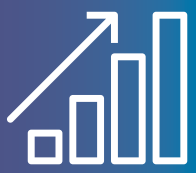
Australian Government

Department of Health and Aged Care
Office of the Gene Technology Regulator

Annual Report
2021–22

2021–22 highlights

97
physical containment facilities certified



Number of applications and notifications increased:
1,624 in 2020–21 to
1,799 in 2021–22

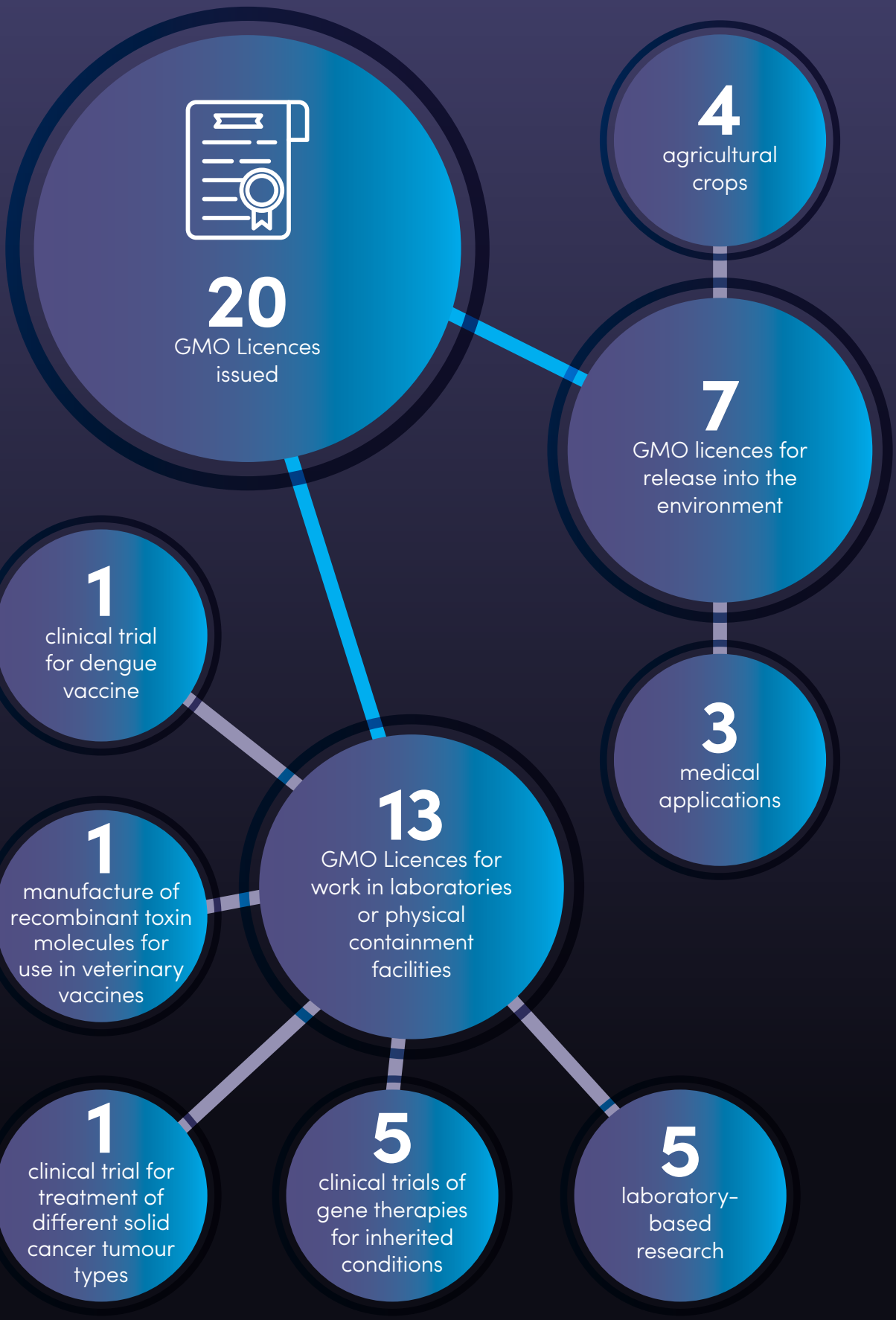
Monitoring and compliance activities

5
field trial sites to monitor for compliance

4
DNIRs for compliance

40
certified facilities

100%
of licence decisions made within statutory timeframes


20
GMO Licences issued
4
agricultural crops
7
GMO licences for release into the environment
3
medical applications
1
clinical trial for dengue vaccine
13
GMO Licences for work in laboratories or physical containment facilities
1
manufacture of recombinant toxin molecules for use in veterinary vaccines
1
clinical trial for treatment of different solid cancer tumour types
5
clinical trials of gene therapies for inherited conditions
5
laboratory-based research

Title: Operations of the Gene Technology Regulator Annual Report 2021–22

ISSN: 1833-6264
Online ISSN: 2205-4502
Publications Number: DT0002929

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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.

Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

Letter of Transmittal

The Honourable Ged Kearney MP

The Assistant Minister for Health and Aged Care

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 2021 to 30 June 2022.

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 1 (Health Policy, Access and Support) of the Department of Health Portfolio Budget Statements for 1 July 2021 to 30 June 2022.

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
13 September 2022

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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 1 (Health Policy, Access and Support) Program 1.8 (Health Protection, Emergency Response and Regulation) of the 2021–22 Department of Health[1] Portfolio Budget Statements.[2]

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:[3]

- 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 5 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 2021–22. 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 2021–22 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 legislative reviews of the Act and Regulations, contributions to the work of other regulatory agencies, 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 Name change to Health and Aged Care as of 1 July 2022.

2 The Department of Health Portfolio Budget Statements 2021-22.

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

Chapter 1

Gene Technology Regulator's overview

This has been a year of consolidation while we learnt to live with a 'new normal' in terms of the impact of COVID-19. In the ACT, as in other parts of the country, we experienced several weeks of lockdown during 2021 which meant everyone was working remotely. This had a significant impact on staff, and supporting each other while keeping focus on our work was extremely important during this time. OGTR staff demonstrated flexibility, patience, humour, responsiveness and professionalism so that the work of the OGTR continued and timeframes were met.

A highlight of our year was the 9th Institutional Biosafety Forum (IBC), which was held over 2 days in May. Over 120 delegates attended in-person and it was wonderful to engage with our IBC members again. We celebrated the achievements of the national gene technology scheme with a range of speakers talking about their experiences over 20 years. We heard reflections from the previous Regulator Dr Joe Smith and the 2 advisory committee chairs, Professor John Rasko and Professor Judy Jones, on their respective roles and interactions with OGTR.

I am pleased to be reappointed to the role of Gene Technology Regulator for another 5 years. I am looking forward to the next 5 years and what we can achieve in terms of our ongoing legislative and modernising program. Exciting times ahead!

Meeting our performance targets

The Department of Health Portfolio Budget Statements (PBS), Program 1.8 (Health Protection, Emergency Response and Regulation) describes the program objective and performance target of the OGTR: to protect human health and the environment through regulatory oversight of genetically modified organisms (GMOs). This objective is delivered by administering the National Gene Technology Scheme by assessing applications and issuing approvals, and by conducting routine inspections of certified facilities and licenced activities with GMOs. In addition, the operational targets are supported by a modern, flexible and innovative National Gene Technology Scheme, by working with Australian and state and territory governments to implement the recommendations outlined in the Third Review of the National Gene Technology Scheme.

The PBS targets were met as follows:

- 100% of GMO licence decisions were made within statutory timeframes.
- 100% of reported non-compliance with licence conditions of GMO approvals were assessed.
- There were no reports of adverse effects on human health or the environment from authorised GMOs.

The OGTR continued to assist the Department and the Gene Technology Standing Committee in work related to implementation of the priorities endorsed by the Gene Technology Ministers' meeting in July 2021.

Applications and licences: what's new

A regulator-initiated process was commenced to include dealings associated with MON-00073-7 (Roundup Ready® Canola) on the GMO Register. The licence for this GMO was issued in 2003. Consultation on this process ended in March and the assessment process is ongoing, while submissions are being considered.

From time to time, when someone unknowingly comes into possession of an unauthorised GMO, a licence is required to undertake disposal of the GMO. One Inadvertent Dealings licence was issued to allow for disposal of GM alfalfa seed, which was identified as a contaminant in imported seed.

Our licensed applications are categorised according to whether dealings with a GMO involve intentional release into the environment (DIR) or are contained and are primarily for research and do not involve release into the environment (DNIR). This year, 7 DIR licences were issued, of which 4 were for agricultural crops and 3 for medical applications.

Of the 4 GM crop licences, 3 were for field trials in sorghum, Indian mustard and wheat and barley and there was one commercial licence for canola. The medical research licences were for clinical trials for a whooping cough vaccine, investigation of antibiotic resistance and clinical trials of a cystic fibrosis treatment.

For the contained research DNIR category, 13 licences were issued of which 4 involved laboratory-based research, 2 licences were for manufacture of veterinary vaccines and 7 were for clinical trials of gene therapies and cancer treatments.

Trend data from the past 5 years show a clear change from crop-based research to translation of research into commercial vaccines, development of gene therapies for inherited diseases and cancer treatments.

Monitoring and compliance activities

As was the case last year, travel interruptions, lockdowns and border restrictions across Australian states and territories impacted our monitoring and compliance program. Some inspections of field sites were necessary due to adverse weather events leading to damage and clean-up of sites and facilities. Compliance against licence conditions was monitored through desk-top audits and inspections in addition to on-site inspections.

During the 2021–2022 period, 5 field trial sites were inspected for 3 plant species, namely ryegrass, sorghum and wheat. Inspections of 5 licences for clinical trials or contained licences were conducted and 2 practice reviews were undertaken. In addition, 40 facilities were inspected against certification requirements. The Monitoring and Compliance team received 48 reports relating to licences, notifications and certifications. All 48 reports were assessed for non-compliance.

Business improvement activities

As part of our business improvement activities, we have modernised our systems for receipt and processing of applications. One new form was released during 2021–2022, while several new forms are in development and testing for release next financial year. Ongoing work as part of the Department of Health Information and Communications Technology (ICT) Strategy to provide secure, innovative and sustainable ICT services, involves modernising internal IT information management systems, which has been a key focus of the work of the office this financial year.

International harmonisation and capacity building: sharing our knowledge

OGTR staff continued to participate in international meetings on harmonising risk assessment and regulation of GMOs. Virtual meetings and conferences have allowed international engagement to continue with biotechnology regulators. Meetings focused on biotechnology in food and agriculture, synthetic biology and stacking of traits in GM crops.

The OGTR continues to lead Australian representation on, and coordinates Australian input into, the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology (WGHROB). The working group develops scientific guidance to support the risk assessment of GMOs. Dr Peter Thygesen continued in the role of Chair of the Working Group this year.

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

This year, 2 teams received the Regulator's Achievement Award. The awards were in recognition of inclusive leadership, cross-office collaboration, and intense periods of work to meet short timeframes.

The Application Entry Point/Customer Relationship Management (CRM) team undertook extensive consultation and engagement within the office when developing the new database application and systems. The team put in long hours, and still kept up with their day-to-day work. The result is that staff are well trained in how to use this wonderful, powerful product which is an integral part of the OGTR business systems.

The Scheme Review Team in the Regulatory Practice Section has been heavily involved in working with the department to implement recommendations from the Third Review of the National Gene Technology Scheme. The commitment, hard work and collaborative attitude of the team members is a great example of leadership and professionalism at the OGTR.

Challenges ahead

An important task for the next few years will be workforce planning and ensuring that the Office has the skillsets needed to meet the challenges of the future. A number of longstanding, experienced staff members have retired, including Dr Michael Dornbusch who was a Branch Head of the Evaluation teams for 12 years.

Preparing for new legislation and changes to the legislative framework will be a large task, but with planning and the right approach and mindset, it is not insurmountable!

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 Gene Technology Ministers' Meeting (GTMM). 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.

Regulatory performance reporting

The OGTR undertakes its regulatory functions by applying the 3 principles of regulator best practice:

1. Continuous improvement and building trust. We adopt a whole-of-system perspective to regulation, continuously improving our performance, capability and culture to build trust and confidence in our regulatory system.
2. Risk-based and data-driven. We manage risks proportionately, apply treatments which are specific to the prevailing risks and maintain essential safeguards while minimising unnecessary regulatory burden, and leverage data and digital technology to support those we regulate to comply and grow.
3. Collaboration and engagement. We are transparent and responsive communicators, implementing regulations in a modern and collaborative way.

The OGTR implements these best practice principles by facilitating regular engagement with key stakeholders to provide opportunities for continual improvement and to ensure regulator practices are fit-for-purpose. We also maintain and review compliance and enforcement policies that outline regulatory approaches to identify and manage risk.

We recognise that we have a shared responsibility for the stewardship of our regulatory system. We adopt a whole-of-system view of our regulation and take a proactive and collaborative approach to the care of the regulatory functions which the Regulator oversees.

The Department's corporate plan[4] sets out how its regulators intend to apply these principles. It then reports on the performance of its regulators in its annual report[5]. The OGTR's regulatory performance is included in these documents.

We are also committed to meeting the expectations of our Minister, as set out in the Statement of Expectation for regulatory functions applicable to the Guide. The Regulator's Statement of Intent outlines how we will achieve our regulatory objectives and carry out our regulatory functions.[6]

Chapter 3 provides detailed information on the Regulator's risk based and data driven management of applications and authorisations.

Chapter 4 outlines further activities that contribute to our continuous improvement and building trust in the regulatory scheme. It also outlines activities undertaken to engage and collaborate with our stakeholders.

4 https://www.health.gov.au/about-us/corporate-reporting/corporate-plan

5 https://www.health.gov.au/about-us/corporate-reporting/annual-reports

6 https://www.ogtr.gov.au/about-ogtr/what-we-do

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.

The then Senator the Hon Richard Colbeck, Minister for Senior Australians and Aged Care Services, Minister for Sport, was the minister responsible for gene technology regulation until the change of government. 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 2021–22 Department of Health Annual Report. While contributing to the Department's Corporate Plan, we maintain our own business and risk plans, against which senior OGTR staff report periodically.

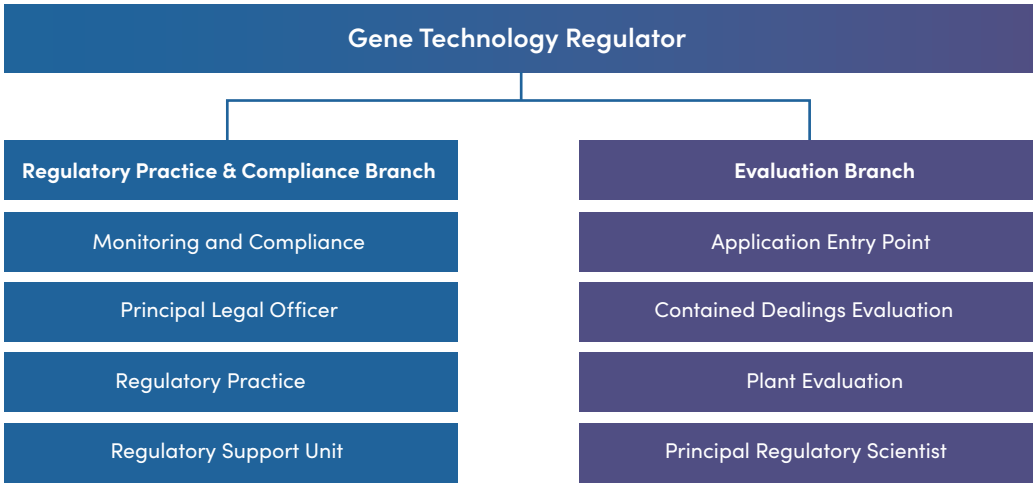
The employment framework for the OGTR is the *Public Service Act 1999*. The Department's enterprise agreement, governance policies and practices cover OGTR staff. These include application of appropriate ethical standards under the Australian Public Service Values and Code of Conduct; compliance with 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, 2021–22



Office of Gene Technology Regulators Executive Team

Gene Technology Regulator

The Regulator is an independent statutory office holder who administers the nationally consistent scheme for regulating gene technology, comprising the *Gene Technology Act 2000* and corresponding state and territory laws. In administering this regulatory system, the Regulator has specific responsibility to protect the health and safety of people, and to protect the environment, by:

- identifying risks posed by, or as a result of, gene technology
- managing those risks through regulating certain dealings with genetically modified organisms (GMOs).

Dr Raj Bhula commenced as the Gene Technology Regulator on 18 July 2016 and has been re-appointed until July 2026.

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, Monitoring and Compliance Section, Regulatory Practice Section and 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.[7]

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 Gene Technology Policy and Governance Section. 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.

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.

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

Evaluation Branch

Dr Kylie Tattersall has been acting Assistant Secretary of the Evaluation Branch since May 2022 when the long-standing Assistant Secretary Dr Michael Dornbusch commenced leave prior to retirement. Her 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, Contained Dealings Evaluation Section, 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 assessment and 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 2 committees to provide advice to the Regulator and the GTMM. 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 on 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 GTMM, on:

- gene technology, GMOs, and 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.

