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

Annual Report
2022–23

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 2022 to 30 June 2023.

The annual report details the operations of the Gene Technology Regulator (the Regulator) in line with 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 and Aged Care Portfolio Budget Statements for 2022 – 2023.

The annual report has been prepared in accordance with section 136 (1) of the Act, which requires that, as soon as practical 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 2023

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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 2022–23 Department of Health and Aged Care Portfolio Budget Statements[1]

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

- genetically modified organism (GMO) licences issued during the financial year
- breaches of conditions of a GMO licence that have come to the Regulator's attention during the financial year
- Emergency Dealing Determinations (EDDs) made by the Minister during the financial year
- any breaches of conditions of an Emergency Dealing Determination that have come to the Regulator's attention during the financial year
- auditing and monitoring of dealings with GMOs under the Act by the Regulator or an inspector during the financial year.

The report contains five chapters:

- **Chapter 1: Gene Technology Regulator's overview**—summarises the OGTR's activities over the past year, including major achievements and the outlook for the coming year.
- **Chapter 2: Office of the Gene Technology Regulator**—describes the Regulator's corporate and regulatory governance arrangements, including the structure of the OGTR and functions of its advisory committees.
- **Chapter 3: Functions of the Gene Technology Regulator**—describes the OGTR's operational performance as well as achievements against priorities during 2022–23. 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 measures published in the 2022–23 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 The Department of Health and Aged Care Portfolio Budget Statements October 2022.

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

Chapter 1

Gene Technology Regulator's overview

Chapter 1

Gene Technology Regulator's overview

The role of the Gene Technology Regulator and the Office of the Gene Technology Regulator (OGTR) is clearly set out in the Object of the *Gene Technology Act 2000:* "*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*". The Act is now over 22 years old, but during this past 12 months the integral and expanding role of the Office in contributing to government strategies and policies is even more evident.

For example, our role in supporting health and medical research through clinical trials is documented in the *National One Stop Shop* report[3] published by the Australian Commission on Safety and Quality in Health Care. Our role in regulating gene technology can be seen in the *Critical Technologies Statement* and the *List of Critical Technologies in the National Interest*, which features a broad range of applications of biotechnology, including manufacturing, sustainable agriculture and livestock disease treatments[4]. As technology progresses and is applied in different sectors across Australia, the Regulator's role continues to be defined and legislative amendments to modernise the scheme are even more important.

This 2022–23 period has been busy, with staff involved in many different activities across the office. Over 1000 authorisations and approvals were issued, a higher number than the previous four years. We processed over 70 self-reported incidents and have increased our monitoring and enforcement presence. The activities of the Monitoring and Compliance team this year resulted in issuing an inadvertent dealings licence and suspension of some certified facilities.

With funding from the Department, we successfully moved our old IT legacy systems onto new platforms that meet the government requirements for providing secure services to applicants and storage of data and information. Significant contributions were made in supporting the department with legislative drafting of amendments to the Act, to implement recommendations of the Third Review of the Gene Technology Scheme.

3 https://www.safetyandquality.gov.au/our-work/health-and-human-research/national-one-stop-shop-national-platform-health-related-human-research

4 https://www.industry.gov.au/publications/list-critical-technologies-national-interest/biotechnologies

In July 2022[5] we published a clarification note on our website articulating the legislative basis for our licence categories, and what the term "intentional release into the environment" means in the context of gene technology regulation. This was in response to numerous inquiries to the OGTR from concerned citizens regarding approval of GM vaccines, an example which adds to the case for modernisation of our authorisation pathways.

Our operating environment also changed with the retirement of the Secretary of Health and Aged Care, Professor Brendan Murphy, who was a great advocate for the work of the OGTR.

Meeting Our Performance Targets

The Department of Health and Aged Care Portfolio Budget Statements (PBS), Outcome 1, Program 1.8 (Health Protection, Emergency Response and Regulation) describe the program objectives and performance targets for 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 include working with the Australian and state and territory governments to implement recommendations outlined in the Third Review of the National Gene Technology Scheme, to deliver a modern, flexible and innovative 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 conditions of GMO approvals were assessed.
- There was a high level of compliance with gene technology legislation, with no evidence of any adverse effects on human health or the environment from authorised GMOs.

The OGTR continued to support the work of the Department, and the Gene Technology Standing Committee, to action and implement priorities endorsed by the Gene Technology Ministers Meeting in April 2023, and included in the new Gene Technology Ministers' Meeting Action Plan 2023–2025[6].

5 https://www.ogtr.gov.au/news/announcement/what-do-we-mean-intentional-release

6 https://www.genetechnology.gov.au/news/outcome-gene-technology-ministers-meeting-13-april-2023

Applications and Licences: What's New

Our licenced approvals are categorised according to whether dealings (activities) 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.

This year five DIR licences were issued of which two were for GM plants, two for animal vaccines and one for a human therapeutic. The plant licences were for commercial cropping of a herbicide-tolerant canola, and for import and supply of a GM chrysanthemum. The animal vaccines included commercial supply of a chicken vaccine and trials in Tasmania of a GM vaccine for treatment of Tasmanian devil facial tumour disease. The human therapeutic licence is for clinical trials of a potential cancer treatment.

For the contained research DNIR licence category, 12 licences were issued of which four are for clinical trials of human therapeutics, four licences for research work in laboratories, two for manufacturing molecules used for therapeutic purposes, and two for specialised patient treatments, including a gene therapy for an inherited disease.

Trend data for the past five years continue to show a change from crop-based licence applications to vaccine development and commercialisation, clinical trials of gene therapies, cancer treatments, and manufacture of therapeutics.

One inadvertent dealings licence was also issued allowing destruction of unapproved GM soya bean imported into Australia.

Monitoring and Compliance Activities

The Monitoring and Compliance team had an intensive program of on-site visits, face-to-face inspections and audits this year, due to decreased physical presence over the past two years while restrictions associated with the Covid-19 pandemic were in place.

During the 2022–2023 period, 10 field trial sites were inspected for three plant species, namely canola, sorghum and white clover. This was 40% of the total number of current trial sites. Monitoring inspections of five licences for clinical trials or contained work were conducted and three practice reviews were undertaken. In addition, 49 certified facilities were inspected against certification requirements, of which seven were high-level containment facilities. The Monitoring and Compliance team received and assessed 70 reports relating to possible non-compliances with GMO approvals (licences, notifiable low risk dealings and certifications). Inspectors assessed all reports received during the 2022–2023 period.

Business Improvement Activities

Our IT modernisation project has been progressing well with the movement of legacy systems, including our applications database and monitoring and compliance database, from old platforms to new CRM systems. The new systems meet the government requirements for providing secure ICT services to applicants. Planning for additional capability continues in anticipation of new legislation. This 2022–2023 period included the release of two new forms and additional functionality improvements in several existing forms.

International Harmonisation and Capacity Building: Sharing our Knowledge

OGTR staff continued participating in international meetings, attending virtually at some conferences and face-to-face at others. One of the highlights included an OGTR staff member attending in a technical capacity as part of the Australian delegation to the UN Convention on Biological Diversity – COP 15 – in Montreal Canada. These meetings are held every two years, and this event included Australia's Environment Minister. Another highlight was an OGTR staff member presenting at the International Society for Biosafety Research Symposium in the United States of America, which included side events such as a meeting of the like-minded group on agricultural biotechnology. This is held every two years.

Closer to home, our staff attended a number of major presentations and events. This included a staff member presenting at an international conference on gene-edited crops, held in Canberra.

The OGTR continues to lead Australian representation the Organistion for Economic Co-operation and Development (OECD) Working Group on the Harmonisation of Regulatory Oversight in Biotechnology, including Chair of the Working Group.

Our People: Our Most Important Resource Now and Into the Future

We welcomed Dr Matthew O'Mullane to the OGTR, as the new Executive Director of the Evaluation Branch. Dr O'Mullane brings a wealth of regulatory experience, extensive risk assessment expertise and a new outlook having worked in different regulatory schemes in Australia.

The nominations for the Regulator's Achievement Award included themes of cooperation, leadership, demonstrated professionalism and dedication to task. Two teams received the award this year.

In recognition of increased compliance and enforcement activity over this period, as well as managing through Covid-19 with desk-top audits and remote inspections, the Monitoring and Compliance team was acknowledged for its contribution to the important work of the OGTR. The team received the award for demonstrating professionalism and dedication to their work which takes them to inspections and audits across the country.

A second award was given to team members in the Plant Evaluation Section for their approach in assessing and managing a difficult application with multiple challenges within a statutory deadline. The team sought specialised advice (in addition to GTTAC), engaged early with prescribed agencies to highlight the issues with the application, and developed detailed summaries of public submissions to present a robust and technically sound decision package to the Regulator.

Challenges Ahead

The challenges to the OGTR for the next 12 months will be around staffing to undertake several pieces of important work that will change the operations and functions of the Regulator. We continue to dedicate resources to inform and provide technical support to legislative amendments to implement the recommendations from the 3rd Review of the Gene Technology Scheme, assist in stakeholder consultations for amendments to legislation, develop and refine new IT business solutions, seek additional government funding to continue our modernisation program, and most importantly, prepare our staff for the change ahead.

CHAPTER 1

Chapter 2

Office of the Gene Technology Regulator

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 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 Act), 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. 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 therapeutic 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 practical within the limits of the relevant legislation.

Regulatory performance reporting

The OGTR undertakes its regulatory functions by applying the three principles of regulator best practice outlined in Resource Management Guide 128 Regulator Performance (RMG 128)[7]:

1. Continuous improvement and building trust. We adopt a whole-of-system perspective, continuously improving our performance, capability and culture.
2. To build trust and confidence in our regulatory system.
3. Risk-based and data-driven. We manage risks proportionately and maintain essential safeguards while minimising regulatory burden, and leveraging data and digital technology to support those we regulate to comply and grow.
4. 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[8] sets out how its regulators intend to apply these principles. It then reports on the performance of its regulators in its annual report[9]. 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 RMG 128. The Regulator's Statement of Intent outlines how we will achieve our regulatory objectives and carry out our regulatory functions[10].

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.

7 https://www.finance.gov.au/government/managing-commonwealth-resources/regulator-performance-rmg-128

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

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

10 https://www.ogtr.gov.au/resources/publications/gtr-statement-intent

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 Assistant Minister for Health and Aged Care, the Hon Ged Kearney MP, is the minister responsible for gene technology regulation. Under section 133 of the Act, the Secretary of the Australian Government Department of Health and Aged Care 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 Aged Care 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 and Aged Care. 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* (PGPA) sets out the financial framework for OGTR's governance. The Regulator meets the obligations under the PGPA Act by reporting financial performance to the Secretary as the Accountable Authority under the PGPA Act. 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 2022–23 Department of Health and Aged Care 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.

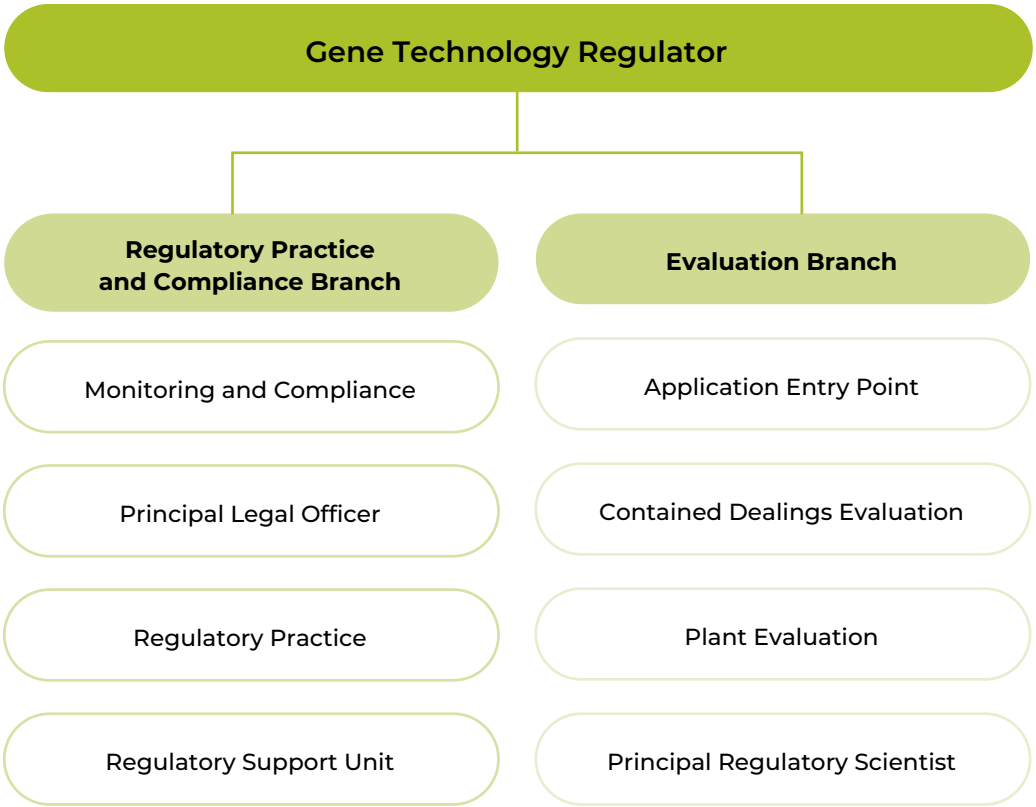
The employment framework for the OGTR is the *Public Service Act 1999*. The Department's enterprise agreement, governance policies and practices cover OGTR staff. These include application of appropriate ethical standards under the Australian Public Service Values and Code of Conduct; compliance with 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, 2022–23



Office of the Gene Technology Regulator 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 Act 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 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 Branch Head 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 Confidential Commercial Information (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.[11]

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

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 manages risks in relation to any potential breach of conditions. It conducts audits, practice reviews and investigations of organisations and individuals involved in GMO dealings practice (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 and Aged Care 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.

