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Department of Health and Aged Care

Office of the Gene Technology Regulator

Annual Report
2023–24

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

Letter of Transmittal

The Honourable Ged Kearney MP
Assistant Minister for Health and Aged Care
Assistant Minister for Indigenous Health

Dear Minister

I am pleased to present to you the annual report on the Office of the Gene Technology Regulator covering the period 1 July 2023 to 30 June 2024.

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 2023–2024.

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

24 September 2024

Contents

Figures

Tables

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 2023–24 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 is 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 EDD 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.

1 The Department of Health and Aged Care Portfolio Budget Statements May 2023.

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

The report contains 5 chapters:

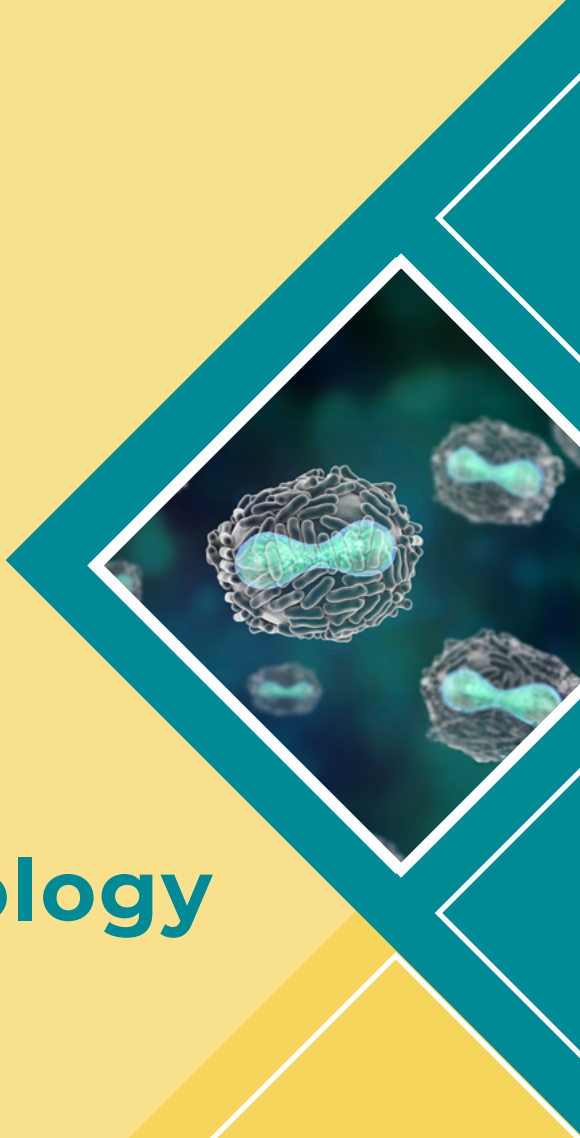
Chapter 1: Gene Technology Regulator's overview – summarises the Regulator's activities over the past year, including major achievements and the outlook for the coming year.

Chapter 2: Office of the Gene Technology Regulator – describes the OGTR'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 2023–24. 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 2023–24 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 the Gene Technology Regulations 2001, 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.



Chapter 1

Gene Technology Regulator's overview

Chapter 1

Gene Technology Regulator's overview

The highlights of this year have centred around greater collaboration to inform strategies and frameworks for applications of biotechnology across different sectors such as manufacturing, agriculture, environmental protection and personalised medicines.

Of note have been discussions with the New Zealand Ministry of Business, Innovation and Employment, which is responsible for developing a new regulatory regime for gene technology in New Zealand. This regime comprises new legislation largely based on our *Gene Technology Act 2000* and includes risk-based and proportionate regulation. One of the first questions we were asked was: What lessons can we take from your experience of over 20 years of administering the Australian scheme?

The Australian and New Zealand prime ministers decided to 'promote collaboration and alignment of our regulatory approaches for GMOs, noting the unique environment of Australia and New Zealand'.[3] With this important commitment in mind, I look forward to working more closely with our New Zealand colleagues as they progress towards setting up a New Zealand OGTR.

The Australian Government Department of Industry, Science and Resources released *Australia's RNA blueprint: understanding our ribonucleic acid (RNA) potential*.[4] The blueprint includes implementation of recommendations from the Third Review of the National Gene Technology Scheme, as part of a goal for leading RNA regulation and guidance development together with the Therapeutic Goods Administration and the Australian Pesticides and Veterinary Medicines Authority (APVMA).

During the year, we worked with Food Standards Australia New Zealand (FSANZ) to undertake a parallel assessment of an application from Queensland University of Technology (QUT) for commercial cultivation of a genetically modified (GM) banana. The GM banana was developed for resistance to Panama disease, which is a fungal pathogen that lives in soil and has decimated commercial banana cultivation around the world. The commercial licence was issued in February 2024. This was the culmination of joint public consultation processes on the OGTR risk assessment and risk management plan and the FSANZ food safety risk assessment. This was the first time a commercial cultivation licence assessment and a food safety assessment had been conducted in parallel. It was also the first GM banana approval in the world.

3 www.pm.gov.au/media/australia-new-zealand-leaders-meeting-2024

4 www.industry.gov.au/publications/australias-rna-blueprint

This 2023–24 period has been another busy year, with staff involved in many different activities across the office. Just over 800 authorisations and approvals were issued, and we processed over 100 self-reported incidents.

With funding from the department, we successfully launched a new online services portal. The portal has notifiable low risk dealing (NLRD) forms and certifications embedded, and applicant dashboards showing authorisations and notifications held by regulated entities.

The OGTR made significant contributions in supporting the department with legislative drafting of amendments to the Act, to implement recommendations of the Third Review of the National Gene Technology Scheme. We also contributed to the development of the national gene drive policy guide, which underwent public consultation in January 2024. This was developed by the department to provide information to prospective applicants and researchers on specific issues that fall outside the remit of the Act but are part of the national scheme and of importance to the community and those impacted by the environmental release of a gene drive GMO.

Communication about our role and what we regulate has been important. We published 2 pieces on our website addressing misinformation about regulation of the COVID-19 mRNA vaccines and the difference between gene therapies and vaccines as different forms of medical treatments.

We commissioned a Community Attitudes Survey this reporting period, the results of which are published on our website and will be described in more detail in our next annual report.

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 objective and performance targets for the OGTR. Our objective is to protect human health and the environment through regulatory oversight of genetically modified organisms (GMOs). This objective is delivered through the key activities of administering the national gene technology scheme by assessing applications and issuing approvals and by conducting routine inspections of certified facilities and licensed activities with GMOs.

The OGTR performed against the PBS targets as follows:

- 100% of GMO licence decisions were made within statutory timeframes
- 99.1% (against the target of 100%) of reported non-compliance with conditions of GMO approvals were assessed.

The OGTR continued to support the work of the department and of the Gene Technology Standing Committee to action and implement priorities endorsed by the Gene Technology Ministers' Meeting and included in the Gene Technology Ministers' Meeting Action Plan 2023–2025.[5]

Applications and licences: what's new

Our licensed 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 (DNIR).

This year, 6 DIR licences were issued, of which 3 were for GM plants, one for a clinical trial, one for commercial supply of a human vaccine and one for biomanufacturing. Two of the plant licences were for field trials: GM wheat and barley for yield enhancement; and insect-resistant, herbicide-tolerant GM cotton. The other was for commercial release of a GM banana resistant to Panama disease.

The clinical trial was to investigate an inflammatory bowel disease treatment, and the commercial vaccine was for dengue fever. The biomanufacturing licence was an approval for use of GM yeast modified to produce milk proteins, egg proteins and spider silks.

For the contained research DNIR licence category, 26 licences were issued, of which 15 were for clinical trials of human therapeutics, 6 for research work in laboratories, 2 for commercial manufacturing of vaccines, and 3 for medical laboratory research.

Trend data for the past 5 years continue to show a change from crop-based licence applications to vaccine development and commercialisation (human and veterinary), clinical trials of various gene therapies, and manufacture of human therapeutics.

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

Monitoring and compliance activities

The Monitoring and Compliance team had a record year of activity with its program of on-site visits, face-to-face inspections and audits, and assessment of reports of non-compliance. Greater numbers of inspections were needed after the pandemic years, when entry and travel restrictions led to decreased physical presence.

During the 2023–24 period, 5 field trial sites were inspected for 3 plant species: canola, cotton and wheat. This was 42% of the total number of trial sites current at the start of the reporting period. Monitoring inspections of 12 licences for clinical trials or contained work were conducted, and 4 practice reviews were undertaken. In addition, 155 certified facilities were inspected against certification requirements, of which 6 were high-level containment facilities. The Monitoring and Compliance team received 109 reports relating to possible non-compliances with GMO approvals (licences, NLRDs and certifications) and assessed 108 of these. Inspectors assessed all but one of the reports received, leading to a performance of 99.1% against the PBS target of 100% during the 2023–24 period.

Business improvement activities

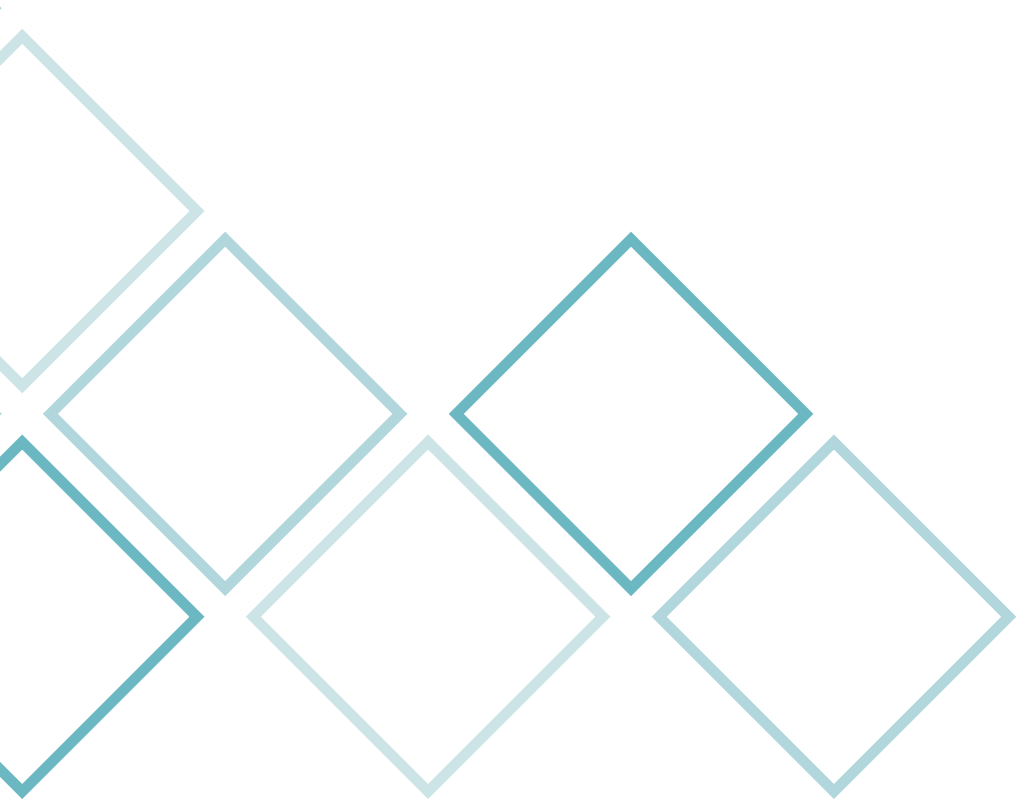
Our ICT modernisation project has been progressing well with the movement of legacy systems, including our applications database and monitoring and compliance database, from old platforms to new customer relationship management systems. The new systems meet the government requirements for providing secure ICT services to applicants. Planning for additional capability continues in anticipation of new legislation.

International harmonisation and capacity building: sharing our knowledge

OGTR staff continued to participate in international meetings, attending some conferences virtually and others face to face. One of our senior staff presented at the Asia-Pacific Economic Cooperation (APEC) Senior Officials Meeting in Seattle in August 2023. As part of the same event they also attended an APEC High Level Policy Dialogue on Agricultural Biotechnology, which brings together government and research attendees from APEC economies.

Another senior staff member participated in a Gene Drive Research Forum in California in March 2024, and informed attendees about the development of a national gene drive policy guide in Australia.

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



Our people: our most important resource

This year, 2 teams received the Regulator's Achievement Award, recognising their high degree of stakeholder engagement and innovation in the workplace.

The Low-Level Certifications team had received around 1,000 certification applications since January 2023, including certification variations. The team achieved significant time reductions in processing these applications through the development of new forms and associated guidance to reduce administrative burden for the OGTR and for applicants. This received a great deal of positive feedback from stakeholders.

The Plant Evaluation Section piloted a parallel licence assessment with FSANZ for the commercial cultivation of a GM banana resistant to Panama disease. This was the first time the OGTR had undertaken an assessment and approval process with another agency. The 'Banana Team' was involved in project planning with the applicant, QUT and FSANZ before the application was received. The aim of the exercise was to align the public consultation processes of the OGTR and FSANZ so that the public could understand the agencies' respective roles in the commercial approval. The public consultation process resulted in over 270 submissions being made to the OGTR alone.

We farewelled Dr Matthew O'Mullane, the Executive Director of the Evaluation Branch. Dr O'Mullane left the OGTR to take up a position at FSANZ.

Challenges ahead

Our continued legislative reform program will be the major challenge next year. This will involve work to develop regulations and rules for implementation of new amendments to the Act, as well as other preparations to transition the OGTR to a different operating framework. The commitment of staff and stakeholders will be paramount to make these changes work. I look forward to the months ahead.

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, and a description of the OGTR's organisational structure and 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 (the Regulations), 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 Gene Technology 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 both to human health and safety and to the environment, relating to dealings with genetically modified organisms (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 genetically modified (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 (APVMA) – which is responsible for regulating all agricultural and veterinary chemicals – must register the insecticide produced in the GM plant. The APVMA 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 3 principles of regulator best practice outlined in the Department of Finance's Resource Management Guide – Regulator Performance (RMG 128):[6]

1. Continuous improvement and building trust. We adopt a whole-of-system perspective, continuously improving our performance, capability and culture to build trust and confidence in our regulatory system.

2. Risk-based and data-driven. We manage risks proportionately and maintain essential safeguards while minimising regulatory burden, and leveraging data and digital technology to support those we regulate to comply and grow.

3. Collaboration and engagement. We are transparent and responsive communicators, implementing regulations in a modern and collaborative way.

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

The department's corporate plan[7] sets out how its regulators intend to apply these principles. It then reports on the performance of its regulators in its annual report.[8] 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 minister's Statement of Expectations for regulatory functions applicable to RMG 128. Our Regulator's Statement of Intent outlines how we will achieve our regulatory objectives and carry out our regulatory functions.[9]

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 of trust in the regulatory scheme. It also outlines activities undertaken to engage and collaborate with our stakeholders.

6 www.finance.gov.au/government/managing-commonwealth-resources/regulator-performance-rmg-128

7 www.health.gov.au/about-us/corporate-reporting/corporate-plan

8 www.health.gov.au/about-us/corporate-reporting/annual-reports

9 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). The OGTR is administered as a separate division of the Department of Health and Aged Care and funded by the Gene Technology Special Account.

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 Act) 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. The OGTR complies with the Commonwealth Fraud and Corruption Control Framework 2024 as the department requires. More information will be available in the 2023–24 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.

