Monash Institute of Medical Engineering, Monash University (VIC)
Professor Jane Visvader	Joint Head, Breast Cancer Laboratory and Cancer Biology and Stem Cells Division, Walter and Eliza Hall Institute of Medical Research (VIC)
Professor Calum Wilson	Professor (Plant Pathology), University of Tasmania (TAS)
Professor Paul Young	Head of School and Professor of Virology, 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 20: Gene Technology Ethics and Community Consultative Committee members 2020–23

Member	Position
Associate Professor Judith Jones (Chair)	Associate Professor, College of Law, The Australian National University (ACT)
Professor Rachel Ankeny	Professor, School of Humanities, University of Adelaide
Dr Deborah Cleland	Postdoctoral Fellow, School of Regulation and Global Governance, The Australian National University (ACT)
Dr Paul Downey	CEO/Principal Consultant – environmental management, Paul Downey Consulting (NSW)
Ms Paula Fitzgerald	Director and consultant (Vic)
Dr Jaden Hastings (expert adviser)	Founder/Director, Alpha Space Pty Ltd
Rabbi Dr Aviva Kipen	Member, Australian Health Ethics Committee (Vic)
Dr Rachel Nowak	Director, Research Marketing and Communications, University of Melbourne (Vic)
Dr Gabrielle O'Sullivan (GTTAC cross-member)	Executive Officer and Member, Institutional Biosafety Committee, Royal Prince Alfred Hospital (NSW)
Dr Kelly Pearce	Director and Founder, Wheatbelt Science Pty Ltd (WA)
Professor Stephen Robson	Professor in Reproductive Medicine, The Australian National University (ACT)
Dr Robert Sward	Director, BioBotanicals Consulting (Vic)
Dr Lynn Woodward	Senior Lecturer - College of Medicine & Dentistry, James Cook University (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.

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)
- licensed 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 21 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 21: 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