Evaluation Branch

Dr Matthew O'Mullane has been the Executive Director of the Evaluation Branch since October 2022. His responsibilities encompass overseeing the evaluation of licence applications and other authorisations relating to dealings with GMOs, as well as science-related projects that maintain and improve the technical capabilities of the OGTR.

The branch is made up of the Application Entry Point, 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 process accreditation applications, manage information management systems, provide trend and statistical analyses of application receipts and authorisations, and report on workflows. Staff also manage or assist withbusiness process, administrative activities, and information technology improvement projects. The section supports the Evaluation Branch by sourcing scientific literature, and it manages a small range of journal subscriptions for the office library.

The Contained Dealings Evaluation Section prepares risk assessment and risk management plans (RARMPs) in response to applications for dealings not involving intentional release of GMOs into the environment (DNIRs)—also known as 'contained dealings'—and applications for non-plant dealings involving intentional release (DIRs). 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 also assesses some RARMPS licence applications for GM therapeutics. 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 to keep pace with developments in science and regulatory risk analysis.

Advisory committees

The Act establishes two committees to advise the Regulator and the GTMM. These are the:

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

Membership of the statutory committees is listed in Appendix 1. Current memberships expire on 31 January 2026.

Gene Technology Technical Advisory Committee

The functions of GTTAC, 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 GTTAC's advice twice. The first consultation is on matters to consider when preparing a RARMP and the second is on the RARMP itself. For limited and controlled DIR applications, the Regulator must seek GTTAC advice only once on a RARMP. 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 Assistant Minister Kearney.

The committee met four times during 2022–23. 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 GTECCC 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 Assistant Minister Kearney.

There is no statutory requirement for the Regulator to seek advice from GTECCC on licence applications. GTECCC met twice during 2022–23. Communiqués from previous committee meetings, which provide an overview of key matters discussed and resolutions, are published on the OGTR website.

CHAPTER 2

Chapter 3

Functions of the Gene Technology Regulator

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 2022–23 Department of Health and Aged Care Portfolio Budget Statements. The functions of the Regulator and the regulatory processes for authorising and monitoring dealings with GMOs that are defined by the Act, the Gene Technology Regulations 2001 (the Regulations), and corresponding state and territory laws are described in Appendix 2.

Operational performance

This section describes the achievements and performance against Outcome 1, Program 1.8 (Health Protection, Emergency Response and Regulation) of the 2022–23 Department of Health and Aged Care 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, is summarised in the second part of this chapter.

Summary of approvals in 2022–23

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 therapeutic or vaccine, or commercial sale of a GM therapeutic 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 two different types of work involve different contexts, the gene technology laws have two different types of licences to cover them.

Licences for research or other work in special facilities are called dealings not involving intentional release into the environment' (DNIR) licence. The work is contained within a building or other structure (such as in a hospital), rather than outside. These facilities must be certified by the Regulator as suitable for containing work with GMOs. Other DNIR licences are for activities where the GMO may be contained within a person, such as administration of a GM therapeutic or vaccine that will not be released into the environment.

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

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

In 2022–23 the OGTR received 1045 applications and 932 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 1070 approvals over a range of application types. There were no appeals associated with decisions made on applications under the gene technology legislation. Currently there are 2189 certified facilities, 56 DIR licences where release of GMOs into the environment is authorised and 157 DNIR licences where GMOs must be contained (Table 2) at 30 June 2023.

Table 1:
Applications and notifications, 2022–23

Application type	Received	Withdrawn	Approved[a]	Refused	Ceased Consideration[b]	Under Consideration[c]
Accreditation	12		13			2
Alternate facility request for an NLRD	1					1
CCI declaration for Accreditation						
CCI declaration for DIR Licence	5		6			
CCI declaration for DNIR Licence	12		13			7
Certification	134	1	132			6
DIR Licence	6	1	5			4
DNIR Licence	23		12			12
Lifting suspension of certification	63	1	62			
NLRD notification	932					
GMO Register						
Surrender of accreditation	9		6			3
Surrender of certification	51		52			
Surrender of DIR licence[d]	7		5			2
Surrender of DNIR licence	5		5			1
Suspension of certification	85	2	82			1
Transfer of certification	43		43			
Transfer of DIR licence	1		1			
Transfer of DNIR licence						
Variation of certification	538	8	589			26

Application type	Received	Withdrawn	Approved[a]	Refused	Ceased Consideration[b]	Under Consideration[c]
Variation of DIR licence	14	1	12			2
Variation of DNIR licence	36	1	32			7
Total	**1977**	**15**	**1070**			**74**

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 2022-23 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 2023.

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 2022-23 were all requested by the applicant.

Table 2:
Status of primary applications and notifications from the start of the scheme until 30 June 2023

Application type	Received	Withdrawn	Approved	Not Approved[a]	Under Consideration[b]	Current	Expired	Surrendered
Certification	4957	159	4787	5	6	2189	370	2066
DIR Licence	199	19	170	6	4	56	1	113
DNIR Licence	677	116	527	2	12	157	167	203
NLRD	13735	36	n/a	n/a	n/a	3313	10386	n/a
Total notification	**19568**	**330**	**5484**	**13**	**22**	**5715**	**10924**	**2382**

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

b Under consideration as at 30 June 2023

Primary applications

Licences for dealings involving intentional release of GMOs

Activities with GMOs under the DIR category require authorisation by a licence. DIR licences may contain specific conditions to manage any identified risks. The Regulator issued five DIR licences during 2022–23.

Details of the traits introduced into the modified organisms are provided in Table 3. Two licences issued in 2022–23 were modified for research trials (limited and controlled releases) as follows:

- DIR-192 Clinical trial of a genetically modified (GM) chimeric Orthopoxvirus as a cancer treatment
- DIR-195 Trial of a genetically modified vaccine against devil facial tumour disease in Tasmanian devils

Three licences issued in 2022–23 were for the following commercial/general supply:

- DIR-190 Commercial release of Indian mustard genetically modified for herbicide tolerance (RF3)
- DIR-191 Commercial import and distribution of chrysanthemum genetically modified for altered flower colour
- DIR-193 Commercial supply of a genetically modified vaccine against infectious laryngotracheitis virus in chickens.

Of the five DIR licences issued in 2022–23, four were issued to companies and one to a university (Table 3). All of the licence decisions were made within statutory timeframes (see 'Timeframes', Appendix 2).

Canola field trial site

Table 3:
DIR licences issued 2022–23

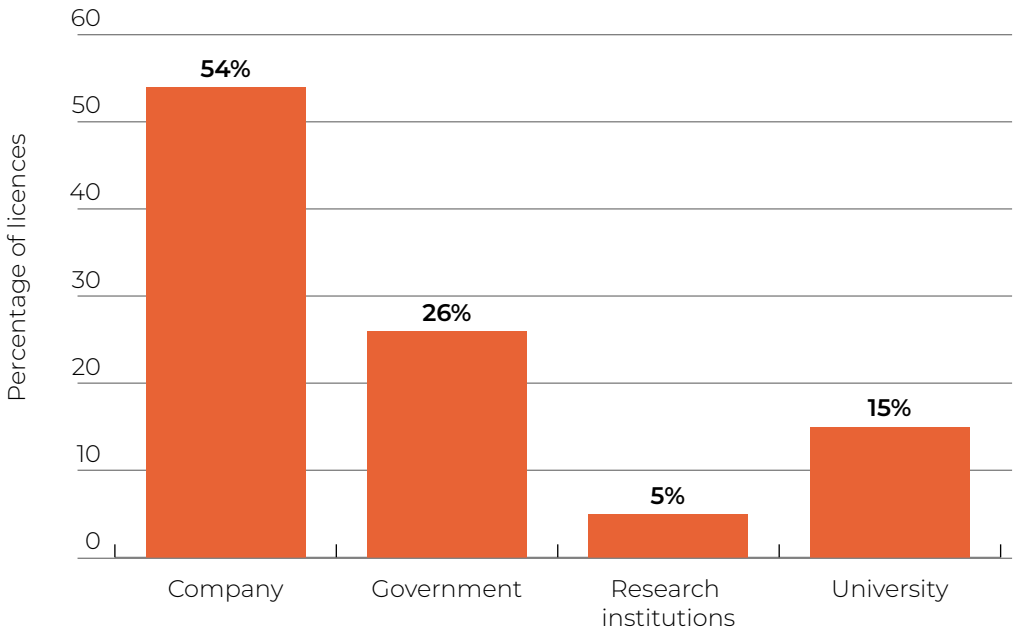
OGTR ID	Applicant	Parent Organism	Introduced Trait	Type of authorisation	Received	Issued
DIR-190	BASF Australia Ltd	*Brassica juncea* (Indian mustard)	herbicide tolerance	Commercial	25-Nov-21	13-Oct-22
DIR-191	International Flower Developments Pty Ltd	Chrysanthemum	flower colour	Commercial	18-Feb-22	07-Feb-23
DIR-192	Medpace Australia Pty Ltd	Chimeric poxvirus	Viral attenuation, insertion of marker gene	Limited and Controlled	21-Mar-22	15-Sep-22
DIR-193	Bioproperties Pty Ltd	Infectious Laryngotracheitis Virus	Attenuation of pathogenicity	Commercial	19-Apr-22	19-Apr-23
DIR-195	University of Tasmania	Human Adenovirus 5	Vaccine – replication incompetent, altered antigen expression	Limited and Controlled	23-Nov-22	14-Jun-23

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 170 DIR licences issued to date:

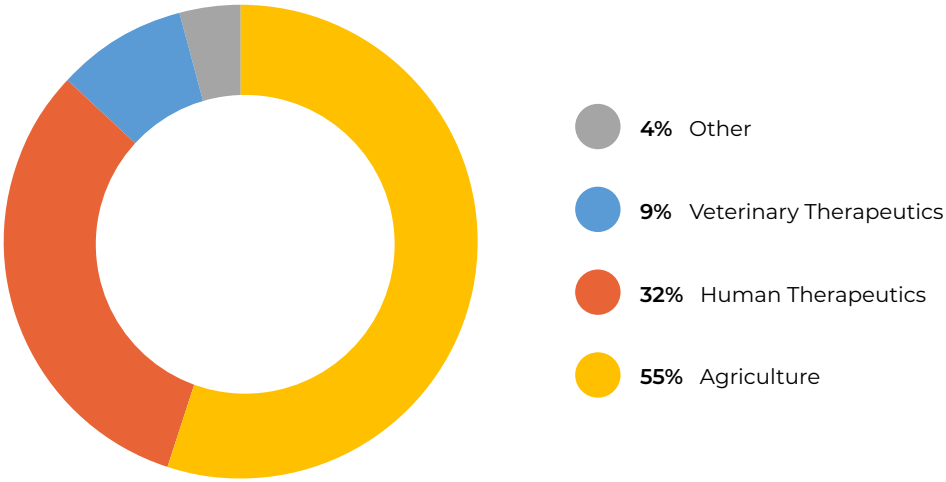
- 91 (54%) have been to companies
- 44 (26%) to government agencies
- 8 (5%) to research institutes
- 27 (15%) to universities.

Figure 2:
Organisations issued with DIR licences since commencement of the Gene Technology Act 2000



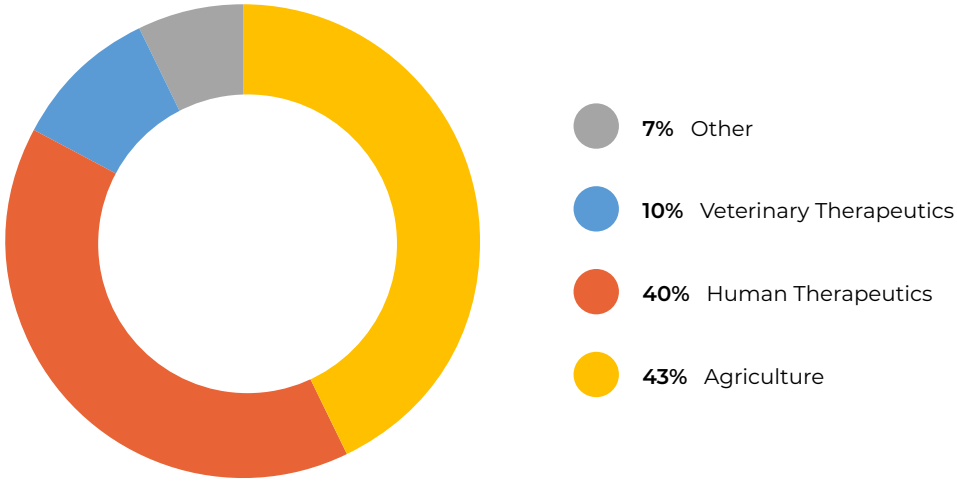
56 of the 170 DIR licences issued since the beginning of the scheme were current as at 30 June 2023. This consists of 31 (55%) Agricultural, 18 (32%) Human Therapeutics, five (9%) Veterinary Therapeutics, and 2 (4%) Other licences (one licence for microalgae genetically modified for increased production of fatty acids, and one licence for commercial import and distribution of chrysanthemum genetically modified for altered flower colour) (Figure 3).

Figure 3:
Distribution of DIR licences current as at 30 June 2023, by purpose



Although current DIR licences are for agricultural crops, over the past five years, the majority of new DIR licences issued have been for human and veterinary therapeutics (Figure 4).

Figure 4:
Distribution of DIR licences issued over the past 5 years, by purpose



Of the current DIR licences, 38 (68%) were issued to companies, one (2%) to a government organisation, eight (14%) to research institutes and nine (16%) to universities (Figure 5). One (2%) DIR licence was held by an organisation in the ACT, one (2%) in TAS, 18 (32%) in NSW, 6 (11%) in Qld, 3 (5%) in SA and 27 (48%) in Victoria (Figure 6).

