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AUSTRALIAN CAPITAL TERRITORY

ELEVENTH ASSEMBLY

Office of the Gene Technology Regulator Annual Report 2024-25

Presented by
Rachel Stephen-Smith MLA
Minister for Health
May 2026

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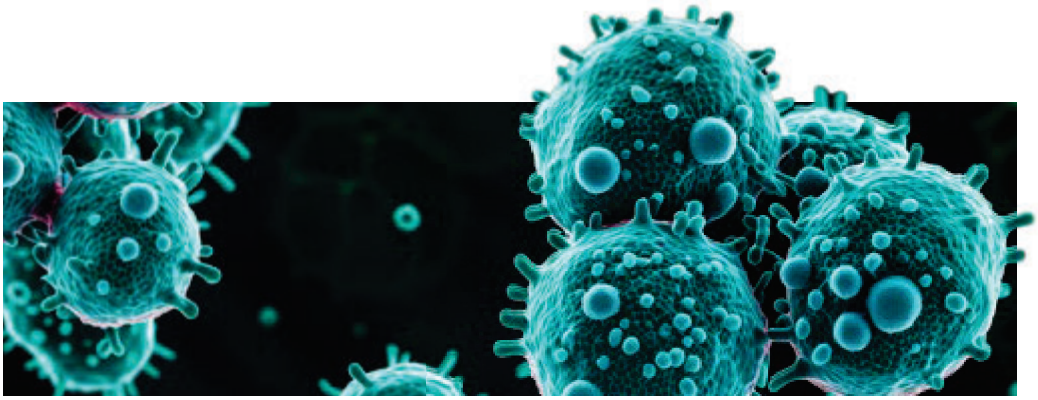

Australian Government

Department of Health, Disability and Ageing

Office of the Gene Technology Regulator

Annual Report 2024–25

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Contacts

Office of the Gene Technology Regulator
MDP 54
GPO Box 9848
Canberra ACT 2601 Australia

Level 10, Yaradhang Building
23 Furzer Street, Phillip ACT

Telephone: 1800 181 030
Fax: (02) 6113 8303
Email: ogtr@health.gov.au
Website: www.ogtr.gov.au

ABN 15 862 053 538

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

Australian Government
Department of Health, Disability and Ageing
Office of the Gene Technology Regulator

Letter of transmittal

The Honourable Rebecca White
Assistant Minister for Women
Assistant Minister for Indigenous Health
Assistant Minister for Health and Aged Care

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 2024 to 30 June 2025.

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 2024–25.

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

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

Yours sincerely

Dr Raj Bhula
Gene Technology Regulator
30 September 2025

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About this report

The report describes the roles and responsibilities of the Gene Technology Regulator (the Regulator) and the Office of the Gene Technology Regulator (OGTR). It is a formal accountability document that summarises the OGTR's performance against deliverables and key performance indicators in Outcome 1 (Health Policy, Access and Support), Program 1.8 (Health Protection, Emergency Response and Regulation) of the 2024–25 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] Budget 2024–25: Health and Aged Care Portfolio Budget Statements | Australian Government Department of Health, Disability and Ageing.

[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 OGTR's activities over the past year, including major achievements and the outlook for the coming year.

Chapter 2: Office of the Gene Technology Regulator
– describes the Regulator's corporate and regulatory governance arrangements, including the structure of the OGTR and functions of its advisory committees.

Chapter 3: Functions of the Gene Technology Regulator
– describes the OGTR's operational performance as well as achievements against priorities during 2024–25. 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 2024–25 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.

1

Gene Technology Regulator's overview

This has been a very busy year with some notable highlights, such as hosting the 10th National Institutional Biosafety Committee Forum (IBC Forum), and a major milestone with public consultation on draft amendments to the *Gene Technology Act 2000*.

1

The 10th National IBC Forum was held in Canberra from 16 to 18 September 2024 and the theme was ‘Emerging Technology and Horizon Scanning’. The intention behind the program was not only to look ahead but also to remember where the scheme started and how far it has progressed in terms of research, translation of that research into commercial reality, and the impacts on the Australian community.

Deputy Secretary Professor Tony Lawler welcomed attendees, followed by the then Assistant Minister for Health and Aged Care and Assistant Minister for Indigenous Health, the Hon Ged Kearney, who formally opened the forum. The two keynote speakers were Mr Tony Mahar, CEO of the National Farmers Federation; and Dr Elizabeth de Somer, CEO of Medicines Australia. Each spoke about issues in their respective sectors and how access to new and emerging technologies in agriculture and medicines brought benefits to the Australian community. The theme continued with presentations on applications of gene technology in agriculture, manufacturing and personalised medicines.

Professor Tony Lawler, the Hon Ged Kearney, Dr Elizabeth de Somer, Dr Raj Bhula

Two members of the Gene Technology Ethics and Community Consultative Committee presented on the committee’s development of guiding principles for communication about gene technology, which included a workshop during the year with various industry and research stakeholders.

Highlights from the 2024 Community Attitudes Survey were presented following publication of the survey report in July 2024. One of the interesting trends in the report is that attitudes towards biotechnology and genetic modification seem to have changed less in the past 10 or so years than previously. Support for the use of gene technology in food sits at just over half the community, or 53%.

The second day of the forum allowed IBC members to share their site-specific issues in a dedicated session on compliance culture, followed by operational updates from OGTR staff.

A noteworthy milestone during the year was the consultation on draft amendments to the *Gene Technology Act 2000*, which commenced on 13 September 2024. This was the culmination of many months of work by OGTR staff in supporting the then Department of Health and Aged Care with legislative drafting of amendments to the Act, to implement recommendations of the Third Review of the National Gene Technology Scheme.

Day 3 of the IBC Forum was dedicated to presentations and workshops on various amendments in the draft bill and new approaches to risk-tiering of applications. Webinars, jurisdictional roundtables and meetings with regulated entities were conducted during the public consultation period.

At the Australia–New Zealand Leaders meeting in 2024, the prime ministers decided to promote collaboration and alignment of regulatory approaches for genetically modified organisms (GMOs), noting the unique environments of Australia and New Zealand.[3]

With this objective in mind there were several meetings and exchanges of cooperation between the OGTR, the Department of Health, Disability and Ageing, the New Zealand Ministry of Business, Innovation and Employment (MBIE) and other New Zealand government agencies and stakeholders. Our package of legislative reforms assisted the MBIE in its development of the New Zealand regulatory framework for GMOs, as large parts of New Zealand's Gene Technology Bill 2024 are based on the Australian legislation.

The Hon Dr Shane Reti, New Zealand Minister for Science, Innovation and Technology, visited the OGTR and policy staff in the Department of Health, Disability and Ageing in May 2025. It was a welcome opportunity to meet with the minister, share experiences, discuss common areas of interest and acknowledge areas of difference.

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

Interactions and dialogue between the OGTR and New Zealand government agencies (including the responsible minister) have been collaborative, open and informative, with a view to greater cooperation between the OGTR and the New Zealand OGTR once it is established.

Minor amendments to the Gene Technology Regulations 2001 came into force in February 2025. These amendments were made to give the Gene Technology Regulator an additional function enabling appointed inspectors to audit Australian laboratories that hold poliovirus. Audits are required to meet Australia's international obligation of compliance with the World Health Organization's Global Action Plan for Poliovirus Containment.

This reporting period has been another busy year, with staff involved in many different activities across the office. Over 900 authorisations and approvals were issued, and we processed almost 100 self-reported incidents.

Meeting our performance targets

The Department of Health and Aged Care Portfolio Budget Statements (PBS), Outcome 1, Program 1.8 (Health Protection, Emergency Response and Regulation) describe the program objectives and performance targets for the OGTR: to protect human health and the environment through regulatory oversight of GMOs. This objective is delivered through the key activity of administering the National Gene Technology Scheme by assessing applications and issuing approvals, and by conducting monitoring and compliance activities for GMO approvals.

The PBS targets were met as follows:

- ≥98% of application decisions were made within statutory timeframes
- ≥98% of reported instances of non-compliance with conditions of GMO approvals were assessed.

The OGTR continued to support the work of the department and the Gene Technology Standing Committee to action and implement priorities endorsed by the Gene Technology Ministers' Meeting as set out in the Gene Technology Ministers' Meeting Action Plan 2023–2025.[4]

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

Applications and licences – what's new

Our licence approvals are categorised according to whether dealings (activities) with a GMO involve intentional release into the environment (DIR) or are contained, are primarily for research and do not involve release into the environment (DNIR). This year a total of 44 licences were issued, compared to 32 in the last reporting year.

We issued 12 DIR licences, of which 6 were for field trials of GM plants, 4 for clinical trials in humans, one for trial of a GM vaccine for respiratory disease in horses, and one for commercial supply of a puppy vaccine containing GM canine parvovirus.

Two of the plant field trials are for dairy protein production in canola and safflower; 2 are for canola modified for increased tolerance to abiotic stress and increased photosynthesis; one is for wheat modified for increased tolerance to environmental stress; and one is for sorghum modified for altered reproduction.

For the contained research DNIR licence category, 32 licences were issued this reporting period, of which the majority were for conduct of clinical trials (15) and for laboratory research, including medical research (11). The remaining licences were for manufacturing of vaccines, commercial supply of a gene therapy, and importation of GM grain.

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 and veterinary therapeutics.

Another determination was added to the GMO Register. Dealings with glyphosate-tolerant canola were considered to pose minimal risks to people or the environment after over 20 years of approval under a commercial licence. This is the first broadacre crop to be added to the register.

1

Monitoring and compliance activities

The Monitoring and Compliance team had another record year of activity with its program of site visits, face-to-face inspections and audits, and assessment of reports of non-compliance.

During 2024–25, 13 field trial sites were inspected for 3 plant species: canola, wheat and white clover. This was 42% of the total number of trial sites in operation at the start of the reporting period. Monitoring inspections of 10 licences for clinical trials or contained work were conducted, including one practice review. Findings of non-compliance were reported against conditions of 4 DIR licences. In addition, 128 certified facilities were inspected against certification requirements, of which 8 were high-level containment facilities.

The Monitoring and Compliance team received and assessed 98 reports relating to possible non-compliances with GMO approvals (licences, notifiable low risk dealings and certifications), achieving an outcome of 100% against the performance target of ≥98%.

Business improvement activities

Our IT modernisation project has been progressing well with the movement of legacy systems, including our applications database and monitoring and compliance database, from old platforms to new 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

In addition to our collaboration with New Zealand, OGTR staff continued to participate in international meetings, attending virtually at some conferences and face to face at others.

Our Assistant Secretary presented at a Life Sciences Network meeting in Wellington, New Zealand, in March 2025. This was an opportunity to share OGTR experiences of administering a national regulatory scheme for over 20 years, while the New Zealand Government was in consultation with stakeholders on new gene technology legislation.

We also hosted a delegation of gene technology regulators from West Africa and members of the African Agricultural Technology Foundation, which included government representatives from Nigeria, Burkina Faso, Ghana and Kenya.

The OGTR continues to lead Australian representation at the OECD Working Party on the Harmonisation of Regulatory Oversight in Biotechnology, including as chair of the working party.

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

As part of our program of IT modernisation and business improvement, we commenced a project of business process mapping across a range of applications received by the office. The purposes of this exercise were to realise efficiencies and to prepare for new legislation.

The team that is undertaking this complex task, the Business Process Mapping team, was the recipient of this year's Regulator's Achievement Award.

Complex processes for licence applications, approvals and variations of certifications and accreditations were investigated and mapped. The team delivered an excellent project in a short time, with well-developed stakeholder engagement and communication strategies.

Team members demonstrated leadership in bringing together different sections and sought ways to improve each business process, either by identifying redundancies in work practices or by reducing times for processing. This effort will result in improved processes that will support staff in achieving the object of the legislation.

The OGTR welcomed Dr Chris Schyvens, who commenced as the acting Executive Director of the Evaluation Branch in January 2025.

Challenges ahead

With many external factors influencing and impacting the work of government, maintaining a trusted and steady regulatory approach while being adaptable against a backdrop of fast-paced change is a constant challenge for all regulators. While we work on legislative changes to our own regulatory scheme, increasing our collaboration with other regulators at a national level and with New Zealand will make for more transparent decisions and outcomes. Stakeholder engagement will be even more important as we work to modernise the scheme and implement reform.

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.

2

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):[5]

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.

[5] www.finance.gov.au/government/managing-commonwealth-resources/regulator-performance-rmg-128

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 corporate plan[6] of the Department of Health, Disability and Ageing (formerly the Department of Health and Aged Care) sets out how its regulators intend to apply these principles. The department then reports on the performance of its regulators in its annual report.[7] 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 Letter 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.[8]

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.

Corporate governance arrangements

The Regulator is a statutory office holder with specific powers and functions under the Act. In exercising these functions, the Regulator is directly responsible to the Australian Parliament.

The then Assistant Minister for Health and Aged Care and for Indigenous Health, the Hon Ged Kearney MP, was the minister responsible for gene

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

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

8 www.ogtr.gov.au/resources/publications/gtr-statement-intent

technology regulation during the reporting period. Under section 133 of the Act, the Secretary of the Australian Government Department of Health, Disability and Ageing supports the Regulator with administrative and scientific staff. For administrative purposes, these 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 and funded by the Gene Technology Special Account.