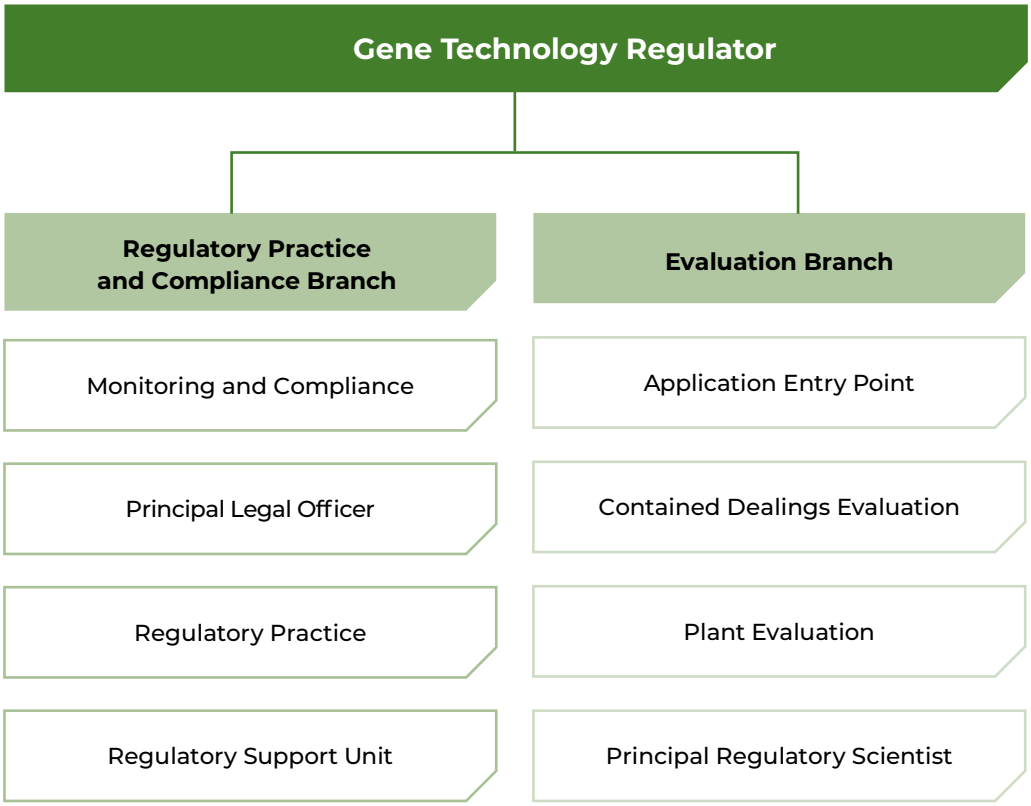
The employment framework for the OGTR is the *Public Service Act 1999*. The department's enterprise agreement, governance policies and practices cover OGTR staff. These include application of appropriate ethical standards under the Australian Public Service (APS) Values and Code of Conduct; compliance 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 a Regulatory Practice and Compliance Branch and an Evaluation Branch. Sections in these branches focus on particular activities relating to regulation of gene technology (Figure 1).

Figure 1: Organisational structure, 2023–24



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 GMOs.

Dr Raj Bhula commenced in the role of Gene Technology Regulator in July 2016 and was reappointed for another 5 years in June 2021. Dr Bhula is an experienced regulator, with over 8 years at the Office of the Gene Technology Regulator in the Department of Health and Aged Care.

In her executive career, Dr Bhula had 10 years of experience in the regulation of pesticides in Australia.

Dr Bhula joined the APS after completing a PhD in Chemistry and over 6 years of postdoctoral research into bioinorganic chemistry and drug design in the UK, New Zealand and Australia. She is a graduate of the Australian Institute of Company Directors.

Regulatory Practice and Compliance Branch

Mr Neil Ellis has been the Branch Head of Regulatory Practice and Compliance 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 Monitoring and Compliance Section, Principal Legal Officer, Regulatory Practice Section and Regulatory Support Unit.

The Monitoring and Compliance Section monitors and inspects dealings with GMOs conducted at field trial sites, in 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 (including self-reported incidents and allegations made by third parties) to ensure compliance with the Act.

The OGTR's Principal Legal Officer advises the Regulator and the OGTR on how Commonwealth, state and territory laws affect their functions, including setting licence conditions and handling CCI. The Principal 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.[10]

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 enquiries (to ogtr@health.gov.au) and managing the OGTR website.

Evaluation Branch

Dr Kylie Tattersall has been the acting Executive Director of the Evaluation Branch since April 2024. Her responsibilities encompass overseeing the evaluation of licence applications and other authorisations relating to dealings with GMOs, as well as science-related projects that maintain and improve the technical capabilities of the OGTR.

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

The Application Entry Point receives and acknowledges all applications to the OGTR. Staff in this area process accreditation applications, manage information management systems, provide trend and statistical analyses of application receipts and authorisations, and report on workflows. They also manage business processes, 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

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

(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 licence applications for DIRs for GM plants and prepares RARMPs for consultation with key stakeholders, including the public. The section also assesses some licence applications for GM therapeutics. It 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 2 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 the 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 technical and procedural guidelines in relation to GMOs and GM products.

The current members of the committee, including the Chair, Professor John Rasko AO, were appointed by Assistant Minister Kearney.

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 committee met 6 times during 2023–24. 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 technical and procedural guidelines relating to GMOs and GM products.

There is no statutory requirement for the Regulator to seek advice from the GTECCC on licence applications.

The current members of the committee, including the Chair, Associate Professor Judith Jones, were appointed by Assistant Minister Kearney.

The GTECCC met twice during 2023–24. Communiqués from previous committee meetings, which provide an overview of key matters discussed and resolutions, are published on the OGTR website.

Chapter 3

Functions of the Gene Technology Regulator

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 *Gene Technology Act 2000* (the Act), and against the performance indicators in Outcome 1 (Health Policy, Access and Support) of the 2023–24 Department of Health and Aged Care Portfolio Budget Statements. Appendix 2 describes the functions of the Regulator and the regulatory processes for authorising and monitoring dealings with genetically modified organisms (GMOs) as defined by the Act, the Gene Technology Regulations 2001 (the Regulations) and corresponding state and territory laws.

This section describes the achievements and performance of the Office of the Gene Technology Regulator (OGTR) against Outcome 1, Program 1.8 (Health Protection, Emergency Response and Regulation) of the 2023–24 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 provided in the second part of this chapter.

Summary of approvals in 2023–24

Categories of licences

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 that have been designed to contain the GMOs. The other licences issued are for activities – like planting and growing genetically modified (GM) crops, clinical trials of a new therapeutic or vaccine, or commercial sale of a GM therapeutic – that cannot be done in a laboratory. Instead, they take place in a range of settings. For example, they may be grown in a field, administered in a clinic or hospital, or manufactured in a factory and sold in a chemist or pharmacy. Because these 2 different types of work involve different contexts, the gene technology laws have 2 different types of licences to cover them.

Licences for research or other work in special facilities are called 'dealings not involving intentional release into the environment' (DNIR) licences. The work is contained within a building or other structure (such as 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) licences. These are for work where the GMOs are not contained within a facility. This category includes:

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

In 2023–24 the OGTR received 948 applications and 565 notifications, as defined under the Act (see 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 838 approvals over a range of application types. There were no appeals associated with decisions made on applications under the gene technology legislation. There are 2,155 certified facilities, 56 DIR licences where release of GMOs into the environment is authorised, 167 DNIR licences where GMOs must be contained (Table 2), and 3,087 active notifiable low risk dealings (NLRDs) as at 30 June 2024.

Table 1: Applications and notifications, 2023–24

Application type	Received	Withdrawn	Approved[a]	Refused	Ceased consideration[b]	Under consideration[c]
Accreditation	15		10			7
Alternate facility request for an NLRD						
CCI declaration for accreditation						
CCI declaration for DIR licence	5		8			1
CCI declaration for DNIR licence	17		14		1	12
DIR licence	7		6			4
DNIR licence	25		26			8
Facility certification	102	3	94		3	5
Lifting suspension of certification[d]	55	1	50		1	3
NLRD notification	565					
GMO Register						
Surrender of accreditation	7		7			
Surrender of certification	81	1	79		1	
Surrender of DIR licence	5		5			
Surrender of DNIR licence	8	1	5			2
Suspension of certification[d]	120	2	117			1
Transfer of certification	9		9			
Transfer of DIR licence						
Transfer of DNIR licence	2		2			

Application type	Received	Withdrawn	Approved[a]	Refused	Ceased consideration[b]	Under consideration[c]
Variation of accreditation	4		3			1
Variation of certification	452	11	379			61
Variation of DIR licence	6		6			
Variation of DNIR licence	27	1	17			8
Cancellation of accreditation	1		1			
Total	**1,513**	**20**	**838**	**0**	**6**	**113**

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 2023–24 were received in the previous year.
b. Includes both 'ceased consideration' and 'not considered' under section 43 of the Act.
c. Under consideration as at 30 June 2024.
d. Suspension and lifting of suspension of certifications include both those requested by the applicant and those initiated by the Regulator. Those reported in 2023–24 were all requested by the applicant.

Table 2: Status of primary applications and notifications from the start of the scheme until 30 June 2024

Application type	Received	Withdrawn	Approved	Not approved[a]	Under consideration[b]	Current	Expired	Surrendered
Certification	5,059	164	4,881	9	5	2,155	383	2,145
DIR	206	19	176	6	5	56	1	119
DNIR	702	119	553	2	8	167	177	209
NLRD	14,299	36	n/a	n/a	n/a	3,087	11,176	n/a
Total	**20,266**	**338**	**5,610**	**17**	**18**	**5,465**	**11,737**	**2,473**

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. 'Not approved' includes 'refused', 'ceased consideration' and 'not considered'.
b. Under consideration as at 30 June 2024.

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 6 DIR licences during 2023–24.

Details of the traits introduced into the modified organisms are provided in Table 3. Four licences issued in 2023–24 were for research (limited and controlled releases):

- DIR-197 Clinical trial of genetically modified *Lactobacillus brevis* for treatment of inflammatory bowel disease
- DIR-200 Fermentation and processing of recombinant proteins using genetically modified *Pichia pastoris*
- DIR-201 Limited and controlled release of wheat and barley genetically modified for yield enhancement
- DIR-203 Limited and controlled release of cotton genetically modified for herbicide tolerance and insect resistance.

Two licences issued in 2023–24 were for commercial/general use:

- DIR-196 Commercial supply of Qdenga, a live attenuated GM dengue vaccine
- DIR-199 Commercial release of banana genetically modified for resistance to fusarium wilt tropical race 4 (TR4).

Of the 6 DIR licences issued in 2023–24, 4 were issued to companies and 2 were issued to universities. All of the licence decisions were made within statutory timeframes (see 'Timeframes' in Appendix 2).

Cotton field trial site

Table 3: DIR licences issued 2023–24

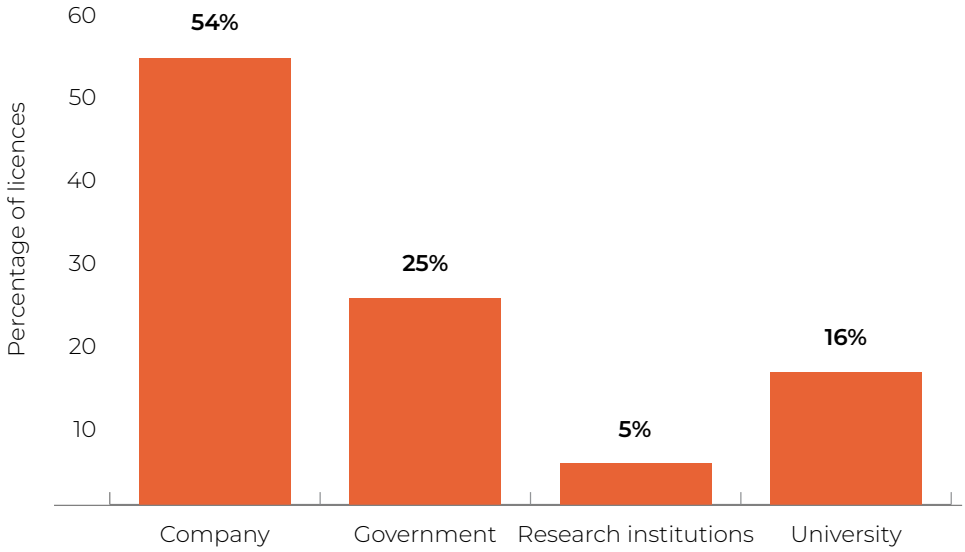
OGTR ID	Applicant	Parent organism	Introduced trait	Type of release	Received	Issued
DIR-196	Takeda Pharmaceuticals Australia Pty Ltd	*Dengue vaccine*	Vaccine – altered antigen expression	Commercial release	15-Feb-23	23-Nov-23
DIR-197	Novotech (Australia) Pty Ltd	*Lactobacillus brevis*	Treatment – for inflammatory bowel disease	Limited and controlled release	16-Feb-23	21-Sep-23
DIR-199	Queensland University of Technology	Banana	Disease resistance	Commercial release	6-Apr-23	12-Feb-24
DIR-200	Cauldron Molecules Pty Ltd	*Pichia pastoris*	Insertion of bovine and chicken egg protein and silk fibre	Limited and controlled release	28-Jul-23	7-Feb-24
DIR-201	The University of Adelaide	Barley and wheat	Yield	Limited and controlled release	13-Sep-23	15-Apr-24
DIR-203	Monsanto Australia Pty Ltd	Cotton	Herbicide tolerance(s) and insect resistance(s)	Limited and controlled release	16-Oct-23	13-May-24

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 176 DIR licences issued to date:

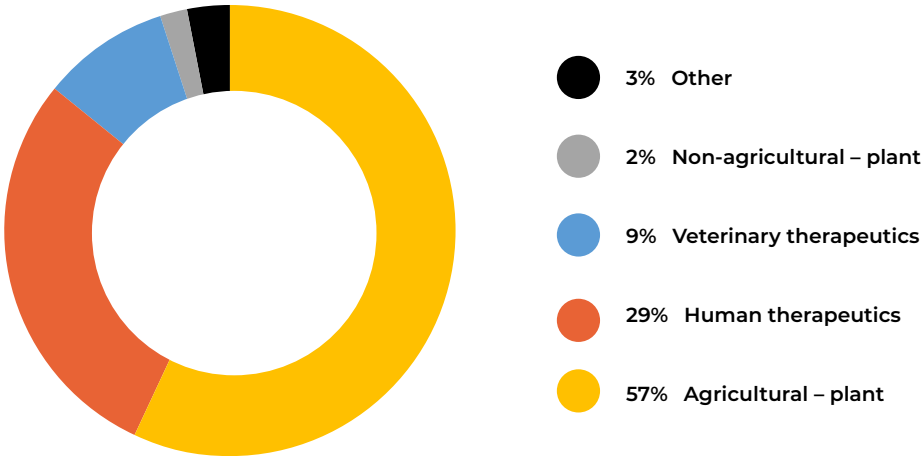
- 94 (54%) have been to companies
- 44 (25%) have been to government agencies
- 9 (5%) have been to research institutes
- 29 (16%) have been to universities.

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



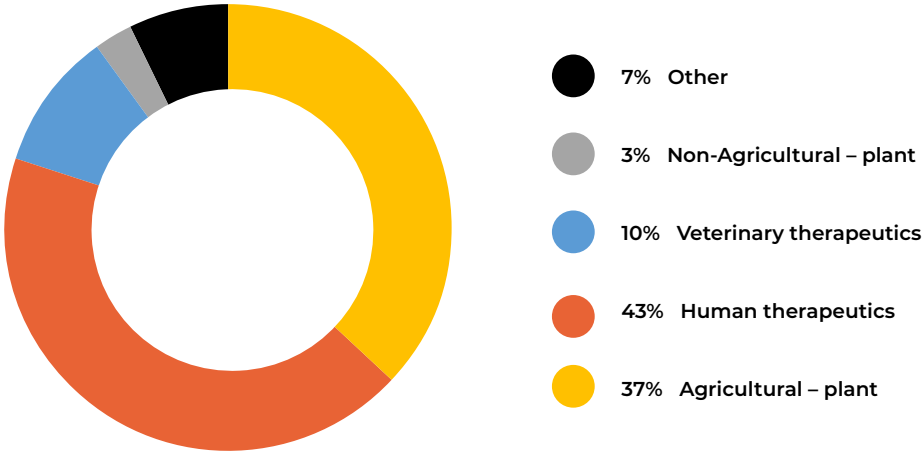
As at 30 June 2024, 56 of the 176 DIR licences issued since the beginning of the scheme were current. This consists of 32 (57%) agricultural – plant, 16 (29%) human therapeutics, one (2%) non-agricultural – plant, 5 (9%) veterinary therapeutics, and 2 (3%) other licences (Figure 3).

Figure 3: Distribution of DIR licences current as at 30 June 2024, by purpose



Although most current DIR licences are for agricultural crops, over the past 5 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 shown in Figure 5, 38 (68%) are issued to companies, one (2%) to a government organisation, 8 (14%) to research institutes and 9 (16%) to universities. One (2%) DIR licence is held by an organisation in the Australian Capital Territory (ACT), one (2%) in Tasmania (Tas), 17 (30%) in New South Wales (NSW), 5 (9%) in Queensland (Qld), 4 (7%) in South Australia (SA) and 28 (50%) in Victoria (Vic) (Figure 6).

