Australian Government

Department of Health

Office of the Gene Technology Regulator

ANNUAL REPORT 2020–21

20TH ANNIVERSARY

2001–2021

CELEBRATING 20 YEARS OF OGTR

2001–2021

20TH ANNIVERSARY

502 GMO LICENCES

for work in laboratories or physical containment facilities

- 230 Basic Research
- 10 Horticulture
- 10 Agriculture
- 19 Veterninary
- 228 Medical

184 GMO LICENCES

for release into the environment

- 23 Medical
- 2 Other
- 127 Agriculture
- 9 Veterninary
- 23 Horticulture

16 types of containment facility guidelines developed

Monitoring and Compliances inspections

1,378 containment facilities

1,362 field trial sites

316 DNIRs for compliance

2,082 PHYSICAL CONTAINMENT FACILITIES CERTIFIED

OGTR HAS RECEIVED

17,516 APPLICATIONS AND NOTIFICATIONS

2020-21 HIGHLIGHTS

101
PHYSICAL CONTAINMENT FACILITIES CERTIFIED

100%
of licence decisions made within statutory timeframes

INTERNATIONAL ENGAGEMENT

Input and advice on GMO regulationto support engagement in the **UN convention on Biological Diversity and UN Cartagena Protocol on Biosafety.**

OGTR staff member Dr Thygesen was appointed Chair of the **OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology** (WGHROB).

9 GMO LICENCES
for release into the environment

3 **AGRICULTURAL CROPS**

6 **MEDICAL APPLICATIONS**

19 GMO LICENCES
for work in laboratories or physical containment facilities

6 **manufacture or clinical trial** of vaccines for COVID-19

5 **clinical trials** of gene therapies for inherited conditions

1 **commercial supply** of a gene therapy for patients with spinal muscular atrophy

3 **clinical trials** for the treatments of cancer, arthritis, and dementia

4 **laboratory based research**

Number of applications and notifications increased

1,557 in 2019-20

1,624 in 2020-21

MONITORING AND COMPLIANCES ACTIVITIES

11 field trial sites to monitor compliance

60 containment facilities

11 DNIRs for compliance

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

Letter of Transmittal

Australian Government
Department of Health
Office of the Gene Technology Regulator

Senator the Hon Richard Colbeck
Minister for Senior Australians and Aged Care Services
Minister for Sport
Parliament House
Canberra ACT 2600

Dear Minister

I am pleased to present to you the annual report on the Operations of the Gene Technology Regulator covering the period 1 July 2020 to 30 June 2021.

The annual report details the operations of the Gene Technology Regulator (the Regulator) as per the reporting requirements in section 136 (1A) of the *Gene Technology Act 2000* (the Act) and against the performance indicators in Outcome 5 (Regulation, Safety and Protection) of the Department of Health Portfolio Budget Statements for 1 July 2020 to 30 June 2021.

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
17 September 2021

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About this report

The report describes the roles and responsibilities of the Gene Technology Regulator (the Regulator) and the Office of the Gene Technology Regulator (OGTR). It is a formal accountability document that summarises the OGTR's performance against deliverables and key performance indicators in Outcome 5 (Regulation, Safety and Protection) of the 2020–21 Department of Health Portfolio Budget Statements.[1]

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

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

The report contains five chapters:

- **Chapter 1: Gene Technology Regulator's overview**—summarises the OGTR's activities over the past year, including major achievements, and the outlook for the coming year.
- **Chapter 2: Office of the Gene Technology Regulator**—describes the Regulator's corporate and regulatory governance arrangements, including the structure of the OGTR and functions of its advisory committees.
- **Chapter 3: Functions of the Gene Technology Regulator**—describes the OGTR's operational performance, as well as achievements against priorities during 2020–21. The chapter reports deliverables and performance targets achieved for assessments and approvals, as well as for monitoring and compliance activities. It concludes with a summary of performance against the reporting structure published in the 2020–21 Portfolio Budget Statements.
- **Chapter 4: Other functions of the Gene Technology Regulator**—provides information on other activities relating to the Regulator's statutory functions, including legislative reviews of the Act and Regulations, contributions to the work of other regulatory agencies, various consultations with stakeholders, and international engagements.
- **Chapter 5: Management and accountability**—provides an overview of the OGTR's resource management practices and reporting against Australian Government accountability principles.

1 The 2020–21 annual report of the Australian Government Department of Health prepared in accordance with the *Public Governance, Performance and Accountability Act 2013* also contains information about the OGTR. This includes the OGTR financial statements, which are consolidated into the department's financial statements.

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

Chapter 1

Gene Technology Regulator's overview

This year, we celebrate 20 years of the National Gene Technology Scheme and the operation of the OGTR. On 21 December 2000, the *Gene Technology Act 2000*[3] received assent and the Gene Technology Regulations 2001 were made on 30th May 2001. The Act and the Regulations came into force on 21 June 2001, and the Interim Office of the Gene Technology Regulator (IOGTR) became the Office of the Gene Technology Regulator (OGTR). This signified the end of the voluntary arrangements that Australia had in place over the previous 25 years[4] and the start of a new regulatory system for dealings with genetically modified organisms (GMOs).

Before June 2001, approximately 1800 deemed licenses, 1700 deemed certifications and 120 deemed accreditations were issued to bring the Genetic Manipulation Advisory Committee (GMAC) approvals in line with the new legislative requirements. The new OGTR website was launched on 21 June 2001 when information on field trial site locations was released for the first time.

This is a notable milestone of the regulatory scheme that could not pass unnoticed, despite the continuing COVID-19 pandemic which did not allow us to celebrate with our stakeholders. The achievements of the scheme, statistical trends and reflections on the past 20 years are included in this report, and a number of individual reports are published on the OGTR website to mark the 20th anniversary.

In terms of looking ahead and modernising the scheme, it is important to recognise past achievements, analyse how things have changed over time and use those reflections to inform how the OGTR can continue to be a well-respected and best practice regulator.

Meeting our performance targets

During the year, I received Minister Colbeck's Letter of Expectations of the Gene Technology Regulator and my response was published on our website in a Letter of Intent. The letter outlines the activities and priorities of the OGTR from 2020 to 2023.

The Department of Health Portfolio Budget Statements (PBS), Outcome 5 (Regulation, Safety and Protection) describe the performance target of the OGTR *to protect the health and safety of the Australian community through regulation, monitoring, assessment and awareness-raising in relation to genetically modified organisms (GMOs)*. This target is delivered by administering the National Gene Technology Scheme by assessing applications and issuing approvals, and by conducting routine inspections of certified facilities and licensed activities with GMOs. In addition, the operational targets are supported by a modern, flexible and innovative National Gene Technology Scheme, ensuring protection of humans and the environment by working with Australian and state and territory governments to implement the recommendations outlined in the Third Review of the National Gene Technology Scheme.

The PBS targets were met as follows:

- Risk assessments and risk management plans were prepared, and decisions made within statutory timeframes for 100% of licensed dealings
- Stakeholders including the public were consulted on all assessments for proposed release of GMOs into the environment
- There was a high level of compliance with gene technology legislation, with no evidence of any adverse effect on human health or the environment from authorised GMOs.

3 This also included, the *Gene Technology (Licence Charges) Act 2000* and *Gene Technology (Consequential Amendments) Act 2000*.

4 Since 1975, GMAC and its predecessors (the Academy of Science Committee on Recombinant DNA and the Recombinant DNA Monitoring Committee) had scrutinised the development and use of novel genetic manipulation techniques in Australia. [Explanatory memorandum to the Gene Technology Bill 2000 Gene Technology Bill 2000 (legislation.gov.au)

To implement priority recommendations set out in the Forum Action Plan, as endorsed by the Legislative and Governance Forum on Gene Technology (LGFGT)[5], the OGTR continued to assist the Department in consultation webinars on a Consultation Regulatory Impact Statement (C-RIS) held between December 2020 and March 2021. The OGTR also assisted in the preparation of the Explanatory Document that accompanied the C-RIS and continued to inform the Gene Technology Standing Committee from a technical and operational perspective.