The OGTR accesses a range of business management and reporting services directly through the department's Shared Services Centre. 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 the 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 2024–25 Department of Health, Disability and Ageing 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 (WHS) legislation; and compliance with the National Disability Strategy and the Australian Government's Workplace Diversity Policy.

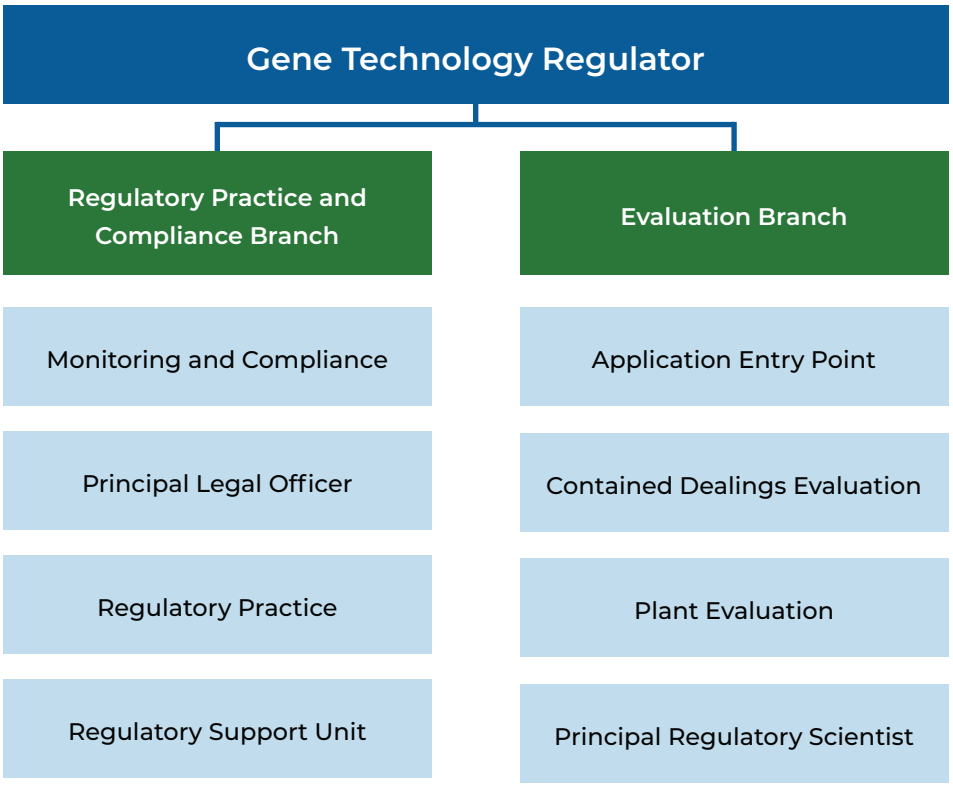
OGTR internal policies and practices cover the physical security and protection of confidential commercial information (CCI) received from applicants as required under the Act.

2

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, 2024–25



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 9 years at the Office of the Gene Technology Regulator. In her executive career, she 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 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.[9]

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.

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

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 departmental 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.

Office of the Gene Technology Regulator Executive Team

Evaluation Branch

Dr Chris Schyvens has been the acting Executive Director of the Evaluation Branch since January 2025. His responsibilities encompass overseeing the evaluation of licence applications and other authorisations relating to dealings with GMOs, as well as science-related projects that maintain and improve the technical capabilities of the OGTR.

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

The Application Entry Point receives and acknowledges all applications to the OGTR. Staff in this area 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 the office library.

The Contained Dealings Evaluation Section prepares risk assessment and risk management plans (RARMPs) in response to applications for dealings not involving intentional release of GMOs into the environment (DNIRs) – also known as 'contained dealings' – and applications for non-plant dealings involving intentional release (DIRs). These include clinical trials of live GMOs such as vaccines or gene therapies. The section also processes applications for certification of containment facilities. This includes inspecting high-level and large-scale facilities and providing advice to accredited organisations and institutional biosafety committees on the classification of dealings with GMOs.

The Plant Evaluation Section assesses 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.

2

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.

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 once on the RARMP. The Regulator may also seek advice on other applications.

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

The committee met 7 times during 2024–25. 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 once during 2024–25. Communiqués from previous committee meetings, which provide an overview of key matters discussed and resolutions, are published on the OGTR website.

The GTECCC has been developing its draft guidance for communicating on gene technology. The draft was published on 12 September 2024 with a public call for comment. GTECCC members also presented the document at the 10th Institutional Biosafety Committee Forum on 16 September. The public comment period closed on 8 November 2024 and the GTECCC considered submissions and other amendments at its meeting on 6 February 2025.

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 2024–25 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.

3

Operational performance

This section describes the OGTR's achievements and performance against Outcome 1, Program 1.8 (Health Protection, Emergency Response and Regulation) of the 2024–25 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 2024–25

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 GM therapeutic or GM 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, GMOs 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 may 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 2024–25 the OGTR received 952 applications and 751 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 941 approvals over a range of application types. There were no appeals associated with decisions made on applications under the gene technology legislation.

As at 30 June 2025 there are 2,309 certified facilities, 66 DIR licences where release of GMOs into the environment is authorised, 172 DNIR licences where GMOs must be contained (Table 2), and 3,077 active notifiable low risk dealings (NLRDs).

Table 1: Applications and notifications, 2024–25

Application type	Received	Withdrawn	Approved[a]	Refused	Ceased consideration[b]	Under consideration[c]
Accreditation	18	1	17			7
Alternative facility request for an NLRD						
CCI declaration for accreditation						
CCI declaration for DIR licence	12		10		1	6
CCI declaration for DNIR licence	19		3		1	32
Certification	90	4	86			5
DIR licence	13		12		1	5
DNIR licence	32		32		1	7
Lifting suspension of certification[d]	66		68			
NLRD notification	751					
GMO Register						
Surrender of accreditation	6		5			1
Surrender of certification	108		107			1
Surrender of DIR licence	2		2			1
Surrender of DNIR licence	13		12		1	2

Table 1: Continued

Application type	Received	Withdrawn	Approved[a]	Refused	Ceased consideration[b]	Under consideration[c]
Suspension of certification[d]	99	2	97			
Transfer of certification	15		15			
Transfer of DIR licence						
Transfer of DNIR licence	1		1			
Variation of accreditation	7		6			2
Variation of certification	407	21	422	1		24
Variation of DIR licence	8		8			
Variation of DNIR licence	33		35			6
Cancellation of accreditation	1		1			
Inadvertent dealings	2		2			
Total	**1,703**	**28**	**941**	**1**	**5**	**99**

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 2024–25 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 2025.

[d] Suspension and lifting of suspension of certification include both those requested by the applicant and those initiated by the Regulator. Those reported in 2024–25 were all requested by the applicant.

Table 2: Status of primary applications and notifications from the start of the scheme until 30 June 2025

Application type	Received	Withdrawn	Approved	Not approved[a]	Under consideration[b]	Current	Expired	Surrendered
Accreditation	330	3	321	1	7	221	n/a	98
Certification	5,149	168	4,967	9	5	v	406	2,252
DIR	214	19	188	7	5	66	1	121
DNIR	734	119	585	3	7	172	192	220
NLRD	15,014	36	n/a	n/a	n/a	3,077	11,937	n/a
Total	**21,441**	**345**	**6,061**	**20**	**24**	**5,845**	**12,536**	**2,691**

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 2025.

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 12 DIR licences during 2024–25.

Details of the traits introduced into the modified organisms are provided in Table 3. Eleven licences issued in 2024–25 were for research (limited and controlled releases).

Of the 12 DIR licences issued in 2024–25, 7 were issued to companies, 3 to universities, one to CSIRO and one to a local health district. All licence decisions were made within statutory timeframes (see 'Timeframes' in Appendix 2).

Table 3: DIR licences issued, 2024–25

OGTR ID	Applicant	Parent organism	Introduced trait	Type of release	Issued
DIR-202	Intervet Australia Pty Ltd	Canine parvovirus (CPV)	Viral attenuation, vaccine	Commercial release	21/08/2024
DIR-204	Trigall Australia Pty Ltd	Wheat	Abiotic stress tolerance; selectable marker	Limited and controlled release	15/08/2024
DIR-205	CSIRO	Canola	Abiotic stress tolerance	Limited and controlled release	30/09/2024
DIR-206	Western Sydney Local Health District	Bacteriophage	Lytic and/or non-integrating	Limited and controlled release	10/02/2025
DIR-208	Novotech (Australia) Pty Limited	Vaccinia virus	Conditional replication in cancer cells	Limited and controlled release	11/03/2025
DIR-209	The University of Queensland	Sorghum	Altered reproduction	Limited and controlled release	6/03/2025
DIR-210	Doherty Clinical Trials Ltd	Influenza virus	Wild-type genome synthesised via gene technology	Limited and controlled release	2/04/2025
DIR-211	Miruku Australia Pty Ltd	Safflower	Introduction of dairy protein	Limited and controlled release	29/05/2025

Table 3: Continued

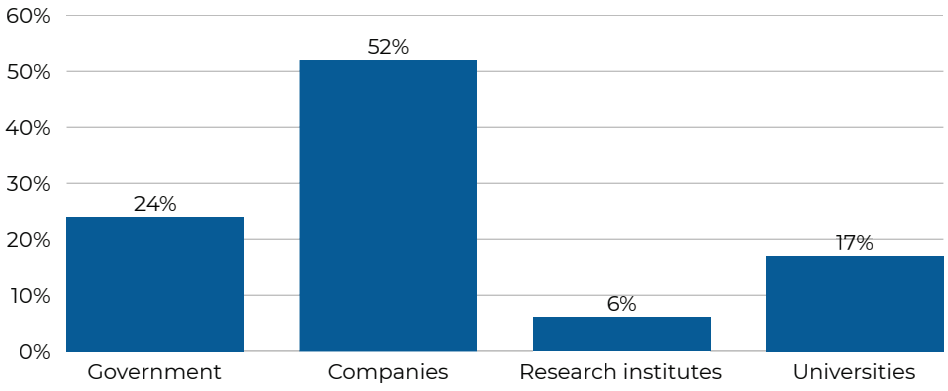
OGTR ID	Applicant	Parent organism	Introduced trait	Type of release	Issued
DIR-212	The University of Adelaide	Canola	Increased photosynthesis; increased photorespiration	Limited and controlled release	21/05/2025
DIR-213	Novotech (Australia) Pty Limited	Adenovirus	Replication competent oncolytic adenovirus expressing an immunomodulatory molecule	Limited and controlled release	11/06/2025
DIR-214	The University of Queensland	Adenovirus	Antigen expression	Limited and controlled release	4/06/2025
DIR-215	Miruku Australia Pty Ltd	Canola	Dairy protein production	Limited and controlled release	16/06/2025

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 188 DIR licences issued to date:

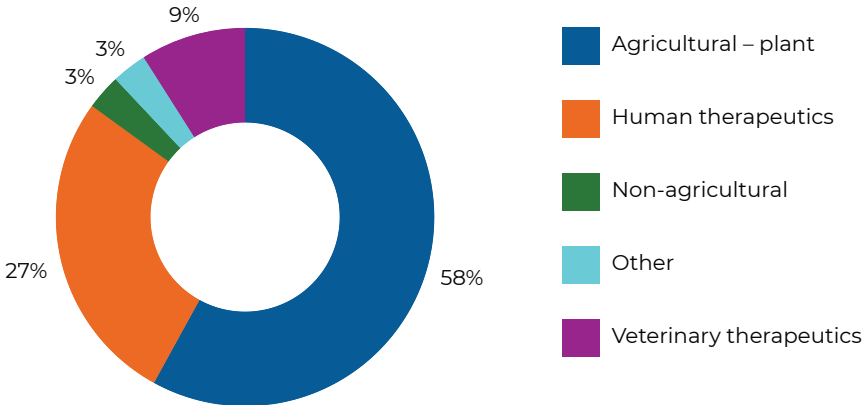
- 52% have been to companies
- 24% have been to government agencies
- 6% have been to research institutes
- 17% have been to universities.

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



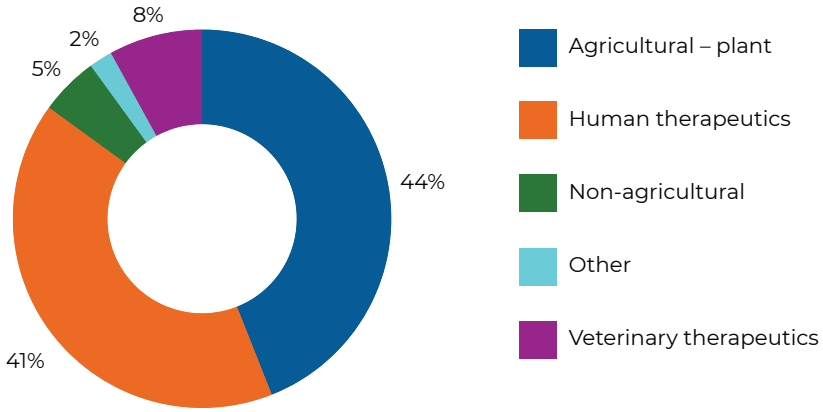
As at 30 June 2025, 66 of the 188 DIR licences issued since the beginning of the scheme were current. This consists of 38 (58%) agricultural – plant, 18 (27%) human therapeutics, 2 (3%) non-agricultural – plant, 6 (9%) veterinary therapeutics, and 2 (3%) other licences (Figure 3).