For commercial DIR applications, the Regulator must seek the committee's advice twice. The first consultation is on matters to consider when preparing the risk assessment and risk management plans and the second is on the risk assessment and risk management plan itself. For limited and controlled DIR applications, the Regulator must seek GTTAC advice only once on the risk assessment and risk management plan. The Regulator may also seek advice on other applications.

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 5 times during 2021–22 via videoconference. Communiqués from committee meetings, which provide an overview of key matters discussed and resolutions, are published on the OGTR website.

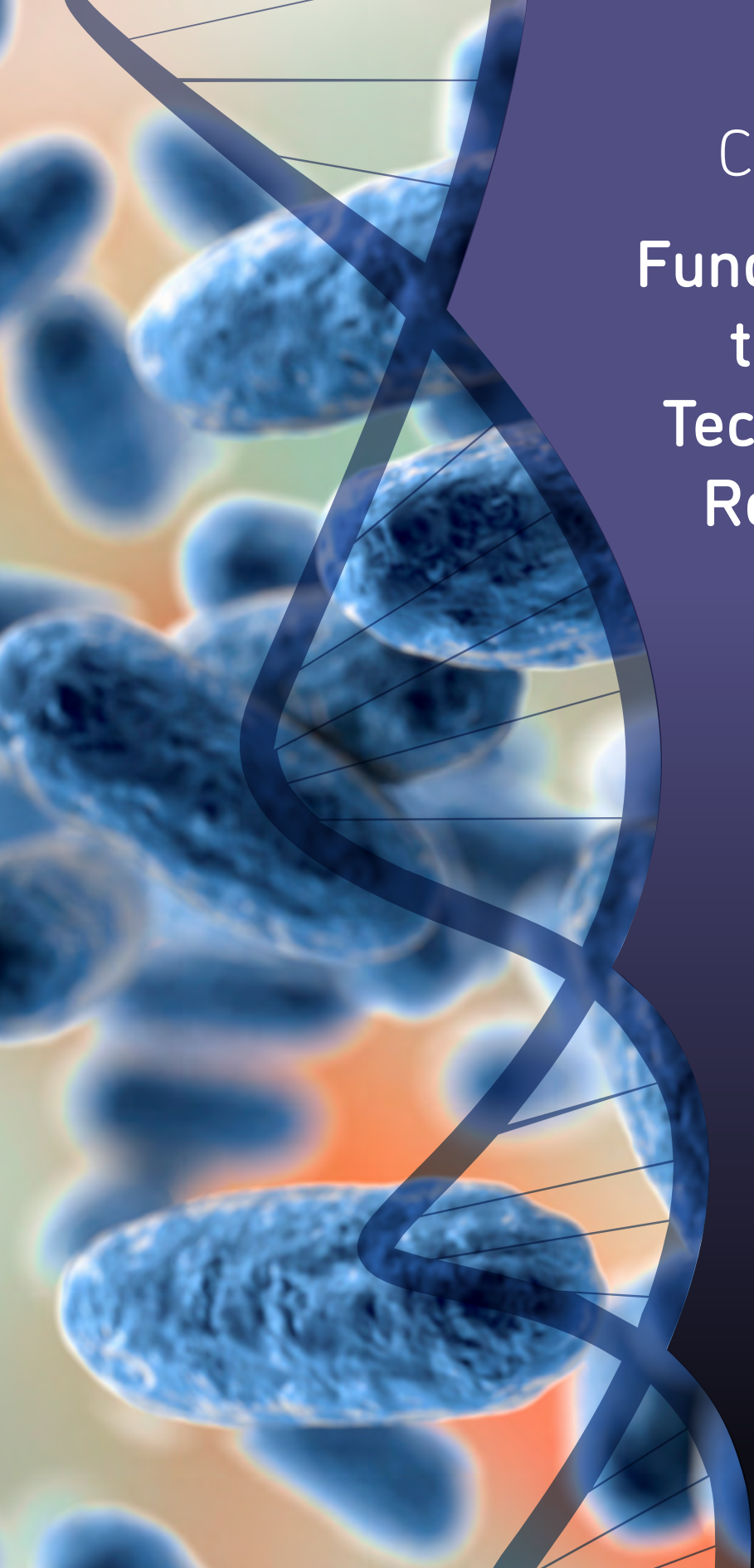
Gene Technology Ethics and Community Consultative Committee

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 GTMM, 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.

There is no statutory requirement for the Regulator to seek advice from GTECCC on licence applications. GTECCC met twice during 2021–22 over a total of 4 videoconference sessions. Communiqués from previous 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 1 (Health Policy, Access and Support) of the 2021–22 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 in Outcome 1 (Health Policy, Access and Support) of the 2021–22 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 2021–22 Department of Health Portfolio Budget Statements, is summarised in the second part of this chapter.

Summary of approvals in 2021–22

Categories of licence

The Regulator issues licences that allow people to work with GMOs. Most licences issued are for scientific research in laboratories, greenhouses, insectaries and other specialised facilities which have been designed to contain the GMOs. Some work like planting and growing GM crops, clinical trials of a new medicine or vaccine, or commercial sale of a GM medicine cannot be done in a laboratory. Instead, they take place in a range of settings, like growing in a field, being administered in a clinic or hospital, or manufactured in a factory and sold in a chemist or pharmacy. Because these 2 different types of work involve different contexts, the gene technology laws have 2 different types of licences to cover them.

Licences for research or other work in special facilities are called a 'dealing not involving release into the environment' (DNIR). The work is contained within a building or other structure rather than outside, or in a hospital, or sold in a store. These facilities must be certified by the Regulator as suitable for containing work with GMOs.

Licences for all other work with GMOs are called a 'dealing involving intentional release into the environment' (DIR). The GMOs are not contained within a facility. This category includes:

- GM crops grown in a field, either commercially or experimentally
- GM medicines and vaccines tested in a clinical trial
- GM medicines and vaccines for sale in a pharmacy or chemist.

The OGTR received 1,799 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 905 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 2,133 certified facilities, 56 environmental release licences and 152 contained research licences (Table 2) at 30 June 2022.

Table 1: Applications and notifications, 2021–22

Application type	Received	Withdrawn	Approved[a]	Refused	Ceased Consideration[b]	Under Consideration[c]
Accreditation	19		18			3
Alternate facility request for an NLRD						
CCI declaration for Accreditation						
CCI declaration for DIR Licence	5		8			8
CCI declaration for DNIR Licence	5		10			18
Certification	110	11	97			5
DIR Licence	8		7		1	4
DNIR Licence	8	2	13			1
Lifting suspension of certification[d]	59		60			
NLRD notification	830					
GMO Register	1[e]					1
Surrender of accreditation	5	1	4			
Surrender of certification	50		50			1
Surrender of DIR licence	1		1			
Surrender of DNIR licence	3		3			1
Suspension of certification[d]	91	1	94			
Transfer of certification	19		19			0
Transfer of DIR licence	2		2			
Transfer of DNIR licence						
Variation of certification	542	10	478	1		83
Variation of DIR licence	7	1	6			1
Variation of DNIR licence	34	3	35			5
Total	**1,799**	**29**	**905**	**1**	**1**	**131**

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 2021–22 were received in the previous year.

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

c Under consideration as at 30 June 2022.

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 2021–22 were all requested by the applicant.

e This was initiated by the Regulator.

Table 2: Status of primary applications and notifications from the start of the scheme until 30 June 2022[a]

Application type	Received	Withdrawn	Approved	Not Approved[b]	Under Consideration[c]	Current	Expired	Surrendered
Certification	4,823	158	4,655	5	5	2,133	357	2,014
DIR	193	18	165	6	4	56	1	108
DNIR	654	116	515	2	1	152	165	198
NLRD	12,802	35	n/a	n/a	n/a	3245	9,521	n/a
Total	**18,472**	**327**	**5,335**	**13**	**10**	**5,586**	**10,044**	**2,320**

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 2022

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 licences may contain specific conditions to manage any identified risks. The Regulator issued 7 DIR licences during 2021–22 (Table 3).

Details of the traits introduced into the organisms for release are provided in Table 3. Six licences issued in 2021–22 were for the following limited and controlled releases:

- DIR-181 Clinical trial of a genetically modified Herpes virus for the treatment of cystic fibrosis
- DIR-183 Clinical trial with genetically modified *E.coli* to reduce antibiotic resistance
- DIR-185 Clinical trial with a genetically modified *Bordetella pertussis* for the prevention of whooping cough
- DIR-186 Limited and controlled release of wheat and barley genetically modified for yield enhancement and improved abiotic stress tolerance
- DIR-188 Limited and controlled release of canola and Indian mustard genetically modified for altered oil content and herbicide tolerance
- DIR-189 Limited and controlled release of sorghum genetically modified for asexual seed formation.

One DIR licence for commercial release of GMOs was issued in 2021–22:

- DIR-178 Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system.

Of the 7 DIR licences issued in 2021–22, 4 were issued to companies, 2 for universities and one to a research institute (Table 3). All of the licence decisions were made within statutory timeframes (see 'Timeframes', Appendix 2).

Table 3: DIR licences issued, 2021–22

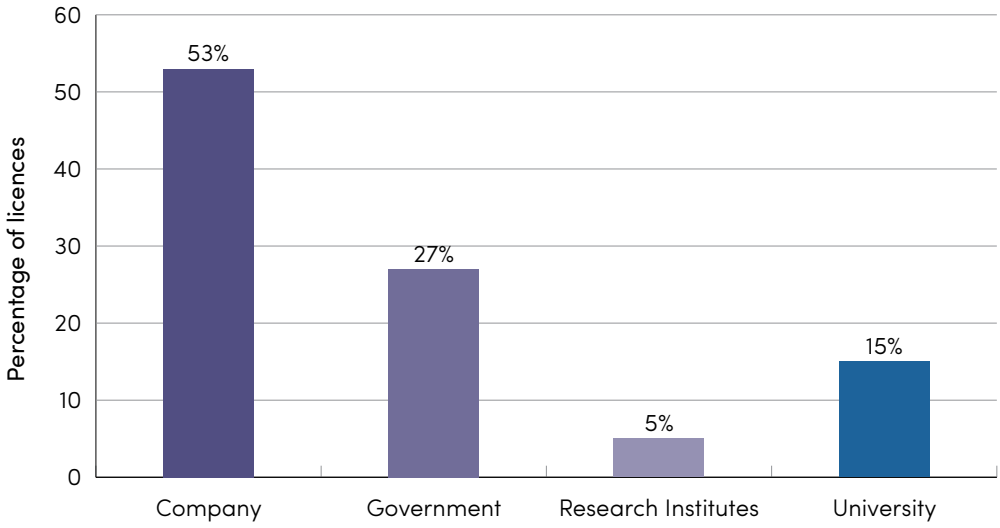
DIR No	Applicant	Parent Organism	Introduced Trait	Type of Release	Received	Issued
DIR-178	BASF Australia Ltd	Canola	Herbicide tolerance and hybrid breeding system	Commercial Release	09-Oct-20	16-Sep-21
DIR-181	Novotech (Australia) Pty Limited	Herpes simplex virus type 1 (HSV-1)	Human therapeutic - replication incompetent; Human therapeutic - protein expression	Limited and Controlled Release	27-Nov-20	14-Dec-21
DIR-183	Westmead Institute for Medical Research	*E.coli*	Introduction of interference plasmids that disrupts genes associated with anti-microbial resistance	Limited and Controlled Release	15-Dec-20	20-Jul-21
DIR-185	PPD Australia Pty Ltd	*Bordetella pertussis* Tohama I (BPSM)	Deletion or alteration of toxin genes	Limited and Controlled Release	08-Jun-21	07-Jan-22
DIR-186	The University of Adelaide	Barley, Wheat	Abiotic stress tolerance; Yield	Limited and Controlled Release	28-Jul-21	15-Feb-22
DIR-188	Nuseed Pty Ltd	Indian Mustard, Canola	Altered oil content; Herbicide tolerance	Limited and Controlled Release	12-Nov-21	08-Jun-22
DIR-189	The University of Queensland	*Sorghum bicolor*	Asexual seed formation	Limited and Controlled Release	22-Nov-21	23-Jun-22

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 165 DIR licences issued to date:

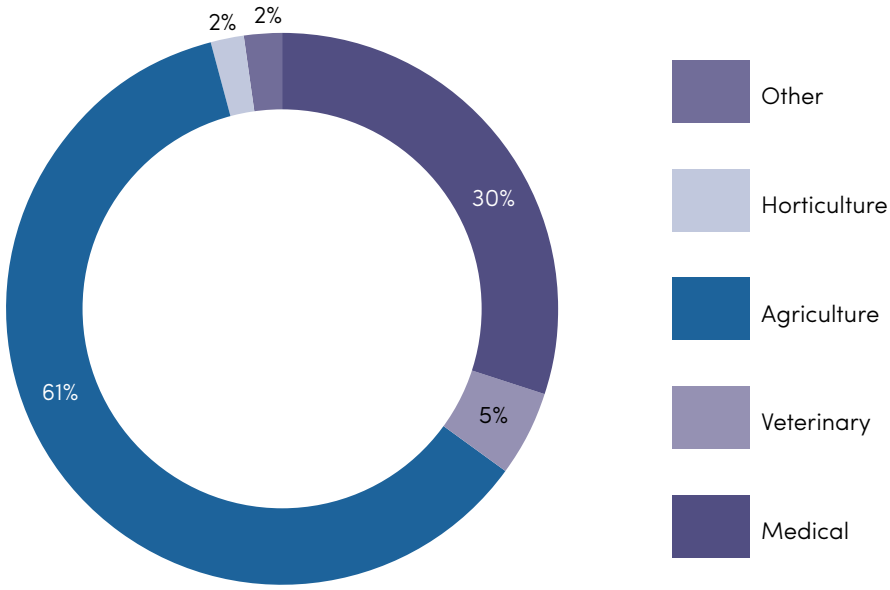
- 87 (53%) have been to companies
- 44 (27%) to government agencies
- 8 (5%) to research institutes
- 26 (15%) to universities.

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



Fifty-six of the 165 DIR licences issued since the beginning of the scheme were current as at 30 June 2022. This consists of 34 (61%) agricultural licences, 17 (30%) medical, 3 (5%) for veterinary and one each (2%) for horticulture and other research. (Figure 3).

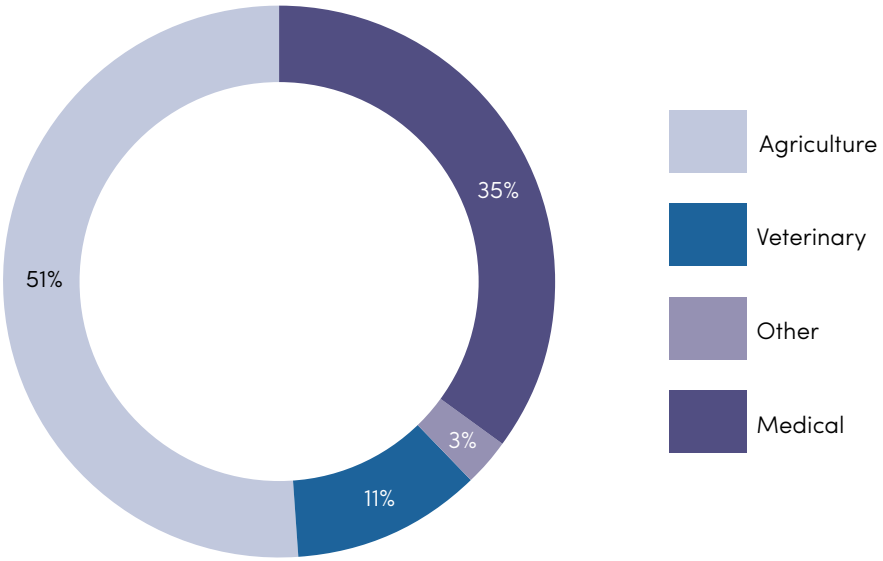
Figure 3: Agricultural vs non-agricultural purposes of DIR licences current as at 30 June 2022



Of the 7 DIR licences issued during 2021–22, 4 (57%) had an agricultural focus and the remaining 3 (43%) had a medical focus.

Although around 60% of all current DIR licences are for agricultural crops, in the past 5 years there has been a shift to medical applications and work involving veterinary uses of GMOs (Figure 4).

Figure 4: Agriculture vs non-agriculture purposes of DIR licences issued over the past 5 years



Thirty-six (65%) of the current DIR licences were issued to companies, 2 (4%) to government organisations, 8 (14%) to research institutes and 10 (17%) to universities (Figure 5). Two (4%) of the DIR licences were held by organisations in the ACT, 18 (32%) in NSW, 6 (10%) in QLD, 4 (7%) in SA and 26 (47%) in Victoria (Figure 6). These numbers are similar to last year's.