Figure 5:
Distribution of DIR licences current as at 30 June 2023, by organisation type

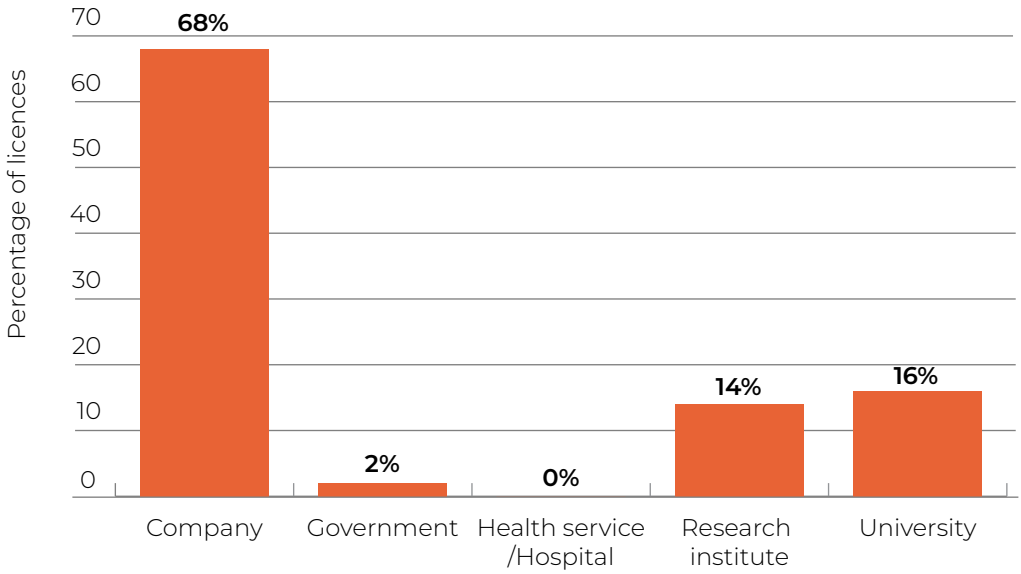
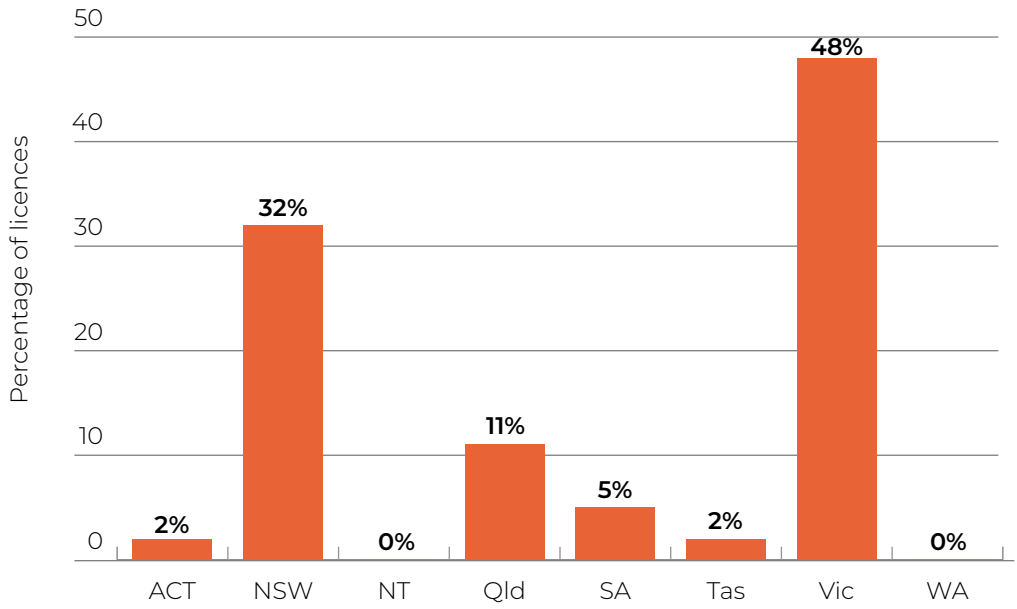


Figure 6:
Distribution of DIR licences current as at 30 June 2023, by state or territory



Licences for dealings not involving intentional release of GMOs

DNIR licences authorise dealings with GMOs in laboratories and other physical containment facilities. This category also includes clinical trials of live and viable GMOs that meet certain containment criteria.

In 2022–23 the Regulator issued 12 DNIR licences (see Table 4), for work in laboratories, to manufacture therapeutics using GMOs, and clinical trials of GMO therapeutics. All decisions were made within the statutory timeframe of 90 days.

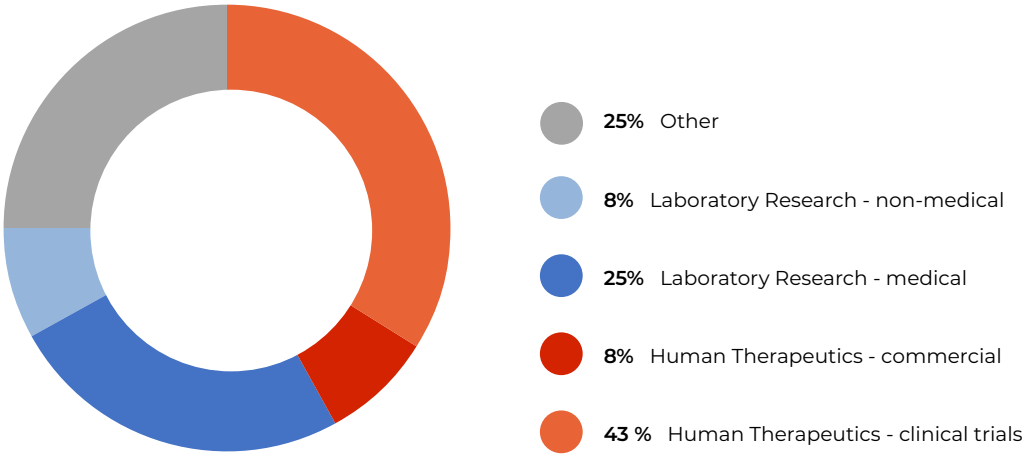
Two of the DNIR licences issued were for the manufacture of recombinant toxin molecules for use in therapeutics or cancer treatment. Four DNIR licences were for research work in laboratories for medical applications including coronaviruses, and research into vaccines, as well as work on control of mice populations.

Two DNIR licences issued were for clinical trials of gene therapies for the inherited conditions autosomal dominant optic atrophy and Dravet syndrome. One of the licences issued was for treatment of a patient with a bacterial lung infection using phage therapy. One licence was for treatment of patients with haemophilia B to repair a defective gene. One licence was for a clinical trial with a GM influenza vaccine and another licence for a clinical trial of a cancer treatment (Figure 7).

Table 4:
DNIR licences issued, 2022–23

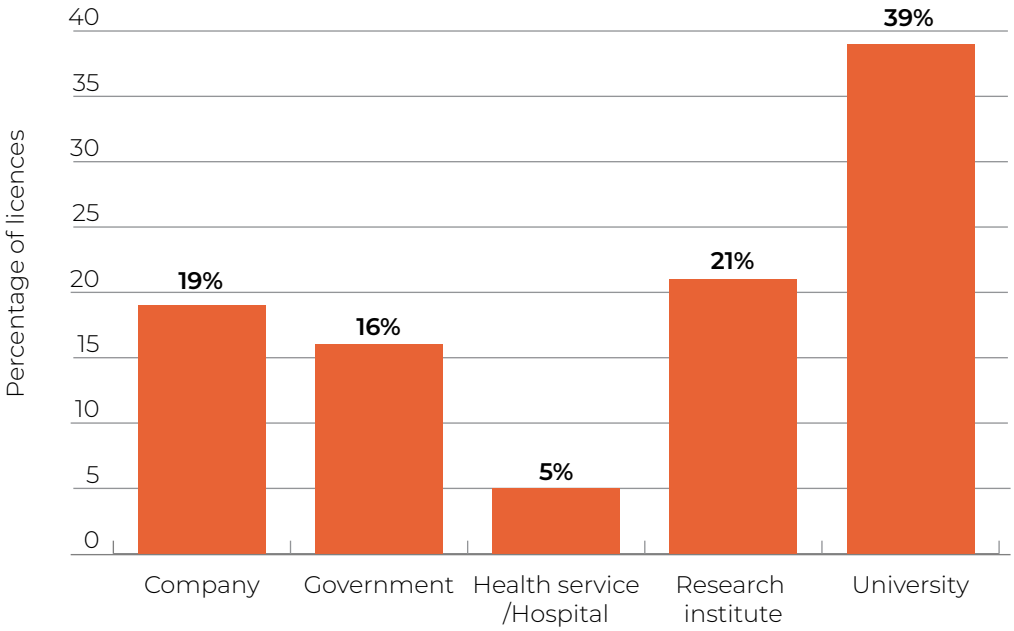
DNIR No.	Applicant	Title	Received	Issued
DNIR-654	The University of Melbourne	Understanding Coronavirus infection and disease	17-Jun-22	17-Oct-22
DNIR-655	The Alfred Hospital	Phage therapy for severe lung disease due to *Mycobacterium abscessus*	06-Jul-22	12-Jul-22
DNIR-656	BioCina Pty Ltd	Expression and purification of fusion protein targeting tumor specific cells	20-Sep-22	12-Jan-23
DNIR-657	Seqirus Pty Ltd	Influenza prophylactic vaccine for use in a clinical trial	07-Oct-22	23-Jan-23
DNIR-658	Flinders University	Testing of immortalised cell lines for replication competent retroviruses	21-Oct-22	23-Feb-23
DNIR-659	CSL Innovation Pty Ltd	Supply of etranacogene dezaparvovec for the treatment of people with haemophilia B	28-Nov-22	05-Apr-23
DNIR-660	The University of Queensland	Use of recombinant Adeno-associated viral vectors to enable evaluation of human vaccine responses in mice	14-Dec-22	19-Apr-23
DNIR-661	Novotech (Australia) Pty Limited	Clinical trial of genetically modified HSV-1-based vector for the treatment of solid tumours	20-Dec-22	21-Apr-23
DNIR-662	Australian Veterinary Serum Laboratories	Expression of Australian paralysis tick holocyclotoxins in *Pichia pastoris* for development of therapeutics	16-Jan-23	19-May-23
DNIR-663	Syneos Health Australia Pty Ltd	A Clinical Study to Evaluate the Safety and Efficacy of ETX101, an AAV9-Delivered Gene Therapy in Children with SCN1A positive Dravet Syndrome.	31-Jan-23	06-Jun-23
DNIR-664	Novotech (Australia) Pty Limited	Clinical trial of genetically modified adeno-associated virus for the treatment of autosomal dominant optic atrophy (ADOA)	10-Feb-23	16-Jun-23
DNIR-665	South Australian Health and Medical Research Institute	Generating mouse models with altered inheritance	16-Feb-23	26-Jun-23

Figure 7:
Focus of DNIR licences issued during 2022–23



The types of organisations to which DNIR licences have been issued since commencement of the scheme are shown in Figure 8. Of the 527 DNIR licences issued to date, 102 (19%) have been issued to companies, 86 (16%) to government agencies, 27 (5%) to health services/hospitals, 112 (21%) to research institutes and 200 (39%) to universities.

Figure 8:
Types of organisations issued with DNIR licences since commencement of the Act



- Of the 527 DNIR licences issued these are categorised as follows: Human Therapeutic licences make up 81 (15%), 4 (1%) for Veterinary Therapeutics, 425 (81%) for Laboratory Research, 7 (1%) for Agricultural, and 10 (2%) for Other (Figure 9)
- There are 157 DNIR licences that are current to end of June 2023. Of these, 41 (26%) are held by companies, 13 (8%) by government agencies, 3 (2%) by health services/ hospitals, 39 (25%) by research institutes and 61 (39%) by universities (Figure 10)
- 11 (7%) of the current DNIRs are held by organisations in the ACT, 49 (31%) in NSW, 28 (18%) in Qld, 14 (9%) in SA, 50 (32%) in Vic and 5 (3%) in WA. There are no DNIR's currently held in the NT and Tasmania. (Figure 11)

Figure 9:
Focus of DNIR licences issued from the start of the scheme

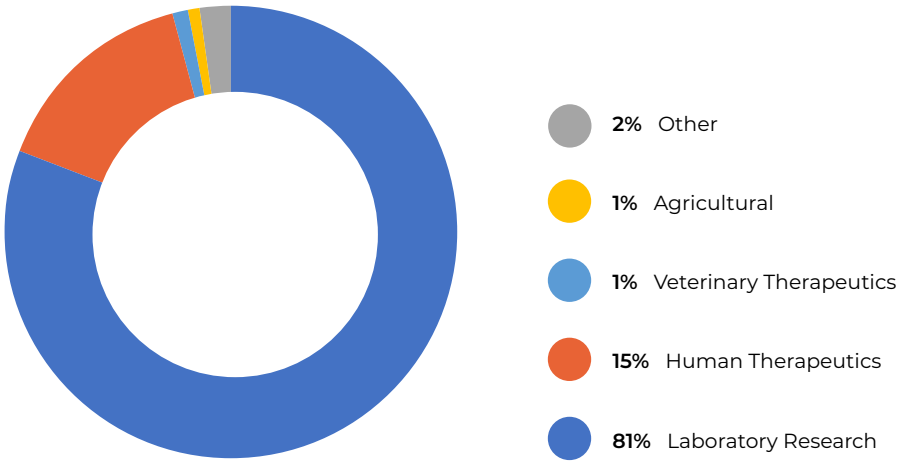


Figure 10:
Distribution of DNIR licences current as at 30 June 2023, by organisation type