Figure 3: Distribution of DIR licences current as at 30 June 2025, by purpose



Most current DIR licences are for agricultural crops. Over the past 5 years the majority of new DIR licences issued have been for agricultural crops and human 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, 40 (61%) are issued to companies, 12 (18%) to universities, 11 (17%) to research institutes and 3 (4%) to government organisations.

Of the current DIR licences shown in Figure 6, 29 (44%) are held by organisations in Victoria (Vic), 20 (30%) in New South Wales (NSW), 9 (14%) in Queensland (Qld), 5 (8%) in South Australia (SA), 2 (3%) in the Australian Capital Territory (ACT) and one (1%) in Tasmania (Tas).

Figure 5: Distribution of DIR licences current as at 30 June 2025, by organisation type

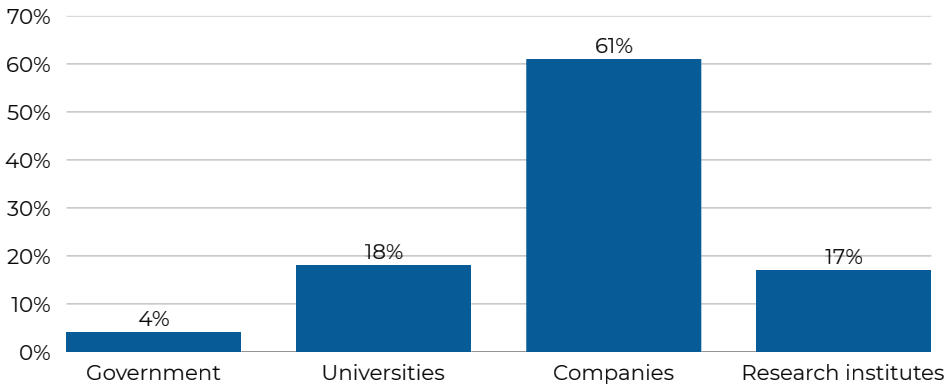
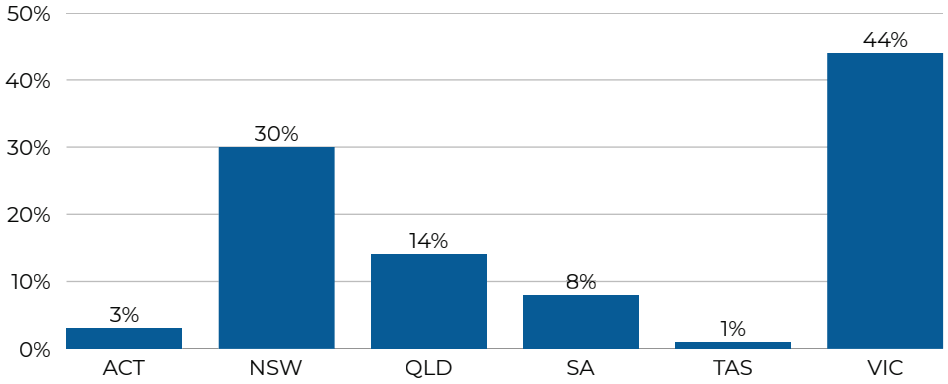


Figure 6: Distribution of DIR licences current as as at 30 June 2025, by state or territory



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 2024–25 the Regulator issued 32 DNIR licences (see Table 4) for work in laboratories, to manufacture therapeutic GMOs, to import GM seed, and for clinical trials or commercial supply of GMO therapeutics. All decisions were made within the statutory timeframe (see 'Timeframes' in Appendix 2).

Table 4: DNIR licences issued, 2024–25

OGTR ID	Applicant	Project title	Date issued
DNIR-695	BioMarin Pharmaceutical Australia Pty Ltd	Supply of Roctavian (valoctocogene roxaparvovec) to patients with severe haemophilia A	20 August 2024
DNIR-696	Seqirus Pty Ltd	Clinical trial of self-amplifying mRNA vaccine for pandemic influenza	31 July 2024
DNIR-697	Public and Environmental Health Reference Laboratories, Pathology Queensland	Destruction of nonviable Hendra virus (HeV) and Australian bat lyssavirus (ABLV) recombinant plasmids	10 September 2024
DNIR-698	Murdoch Children's Research Institute	A clinical trial of ECUR-506 for treatment of males with genetically confirmed neonatal onset ornithine transcarbamylase (OTC) deficiency	19 September 2024
DNIR-699	Seqirus Pty Ltd	Clinical trial of a multi-valent self-amplifying mRNA vaccine for the prevention of Influenza	31 July 2024
DNIR-700	TFS Trial Form Support Australia Pty Ltd	Clinical trial of AAV gene therapy (AGTC-501) for X-linked retinitis pigmentosa	3 October 2024
DNIR-701	Source Certain Operations Pty Ltd	Import of corn, soybean and wheat	10 October 2024
DNIR-702	The University of Adelaide	Engineering bacteria to make bacterial toxins for cancer treatment	17 October 2024
DNIR-703	Medpace Australia Pty Ltd	A clinical trial of UB-VV111 in combination with rapamycin for the treatment of relapsed/refractory CD19+ hematologic malignancies	19 November 2024

OGTR ID	Applicant	Project title	Date issued
DNIR-704	The Children's Hospital Westmead	A clinical trial of ECUR-506 for treatment of males with genetically confirmed neonatal onset ornithine transcarbamylase (OTC) deficiency	30 October 2024
DNIR-705	Western Sydney Local Health District	Clinical trial of GM AAV for treatment of genetic XYLT2 deficiency	12 November 2024
DNIR-706	La Trobe University	Expression of *Staphylococcus aureus* toxins	14 January 2025
DNIR-707	The Royal Children's Hospital	Bermagene geperpavec (B-VEC)	19 December 2024
DNIR-708	Seqirus Pty Ltd	Preparation of influenza vaccines using attenuated influenza A viruses	22 January 2025
DNIR-709	BioCina Pty Ltd	Manufacture of genetically modified *Salmonella enterica enterica* serovar typhimurium bacterial strains to derive nanocells	13 January 2025
DNIR-710	The University of Melbourne	Exploring gene drives in *Plasmodium* to control malaria	12 February 2025
DNIR-711	The University of Melbourne	Understanding seasonal coronavirus infection and disease	10 February 2025
DNIR-712	The Florey Institute of Neuroscience and Mental Health	Prodromal disease characterisation in murine models of familial prion disease	24 February 2025
DNIR-713	The University of Sydney	A constitutive VenomORF library expression platform	10 February 2025
DNIR-714	IQVIA RDS Pty Ltd	In vivo gene therapy to generate anti-BCMA CAR-T cells in patients with relapsed and refractory multiple myeloma	6 March 2025

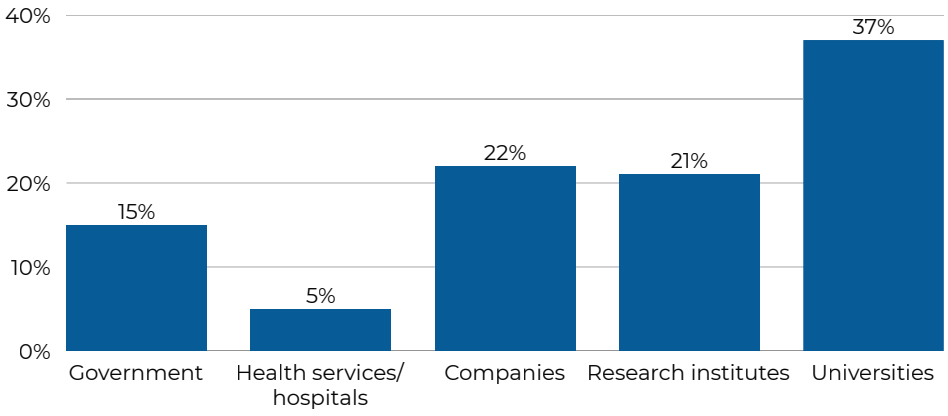
OGTR ID	Applicant	Project title	Date issued
DNIR-716	PPD Australia Pty Ltd	A clinical trial of an AAV-based gene therapy (EPI-321) for the treatment of facioscapulohumeral muscular dystrophy (FSHD) in adults	24 March 2025
DNIR-717	PPD Australia Pty Ltd	Phase 1 multicentre, open-label study of CB-010, a CRISPR-edited allogeneic anti-CD19 CAR-T cell therapy in patients with refractory systemic lupus erythematosus	25 March 2025
DNIR-718	The University of Adelaide	Investigating immune evasion mechanisms in cancer	31 March 2025
DNIR-719	The University of Adelaide	Use of genetically modified *Staphylococcus aureus* strain to express an extracellular virulence factor	24 March 2025
DNIR-720	The University of Newcastle	Characterisation of toxin biosynthesis pathways from environmental microorganisms	12 May 2025
DNIR-721	QIMR Berghofer	Obesity linked cancer	16 April 2025
DNIR-722	James Cook University	Production of transgenic *Nippostrongylus brasiliensis* hookworms that secrete therapeutic foreign molecules	28 April 2025
DNIR-723	Boehringer Ingelheim Pty Ltd	Phase I open-label, dose escalation trial of BI 1831169 monotherapy and in combination with an anti-PD-1 mAb in patients with advanced or metastatic solid tumors	2 May 2025
DNIR-724	Novotech (Australia) Pty Limited	Clinical trial of GM AAV for treatment of amyotrophic lateral sclerosis	30 January 2025
DNIR-725	ICON Clinical Research Pty Limited	Clinical trial of genetically modified adeno-associated virus for the treatment of haemophilia B	30 April 2025

OGTR ID	Applicant	Project title	Date issued
DNIR-726	CTI Clinical Trial and Consulting Services Australia Pty Ltd	Clinical trial of GM adeno-associated virus for treatment of frontotemporal dementia	13 May 2025
DNIR-727	Premier Research (Australia) Pty Ltd	A Phase I study to evaluate the safety and tolerability of a lentiviral vector (INT2106) in participants with refractory generalised myasthenia gravis	17 June 2025

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

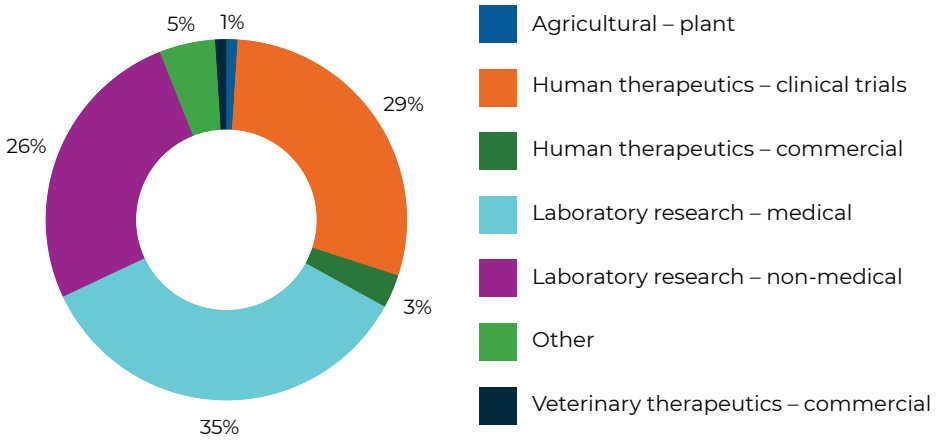
The types of organisations to which DNIR licences have been issued since commencement of the scheme are shown in Figure 7. Of the 585 DNIR licences issued to date, 215 (37%) have been issued to universities 127 (22%) to companies, 124 (21%) to research institutes, 90 (15%) to government agencies and 29 (5%) to health services/hospitals.

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



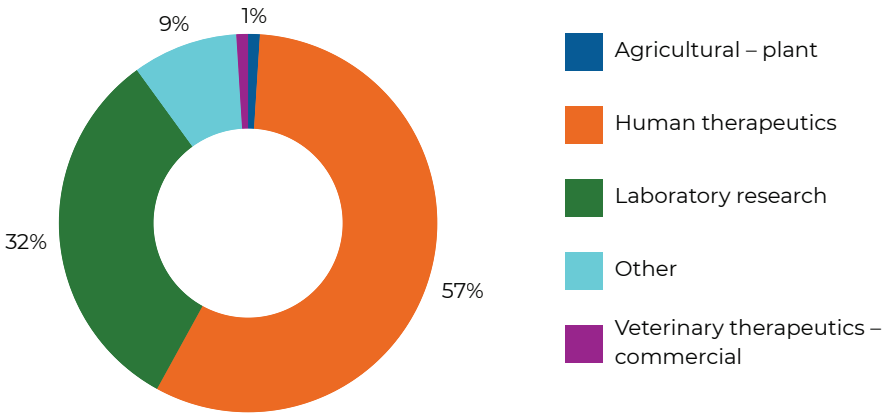
At 30 June 2025, 172 DNIR licences are current. The majority of these are for laboratory research – 35% for medical research and a further 26% for non-medical laboratory research. Clinical trials with GMO therapeutics comprised 29%, commercial therapeutics 3%, veterinary therapeutics 1% and agricultural plant licences (bulk grain imported for crushing) 1%. Five per cent of the licences issued were for the manufacture of vaccines and toxins or for the treatment of patients under compassionate use provisions (Figure 8).