Figure 5: Distribution of DIR licences current as at 30 June 2022, by organisation type

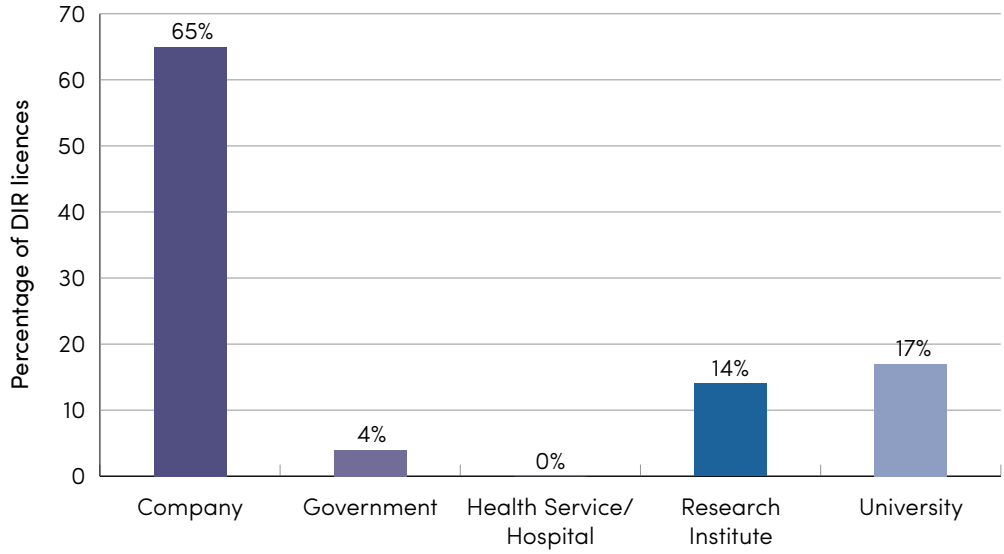
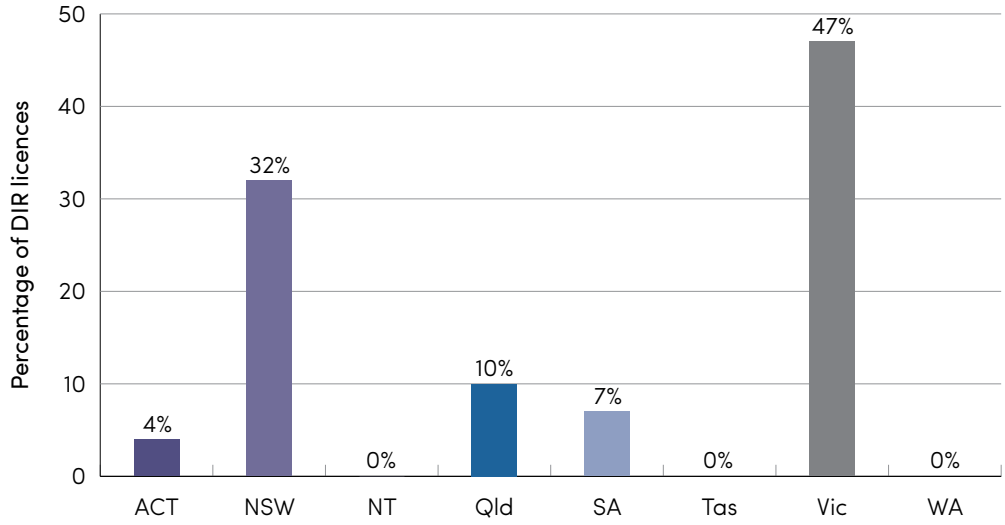


Figure 6: Distribution of DIR licences current as at 30 June 2022, by state or territory



Licences for dealings not involving intentional release of GMOs

Dealings not involving intentional release (DNIR) licences authorise dealings with GMOs in laboratories and other physical containment facilities and include conditions that manage any identified risks. This category also includes clinical trials of live and viable GMOs that meet certain containment criteria.

In 2021–22, the Regulator issued 13 DNIR licences (see Table 4). All decisions were made within the statutory timeframe of 90 days.

Only 4 DNIR licences were issued in 2021–22 for laboratory-based research, with the majority being for clinical trials of GMOs.

Two of the DNIR licences issued were for the manufacture of recombinant toxin molecules for use in veterinary vaccines. Five DNIR licences were for clinical trials of gene therapies for inherited conditions such as Haemophilia B (DNIR-648) or Hereditary Angioedema (DNR-651). One of the licences issued was for a clinical trial for treatment of different solid cancer tumour types (DNIR-653) and one for a vaccine for protection against Dengue (DNIR-650).

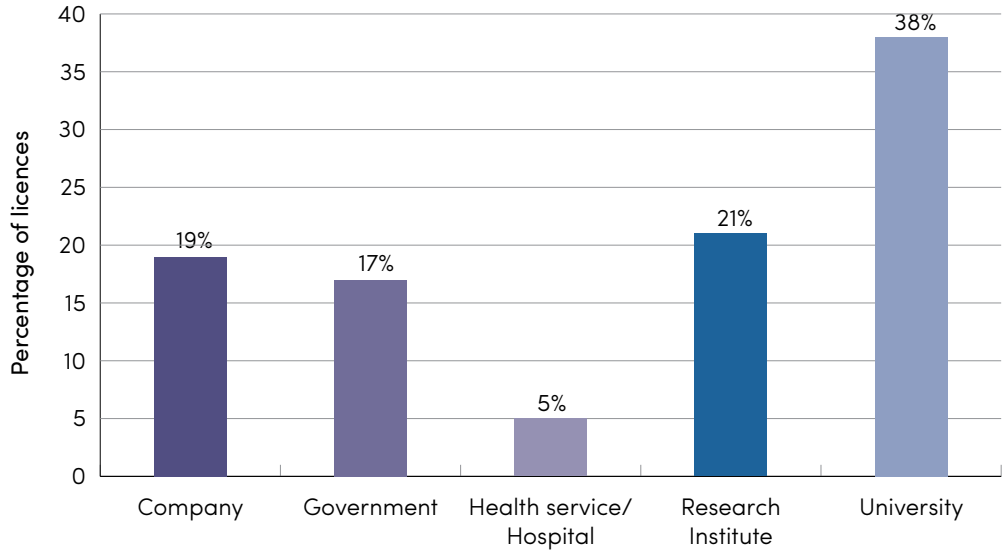
Table 4: DNIR licences issued, 2021–22

DNIR No.	Applicant	Title	Received	Issued
DNIR-639	Monash University	Investigating the genetic basis of dengue and chikungunya virus resistance to Wolbachia	27-Apr-21	25-Aug-21
DNIR-640	Treidlia Biovet Pty Ltd	Generation of recombinant toxin molecules from *Clostridium tetani*	30-Apr-21	20-Aug-21
DNIR-641	Treidlia Biovet Pty Ltd	Generation of recombinant toxin molecules	30-Apr-21	25-Aug-21
DNIR-643	Griffith University	Development of heterologous viral envelope pseudotyped virus platforms for research in emerging viral pathogens	18-May-21	28-Sep-21
DNIR-644	Pfizer Australia Pty Ltd	Establish safety and efficacy of PF- 06939926 in patients with Duchenne Muscular Dystrophy	28-May-21	08-Sep-21
DNIR-646	The University of Melbourne	Two types of split gene drive for *D. melanogaster* lab experiments	08-Jun-21	11-Oct-21
DNIR-647	Medpace Australia Pty Ltd	A Phase I/II, multicentre, open-label, single dose, dose ranging study to assess the safety and tolerability of ST-920, an AAV2/6 human alpha galactosidase A gene therapy in subjects with Fabry disease.	29-Jul-21	21-Oct-21
DNIR-648	Medpace Australia Pty Ltd	Clinical trial to determine the safety and efficacy of FLT180a, an Adeno-associated virus vector-mediated gene transfer of the Padua variant of human Factor IX in patients with haemophilia B	18-Aug-21	01-Nov-21
DNIR-649	The Walter and Eliza Hall Institute of Medical Research	Use of the inducible gametocyte producing *P. falciparum* line NF54/iGP3 for controlled human malaria infection model	29-Sep-21	10-Jan-22
DNIR-650	Merck Sharp & Dohme (Australia) Pty Ltd	Clinical trial of a live attenuated tetravalent Dengue vaccine (V181) in adults	28-Oct-21	01-Mar-22
DNIR-651	BioMarin Pharmaceutical Australia Pty Ltd	Clinical trial with BMN 331 in patients with hereditary angioedema	10-Dec-21	30-Mar-22
DNIR-652	PPD Australia Pty Ltd	A Phase 3 clinical trial with DTX301 in patients with late-onset ornithine transcarbamylase deficiency	22-Dec-21	11-Apr-22
DNIR-653	Novotech (Australia) Pty Limited	An oncolytic immunotherapy product for use in clinical trials	07-Jan-22	02-May-22

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 7. Of the 515 DNIR licences issued to date, 97 (19%) have been to companies, 86 (17%) to government agencies, 26 (5%) to health services/hospitals, 109 (21%) to research institutes and 197 (38%) to universities.

Figure 7: Types of organisations issued with DNIR licences since commencement of the Act



One hundred and fifty-two (152) of the 515 DNIR licences issued since the beginning of the scheme were current at 30 June 2022. Of these:

- 103 (68%) are medical, 41 (27%) for basic research,[8] 4 (3%) each for agriculture and veterinary (Figure 8)
- 38 (25%) are held by companies, 14 (9%) by government agencies, 2 (2%) by health services/ hospitals, 38 (25%) by research institutes, and 60 (39%) by universities (Figure 9)
- 12 (8%) of the current DNIR's are held by organisations in the ACT, 48 (32%) in NSW, 27 (18%) in QLD, 11 (7%) in SA, 49 (32%) in Vic and 5 (3%) in WA (Figure 104).

8 The term basic research is used for work which is primarily concerned with expanding human knowledge rather than creating or inventing something.

Figure 8: Medical vs non-medical focus of DNIR licences current as at 30 June 2022

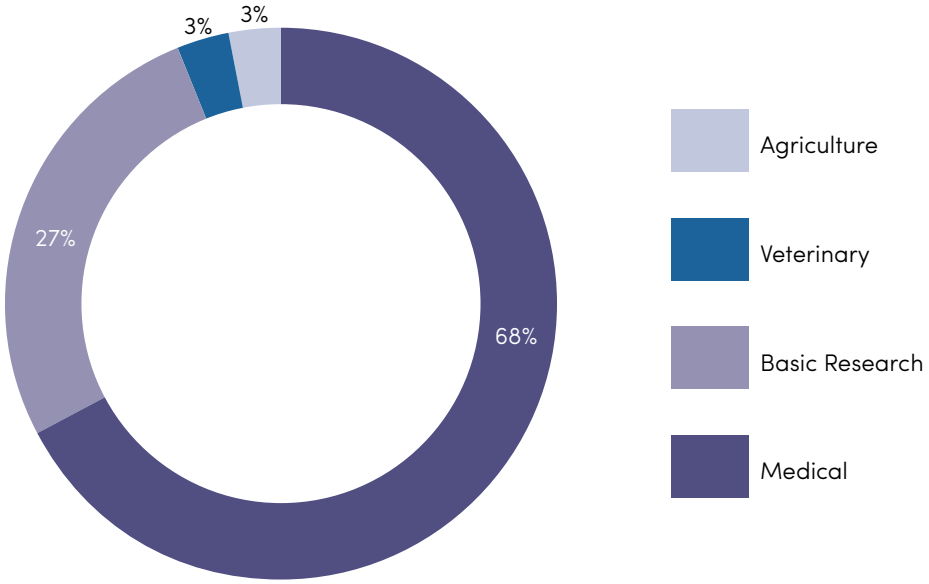


Figure 9: Distribution of DNIR licences current as at 30 June 2022, by organisation type

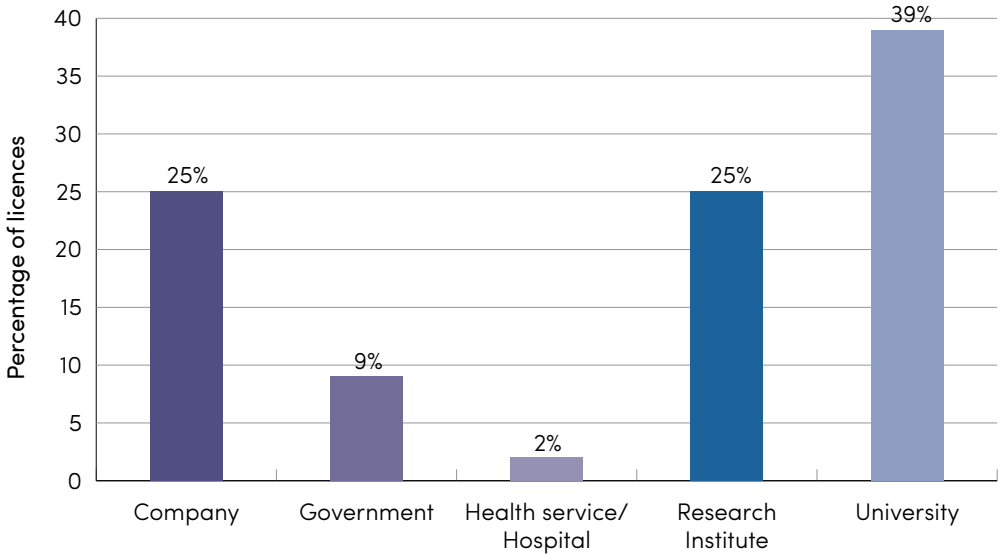
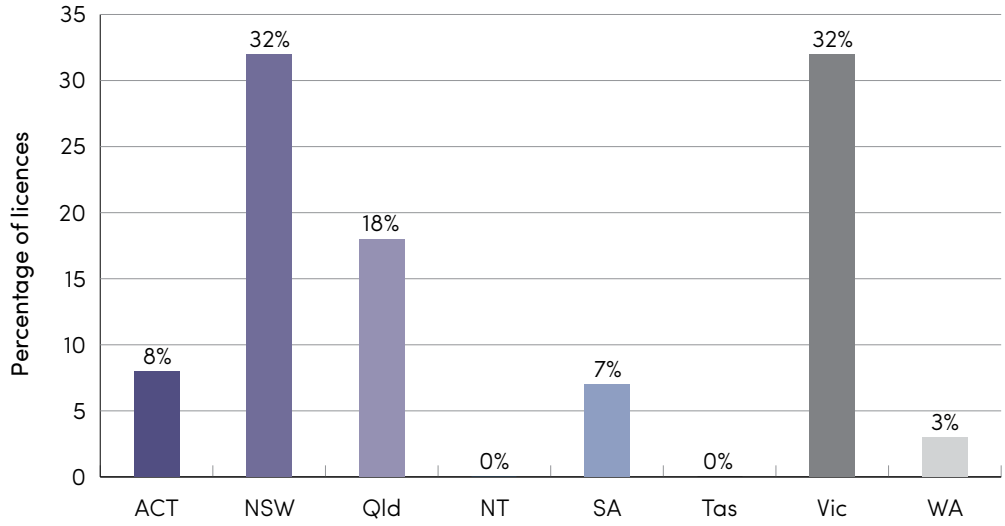


Figure 10: Distribution of DNIR licences current as at 30 June 2022, by states and territories



Of the 13 DNIR licences issued during 2021–22, 9 (69%) had a medical focus, 3 (23%) had a basic research focus and the remaining one (8%) had a veterinary focus (Figure 11).

In the past 5 years the medical focus for DNIRs has increased to almost 90% (Figure 12).