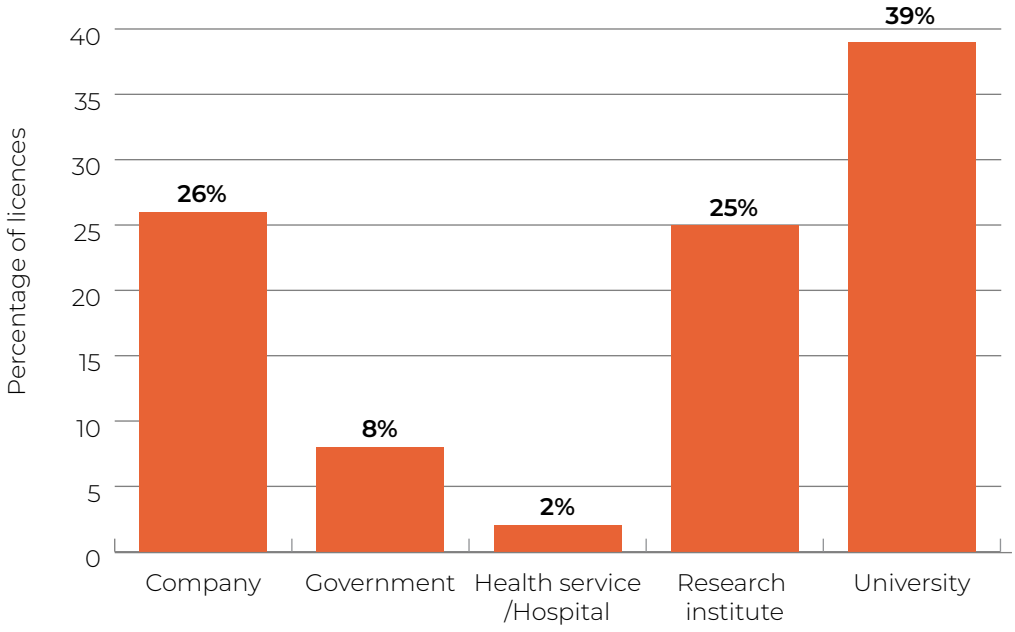
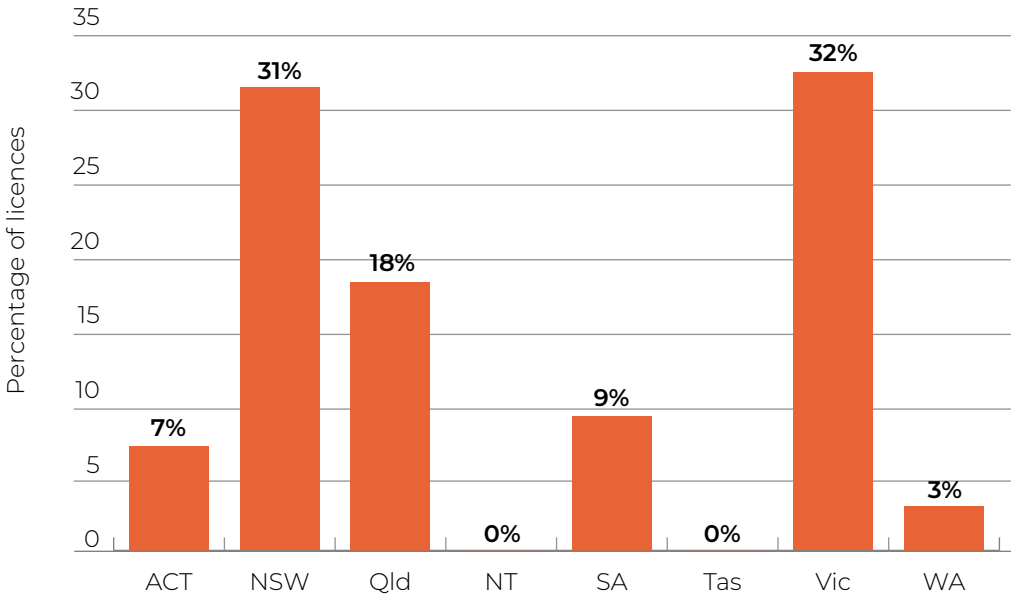
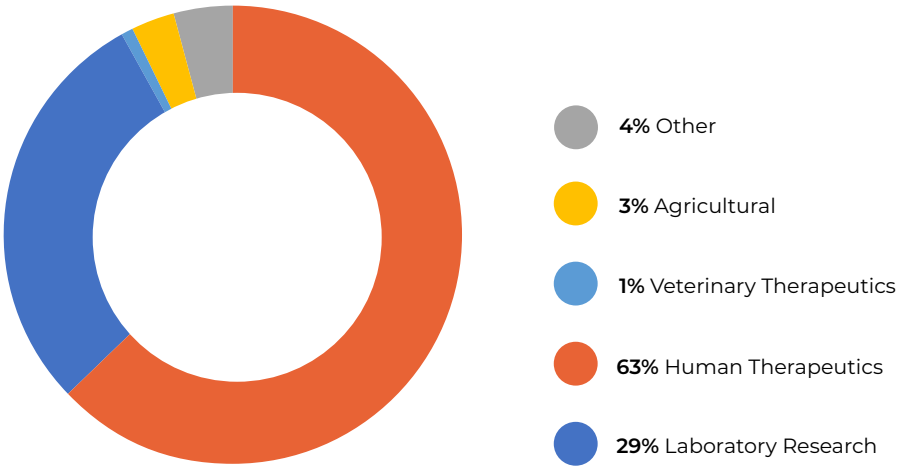


Figure 11:
Distribution of DNIR licences current as at 30 June 2023, by states and territories



In the past 5 years the focus of DNIRs has been with Human Therapeutics and Laboratory Research, predominantly with a medical focus (92%). There has been an increase in licences issued for Human Therapeutics over the last 5 years, compared with those issued from the start of the scheme (Figure 12).

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 five years after which they expire and a new NLRD must be assessed by an institutional biosafety committee (IBC) in order for the dealings to continue.

During 2022–23, 932 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 2022–23 reporting period compared to the past four years. This increase may largely reflect administrative changes to the reporting mechanism resulting from the rollout of the new OGTR Online Services Portal. Organisations conducting NLRDs were encouraged to report their NLRDs earlier to avoid disturbances during the deployment of the Portal.

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

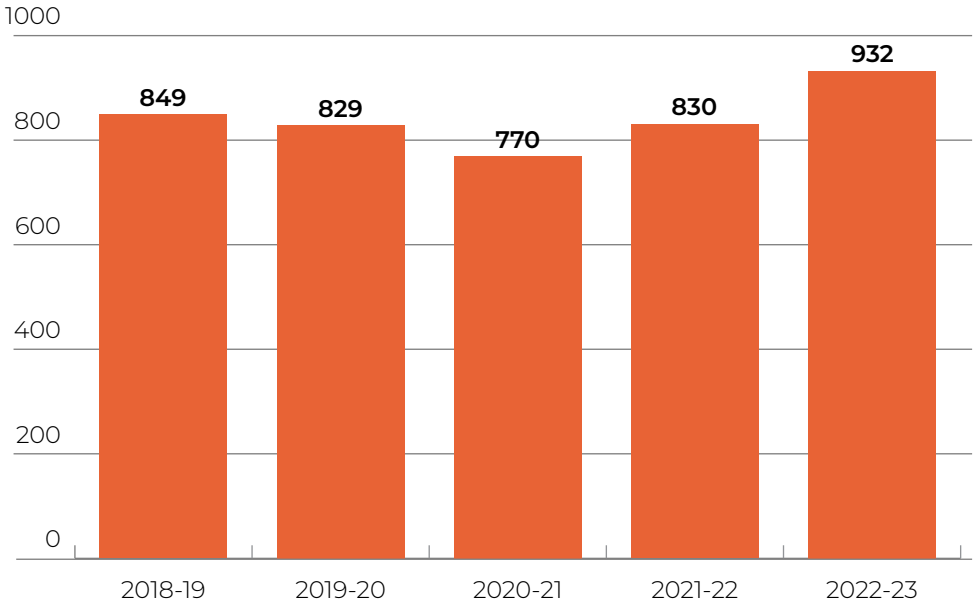
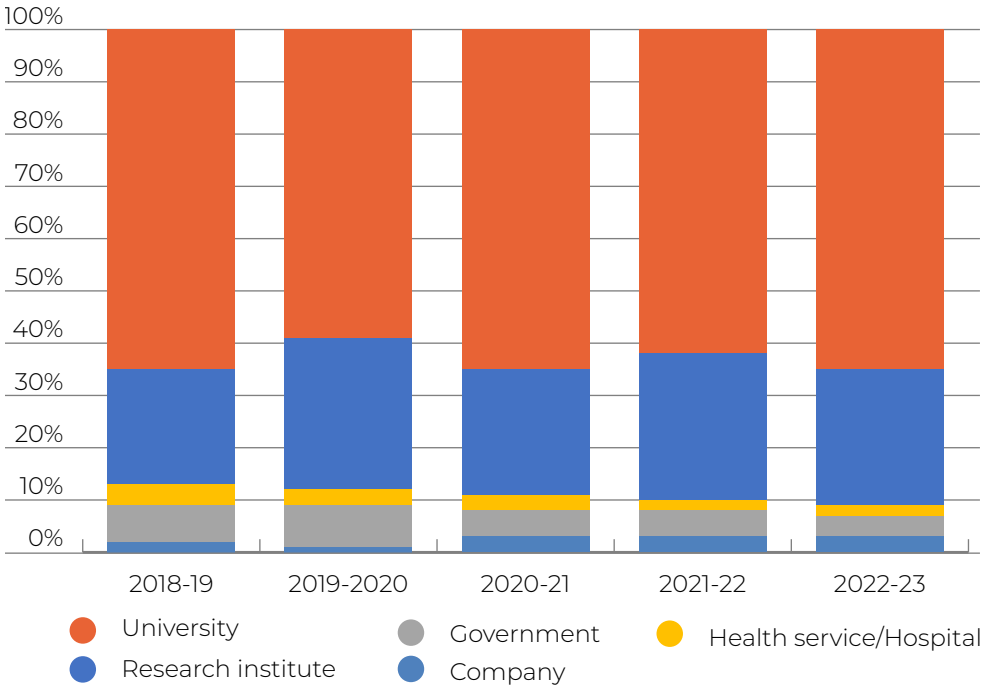


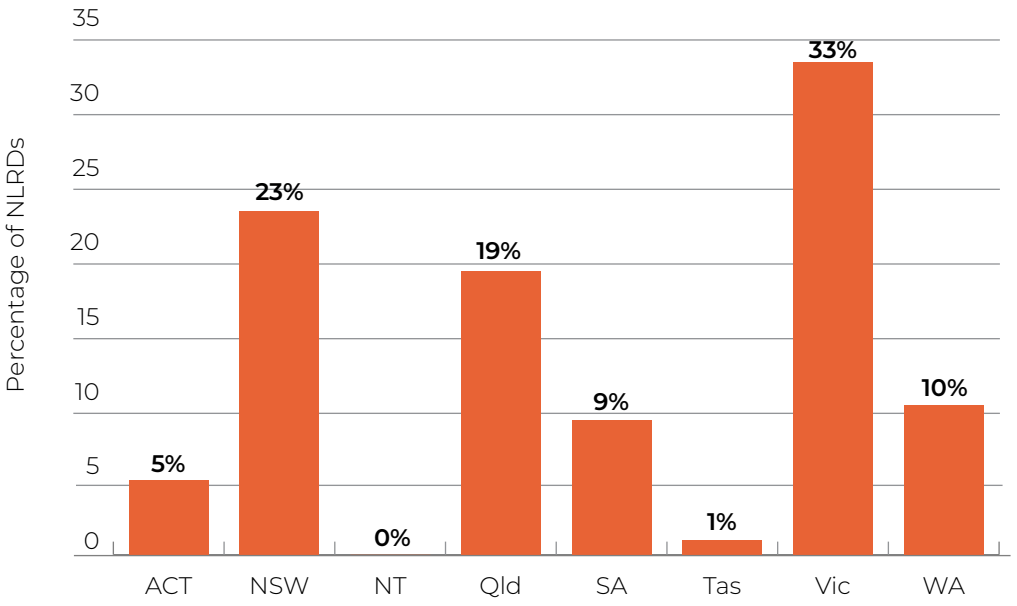
Figure 14 shows the proportion of NLRDs reported by different types of organisations over the last five years. The distribution has not notably changed over the past five years.

Figure 14:
Proportion of NLRDs reported by different type of organisations over the last five years



The proportion of NLRDs notified in each state or territory which were current at 30 June 2023 is shown in Figure 15.

Figure 15:
Distribution of all current NLRDs at 30 June 2023 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 2022–23, the Regulator received one request for an alternate facility. 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. No dealings were added to the GMO Register during this reporting period.

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 2022–23, 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.

In 2022–23, the Regulator issued one inadvertent dealings licence, ID-07. The purpose of this licence was to enable disposal of GM soybean that was inadvertently imported into Australia.

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 IBC, and must comply with other requirements of the Regulator's Guidelines for Accreditation of Organisations.

In 2022–23, 13 accreditations were issued, with a total of 207 organisations holding accreditation at 30 June 2023.

Accredited organisations are located in all Australian states and territories (Figure 16). Over time, organisations accredited by the Regulator have not changed substantially: a large proportion (55%) are primarily publicly funded through government, hospital/ health services and universities, and most research institutes. (Figure 17).