Figure 5: Distribution of DIR licences current as at 30 June 2024, by organisation type

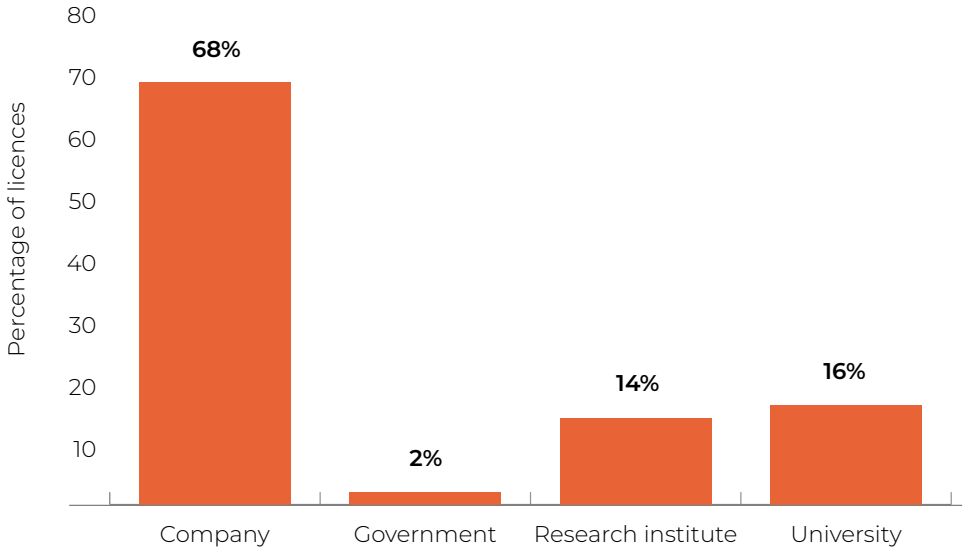
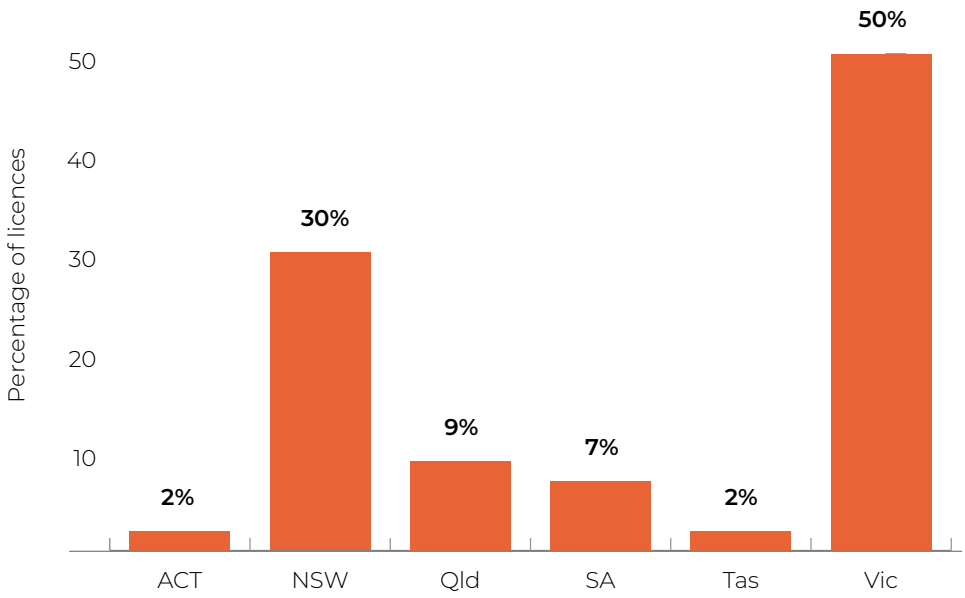


Figure 6: Distribution of DIR licences current as at 30 June 2024, by state or territory



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 2023–24 the Regulator issued 26 DNIR licences (see Table 4) for work in laboratories, to manufacture therapeutic GMOs, and for clinical trials of GMO therapeutics. All decisions were made within the statutory timeframe (see 'Timeframes' in Appendix 2).

Table 4: DNIR licences issued, 2023–24

DNIR No.	Applicant	Title	Received	Issued
DNIR-666	Beyond Drug Development Pty Ltd	Clinical evaluation of VOY-101 in patients with advanced non-neovascular age-related macular degeneration	14-Mar-23	03-Jul-23
DNIR-667	The Children's Hospital Westmead	Clinical trials involving adeno-associated virus (AAV) gene therapy	11-Apr-23	10-Aug-23
DNIR-668	Parexel International Pty Ltd	A Phase 3, multinational, randomised, double-blind, placebo-controlled systemic gene transfer therapy study to evaluate the safety and efficacy of SRP9001 in non-ambulatory and ambulatory subjects with Duchenne muscular dystrophy (ENVISION)	17-Apr-23	22-Aug-23
DNIR-669	Janssen-Cilag Pty Ltd	Clinical trial of genetically modified adeno-associated virus for treatment of geographic atrophy secondary to age-related macular degeneration	21-Apr-23	07-Aug-23
DNIR-670	QIMR Berghofer Medical Research Institute	Gene drive *Anopheles farauti*	02-May-23	25-Aug-23
DNIR-671	Novotech (Australia) Pty Ltd	Clinical trial with a genetically modified *Salmonella typhimurium* in patients with advanced solid tumours	27-Apr-23	01-Sep-23

DNIR No.	Applicant	Title	Received	Issued
DNIR-672	IQVIA RDS Pty Ltd	Clinical trial with anti-CD19 CAR-T cell therapy in patients with relapsed/refractory B cell non-Hodgkin lymphoma	11-May-23	11-Sep-23
DNIR-673	CSIRO	Molecular determinants of Newcastle disease virus pathogenicity	18-May-23	25-Sep-23
DNIR-677	Monash University	Use of transgenic mice expressing diphtheria toxin A to study roles of various cellular processes	26-Jun-23	31-Oct-23
DNIR-678	Novotech (Australia) Pty Ltd	Clinical trial of a genetically modified alphavirus replicon-based vaccine for the prevention of influenza	11-Jul-23	18-Oct-23
DNIR-679	Advanced Clinical Pty Ltd	Clinical trial with a genetically modified alphavirus for the treatment of patients with advanced solid tumours	21-Aug-23	30-Nov-23
DNIR-680	The University of Melbourne	Vaccinia vectored vaccines against SARS-CoV-2 and influenza A virus	21-Aug-23	12-Dec-23
DNIR-681	The University of Adelaide	Testing of mammalian cell lines for replication competent virus associated with prior genetic modification	13-Sep-23	16-Jan-24
DNIR-682	Beyond Drug Development Pty Ltd	Clinical evaluation of RZ-004 in patients with retinitis pigmentosa	29-Sep-23	10-Jan-24
DNIR-683	Novotech (Australia) Pty Ltd	Clinical trial of genetically modified alphavirus replicon-based vaccine for the prevention of COVID-19	05-Oct-23	12-Jan-24
DNIR-684	Beyond Drug Development Pty Ltd	A clinical trial to evaluate the safety, tolerability and efficacy of an AAV9 gene therapy in female children with Rett syndrome	05-Oct-23	15-Jan-24

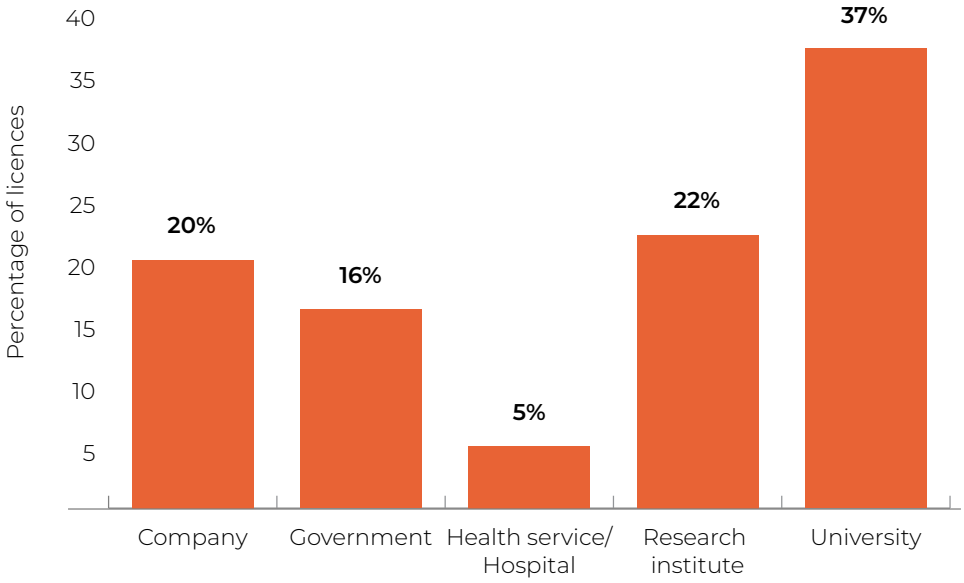
DNIR No.	Applicant	Title	Received	Issued
DNIR-685	Bioproperties Pty Ltd	Formulation and filling of a genetically modified infectious laryngotracheitis virus for the vaccination of chickens	26-Oct-23	13-Feb-24
DNIR-686	The University of Melbourne	In vitro and in vivo studies with feline alphaherpesvirus-1 derived immunocontraceptives	01-Nov-23	30-Apr-24
DNIR-687	BioCina Pty Ltd	Expression and purification of an epsilon toxin (ETX) vaccine candidate	28-Nov-23	07-Mar-24
DNIR-688	Premier Research (Australia) Pty Ltd	Clinical trial of a treatment for refractory/relapsing B-cell malignancies	05-Dec-23	17-Apr-24
DNIR-689	The University of Sydney	An intracellular VenomORF library expression platform	05-Dec-23	12-Apr-24
DNIR-690	PPD Australia Pty Ltd	Clinical trial of a genetically modified adeno-associated virus in patients with peripheral manifestations of Gaucher disease	20-Dec-23	19-Mar-24
DNIR-691	The University of Melbourne	Demonstration of split gene drives in zebrafish	20-Feb-24	11-Jun-24
DNIR-692	Syneos Health Australia Pty Ltd	A clinical trial to evaluate the safety and efficacy of SPK-8011 in adults with severe or moderately severe haemophilia A	28-Feb-24	25-Jun-24
DNIR-693	CSL Innovation Pty Ltd	Clinical trial of etranacogene dezaparvovec in patients with haemophilia B	29-Feb-24	03-May-24
DNIR-694	BioCina Pty Ltd	Manufacturing unencapsulated *Streptococcus pneumoniae* as a whole cell vaccine	07-Mar-24	22-May-24

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

In 2023–24, 15 licences were issued for clinical trials of human therapeutics (58% of DNIR licences issued). Another 2 (8%) of DNIR licences were for laboratory research for medical purposes, and 7 (27%) were for non-medical laboratory research. The final 7% comprised 2 licences for commercial production of GMOs.

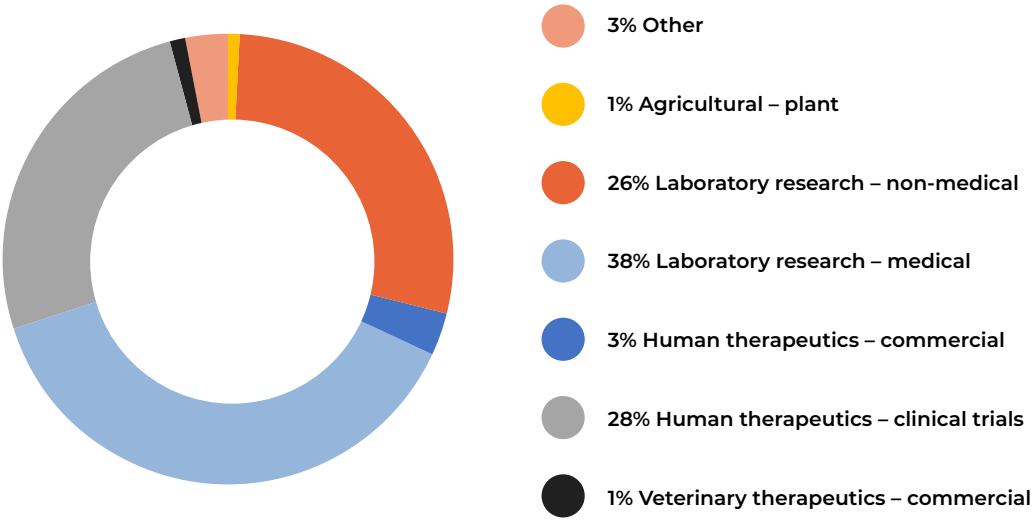
The types of organisations to which DNIR licences have been issued since commencement of the scheme are shown in Figure 7. Of the 553 DNIR licences issued to date, 113 (20%) have been issued to companies, 87 (16%) to government agencies, 28 (5%) to health services/hospitals, 119 (22%) to research institutes and 206 (37%) to universities.

Figure 7: Organisations issued with DNIR licences since commencement of the Gene Technology Act 2000



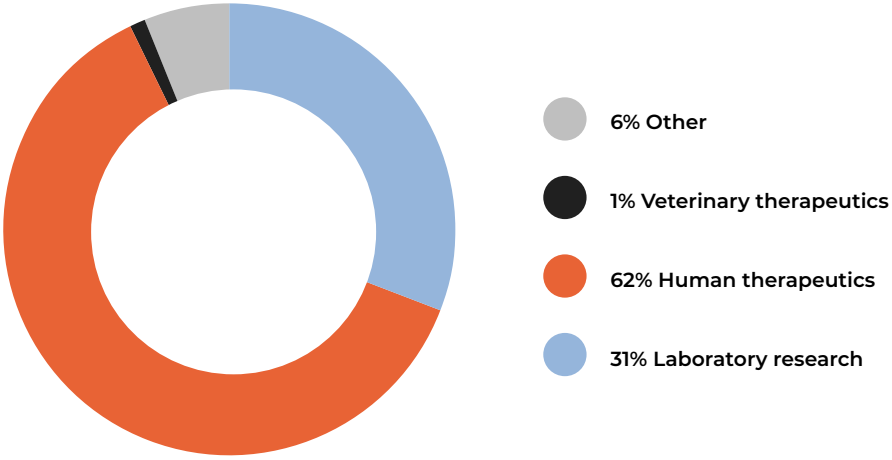
At 30 June 2024, 167 DNIR licences are current. The majority of these are for lab research – 38% for medical research and a further 26% for non-medical lab research. Clinical trials with GMO therapeutics comprised 28%, commercial therapeutics 3%, veterinary therapeutics 1% and agricultural plant licences 1% (Figure 8).

Figure 8: Distribution of DNIRs current as at 30 June 2024, by purpose



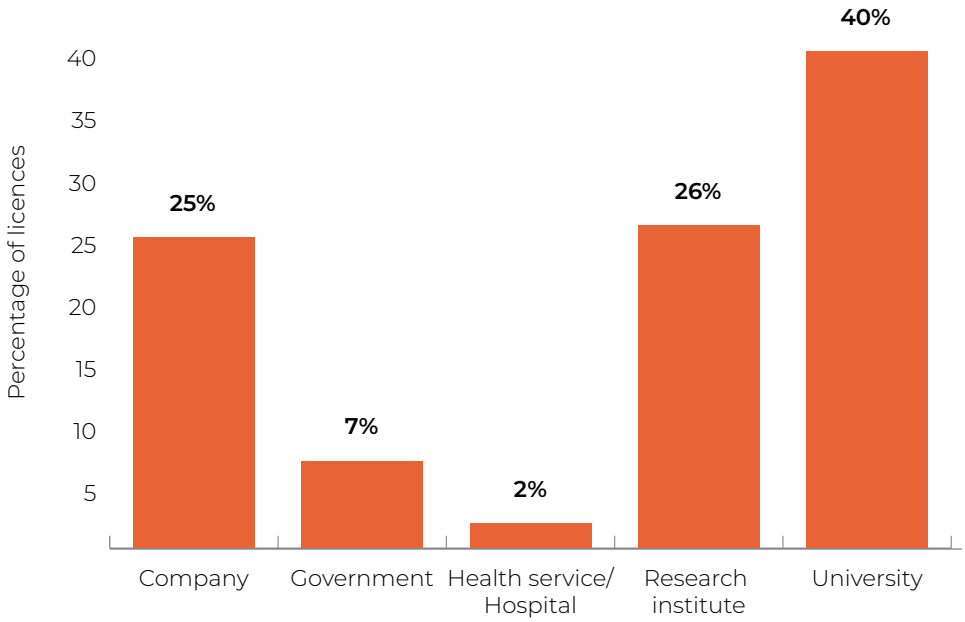
In the past 5 years, the focus of DNIRs has been human therapeutics and laboratory research, predominantly with a medical focus (93%). There has been an increase in licences issued for human therapeutics over the last 5 years (Figure 9), compared with those issued from the start of the scheme and still current.