Applications and licenses: what's new

A determination was made to include dealings on the GMO Register for cut flowers of 3 GM carnation lines. The determination came into effect on 17 July 2020 and is only the second entry in the GMO Register.

Our licensed applications are categorised according to whether dealings with a GMO involve intentional release into the environment (DIR) or are contained and are primarily for research and do not involve release into the environment (DNIR). This year, 9 DIR licenses were issued, of which 3 were for agricultural crops and 6 for medical applications.

Four licenses were issued for limited and controlled release, authorising clinical trials with a COVID-19 vaccine, clinical trials with a modified vaccinia virus for treatment of solid cancers, clinical trials with a modified adenovirus for treatment of bladder cancers and research with GM white clover. Five commercial licenses were issued, of which 2 were for commercial supply of modified COVID-19 vaccines, commercial supply of a genetically modified cholera vaccine, and 2 crop licenses for GM canola and GM cotton.

For the DNIR category, 19 licenses were issued of which 4 involve laboratory-based research, and the remaining 15 involve clinical trials of GMOs. Six of the DNIR licenses issued were for the manufacture or clinical trial of vaccines for COVID-19. Five licenses were for clinical trials of gene therapies for inherited conditions such as haemophilia A or phenylketonuria. One of the DNIRs issued was for commercial supply of a gene therapy for patients with spinal muscular atrophy. One licence was for agricultural research into fungal pathogens.

Data from the past 5 years shows a clear trend towards research and translation of research into medical applications including vaccine development, gene therapies for inherited conditions and various cancer treatments.

Monitoring and compliance activities

Interruptions to travel, ongoing border restrictions across Australian states and territories and lockdowns impacted our monitoring and compliance program again this year. Although our inspectors were unable to have a physical presence at a number of trial locations, they worked very closely with regulated entities to ensure that compliance against licence conditions was achieved through desk-top audits and inspections in addition to on-site inspections.

During the 2020–21 period, 11 field trial sites were inspected for 5 plant species, namely banana, barley, cotton, sorghum and wheat. Inspections of 13 licenses for clinical trials or contained licenses were conducted and 3 practice reviews undertaken. In addition, 60 facilities were inspected against certification requirements.

5 The LGFGT is now known as the Gene Technology Minister's Meeting, following the outcomes of the Conran Review of COAG Councils and Ministerial Forums, October 2020.

The Third Review of the Gene Technology Scheme: implementation phases

OGTR continued administrative implementation of the scheme review recommendations to reduce regulatory burden. Our focus on digital service delivery for applications and reporting to the OGTR continued this year. Enhancements were made to existing forms, while 4 new forms are in development and testing for release next financial year. To date, 9 online forms have been released since the start of our business improvement program.

The OGTR has also initiated a project to modernise internal IT information management systems, in line with the Australian government's Digital Transformation Strategy to provide innovative, secure and sustainable ICT services. This will provide a platform to build greater IT capabilities and responses to implementing recommendations from the Third Review of the National Gene Technology Scheme.

International harmonisation and capacity building: sharing our knowledge

The OGTR continued to participate in international meetings on harmonising risk assessment and regulation of GMOs. With the ongoing pandemic, virtual meetings and conferences have allowed international engagement to continue with biotechnology regulators. Meetings focused on applications of genome editing in agriculture, including livestock, while international dialogue is ongoing on regulation of new breeding technologies.

The OGTR leads Australian representation on, and coordinates Australian input to, the OECD Working Group[6] on the Harmonisation of Regulatory Oversight in Biotechnology (WGHROB). The working group develops scientific guidance to support the risk assessment of GMOs. Notably, Dr Peter Thygesen was appointed as Chair of the Working Group this year, which is a reflection of his expertise and years of experience in risk assessment of GMOs.

6 The OECD Working Group changed their name during the 2020-21 financial year to OECD Working Party.

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

This year, the Regulator's Achievement Award recognised years of individual contribution to the work of the OGTR, as well as a team effort to meet the priorities for approvals for COVID-19 vaccines.

Dr Peter Thygesen was recognised for his many years of work at the OGTR and his representation and international involvement in the regulation of biotechnology and gene technology. Dr Thygesen was appointed Chair of the OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology (WGHROB). This has meant many late hours so that Australia could maintain international connections and remain engaged in international regulatory harmonisation activities. Dr Thygesen has a wealth of experience and passion for the work that has benefitted the OGTR over many years.

The Contained Dealings Evaluation Section received a team achievement award to recognise work delivered within timeframes during an unusually demanding period of uncertainty. While expediting applications for COVID-19 vaccine manufacture and commercial release, team members worked together to continue to process the ongoing workload of DIRs, DNIR and certifications. The team has been a model for collaboration and flexible work arrangements.