Figure 16:
Organisations accredited as at 30 June 2023, by location of headquarters

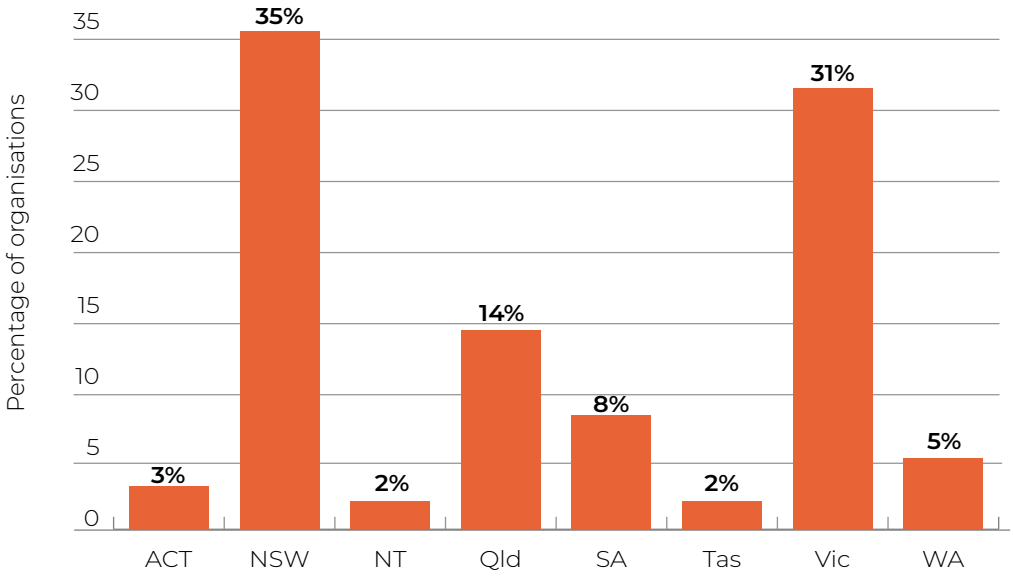
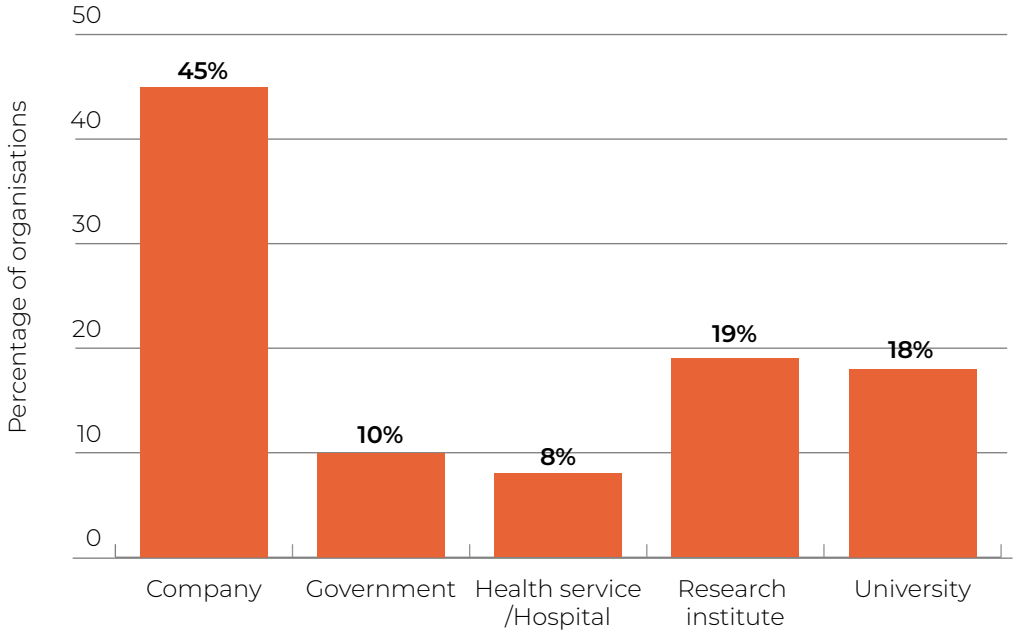


Figure 17:
Types of organisations accredited as at 30 June 2023



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.

In 2022–23, 132 new certifications for physical containment facilities were issued. This is a larger number than in previous years (see Table 6). About one third of the facilities certified were to universities and one third to companies, with the remainder to government and research institutes (Figure 18).

Table 5:
Number of OGTR-certified facilities at 30 June 2023

Facility Type	PC1	PC2	PC3	PC4	Grand Total
Animal		233	7		240
Aquatic		31			31
Constant Temperature Room		45			45
Facility	315		2	4	321
Invertebrate		49	2		51
Laboratory		1283	21		1304
Large Grazing Animal		58			58
Large Scale		19			19
Plant		120			120
Total	**315**	**1838**	**32**	**4**	**2189**

High-level facilities (PC4, PC3 and PC2 large scale) are generally only certified for three years and require inspection by OGTR staff prior to re-certification. During 2022–23 OGTR staff inspected two PC2 large scale facilities, eight PC3 laboratories, one PC3 invertebrate facility and three PC4 facilities. Staff also re-certified six PC2 large scale facilities, seven PC3 laboratories, one PC3 invertebrate facility and one PC4 facility. Four new PC2 large scale facilities were inspected, but their certification process was not completed by the end of the financial year.

The number of OGTR-certified facilities at 30 June 2023 is listed by facility type and containment level in Table 5. PC2 laboratories are the most common type of facility certified by the Regulator (1283 PC2 laboratories).

Figure 18:
Facilities certified in 2022–23 by organisation type

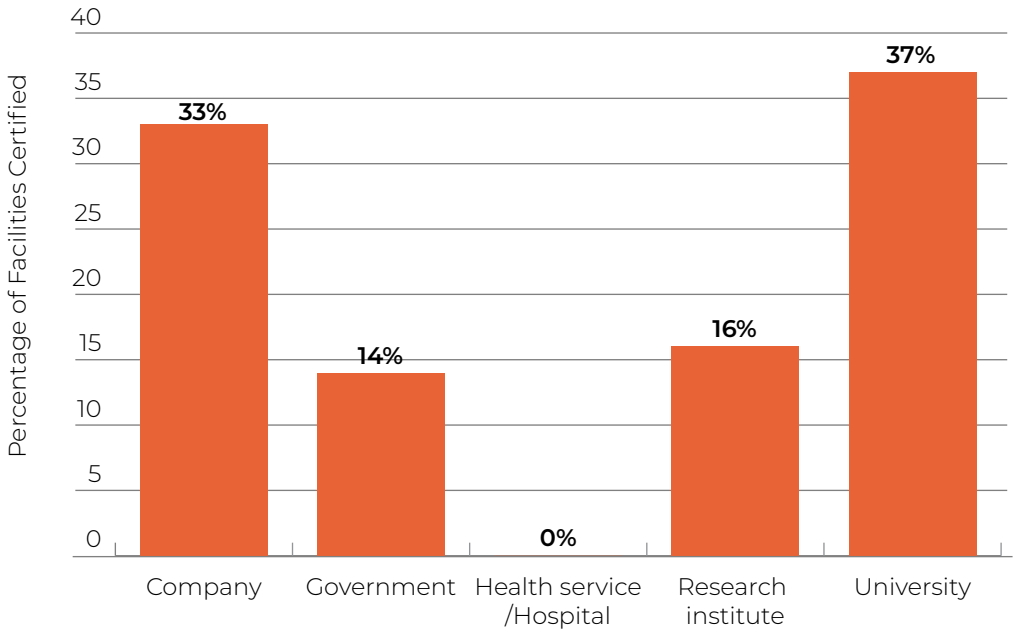


Figure 19:
OGTR-certified facilities as at 30 June 2023, by organisation type

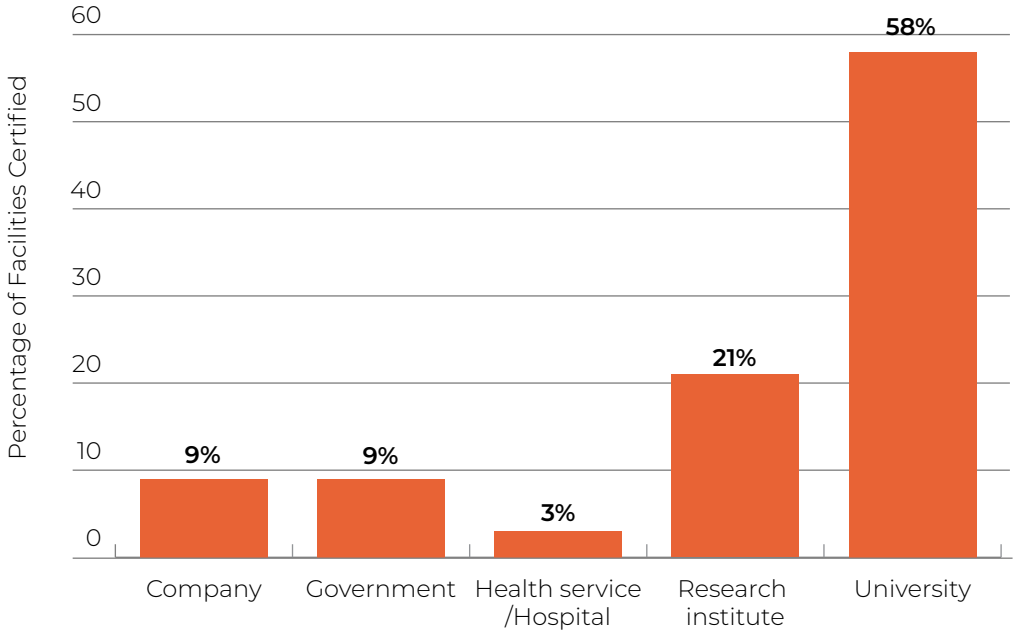
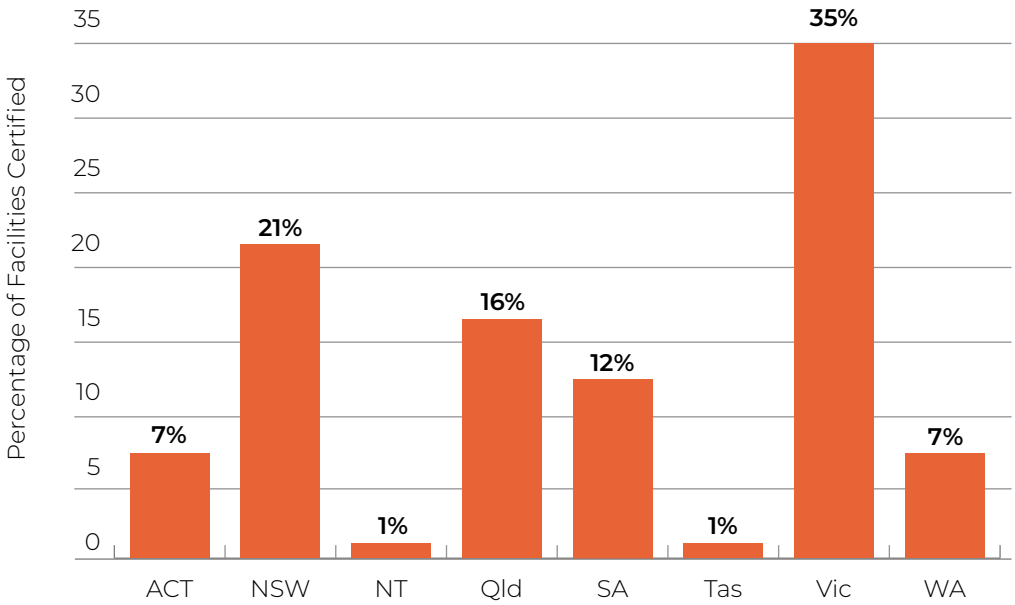


Figure 20:
OGTR-certified facilities as at 30 June 2023, by location



Application trends

The numbers of most primary authorisation types issued during 2022–23 were similar to those in previous years (Table 6). The number of licences (DIR and DNIRs) issued have remained reasonably consistent for the past five years. The number of new accreditations issued to organisations has reduced back closer to average levels, following a peak in 2021–22. There has been an increase in the number of new facilities which were certified in 2022–23. In this period 33% of the new facilities certified belonged to companies, compared to the historical data where 9% of certified facilities are owned by companies.

Table 6:
Approval of main types of applications

Application type	2018–2019	2019–2020	2020–2021	2021-2022	2022-2023
Accreditation	8	10	10	18	13
Certification	114[b]	100	101	97	132
DIR	6	3	9	7	5
DNIR[a]	11	20	19	13	12

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

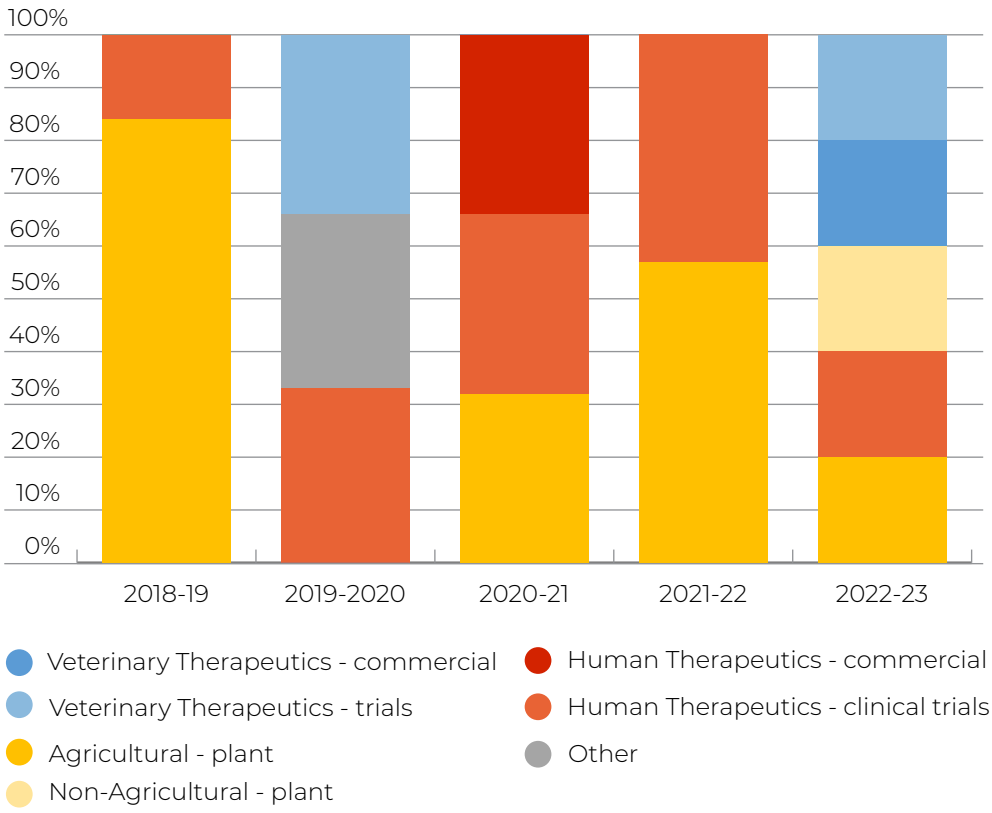
a 'Approval' for DNIR refers to the number of licences issued. This can differ from the total number of applications approved when two or more applications are integrated into a single licence.

b Correction to the number (108) reported in the 2018-2019 report.