Figure 9: Distribution of DNIR licences issued over the last 5 years, by purpose



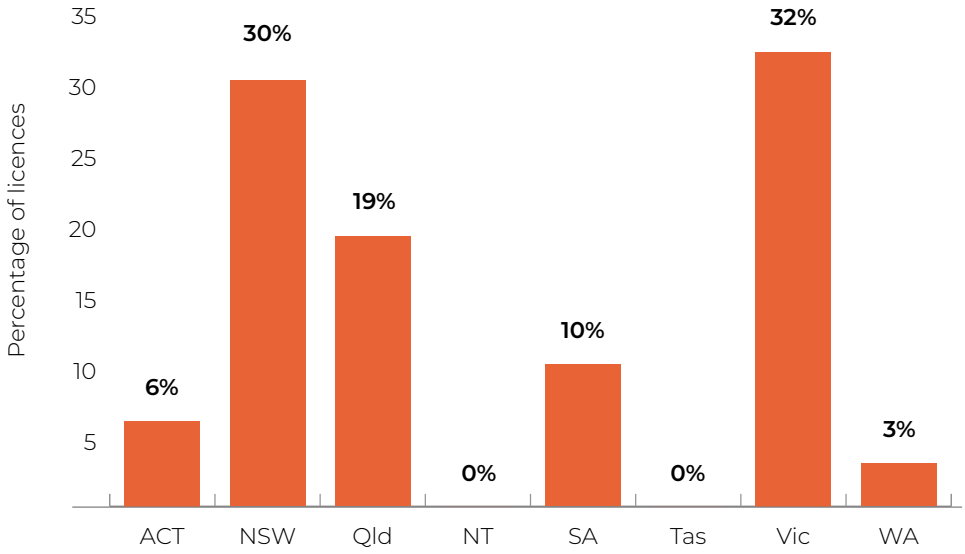
Of the current DNIR licences, 67 (40%) are held by universities, 44 (26%) by research institutes, 41 (25%) by companies, 12 (7%) by government agencies and 3 (2%) by health services/hospitals (Figure 10).

Figure 10: Distribution of DNIR licences current as at 30 June 2024, by organisation type



The current DNIR licences are held by organisations in 6 states and territories. Most of them are held in Vic (53 DNIRs, 32%) and NSW (51 DNIRs, 30%). Of the rest, 31 (19%) are held in Qld, 17 (10%) in SA, 7 (6%) in the ACT and 5 (3%) in WA. There are no DNIRs currently held in the NT and Tas (Figure 11).

Figure 11: Distribution of DNIR licences current as at 30 June 2024, by states and territories



Notifiable low risk dealings

NLRDs are GMO dealings that have been assessed, based on previous experience and current scientific knowledge, as posing a low risk, provided certain criteria and risk management conditions are met. The criteria are published in Schedule 3, Parts 1 and 2 of the Regulations. NLRDs can be conducted for a maximum of 5 years, after which they expire and a new NLRD must be assessed by an institutional biosafety committee (IBC) in order for the dealings to continue. NLRDs must be reported by 30 September in the financial year following the financial year in which they were assessed.

During 2023–24, 565 NLRD notifications were received. As in past years, these were predominantly for research work. Figure 12 shows a decrease in the number of NLRDs received in 2023–24 compared to the past 4 years. Many NLRDs were reported earlier than usual during 2022–23 using a familiar reporting form, as the OGTR released a new online services portal and NLRD reporting form at the start of 2023–24.

Figure 12: Number of NLRDs notified to the OGTR over the last 5 years

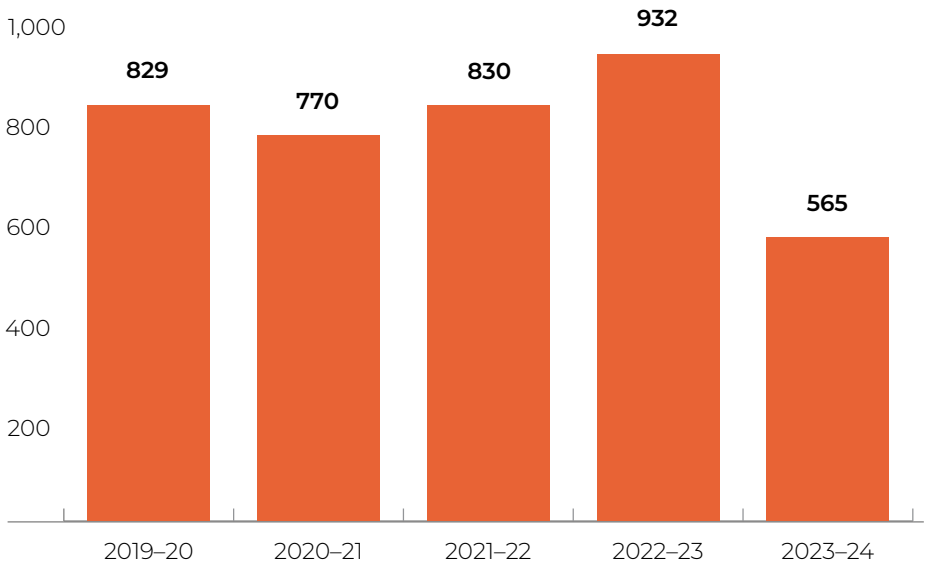


Figure 13 shows the proportion of NLRDs reported by different types of organisations over the last 5 years. Aside from a gradual increase in the number of NLRDs reported by companies, the distribution has not notably changed over the past 5 years.

Figure 13: Proportion of NLRDs reported by different types of organisations over the last 5 years

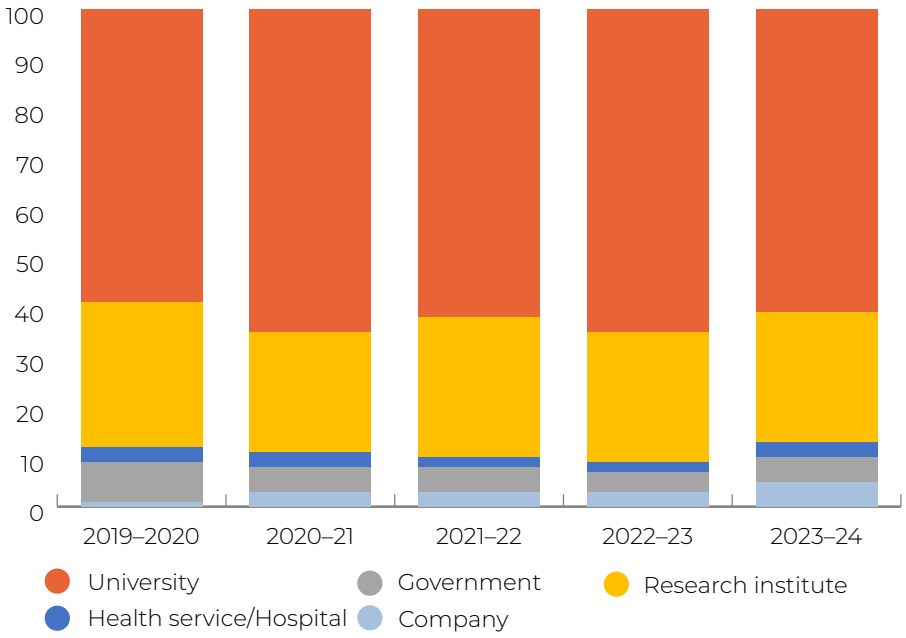
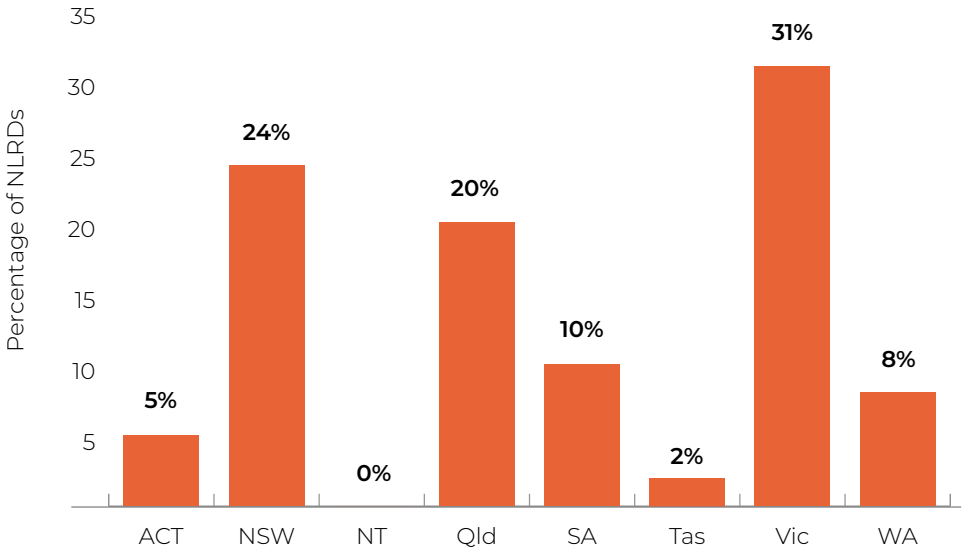


Figure 14 shows the proportion by state or territory of NLRDs notified by an organisation that were current at 30 June 2024.

Figure 14: Distribution of all current NLRDs at 30 June 2024, by state or territory



The Regulations require NLRDs to be conducted in facilities certified by the Regulator that are of an appropriate type and containment level relevant to the dealing, or alternative facilities agreed by the Regulator (Regulation 13(2)). Transport, storage and disposal of GMOs in the course of NLRDs may happen outside approved facilities if conducted according to the Regulator's Guidelines for Transport, Storage and Disposal of GMOs, or alternative requirements agreed by the Regulator (Regulation 13(3)).

During 2023–24 the Regulator received no requests for an alternative facility. Since the relevant provisions in Regulation 13 were introduced in September 2011 the Regulator has approved 11 alternate facility requests and 12 alternate transport, storage and disposal requests.

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 they 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 2023–24 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 2023–24 the Regulator issued no inadvertent dealings licences.

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 2023–24, 10 accreditations were issued. A total of 207 organisations held accreditation at 30 June 2024.

Accredited organisations are located in all Australian states and territories (Figure 15). The types of organisations accredited by the Regulator have not changed substantially over time: the majority (55%) are primarily publicly funded, such as government entities, hospital/health services, universities and most research institutes (Figure 16).

Figure 15: Organisations accredited as at 30 June 2024, by location of headquarters

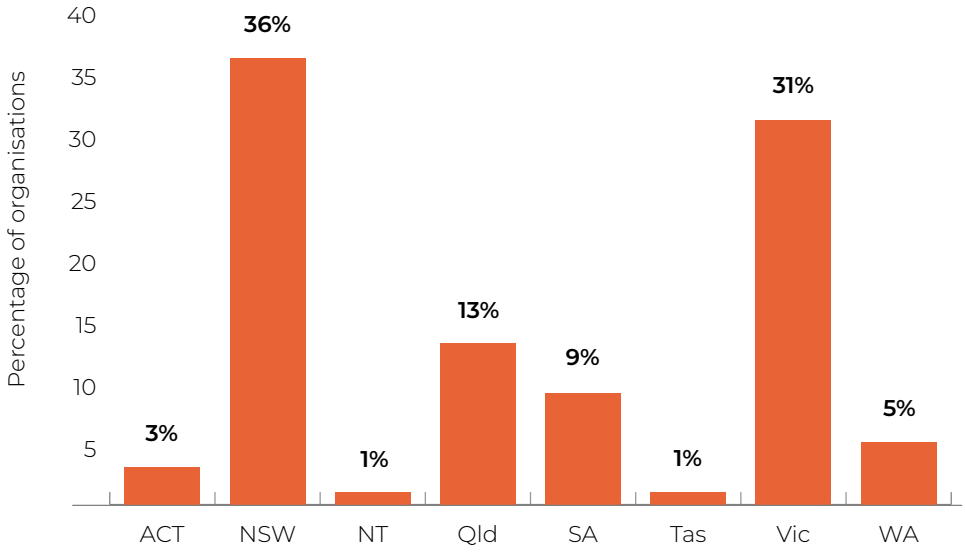
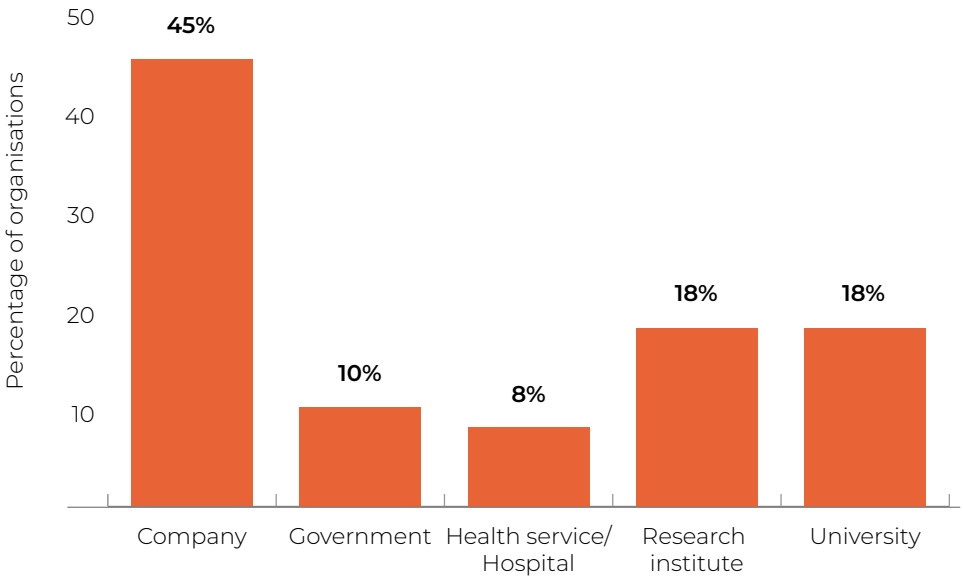


Figure 16: Types of organisations accredited as at 30 June 2024



Certification of physical containment facilities

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

Physical containment facilities are classified according to how stringent the measures are for containing GMOs, and the types 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 facilities as represented in Table 5, Figure 18 by organisation type and Figure 19 by location. The guidelines are informed by the Australian standard AS/NZS 2243.4:2010 and by international best practice for biosafety containment.

In 2023–24, 94 new certifications for physical containment facilities were issued. The majority (67%) were to universities, 18% were to companies, 9% were to research institutes and the remainder were to government and hospitals (Figure 17).

Table 5: Number of OGTR-certified facilities at 30 June 2024

Facility type	PC1	PC2	PC3	PC4	Grand total
Animal facility		247	6		253
Aquatic facility		31			31
Constant temperature room		38			38
Facility	297		3	4	304
Invertebrate facility		48	2		50
Laboratory		1,281	18		1,299
Large grazing animal facility		59			59
Large scale facility		17			17
Plant facility		104			104
Total	**297**	**1,825**	**29**	**4**	**2,155**

High-level facilities (PC4, PC3 and PC2 large scale) are generally only certified for 3 years and require inspection by OGTR staff before recertification. During 2023–24, OGTR staff performed recertification inspections of 17 facilities (5 PC2 large-scale facilities, 9 PC3 laboratories, 2 PC3 animal facilities and one PC4 facility) and recertified 9 facilities. Some of the certification processes for these facilities are still in progress.

In addition, 4 new PC2 large-scale facilities had been inspected for certification in 2022–23 and were certified in 2023–24.