Figure 11: Focus of DNIR licences issued during 2021–22

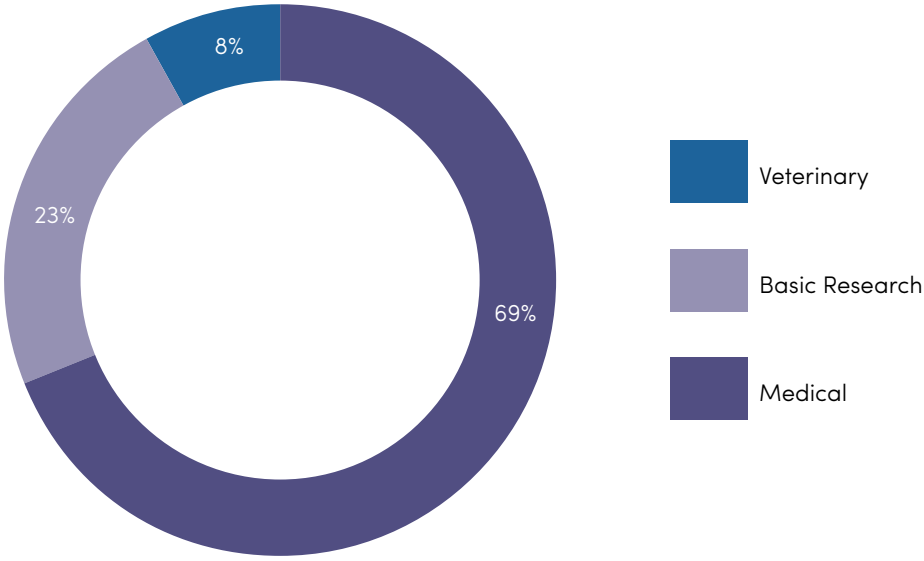
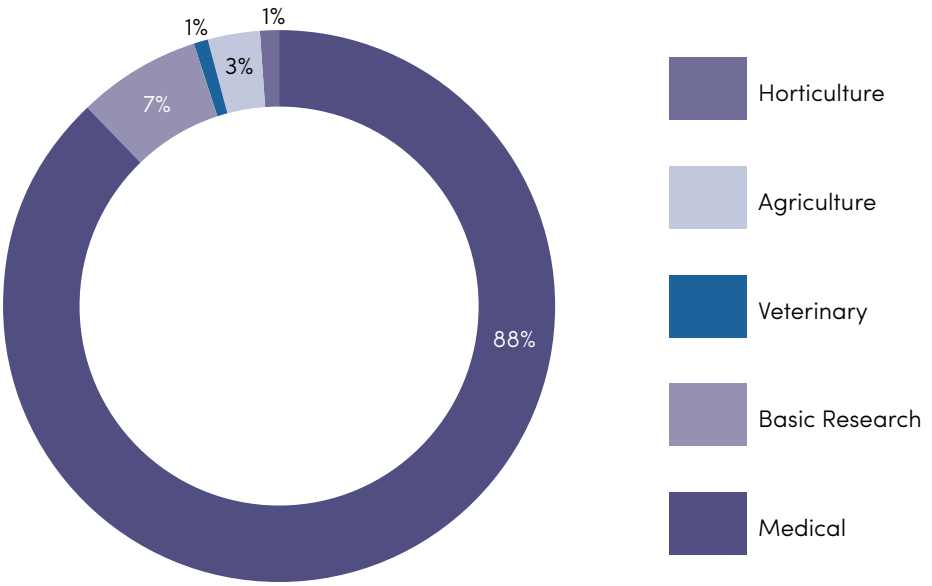


Figure 12: Focus of DNIR licences issued over the last 5 years



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 Gene Technology Regulations 2001. NLRDs can be conducted for a maximum of 5 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 2021–22, 830 NLRD notifications were received. As in past years, these were predominantly for research work. Figure 13 shows an increase in the number of NLRDs received for 2021–22 reporting period compared to 2020–21.

Figure 13: Number of NLRDs notified to the OGTR over the last 5 years

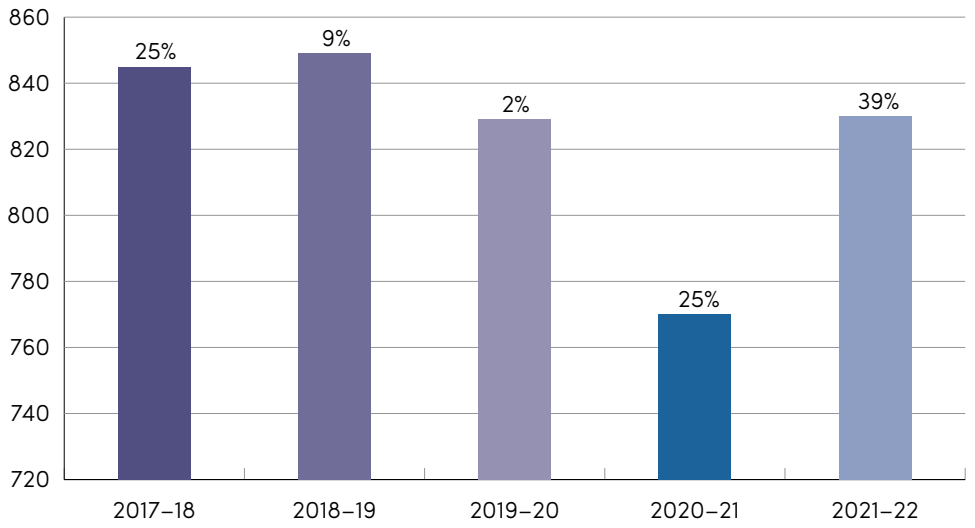
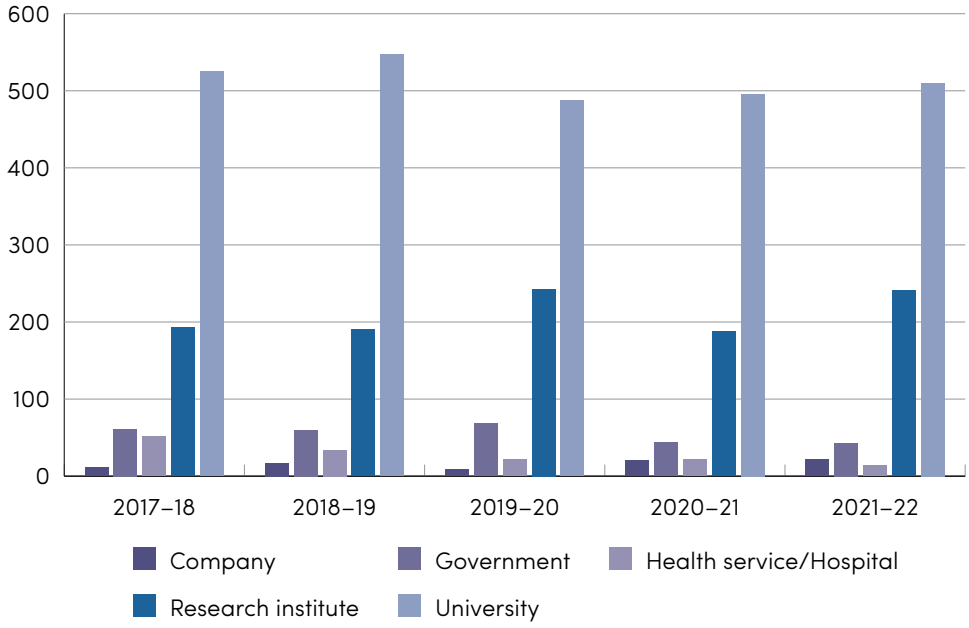


Figure 14 shows the types of organisations that reported NLRDs over the last 5 years. In 2019–20, when the outbreak of COVID-19 started, Figure 14 shows a reduction in the number of NLRDs submitted from universities, health services/hospitals, and companies, but an increase from research institutes and government compared to the previous 2 years. In 2020–21, there was a reduction of NLRD's reported by research institutes and government, contributing to the overall reduction in NLRD's reported in 2020–21. In 2021–22, there was an increase in notifications from research institutes returning the overall number of NLRD's reported to the OGTR to the notification numbers of previous years, as seen in Figure 13.

Many factors could impact the shifts in numbers that we have seen including the impact of the COVID-19 lockdowns. Factors could include the strain on health services and hospitals, the lack of university research activities as there was a shift to online learning and a reduction in international students, and the type of NLRD work being able to progress in the essential work environment.

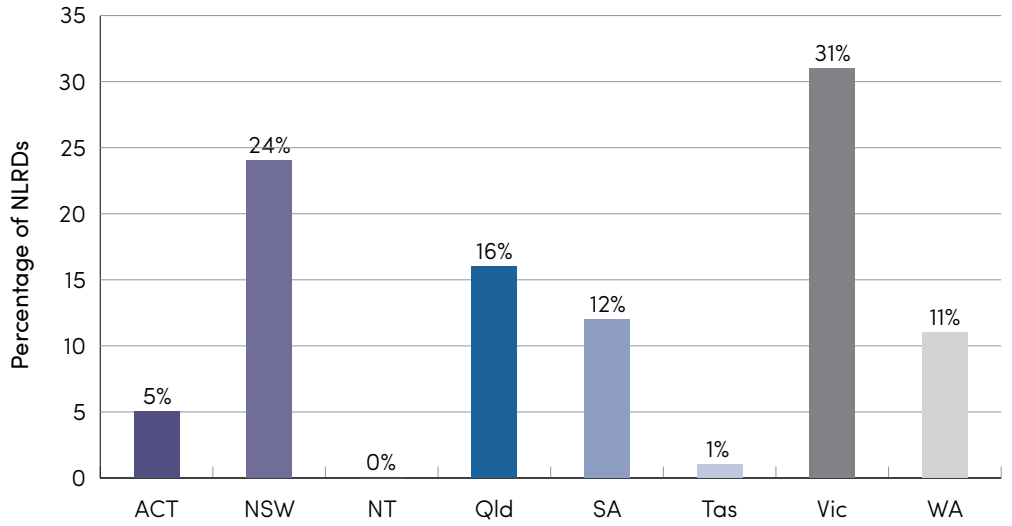
Figure 14: Types of organisations that notified to the OGTR over the last 5 years



The types of organisations that notified to OGTR during this financial year are the same as those that currently hold NLRDs.

The proportion of NLRDs notified in each state or territory which were current at 30 June 2022 is shown in Figure 15.

Figure 15: Distribution of all current NLRDs at 30 June 2022 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 2021–22, the Regulator received no requests for alternate facilities. Ten alternate facility requests and 11 alternate transport, storage and disposal requests have been approved since the relevant provisions in Regulation 13 were introduced in 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.

The Regulator has initiated a process to consider including dealings with MON-00073-7 (also known as Roundup Ready®) canola, genetically modified for herbicide tolerance, on the GMO Register. This is the first GM food crop considered for placing on the GMO Register and the first time this has occurred on the Regulator's initiative. The Regulator sought submissions on a consultation Risk Assessment and Risk Management Plan (RARMP) prepared as part of the process from the public and from a broad range of experts and agencies. The consultation was open from 3 February 2022 to 31 March 2022 and the assessment process is ongoing.

Emergency dealing determinations

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

During 2021–22, 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 2021–22, the OGTR issued one inadvertent dealings licence. The purpose of the dealings was to destroy genetically modified alfalfa seeds, and enable disposal of the GMO.

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 2021–22, 18 accreditations were issued, with a total of 200 organisations holding accreditation at 30 June 2022. Accredited organisations are located in all Australian states and territories (Figure 16). Over time, the profile of the types of organisations accredited by the Regulator has not changed significantly: a large proportion (56%) are primarily publicly funded, that is, government, hospital/health services, universities, and most research institutes. (Figure 17).

Figure 16: Organisations accredited as at 30 June 2022, by location of headquarters

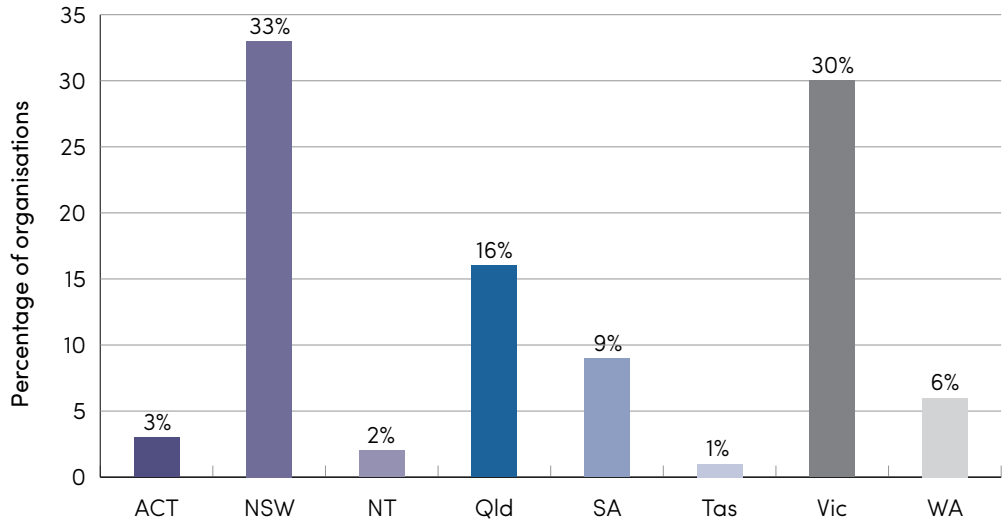
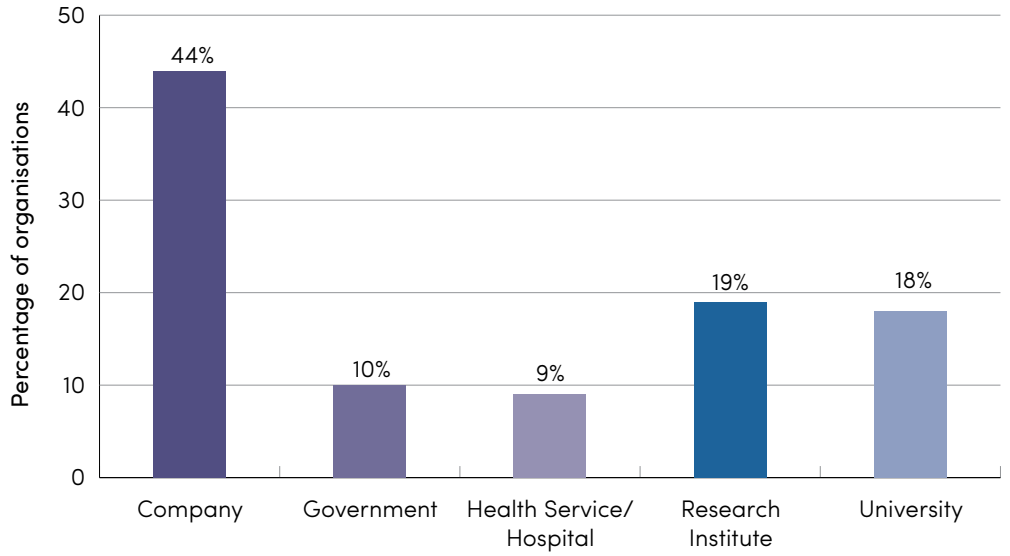


Figure 17: Types of organisations accredited as at 30 June 2022



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. Physical Containment 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 for biosafety containment.

During 2021–22, 97 new certifications for physical containment facilities were issued. There were 3 new multi-purpose high-level facilities (1 PC3 invertebrate, 1 PC3 animal and 1 PC2 large scale facility) certified which were inspected by OGTR staff prior to certification.

High-level facilities (PC4, PC3 and PC2 large scale) are generally only certified for 3 years and require inspection by OGTR staff prior to re-certification. During 2021–22 OGTR staff inspected and re-certified 9 high level facilities. A further 8 facilities were unable to be inspected in person due to COVID-19 travel restrictions and were re-certified based on a desktop audit and virtual inspection.

The number of OGTR-certified facilities at 30 June 2022 is listed by facility type and containment level in Table 5. PC2 laboratories are the most common type of facility certified by the Regulator (1226 PC2 laboratories).

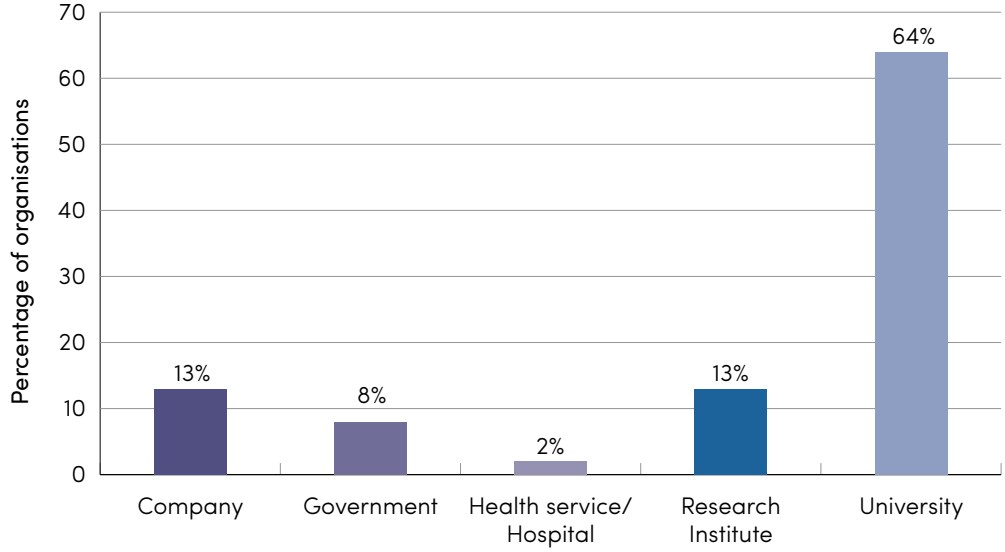
Table 5: Number of OGTR-certified facilities at 30 June 2022

Facility Type	PC1	PC2	PC3	PC4	Grand Total
Animal		232	7		239
Aquatic		30			30
Constant Temperature Room		45			45
Facility	304			4	308
Invertebrate		53	3		56
Laboratory		1,226	26		1252
Large Grazing Animal		58			58
Large Scale		20			20
Plant		125			125
Grand Total	**304**	**1,789**	**36**	**4**	**2,133**

Note: PC = physical containment. PC1 and PC4 facilities are not categorised into types. This table excludes facilities for which the certifications were suspended (at the request of the certification holders) as at 30 June 2022.

Of the 97 new certifications issued in 2021–22, 62 were to universities (64%), followed by 13 to companies (13%),13 to research institutes (13%), 7 to government (8%) and 2 to health service/ hospitals (2%) (Figure 18).