One licence was issued for a commercial GMO human therapeutic in 2022–23 (DNIR-659) for treatment of patients with haemaphilia B). This is similar to the small number of commercial licences for GMO therapeutics over the past few years, with the exception of a peak of four licences in 2020–21. Over the past 21 years there have been 11 licences issued for commercial GMO human therapeutics, with six issued in the past four years. There were also five clinical trials with GMOs issued in 2022–23, continuing the trend for increased interest in this area. A licence was issued for a commercial veterinary GM vaccine (DIR 193). To date, there have been two commercial GM vet vaccines approved by the GTR, both for the prevention of disease in chickens. The Regulator has also issued a licence for a trial of a vaccine that aims to protect Tasmanian devils against devil facial tumour disease. This is the first licence issued for a GMO to be used in conservation biology.

Over the past five years, four licences have been issued for commercial cultivation of GM crops in Australia. The commercial GM crops approved in this period were cotton, canola (2) and Indian mustard.

Figure 21:
Focus of DIR licences, 2018–19 to 2022–23

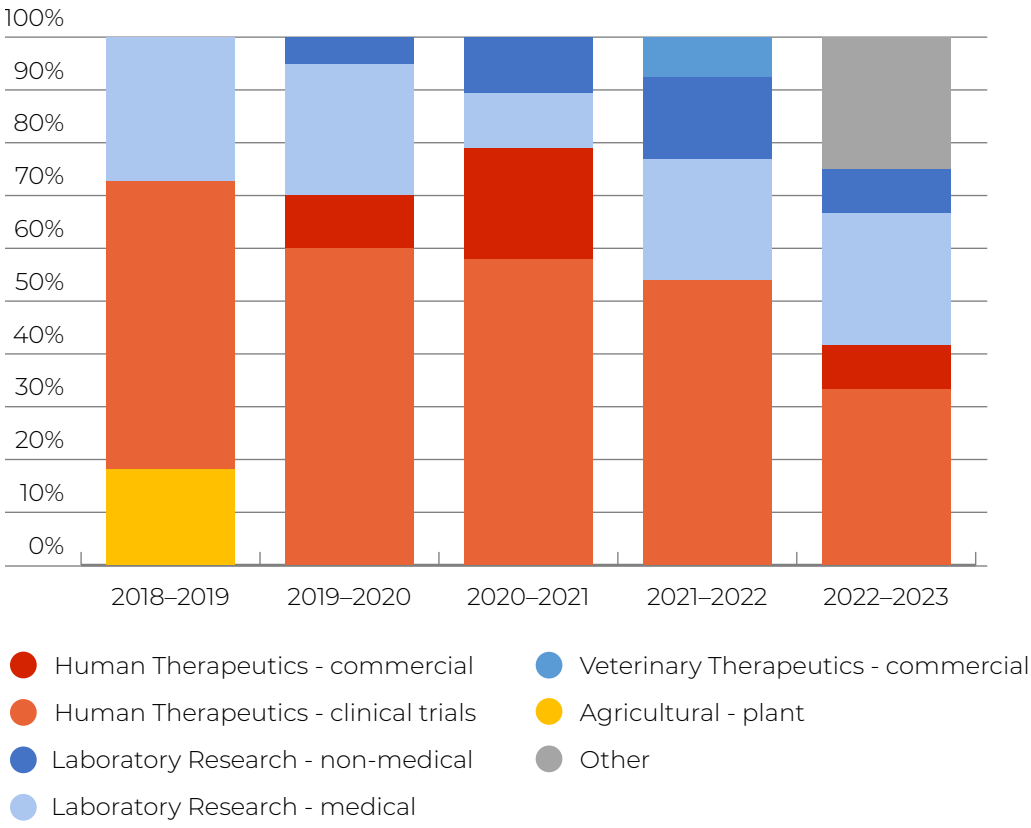


The number of DNIR applications in 2022–23 (13) remains higher than the 10-year average of 11.8 DNIR applications a year. The scope of DNIR licence applications received has also changed, with a higher proportion of DNIR licences to conduct clinical trials with GMOs compared to contained laboratory work. 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 five years is further analysed in Figure 22. This shows the strong interest in gene therapy, and fewer licences issued over the past two years for cancer treatments.

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

	2018–2019	2019–2020	2020–2021	2021–2022	2022–2023
Clinical trial DNIRs (% of DNIR licences)	9 (82%)	10 (50%)	12 (53%)	7 (54%)	4 (33%)
Percentage of accreditation applications received from companies involved in clinical trials or human therapeutic GMO development.	88%	60%	40%	83%	33%

Figure 22:
Fields of research authorised under DNIR licences, 2018–19 to 2022–23



Secondary applications

Confidential commercial information

Applications can be made to the Regulator under section 184 of the Act for specified information—that has not previously been made public—to be declared CCI. The extent of 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 2022–23, the Regulator made 19 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 72 surrender requests in 2022–23 and approved 52 for surrender of certification of a physical containment facility, five for surrender of a DIR licence, five for surrender of DNIR licences and six for surrender of accreditations. In addition, at 30 June 2023 six requests were 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 633 variation requests in 2022–23. Of these, 12 were for DIRs, 32 for DNIRs and 589 for certifications.

Monitoring dealings with genetically modified organisms

This section provides information on the OGTR's inspection activities during 2022–23. Travel restrictions during the COVID-19 pandemic has led to a backlog in onsite inspections and audits. OGTR's focus for this year has been addressing these backlogs.

During 2022–23, the OGTR conducted:

- six monitoring inspections of DIR licences
- four monitoring inspections of DNIR licences
- 49 monitoring inspections of certified facilities
- four Practice Reviews.

Monitoring and compliance activities involving DNIR licences have concentrated more on clinical trials rather than contained laboratory work. This is because many groups conducting clinical trial work have less experience with the scheme than those conducting contained research, and effort is better placed helping to educate new licence holders to ensure compliance. For further information see sections on 'Inspections of contained dealings' and 'Practice Reviews'.

Inspections of DIR licences

The Regulator's strategy for monitoring 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.[12]

In 2022–23, there were 56 DIR licences in force held by 27 accredited organisations. These comprised:

- 26 limited and controlled release licences for research purposes (11 for plant field trials)
- 11 human clinical trials
- three animal vaccine trials
- one for microalgae
- 30 commercial release licences[13] (21 for plant crops, seven for human clinical products and two animal vaccine products).

The OGTR inspected four of the 11 limited and controlled plant field trial licences (which may have comprised multiple site visits per licence). OGTR also inspected one limited and controlled clinical trial licence. None of the commercial release licences imposed conditions that necessitated site inspections.

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

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

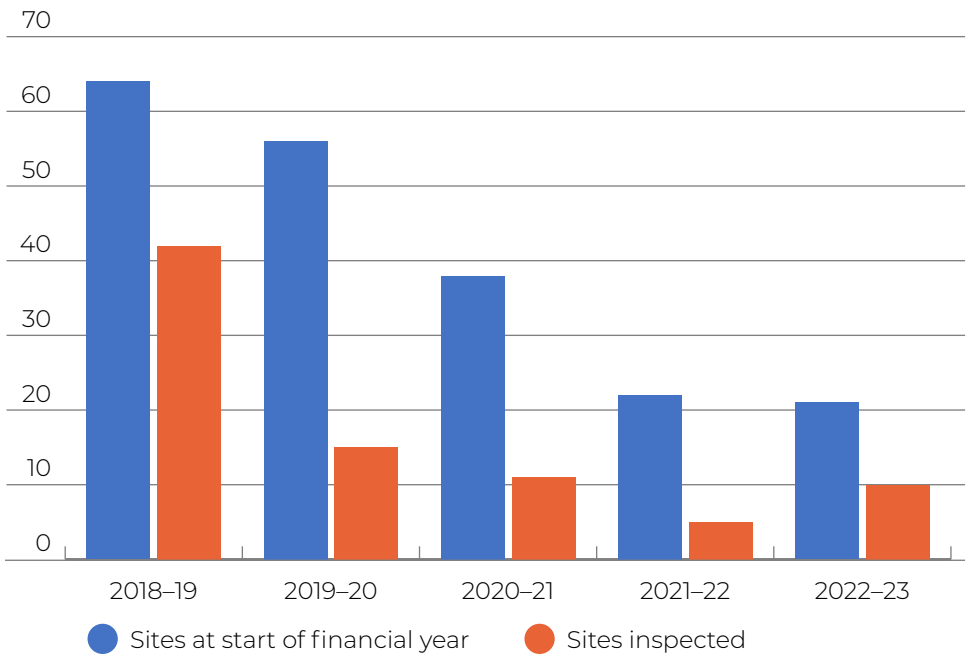
Outcome of inspection activities

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)
- the novelty or complexity of the GMO or protocols
- reports of incidents of potential non-compliances at sites or facilities
- after adverse weather events such as storms, floods or cyclones
- the level of experience of the licence holder and the potential for inspection activities or practice reviews to educate the licence holder and help ensure compliance.

At the beginning of 2022–23, 24 licensed field trial sites were operating, 12 of which were current and 12 were subject to post-harvest monitoring conditions (Figure 23). Forty-two per cent of the plant field trial sites were inspected in the year.

Figure 23:
Number of field trial sites and number inspected each year, 2018–19 to 2022–23



Types of GM crops inspected

OGTR inspected three plant species across 10 field trial sites during 2022–23 (Table 8).

The OGTR inspected field trial sites in Queensland, Western Australia and Victoria.

Table 8:
Number of licensed GM plant DIR trial sites at beginning and end of 2022–23, and number inspected in 2022–23, by plant type

Species	Trial sites as at 1-Jul-22	Trial sites as at 30-Jun-23	Trial sites inspected during 2022-2023
Banana	2	2	0
Canola	5	11	4
Chickpea	1		
Cotton	4	2	
Sorghum	4	1	5
Wheat	4	5	
Wheat and barley	1	2	
White clover		1	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 2022–23, 49 certified facilities were inspected across the range of facility types (Table 9); this includes seven of the higher-level containment facilities that had certification approvals in force at the beginning of 2022–23 (representing 12 per cent).

In addition, nine licences for clinical trials or contained dealings were subject to monitoring inspections or practice reviews throughout 2022–23 (Table 10).

Table 9:
Number of inspections of certified facilities (by type) conducted during 2022–23

Containment type	PC level and facility type	Inspections
Lower level	PC1 Facility	
	PC2 Animal	20
	PC2 Laboratory	14
	PC2 Plant	3
	PC2 Aquatic	2
	PC2 Large Grazing Animal	
	PC2 Constant Temperature	
	PC2 Invertebrate	3
Higher level	PC2 Large Scale	1
	PC3 Laboratory	3
	PC3 Animal	2
	PC3 Invertebrate	1
	PC4 Facility	

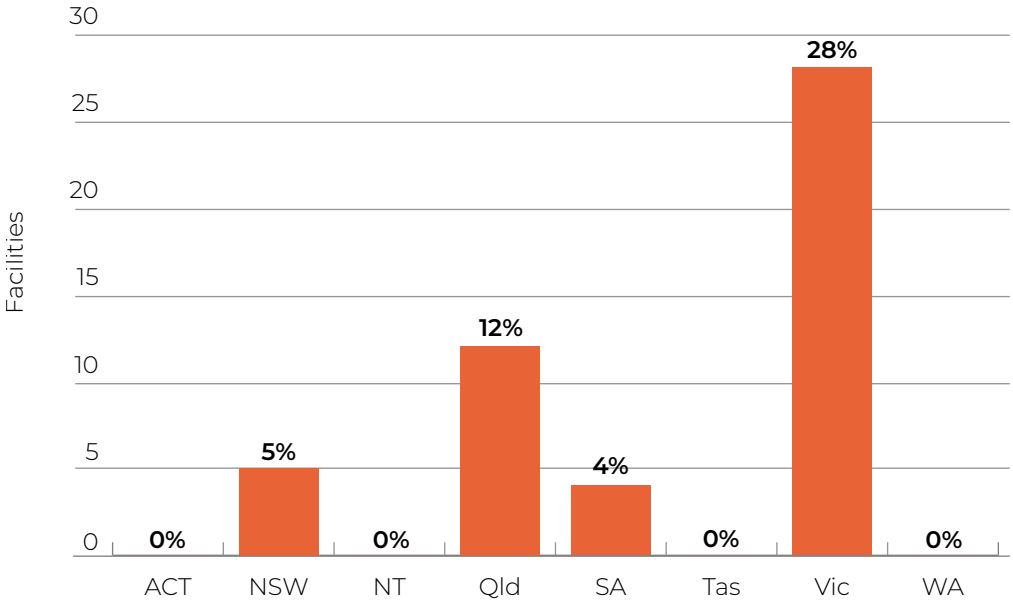
Table 10:
Number of inspections or practice reviews (PR) of contained licences and clinical trials conducted during 2022–23

Organisation	State	Licence
Merck Sharp & Dohme (Australia) Pty Ltd	NSW	DNIR-650
South Australian Health and Medical Research Institute	SA	DNIR 627
Treidlia Biovet Pty Ltd	NSW	DNIR 640
The University of Queensland	Qld	DNIR 634
PPD Australia Pty Ltd	NSW	DIR 185
The University of Melbourne	Vic	DNIR 654 (PR)
Merck Sharp & Dohme (Australia) Pty Ltd	Desktop	DNIR-650 (PR)
P Brodie Holdings Pty Ltd t/a PB Agrifood	Desktop	ID-07 (PR)
Westmead Institute for Medical Research	NSW	DIR-183 (PR)
Total		**9**

Locations of facility inspections

Certified facilities are located in all Australian states and territories (Figure 20). In 2022–23, monitoring activities took place in New South Wales, Queensland, South Australia and Victoria (Figure 24).