Figure 8: Distribution of DNIRs current as at 30 June 2025, by purpose



In the past 5 years, the focus of DNIRs has been on human therapeutics and laboratory research, predominantly with a medical focus (89%). 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



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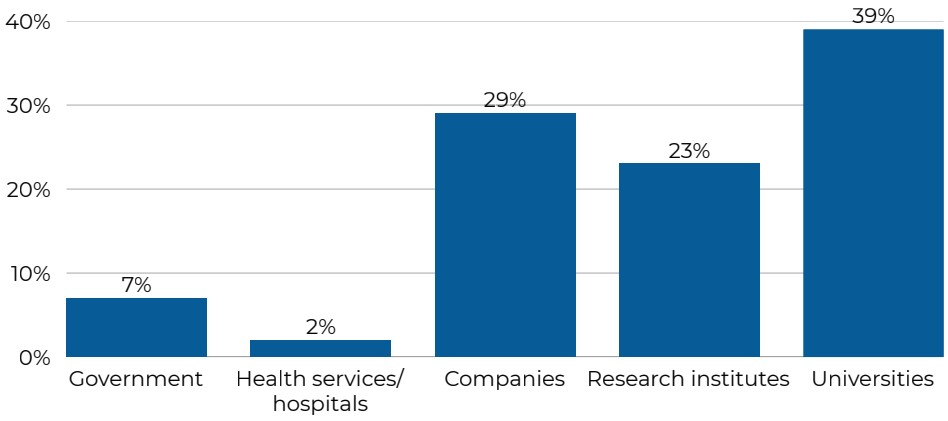
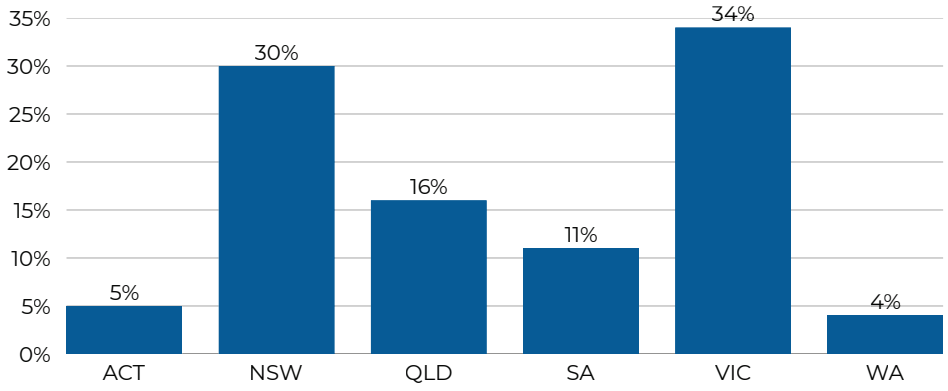
Of the current DNIR licences, 67 (39%) are held by universities, 40 (23%) by research institutes, 49 (29%) by companies, 12 (7%) by government agencies and 4 (2%) by health services/hospitals (Figure 10).

Figure 10: Distribution of DNIR licences current as at 30 June 2025, by organisation type



The current DNIR licences are held by organisations in 6 states and territories. Most of them are held in Vic, 59 (34%) and NSW, 51 (30%). Of the rest, 28 (16%) are held in Qld, 19 (11%) in SA, 9 (5%) in the ACT and 6 (4%) 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 2025, 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 2024–25, 751 NLRD notifications were received. As in past years, these were predominantly for research work. Figure 12 shows an increase in the number of NLRDs received in 2024–25 compared to 2023–24; however, this is still lower than the numbers for the previous 3 years. The majority of NLRDs (643 NLRDs, 86%) were received via the online services portal.

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

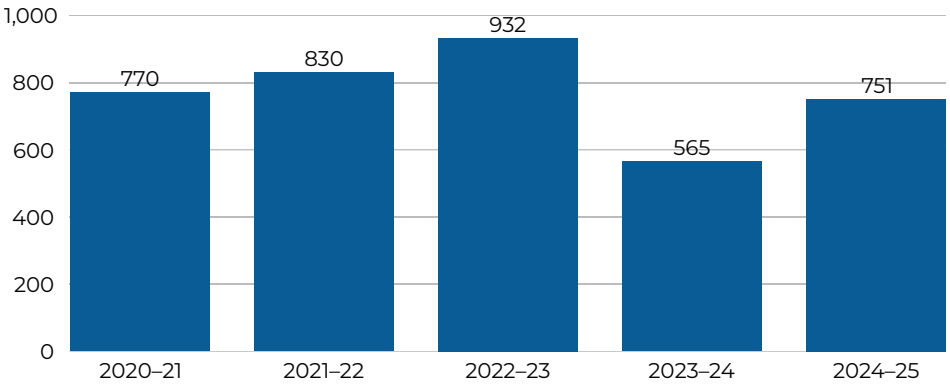


Figure 13 shows the proportion of NLRDs reported by different types of organisations over the last 5 years. The distribution has not notably changed over the past 5 years.

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

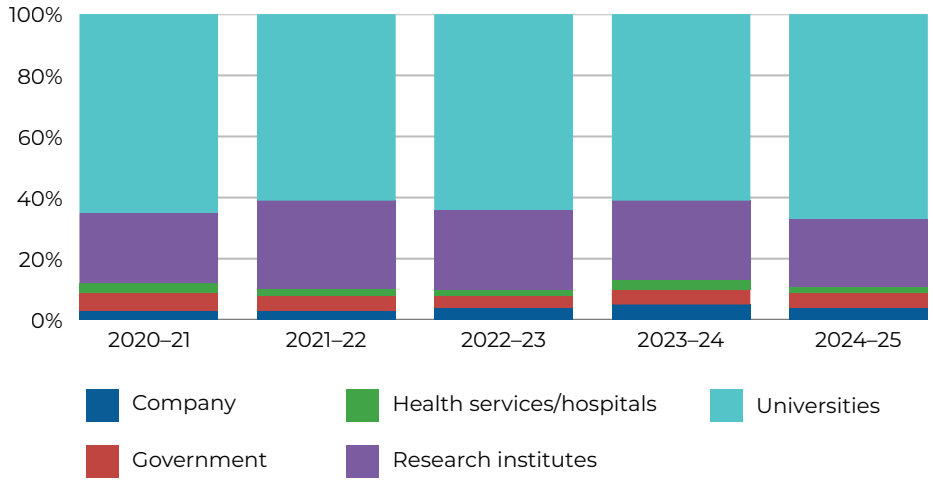
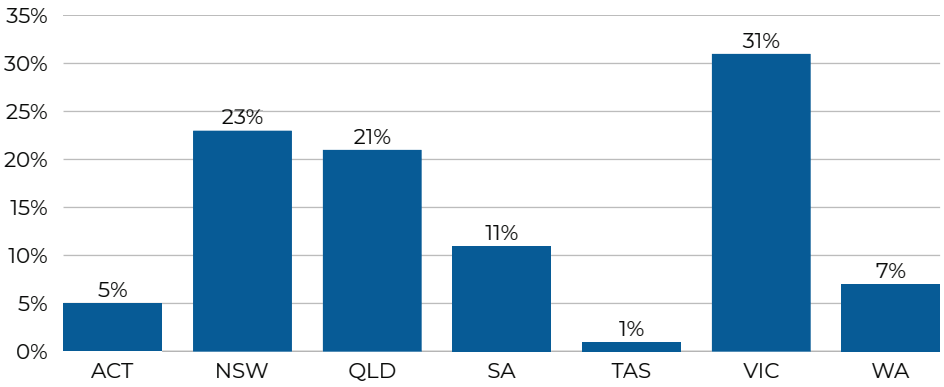


Figure 14 shows the proportion by state or territory of NLRDs notified by an organisation that were current at 30 June 2025.

Figure 14: Distribution of all current NLRDs at 30 June 2025, 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 for 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 2024–25 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 alternative facility requests and 12 alternative 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. One dealing was added to the GMO Register during this reporting period: Register 003. This addition to the GMO Register was for all dealings with a GM canola known as MON-00073-7 canola, which is tolerant to the herbicide glyphosate.

GM canola

Emergency dealing determinations

An emergency dealing determination (EDD) 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 2024–25 the OGTR did not receive any requests for advice in relation to making EDDs. No determinations were made, and none were in effect.

Licences for inadvertent dealings

Part 5 of the Act allows the Regulator to grant an inadvertent dealings licence (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 2024–25 the Regulator issued 2 inadvertent dealings licences (Table 5).

Table 5. Inadvertent dealings licences issued, 2024–25

Title	Description	Issue date	Expiry date
ID-08	Licence authorising anyone who inadvertently comes into possession of GM maize to dispose of it	18 December 2024	17 December 2025
ID-09	Licence authorising anyone who inadvertently comes into possession of GM soybean to dispose of it	11 April 2025	10 April 2026

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 2024–25, 17 accreditations were issued. One accreditation was cancelled in this period. A total of 221 organisations held accreditation at 30 June 2025.

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 (52%) 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 2025, by location of headquarters

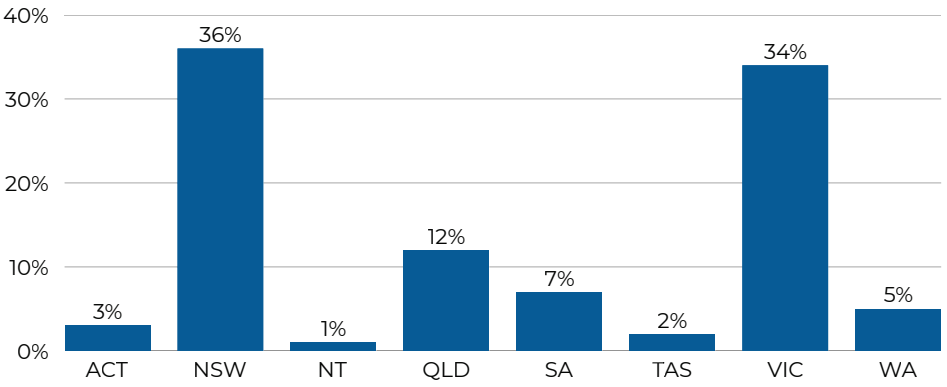
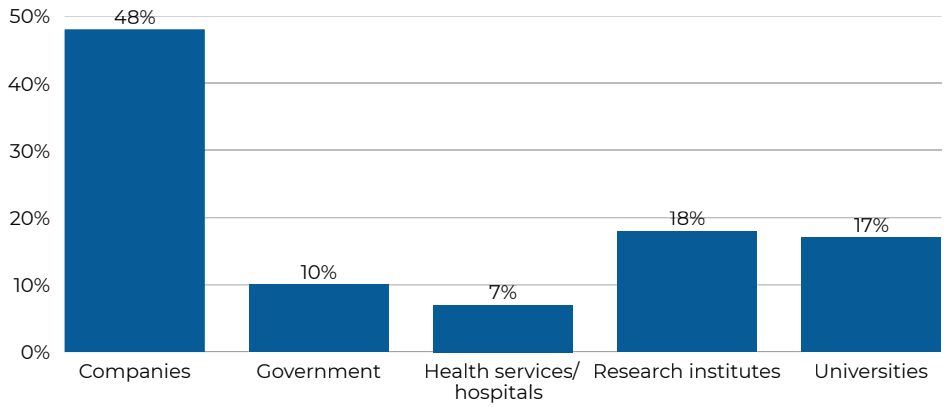


Figure 16: Types of organisations accredited as at 30 June 2025



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 6. The guidelines are informed by the Australian standard AS/NZS 2243.3 (2022) and by international best practice for biosafety containment.

The OGTR-certified facilities at 30 June 2025 are listed by facility type and containment level in Table 6. PC2 laboratories are the most common type of facility certified by the Regulator (1,381 PC2 laboratories).

Table 6: Number of OGTR-certified facilities at 30 June 2025

Facility type	PC1	PC2	PC3	PC4	Total
Animal facility		256	6		262
Aquatic facility		36			36
Constant temperature room		39			39
Facility	288		8	5	301
Invertebrate facility		51	2		53
Laboratory		1,381	15		1,396
Large grazing animal facility	1	61			62
Large-scale facility		20			20
Plant facility		140			140
Total	**289**	**1,984**	**31**	**5**	**2,309**

In 2024–25, 86 new certifications for physical containment facilities were issued. The majority (50%) were issued to universities. A further 27% were issued to companies, 12% to research institutes, 7% to health services/hospitals and 5% to government organisations (Figure 17).

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 2024–25, OGTR staff performed inspections and certified 2 new PC2 large-scale facilities. In addition, OGTR staff performed recertification inspections of 19 facilities (7 PC2 large scale, 9 PC3 laboratory, 2 PC3 animal and 1 PC3 invertebrate facility) and recertified 13 of these facilities. One facility was recertified without an inspection as it was recertified under suspension and will be inspected before the suspension is lifted. One facility was inspected but not recertified. Three of the facility recertification processes are still in progress.

In addition, 14 facilities inspected in 2023–24 were certified in 2024–25.

Figure 18 shows the proportion of current OGTR-certified facilities by organisation type. The majority (58%) belong to universities, followed by research institutes (22%), others (9%), health services/hospitals (4%) and government organisations (7%).

Figure 19 shows the proportion of current OGTR-certified facilities by location. The majority are in Vic (37%), then NSW (23%), Qld (17%), SA (11%), WA (7%), ACT (4%), Tas (1%) and NT (1%).