Figure 18: Facilities certified in 2021–22 by organisation type



The distribution corresponds with the high number of authorisations for dealings requiring containment (DNIRs and NLRDs) held by universities and research institutes (see Figures 9, 14 and 19). OGTR certified physical containment facilities are located in all Australian states and territories (Figure 20).

Figure 19: OGTR-certified facilities as at 30 June 2022, by organisation type

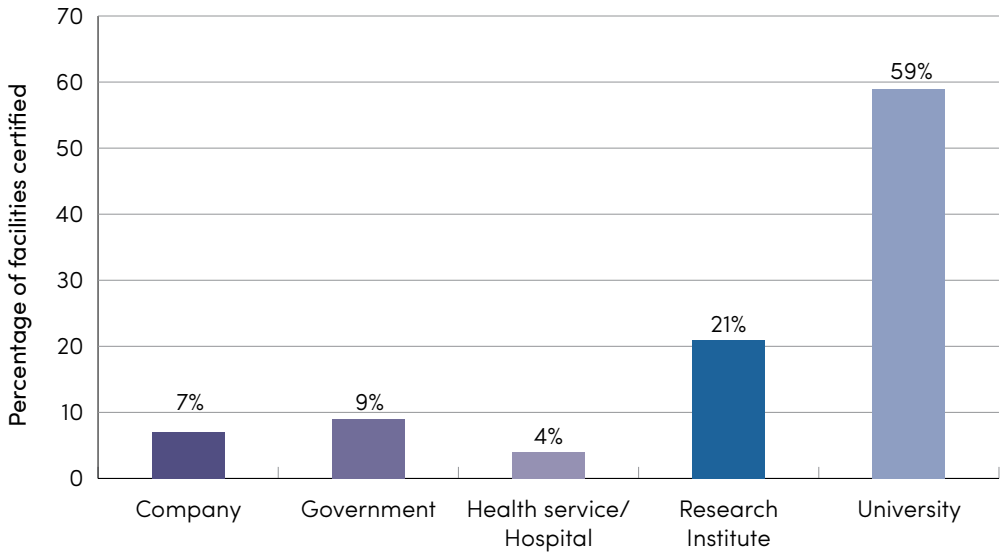
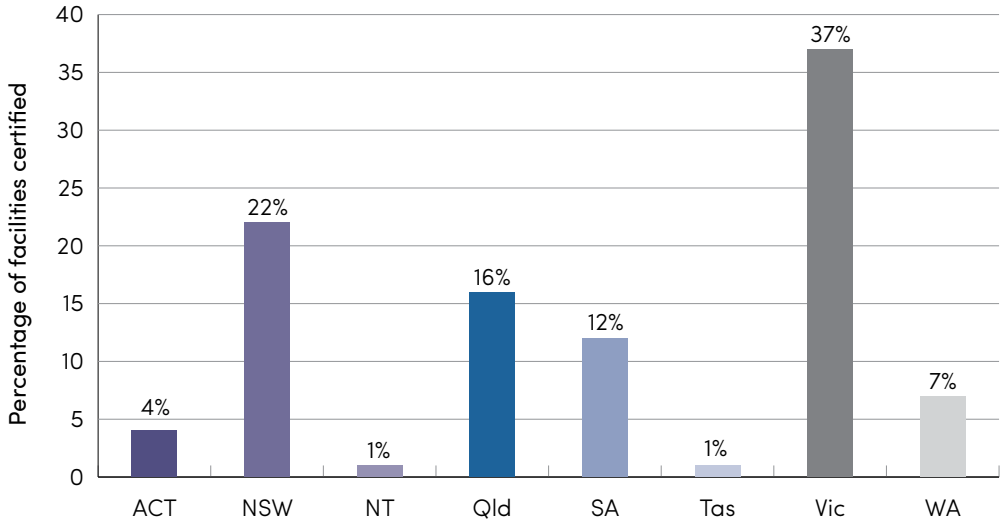


Figure 20: OGTR-certified facilities as at 30 June 2022, by location



Application trends

The numbers of most primary authorisation types issued during 2021–22 were similar to those in previous years (Table 6). However, there has been an increase in the number of Accreditation applications in the past 12 months, the majority of which were received from organisations involved in therapeutic development, clinical trials, and medical diagnostics. There has been a drop in the number of new certifications in the past 3 financial years.

Table 6: Approval of main types of applications, 2017–18 to 2021–22

Application type	2017–18	2018–19	2019–2020	2020–2021	2021-2022
Accreditation	9	8	10	10	18
Certification	135	114[a]	100	101	97
DIR	9	6	3	9	7
DNIR	9	11	20	19	13

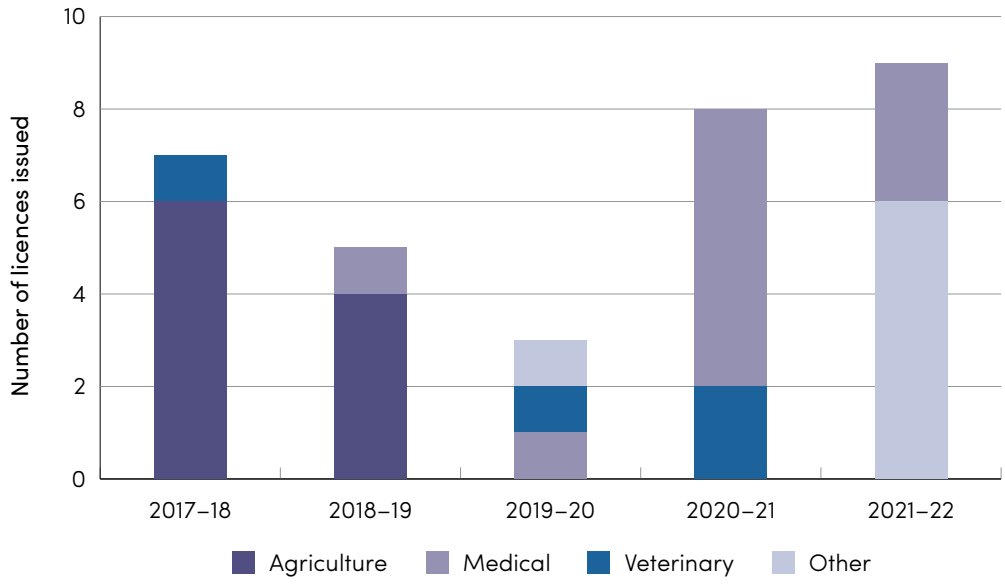
DIR = dealing involving intentional release of a genetically modified organism (GMO) into the environment; DNIR = contained dealing with a GMO not involving intentional release into the environment; NLRD = notifiable low risk dealing

a Correction to the number (108) reported in the 2018–19 report.

No licences were issued for commercial GMO therapeutics in 2021–22. This is in contrast to one licence issued in 2019–20 and 4 in 2020–21. Over the past 20 years there have been 10 licences issued for commercial GMO therapeutics, with 5 issued in the previous 2 years.

Canola/Indian mustard, wheat/barley and sorghum have been the most common crops for environmental release over the last 5 financial years. New crop licences in the last 5 years include trials of chickpea and perennial ryegrass. There has also been a marked increase in human vaccines and therapeutics being trialled and commercialised. In 2021–22, 3 new licences (limited and controlled) were issued for trials of GM therapeutics (Figure 21).

Figure 21: Focus of DIR licences, 2017–18 to 2021–22

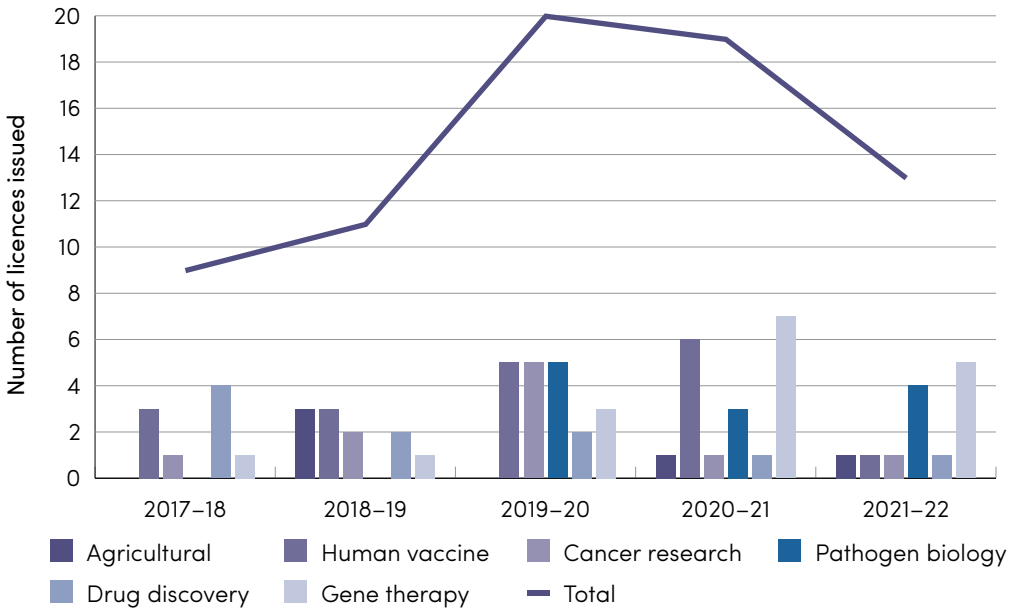


The number of DNIR applications in 2021–22 (13) remains higher than the 10-year average of 11.8 DNIR applications per year. The character of DNIR licence applications received has also changed, with a higher proportion of DNIR licences to conduct clinical trials with GMOs compared to contained laboratory work. This trend is also seen in the applications for organisations to be accredited to work with GMOs, where in some years over 80% of these applications are from organisations involved in human therapeutics (see Table 7). The fields of research authorised under DNIR licences over the past 5 years is further analysed in Figure 22. This shows the strong interest in gene therapy, and fewer licences issued over the past 2 years for cancer treatments.

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

	2017–2018	2018–2019	2019–2020	2020–2021	2021–2022
Clinical trial DNIRs (% of DNIR licences)	6 (66%)	9 (82%)	10 (50%)	12 (53%)	7 (54%)
Percentage of accreditation applications received from companies involved in clinical trials or human therapeutic GMO development.	57%	88%	60%	40%	83%

Figure 22: Fields of research authorised under DNIR licences, 2017–18 to 2021–22



Note: Agricultural include animal vaccines, importing grain for food or feed use, and studying the biology of plant and animal pathogens.

Cancer research involves both studying cancer mechanisms as well as developing and testing potential treatments.

Drug discovery involves identifying and testing possible new human therapeutics and delivery methods.

Human vaccines include both the development and testing of vaccines to be used in humans.

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

Gene therapy allows treatment of a genetic disorder by inserting a gene into a patient's cells.

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 information that 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 2021–22, the Regulator made 18 CCI declarations.

Surrenders

The surrender of licences and certifications usually occurs when GMO dealings have concluded. Before a 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 59 surrender requests in 2021–22 and approved 50 for surrender of certification of a physical containment facility, one for surrender of a DIR licence, 2 for surrender of DNIR licences and 4 for surrender of Accreditations. In addition, at 30 June 2022 one request for surrender had been withdrawn and one was still under consideration.

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).

The Regulator approved 519 variation requests in 2021–22. Of these, 6 were for DIRs, 35 for DNIRs and 478 for certifications.

Monitoring dealings with genetically modified organisms

This section provides information on the OGTR's inspection activities during 2021–22. Due to the COVID-19 pandemic travel restrictions, some of the monitoring and compliance activities were conducted in a desktop capacity. During 2021–22, the OGTR conducted:

- 6 monitoring inspections of DIR licences
- 4 monitoring inspections of DNIR licences
- 40 monitoring inspections of certified facilities
- 2 Practice Reviews.

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 assist with educating new licence holders about the gene technology scheme. For further information see sections on 'Inspections of contained dealings' and also 'Practice Reviews'.

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 that are conducting dealings.[9]

During 2021–22, there were 56 DIR licences in force held by 25 accredited organisations. These comprised:

- 27 commercial release licences[10] (19 for plant crops, 7 for human clinical products and one animal vaccine product)
- 29 limited and controlled release licences for research purposes (16 for plant field trials, 10 human clinical trials, 2 animal vaccine trials and one for microalgae).

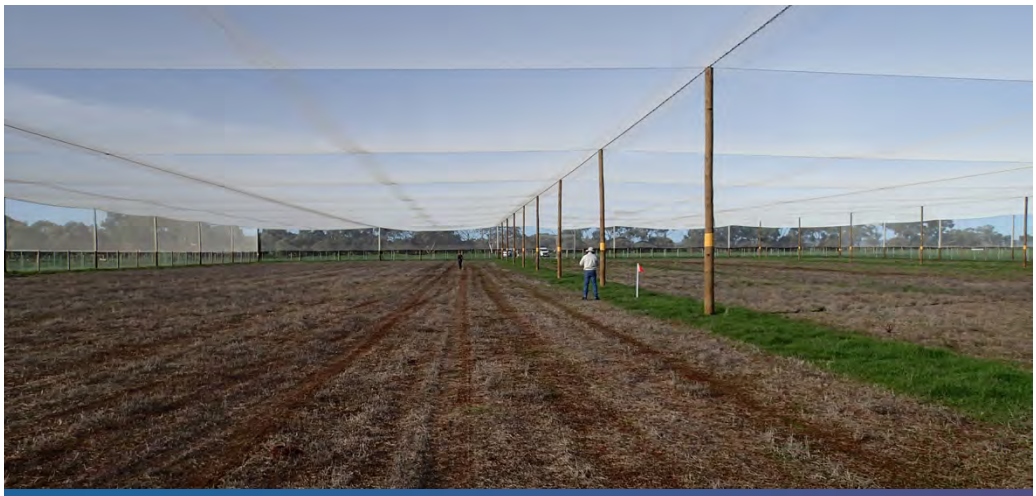
None of the commercial release licences imposed conditions that necessitated site inspections.

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 (that is, 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 2021–22, 22 licensed field trial sites were operating, 4 of which were current and 18 were subject to post-harvest monitoring conditions (Figure 23). Twenty-three per cent of the plant field trial sites were inspected in the year.

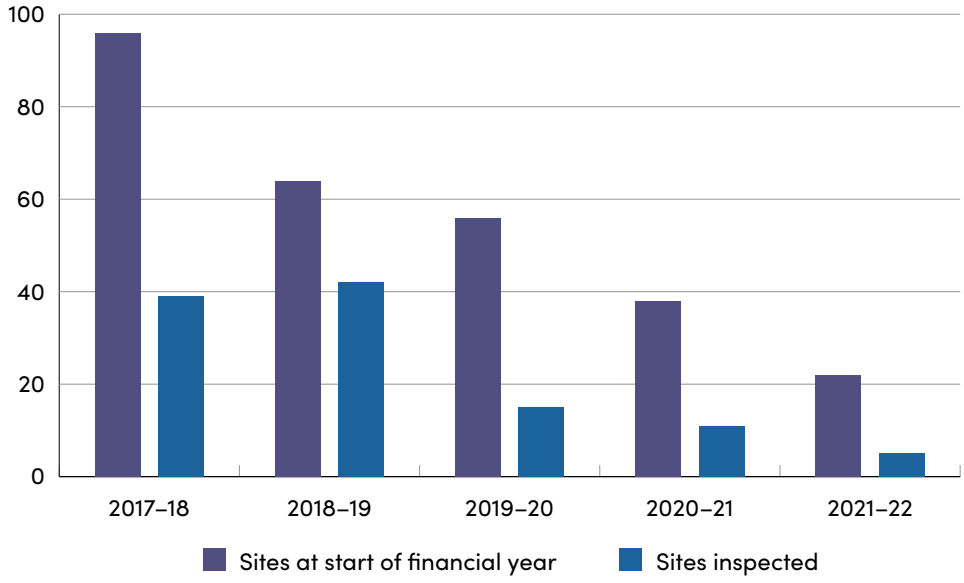


Wheat field trial site

9 Details are in the Monitoring Protocol on the OGTR website.

10 For more information see Categories of Licence at the beginning of Chapter 3.

Figure 23: Number of field trial sites and number inspected each year, 2017–18 to 2021–22



Types of GM crops inspected

OGTR inspected 3 plant species across 5 field trial sites during 2021–22 (Table 8). In 2021–22, the OGTR inspected field trial sites in Queensland, South Australia and Victoria. No trials were undertaken in Tasmania during 2021–22.

Table 8: Number of licensed GM plant DIR trial sites at beginning and end of 2021–22, and number inspected in 2021–22, by plant type

Species	Trial sites as at 1 July 2021	Trial sites as at 30 June 2022	Trial sites inspected during 2021–22
Banana	2	2	0
Barley, Wheat	1	1	0
Canola	0	5	0
Chickpea	1	1	0
Cotton	8	4	0
Perennial ryegrass	1	0	1
Sorghum	4	4	3
Wheat	5	4	1

Inspections of contained dealings

OGTR's 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.

During 2021–22, 40 certified facilities were inspected across the range of facility types (Table 9); this includes 2 of the 56 higher-level containment facilities that had certification approvals in force at the beginning of 2021–22 (representing 6%).