Figure 24:
Number of certified facility inspections in 2022–23, by state and territory

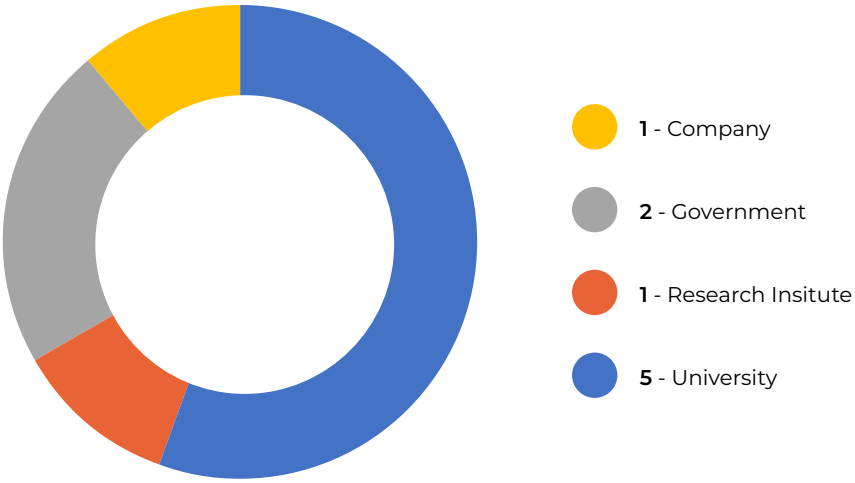


PC2 plant facility

Types of organisations inspected

Of the four categories of applicant organisations, universities held the largest number of certified facilities during 2022–23 (Figure 19). Figure 25 shows the distribution of inspections during 2022–23 by organisation type. Universities comprised the majority of inspections followed by government, companies and research institutes.

Figure 25:
Certified facility inspections in 2022–23, 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.[14]

During 2022–23, the regulated community continued to demonstrate a high level of compliance with the gene technology legislation.

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

Non-compliance findings for GMO dealings involving intentional release

In 2022–23, non-compliances were identified against two DIR licences. The findings are outlined below.

Organisation	Monsanto Australia Pty Ltd
Licence number	DIR-164
Summary of dealing	This licence allows Monsanto Australia Pty Ltd to conduct a limited and controlled release of canola genetically modified for herbicide tolerance. The dicamba-tolerant canola line contains a gene from a soil bacterium that confers tolerance to dicamba herbicide.
Findings	Monsanto Australia Pty Ltd did not correctly authorise an external contractor prior to their undertaking inspection activities at a trial site for DIR-164. Licence condition 15(c) requires that the licence holder not authorise an individual to undertake licensed dealings until they have obtained a signed statement confirming that the individual has been trained in, understands and agrees to be bound by licence conditions. In this instance such a record was not obtained by Monsanto Australia Pty Ltd prior to the contractor commencing activities on the site.
Assessment	People conducting dealings with the GMOs who are not fully trained or authorised in licence conditions pose risks to containment. In this instance the unauthorised contractor had completed the training, but Monsanto Australia Pty Ltd did not obtain a signed statement confirming that the individual had been trained, and that they had agreed to be bound by licence conditions. There is no evidence of any harm to human health or loss of containment of the GMO and as such, no additional risks were identified.
Compliance management	OGTR has reminded Monsanto Australia Pty Ltd of its obligation to ensure that all people undertaking licensed dealings are trained in licence conditions and have provided signed statements. No additional actions are required from the licence holder as the matter was rectified immediately.

Organisation	PPD Australia Pty Ltd
Licence number	DIR-185
Summary of dealing	The purpose of this licensed dealing is a clinical trial with genetically modified Bordetella pertussis for the prevention of whooping cough.
Findings	At the time of inspection, the GMOs were stored in a restricted access location and were labelled with a traceable unique identifier. However, the label did not explicitly identify the contents as GMO and therefore did not meet the requirements under the licence DIR-185.
Assessment	Licence condition 35 (a) imposes labelling requirements to inform handlers that the material is a GMO and to provide specific details on how this material must be handled. In this circumstance, the GMOs were only handled by trained staff under the licence conditions. There is a negligible risk posed to the health and safety of people and the environment by this non-compliance.
Compliance management	The licence holder was reminded of labelling requirements and rectified the issue accordingly.

PC2 animal facility

Non-compliance findings for GMO dealings not involving intentional release

In 2022–23, non-compliances were identified against two DNIR licences. The findings are outlined below.

Organisation	Merck Sharp & Dohme (Australia) Pty Ltd (MSD)
Licence number	DNIR-650
Summary of dealing	The proposed clinical trial will evaluate the safety and tolerability of the GMOs when administered to healthy adults. Secondary objectives are to measure the immune response induced by the GMOs.
Findings	A study nurse who inoculated patients did not receive all of the required training in respect of DNIR-650 licence conditions (as per Conditions 18 and 30(a)) at the clinical trial site before undertaking dealings with the GMO. MSD did not obtain a signed statement indicating that the Study Nurse had been trained in, understood and had agreed to be bound by licence conditions (Condition 19).
Assessment	It was identified that site-specific training provided to the Study Nurse addressed many of the elements required by the licence, including appropriate personal protective equipment and transport, storage and disposal of GMOs. As such, no additional risks to human health and safety or the environment were identified. MSD self-reported this matter to OGTR, and the Study Nurse ceased handling GMOs until they had received the appropriate licence training.
Compliance management	MSD was reminded of their obligations to ensure that all authorised persons are informed of applicable conditions, receive appropriate training and generate appropriate records prior to undertaking dealings. It was recommended that MSD update their policies and procedures to address the risk of this issue recurring.

Organisation	Novotech (Australia) Pty Ltd
Licence number	DNIR-629
Summary of dealing	Clinical trial with ICM-203 for the treatment of arthritis.
Findings	Novotech (Australia) Pty Ltd failed to meet a reporting condition (Condition 41(a))
Assessment	The delay in reporting occurred because of an administrative oversight and all persons involved were appropriately trained in their obligations. Furthermore, the delayed reporting did not impact the management of risks associated with the licence. It was also noted that Novotech (Australia) Pty Ltd self-reported this matter to OGTR and have undertaken corrective actions to improve reporting procedures.

Organisation	Novotech (Australia) Pty Ltd
Compliance management	Novotech (Australia) Pty Ltd have been reminded of their obligations to ensure that reporting occurs within specified timeframes. Novotech (Australia) Pty Ltd are also required to update their policies and procedures to address the risk of this issue recurring.

Non-compliance findings for notifiable low risk dealings

In 2022–23, two organisations were found to be non-compliant against the Act, in that dealings were being undertaken without a current NLRD.

In both cases, the organisations took corrective and preventative measures and no further actions were recommended.

Non-compliance findings for physical containment facilities

In 2022–23, 26 certified physical containment facilities were found to be non-compliant with a total of 32 certification conditions. These findings are summarised in Table 11.

Table 11:
Number of non-compliances identified in certified facilities during 2022–23, by non-compliance type

Nature of non-compliance	Number
Equipment	
Training and authorisation	
Reporting	
Structure	25
Control measures	
Governance	3
Trial management	
Transport, storage and disposal	1
Work practices	3

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 four practice reviews with four organisations during this reporting period. Two are still ongoing and the results of which will be included in the 2023–24 Annual Report. Two have been finalised with the findings outlined below.

All practice reviews covered the preparedness of the organisations to undertake licensed dealings under DNIRs, DIRs and Inadvertent dealing licences respectively.

PC2 animal facility

	Preparedness of Merck Sharp & Dohme (Australia) Pty Ltd to undertake licensed dealings not involving intentional release – human clinical trials
Aim	This is part of the OGTR's ongoing practice review program. The OGTR recognises that effective compliance is dependent on: • suitable arrangements to manage compliance for GMO dealings • suitable site selection and appropriate use of containment measures • staff training and provision of resources necessary to manage compliance obligations.
Participants	The review focused primarily on Merck Sharp & Dohme (Australia) Pty Ltd preparedness to undertake dealings under DNIR-650. The review assessed: • site selection and planning considerations for containment measures • the suitability of the organisations' arrangements to manage compliance risks, including training and oversight of staff, collaborating organisations and resourcing • any industry or other regulatory issues which could impinge on the organisations' effective compliance performance.
Findings	The review found that Merck Sharp & Dohme (Australia) Pty Ltd had considered and implemented effective measures in relation to site selection and planning for a licenced dealing involving an intentional release.
Outcomes	The OGTR practice review program continued to assess vulnerabilities to containment and compliance with the *Gene Technology Act 2000*. Such information contributed to: • an overall understanding of compliance performance and emerging barriers to effective compliance • the continual improvement of compliance management processes • the prevention of practices and arrangements that could lead to non-compliance • compliance management and awareness activities.

	Preparedness of Westmead Institute for Medical Research (WIMR) to undertake licensed dealings involving intentional release – practice review
Aim	This is part of the OGTR's ongoing practice review program. The OGTR recognises that effective compliance is dependent on • suitable arrangements to manage compliance for GMO dealings • suitable site selection and appropriate use of containment measures • staff training and provision of resources necessary to manage compliance obligations.
Participants	The review focused primarily on the preparedness of WIMR to undertake dealings under DIR-183. The review assessed: • planning considerations for containment measures • the suitability of the organisations' arrangements to manage compliance risks, including training and oversight of staff, collaborating organisations and resourcing • any industry or other regulatory issues which could impinge on the organisations' effective compliance performance.
Findings	The review found that WIMR had considered and implemented effective measures in relation to site selection and planning for a licenced dealing involving an intentional release.
Outcomes	The OGTR practice review program continued to assess vulnerabilities to containment and compliance with the *Gene Technology Act 2000*. Such information contributed to: • an overall understanding of compliance performance and emerging barriers to effective compliance • the continual improvement of compliance management processes • the prevention of practices and arrangements that could lead to non-compliance • compliance management and awareness activities.

Audits

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

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

These activities are conducted to:

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

Audits are an opportunity for organisations and the OGTR to share information to improve the risk management of dealings with GMOs under the Act. Audits may focus on a single dealing or issue, a range of dealings (e.g. dealings with a common host organism or dealings within a common climatic zone), the activity of an organisation across a range of dealings, or an activity common to a range of organisations. During 2022–23, the OGTR continued an audit of the University of Adelaide in South Australia and commenced an audit of Monash University in Victoria. Findings will be reported once the audits are completed.

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 2022–23 we continued to liaise with the seed industry to raise awareness about management of low-level presence of GMOs, and to ensure their ongoing voluntary cooperation and action regarding this issue.

We continued to engage with other government departments, including the Australian Government Department of Agriculture, 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 2022–23, the OGTR continued to work with the Office of Health Protection and Response to operationalise these monitoring arrangements.

PC2 laboratory

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 2022–23 annual report, is summarised below.

Our activities for 2022–23 are described under Program 1.8 in Outcome 1 (Health Protection, Emergency Response and Regulation) of the 2022–23 Department of Health and Aged Care Portfolio Budget Statements.[15] 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.

2022–23 target	2022–23 result: Met
100%	100% of licensed decisions were made within statutory timeframes, with all decisions based on sound scientific analysis.

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

The following licences were issued during 2022–23:

- one agricultural – commercial plant licence
- five human therapeutics – clinical trial licences
- one human therapeutics – commercial licence
- three laboratory research – medical licences
- one laboratory research – non-medical licence
- one non-agricultural – commercial plant licence
- two manufacturing licences
- one therapeutic administration licence
- one veterinary therapeutics – commercial licence
- one veterinary therapeutics – trial licence.

15 The Portfolio Budget Statement is on the Department's website.

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

2022–23 target	2022–23 result: Met
100%	100% of reported non-compliance with conditions were assessed.

The OGTR received and assessed 70 reports during 2022-23, relating to possible non-compliances with GMO approvals (licences, notifiable low risk dealings and certifications).

Inspectors assessed all reports received. Assessments consider the circumstances of the report in accordance with the Gene Technology Act 2000, and Gene Technology Regulations, Guidelines and the conditions relating to each authorisation. For any non-compliance identified, inspectors consider the compliance history of the entities involved, whether the non-compliance has been rectified or can easily be rectified, and whether the non-compliance had the potential to result in harm to human health or the environment.

The OGTR takes a cooperative compliance approach, with an emphasis on education, engagement and awareness raising. When assessing non-compliance, OGTR considers appropriate measures to address the non-compliance, and continues to work with the entity following a non-compliance to ensure they remain in compliance.

Chapter 4

Other Functions of the Gene Technology Regulator

Chapter 4

Other Functions of the Gene Technology Regulator

This chapter describes achievements and other function of the Gene Technology Regulator.