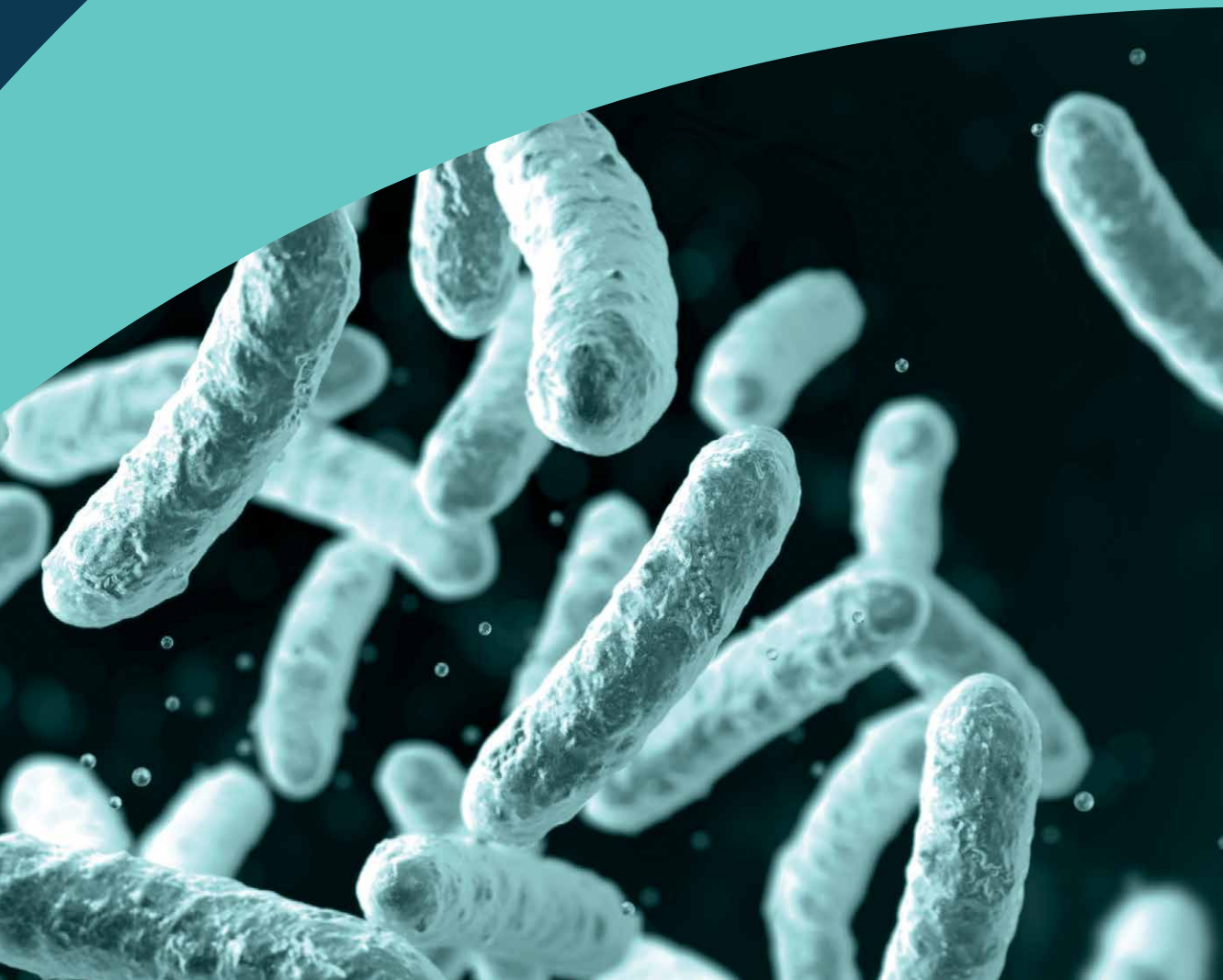
Under section 43(3) of the Act, the Regulator must issue, or refuse to issue, a licence within a time limit prescribed by the Regulations. The Regulations also prescribe a timeframe for consideration of applications to accredit organisations and to certify facilities. These statutory timeframes are shown in Table 22. 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 22: 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



GLOSSARY AND SHORTENED FORMS

The terms described in this glossary are important to understanding this report; however, they do not substitute for the definitions of terms relevant to the operation of the gene technology regulatory system in section 10 of the Act.

Term	Description
Accredited organisation	An organisation that is accredited under section 92 of the *Gene Technology Act 2000*
Act	*Gene Technology Act 2000*
APVMA	Australian Pesticides and Veterinary Medicines Authority
CCI	Confidential commercial information declared under section 185 of the *Gene Technology Act 2000*
Contained dealing	See DNIR
CSIRO	Commonwealth Scientific and Industrial Research Organisation
Dealing	To 'deal with' a GMO is defined in section 10 of the *Gene Technology Act 2000*. It includes to experiment with, manufacture, breed, propagate, grow, culture, import, transport and dispose of a GMO, and to possess, supply or use a GMO in the course of any of these activities.
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 of a GM plant or animal vaccine)
DNIR	A dealing not involving intentional release of the GMO into the environment (e.g. experiments with GMOs in a certified facility such as a laboratory or manufacture of a commercial therapeutic from a GMO in a large scale facility)
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

Term	Description
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
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