In addition, 5 licences for clinical trials or contained licences were subject to monitoring inspections or practice reviews throughout 2021–22 (Table 10).

Table 9: Number of inspections of certified facilities (by type) conducted during 2021–22

Containment type	PC level and facility type	Inspections
Lower level	PC1 Facility	0
	PC2 Animal	5
	PC2 Laboratory	23
	PC2 Plant	8
	PC2 Aquatic	0
	PC2 Large Grazing Animal	1
	PC2 Constant Temperature	0
	PC2 Invertebrate	1
Higher level	PC2 Large Scale	2
	PC3 Laboratory	0
	PC3 Animal	0
	PC3 Invertebrate	0
	PC4 Facility	0
Total		**40**

PC2 laboratory

PC2 laboratory

Table 10: Number of inspections or practice reviews of contained licences and clinical trials conducted during 2021–22

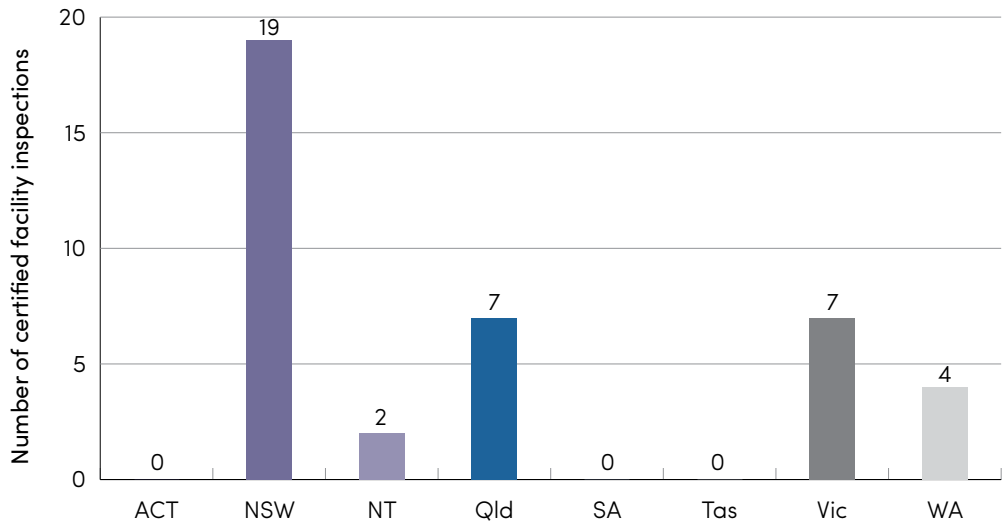
Organisation	State	Licence
Novotech Australia Pty Ltd	Qld	DIR 181 (PR)
Ascend Biopharmaceuticals Ltd	Qld	DNIR 536
Pfizer Australia Pty Ltd	NSW	DNIR 569
BioMarin Pharmaceutical Australia Pty Ltd	NSW	DNIR 600
CSIRO	ACT	DNIR 618
Total		**5**

PR – Practice review

Locations of facility inspections

Certified facilities are located in all Australian states and territories (Figure 20). In 2021–22, monitoring activities took place in each state and territory except the Australian Capital Territory, South Australia and Tasmania (Figure 24).

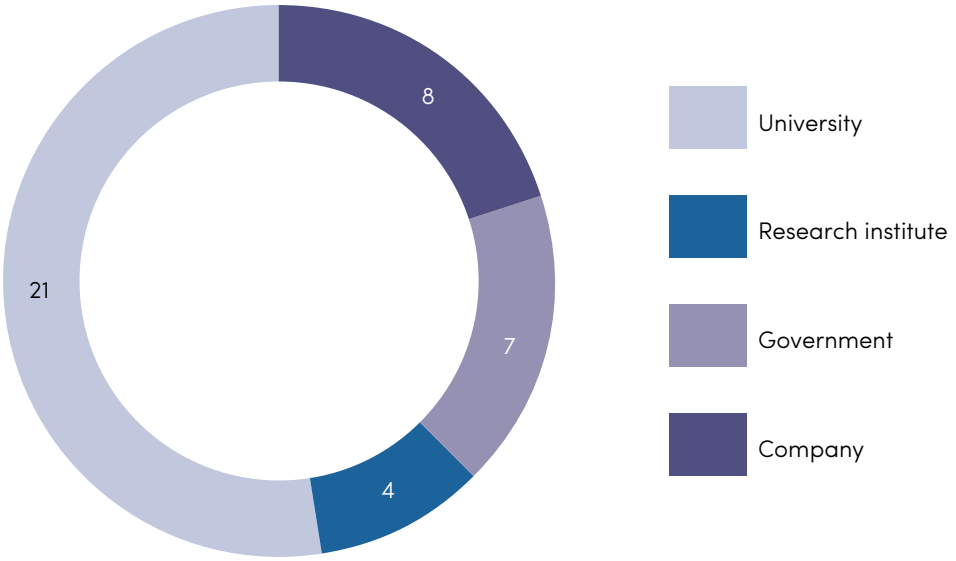
Figure 24: Number of certified facility inspections in 2021–22, by state and territory



Types of organisations inspected

Of the 5 categories of applicant organisations, universities held the largest number of certified facilities during 2021–22 (Figure 19). Figure 25 displays the distribution of inspections during 2021–22 by organisation type. Universities comprised the majority of inspections followed by companies, government and research institutes.

Figure 25: Certified facility inspections in 2021–22, 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.[11]

During 2021–22, the regulated community continued to demonstrate a high level of compliance with the gene technology legislation.

11 The Compliance and Enforcement Policy is on the OGTR website.

Non-compliance findings for GMO dealings involving intentional release

In 2021–22, non-compliances were identified against one DIR licence. The findings are outlined below.

Organisation	Bioproperties Pty Ltd.
Licence number	DIR-154
Summary of dealing	The purpose of the field trial is to assess the efficacy and safety of the GMO under field conditions for protection of chickens from infectious laryngotracheitis disease, including likelihood of challenge with a range of distinct field ILTV strains. The field trials would also assess the capacity of the GMO for transmission and recombination with other ILTV strains.
Findings	1. At least 14 days prior to undertaking inoculation of chickens with the GMO, Bioproperties Pty Ltd did not provide a Compliance Management Plan to the Regulator as required (Licence Condition 16). 2. At least 14 days prior to undertaking inoculation of chickens with the GMO at each participating farm, Bioproperties Pty Ltd did not provide a Contingency Plan to the Regulator as required (Licence Condition 70). 3. At least 7 days prior to commencing dealings at each participating farm, Bioproperties Pty Ltd did not provide the Regulator with the information as required (Licence Condition 72 a–d). 4. At least 7 days prior to commencing dealings with the GMO at each participating farm, Bioproperties Pty Ltd did not provide the Regulator the information as required (Licence Condition 73 a–i).
Assessment	1. Bioproperties Pty Ltd have provided all the documents as mentioned under Findings on 29 April 2022, the day they started dealing with the GMOs. 2. Inspectors of the Monitoring and Compliance section of the OGTR inspected Farm Site 4, discussed the above findings with Bioproperties Pty Ltd and were assured of stringent compliant behaviour in the future. 3. Bioproperties Pty Ltd have developed new procedures establishing a clear reporting hierarchy to control all methods of distribution of the vaccine under the licence conditions for DIR-154, including requiring evidence of completion of all licence conditions obligations before releasing the vaccine for trials at each participating farm or facility.
Compliance management	Bioproperties Pty Ltd has been reminded of their obligations as a licence holder under the *Gene Technology Act 2000*.

Non-compliance findings for GMO dealings not involving intentional release

In 2021–22, non-compliances were identified against one DNIR licence. The findings are outlined below.

Organisation	CSIRO
Licence number(s)	DNIR-618
Summary of dealing	To determine if new genetic technologies, namely gene drives, can be used to control plant pathogenic fungi.
Findings	1. Prior to undertaking transport and decontamination of waste containing GMOs, CSIRO did not inform a number of support staff and external contractors authorised by the licence of relevant licence conditions that applied to them (Condition 12) or obtain signed statements from these people confirming that they had been trained in, understood and had agreed to be bound by licence conditions (Condition 17). 2. Support staff transported liquid waste containing GMOs in a manner inconsistent with licence conditions (Condition 23). Waste was not packed inside a sealed, unbreakable secondary container nor labelled as containing GMOs.
Assessment	Licence conditions place specific controls on the transport and disposal of GMOs to manage risks to people and the environment arising as a result of unintentional exposure. Support staff who transport and dispose of GMO waste were not informed of these licence conditions and consequently transported liquid waste containing GMOs incorrectly. Despite this, there were no reported spills of GMOs and records and information provided by CSIRO show that GMOs were decontaminated in an appropriate manner so as to render them non-viable. As such no additional risks were identified.
Compliance management	OGTR has reminded CSIRO of its obligation to ensure that all people undertaking licensed dealings are trained in licence conditions and have provided signed statements. CSIRO is also required to review and update where necessary the training of all authorised persons with regards to transport and disposal requirements.

Non-compliance findings for notifiable low risk dealings

In 2021–22, 2 NLRDs were found to be non-compliant against the Act, in that dealings were being undertaken without a current NLRD.

In both cases, the licence holders took corrective and preventative measures for the future and no further actions were recommended.

Non-compliance findings for physical containment facilities

In 2021–22, 10 certified physical containment facilities were found to be non-compliant with a total of 11 certification conditions. These findings are summarised in Table 11.

Table 11: Number of non-compliances identified in certified facilities during 2021–22, by non-compliance type

Nature of non-compliance	Number
Equipment	0
Personal protective equipment	0
Structure	4
Transport	1
Waste disposal	1
Work practices	5

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 of cooperative compliance.

Compliance and enforcement mechanisms

Practice reviews

The OGTR may initiate practice reviews:

- to explore topics that could potentially pose compliance issues in the future
- to assess the effectiveness of systems used by licence holders and IBCs
- 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 2 practice reviews with 2 organisations during this reporting period. In addition to these, one practice review from 2020–21 was not finalised until 2021–22 and is now included in this report. All 3 practice reviews covered the preparedness of the organisations to undertake licensed dealings under DIRs and DNIR respectively. The findings for the reviews are outlined below.

Topic	Preparedness of accredited organisations to undertake licensed dealings involving an intentional release – limited and controlled
Aim	This is part of the OGTR's ongoing practice review program. The OGTR recognises that effective compliance is dependent on: • suitable arrangements to manage compliance for GMO dealings • suitable site selection and appropriate use of containment measures • staff training and provision of resources necessary to manage compliance obligations.
Participants	The review focused primarily on the organisations' preparedness to undertake licensed dealings and included: PTM Solutions Australia Pty Ltd and Novotech (Australia) Pty Ltd**.** The review assessed: • site selection and planning considerations for containment measures • the suitability of the organisations' arrangements to manage compliance risks, including training, oversight of staff, collaborating organisations and resourcing • any industry or other regulatory issues which could impinge on the organisations' effective compliance performance.
Findings	The review found that the participating accredited organisations had considered and implemented effective measures in relation to site selection and planning for a licensed dealing involving a limited and controlled release.
Outcomes	The OGTR practice review program continued to assess vulnerabilities to containment and compliance with the *Gene Technology Act 2000*. Such information contributed to: • an overall understanding of compliance performance and emerging barriers to effective compliance • the continual improvement of compliance management processes • the prevention of practices and arrangements that could lead to non-compliance • compliance management and awareness activities.

Topic	Preparedness of accredited organisations to undertake licensed dealings not involving intentional release – practice review
Aim	This is part of the OGTR's ongoing practice review program. The OGTR recognises that effective compliance is dependent on: • suitable arrangements to manage compliance for GMO dealings • suitable site selection and 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. The organisation included in the practice review was the University of Queensland The review assessed: • certified facilities selection and planning considerations for containment measures • 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 organisations effective compliance performance.
Findings	• The review found that the participating accredited organisation had considered and proposed to implement effective measures and planning for a licensed dealing not involving an intentional release. • The review also found some deficiencies in the certified animal facility that would be used for the dealing, notably that individually ventilated cages (IVC) to house the animals were lacking at that facility.
Outcomes	The OGTR practice review program continued to assess vulnerabilities to containment and compliance with the *Gene Technology Act 2000*. Such information contributed to: • an overall understanding of compliance performance and emerging barriers to effective compliance • the continual improvement of compliance management processes • the prevention of practices and arrangements that could lead to non-compliance • compliance management and awareness activities.

Audits

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

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

These activities are conducted to:

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

Audits are an opportunity for organisations and the OGTR to share information to improve the risk management of dealings with GMOs under the Act. Audits may focus on a single dealing or issue, a range of dealings (e.g., dealings with a common host organism or dealings within a common climatic zone), the activity of an organisation across a range of dealings, or an activity common to a range of organisations. During the period 2021–22, the OGTR undertook audits on the management and segregation of non-GMO and GMO dealings as summarised below.

Audit	Total Livestock Genetics Pty Ltd PTM Solutions Australia Pty Ltd
Aim	To provide advice to the Regulator with regards to ensuring handling of GMOs comply with requirements and to manage and segregate GMO from non-GMO dealings.
Determination	These audits focused primarily on management of GMO animal dealings under consideration by each audited entity. The audit assessed: • existing quality assurance procedures • segregation of non-GMO and GMO dealings • training, procedures and documentation • the suitability of arrangements to manage transport, storage and disposal of organisms • any industry or other regulatory issues which could impinge on effective compliance performance.
Action	The audit found that both organisations had considered and implemented effective measures in relation to planning for dealings to manage and segregate GMO from non-GMO dealings.

Audits are also undertaken as part of the national strategy for unintended presence of unapproved GMOs in agricultural crops. 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 in agricultural crops. We have worked with the Australian Seed Federation (ASF) to develop a voluntary testing program of existing industry quality assurance measures.

In 2021–22, 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. The OGTR audited the following organisation's quality assurance systems and did not identify any issues of concern: PGG Wrightson Seeds.

We continued to engage with other government departments, including the Australian Government Department of Agriculture, regarding low-level presence of unapproved GMOs.

Investigations

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

No investigations were undertaken in this reporting period.

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 2021–22, the OGTR continued to work with the Office of Health Protection and Response 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 2021–22. Some inspections continued in a desktop capacity during this time.

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 2021–22 annual report, is summarised below.

Our activities for 2021–22 are described under Program 1.8 in Outcome 1 (Health Policy, Access and Support) of the 2021–22 Department of Health Portfolio Budget Statements.[12] The key objective of the subprogram relating to gene technology regulation is:

> ***Protect human health and the environment through the regulatory oversight of genetically modified organisms.***

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

Percentage of GMO licence decisions made within statutory timeframes.

2021–22 target	2021–22 result: Met
100%	100% of licensed dealings were made within statutory timeframes, with all decisions based on sound scientific analysis.

The Office of the Gene Technology Regulator has skilled technical staff to conduct science-based risk analysis. Project management structures are in place for all licence applications, including timeframe and quality assurance reporting, with public consultation procedures built into relevant decision-making processes.

The following licences were issued during 2021–22:

- 4 agricultural licences including 1 licence for the commercial release of a GM crop, and 3 licences for trials of GM crops
- 10 clinical trial licences:
  - 2 licences for the trial of GM cancer treatments
  - 5 licences for gene therapy trials
  - 3 licences for GM vaccine trials
- 4 laboratory-based research licences
- 2 manufacturing licences.