- Technical and procedural guidelines issued by the Regulator
- Implementing recommendations from the Third Review of the National Gene Technology Scheme.
- Advice on GMOs and GM products
- Engagement with stakeholders
- Promoting harmonisation

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 2022–23 the revised PC 3 guidelines were issued. These guidelines were updated in response to both new information and changes in industry practice.

The review of the PC3 Guidelines began in 2019 with a consultation round directed at internal and external stakeholders. This resulted in draft PC3 Modular Guidelines and a PC3 Guidance Facility document being created which were consulted on in 2022. Further changes were made in response to input received and the final package of new guidelines as well as a guidance document were released in December 2022.

A new application form was released in September 2022 for clinical trials using GMOs. This form was designed to elicit the specific information needed for clinical trials, given that we are receiving increasing numbers of these types of applications. The new form accommodates applications for both DIR and DNIRs, noting that different evaluation processes and timeframes still apply to these different licence types. The scientific questions are tailored specifically to the information needed for risk assessment of human clinical trials involving GMOs.

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 and Aged Care team, which leads the implementation of 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. In April 2023 the Gene Technology Ministers' Meeting agreed to a revised timeline, in which the new legislation is expected to be introduced into the Commonwealth Parliament in 2024 after a period of extensive jurisdictional, targeted and public consultation that is managed through the Department.

Advice on GMOs and GM products

During 2022–23, the OGTR advised other regulatory agencies and the public on the regulation of GMOs and GM products.

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 in the Evaluation Branch during the year-one in the Contained Dealings Evaluation Section and one in the Plant Evaluation Section to experience 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 biological agents. It aims to strengthen the regulatory science underpinning the regulation of these agents across government agencies. It also provides a forum for regulatory and technical issues and enhancing interagency cooperation.

OGTR participated in the 2022 RSN Annual Symposium on 'Adapting to Change' which featured a presentation by Dr Heidi Mitchell on 'Evaluating the changing nature of genetically modified organisms (GMOs) in Australia.' The symposium was held at the Hellenic Club and was well-attended by OGTR staff. OGTR continues to be active in the RSN, and two OGTR staff members are on the RSN committee.

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.[16] The GMO Record contains information on licences issued, NLRDs notified, GMO dealings included on the Register, and emergency dealing determinations. In 2022–23, OGTR maintained the GMO Record and updated it with new authorisations.

16 The OGTR website includes current lists of GMO dealing authorisations..

Engagement with stakeholders

OGTR newsletters

The OGTR releases a regular newsletter to stakeholders as part of our communications with the regulated community. 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 2022–23, two newsletters were produced:

- The first featured information on what 'intentional release' means in relation to dealings involving intentional release.
- The second featured:
  - information on the new OGTR Online Services Portal
  - the benefits of NLRD intermittent reporting
  - new PC3 lab certification guidelines
  - meet-the-team articles for two different sections in OGTR that have substantial interaction with our regulated stakeholders, and
  - information about the role other agencies play in the National Gene Technology Scheme.

Digital service delivery for applications to the Regulator

As part of the ongoing business improvement initiatives and development of digital service delivery, two new forms were released during 2022–23:

- Application for Accreditation of an Organisation form
- External IBC Declaration form.

In addition, several existing forms had additional functionality added. These include:

- updates to the Application to Vary a DIR Licence form to include the ability to surrender a DIR licence
- updates to the Application to Vary a DNIR Licence form to include the ability to surrender a DNIR licence.

No further forms will be developed using the existing Smart Form platform as the IT systems modernisation project has reached the milestone of adding forms into the new Portal.

IT systems modernisation project update

The OGTR is engaged in a project to modernise 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 and Online Services Portal will streamline application submissions through new forms with two-way data flow for authenticated portal users, and improve OGTR processing of applications. Dashboards will improve transparency of applicant submissions, and organisation contact information.

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.

Meetings, conference attendance and presentations on gene technology in Australia

The Regulator and staff from the OGTR attend and present papers to meetings, forums and conferences in Australia. During 2022–23, 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:

- August 2022, Biosecurity Containment Level 2 Conditions
- September 2022, Next Generation Biocontrol of Invasive Vertebrate Pests
- September 2022, 20th Australian Agronomy Conference, virtual attendance
- September 2022, Association of Biosafety for Australia and New Zealand webinar 'The Commissioning of High Containment Facilities'
- September 2022, 22nd Australasian Weeds Conference
- October 2022, Association of Biosafety for Australia and New Zealand webinar 'Gaseous Fumigation of Containment Cabinets'
- November 2022 CropLife Forum.

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 2022–23, OGTR updated two biology documents:

- The Biology of *Musa* L. (banana)
- The Biology of *Lolium multiflorum Lam.* (Italian ryegrass), *Lolium perenne L.* (perennial ryegrass) and *Lolium arundinaceum* (Schreb.) Darbysh (tall fescue).

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

Promoting harmonisation

The Regulator and OGTR continued to liaise with other regulatory and Australian Government agencies on relevant issues during 2022–23.

International regulatory liaison

International engagement 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 Party on the Harmonisation of Regulatory Oversight in Biotechnology, with an OGTR officer currently chair. The working party develops scientific guidance to support the risk assessment of GMOs. The OGTR provides technical advice to support Australian engagement in activities under the United Nations (UN) Convention on Biological Diversity, most recently regarding the development and adoption of the Post-2020 Global Biodiversity Framework, and Cartagena Protocol on Biosafety (the Protocol).

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[17] and the UN Biosafety Clearing-House.[18]

17 The BioTrack Product Database is on the OECD website.

18 The Biosafety Clearing-House is online.

By participating in and presenting at international forums, the OGTR continued to interact with key regulatory counterparts in other countries during the year, both in person and virtually. Meetings held in person were:

- September 2022 – Fourth International Workshop for Regulation of Animal Biotechnology, Sao Paulo, Brazil
- September 2022 – update on Australian GMO regulation to Federal Office of Consumer Protection and Food Safety, Berlin, Germany
- September 2022 – 9th meeting of the International Organisation for Biological Control working group 'Modern Biotechnology in Integrated Plant Production': 'Moving to Sustainable Agriculture – how can biotechnology help' Berlin, Germany
- December 2022 – United Nations, Convention on Biological Diversity Conference of Parties meeting 15, Montreal, Canada
- February 2023, RACT 2023 – International Conference on the Regulation of AgVet Chemicals and Technologies,
- April 2023 – 37th meeting of the OECD Working Party on the Harmonisation of Regulatory Oversight in Biotechnology, Paris, France
- April 2023 – International Conference on Gene-Edited Crops: Enabling Future Commercialisation and Trade, Canberra, Australia
- April 2023 – Like Minded Group on agricultural biotechnology meeting, St Louis, USA
- April–May 2023 – International Society for Biosafety Research Symposium, St Louis, USA
- May 2023 – Update on Australian GMO regulation to Belgian Directorate Animals, Plants & Foodstuffs and Biosafety & Biotechnology Unit, Brussels, Belgium
- May 2023 – Sustainability in Agriculture & Food Systems – Innovation, Indicators and Implementation conference, Brussels, Belgium.

The following meetings where attended virtually

- November 2022 – Global Biotechnology Regulators meeting
- April 2023 – Cartagena Protocol Open-Ended Online Forum on Risk Assessment
- April 2023 – International Seed Federation webinar: Current genome editing technologies, applications and evolution
- June 2023 – Global Low Level Presence Initiative meeting
- June – New Genomic Techniques: a state of play, Brussels, Belgium.

Chapter 5

Management and accountability

Chapter 5

Management and accountability

Managment 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 had a workforce of 51 employees at 30 June 2023. All permanent employees other than the Regulator are Australian public service staff employed by the Department of Health and Aged Care 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.

Monitoring and Compliance Team

Plant Evaluation Team

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 22nd year of operation.

A weekly all-staff Friday morning tea was a successful way to keep staff up-to-date on major issues, and provided opportunities for input, participation and feedback. It was also promoted as casual dress day, and staff who took up that option were encouraged to contribute a gold coin for charities including ACT Pet Crisis Support and Give me 5 for Kids.

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

Regulator's Achievement Award

The 2023 recipients of the Regulator's Achievement Award were two teams recognised for their contributions to the work of the OGTR. Common themes of cooperation, leadership, professionalism in approach to their work and dedication to task were mentioned in staff nominations.

The Monitoring and Compliance team received the award for handling of complex and sensitive issues, and for the professionalism with which they approach audits, inspections and monitoring visits to all parts of Australia. As part of their work, the team undertakes a considerable amount of travel on behalf of the OGTR which requires commitment and flexibility from each team member as well as their families. With travel restrictions over the past two years, the team has spent considerable time working on a backlog of inspections, while ensuring that a physical presence has returned to the compliance work of OGTR.

Team members from the Plant Evaluation Section (Kylie Tattersall, Laura Ferguson and Helen Holt) were acknowledged for their approach to a challenging licence application. Writing the RARMP involved tackling new science and seeking specialised advice from external experts in addition to the GTTAC, which was challenging within the statutory timeframe. The out-of-the-box thinking, collaboration, and curiosity to ask relevant questions resulted in publication of a robust and technically sound RARMP. Early engagement with prescribed agencies meant that issues raised in submissions from the public consultation process could be clearly addressed. The Regulator considered all of the information presented to make a final decision.

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 2022–23, refresher training was given to the emergency control team, which comprises three fire wardens and 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 2022–2023, the OGTR Principal Legal Officer provided introductory and ongoing training for OGTR staff on legal issues. Legal training sessions were conducted on 'Fundamentals for contractors and new starters', 'Principles of administrative decision-making' and 'Information handling: Freedom of Information and Confidential commercial information.'

During 2022–23, the OGTR Principal Regulatory Scientist provided introductory training for OGTR staff on risk analysis. Two sessions were held on 22 August 2022 and 16 May 2023: '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.

Initiatives to ensure workers' health, safety and welfare

The department is improving wellness and motivation in the workplace by:

- creating, promoting and maintaining a safe and healthy working environment
- encouraging productive working relationships
- promoting and encouraging 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 2022–23, 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.

Freedom of information contact details and procedures

The OGTR received five 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.

Stakeholder and public access to the OGTR

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

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, 2022–23

Month	Visits[a]	Users[b]
July	63,069	47,022
August	16,733	11,908
September	11,614	8,178
October	11,401	7,856
November	12,477	9,446
December	6,321	4,538
January	6,563	4,827
February	21,753	16,701
March	18,928	13,507
April	10,316	7,519
May	10,921	7,376
June	9,560	6,529

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.

The most viewed pages on the OGTR website during 2022–23 were, in descending order:

- Dealings involving intentional release
- Office of the Gene Technology Regulator (home page)
- DIR 184 – Clinical trial with a genetically modified human adenovirus COVID-19 vaccine
- What we've approved
- About the OGTR
- Resources
- DIR 182 – Commercial supply of a genetically modified COVID-19 vaccine

- Types of GMO dealings
- DIR 180 - Commercial supply of a genetically modified COVID-19 vaccine
- Genetically modified (GM) crops in Australia.

The most downloaded applications in 2022–23 were:

- Application for a licence for dealings not involving intentional release of a GMO (DNIR)
- Application for a licence to conduct a human clinical trial of a GMO
- Application Checklist for a Physical Containment Level 2 Laboratory
- Application for Accreditation of an Organisation
- Application for a DIR licence for the limited and controlled release of GM plants
- Application for a DIR licence involving a non-plant GMO
- Application for a confidential commercial information (CCI) declaration
- Application Checklist for a Physical Containment Facility Level 1
- Application for the Certification of a Physical Containment Facility
- Application Checklist for a Physical Containment Level 2 Animal Facility.

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 2022–23, use of the email address decreased compared with the previous year (Table 14).

Table 14: Email activity, 2022–23 and 2021–22

	Emails	
Month	**2022-23**	**2021-22**
July	81	31
August	50	38
September	31	55
October	52	40
November	40	39
December	36	53
January	30	43
February	49	41
March	45	110
April	30	170
May	41	80
June	39	65
Total	**524**	**765**

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 878 emails during 2022–23 (compared to 702 in 2021–22).

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 853 emails during 2022–23 (compared to 615 in 2021–22).

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 4,115 emails during 2022–23 (compared to 3,536 in 2021–22).

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 2023–26 – current members

Member	Position
Professor John Rasko AO (Chair)	Director, Cell & Molecular Therapies, Royal Prince Alfred Hospital; Program Head, Centenary Institute, Professor, Faculty of Medicine & Health, University of Sydney (NSW)
Dr Graham Bonnett	Lead Drought Resilience Mission, CSIRO Agriculture and Food (Qld)
Honorary Professor Fiona Cameron	Honorary Professor, College of Science, ANU; Adjunct Professor, College of Science, Health and Engineering, La Trobe University (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 2023–26 – 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
Professor Ainsley Newson (Australian Health Ethics Committee, National Health and Medical Research Council cross-member)	Professor, Sydney Health Ethics, Sydney School of Public Health, Faculty of Medicine and Health, University of Sydney
Dr Rachel Nowak	Senior Editor, Custom Media, APAC, Springer Nature (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 and 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 oncomprehensive 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 IBC 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

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 and Aged Care
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

Term	Description
Incident	A self-reported event that may constitute a non-compliance with regulatory requirements and a risk to public health or the environment
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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136(1A)(b)	Pg 54 - 58	Any breaches of conditions of a GMO licence that have come to the Regulator's attention during the financial year
136(1A)(c)	Pg 39	Emergency dealing determinations made by the Minister during the financial year
136(1A)(d)	Pg 39	Any breaches of conditions of an emergency dealing determination that have come to the Regulator's attention during the financial year
136(1A)(e)	Pg 49 -63	Auditing and monitoring of dealings with GMOs under this Act by the Regulator or an inspector during the financial year

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