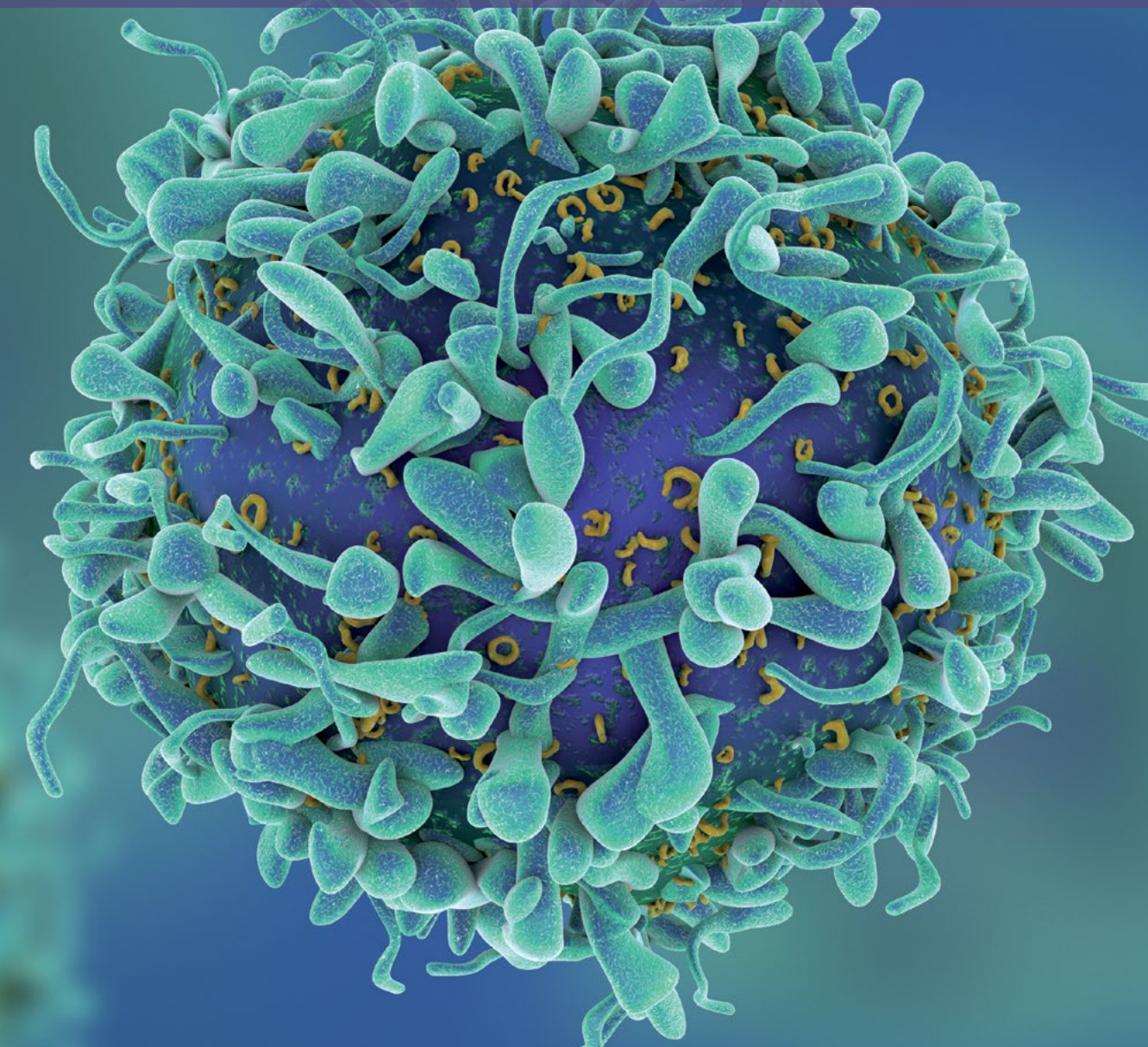
Challenges ahead

As we acknowledge and celebrate 20 years of the National Gene Technology Scheme, the work of OGTR is even more important now than ever. The pandemic continues to impact the lives of everyone, and OGTR's work in assessing clinical trials and issuing licenses for COVID-19 vaccines is an integral part of the government and Health Department strategy for protecting the Australian community.

The big challenge ahead is in the task of modernising the scheme and the regulatory framework so that it can accommodate new technologies as they are developed and remains fit for purpose into the future.

Chapter 2

Office of the Gene Technology Regulator



This chapter provides an overview of the regulatory and corporate governance arrangements for the Gene Technology Regulator (the Regulator), and a description of the organisational structure of the OGTR and its advisory committees.

Our vision

To be a trusted and respected regulator of gene technology, safeguarding the Australian people and the environment.

Our mission

Dedicated to ensuring that genetically modified organisms are safely managed in Australia.

Our role

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

Regulatory governance arrangements

The *Gene Technology Act 2000*, the Gene Technology Regulations 2001, and corresponding state and territory laws provide a nationally consistent system to regulate the development and use of gene technology in Australia. The legislation establishes the Regulator as an independent statutory office holder to administer the national scheme. Overarching responsibility for the scheme is held at Ministerial level by the Gene Technology Ministers' Meeting (GTMM). Under the intergovernmental Gene Technology Agreement, the states and territories have committed to maintaining corresponding legislation with the Commonwealth. The Regulator is charged with performing functions and exercising powers under the Act and corresponding legislation.

The Regulator must consider risks to both human health and safety, and the environment, relating to dealings with GMOs. Other agencies, however, have responsibility for regulating GMOs or genetically modified (GM) products as part of a broader or different legislative mandate. Under gene technology legislation, the Regulator's activities form part of an integrated legislative framework that includes a number of other existing regulatory authorities with complementary responsibilities and expertise.

Conducting activities with a GMO sometimes requires approval from both the Regulator and another regulatory body. For example, dealings with a human medicine that is a GMO, such as a live GM vaccine, requires a licence from the Regulator as well as registration by the Therapeutic Goods Administration, which authorises administration of vaccines to people.

Similarly, while the Regulator is responsible for approving release of GM insect-resistant or herbicide-tolerant plants into the environment, the Australian Pesticides and Veterinary Medicines Authority—which is responsible for regulating all agricultural and veterinary chemicals—must register the insecticide produced in the GM plant. It also approves the application of pesticides to GM herbicide-tolerant plants.

Although these other agencies have a different focus and responsibility from those of the Regulator, the Regulator has a policy of aligning decision-making processes to the extent that is practicable within the limits of the relevant legislation.

Corporate governance arrangements

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

Senator the Hon Richard Colbeck, Minister for Senior Australians and Aged Care Services, Minister for Sport, is the minister responsible for gene technology regulation. Under section 133 of the *Gene Technology Act 2000*, the Secretary of the Australian Government Department of Health supports the Regulator with administrative and scientific staff. For administrative purposes, staff and the Regulator are collectively referred to as the Office of the Gene Technology Regulator (OGTR). They are administered as a separate division of the Department of Health and the Gene Technology Special Account funds the OGTR.

OGTR accesses a range of business management and reporting services directly through the Shared Services Centre of the Department of Health. These include information technology, financial reporting and accounting, human resources management, ministerial support and property management. The department reviews the cost of these services annually.

The *Public Governance, Performance and Accountability Act 2013* sets out the financial framework for OGTR's governance. We maintain integrity in financial reporting through internal audit arrangements as part of the Shared Services Agreement. OGTR complies with the Commonwealth Fraud Control Framework 2017, as the Department requires. More information will be available in the 2020–21 Department of Health Annual Report. While contributing to the Department's Corporate Plan, we maintain our own business and risk plans, against which senior OGTR staff report periodically.

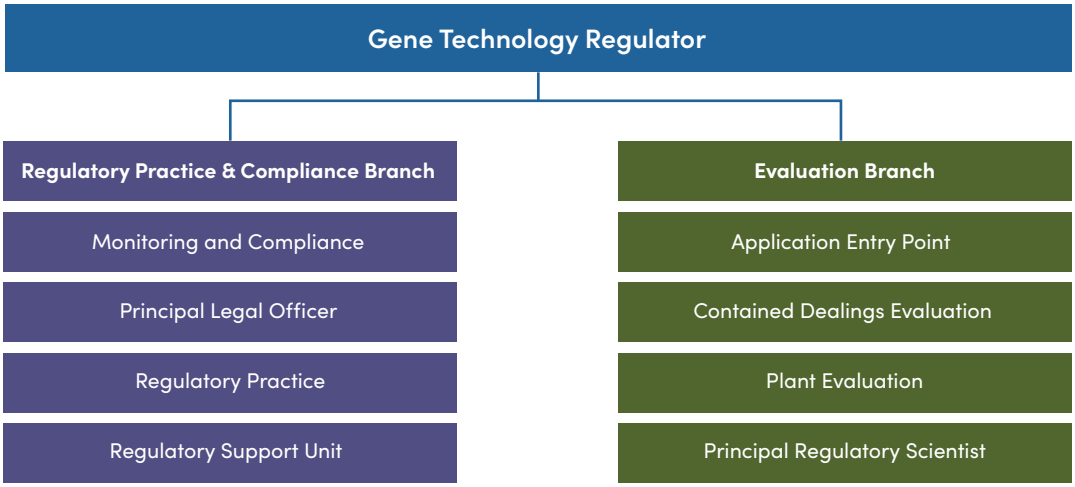
The employment framework for the OGTR is the *Public Service Act 1999*. The Department's enterprise agreement, governance policies and practices cover OGTR staff. These include application of appropriate ethical standards under the Australian Public Service Values and Code of Conduct; compliance with Australian Government freedom of information (FOI), privacy, and work health and safety legislation; and compliance with the National Disability Strategy and the Australian Government's Workplace Diversity Policy.

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

Organisational structure

The OGTR comprises an Evaluation Branch and a Regulatory Practice and Compliance Branch. Sections in these branches focus on particular activities relating to regulation of gene technology (Figure 1).

Figure 1: Organisational structure, 2020–21



Office of Gene Technology Regulators Executive Team

Gene Technology Regulator

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

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

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

Dr Bhula has a background of over 20 years' experience in regulating pesticides in Australia. She was the Executive Director of Scientific Assessment and Chemical Review at the Australian Pesticides and Veterinary Medicines Authority and Program Manager, Pesticides at the authority for almost 10 years. Dr Bhula has represented Australia at international expert committees, such as the Codex Committee on Pesticide Residues, and contributed to technical groups of the Organisation for Economic Co-operation and Development (OECD) Working Group on Pesticides. Much of this work included developing technical policy and risk assessment methodologies.