Figure 17: Facilities certified in 2023–24, by organisation type

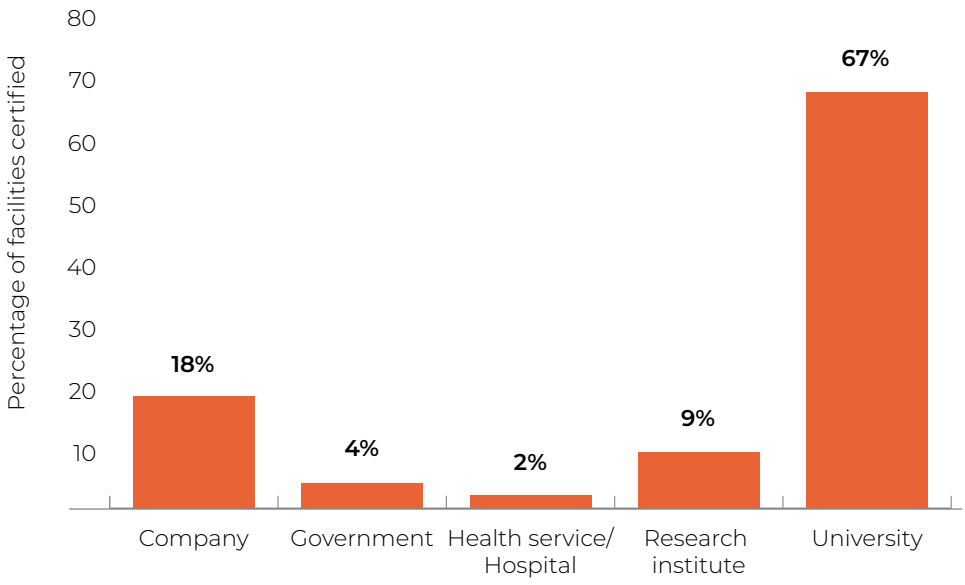


Figure 18: OGTR-certified facilities as at 30 June 2024, by organisation type

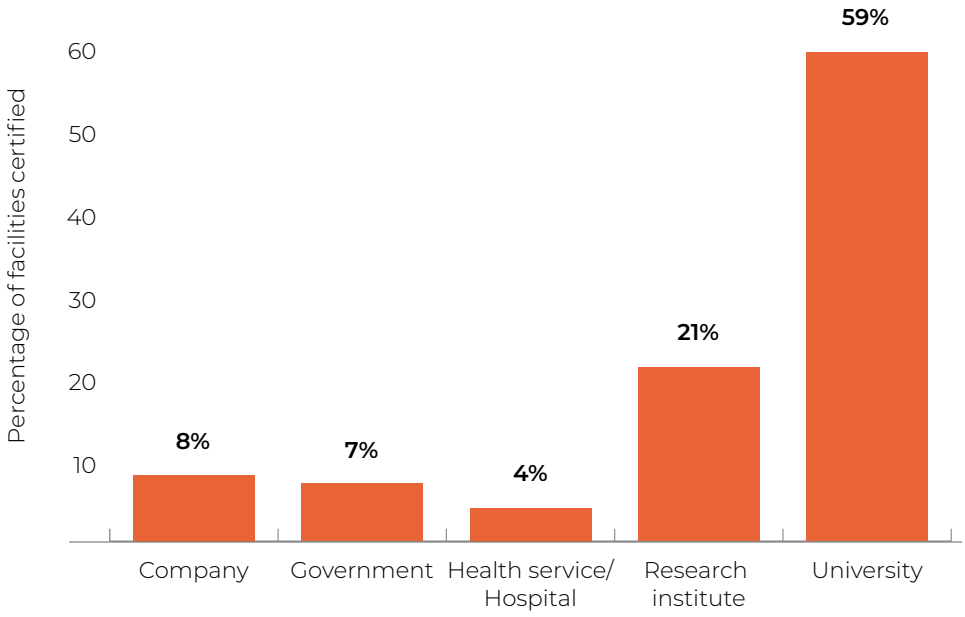
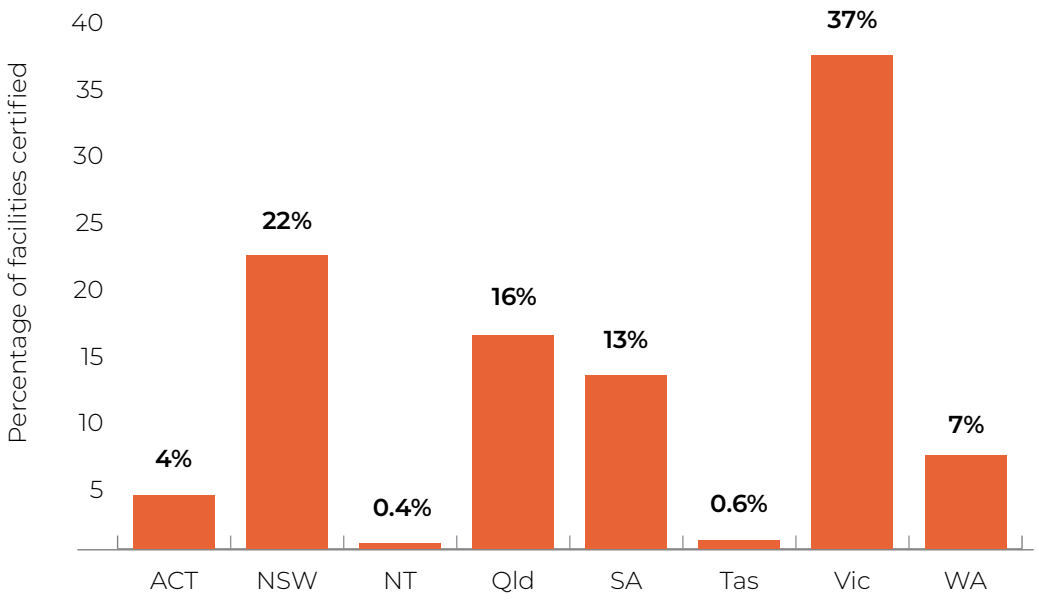


Figure 19: OGTR-certified facilities as at 30 June 2024, by location



Application trends

The numbers of most types of primary authorisations issued during 2023–24 were largely similar to those in previous years (Table 6). The number of DIR licences issued has remained reasonably consistent for the past 5 years, whereas the number of DNIR licences issued was unusually high this year, with twice the number of approvals as in the previous 2 years. The number of new accreditations issued to organisations has returned to typical levels, following a peak in 2021–22. In 2023–24 there was a decrease in the number of new facilities certified, after a peak in 2022–23. In this period 33% of the new facilities certified belonged to companies; this is high compared with the historical data, in which 9% of certified facilities are owned by companies.

Table 6: Approval of main types of applications

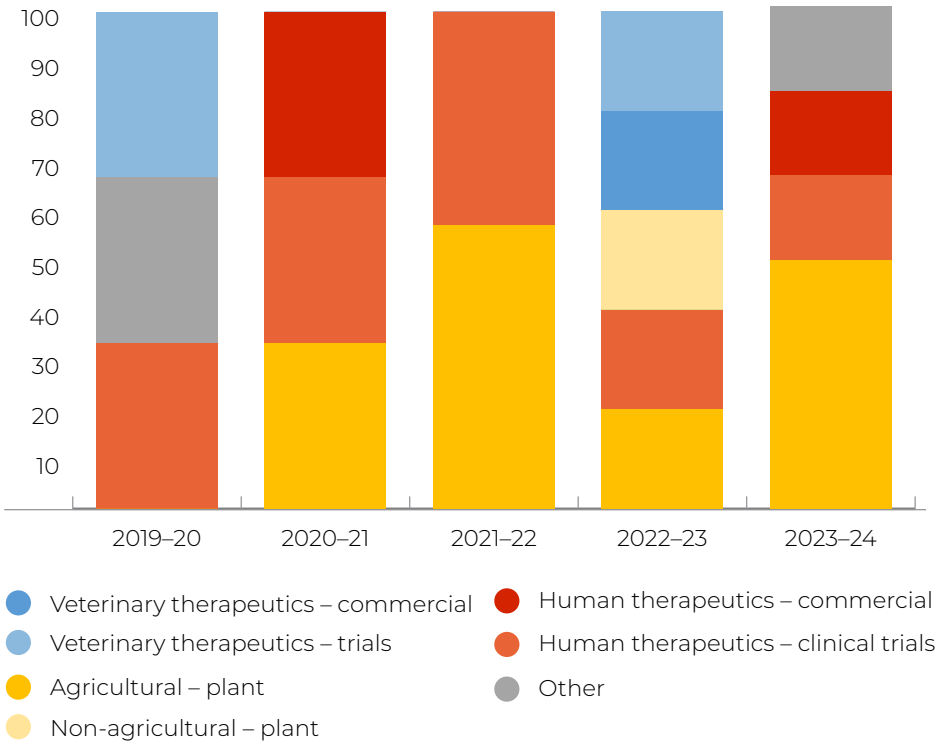
Application type	2019–20	2020–21	2021–22	2022–23	2023–24
Accreditation	10	10	18	13	10
Certification	100	101	97	132	94
DIR	3	9	7	5	6
DNIR	20	19	13	12	26

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

One licence was issued for a commercial GMO human therapeutic in 2023–24: DIR-196 for a dengue vaccine. 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 4 licences in 2020–21. Over the past 22 years there have been 12 licences issued for commercial GMO human therapeutics, of which 7 were issued in the past 5 years. There were also 16 clinical trials with GMOs issued in 2023–24, continuing the trend of increased interest in this area.

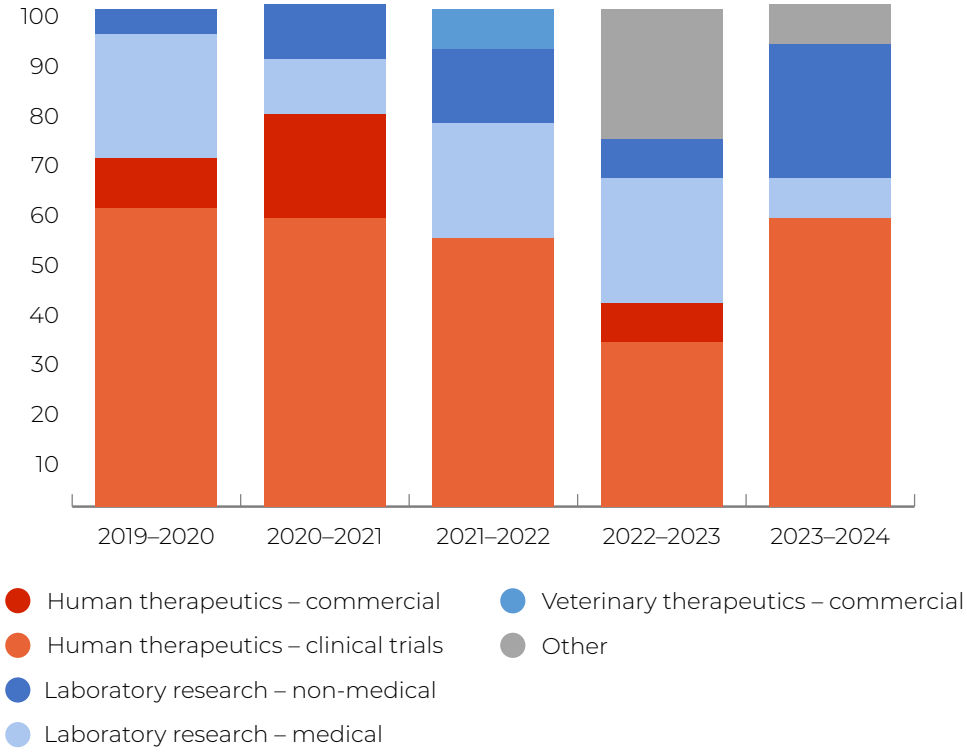
One licence was issued for a commercial GM crop in 2023–24: DIR-199 for disease-resistant banana. Over the past 5 years, 5 licences have been issued for commercial cultivation of GM crops in Australia. The commercial GM crops approved in this period were banana, cotton, canola (2 licences) and Indian mustard (Figure 20).

Figure 20: Focus of DIR licences, 2019–20 to 2023–24



The number of DNIR applications in 2023–24 (26) was higher than the 10-year average of 15.2 DNIR applications a year – a continuing trend. The scope of DNIR licence applications received has also changed, with a higher proportion of DNIR licences to conduct clinical trials with GMOs than to conduct contained laboratory work. The fields of research authorised under DNIR licences over the past 5 years are further analysed in Figure 21. In 2023–24 the largest proportion of applications (50% to 60%) were for clinical trials with therapeutic GMOs, as also seen in 2019–2022.

Figure 21: Fields of research authorised under DNIR licences, 2019–20 to 2023–24



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 2023–24 the Regulator made 22 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 101 surrender requests in 2023–24 and approved 79 for surrender of certification of a physical containment facility, 5 for surrender of DIR licences, 5 for surrender of DNIR licences and 7 for surrender of accreditations. In addition, at 30 June 2024, 2 requests were still under consideration and 3 requests were withdrawn or had ceased 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 405 variation requests in 2023–24. Of these, 3 were for accreditations, 6 were for DIRs, 17 were for DNIRs and 379 were for certifications.

Cancellation

The Regulator cancelled one accreditation during 2023–24.

Monitoring dealings with genetically modified organisms

This section provides information on the OGTR's compliance inspection activities during 2023–24.

During 2023–24 the OGTR conducted:

- 5 monitoring inspections of DIR licences
- 12 monitoring inspections of DNIR licences
- 155 monitoring inspections of certified facilities
- 4 practice reviews.

Compliance inspections of DIR plant field trial 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.[11]

During 2023–24 there were 62 DIR licences in force, held by 29 accredited organisations. These comprised:

- 30 limited and controlled release licences for research purposes (13 for plant field trials)
- 32 commercial release licences (22 for plant crops).

The OGTR inspected 3 of the 13 limited and controlled plant field trial licences (which may have comprised multiple site visits per licence).

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

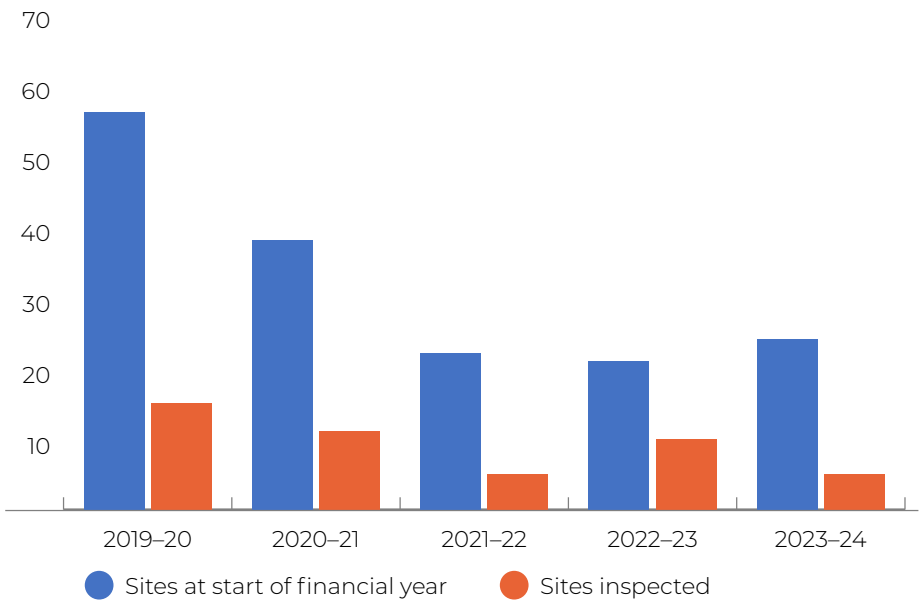
Outcome of compliance inspection activities

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
- effects of 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 2023–24, 24 licensed field trial sites were operating, of which 12 were current and 12 were subject to post-harvest monitoring conditions (Figure 22).

Figure 22: Number of field trial sites and number inspected each year, 2019–20 to 2023–24



The OGTR inspected 3 plant species across 5 field trial sites, all in NSW, during 2023–24 (Table 7).

Table 7: Number of licensed GM plant DIR trial sites at beginning and end of 2023–24, and number inspected in 2023–24, by plant type

Species	Trial sites as at 1 July 2023	Trial sites as at 30 June 2024	Trial sites inspected during 2023–24
Banana	2	2	0
Canola	11	13	3
Cotton	2	4	1
Sorghum	1	1	0
Wheat	7	10	1
White clover	1	1	0
Total	24	31	5

Compliance inspections of clinical trials and contained dealings

The 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 and PC3 facilities and PC2 large-scale facilities 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 facility's physical structure, inspections cover the general work practices used in handling GMOs.