12 The Portfolio Budget Statement is on the department's website.

Percentage of reported non-compliance with the conditions of GMO approvals assessed

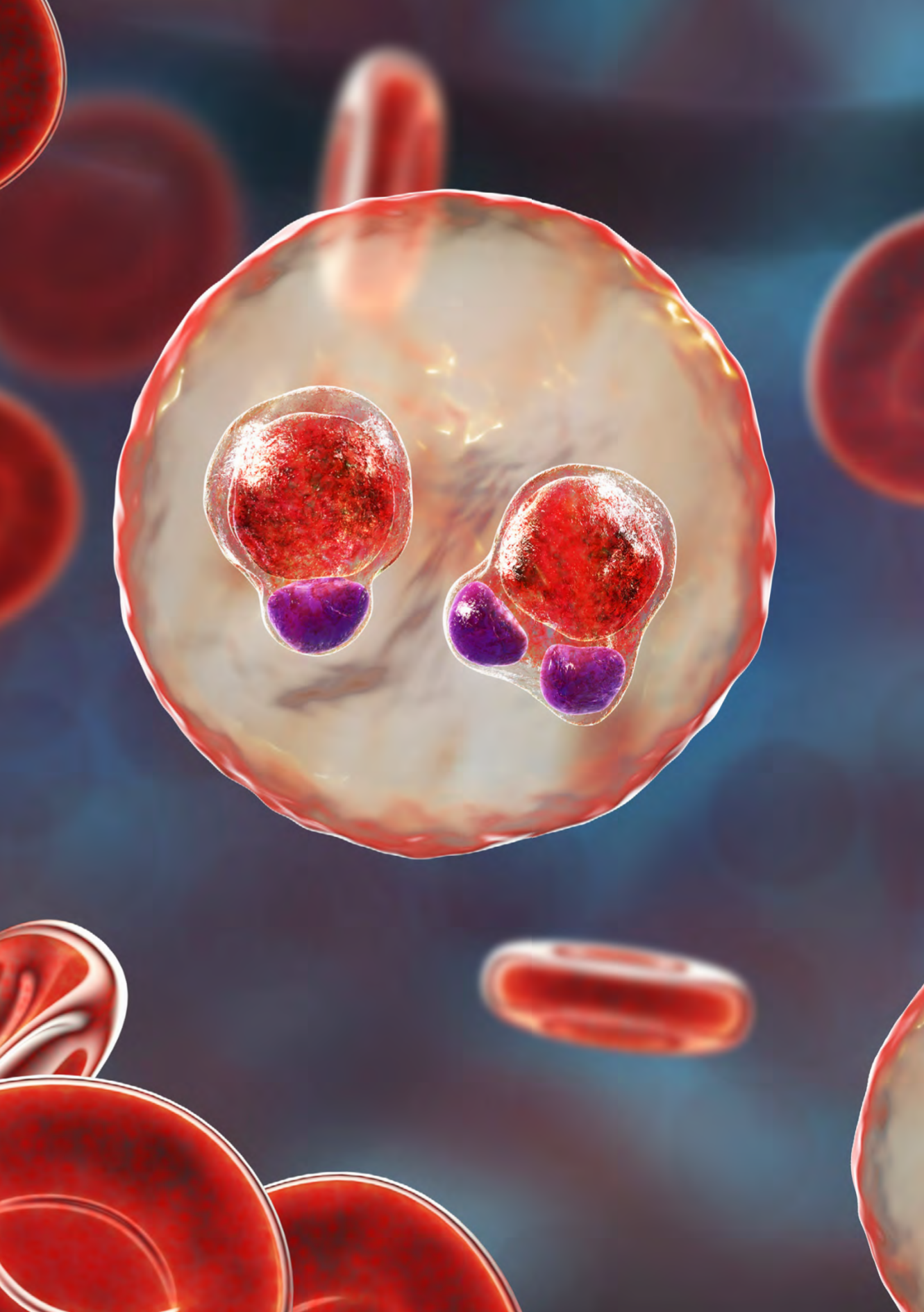
2021–22 target	2021–22 result: Met
100%	100% of reported non-compliance with conditions were assessed.

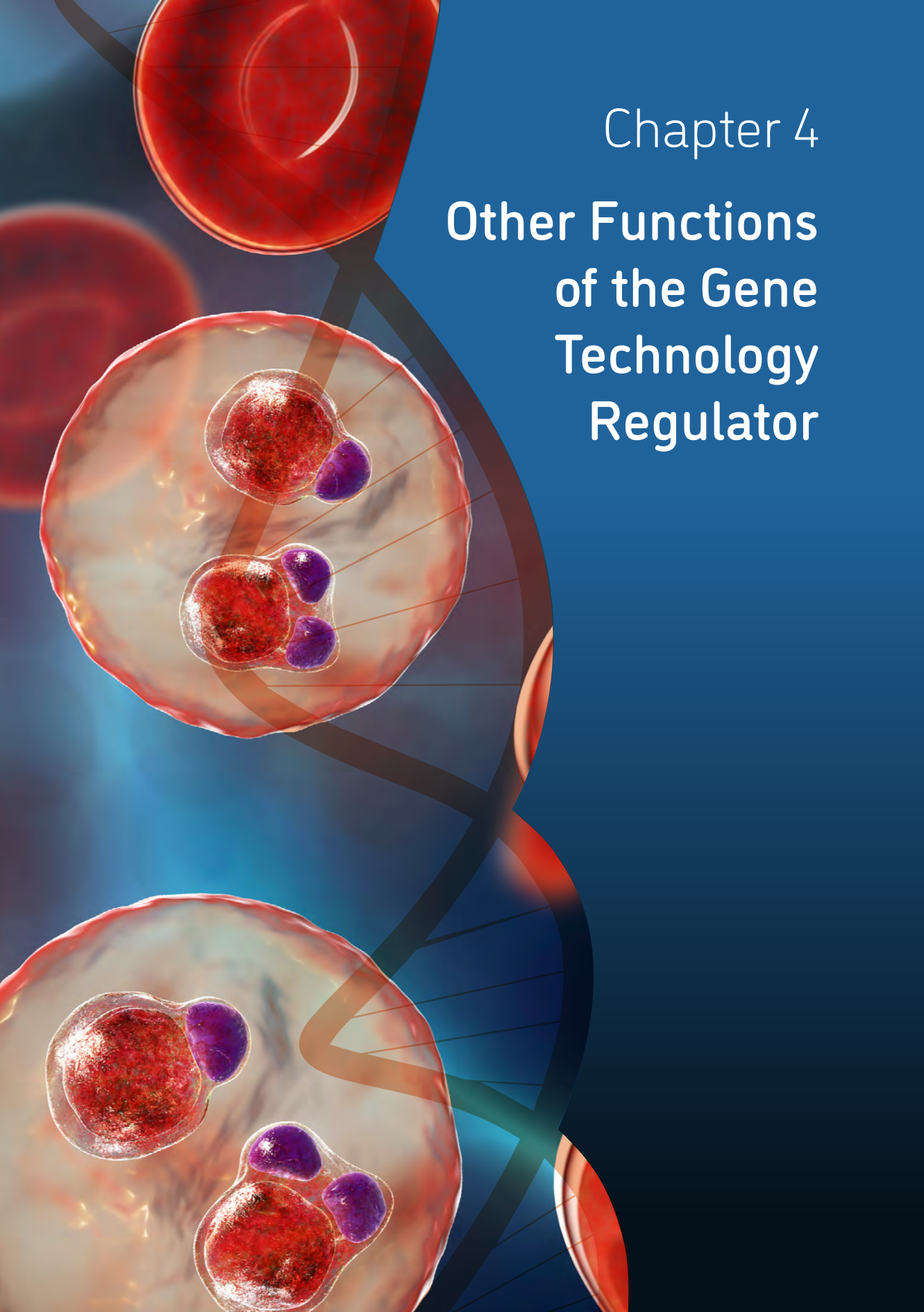
OGTR Monitoring and Compliance received 48 reports relating to Licences, Notifiable Low Risk Dealings or Certifications during the 2021–22 year. All 48 reports were assessed, meeting the target of 100%.

OGTR Monitoring and Compliance inspectors assess all reports received. Each report is assessed for risks to human health and the environment.

Assessments consider the circumstances of the report in accordance with the *Gene Technology Act 2000*, and Gene Technology Regulations and Guidelines. For any non-compliance identified, inspectors will consider the compliance history of entities involved, whether the non-compliance has been rectified or can easily be rectified, and whether the non-compliance resulted in harm to human health or the environment.

OGTR Monitoring and Compliance takes a cooperative compliance approach with an emphasis on education, engagement and awareness-raising. When assessing a non-compliance the aim is to bring the entity back into compliance and work with them to ensure they remain compliant.





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 GTMM
- 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 GTMM 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 2021–22, OGTR has continued reviewing the PC3 Certification Guidelines. This activity follows on from regulated stakeholder workshops held in 2018–19 in Melbourne, Sydney and Brisbane, and at the 2019 IBC Forum. Work in 2021–22 has focused on drafting the revised Guidelines and accompanying guidance document and consulting on the draft Guidelines with regulated stakeholders and technical experts.

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

OGTR has continued to provide technical and operational information to assist the Department of Health team who lead the implementation of the 27 recommendations of the Third Review of the National Gene Technology Scheme. This 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.

Advice on GMOs and GM products

During 2021–22, 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 product regulators and other agencies on assessing and approving GMOs and GM products a new Memorandum of Understanding was established with the National Health and Medical Research Council regarding general information sharing.

Work experience

The Regulator maintains a Memorandum of Understanding with the University of Canberra which allows students undertaking relevant studies to gain work experience in a regulatory science environment by spending a short period of time at the OGTR.

Two students undertook work experience with the Contained Dealings Evaluation Section to gain experience of working in the public service.

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.

Dr Heidi Mitchell from OGTR was the 2021 chair of the RSN.

OGTR organised the 2021 RSN Annual Symposium on 'Regulating for human health – lessons learned from COVID-19' which was chaired by Dr Heidi Mitchell and featured a keynote presentation by Ms Geraldine Lester. The symposium was run in an online format and was well-attended by OGTR staff.

OGTR continues to be active in the RSN. Dr Peter Thygesen from OGTR has presented in the lunchtime webinars about his work and how it connects with the work of other RSN agencies.

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.[13] The GMO Record contains information on licences issued, NLRDs notified, GMO dealings included on the Register, and emergency dealing determinations. During 2021–22, OGTR maintained the GMO Record and updated it with new authorisations.

Engagement with stakeholders

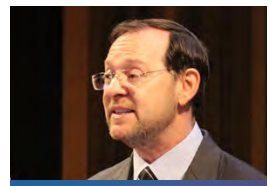
9th National Institutional Biosafety Committee Forum

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

The 9th National IBC Forum was held in Canberra on 12 and 13 May 2022 at the Academy of Science. Representatives of IBCs and accredited organisations from most states and territories attended with 121 delegates from 80 organisations. Professor John Rasko, Chair of the Gene Technology Technical Advisory Committee, opened the forum and also gave the keynote address on 20 years of clinical trials.

Guest speakers and panel members from organisations and IBCs, together with OGTR staff, contributed to an engaging and well-received program. The forum provided an important opportunity for feedback and exchange of information between IBCs and the OGTR, enhancing regulation of gene technology. The forum also provided an opportunity to celebrate 20 years of gene technology regulation. Dr Fay Jenkins gave a presentation on her experience of 20 years of regulation from the perspective of a state government representative. Dr Craig Cormick presented his work studying 20 years of community attitudes to gene technology and Prof Peter Langridge spoke on 20 years of GM plants.

9th National Institutional Biosafety Committee Forum



Professor John Rasko

Professor Paul Young

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

OGTR website

A new OGTR website was launched on 7 September 2021. The new and improved ogtr.gov.au is easier to read and use and is more accessible for mobile phones. The new website has been updated to meet the requirements for an Australian government website and is also consistent with the Department of Health's new website. The new website is easier to navigate and find the required content.

OGTR newsletters

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

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

In 2021–22 one newsletter was produced. It featured information on 20 years of OGTR, the IBC Forum, the 2021 survey of community attitudes towards gene technology commissioned by OGTR, and an update on a recently introduced Smart Form – Notification of Minor Works.

Digital service delivery for applications to the Regulator

As part of the ongoing business improvement initiatives and development of digital service delivery, one new form was released during 2021–22. The Notification of Minor Works form was developed for certified facilities to mitigate the need to vary or suspend an existing certification when minor work to a PC1 or PC2 certified facility is being undertaken, provided certain criteria are met.

In addition, work on several forms has progressed during 2021–22 with the view to releasing these within the 2022–23 financial year. These forms include:

- Authorisation Guidance Tool
- Application for Accreditation of an Organisation
- Application to Vary a DIR Licence
- Application to Vary a DNIR Licence
- Application to Transfer an Authorisation.

IT systems modernisation project

The OGTR is engaged in a project to modernise internal IT information management systems. This is in line with the Government's Digital Transformation Strategy to ensure that stakeholder interactions with government can occur in a simple and accessible way. It is also part of the Department of Health's ICT Strategy to provide innovative, secure and sustainable ICT services. The new system will streamline and improve OGTR processing of applications and capitalise on initiatives in the digital service delivery space enabling automated application receipt via online forms. It also provides a platform to build greater capabilities for enabling more agile and scalable responses to implementing recommendations from the Third Review of the National Gene Technology Scheme.

Information on COVID-19

In response to the COVID-19 pandemic and the associated border closures, travel restrictions and physical distancing restrictions, the OGTR maintained 2 factsheets. These provided information about how the OGTR was continuing to engage with stakeholders and suggestions for how to manage certified facilities and licences during COVID-19 restrictions. The OGTR also continued to work with stakeholders to ensure protection of people and the environment from GMO dealings whilst also recognising the disruption caused by the pandemic and the implementation of COVID-19 response measures. This has included using remote and desktop inspections, facilitating online meetings and prioritising applications for COVID research or therapeutics, where possible.

OGTR staff were also part of the Department's scientific reference panel for new COVID-19 therapeutics.

Meetings, conference attendance and 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. During 2021–22, the Regulator and 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. These included:

- Presentation to La Trobe University students, 20 August 2021
- CSIRO webinar on Synthetic Biology, 26 August 2021
- University of Queensland workshop on Emerging Issues in the Regulation of Synthetic Biology in Australia, 2 September 2021
- AusBiotech (Australia's life sciences conference), 26–29 October 2021
- Regulatory Science Network Symposium—'Regulating for human health – lessons learnt from COVID-19', 3–4 November 2021
- Institute of Public Administration Australia conference on Regulatory Reform, 16–17 February 2022
- ISCT ANZ Regional Meeting, 24–25 February 2022
- ARCS Annual Conference, Sydney, 23–25 May 2022
- ISAAA Gene drive webinar series – May 19 and June 16 2022
- Meeting of the Advanced Biomanufacturing Working Group, QLD 8 June 2022
- RSN Seminar, 'Environmental risk assessment of organisms – are there generic considerations?', online 16 June 2022
- Annual ABSANZ Biosafety and Biocontainment Conference – 27–28 June 2022.

ARCS Annual Conference booth

Research undertaken or commissioned by the Regulator

Documents to support the risk analysis of GMOs

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

During 2021–22, OGTR updated one biology document:

The Biology of *Hordeum vulgare* L. (barley).

This, and other biology and risk analysis documents, are available on the OGTR website.

Genetically Modified Organism Herbicide Tolerance Trait Review

After almost 20 years of GM cropping experience with cotton and canola in Australia, it is timely to consider issues associated with herbicide-tolerant traits, weed resistance and changes in weed management measures. As part of 20 years of operation of the *Gene Technology Act 2000*, the Regulator commissioned a report to provide advice on genetically modified organisms (GMOs) (crops) containing multiple herbicide-tolerant traits and impacts on herbicide use, herbicide tolerance and herbicide resistance management issues in Australia.

The report was prepared by Dr Rohan Rainbow, Managing Director of Crop Protection Australia. It was peer reviewed by industry and regulatory experts before being finalised and published on the OGTR website[14] on 27 January 2022.

Community attitudes survey

Since 2015, the Regulator has commissioned surveys of community attitudes towards gene technology to gauge the state of Australian public awareness of gene technology, to identify knowledge gaps and to track changes in awareness and attitudes over time. A survey was commissioned in 2021 and, in broad terms, community attitudes and beliefs about genetic modification have changed little since the last survey in 2019. Similarly, understanding of genetic modification is unchanged. Since 2019, however, more people now say that GMOs will improve our way of life (up 9% since 2019), while support for genetic modification in general is up (by 6%), including for: medical uses (up 8%), using genetic modification to assist growing food (up 9%), and its use in modification of plant genes (up 8%).

The full report, and the 3 previous reports, can be found on the OGTR website.[15]

14 https://www.ogtr.gov.au/resources/publications/genetically-modified-organism-herbicide-tolerance-trait-review

15 https://www.ogtr.gov.au/resources/collections/community-attitudes-gene-technology-reports

Promoting harmonisation

The Regulator and OGTR continued to liaise with other regulatory and Australian Government agencies on relevant issues, but in a somewhat different format to usual during 2021–22 due to the COVID-19 pandemic.

International regulatory liaison

All international engagement and participation in 2021–22 was virtual and online and did not involve any travel, due to COVID-19 travel restrictions.

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 United Nations (UN) Convention on Biological Diversity and Cartagena Protocol on Biosafety (the Protocol), most recently regarding the development of the Post-2020 Global Biodiversity Framework. OGTR also contributes to Australian submissions on the regulation of GMOs, and is the national focal point for the Protocol and for the Biosafety Clearing-House.

The OGTR is also responsible for entering Australian commercial approvals of GMOs into the OECD BioTrack Product Database[16] and the UN Biosafety Clearing-House.[17]

By participating in and presenting at international forums, the OGTR continued to interact with key regulatory counterparts in other countries during 2021–22, including:

- Online meetings with African countries on stacking of GM traits in plants, July 2021
- Association of Southeast Asian Nations (ASEAN) GM Food Testing Network Gene Editing Workshop (online), 21 July 2021
- UN Convention on Biological Diversity meeting: Post-2020 Global Biodiversity Framework, 30 July 2021
- APEC High Level Policy Dialogue on Agricultural Biotechnology plenary, 3 August 2021
- Asia-Pacific Association of Agricultural Research Institutions webinar on enabling policies for genome editing in agriculture, 18 August 2021
- International Service for the Acquisition of Agri-Biotech Applications (ISAAA) virtual workshop on science and opportunities of animal biotechnology for food and agriculture, 21 August to 1 September 2021
- The Science, the Opportunities and Regulation of Animal Biotechnology: Genome Engineering (GE) and Gene Editing (GnEd) webinar series – 31 August – 1 Sept 2021
- Presentation to the Genetic Modification Advisory Committee of Malaysia, 1 September 2021

16 The BioTrack Product Database is on the OECD website.

17 The Biosafety Clearing-House is online.

- Global Low-Level Presence Initiative intersessional meeting, 15 November 2021 and 8th meeting, 23 March 2022
- Presentation at the International Cell and Gene Therapy ANZ Regional Meeting, 24–25 February 2022
- 36th meeting of the OECD WPHROB, online, 18–20 May 2022
- ISAAA Webinar – Key Considerations for Risk Assessment of Gene Drive Technologies, 16 June 2022
- Meeting of the like-minded group on Agricultural Applications of Precision Biotechnology, 30 June 2022.