Regulatory Practice and Compliance Branch

Mr Neil Ellis has been the Executive Director of the Regulatory Practice and Compliance Branch since December 2016. He is responsible for regulatory practice policy, oversight of monitoring and compliance activities, corporate business and regulatory support, performance reporting, coordinating expert advisory committees, stakeholder communication and international cooperation activities.

The branch is made up of the Principal Legal Officer, Monitoring and Compliance Section, Regulatory Practice Section and Regulatory Support Unit.

The OGTR's Principal Legal Officer advises the Regulator and the OGTR on how Commonwealth, state and territory laws affect their functions, including setting licence conditions and handling CCI. The Legal Officer also trains OGTR staff on legal issues, provides advice in relation to FOI requests, and is the designated Privacy Officer for the Regulator for the purposes of the Australian Government Agencies Privacy Code.[7]

The Monitoring and Compliance Section monitors and inspects dealings with GMOs conducted at field trial sites, clinical settings and within certified contained facilities. It ensures that dealings with GMOs comply with legislative obligations and are consistent with the object of the Act. The section monitors compliance with conditions of licenses or other instruments and restrictions and manages risks in relation to any potential breach of conditions. It conducts audits, reviews and investigations of organisations and individuals involved in GMO dealings (including self-reported incidents and allegations made by third parties) to ensure compliance with the Act.

The Regulatory Practice Section works collaboratively with the Department's Gene Technology Policy and Governance Section. It provides technical and operational information to assist the Department of Health team leading implementation of recommendations from the Third Review of the National Gene Technology Scheme. It delivers operational policies, provides technical support, liaises with state and territory officers and coordinates technical reviews of the Regulations. It also provides secretariat services to the Gene Technology Ethics and Community Consultative Committee (GTECCC) and the Gene Technology Technical Advisory Committee (GTTAC), coordinates ministerial correspondence and briefings, and contributes to international regulatory harmonisation activities.

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

It serves as the contact point for other Australian Government agencies and national and international organisations involved in regulating GMOs.

The Regulatory Support Unit advises and supports the OGTR's regulatory capacity. This includes whole-of-office strategic planning activities, managing the Gene Technology Special account, performance and risk reporting, project design and management, and ensuring the office has access to the appropriate resources. The unit coordinates departmental engagement and interactions and produces the annual report. It serves as the first point of contact for many external stakeholders by managing the freecall number (1800 181 030), coordinating responses to general email inquiries (to ogtr@health.gov.au) and managing the OGTR website.

Evaluation Branch

Dr Michael Dornbusch has been Assistant Secretary of the Evaluation Branch since 2009. His responsibilities encompass overseeing the evaluation of licence applications and other authorisations relating to dealings with GMOs, as well as science-related projects that maintain and improve the technical capabilities of the OGTR.

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

The Application Entry Point receives and acknowledges all applications to the OGTR. Staff in this area also process accreditation applications, manage databases, provide trend and statistical analyses of application receipts and authorisations, and report on workflows. Staff also manage or assist with business process and administrative improvement projects. The section also helps the Evaluation Branch source scientific literature, and it manages a range of journal subscriptions for the office library.

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

The Plant Evaluation Section assesses applications for DIRs for GM plants and prepares risk management plans for consultation with key stakeholders, including the public. The section gathers scientific data and publishes reference documents to inform the risk analysis process.

The Principal Regulatory Scientist provides advice on the risk assessment of GMOs, including the review and implementation of the OGTR's Risk Analysis Framework. The Principal Regulatory Scientist, together with other staff, is also engaged in national and international harmonisation activities in order to keep pace with developments in science and regulatory risk analysis.

Advisory committees

The Act establishes 2 committees to provide advice to the Regulator and the GTMM. These are the:

- Gene Technology Technical Advisory Committee
- Gene Technology Ethics and Community Consultative Committee.

Membership of the statutory committees is listed in Appendix 1. Current memberships expire on 31 January 2023.

Gene Technology Technical Advisory Committee

The functions of the Gene Technology Technical Advisory Committee, as set out in section 101 of the Act, are to provide scientific and technical advice, at the request of the Regulator or the GTMM, on:

- gene technology, GMOs and GM products
- applications made under the Act
- the biosafety aspects of gene technology
- the need for and content of:
  - policy principles
  - policy guidelines
  - codes of practice
  - technical and procedural guidelines in relation to GMOs and GM products.

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

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

The committee met 7 times during 2020–21, 6 times via videoconference and once face-to-face. Communiqués from committee meetings, which provide an overview of key matters discussed and resolutions, are published on the OGTR website.

Gene Technology Ethics and Community Consultative Committee

The functions of the Gene Technology Ethics and Community Consultative Committee are set out in section 107 of the Act. They are to provide advice, at the request of the Regulator or the GTMM, on:

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

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

There is no statutory requirement for the Regulator to seek advice from GTECCC on licence applications. Due to the COVID-19 pandemic, GTECCC did not meet during 2020–21. Communiqués from previous committee meetings, which provide an overview of key matters discussed and resolutions, are published on the OGTR website.

Work experience

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

Students engage with all sections of the office to gain an understanding of the range of job opportunities available and also to experience working within the public service. OGTR was able to host two students in June 2021.

Twenty years of OGTR

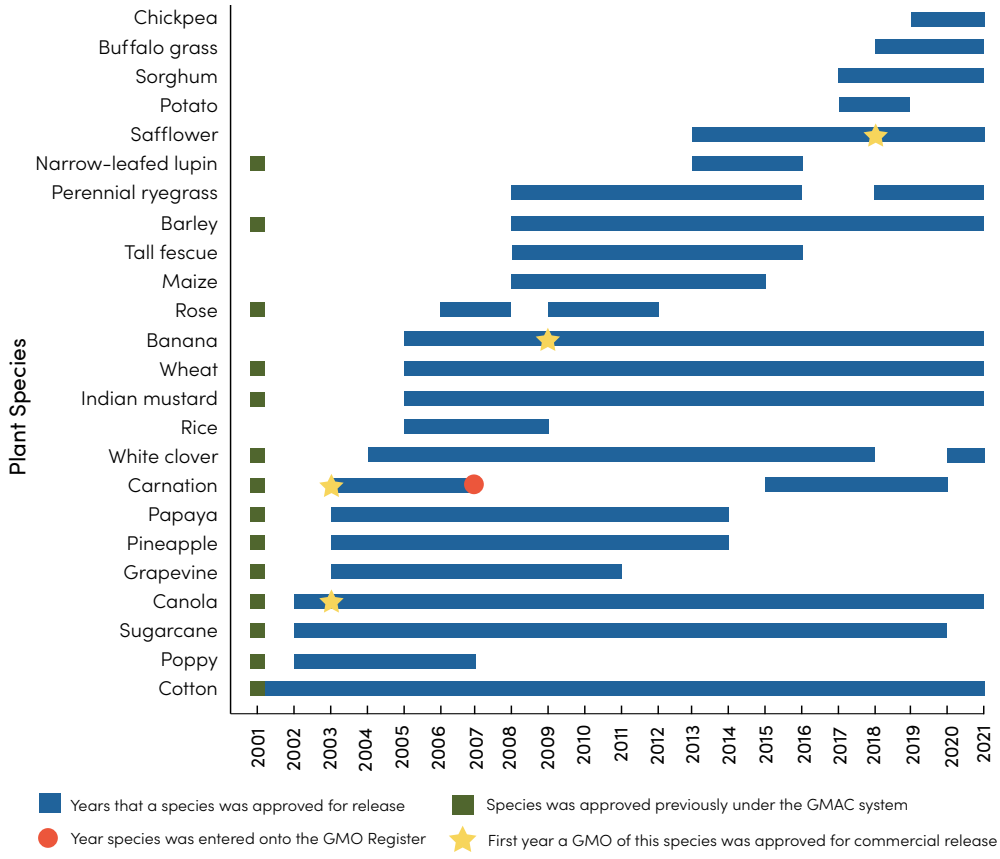
Over the past twenty years, the field of gene technology has seen many exciting developments, some of which could not have been imagined when the Act was written. In gene technology research, new tools are being used to enable scientists to modify the genes or genomes of organisms much faster, cheaper, and easier than ever before. These developments have also increased the extent and precision with which genetic modifications can be made. Reductions in cost have made gene technology more accessible leading to community science organisations entering the scheme and having certified facilities in which to conduct NLRDs.