During 2023–24, 155 certified facilities were inspected for compliance across the range of facility types (Table 8); this includes 6 high-level containment facilities.

In addition, 18 licences for clinical trials or contained dealings were subject to monitoring inspections or practice reviews in 2023–24 (Table 9). Of these, 17 were physical inspections and one was a desktop inspection.

Table 8: Number of compliance inspections of certified facilities (by type) conducted during 2023–24

Containment type	PC level and facility type	Inspections
Lower level	PC1 facility	2
	PC2 animal	16
	PC2 aquatic	2
	PC2 invertebrate	9
	PC2 laboratory	104
	PC2 plant	16
Higher level	PC2 large scale	3
	PC3 facility	1
	PC3 laboratory	2
Total		155

In addition to the inspections listed above, 4 facilities were subject to a joint inspection with the Contained Dealings Evaluation Section.

Table 9: Compliance inspections and practice reviews of contained licences and clinical trials conducted during 2023–24

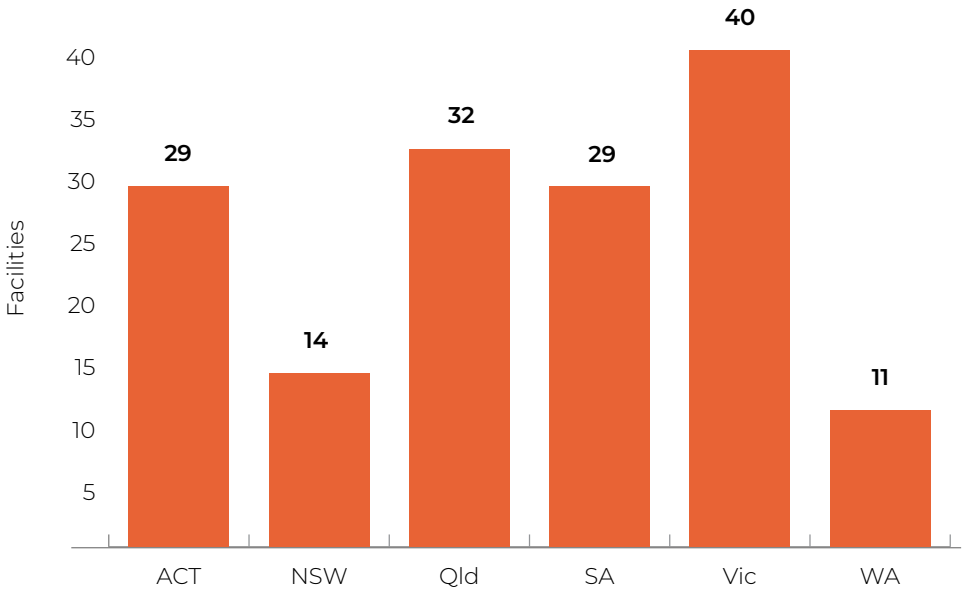
Organisation	State	Licence
Australian Veterinary Serum Laboratories	NSW	DNIR-662 (PR)
Avance Clinical Pty Ltd	Qld	DIR-184
Beyond Drug Development Pty Ltd	Vic	DNIR-666
BioCina Pty Ltd	SA	DNIR-694
BioMarin Pharmaceutical Australia Pty Ltd	WA	DNIR-600
CSIRO	Vic	DNIR-584
Curtin University	WA	DNIR-563
James Cook University	Qld	DNIR-576
Janssen-Cilag Pty Ltd	Multiple	DNIR-669 (PR)
Novotech (Australia) Pty Ltd	Vic	DIR-140
Novotech (Australia) Pty Ltd	Vic	DIR-197 (PR)
Novotech (Australia) Pty Ltd	Qld	DNIR-678
Pfizer Australia Pty Ltd	Vic	DNIR-569
QIMR Berghofer Medical Research Institute	Qld	DNIR-670 (PR)
RMIT University	Vic	DNIR-560
The University of Melbourne	Vic	DNIR-525
The University of Sydney	NSW	DNIR-689
University of South Australia	SA	DNIR-529
Total		**18**

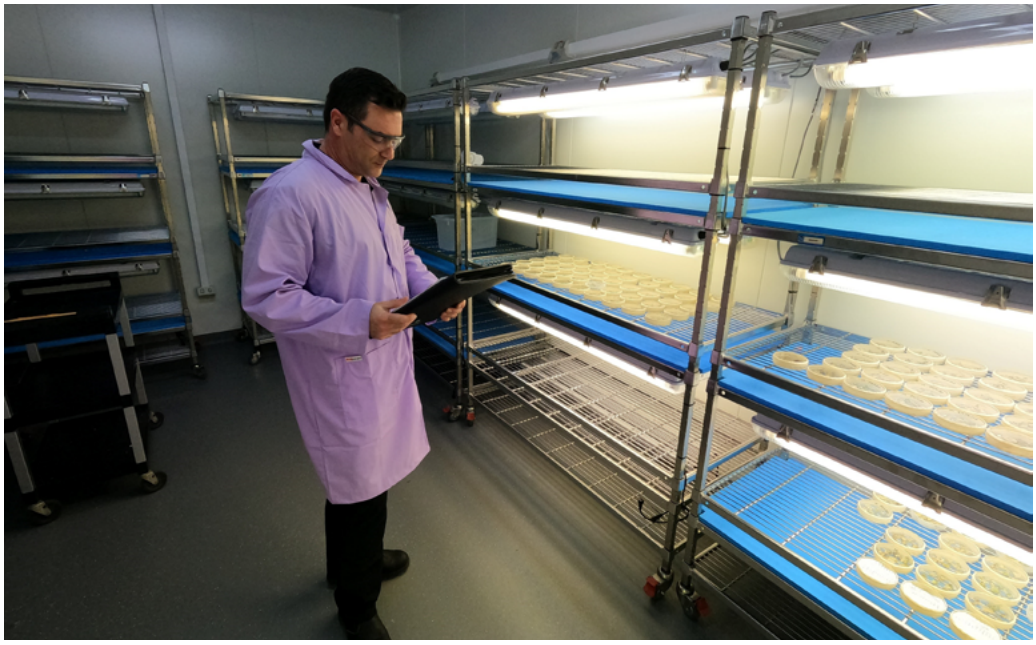
DIR = dealing involving intentional release of a GMO into the environment; DNIR = contained dealing with a GMO not involving intentional release into the environment; PR = practice review.

Locations of facility compliance inspections

Certified facilities are located in all Australian states and territories (Figure 19). In 2023–24, monitoring activities took place in the ACT, NSW, Qld, SA, Vic and WA (Figure 23).

Figure 23: Number of certified facility compliance inspections in 2023–24, by state and territory



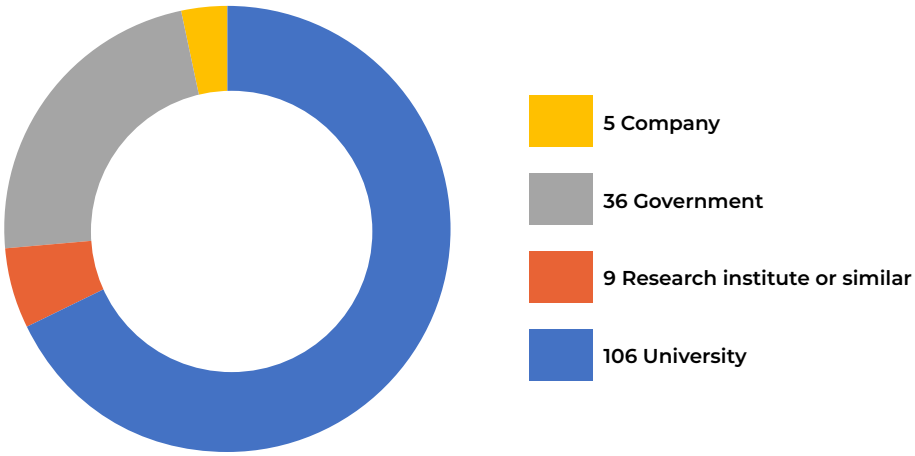


PC2 plant facility

Types of organisations inspected

Figure 24 shows the distribution of inspections during 2023–24 by organisation type. Universities comprised the majority of inspections, followed by government, research institutes and companies. This distribution is broadly similar to the overall distribution of certified facilities by organisation type, as seen in Figure 18.

Figure 24: Certified facility compliance inspections in 2023–24, by organisation type



Compliance with the Act

This section reports on 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.

Matters referred to in this report as non-compliances reflect situations where inspectors have found inconsistencies relating to requirements imposed by a GMO authorisation. 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.[12]

Non-compliance findings for GMO dealings involving intentional release

In 2023–24 the OGTR made a total of 10 findings of non-compliance with the conditions of DIR licences. Two findings of non-compliance were made against DIR-140 and DIR-186. Six findings of non-compliance were made against DIR-164.

Organisation	Novotech (Australia) Pty Ltd
Licence number	DIR-140
Summary of dealing	Clinical trial of a genetically modified virus for treatment of liver, kidney and prostate cancer.
Findings	Novotech was found to be non-compliant with licence conditions as, on multiple occasions, it did not obtain a signed and dated record from individuals indicating that they had been informed of, understood and agreed to be bound by licence conditions, prior to permitting the individuals to administer GMOs to clinical trial participants or handle the GMOs. This is inconsistent with licence condition 14.
Assessment	Novotech self-reported 2 contraventions to the OGTR, which resulted in an OGTR inspection of the Royal Melbourne Hospital clinical site where the trial was occurring. During the inspection OGTR inspectors identified further occasions on which Novotech had contravened licence condition 14. Inspectors determined that although Novotech had not obtained appropriate documentation in accordance with licence condition 14, persons undertaking dealings with the GMO complied with work practices mandated by the licence regarding containment of the GMO and the minimisation of risks to human health and safety and the environment. Therefore, no adverse outcomes were identified as eventuating because of these non-compliances.
Compliance management	The Gene Technology Regulator has reminded Novotech of its obligation to ensure that all authorised persons are informed of applicable conditions, receive required training and generate appropriate records prior to undertaking dealings. To prevent recurrence of this issue Novotech must update its policies and procedures and ensure all authorised persons receive training and generate appropriate records.

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

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 self-reported the following non-compliant activities to the OGTR: 1. GM seed harvested at site 3 (Rupanyup, Vic) was stored on site in a manner inconsistent with licence requirements (condition 43) prior to disposal by deep burial. 2. On 2 occasions reporting timeframes specified by the licence (condition 57) were not met. 3. An external contractor engaged by Monsanto was found to have processed GM seed samples despite not being informed of licence conditions that apply to them (condition 15). 4. Two flowering volunteer canola plants were reported on site 5 (Beverley, WA) while the site was in the post-harvest monitoring (PHM) phase. On a second occasion one flowering volunteer canola plant was reported while the site was in the PHM phase. This is inconsistent with condition 50 of the licence, which requires volunteers to be destroyed before flowering. 5. 50 flowering plants of a related species were reported within the monitoring zone on site 11 (Beverley, WA) while 10% of the trial was flowering. This is inconsistent with condition 32 of the licence, which requires related species to be destroyed or prevented from flowering.
Assessment	1. Although not in accordance with storage requirements, in this instance GM seed was found to have remained contained and not dispersed to the environment. The seed was disposed of in accordance with licence requirements and no additional risks were identified. 2. The delayed reporting was minor in nature, relating to routine notifications for planting and grazing. These instances were found not to have impacted the management of risks associated with the dealings. 3. Persons conducting dealings with the GMOs who are not fully trained in licence conditions pose risks to containment. However, in this instance the external contractor was found to have handled the GM seed appropriately and no loss of containment was identified. The contractor was trained in licence conditions as soon as Monsanto became aware of the matter. 4. In both instances the flowering volunteers on site 5 were destroyed prior to setting seed and no mature canola crops were within 1 km of the site, reducing the likelihood of any gene flow from the site. These incidents have been assessed as posing no additional risks to human health and safety and the environment. 5. The flowering related species on site 11 were destroyed prior to setting seed. The OGTR has assessed the likelihood of hybridisation in the field between the GMO (*Brassica napus*) and the related species (*Raphanus raphanistrum*) as very low. This incident poses no additional risks to human health and safety or to the environment.

Organisation	Monsanto Australia Pty Ltd
Compliance management	Monsanto is required to increase the frequency of post-harvest monitoring inspections for site 5 and must ensure that only senior, authorised persons who have been approved in writing by the Regulator conduct these inspections. The Regulator has also reminded Monsanto of its obligations to ensure that all persons undertaking dealings with GMOs are appropriately trained in licence conditions, and that licence conditions (including those relating to storage, reporting and controlling gene flow) are followed. Monsanto will also be subject to enhanced responsive monitoring by the OGTR to assess ongoing compliance with licence conditions.

Organisation	The University of Adelaide
Licence number	DIR-186
Summary of dealing	This licence allows the University of Adelaide to conduct a limited and controlled release of wheat and barley genetically modified for yield enhancement and improved abiotic stress tolerance.
Findings	On 8 April 2024 the University of Adelaide self-reported the following non-compliant activities to OGTR: • Failed to notify the Regulator of an intention to plant for 2 GM plant lines to be planted in the planting area. (Condition 50(a)(iii)) • Failed to notify the Regulator of the planting of 2 GM plant lines, which includes any changes to the details under part (a) of condition 50. (Condition 50(b)(ii))
Assessment	This matter is an administrative non-compliance; there was no risk to human health or the environment. The University of Adelaide has self-reported this matter to the OGTR and has undertaken corrective actions. The 2 lines omitted were authorised under DIR-186.
Compliance management	In future the University of Adelaide will add additional signature fields in the Intention to Plant and Notice of Planting templates. This will require all personnel involved in field trials to sign off on the plant identifications and lines intended to be planted and confirm what was planted before submitting the notices to the Regulator.

Non-compliance findings for GMO dealings not involving intentional release

In 2023–24 a total of 4 findings of non-compliance were made against 3 DNIR licences.

Organisation	Pfizer Australia Pty Ltd
Licence number	DNIR-624
Summary of dealing	A clinical trial to evaluate the efficacy and safety of PF-07055480 in adult male participants with moderately severe to severe haemophilia A.
Findings	Pfizer Australia Pty Ltd failed to meet a reporting condition (condition 37(a)).
Assessment	The delay in reporting occurred because of an administrative oversight. The delay in reporting did not impact the management of the risks associated with the licence. It is noted that Pfizer Australia Pty Ltd self-reported this matter to the OGTR and has undertaken corrective actions to improve reporting procedures.
Compliance management	Pfizer Australia Pty Ltd has been reminded of its obligations to ensure that reporting occurs within specified timeframes. Pfizer Australia Pty Ltd is also required to update its policies and procedures to address the risk of this issue recurring.

Organisation	Pfizer Australia Pty Ltd
Licence number	DNIR-644
Summary of dealing	A clinical trial to evaluate the efficacy and safety of PF-06939926 in patients with Duchenne muscular dystrophy (DMD).
Findings	Pfizer Australia Pty Ltd self-reported the following non-compliant activity to OGTR: • Failed to meet a reporting condition (condition 39(a)).
Assessment	The delay in reporting occurred because of an administrative oversight. The delay in reporting did not impact the management of the risks associated with the licence. It is noted that Pfizer Australia Pty Ltd self-reported this matter to the OGTR and has undertaken corrective actions to improve reporting procedures.
Compliance management	Pfizer Australia Pty Ltd has been reminded of its obligations to ensure that reporting occurs within specified timeframes. Pfizer Australia Pty Ltd is also required to update its policies and procedures to address the risk of this issue recurring.