Figure 17: Facilities certified in 2024–25, by organisation type

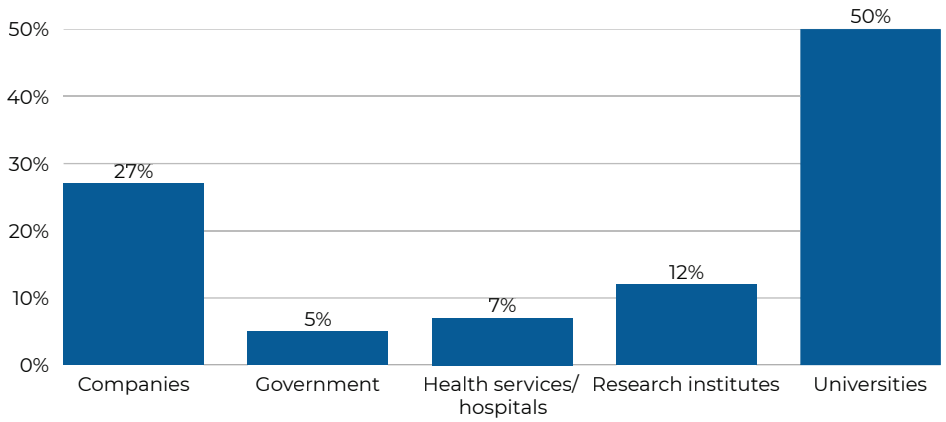


Figure 18: OGTR-certified facilities as at 30 June 2025, by organisation type

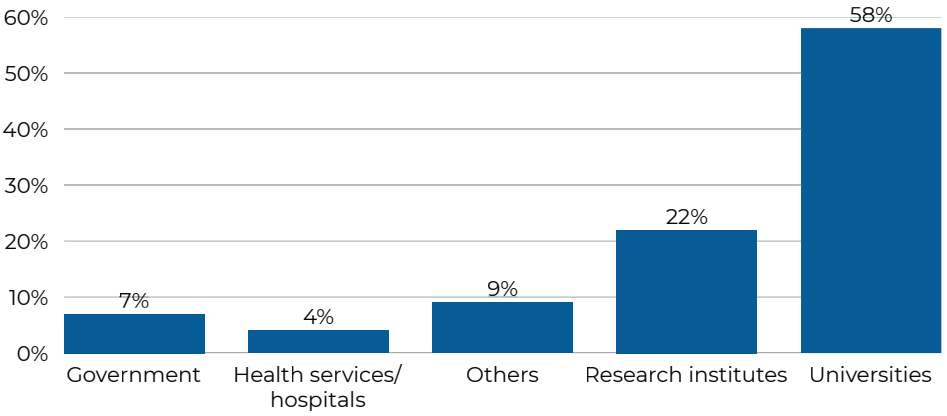
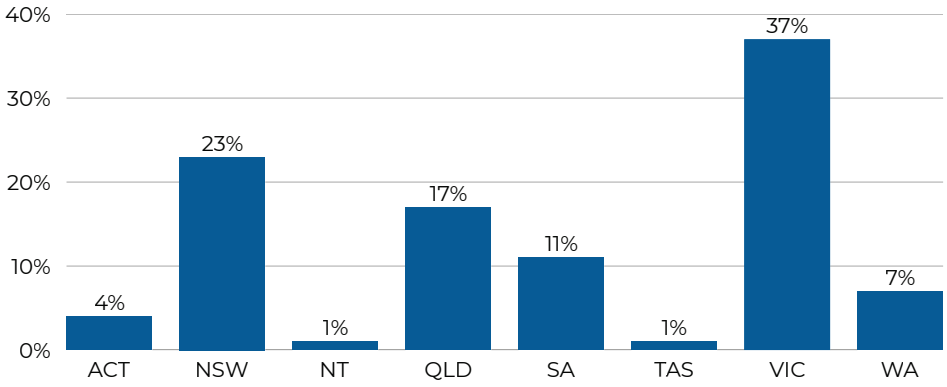


Figure 19: OGTR-certified facilities as at 30 June 2025, by location



Application trends

The numbers of some types of primary authorisations issued during 2024–25 were largely similar to those in previous years. However, there was an increase in the number of licence applications approved this year for both DIRs and DNIRS (Table 7). The number of DIR licences issued was double the number issued in the previous year. The number of accreditation applications approved has fluctuated in the last 5 years, 2024–25 being a period when a large number of accreditation applications was received and approved. However, the number of certifications approved was the lowest for the past 5 years.

Table 7: Approval of main types of applications

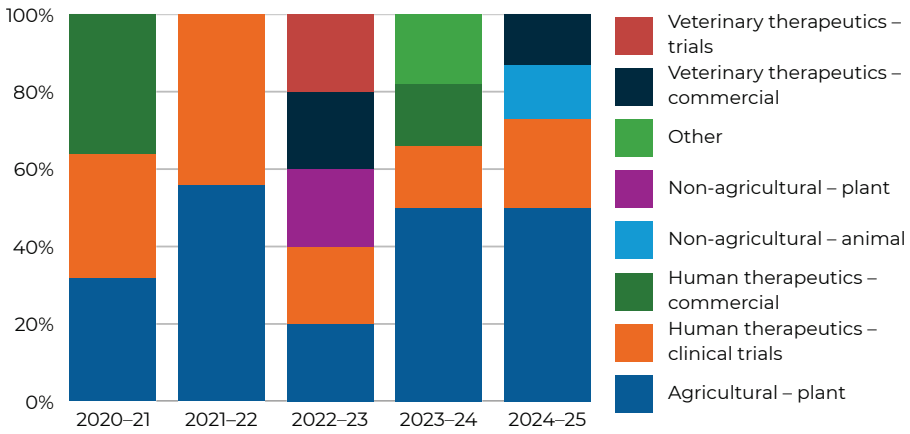
Application type	2020–21	2021–22	2022–23	2023–24	2024–25
Accreditation	10	18	13	10	17
Certification	101	97	132	94	86
DIR	9	7	5	6	12
DNIR	19	13	12	26	32

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 DIR licence was issued for a commercial GMO veterinary therapeutic in 2024–25: DIR-202 for a vaccine for dogs. One DNIR licence was issued for supply of a gene therapy for patients with haemophilia A. This is similar to the small number of commercial licences for GMO human or animal therapeutics over the past few years, with the exception of a peak of 4 licences in 2020–21. There were also 20 clinical trials (DIR and DNIR) with GMOs issued in 2024–25, continuing the trend of increased interest in this area (Figure 20).

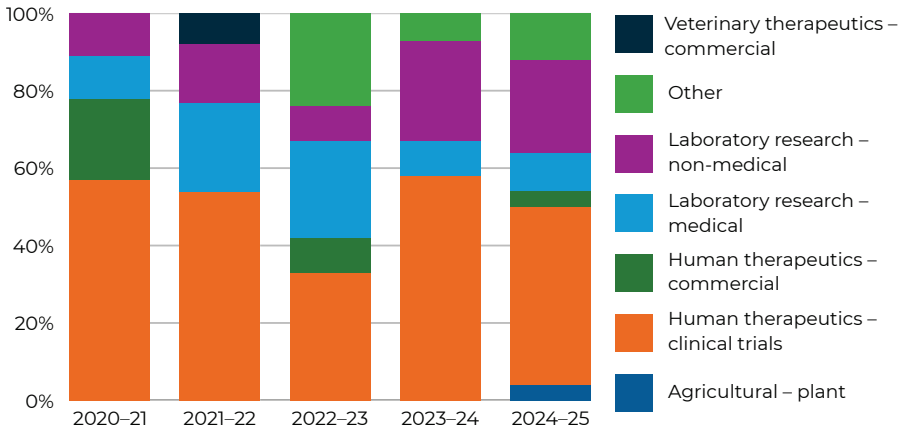
No licences were issued for commercial GM crops in 2024–25, but the trend of a variety of plant species being approved for field trials continued. For the first time, field trials of GM plants (canola and safflower) producing dairy proteins were authorised.

Figure 20: Focus of DIR licences, 2020–21 to 2024–25



The number of DNIR applications in 2024–25 (32) was higher than the 10-year average of 19.7 DNIR applications per year – a continuing trend of increasing work with GMOs in clinical research. The fields of research authorised under DNIR licences over the past 5 years are further analysed in Figure 21. In 2024–25, approximately 50% were for clinical trials with therapeutic GMOs, as also seen in previous years, with the exception of 2022–23, when relatively few DNIR licences for clinical trials were issued.

Figure 21: Fields of research authorised under DNIR licences, 2020–21 to 2024–25



3

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. All these declarations are associated with licence applications. 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 2024–25 the Regulator made 13 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 129 surrender requests in 2024–25 and approved 107 for surrender of certification of a physical containment facility, 2 for surrender of DIR licences, 12 for surrender of DNIR licences and 5 for surrender of accreditations. In addition, at 30 June 2025, 5 requests were still under consideration and no requests had been 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 471 variation requests in 2024–25. Of these, 6 were for accreditations, 8 were for DIRs, 35 were for DNIRs and 422 were for certifications.

Cancellation

The Regulator cancelled 1 accreditation during 2024–25.

Monitoring dealings with genetically modified organisms

This section provides information on the OGTR's compliance inspection activities during 2024–25.

During 2024–25 the OGTR conducted 243 monitoring visits, comprising:

- 6 monitoring inspections of DIR licences
- 9 monitoring inspections of DNIR licences
- 128 monitoring inspections of certified facilities
- 2 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.[10]

During 2024–25 there were 68 DIR licences in force, held by 32 accredited organisations. These comprised:

- 38 limited and controlled release licences for research purposes (17 for plant field trials)
- 30 commercial release licences (22 for plant crops).

The OGTR inspected 5 of the 17 limited and controlled plant field trial licences (which may have comprised multiple site visits per licence).

PC2 plant facility

[10] Details are in the Monitoring Protocol on the OGTR website.

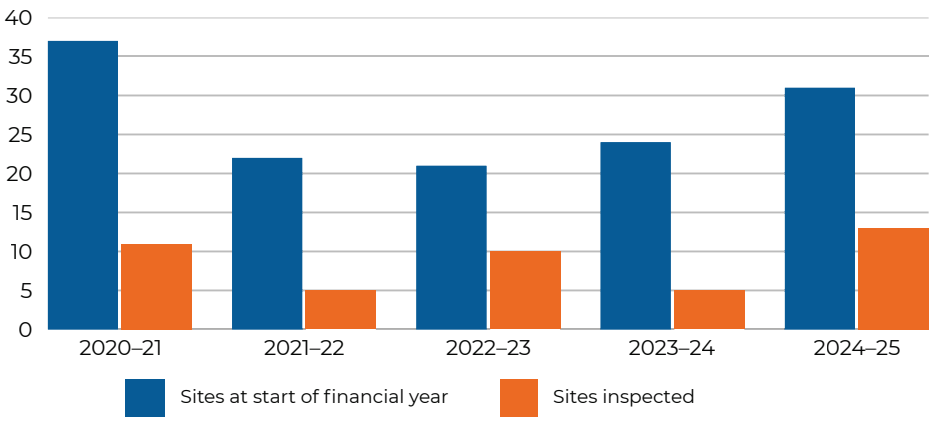
Outcome of compliance inspection activities

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 2024–25, 31 licensed field trial sites were operating, of which 8 were current and 23 were subject to post-harvest monitoring conditions (Figure 22).

Figure 22: Number of field trial sites and number inspected each year, 2020–21 to 2024–25



The OGTR inspected 3 plant species across 13 field trial sites in SA and Vic during 2024–25 (Table 8).

Table 8: Number of licensed GM plant DIR trial sites at beginning and end of 2024–25, and number inspected in 2024–25, by plant type

Species	Trial sites as at 1 July 2024	Trial sites as at 30 June 2025	Trial sites inspected during 2024–25
Banana	2	2	0
Canola	13	15	1
Cotton	4	7	0
Sorghum	1	0	0
Wheat	10	14	11
Wheat and barley	0	1	0
White clover	1	1	1
Total	**31**	**40**	**13**

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 2024–25, 128 certified facilities were inspected for compliance across the range of facility types (Table 9); this includes 8 high-level containment facilities.

In addition, 10 licences for clinical trials or contained dealings were subject to monitoring inspections or practice reviews in 2024–25 (Table 10).

Table 9: Number of compliance inspections of certified facilities (by type) conducted during 2024–25

Containment type	PC level and facility type	Inspections
Lower level	PC1 facility	0
	PC2 animal	15
	PC2 aquatic	4
	PC2 invertebrate	6
	PC2 laboratory	88
	PC2 plant	7
Higher level	PC2 large scale	0
	PC3 animal	1
	PC3 laboratory	1
	PC3 facility	2
	PC4 facility	4
Total		**128**

PC2 laboratory

Table 10: Compliance inspections and practice reviews of contained licences and clinical trials conducted during 2024–25

Organisation	State	Licence
Griffith University	Qld	DNIR-617
Janssen-Cilag Pty Ltd	Vic	DNIR-669
Macfarlane Burnet Institute for Medical Research and Public Health	Vic	DNIR-307
Novotech (Australia) Pty Ltd	SA	DNIR-629
Novotech (Australia) Pty Ltd	SA	DNIR-671
Novotech (Australia) Pty Ltd	SA	DNIR-683
The University of Melbourne	Vic	DNIR-686 (PR)
The University of Queensland	Qld	DNIR-616
The University of Queensland	Qld	DNIR-518
The Walter and Elizabeth Hall Institute of Medical Research	Vic	DNIR-649
Total		**10**

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.