Twenty- year trends

Licenses

The first DIR licenses issued by the Regulator were for varieties of cotton, which had been modified by the introduction of genes from common bacteria to help farmers with insect pest and weed control. In 2003, GM canola varieties were first approved for commercial release. Cotton and canola with useful farming traits remain the most common subject of DIR licenses, with 50 and 18 licenses issued in the past 20 years, respectively. In 2020–21, more than 99.5% of the cotton grown in Australia was genetically modified and about 20% of the national canola crop was modified. Although the number of licenses issued for GM plants has fallen in recent years, there have also been the first licenses issued for field trials with new crops such as potato, sorghum and chickpea, as well as the first commercial release of GM safflower (Figure 2).

Figure 2: Plant species for which GMOs have been approved for release under DIR licenses

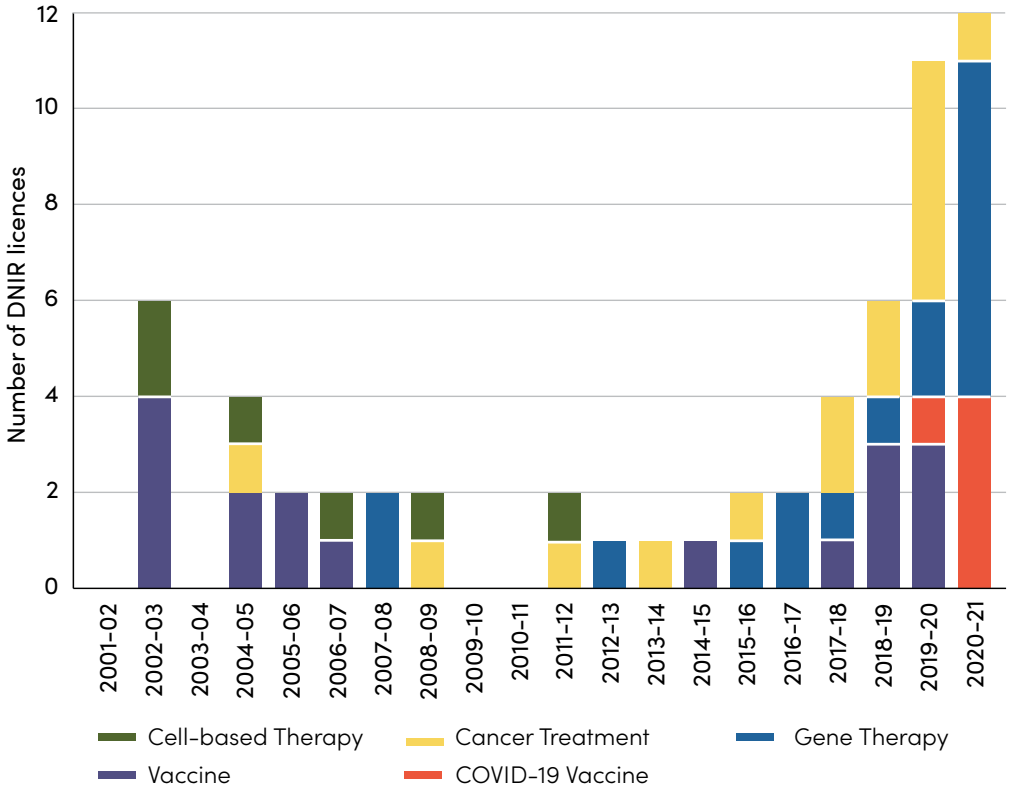


In addition to agronomic traits, the rise of fields such as synthetic biology has seen an increase in the variety and complexity of genetic modifications in crop plants, for example:

- canola modified for altered omega-3 oil content by the introduction of 7 genes involved in metabolism of long-chain polyunsaturated fatty acids
- forage crops with altered nutritional properties to improve digestibility
- safflower modified for high oleic acid composition, which has both industrial and food applications.

In general, the 20 years since the introduction of the Act have seen an increased focus in applications of GM techniques for human therapeutics, i.e., vaccines, cancer treatments and other cell-based therapies. There has been a steady increase in the number of clinical trial licenses issued. The majority of these have been DNIRs (Figure 3), and 7 DIR licenses have also been issued for clinical trials, 5 of which were in the last 5 years.

Figure 3: DNIR licenses for clinical trials by application type, as at the end of June 2021



The last 5 years have also seen a noticeable increase in the number of human therapeutics that advanced from testing and clinical trial stages to commercialisation. In the 20 years since the beginning of the scheme, 10 licenses have been issued for the commercial supply of GMO therapeutics. Five of these have been issued in the last 5 years. Currently approved GM human therapeutics for commercial release under DIR licenses include:

- vaccines using GM viruses (for Japanese encephalitis, influenza, dengue fever and COVID-19)
- a vaccine using GM bacteria (for cholera)
- a GM virus therapy for the treatment of melanoma.

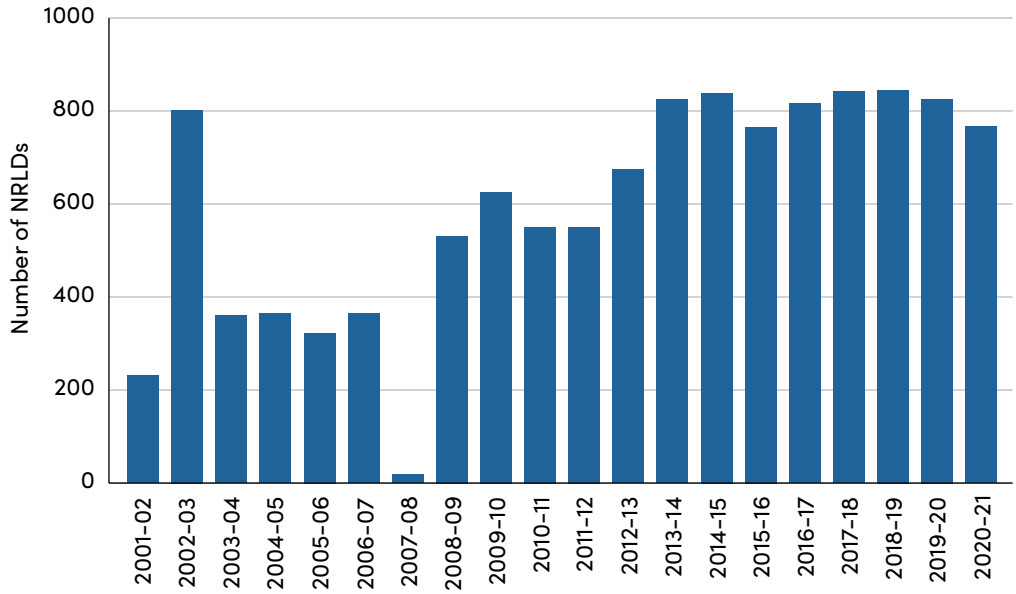
One animal vaccine has been approved for commercial release in Australia: a GM bacteria which protects chickens from disease caused by *Escherichia coli* infection. Approved animal vaccine trials have tested GM viruses in cattle, chickens, crocodiles, and horses.

The vast majority of DNIR licenses issued under the scheme have authorised research into human pathogens and diseases, and their treatment. Recent years have also seen the issuing of the first ever DNIRs to facilitate the special access of patients to experimental treatments and limited access to treatments not yet commercially available in Australia.