Organisation	The University of Melbourne
Licence number	DNIR-525
Summary of dealing	The role of gut-resident T cells in protecting against enteric Listeria infection.
Findings	In permitting waste contractors to transport and dispose of waste containing GMOs off-site, the University of Melbourne was found to be non-compliant with: • licence conditions 9 and 14, for not informing waste contractors of licence conditions that apply to them or obtaining a suitable record • licence condition 27, for permitting waste to be decontaminated outside The University of Melbourne premises.
Assessment	The University of Melbourne identified the matter during an internal audit and took immediate action to stop the transport of waste off site and to notify OGTR. This resulted in an OGTR inspection of the facility where the incident occurred. Inspectors determined that although the University of Melbourne permitted GM waste to be removed by waste contractors and sent for incineration, both the method of transport and the method of destruction were effective and did not result in a release of GMOs from containment. The non-compliances did not result in the occurrence of any adverse events.
Compliance management	The Gene Technology Regulator reminded the University of Melbourne of its obligations to ensure that: • GM waste is disposed of on site, in a manner specified by their licence • all persons undertaking dealings with GMOs are informed of applicable conditions and generate appropriate records prior to undertaking dealings.

In 2023–24, 4 instances were identified where organisations were not conducting NLRDs in accordance with requirements.

In all cases, the organisations took corrective and preventive measures and no further actions were recommended.

Non-compliance findings for physical containment facilities

In 2023–24, 44 certified physical containment facilities were found to have one or more non-compliances (a total of 66 non-compliances against certification conditions were identified). These findings are summarised in Table 10.

Table 10: Number of non-compliances identified in certified facilities during 2023–24, by non-compliance type

Nature of non-compliance	Number
Control measures	3
Equipment	6
Structure	20
Training and authorisation	1
Transport, storage and disposal	2
Work practices	34

Each finding of non-compliance was assessed according to established OGTR protocols. 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.

PC2 plant facility

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 IBC(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 practice reviews of 4 licences during this reporting period. Two practice reviews, involving 3 accredited organisations, were completed. The findings of these reviews are outlined below. One is ongoing; the results will be included in the 2024–25 annual report.

Two practice reviews commenced in previous reporting periods were also finalised in this reporting period:

- A practice review of the University of Melbourne was initiated in 2022–23 covering the preparedness of the organisation to undertake licensed dealing DNIR-654. This review has ceased on the basis that no dealings have been undertaken by the licence holder.
- A practice review of P Brodie Holdings Pty Ltd t/a PB Agrifood was initiated in 2022–23. The findings are outlined below.

All practice reviews covered the preparedness of the organisations to undertake licensed dealings under DNIRs, DIRs or inadvertent dealing licences.

	Preparedness of accredited organisations to undertake licensed dealings not involving intentional release – practice review
Aim	This is part of the OGTR's ongoing practice review program. The OGTR recognises that effective compliance is dependent on: • suitable arrangements to manage compliance for GMO dealings • suitable site selection and appropriate use of containment measures • staff training and provision of resources necessary to manage compliance obligations.
Participants	The review focused primarily on the organisations' preparedness to undertake licensed dealings. The organisations examined by the practice review were QIMR Berghofer Medical Research Institute and Janssen-Cilag Pty Ltd. The review assessed: • certified facility or site selection and planning considerations for containment measures • the suitability of the organisations' arrangements to manage compliance risks, including training and oversight of staff, collaborating organisations and resourcing • any industry or other regulatory issues which could impinge on the organisations' effective compliance performance
Findings	The review found that the participating accredited organisations had considered and proposed to implement effective measures and planning for a licensed dealing not involving an intentional release.
Outcomes	The OGTR practice review program continued to assess vulnerabilities to containment and compliance with the *Gene Technology Act 2000*. Such information contributed to: • an overall understanding of compliance performance and emerging barriers to effective compliance • the continual improvement of compliance management processes • the prevention of practices and arrangements that could lead to non-compliance • compliance management and awareness activities.

PC2 laboratory

	Preparedness of accredited organisations to undertake licensed dealings involving an 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 organisation's preparedness to undertake licensed dealings. It examined Novotech Australia Pty Ltd. The review assessed: • site selection and planning considerations for containment measures • the suitability of the organisation's arrangements to manage compliance risks, including training and oversight of staff, collaborating organisations and resourcing • any industry or other regulatory issues which could impinge on the organisation's effective compliance performance.
Findings	The review found that the participating accredited organisation had considered and implemented effective measures in relation to site selection and planning for a licensed dealing involving a limited and controlled release.
Outcomes	The OGTR practice review program continued to assess vulnerabilities to containment and compliance with the *Gene Technology Act 2000*. Such information contributed to: • an overall understanding of compliance performance and emerging barriers to effective compliance • the continual improvement of compliance management processes • the prevention of practices and arrangements that could lead to non-compliance • compliance management and awareness activities.

	Preparedness of P Brodie Holdings Pty Ltd t/a PB Agrifood to undertake an inadvertent dealing licence – 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 • appropriate use of containment measures • staff training and provision of resources necessary to manage compliance obligations.
Participants	The review focused primarily on the organisation's preparedness to undertake licence ID-07. The organisation included in the practice review was P Brodie Holdings Pty Ltd t/a PB Agrifood. The review assessed: • planning considerations for containment measures • the suitability of the organisation's arrangements to manage compliance risks, including training and oversight of staff, collaborating organisations and resourcing • any industry or other regulatory issues which could impinge on the organisation's effective compliance performance.
Findings	The review found that the participating organisation had considered and implemented effective measures in relation to conducting dealings under licence ID-07.
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.

Wheat field trial site

Audits

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

- examination of 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 2023–24, audits of the University of Adelaide in South Australia and Monash University in Victoria were ongoing. Findings will be reported once the audits are completed. In addition to these, the OGTR undertook and finalised an audit during this reporting period as summarised below.

Audit	QIMR Berghofer Medical Research Institute (QIMR)
Aim	To provide advice to the Regulator with regard to QIMR's ongoing capacity to meet regulatory obligations
Determination	The audit found that QIMR: • has a demonstrated capacity to meet regulatory obligations • demonstrates commitment to continuous improvement • is responsive to challenges in the regulatory landscape.
Action	The OGTR will continue oversight of QIMR regulatory compliance through routine monitoring.

Audits are also undertaken as part of the national strategy for unintended presence of unapproved GMOs in agricultural crops. The 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 to develop a voluntary testing program of existing industry quality assurance measures.

In 2023–24 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, Fisheries and Forestry, 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 the OGTR, self-reporting by an accredited organisation, or third-party reporting.

No investigations were undertaken in the reporting period.

Security Sensitive Biological Agents Regulatory Scheme

The *National Health Security Act 2007*, administered by the department's Health Protection Policy and Surveillance 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 2023–24 the OGTR continued to work with Health Protection Policy and Surveillance to operationalise these monitoring arrangements.

Performance against Portfolio Budget Statements targets

Our performance against the deliverables and key performance indicators set out in the Portfolio Budget Statements is reported in the department's 2023–24 annual report and summarised below.

Our activities for 2023–24 are described under Program 1.8 in Outcome 1 (Health Protection, Emergency Response and Regulation) of the 2023–24 Department of Health and Aged Care Portfolio Budget Statements.[13] 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 activities:

Key activity:

Administering the National Gene Technology Scheme by assessing applications and issuing approvals, and by conducting routine inspections of certified facilities and licensed activities with genetically modified organisms (GMOs).

Source: Health and Aged Care Portfolio Budget Statements 2023–24, p.73 and Health and Aged Care Corporate Plan 2023–24, p.58

Performance Measure 1.8C:

a. Percentage of GMO licence decisions made within statutory timeframes.

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

Source: Health and Aged Care Portfolio Budget Statements 2023–24, p.74 and Health and Aged Care Corporate Plan 2023–24, p.58

2023–24 planned performance	2023–24 result	2022–22	2021–22	2020–21	2019–20
a. 100% b. 100%	a. 100% b. 99.1%	100% 100%	100% 100%	n/a[14] n/a	n/a n/a

Data source and methodology:

Records of licence applications and incidents. Data is analysed and maintained internally by the department. All licence decision timeframes are measured against statutory timeframes within the Gene Technology Regulations 2001.[15] All reports or allegations (incidents) received are assessed in accordance with the Monitoring and Compliance Managing Incidents Reports Standard Operating Procedures.

13 The Portfolio Budget Statements are on the department's website.

14 This was a new performance measure in 2021–22; therefore results are not available for previous years.

15 Available at: www.legislation.gov.au/Details/F2020C0095731

The Office of the Gene Technology Regulator (OGTR) has skilled technical staff conducting science-based risk assessments. 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 2023–24:

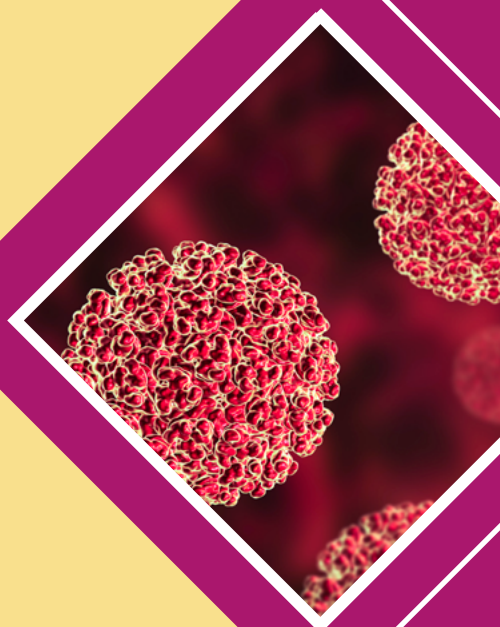
- one agricultural plant – commercial licence
- 2 agricultural plants – field trial licences
- one human therapeutic – commercial licence
- 16 human therapeutics – clinical trial licences
- 2 laboratory research – medical licences
- 7 laboratory research – non-medical licences
- 3 manufacturing licences.

Additionally the OGTR received and assessed 108 reports during 2023–24 relating to possible non-compliances with GMO approvals (licences, NLRDs and certifications).

Inspectors assessed all reports received; however, one report was received in the last 3 business days of the financial year and assessed after June 30. This final report was assessed within 5 business days of receipt. Assessments consider the circumstances of the report in accordance with the *Gene Technology Act 2000*, Gene Technology Regulations 2001, guidelines issued by the Regulator, and the conditions relating to each authorisation. For any non-compliance identified, inspectors will 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, the OGTR considers appropriate measures to address the non-compliance. It continues to work with the entity following a non-compliance to ensure they remain in compliance.

In 2023–24, 100% of GMO licence decisions were made within statutory timeframes and 99.1% of reports of non-compliance with the conditions of GMO approvals were assessed. Skilled technical staff and robust procedures contribute to the Regulator's strong performance against these measures.



Chapter 4

Other functions of the Gene Technology Regulator

Chapter 4

Other functions of the Gene Technology Regulator

This chapter describes achievements relating to other functions 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

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

- developing draft policy principles and policy guidelines, as requested by the Gene Technology Ministers' Meeting (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 Gene Technology Technical Advisory Committee (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 2023–24 a new version of the confidential commercial information (CCI) application form was released to improve the clarity and quality of applications to have information provided to the Regulator declared as CCI. The application form was accompanied by improved guidance material and examples to assist the regulated community when preparing an application.

Several downloadable application forms were updated or converted from online forms. The downloadable forms provide alternative options for applying to deal with GMOs under the scheme.

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

The OGTR has continued to provide technical and operational information to assist the Department of Health and Aged Care team leading the implementation of recommendations of the Third Review of the National Gene Technology Scheme. This was a broad-ranging policy review conducted by a panel of Commonwealth, state and territory officials on behalf of all Australian governments, independently of the Regulator.

Advice on GMOs and GM products

During 2023–24 the OGTR advised other regulatory agencies and the public on the regulation of GMOs and GM products.

Work experience

The Regulator has 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.

In 2023–24 one student undertook work experience in the Evaluation Branch – in the Contained Dealings Evaluation Section and the Application Entry Point – 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 discussion on regulatory and technical issues and enhancing inter-agency cooperation.

Many OGTR staff attended the full-day 2023 RSN Annual Symposium on the topic 'Innovation in regulatory science'. OGTR staff also participated in the RSN Lunchtime Seminar Series. One lunchtime seminar was presented by Dr Peter Thygesen from the OGTR on the topic 'Safer (and sustainable) innovation approach – applications in biotechnology and elsewhere'.

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 2023–24 the OGTR maintained the GMO Record and updated it with new authorisations.

In December 2023 and June 2024, the Regulator issued statements on the OGTR website to address misinformation around mRNA vaccines. The December 2023 statement addressed concerns that Pfizer and Moderna had not received licences from the Regulator for the vaccines. The statement clarified that the vaccines did not require licensing as the Pfizer and Moderna mRNA vaccines are not GMOs. The June 2024 statement explained the difference between vaccines and gene therapy and confirmed that the mRNA vaccines are not gene therapy and do not modify genes within the body. Both statements can be found in the Resources tab of the OGTR website by clicking the Publication Type – Statement or by searching the resources list for mRNA.

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 its 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 2023–24, we produced 2 newsletters:

- The first focused on the updated CCI application form and notification of minor works form.
- The second featured information on the PC2 guidelines and the certification service in the OGTR Online Services Portal.

Digital service delivery for applications to the Regulator

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's ICT Strategy to provide innovative, secure and sustainable ICT services.

The new OGTR Online Services Portal was launched in 2023–24 to replace the end-of-life previous online form system. The first service made available to stakeholders was the reporting of NLRDs, allowing real-time receipt of OGTR NLRD identifiers for users of the portal. A further release in the fourth quarter enabled users to apply for certification of a facility and to apply to vary a facility certification. The portal requires user authentication, which enables the OGTR to increase data transparency and currency for the regulated community. By 30 June 2024 the previous online form service was decommissioned, with most transactions now handled through the portal. Some services have remained on downloadable forms, for future development in the portal.

The portal also provides a platform for building greater capabilities for enabling more agile and scalable responses to implementing recommendations from the Third Review of the National Gene Technology Scheme.

Exploring funding models

The OGTR has been investigating options for a sustainable funding model. This included consideration of cost recovery in accordance with the Australian Government's Cost Recovery Policy. In late 2023 the OGTR consulted regulated stakeholders on their views about the introduction of cost recovery in the context of 5 key criteria:

- Ability to pay
- Unintended consequences
- Impact on the perceived value of the OGTR
- Complexity of required fee structure
- Ease and timing of implementation.

The OGTR has also been undertaking an assessment of the effort involved in its licensing and certification functions to inform possible recovery of costs.

Meetings, conference attendance and presentations

The Regulator and staff from the OGTR attend and present papers at meetings, forums and conferences in Australia. During 2023–24 the Regulator and OGTR staff participated in a range of events on gene technology to inform users, the Australian community and stakeholders about the regulatory system. These included:

- August 2023, Seed Business Convention
- August 2023, The University of Sydney, presentation on regulation of GMOs in Australia
- August 2023, International Society for Cell & Gene Therapy Australia and New Zealand regional meeting
- August 2023, La Trobe University lecture on regulation of GMOs in Australia
- August 2023, OGTR Forum, Danger & Practical Wisdom: Public Views on Synthetic Biology in Australia
- September 2023, National Regulators Community of Practice conference, Regulatory Hindsight, Foresight & Insight
- September 2023, ARC Training Centre for Future Crops Development, presentation on regulation of GMOs in Australia
- September 2023, CropLife Australia National Members' Forum
- October 2023, 11th Annual ABSANZ Biosafety and Biocontainment Conference
- November 2023, Australian Clinical Trials Alliance, International Clinical Trials Symposium
- November 2023, Regulatory Science Network forum
- November 2023, OGTR Forum, Savouring the Future FEAST
- November 2023, OGTR Forum, South Australian Perspectives on the Potential Use of Mouse Gene Drives for Pest Management and Conservation
- November 2023, AusBiotech, Australia's life sciences conference
- December 2024, OGTR Forum, Global Status of Gene Edited Food Animals and their Products
- February 2024, Agricultural Biotechnology Council of Australia meeting

- March 2024, workshop on innovative veterinary vaccines using the platform technology master file concept
- March 2024, Medicines Australia, Medicines of Tomorrow Horizon Scanning Forum
- April 2024, Australian National University biomanufacturing workshop
- April 2024, ARC Training Centre for Future Crops Development, Risk and Regulation – Concepts and Approaches
- May 2024, Protein Futures 2024, Scaling Up for Success
- May 2024, CSIRO and Animal Medicines Australia, Advancing Biosecurity through Innovation in Veterinary Vaccines
- May 2024, Government Scientists Group Meeting
- May 2024, Regulatory Science Network seminar, RNA Development, Quality Control and Manufacturing in Australia
- June 2024, Lessons from COVID-19 vaccine development to advance crop breeding
- June 2024, Data Driven Regulation
- June 2024, ARCS conference.