During 2024–25 the OGTR carried out one inspection and one practice review of DIR licences that were not related to plant field trials or clinical trials (other category) (Table 11).

Table 11: Compliance inspections and practice reviews of other DIR licences conducted during 2024–25

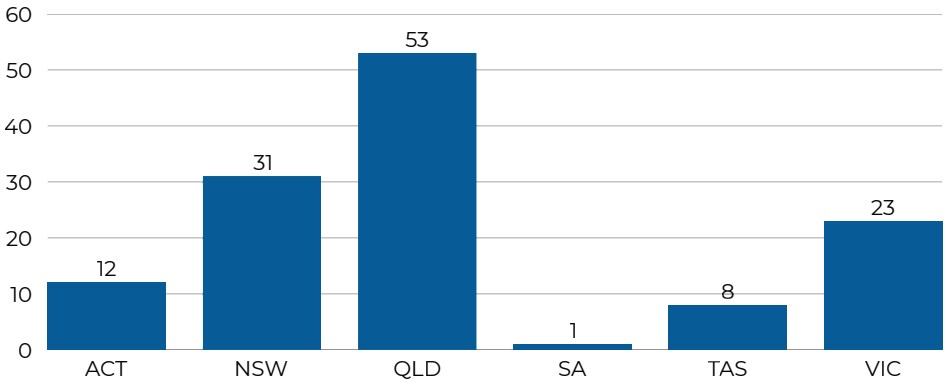
Organisation	State	Licence
Cauldron Molecules Pty Ltd	NSW	DIR-200
University of Tasmania	Tas	DIR-195 (PR)
Total		**2**

DIR = dealing involving intentional release of a GMO into the environment; PR = practice review.

Locations of facility compliance inspections

Certified facilities are located in all Australian states and territories (Figure 19). In 2024–25, monitoring activities took place in the ACT, NSW, Qld, SA, Tas and Vic (Figure 23).

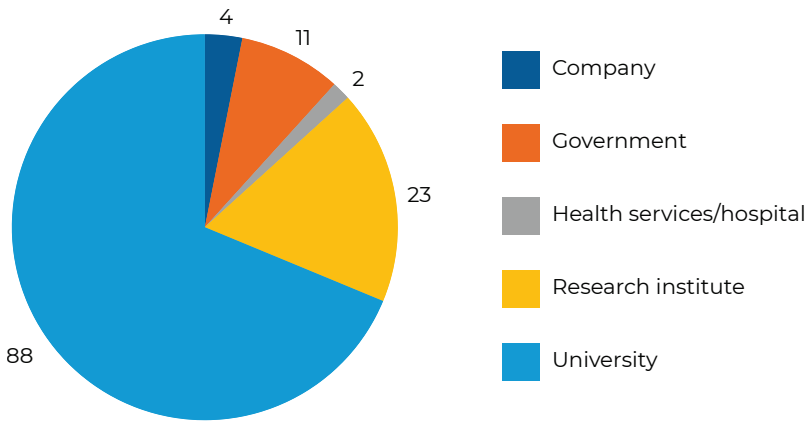
Figure 23: Number of certified facility compliance inspections in 2024–25, by state and territory



Types of organisations inspected

Figure 24 shows the distribution of inspections during 2024–25 by organisation type. Universities comprised the majority of inspections, followed by research institutes, government, companies and health services/hospitals. This distribution is similar to the overall distribution of certified facilities by organisation type, as seen in Figure 18.

Figure 24: Certified facility compliance inspections in 2024–25, 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.[11]

Non-compliance findings for GMO dealings involving intentional release

In 2024–25 the OGTR made findings of non-compliance with the conditions of 4 DIR licences.

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

3

Organisation	The University of Adelaide
Licence number	DIR 201
Summary of dealing	This licence allows the University of Adelaide to undertake field trials with wheat and barley genetically modified for yield enhancement.
Findings	The University of Adelaide was found to be non-compliant with licence condition 13 as it did not obtain a signed and dated record from an individual indicating that they had been informed of, understood and agreed to be bound by licence conditions, prior to permitting the individual to conduct dealings with GMOs.
Assessment	One contravention of the licence was observed during an inspection of the licence. Inspectors determined that there were negligible risks to human health and safety and the environment, as the individual had received training in work practices and was undertaking dealings in a manner consistent with licence conditions.
Compliance management	The University of Adelaide has been reminded of its obligation to ensure signed statements are obtained for all people working with the GMO.

Organisation	Grasslanz Technology Australia Pty Limited (Grasslanz)
Licence number	DIR 176
Summary of dealing	This licence allows Grasslanz to conduct a limited and controlled release of white clover (*Trifolium repens* L.) genetically modified for increased condensed tannins.
Findings	■ On 12 occasions Grasslanz failed to meet inspection timeframes specified by the licence (condition 27) and on 9 occasions it failed to meet reporting timeframes specified by the licence (condition 54). ■ Site 1 was cleaned and replanted without notification to the Regulator. This is inconsistent with condition 54 of the licence, which requires notifications to be provided within 7 days of these activities occurring.

Organisation	Grasslanz Technology Australia Pty Limited (Grasslanz)
Assessment	■ Inspections are now being undertaken as per licence conditions. The delay in reporting was minor in nature. This incident has been assessed as posing no additional risks to human health and safety and the environment. Responsive monitoring occurred in response to this incident, and no further contraventions of the licence were observed. ■ Cleaning and planting notifications have now been provided for Site 1. This incident has been assessed as posing no additional risks to human health and safety and the environment.
Compliance management	Grasslanz proactively undertook additional monitoring and a range of corrective actions to address these incidents. No further additional corrective actions are required. Grasslanz has been reminded of its obligation to ensure licence conditions are understood and met. The OGTR will continue to proactively monitor Grasslanz's dealings to ensure maintained compliance.

Organisation	Novotech (Australia) Pty Ltd (Novotech)
Licence number	DIR-177
Summary of dealing	This licence allows Novotech to conduct clinical trials of genetically modified human adenovirus for bladder cancer treatment.
Findings	Novotech failed to meet timeframes specified under a reporting condition (condition 36).
Assessment	Novotech informed the OGTR that the delay in reporting was due to miscommunication between itself and the trial sponsor. Inspectors did not identify any adverse outcomes resulting from this non-compliance.
Compliance management	The Regulator has reminded Novotech of its obligations to ensure that reporting occurs within timeframes specified by licence conditions. To prevent recurrence of this issue, Novotech must update its policies and procedures regarding mandatory reporting.

3

Organisation	Monsanto Australia Pty Ltd (Monsanto)
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 activity to the OGTR: ■ Eight flowering volunteer canola plants were reported on DIR-164 site 6 while the site was in the post-harvest monitoring phase. This is inconsistent with condition 50 of the licence, which requires volunteers to be destroyed before flowering.
Assessment	The flowering volunteers on DIR-164 Site 6 were destroyed prior to setting seed and the related crop within 1 km of the site had finished flowering, reducing the likelihood of any gene flow from the site. This incident has been assessed as posing no additional risks to human health and safety or to the environment.
Compliance management	Monsanto is required to increase the frequency of post-harvest monitoring inspections for Site 6 and only senior authorised persons approved in writing may conduct these inspections.

Non-compliance findings for GMO dealings not involving intentional release

In 2024–25, findings of non-compliance were made against 5 DNIR licences.

Organisation	The Royal Melbourne Institute of Technology (RMIT) University
Licence number	DNIR-560
Summary of dealing	A project using chimeras of naturally occurring proteins for potential therapeutic use
Findings	An autoclave operator tasked with decontaminating waste generated from DNIR-560 did not receive the required training in respect of the licence conditions (as per conditions 14(a) and (24)) before undertaking dealings with the GMO. RMIT University did not obtain a signed statement indicating the autoclave operator had been trained in, understood and agreed to be bound by licence conditions (condition 14(b)).
Assessment	It was identified that the autoclave operator was trained in OGTR guidelines and was experienced in the decontamination of GMO waste. As the waste was decontaminated appropriately, no additional risks to human health and safety or the environment were identified. The autoclave operator has since received the appropriate licence training.
Compliance management	RMIT University has been reminded of its obligations to ensure that all authorised persons are informed of applicable licence conditions, receive appropriate training and generate appropriate records prior to undertaking dealings.

3

Organisation	Commonwealth Scientific and Industrial Research Organisation (CSIRO)
Licence number	DNIR-496
Summary of dealing	This licence allows CSIRO to conduct research in the characterisation of the molecular determinants of host range and pathogenicity for Henipaviruses.
Findings	On 24 July 2024 the CSIRO self-reported the following non-compliant activities to OGTR: ■ Failure to provide advance notice to the Regulator of the intention to transport freezers containing GMOs between certified PC4 facilities (condition 22(a)). ■ Failure to notify the Regulator (within 7 days) of the completion of transport of freezers containing GMOs between certified PC4 facilities (condition 22(b)).
Assessment	Although the matter was not reported as required by the licence, the transport of the GMOs was found to have occurred in a safe manner consistent with the technical requirements imposed by licence conditions. No risk to human health and the environment because of this omission was identified.
Compliance management	CSIRO has taken steps to address the concerns of the Regulator, including retraining all staff in their regulatory obligations, and developing updated standard operating procedures. CSIRO has been reminded of its obligations to meet reporting requirements. No further actions are required.

Organisation	The University of Queensland
Licence number	DNIR-518
Summary of dealing	Isolation, expression and characterisation of the toxins expressed by the Australian paralysis tick (*Ixodes holocyclus*)

3	

Organisation	The University of Queensland
Findings	The University of Queensland self-reported the following non-compliant activities to the OGTR: ■ The University of Queensland failed to meet condition 15 by permitting people who were not trained in the licence conditions to conduct dealings with the GMO. The dealings conducted included removal of the GMOs from storage and preparation of the GMOs for disposal. ■ The University of Queensland did not obtain a signed statement indicating that the people had been trained in, understood and had agreed to be bound by licence conditions. ■ The University of Queensland failed to meet condition 15 by permitting an external service provider who was not trained in the licence conditions to conduct dealings with the GMO. The dealings conducted included transport, storage and disposal of the GMO. ■ The University of Queensland did not obtain a signed statement indicating that the external service provider had been trained in, understood and had agreed to be bound by licence conditions. ■ The University of Queensland failed to meet condition 31 by not reporting this matter to the Regulator as soon as reasonably possible. ■ The University of Queensland failed to meet condition 24 by not ensuring that storage of the GMO outside a certified facility was in accordance with the Regulator's Guidelines for Transport, Storage and Disposal. The GMOs stored outside a certified facility were not labelled in accordance with the Regulator's Guidelines for Transport, Storage and Disposal. ■ The University of Queensland failed to meet condition 24 by not ensuring that storage of the GMOs outside a certified space was in accordance with the Regulator's Guidelines for Transport, Storage and Disposal. The University of Queensland was unable to provide a record of disposal of the GMOs stored outside a certified facility.

3

Organisation	The University of Queensland
Assessment	Persons who are not trained in licence conditions conducting dealings with GMOs poses risks to containment. However, in this instance the persons who removed the GMOs from storage and prepared them for disposal did so in a manner consistent with containment by double bagging them and placing them in locked bins. No additional risks to human health or to the environment were identified. Similarly, the external service provider who was not trained in the licence conditions transported the GMOs in locked bins and disposed of the GMOs by incineration, which is consistent with the licence conditions. No additional risks to human health or to the environment were identified. As no additional risks resulting from persons untrained in the licence conducting dealings were identified, in this instance delayed reporting of the matter was found not to have impacted the management of risks associated with the dealings. The failure to appropriately label GMOs that were stored outside a certified facility may have contributed to persons untrained in the licence conditions inadvertently conducting dealings with the GMOs. However, in this instance the GMOs were handled in a manner consistent with containment, and no additional risks to human health or the environment were identified. The failure to maintain adequate inventory of GMOs stored outside certified facilities, as observed by the inability to produce a record of disposal for the GMOs covered by the licence, may also have contributed to persons untrained in the licence conditions inadvertently conducting dealings with the GMOs. However, in this instance the GMOs were handled in a manner consistent with containment, and no additional risks to human health or the environment were identified.
Compliance management	The University of Queensland has updated its policies and procedures to reduce the risk of these issues recurring. All persons undertaking dealings with GMOs have now been informed of applicable licence conditions and have generated applicable records prior to undertaking dealings.

Organisation	Novotech (Australia) Pty Ltd (Novotech)
Licence number	DNIR-609
Summary of dealing	This licence allows Novotech to conduct clinical trials with hepatitis treatment vaccine (VTP-300) in virologically suppressed participants.
Findings	On 2 separate occasions, Novotech failed to meet a reporting condition (condition 35).
Assessment	The delay in reporting occurred because of an administrative oversight. This did not impact the management of risks of the licence. Although the matter was not reported as required by the licence, Novotech provided evidence that it had followed all other requirements of the condition.
Compliance management	Novotech has been reminded of its obligations to ensure that reporting occurs within specified timeframes and its obligations as a licence holder under the *Gene Technology Act 2000*.