Notifications

Almost 12,000 NLRDs have been assessed by IBCs over the course of the scheme. A little over a quarter of these are still current. These dealings tend to cover a wider range of research than the licenses and involve the modification of plants, animals, viruses, bacteria and fungi. The number of NRLDs notified to the Regulator each year has generally increased over the period of the scheme as researchers became more familiar with the operations of the scheme and the legislative changes in which more dealings were classed as suitable for NLRDs (Figure 4). 770 NLRD notifications were received in 2020–21, which is a little lower than recent averages, and this may reflect reduced capacity to conduct contained dealings due to various aspects of the COVID-19 response across the country.

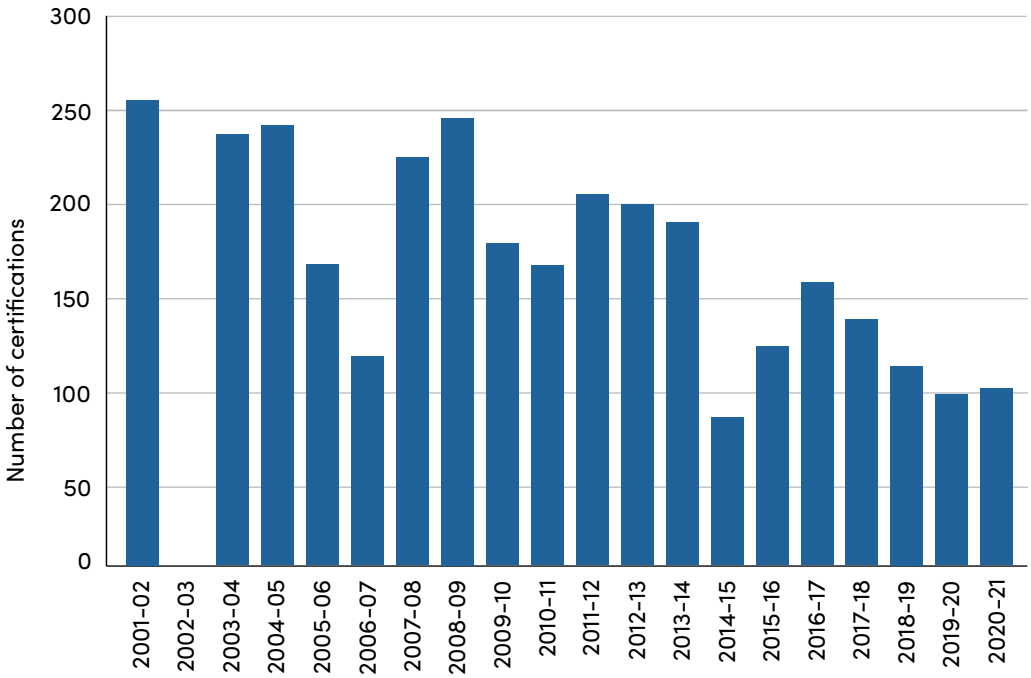
Figure 4: Number of NRLDs notified to the Regulator each year of the scheme



Facilities

Over the last twenty years, the Regulator has certified 4558 facilities as suitable for containing dealings with GMOs, and of these 2082 facilities were current at the end of 2020–21. The number of facilities certified each year has fluctuated over time (Figure 5), with a large peak early in the scheme rapidly reducing to a relatively stable level of new facilities each year. In 2020–21 the Regulator certified 101 facilities. Recent years have seen a slow decrease in the number of new facilities, but the average size and complexity of individual facilities has been increasing. Large, multipurpose facilities are more common and as such can require complex management to ensure GMOs remain appropriately contained.

Figure 5: Number of certifications issued each year of the scheme except 2002–03



Note: Data for 2002–03 is not presented as the large number of pre-existing facilities 'grandfathered' into the scheme (1298) obscured the general trend.

More information about OGTRs achievements and activities over the last 20 year can be found on our website.[8]

8 https://ogtr.gov.au/about-ogtr/twenty-years-ogtr

Thoughts, reflections and celebratory comments from committee chairs and former regulators

Summing up the OGTR and regulatory scheme over 20 years

'A widely respected, highly effective, outcomes-focused and transparent scheme delivered by outstanding staff who are strongly committed to best-practice regulation.'

Dr Joe Smith, former GTR (2009-2014)

'Quiet achievers. A remarkably small expert, dedicated and talented team who nonetheless steadfastly, yet creatively, administer, manage and safeguard a significant and complex regulatory responsibility.'

Associate Professor Judy Jones, Chair of GTECCC

'A robust regulatory scheme for the safe development and application of gene technology in Australia, recognised nationally and internationally for its scientific rigour, transparency and effectiveness.'

Dr Sue Meek, former GTR (2001–2008)

'The Australian Gene Technology Act is the envy of many other regulators around the world as it remains robust, despite many complex challenges. I am always delighted when I attend international committee meetings and hear of the esteem that the Australian Gene technology regulatory scheme is held in.'

Professor John Rasko, Chair of GTTAC

OGTR executive and staff

A key achievement or proudest moment from the committee chairs and former Regulators

'OGTR's strong commitment from its inception to inform that subject to the legislation of their obligations and how to meet them and the active engagement of regulated communities.'

Dr Sue Meek, former GTR (2001–2008)

'I am most proud of the integration of all Gene technology regulations and the fact that experts in all areas come together with the sole intention and commitment to advise our Gene Technology Regulator. Many other countries separate the regulation of GMO crops and agriculture from human gene therapies but in Australia they are combined under one roof – namely the Gene Technology Act 2000.'

Professor John Rasko, Chair of GTTAC

'Ensuring that OGTR's approach to risk analysis and regulation remains at the forefront of best practice and keeps pace with new technologies while the office consistently exceeds all ongoing performance requirements. This has been achieved through the proactive, innovative and collegiate approach of OGTR staff in activities such as reviewing processes and regulations and articulating them in publications such as the Risk Analysis Framework.'

Dr Joe Smith, former GTR (2009–2014)

'I believe that at the time of the National Framework of Ethical Principles in Gene Technology development and publication the document was globally unique within a gene technology regulatory context. Certainly, I recall there wasn't a specific gene technology ethics template to follow and the members of the Committee thoughtfully adapted a broad range of philosophies and ethical perspectives (including from the fields of law, religion, health, environment and agriculture) to formulate the National Framework.'