Research undertaken or commissioned by the Regulator

Documents to support the risk analysis of GMOs

The 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 2023–24 the OGTR updated one biology document:

- The Biology of *Gossypium hirsutum* L. and *Gossypium barbadense* L. (cotton).

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

Community attitudes survey

Since 2015 the Regulator has commissioned surveys of community attitudes towards gene technology to gauge the state of Australian public awareness of gene technology, to identify knowledge gaps and to track changes in awareness and attitudes over time. A 2024 survey was commissioned in 2023–24 and is anticipated to be publicly available in late 2024.

Promoting harmonisation

The Regulator and the OGTR continued to liaise with other regulatory and Australian Government agencies on relevant issues during 2023–24.

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.

As part of the decision between the Australian and New Zealand (NZ) prime ministers to promote collaboration and alignment of our regulatory approaches for GMOs, noting the unique environment of Australia and NZ, OGTR staff met twice with the New Zealand Ministry of Business, Innovation and Employment, who were seeking information on the lessons learnt from the current scheme and what the OGTR consider are any shortcomings of the current scheme.

The OGTR also met with the Federated Farmers of New Zealand and several agriculture groups within NZ, including major export industries. There was interest in gaining an understanding of how the state and territory moratoria legislation operated at the start of the scheme.

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, of which an OGTR officer is currently the 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 the Cartagena Protocol on Biosafety.

The OGTR also contributes to Australian submissions on the regulation of GMOs and is the national focal point for the Protocol on Biosafety and for the UN 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 attended in person were:

- July–August 2023, events at the APEC Third Senior Officials' Meeting and related meetings (High Level Policy Dialogue on Agricultural Biotechnology plenary meeting and workshops, and Early Career and Innovative Start-ups Symposium for Researchers) in Seattle
- September 2023, International Plant and Animal Genome Conference, Perth
- October–November 2023, Association of Biosafety for Australia and New Zealand Conference, Queenstown
- March 2024, Foundation for the National Institutes of Health Gene Drive Research Forum Annual Meeting, Marina Del Rey, California.

The following meetings were attended virtually:

- August 2023, APEC webinar, Ensuring the Safety of Products from Agricultural Biotechnology
- September 2023, Convention on Biological Diversity webinar, 20th Anniversary of the Protocol on Biosafety
- October 2023, American Society of Gene & Cell Therapy, Risk Assessment of Lentiviral and AAV Gene Therapy Vectors
- November 2023, Like Minded Group – APEC
- November 2023, APEC Agricultural Biotechnology Seminar Series for 2023
- January 2024, Indonesian workshop, Overview of National and International Biosafety Regulation II
- March 2024, 38th meeting of the OECD Working Party on the Harmonisation of Regulatory Oversight in Biotechnology, Paris
- April–May 2024, meetings with NZ Ministry of Business, Innovation and Employment and Federated Farmers of New Zealand
- May–June 2024, APEC Agriculture & Food Systems Institute, Agricultural Biotechnology Seminar Series for 2024 and discussion sessions to inform a policy approaches document
- May 2024, meeting with Outreach Network for Gene Drive Research
- June 2024, FDA Genome for Global Regulators webinar

CHAPTER 4

Chapter 5

Management and accountability

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Management and accountability

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

Human resources

The OGTR had a workforce of 51 employees at 30 June 2024. All permanent employees other than the Regulator are APS 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 and Aged Care Enterprise Agreement 2024–2027, 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.

Table 11: 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 23rd year of operation.

A weekly all-staff Friday morning tea was a successful way to keep staff up to date on major issues and provide opportunities for input, participation and feedback. It was also promoted as a 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

This year, 2 teams received the Regulator's Achievement Award. Both teams were very deserving recipients, exemplifying a high degree of stakeholder engagement and innovation in the workplace.

Since January 2023, the Low-Level Certifications team have processed around 1,000 certification applications, including certification variations. The team achieved significant time reductions in processing these applications through the development of new forms and associated guidance to reduce administrative burden for the OGTR and for applicants. Logging and internal processing also improved during this time. The core team consists of staff in the Application Entry Point, who receive and log applications, and in the Contained Dealings Evaluation Section, who evaluate the applications. They are supported by additional staff who develop forms and delegates who approve the certifications. The team received a great deal of positive feedback from stakeholders who had interactions with the OGTR on low-level certification applications.

The Plant Evaluation Section piloted a parallel licence assessment with FSANZ for the commercial cultivation of GM bananas resistant to Panama disease. This was the first time the OGTR had undertaken an assessment and approval process with another agency. The 'Banana Team' was involved in project planning with the applicant, QUT, and FSANZ before both agencies received the application. The aim of the exercise was to align the public consultation processes of both agencies, so that the public could understand their respective roles in the commercial approval. This was a long and complicated process, which involved the preparation of multiple documents, liaison with other government departments, and coordinated communications. The public consultation process resulted in over 270 submissions being made to the OGTR alone. The team approached the project with an innovative attitude despite the additional workload, while looking for streamlining opportunities if the process is used again.

The Banana Team

Low-Level Certifications team

Training and development

OGTR staff can access professional development opportunities through the department's performance development scheme. At the beginning of each 12-month cycle, all employees and their managers agree on key commitments for the employee's professional development, and the associated performance measures and development requirements. Staff can also access financial assistance through the department's studybank program to undertake an approved course of study related to their work or the work of the department. Study provides employees with lifelong benefits and builds ongoing capability and knowledge in an area or discipline. Studybank has direct linkages to the employee's performance development scheme. The OGTR also supports employees who are finance and legal professionals in undertaking their continuing professional development.

In 2023–24 the emergency control organisation team participated in 2 training sessions. Members of the team are self-nominated wardens and first aid officers. On completion of the required training, they receive an allowance in accordance with the Enterprise Agreement.

During 2023–24 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', 'The National Anti-Corruption Commission' and 'APS legal fundamentals and the APVMA case study'.

During 2023–24 the OGTR Principal Regulatory Scientist provided introductory training for OGTR staff on risk analysis. Two sessions of 'Introduction to OGTR risk analysis' were held, on 7 September 2023 and 29 November 2023.

During 2023–24 we developed a Training Action Plan which identified the skills required to carry out the OGTRs statutory functions.

Three key priority areas for development were identified as part of the plan:

- Communication techniques to defuse tensions and guide discussions toward constructive outcomes
- Resilience and change management
- Leadership and team management.

In late 2024 we offered training to improve skills in communication and resilience. Plans are in place to run leadership training in late 2024.

Supportive working environment

OGTR staff have access to a range of departmental assistance measures, as part of the OGTR's 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 endeavours 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 offering 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.

These initiatives complement 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 Enterprise Agreement, the OGTR provided the option of influenza and COVID vaccinations, at no cost, to all staff.

In 2023–24 we conducted training for workplace safety 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 and into 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 which the OGTR became aware of during the year that arose from the conduct of OGTR business or undertakings 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.

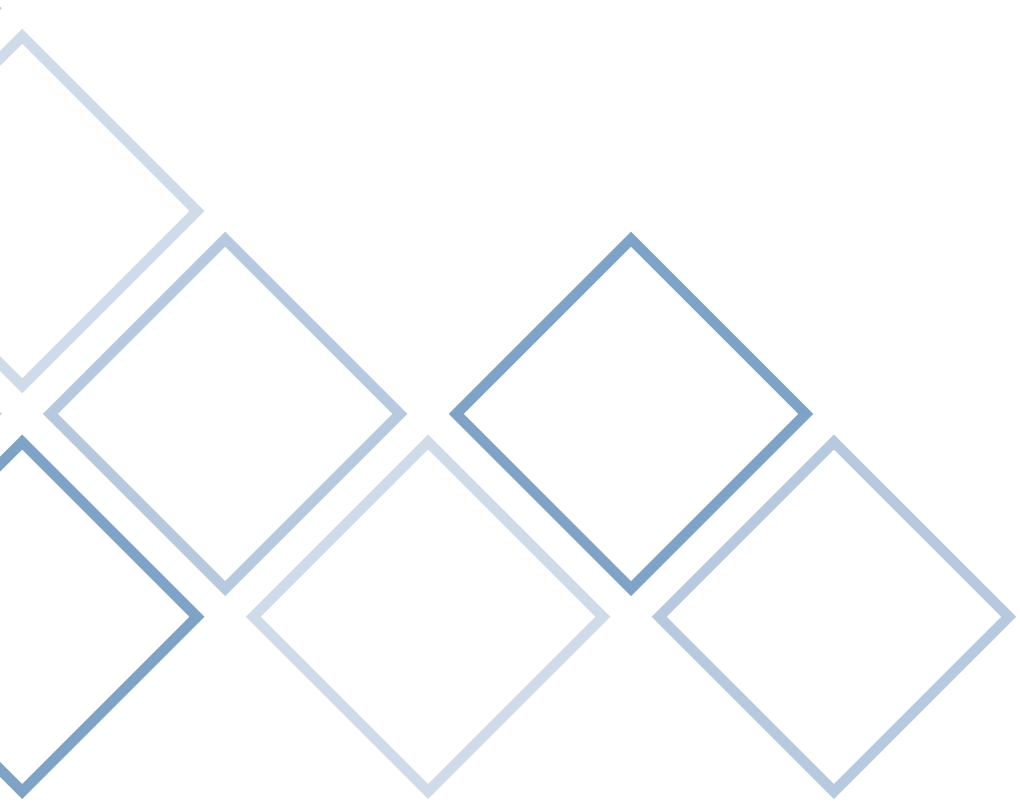
Freedom of information

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 4 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 12 tracks monthly usage numbers for the OGTR website. The most viewed pages and downloaded applications are listed after the table.

Table 12: Website activity, 2023–24

Month	Visits[a]	Users[b]
July	9,117	6,174
August	12,643	8,813
September	8,573	5,523
October	9,743	6,613
November	8,838	6,068
December	9,370	7,341
January	5,612	6,243
February	28,234	23,004
March	13,258	9,436
April	9,760	6,635
May	11,705	8,357
June	11,889	8,756

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 2023–24 were, in descending order:

- Dealings involving intentional release
- Office of the Gene Technology (home page)
- Resources
- Genetically modified (GM) crops in Australia
- What we've approved
- About the OGTR
- Types of GMO dealings
- What are genetically modified organisms (GMOs)?
- Guidelines for the certification of physical containment facilities
- Work with GMOs.

The most downloaded applications in 2023–24 were:

- Application for a licence to conduct a human clinical trial of a GMO
- Application checklist for a physical containment level 2 laboratory
- Application for a licence for dealings not involving intentional release of a GMO (DNIR)
- Application for accreditation of an organisation
- Application for a confidential commercial information (CCI) declaration
- Application for the certification of a physical containment facility
- Application checklist for a physical containment facility level 1
- Application for declaration that specified information is CCI – information for completing the CCI form
- Application for a DIR licence involving a non-plant GMO
- 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 2023–24, use of the email address increased compared with the previous year (Table 13).

Table 13: Email activity, 2023–24 and 2022–23

Emails	Users	
Month	2023–24	2022–23
July	42	81
August	48	50
September	39	31
October	57	52
November	65	40
December	165	36
January	40	30
February	58	49
March	63	45
April	45	30
May	51	41
June	60	39
Total	**733**	**524**

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 the OGTR with queries, legislative notifications and self-reporting of non-compliances, and it ensures that all communications are answered efficiently while staff are away from the office. The inbox received 1,267 emails during 2023–24 (compared to 878 in 2022–23).

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 1,018 emails during 2023–24 (compared to 853 in 2022–23).

The Application Entry Point maintains an email inbox to provide a central, shared communication point, allowing us to efficiently coordinate responses to correspondence and queries about applications. The inbox received 2,180 emails during 2023–24 (compared to 4,115 in 2022–23).

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

Appendices

Appendix 1
Appendix 2

Appendix 1: Membership of statutory committees

Table 14: Gene Technology Technical Advisory Committee 2023–26 – current members

Member	Position
Professor John Rasko AO (Chair)	Director, Cell and Molecular Therapies, Royal Prince Alfred Hospital; Program Head, Centenary Institute, and Professor, Faculty of Medicine and 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	Principal Research Fellow, The University of Western Australia (WA)
Dr Tessa Gargett	Postdoctoral Research Officer, Royal Adelaide Hospital and Centre for Cancer Biology (SA)
Associate Professor 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); 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)	Director, WA Agricultural Research Collaboration, University of Western Australia; 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 and 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 15: Gene Technology Ethics and Community Consultative Committee 2023–26 – current members

Member	Position
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); Chair, Philosophy Group, Wageningen University, The Netherlands
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 (NSW)
Dr Rachel Nowak	Senior Editor, Custom Media, APAC, Springer Nature (Vic); Scientific program manager, NIAID, NIH, Bethesda, Maryland, US.
Dr Gabrielle O'Sullivan (GTTAC cross-member)	Executive Officer and Member, Institutional Biosafety Committee, Royal Prince Alfred Hospital (NSW)
Dr Kelly Pearce	Director, WA Agricultural Research Collaboration, University of Western Australia; Broadacre Farmer (WA)
Dr Robert Sward AM	Director, BioBotanicals Consulting (Vic)
Dr Lynn Woodward	Senior Lecturer, College of Medicine and Dentistry, James Cook University (Qld); Chair, Human Research Ethics Committee, Metro North Health (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 GTTAC
  - 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 states:

'deal with', in relation to a GMO, means 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
- an NLRD
- licensed as:
  - a DNIR
  - a DIR
- an inadvertent dealing
- included on the GMO Register
- specified in an 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 centres on comprehensive 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 GTTAC, 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 (for 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 for making 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 16 summarises the categories of GMO authorisations, the 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 can 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 5-year time limit.

More information on the various categories of GMO authorisations and their assessment processes is 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 16: 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 • 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 • 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

Category	Authorisation requirements	Controls
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 17. 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 17: 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

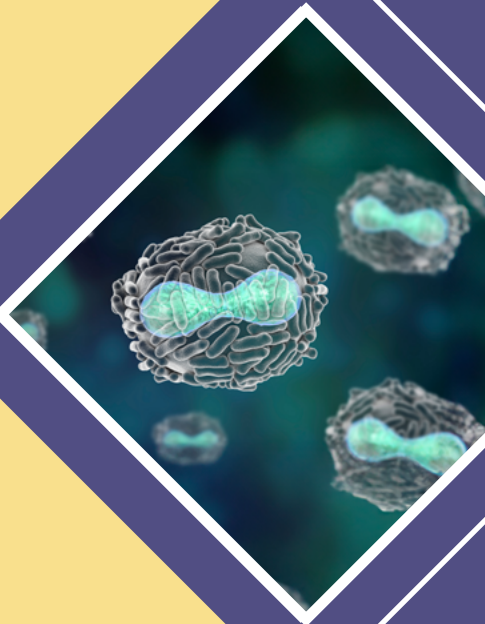
The terms described in this glossary are important to understanding this report; however, they do not substitute for the definitions of terms relevant to the operation of the gene technology regulatory system in section 10 of the Act.

Term	Description
Accredited organisation	An organisation that is accredited under section 92 of the *Gene Technology Act 2000*
Act	*Gene Technology Act 2000*
APEC	Asia-Pacific Economic Cooperation
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
FSANZ	Food Standards Australia and New Zealand
Gene Technology Agreement	An intergovernmental agreement that all Australian jurisdictions signed in 2001, which underpins the nationally consistent regulatory framework for gene technology
GM	Genetically modified
GM product	A thing (other than a GMO) derived or produced from a GMO
GMO	Genetically modified organism
GMO Record	Record of GMO dealings
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTTAC	Gene Technology Technical Advisory Committee

Term	Description
IBC	Institutional biosafety committee
Incident	A self-reported event that may constitute a non-compliance with regulatory requirements and a risk to public health or the environment
GTMM	Gene Technology Ministers' Meeting
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

Indexes

List of requirements Index



List of requirements

Gene Technology Act 2000 reference	Part of report	Description
136(1A)(a)	pp 26–26	GMO licences issued during the financial year
136(1A)(b)	pp 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)	pp 39	Emergency dealing determinations made by the Minister during the financial year
136(1A)(d)	pp 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)	pp 49–63	Auditing and monitoring of dealings with GMOs under this Act by the Regulator or an inspector during the financial year

Index

C

D

E

F

G

P

Q

R

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