Organisation	Medpace Australia Pty Ltd (Medpace)
Licence number	DNIR-647
Summary of dealing	This licence allows Medpace to conduct a Phase I/II multicentre, open-label, single-dose, dose-ranging study to assess the safety and tolerability of ST-920, an AAV2/6 human alpha galactosidase A gene therapy in subjects with Fabry disease.
Findings	Medpace failed to meet timeframes specified under a reporting condition (condition 40).
Assessment	The notification submitted by Medpace advising of the final GMO administration exceeded the 30-day reporting timeframe. Inspectors did not identify any adverse outcomes resulting from this non-compliance.
Compliance management	The Regulator has reminded Medpace of its obligations to ensure that reporting occurs within timeframes specified by licence conditions.

3

In 2024–25, 6 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 2024–25, 18 certified physical containment facilities were found to have one or more non-compliances. A total of 87 findings of non-compliance against certification conditions were identified. These findings are summarised in Table 12.

Table 12: Number of non-compliances identified in certified facilities during 2024–25, by non-compliance type

Nature of non-compliance	Number
Control measures	4
Equipment	3
Governance	4
Reporting	1
Structure	33
Training and authorisation	3
Transport, storage and disposal	2
Work practices	37
Total	**87**

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.

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 and completed practice reviews of 2 licences during this reporting period. The findings are outlined below.

One practice review commenced in the previous reporting period was finalised during this reporting period. The findings are outlined below.

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

3

	Preparedness of the University of Melbourne 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 University of Melbourne's preparedness to undertake dealings under DNIR-686. The review assessed: ■ certified facility or 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 University of Melbourne has considered and implemented effective measures in relation to planning for a licensed dealing. Several issues were identified and addressed during the practice review.
Outcomes	The OGTR practice review program continued to assess vulnerabilities in containment and compliance with the *Gene Technology Act 2000*. Information from this practice review 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 the University of Tasmania to undertake a limited and controlled 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 University of Tasmania's preparedness to undertake dealings under licence DIR-195. The review assessed: ■ site selection and planning considerations for control 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 has considered and implemented effective measures in relation to site selection and planning for a limited and controlled release.
Outcomes	The OGTR practice review program continued to assess vulnerabilities in containment and compliance with the *Gene Technology Act 2000*. Information from this practice review 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.

3

	Preparedness of Australian Veterinary Serum Laboratories (AVSL) 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 preparedness of AVSL to undertake dealings under licence DNIR-662. The review assessed: ■ planning considerations for containment measures and transport considerations for the sourcing of GMOs ■ the suitability of the organisation's arrangements to manage compliance risks, including training and oversight of staff, and resourcing ■ any industry or other regulatory issues which could impinge on the organisation's effective compliance performance.
Findings	This practice review of AVSL was initiated in 2023–24. The review found that AVSL has considered and implemented effective measures in relation to planning for a licensed dealing not involving an intentional release. Since the review, however, no dealings have been undertaken by the licence holder.
Outcomes	The OGTR practice review program continued to assess vulnerabilities in containment and compliance with the *Gene Technology Act 2000* and the Gene Technology Regulations 2001. Information from this practice review 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

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 2024–25 an audit of Monash University in Victoria was ongoing. Findings will be reported once the audit is completed. In addition to this, the OGTR undertook and finalised an audit during this reporting period as summarised on the following page.

3

Audit	The University of Adelaide
Aim	To provide advice to the Regulator about the University of Adelaide's ongoing capacity to meet regulatory obligations.
Audit findings	The University of Adelaide has demonstrated a commitment to improving its compliance status and the management of risks by updating policies and procedures and implementing a new training program. The University of Adelaide has provided additional resources to support the implementation of regular monitoring to ensure the effectiveness of its policies and to identify any possible risk or non-compliance proactively. Overall, the University of Adelaide took significant steps to enhance its governance to support its regulatory obligations.
Determination	The audit found that the University of Adelaide has: ■ a high level of management oversight with a strong organisational focus on risk management and risk mitigation strategies ■ improved its capacity to meet regulatory obligations and proactively manage risk and regulatory challenges.
Action	The OGTR proposes that the University of Adelaide: ■ continue to review the implementation of policies, procedures and training programs related to GMO dealings in order to develop its capacity to meet regulatory obligations ■ continue to work proactively and cooperatively with the OGTR to manage regulatory risks. The OGTR will continue routine monitoring and oversight of the University of Adeliade to ensure this culture shift becomes embedded.

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 2024–25 we continued to liaise with the seed industry to raise awareness about management of low-level presence of GMOs and to ensure the industry's 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.

PC plant facility

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, Interim Australian Centre for Disease Control, 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 2024–25 the OGTR continued to work with the Interim Australian Centre for Disease Control to operationalise these monitoring arrangements.

WHO Global Action Plan for Poliovirus Containment

As the national authority for containment, the Interim Australian Centre for Disease Control is responsible for the implementation and oversight of the poliovirus containment measures set by the World Health Organization (WHO) under the Global Action Plan for Poliovirus Containment (GAPIV) and Containment Certification Scheme, in keeping with Australia's commitment to the Global Polio Eradication Initiative. Regulation 5A of the Gene Technology Regulations 2001 provides for the OGTR to make inspectors available to undertake audits, in relation to the containment of poliovirus, of laboratories in Australia that hold poliovirus. Under a service level agreement, monitoring and compliance arrangements commenced in 2025 with the implementation of an audit framework.

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 2024–25 annual report and summarised below.

Our activities for 2024–25 are described under Program 1.8 in Outcome 1 (Health Protection, Emergency Response and Regulation) of the 2024–25 Department of Health and Aged Care Portfolio Budget Statements.[12] The key objective of the subprogram relating to gene technology regulation is:

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

Progress against this objective is achieved through meeting targets for the following activities.

[12] The Portfolio Budget Statements are on the department's website.

Key Activity 1.8C:

Administering the National Gene Technology Scheme by assessing applications and issuing approvals, and by conducting monitoring and compliance activities for genetically modified organism (GMO) approvals.

Source: Health and Aged Care Corporate Plan 2024–25, p. 50

Performance Measure 1.8C:

a. Percentage of statutory timeframes met for decisions on applications.

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

Source: Health and Aged Care Portfolio Budget Statements 2024–25, p. 74; and Health and Aged Care Corporate Plan 2024–25, p. 50

2024–25 Planned performance	2024–25 Result	2023–24	2022–23
≥98%	100%	100%*	100%*
≥98%	100%	99.1% *Measure was against meeting decisions on licences.	100% *Measure was against meeting decisions on licences.
	Result: Achieved		

Data source and methodology:

Records of applications and incidents are stored in departmental databases and records management systems. Data is analysed and maintained internally by the department. Application decisions are measured against statutory timeframes within the Gene Technology Regulations 2001. All reports or allegations (incidents) received are assessed in accordance with the Monitoring and Compliance Managing Incident Reports Standard Operating Procedures.

The 2024–25 annual report of the Department of Health, Disability and Ageing contains more information on how these results were calculated.

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 regulations issued by the Regulator

The OGTR finalised proposals for minor and technical amendments to the Gene Technology Regulations 2001 following a consultation process in late 2024, and the amendments commenced in February 2025. These changes are distinct from proposed amendments arising from the Third Review of the National Gene Technology Scheme (see below).

From 11 November to 8 December 2024 the Regulator publicly consulted on proposed minor and technical amendments to the Gene Technology Regulations 2001. Submissions received were taken into account by the Regulator in finalising the proposed amendments. The amendments were approved by the Gene Technology Ministers' Meeting (GTMM), and the Gene Technology Amendment (Minor Measures) Regulations 2025 were made by the Governor-General, commencing on 26 February. The primary purpose of the amendments is to enable OGTR inspectors to undertake audits of Australia's designated Poliovirus-Essential Facility, which is a necessary step towards certification of the facility for compliance with the WHO's Global Action Plan for Poliovirus Containment (GAPIV). Other minor and technical amendments were made to increase clarity about the scope of regulation and address administrative matters, including in relation to expert advisory committees.

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

The OGTR continues to support a review of the gene technology legislation. Consultation on the draft Gene Technology Amendment Bill 2024 took place in late 2024.

The OGTR continues to provide technical and operational information to assist the Department of Health, Disability and Ageing team leading the implementation of recommendations from the Third Review of the National Gene Technology Scheme. Proposed amendments to the Gene Technology Act 2000 to implement review recommendations were released for public consultation from 13 September to 8 November 2024. The feedback received is informing changes being considered by the GTMM prior to the amendment bill being introduced into the Australian Parliament.

4

Advice on GMOs and GM products

During 2024–25 the OGTR advised other regulatory agencies and the public on the regulation of GMOs and GM products.

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 risk-based regulation across government agencies. It provides a forum for discussion and exchange of experiences on regulatory and technical issues and enhances inter-agency cooperation. The RSN hosts a webinar series and an annual symposium. The theme for the November 2024 symposium was 'Awareness, Preparedness, Responsiveness'. In 2024–25 the OGTR participated in RSN steering committee meetings and webinar and symposium presentations.

Advice to the public

The Act requires the Regulator to maintain a record of approvals for GMO dealings (the GMO Record) which can be accessed by the public.[13] The GMO Record contains information on licences issued, NLRDs notified, GMO dealings included on the Register, and emergency dealing determinations (EDDs). In 2024–25 the OGTR maintained the GMO Record and updated it with new authorisations.

Engagement with stakeholders

10th National Institutional Biosafety Committee Forum

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

[13] The OGTR website includes current lists of GMO dealing authorisations.

Tony Mahar, Dr Elizabeth de Somer, Dr Raj Bhula, Professor Tony Lawler

The 10th National IBC Forum was held in Canberra on 16, 17 and 18 September 2024 at the National Gallery of Australia. Representatives of IBCs and accredited organisations from most states and territories attended, totalling 143 delegates from 86 organisations. The theme of the forum was 'Emerging technology and horizon scanning'. The forum was opened by the Hon Ged Kearney MP, then Assistant Minister for Health. Speakers discussed current and potential future uses of gene technology in medicine and agriculture. GTECCC members introduced their guiding principles for gene technology communication. Representatives from regulated organisations shared their experiences with organisational and regulatory governance. They also presented on the benefits of designing facilities which enable and encourage safety and regulatory compliance. The third day was dedicated to workshops on anticipated legislative reforms to the Gene Technology Scheme.

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 2024–25 we produced one newsletter, which included:

- information on the IBC forum that took place in September 2024
- links to various reports and consultations, including a request for feedback on
  - the public consultation on the proposed amendments to the *Gene Technology Act 2000*
  - the GTECCC's draft guidance for communicating on gene technology
- promotion of surveys seeking
  - views from interested parties on the need and scope for a unique identifier for GM animals
  - feedback on the design and scope of services provided by the newly introduced OGTR online service portal.

Exploring funding models

Consistent with the Australian Government Charging Framework, we continued to work with the Department of Health, Disability and Ageing and the Department of Finance to explore potential sustainable funding models for the OGTR, including the possible introduction of cost recovery.

Meetings, conference attendance and presentations

The Regulator and staff from the OGTR attend and present papers at meetings, forums and conferences in Australia. In 2024–25 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 2024, lecture to University of Sydney MSc students on regulation of therapeutic GMOs
- September 2024, Global Launch: Ethical Frameworks for Synthetic Biology in the Indo-Pacific
- August 2024, NHMRC webinar on synthetic biology
- August 2024, Grain Growers tour
- September 2024, 10th National Institutional Biosafety Committee Forum
- September 2024, RSN seminar: FSANZ-Health Canada shared assessment process for GM foods
- October 2024, RSN seminar: Incentives matter: Getting the regulations right
- October 2024, CropLife Members Forum 2024

- November 2024, Association of Biosafety for Australia & New Zealand
- November 2024, Australasian Environmental Law Enforcement and Regulators Network
- November 2024, Industrial Biotechnology Community of Practice
- November 2024, Regulatory Science Network Annual Symposium – Awareness, Preparedness, Responsiveness
- November 2024, RSN Symposium: How risk assessment of early stage research on GMOs provides insights for preparedness from both human health and environmental perspectives
- February 2025, meeting of the NSW Non-Animal Technologies Network
- February 2025, International Experts Group of Biosafety and Biosecurity Regulators meeting
- February 2025, Regulation of Agvet Chemicals and Technologies 2025 conference
- March 2025, RSN webinar: The emergence of AI and its risks: Understanding the threat of deepfake
- March, May and June 2025, Inter-Governmental Policy Reform Group meetings
- May 2025, Government Scientists Group
- June 2025, OGTR/RSN Webinar: Novel minimalistic non-viral vectors for gene therapy, mitochondrial gene therapy, and genetic vaccination, Dr Volker Patzel, Singapore National University
- June 2025, OGTR/RSN Webinar: In silico approaches for structure-function prediction of proteins, Dr Sebastian Maurer-Stroh, Singapore National University.

4

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 2024–25 the OGTR updated 2 biology documents:

- The biology of *Sorghum bicolor* (L.) Moench subsp. *bicolor* (sorghum)
- The biology of *Brassica napus* (L.) (canola) and *Brassica juncea* (L.) Czern. & Coss. (Indian mustard).

These 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. These reports, including the 2024 report, are available on the OGTR website.[14]

[14] Community attitudes to gene technology reports | Office of the Gene Technology Regulator

Promoting harmonisation

The Regulator and the OGTR continued to liaise with other regulatory and Australian Government agencies on relevant issues during 2024–25.

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.

At the Australia–New Zealand Leaders meeting in 2024, the prime ministers decided to promote collaboration and alignment of our regulatory approaches for GMOs, noting the unique environments of Australia and New Zealand. With this objective in mind there have been several meetings and exchanges of cooperation between the OGTR, the Department of Health, Disability and Ageing, and New Zealand government agencies and stakeholders.