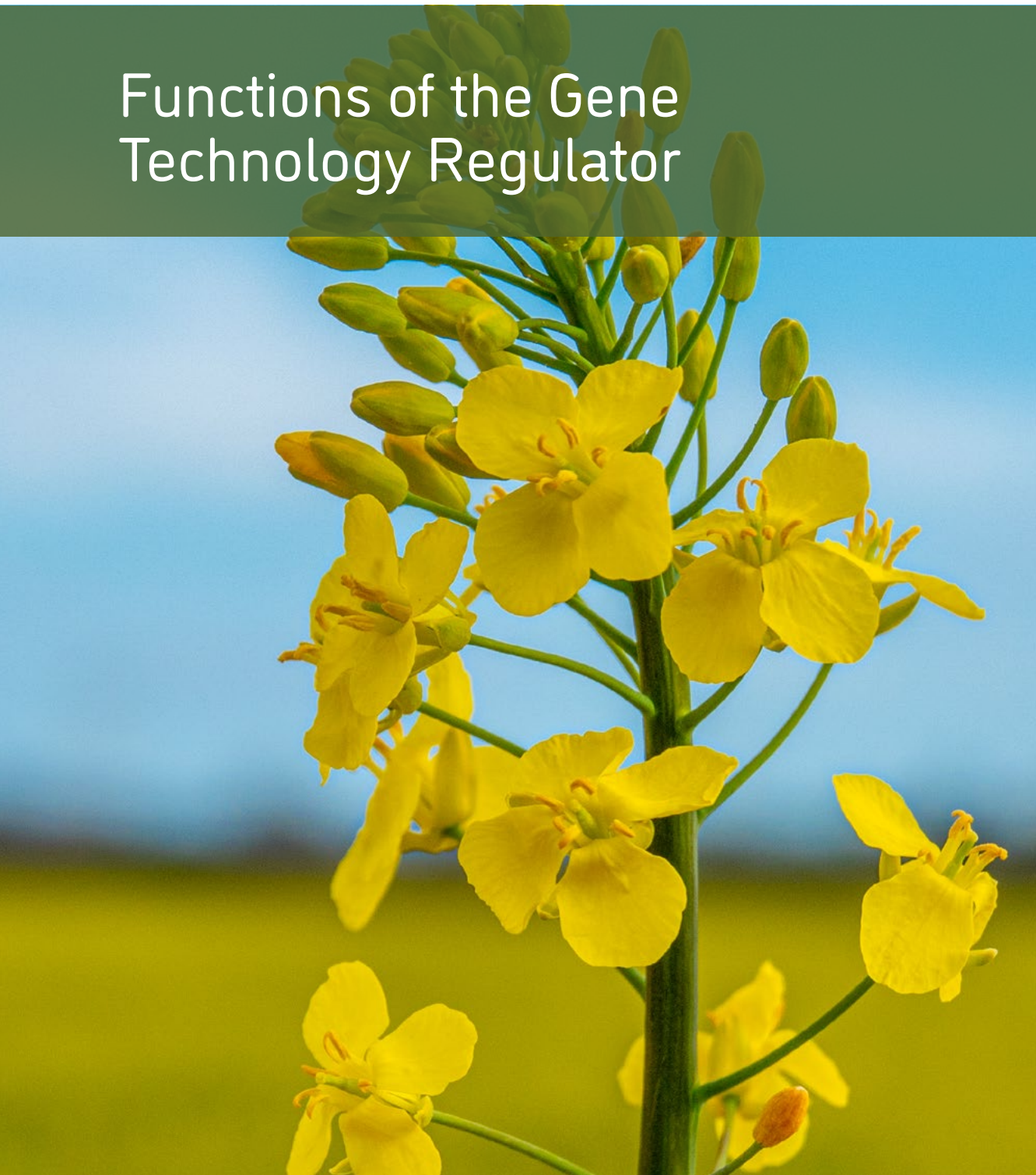
Associate Professor Judy Jones, Chair of GTECCC

OGTR anniversary celebration 20 year timeline

Dr Brendan Murphy, Dr Raj Bhula and Dr Joe Smith at the OGTR 20 year anniversary celebration

Chapter 3

Functions of the Gene Technology Regulator



This chapter describes the operational performance of the Regulator in relation to the functions as required by subsection 136 (1A) of the Act and against the performance indicators in Outcome 5 (Regulation, Safety and Protection) of the 2020–21 Department of Health Portfolio Budget Statements. The functions of the Regulator and the regulatory processes for authorising and monitoring dealings with genetically modified organisms (GMOs) that are defined by the Act, the Gene Technology Regulations 2001 (the Regulations), and corresponding state and territory laws are described in Appendix 2.

Operational performance

This section describes the achievements and performance against Outcome 5 (Regulation, Safety and Protection) of the 2020–21 Department of Health Portfolio Budget Statements. It provides details of achievements on deliverables and performance indicators in the key areas of:

- assessments and authorisations under the Act
- monitoring of GMO dealings
- compliance with the Act.

Information on performance against deliverables and key performance indicators, as set out in the 2020–21 Department of Health Portfolio Budget Statements, is summarised in the second part of this chapter.

Summary of approvals in 2020–21

The OGTR received 1625 applications and notifications, as defined under the Act (Table 1). The timing and volume of applications each year can be influenced by a range of factors, including research grant funding cycles, seasonal agricultural factors and changes to legislation. The Regulator granted 866 approvals over a range of application types. There were no appeals associated with decisions made on applications under the gene technology legislation. As a result of the Regulator's decisions since the beginning of the scheme, currently there are 2082 certified facilities, 50 environmental release licenses and 147 contained research licenses (Table 2) at 30 June 2021.

Table 1: Applications and notifications, 2020–21

APPLICATION TYPE	RECEIVED	WITHDRAWN	APPROVED[a]	REFUSED	CEASED CONSIDERATION[b]	UNDER CONSIDERATION[c]
Accreditation	12		10			2
Alternate facility request for an NLRD	2	1				1
CCI declaration for Accreditation			2			
CCI declaration for DIR Licence	9		7			11
CCI declaration for DNIR Licence	10		7	1		23
Certification	99	1	101			3
DIR Licence	10		9			4
DNIR Licence	22		19			8
Lifting suspension of certification[d]	45	1	45			1
NLRD notification	770					
GMO Register			1			
Surrender of accreditation	4		4			
Surrender of certification	77		76			1
Surrender of DIR licence	7		8			
Surrender of DNIR licence	4		3			1
Suspension of certification[d]	78	2	72			4
Transfer of certification	4		4			
Transfer of DIR licence	4		4			
Transfer of DNIR licence	8		9			
Variation of certification	419	8	449			30
Variation of DIR licence	4		6			1
Variation of DNIR licence	36		30			9
TOTAL	**1624**	**13**	**866**	**1**		**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 2020–21 were received in the previous year.

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

c Under consideration as at 30 June 2021

d Suspension of accreditation or certification, as well as the lifting of a suspension, can include both those requested by the applicant and those initiated by the Regulator. Those reported in 2020–21 were all requested by the applicant.

Table 2: Status of primary applications and notifications from the start of the scheme until 30 June 2021[a]

APPLICATION TYPE	RECEIVED	WITHDRAWN	APPROVED	NOT APPROVED[b]	UNDER CONSIDERATION[c]	CURRENT	EXPIRED	SURRENDERED
Certification	4713	147	4558	5	3	2082	345	1964
DIR	185	18	158	5	4	50	1	107
DNIR	646	114	502	2	8	147	160	195
NLRD	11972	35	n/a	n/a	n/a	3242	8695	n/a
TOTAL	**17516**	**314**	**5218**	**12**	**15**	**5521**	**9201**	**2266**

a Categories and abbreviations as for Table 1 above
b 'Not approved' includes 'refused', 'ceased consideration' and 'not considered' under section 42 of the *Gene Technology Act 2000*
c Under consideration as at 30 June 2021

Primary applications

Licenses for dealings involving intentional release of GMOs

Dealings involving intentional release (DIR) of GMOs to the environment require authorisation by a licence. DIR licenses may contain specific conditions to manage any identified risks. The Regulator issued 9 DIR licenses during 2020–21 (Table 3).

Details of the traits introduced into the organisms for release are provided in Table 3. Four licenses issued in 2020–21 were for the following limited and controlled releases:

- DIR-184 Clinical trial with a genetically modified human adenovirus COVID-19 vaccine
- DIR-179 Clinical trial with a genetically modified Vaccinia virus based treatment for solid cancerous tumours
- DIR-177 Clinical trial of genetically modified human adenovirus for bladder cancer treatment
- DIR-176 Limited and controlled release of white clover genetically modified for increased condensed tannins.

Five DIR licenses for commercial release of GMOs were issued in 2020–21:

- DIR-182 Commercial supply of a genetically modified COVID-19 vaccine – Janssen
- DIR-180 Commercial supply of a genetically modified COVID-19 vaccine – AstraZeneca
- DIR-175 Commercial release of canola (*Brassica napus*) genetically modified for herbicide tolerance and a hybrid breeding system (MS11)
- DIR-174 Commercial supply of a genetically modified cholera vaccine, Vaxchora®
- DIR-173 Commercial release of cotton genetically modified for herbicide tolerance (MON 88701).