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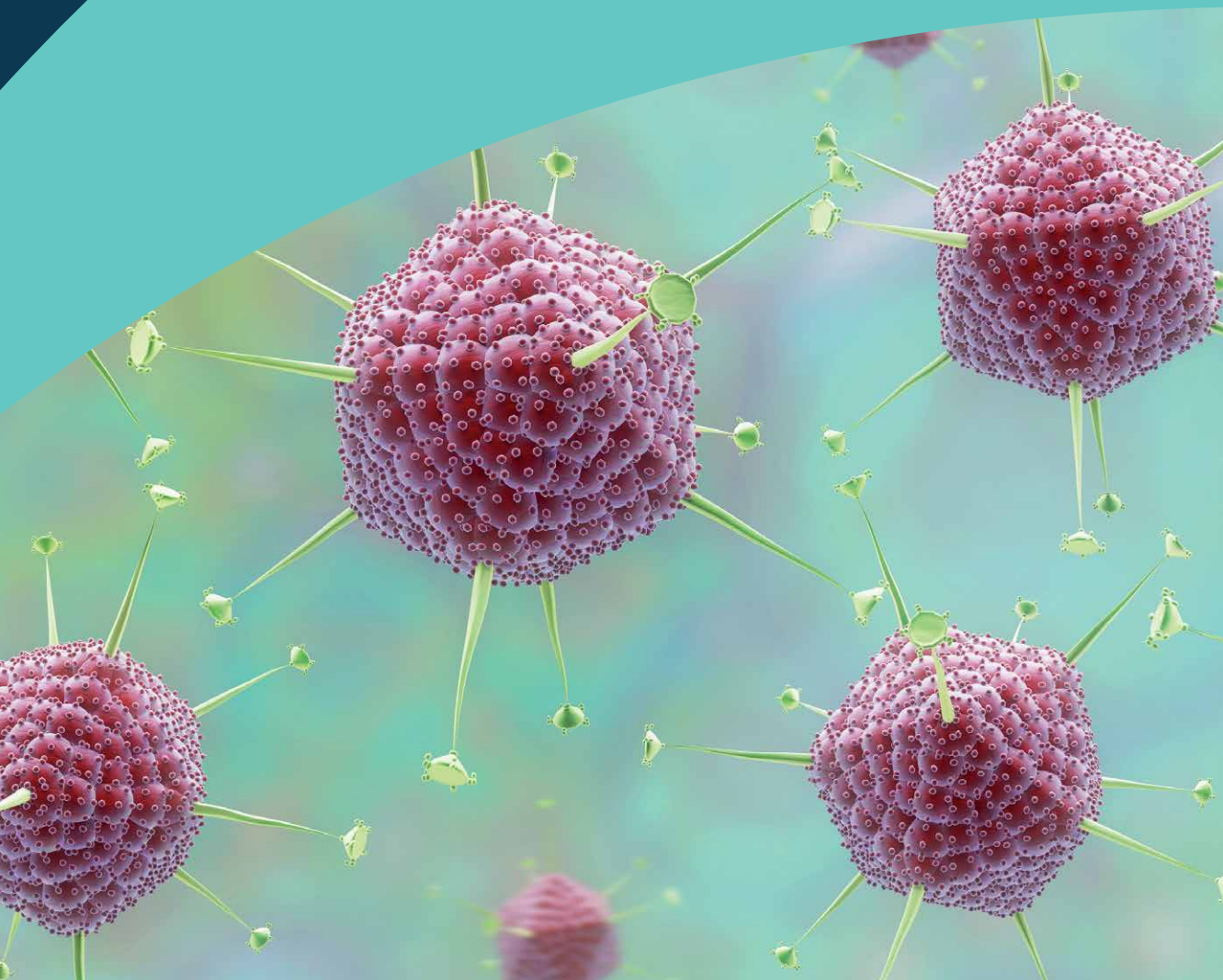

LIST OF REQUIREMENTS

Gene Technology Act 2000 reference	Part of report	Description
136(1A)(a)	22–30	GMO licences issued during the financial year
136(1A)(b)	46–49	Any breaches of conditions of a GMO licence that have come to the Regulator's attention during the financial year
136(1A)(c)	33	Emergency dealing determinations made by the Minister during the financial year
136(1A)(d)	33	Any breaches of conditions of an emergency dealing determination that have come to the Regulator's attention during the financial year
136(1A)(e)	40–53	Auditing and monitoring of dealings with GMOs under this Act by the Regulator or an inspector during the financial year

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