In 2025, OGTR officers met with the New Zealand minister responsible for gene technology regulation and staff from relevant New Zealand departments to discuss lessons learned from over 20 years of experience in Australia and to advise on specific topics of interest. OGTR staff also met with New Zealand stakeholder groups, organised by the Federated Farmers New Zealand and New Zealand Life Sciences Network. In addition, we gave interviews to New Zealand's *Dairy Farmer* magazine and *Farmers Weekly*.

Neil Ellis, Branch Head of Regulatory Practice and Compliance, attending the Life Sciences Summit

A package of reforms to the Australian *Gene Technology Act 2000* are currently under development, and public consultation on draft amendments was completed in November 2024. This package of reforms has assisted New Zealand in its development of legislation and a regulatory framework. Large parts of the New Zealand Gene Technology Bill 2024 are based on the Australian scheme and legislation.

Interactions and dialogue between the OGTR and New Zealand government agencies (including the responsible minister) have been collaborative, open and informative, with a view to close cooperation between the OGTR and, once it is established, the New Zealand OGTR.

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 responsible for entering Australian commercial approvals of GMOs into the OECD BioTrack Product Database[15] and the UN Biosafety Clearing-House.[16]

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.

[15] The BioTrack Product Database is on the OECD website.

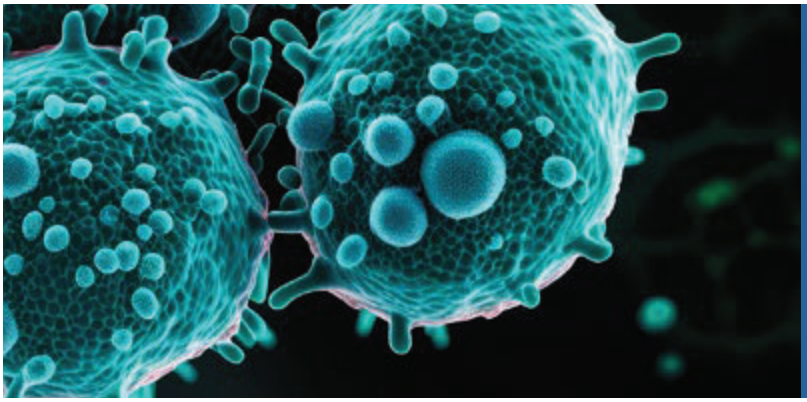
[16] The Biosafety Clearing-House is online.

Meetings attended in person by OGTR officers were:

- August 2024, 5th International Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnologies
- November 2024, WHO GAPIV training for auditors
- February 2025, meeting with gene technology regulators from West Africa hosted by TJ Higgins, CSIRO African Agricultural Technology Foundation, Nigeria, Burkina Faso, Ghana, Kenya
- March 2025, presentation at Life Sciences Summit 2025, Wellington
- March 2025, meeting with Ministry of Business, Innovation and Employment Biotech Policy Team, New Zealand Government
- March 2025, 39th Meeting of the OECD Working Party on the Harmonisation of Regulatory Oversight in Biotechnology, Paris
- May 2025, meeting with New Zealand Minister of Science, Innovation and Technology
- June 2025, scientific program organising committee for International Society for Biosafety Research (ISBR-2025).

OGTR officers attended the following meetings virtually:

- January 2025, meeting with New Zealand Parliamentary Commissioner for the Environment
- February 2025, 9th IEGBBR meeting, France
- March 2025, meeting with officials from Ghana's National Biosafety Authority
- March 2025, meeting with New Zealand Environmental Protection Authority gene technology program implementation team
- March 2025, meeting with UK GAPIV polio regulator
- April 2025, meeting with New Zealand Ministry of Business, Innovation and Employment and Environmental Protection Authority gene technology program implementation team
- April 2025, meeting with WHO to discuss the Therapeutic Goods Administration's clinical trials program
- May 2025, meeting with New Zealand Ministry for Primary Industries
- May 2025, meeting with Japan's GAPIV polio regulator and national authority for containment, with Australia's national authority for containment.



5

Management and accountability

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

5

Human resources

The OGTR had a workforce of 54 employees at 30 June 2025. All permanent employees other than the Regulator are APS staff employed by the Department of Health, Disability and Ageing 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.

The OGTR continued to build a strong team culture in its 24th 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 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's Regulator's Achievement Award went to a project team that worked to deliver outcomes that will make an impact on the efficiency of the office and prepare for implementation of new legislation.

The Business Process Mapping team mapped complex processes for licence applications, including writing of risk assessment and risk management plans (RARMPs) for DIRs and DNIRs. Processes for approvals and variations of certifications and accreditations were also investigated. The team delivered an excellent project in a short time, with well-developed stakeholder engagement and communication strategies. The team listened to staff and made adjustments based on the feedback received, while driving towards shared outcomes. Team members demonstrated leadership in bringing together different sections involved in each approval process and sought ways to improve each business process, either by identifying redundancies in work practices or by reducing times for processing. This effort will result in improved processes that will support staff in achieving the object of the legislation. The team also looked at existing processes for CCI declarations to assist in informing new legislation and drafting amendments to the Act.

Regulator's Achievement Award recipients

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 2024–25 the emergency control organisation team participated in training sessions throughout the year. 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 2024–25 the OGTR Principal Legal Officer provided introductory and ongoing training for OGTR staff on legal issues. Legal training sessions were conducted on the legal obligations of APS employees, information handling, and the operation of the National Gene Technology Scheme:

- July 24 – The National Gene Technology Scheme
- October 2024 – Fundamental APS employee obligations
- November 2024 – FOI and privacy law
- March 2025 – Record keeping obligations.

During 2024–25 the OGTR Principal Regulatory Scientist provided introductory training for OGTR staff on risk analysis. Four sessions of 'Introduction to OGTR risk analysis' were held, in November 2024 and in February, April and May 2025.

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.

Under the Enterprise Agreement, the OGTR provides the option of influenza and COVID vaccinations, at no cost, to all staff.

In 2024–25 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.

During 2024–25 we developed a Training Action Plan which identifies the skills required to carry out the OGTR's statutory functions.

The plan identifies 3 key priority areas for development:

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

In late 2024 we offered training to improve skills in communication and resilience.

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 2 requests for access under freedom of information legislation during the reporting period.

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

Stakeholder and public access to the OGTR

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

Website usage

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

Table 13: Website activity, 2024–25

Month	Visits[a]	Users[b]
July	16,507	13,096
August	12,416	8,639
September	9,771	6,608
October	10,134	6,640
November	9,659	6,174
December	7,271	5,035
January	14,610	10,823
February	9,805	6,013
March	12,252	8,186
April	8,640	5,685
May	8,580	12,425
June	5,790	8,810

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

[b] The number of people who visited the website on a unique device.

The most viewed pages on the OGTR website during 2024–25 were, in descending order:

- Office of the Gene Technology Regulator (home page)
- Dealings involving intentional release
- Snapshot of Genetically Modified (GM) Crops in Australia
- DIR 207
- Resources
- What we've approved
- What are genetically modified organisms (GMOs)?
- About the OGTR
- Types of GMO dealings
- Guidelines for the certification of physical containment facilities.

The most downloaded applications in 2024–25 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 Accreditation of an Organisation
- Application for a licence for dealings not involving intentional release of a GMO (DNIR)
- Application Checklist for a Physical Containment Level 2 Laboratory
- Application for a confidential commercial information (CCI) declaration
- Application for a DIR licence involving a non-plant GMO
- Application to vary or surrender a DNIR licence
- Application for the Variation of a Certification of a Physical Containment Facility
- Application for the Certification of a Physical Containment 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 2024–25, use of the email address increased compared with the previous year (Table 14).

Table 14: Email activity, 2023–24 and 2024–25

Month	Emails 2023–24	Emails 2024–25
July	42	65
August	48	230
September	39	88
October	57	61
November	65	67
December	165	40
January	40	470
February	58	48
March	63	15
April	45	26
May	51	51
June	60	37
Total	**733**	**1,198**

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 1,231 emails during 2024–25 (compared to 1,267 in 2023–24).

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 870 emails during 2024–25 (compared to 1,018 in 2023–24).

The Application Entry Point maintains an email inbox to provide a central, shared communication point, allowing us to efficiently coordinate responses to correspondence and queries about applications. The inbox received 4,848 emails during 2024–25 (compared to 2,180 in 2023–24).

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

Appendices

Appendix 1: Membership of statutory committees

Table 15: Gene Technology Technical Advisory Committee 2023–26 – current members

Member	Position
Professor John Rasko AO (Chair)	Director, Cell and Molecular Therapies, Royal Prince Alfred Hospital (to Nov 2024); 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)

Member	Position
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 of Plant Pathology, Tasmanian Institute of Agriculture, 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 16: 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	Affiliate 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, which are 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 17 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 17: Categories of authorisations for GMO dealings under the Gene Technology Act 2000

Category	Authorisation requirements	Controls
DIR (except for limited and controlled releases)	■ Licence required ■ Review of applications by IBC ■ Consultation on application ■ Preparation of RARMP ■ Consultation on RARMP ■ 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

Category	Authorisation requirements	Controls
EDD	■ Licence not required ■ Determination by minister, subject to advice of threat and utility of GMO from competent authorities, and risk assessment and risk management advice from Regulator ■ Legislative instrument	Containment measures may be included in EDD conditions
Exempt	■ Licence not required ■ GMO dealings classified as exempt are scheduled in the Regulations	No intentional release to the environment
GMO Register	■ Licence not required ■ GMO dealings must have been previously licensed ■ Review of relevant information by Regulator ■ Legislative instrument	Controls may be required
Inadvertent dealings	■ Licence required ■ Licence decision by Regulator only for the purposes of disposal of the GMO	Controls and/or disposal measures will apply
NLRD	■ Licence not required ■ GMO dealings classified as NLRDs are scheduled in Regulations ■ Conduct of NLRDs requires prior assessment by IBC to confirm proper classification ■ Notified in annual report to Regulator	No intentional release to the environment Usually PC1 or PC2 certified physical containment facilities

DIR = dealing involving intentional release of a genetically modified organism into the environment; DNIR = contained dealing with a genetically modified organism not involving intentional release into the environment; EDD = emergency dealing determination; GMO = genetically modified organism; IBC = institutional biosafety committee; NLRD = notifiable low risk dealing; PC1 (or 2) = physical containment level 1 (or 2); RARMP = risk assessment and risk management plan.

Timeframes

Under section 43(3) of the Act, the Regulator must issue, or refuse to issue, a licence within a time limit prescribed by the Regulations. The Regulations also prescribe a timeframe for consideration of applications to accredit organisations and to certify facilities. These statutory timeframes are shown in Table 18. They do not include periods when the Regulator has sought more information from the applicant and the decision-making process cannot proceed until the information is provided. In these instances, the statutory timeframe clock is regarded as stopped.

Table 18: Prescribed timeframes for applications

Category	Timeframe (working days)
Accreditation	90 (r. 16)
Certification	90 (r. 14)
DIR – limited and controlled, no significant risk	150 (r. 8)
DIR – limited and controlled, significant risk	170 (r. 8)
DIR – except for limited and controlled releases	255 (r. 8)
DNIR	90 (r. 8)
Licence variation	90 (r. 11A)

DIR = dealing involving intentional release of a genetically modified organism into the environment; DNIR = contained dealing with a genetically modified organism not involving intentional release into the environment; r = regulation.

Appendix 3: Correction of material errors in the Office of the Gene Technology Regulator Annual Report 2023–24

Our Annual Report 2023–24 contained the following error:

On page 25, in Table 1 in the 'Approved' column it was reported that 6 variations of DIR licences and 17 variations of DNIR licences were approved.

This should have been 7 variations of DIR licences and 24 variations of DNIR licences.

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
AVSL	Australian Veterinary Serum Laboratories
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 (until 13 May 2025) or Australian Government Department of Health, Disability and Ageing (since 13 May 2025)
DIR	A dealing involving intentional release of a GMO into the environment (e.g., field trial or commercial release of a GM plant or animal vaccine)
DNIR	A dealing not involving intentional release of the GMO into the environment (e.g., experiments with GMOs in a certified facility such as a laboratory or manufacture of a commercial therapeutic from a GMO in a large-scale facility)
EDD	Emergency dealing determination
FSANZ	Food Standards Australia New Zealand
GAPIV	Global Action Plan for Poliovirus Containment

Term	Description
Gene Technology Agreement	An intergovernmental agreement that all Australian jurisdictions signed in 2001, which underpins the nationally consistent regulatory framework for gene technology
GM	Genetically modified
GM product	A thing (other than a GMO) derived or produced from a GMO
GMO	Genetically modified organism
GMO Record	Record of GMO dealings
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional biosafety committee
IEGBBR	International Experts Group of Biosafety and Biosecurity Regulators
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
WHO	World Health Organization

Indexes

List of requirements

Gene Technology Act 2000 reference	Part of report	Description
136(1A)(a)	pp. 28–38	GMO licences issued during the financial year
136(1A)(b)	pp. 55–63	Any breaches of conditions of a GMO licence that have come to the Regulator's attention during the financial year
136(1A)(c)	p. 42	Emergency dealing determinations made by the Minister during the financial year
136(1A)(d)	N/A	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. 49–72	Auditing and monitoring of dealings with GMOs under this Act by the Regulator or an inspector during the financial year

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