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 Regulator reports to Parliament annually, as required by legislation.

Human resources

The OGTR has a workforce of 51 employees at 30 June 2022. 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 12.

Table 12: 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 21st 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 but was reinstated in March 2021. 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 Starlight Children's Foundation.

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

Regulator's Achievement Award

This year, 2 teams received the Regulator's Achievement Award. The awards were in recognition of inclusive leadership, cross-office collaboration, and intense periods of work to meet short timeframes. Both teams were informing the work of other groups in the department, and heavily involved in internal staff training and workshops.

The Application Entry Point/Customer Relationship Management (CRM) team undertook extensive consultation and engagement within the office when developing the application part of CRM. This included office-wide presentations, targeted presentations/training, user acceptance testing (UAT) groups, and one-on-one meetings – all of which ensured everyone affected knew what was happening and had the opportunity to have input during the development and testing phases. They also developed an extensive set of standard operating procedures (SOPs) and guidance notes and continue to offer ongoing support. The team put in long hours, and still kept up with their day-to-day work. The result is that staff are well trained in how to use a wonderful, powerful product which is an integral part of the OGTR business systems.

The Application Entry Point/Customer Relationship Management (CRM) team

The Scheme Review Team in the Regulatory Practice Section has been heavily involved in working with the Gene Technology Policy and Governance team of the department to implement recommendations from the Third Review of the Gene Technology Scheme. The team members demonstrated willingness to go above and beyond what could be reasonably expected to ensure the best possible outcomes for the OGTR in the scheme review process. This was demonstrated by the time and energy put in to the work, in less-than-ideal circumstances driven by external time pressures. The commitment, hard work and level headedness of the team members is a great example of leadership and professionalism at the OGTR.

The Scheme Review Team

Training and development

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'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.

In 2021–22, refresher training was given to the emergency control team, which comprises 3 fire wardens and 2 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 2021–22, the OGTR Principal Legal Officer was to provide introductory and ongoing training for OGTR staff on legal issues. Some of this training had to be put on hold due to the COVID-19 pandemic situation. One session was held on 22 June 2022: 'OGTR Legal Training 1: Fundamentals for contractors and new starters'.

During 2021–22, the OGTR Principal Regulatory Scientist was to provide introductory and ongoing training for OGTR staff on risk analysis. Some of this training had to be put on hold due to the COVID-19 pandemic situation. One session was held on 23 June 2022: 'Introduction to OGTR Risk Analysis'.

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 the second half of 2021 the majority of staff worked partially or wholly from home. 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.

Staff were encouraged to return to office in late 2021 but due to further COVID-19 outbreaks staff were encouraged to work from home and can use workplace agreements to continue to access remote working flexibility as appropriate.

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 2021–22, we conducted training for officers, workers, health and safety representatives, and a harassment contact officer. An e-learning module is available for all staff, including contractors and consultants, and an overview of the *Work Health and Safety Act 2011* is available on the Department's intranet site. We have incorporated strategies for identifying and managing work health and safety risks into business planning processes, 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 in 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 in 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.[18]

Freedom of information contact details and procedures

The OGTR received 6 requests for access under freedom of information legislation during the reporting period.

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.[19]

18 The OGTR's Information Publication Scheme Agency Plan is on our website.

19 The OGTR's Freedom of Information Disclosure Log is on our website.

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.

OGTR website

In 2020–21 the OGTR received funding from the department to update the OGTR website to enable it to meet the Australian Government Digital Service Standard.[20] The OGTR worked with the department to improve the content and readability of the website. The new site went live in September 2021, with very positive feedback.

Website usage

Table 13 tracks monthly usage numbers for the OGTR website. The most viewed pages and downloaded applications are listed below.

Table 13: Website activity, 2021–22

Month	Visits[a]	Users[b]
July	6,563	4,779
August	6,878	5,141
September	10,415	7,689
October	6,496	6,124
November	7,675	6,937
December	4,485	4,137
January	5,066	4,538
February	6,750	6,408
March	7,648	4,564
April	5,811	3,688
May	6,512	4,139
June	9,680	6,887

a The number of times the website was visited in the date range.

b The number of people that visited the website on a unique device.

20 https://www.dta.gov.au/help-and-advice/about-digital-service-standard

The most viewed pages on the OGTR website during 2021–22 were, in descending order:

1. Office of the Gene Technology (home page)
2. Dealings involving intentional release
3. Resources
4. What we've approved
5. About the OGTR
6. Apply for GMO approval
7. Types of GMO dealings
8. Ongoing regulatory compliance
9. Guidelines for certification of physical containment facilities
10. Legislative Documents.

The most downloaded applications in 2021–22 were:

1. Application for a licence for dealings not involving intentional release of a GMO (DNIR)
2. Application Checklist for a Physical Containment Level 2 Laboratory
3. Application for Accreditation of an Organisation
4. Application for a DIR licence involving a non-plant GMO
5. Application for a DIR licence for commercial release of GM plants
6. Application for a DIR licence for the limited and controlled release of GM plants
7. Application for a confidential commercial information (CCI) declaration
8. Application for the Certification of a Physical Containment Facility
9. Application Checklist for a Physical Containment Level 2 Large Scale Facility
10. Application to vary a DNIR licence.

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 2021–22, use of the email address increased compared with the previous year (Table 14).

Table 14: Email activity, 2021–22 and 2020–21

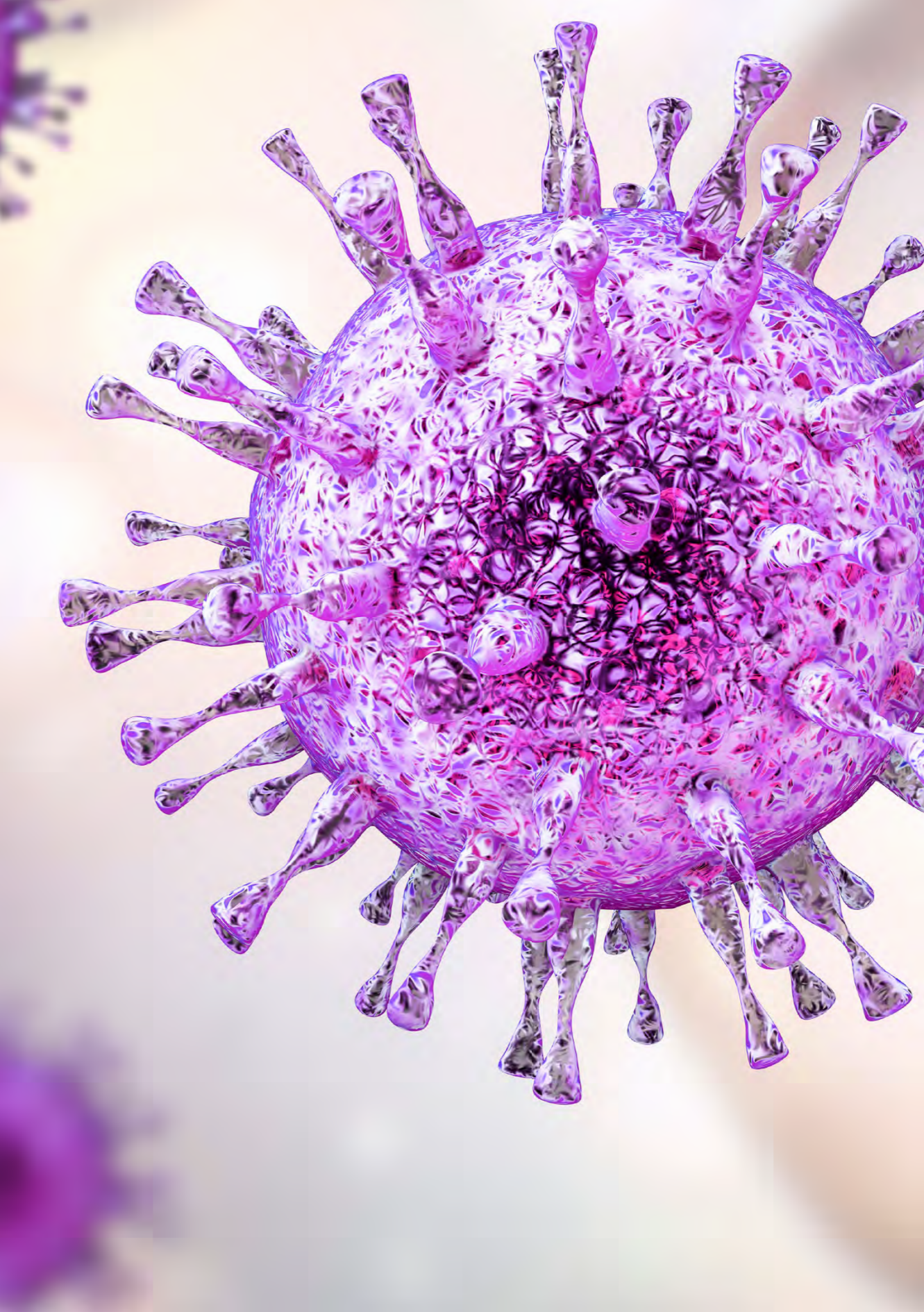
	Emails	
Month	2021–22	2020–21
July	31	34
August	38	27
September	55	25
October	40	28
November	39	38
December	53	30
January	43	92
February	41	55
March	110	64
April	170	53
May	80	60
June	65	45
Total	765	551

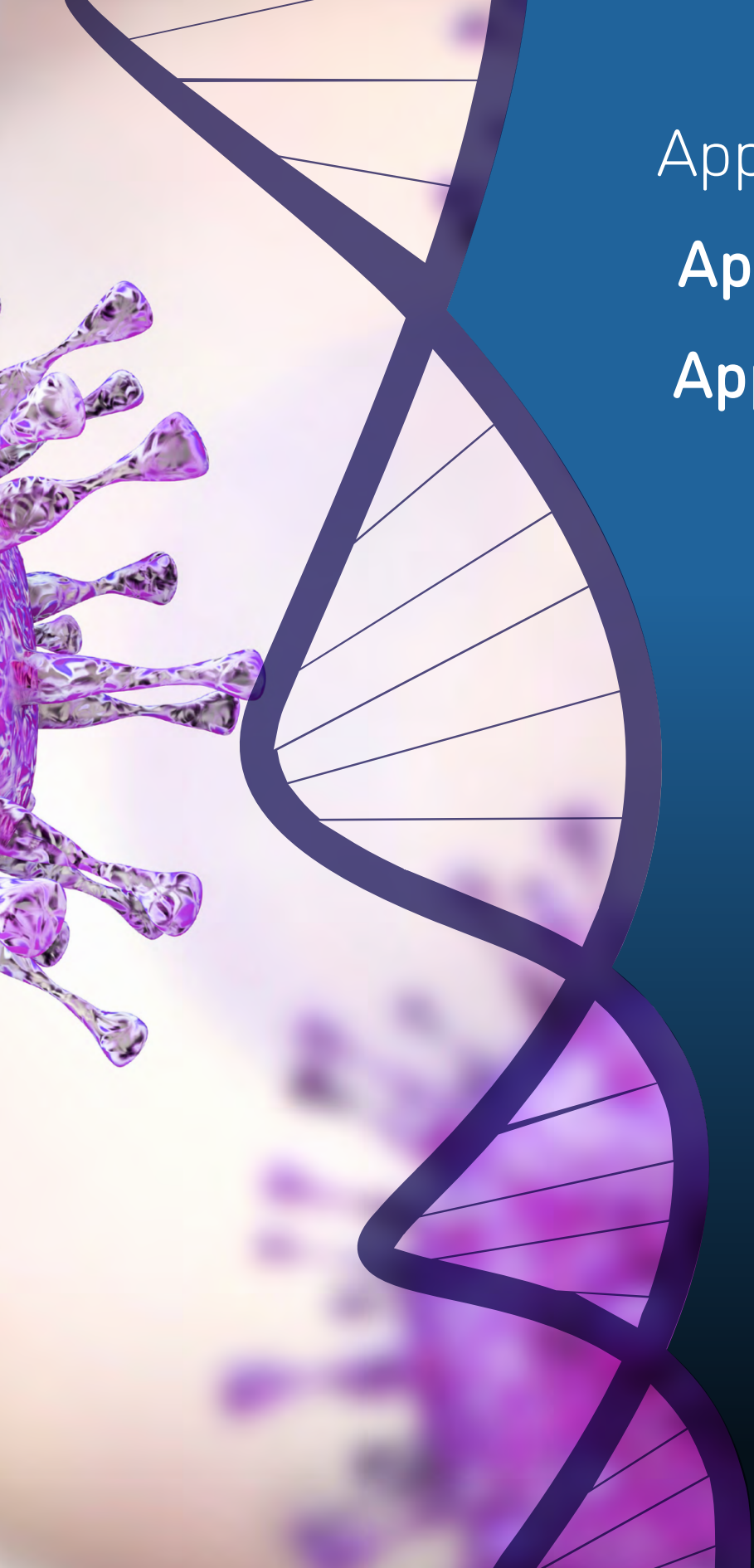
The Monitoring and Compliance Section maintains an email inbox to facilitate efficient communication with accredited organisations. The inbox provides a central point through which accredited organisations can contact OGTR with queries, legislative notifications and self-reporting of non-compliances. The inbox ensures that all communications are answered efficiently while staff are away from the office. The inbox received 702 emails during 2021–22 (compared to 665 in 2020–21).

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 615 emails during 2021–22 (compared to 439 in 2020–21).

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 3,536 emails during 2021–22 (compared to 5,113 in 2020–21).

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





Appendices

Appendix 1

Appendix 2

Appendix 1 – Membership of statutory committees

Table 15: Gene Technology Technical Advisory Committee 2020–23 – current members

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	Lead Drought Resilience Mission, 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 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) Program Lead, Cancer Research, Flinders Health and Medical Research Institute, Flinders University (SA)
Professor Geraldine O'Neill	Head, Children's Cancer Research Unit, The Children's Hospital at Westmead & Conjoint Professor of Cancer Cell Biology, University of Sydney (NSW)
Dr Gabrielle O'Sullivan (GTECCC cross-member)	Executive Officer and Member, Institutional Biosafety Committee, Royal Prince Alfred Hospital (NSW)
Dr Kelly Pearce (layperson)	Chief Executive Officer, The Facey Group (WA). Western Australian Broadacre Farmer. (WA)
Dr Jason Smythe	Biotechnology and Healthcare Consultant, Australis Biosciences (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	Professor of Virology, School of Chemistry & Molecular Biosciences, The 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 16: Gene Technology Ethics and Community Consultative Committee 2020–23 – current members

Member	Position/Comment
Associate Professor Judith Jones (Chair)	Associate Professor, ANU College of Law, The Australian National University (ACT)
Professor Rachel Ankeny	Professor, School of Humanities, University of Adelaide (SA)
Ms Paula Fitzgerald	Chief Executive Officer, Australian Fodder Industry Association (Vic)
Dr Jaden Hastings (expert adviser)	Founder/Director, Alpha Space Pty Ltd
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	Chief Executive Officer, The Facey Group (WA). Western Australian Broadacre Farmer. (WA)
Professor Stephen Robson	Professor in Reproductive Medicine, The Australian National University (ACT)
Dr Robert Sward AM	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 GTMM
- 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 GTMM 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 rigorous risk analysis 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 Commonwealth 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 17 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 17: 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 and risk management 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 18. 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 18: 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
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

Term	Description
GTMM	Gene Technology Ministers' Meeting
MOU	Memorandum of understanding
NLRD	Notifiable low risk dealing (e.g. plant or tissue culture work undertaken in a certified physical containment facility)
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator
PBS	Portfolio Budget Statements
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

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List of requirements

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List of requirements

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

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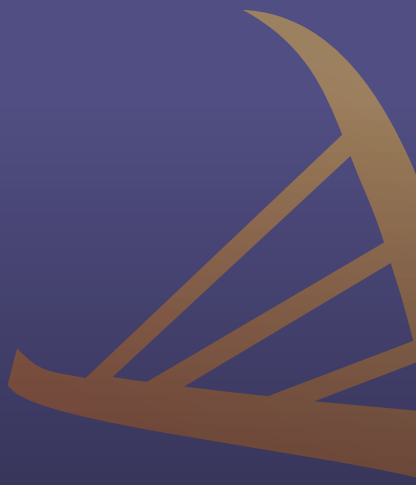

The Object of the *Gene Technology Act 2000* is:

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