Of the 9 DIR licenses issued in 2020–21, 7 were issued to companies, and 2 to research institutes (Table 3). All of the licence decisions were made within statutory timeframes (see 'Timeframes', Appendix 2).

Table 3: DIR licenses issued, 2020–21

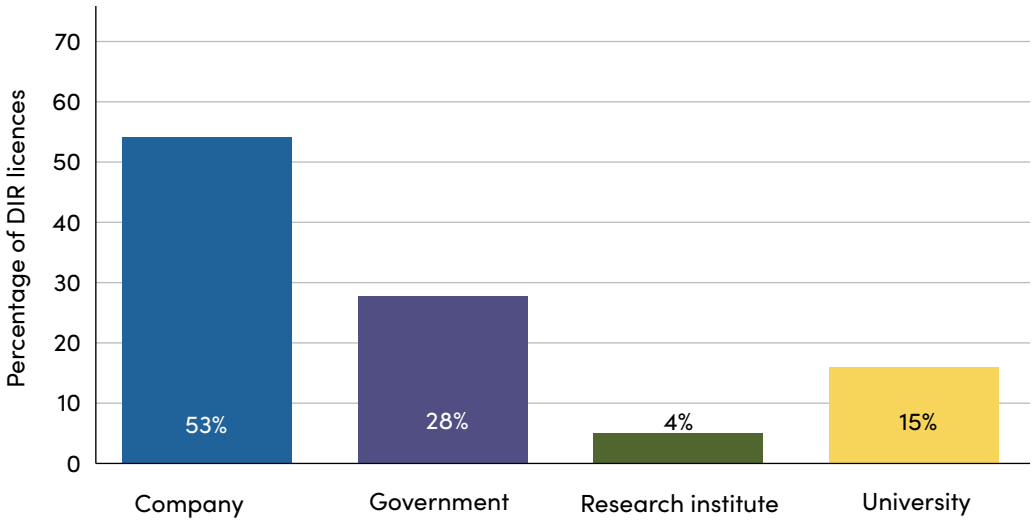
DIR NO.	APPLICANT	PARENT ORGANISM	INTRODUCED TRAIT	TYPE OF RELEASE	RECEIVED	ISSUED
DIR-184	Avance Clinical Pty Ltd	Adenovirus	Vaccine – single-cycle replication, altered antigen expression	Limited and Controlled Release	16-Mar-21	25-Jun-21
DIR-182	Janssen-Cilag Pty Ltd	Adenovirus	Vaccine – replication incompetent, altered antigen expression	General and Commercial Release	02-Dec-20	19-Apr-21
DIR-180	AstraZeneca Pty Ltd	Adenovirus	Vaccine – replication incompetent, altered antigen expression	General and Commercial Release	27-Nov-20	08-Feb-21
DIR-179	Novotech (Australia) Pty Limited	Vaccinia virus	Oncolytic	Limited and Controlled Release	21-Sep-20	14-Apr-21
DIR-177	Novotech (Australia) Pty Limited	Adenovirus	Oncolytic	Limited and Controlled Release	03-Jul-20	01-Feb-21
DIR-176	PTM Solutions Australia Pty Ltd	White clover	Increased production of condensed tannins	Limited and Controlled Release	09-Jul-20	31-Mar-21
DIR-175	BASF Australia Ltd	Canola	Herbicide tolerance and hybrid breeding system	General and Commercial Release	04-Jun-20	12-May-21
DIR-174	Biocelect Pty Ltd	V. Cholerae strain CVD 103-HgR (Cholera Vaccine)	Loss of toxin expression, selectable marker	General and Commercial Release	23-Mar-20	17-Feb-21
DIR-173	Monsanto Australia Pty Ltd	Cotton	Herbicide tolerance	General and Commercial Release	23-Jan-20	15-Oct-20

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

The types of organisations to which DIR licenses have been issued since commencement of the scheme are shown in Figure 6. Of the 158 DIR licenses issued to date:

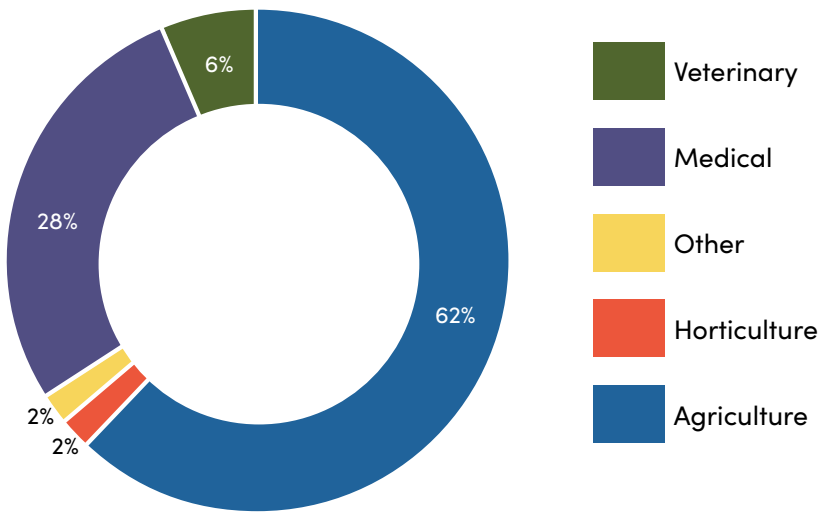
- 83 (53%) have been to companies
- 44 (28%) to government agencies
- 7 (4%) to research institutes
- 24 (15%) to universities.

Figure 6: Types of organisations issued with DIR licenses since commencement of the *Gene Technology Act 2000*



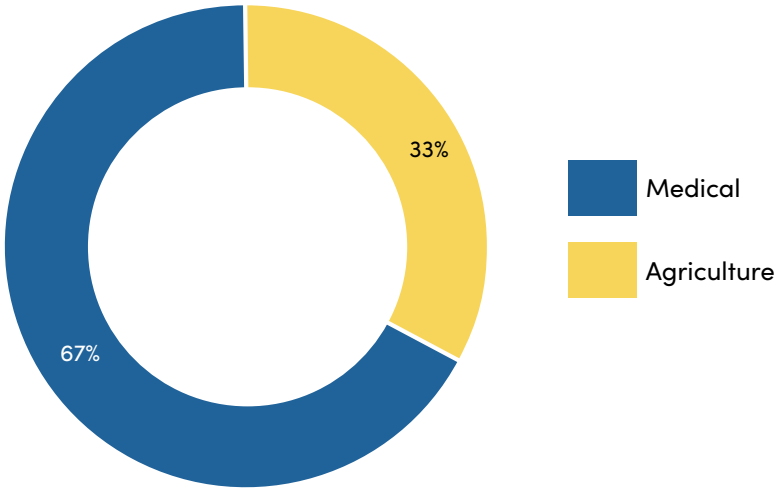
One hundred and thirty one of the 158 DIR licenses issued since the commencement of the scheme were for agricultural purposes including GM crops and algae. The remainder are for medical applications. Fifty of the 158 DIR licenses issued since the beginning of the scheme were current at 30 June 2021. This consists of 31 (62%) agricultural licenses, 14 (28%) medical, 3 (6%) for veterinary and one each (2%) for horticulture and other research. (Figure 7).

Figure 7: Agricultural vs non-agriculture purposes of DIR licenses current as at 30 June 2021



Of the 9 DIR licenses issued during 2020–21, 6 had a medical focus and the remaining 3 had an agricultural focus (Figure 8). This shows a shift in the focus of new DIR licenses where historically they have been more focused on agricultural work; they are now more medically focused. The DIR licence work which falls under the category of being medically focused includes activities such as clinical trials and commercial supply of vaccines.

Figure 8: Agricultural vs non-agricultural purposes of DIR licenses issued during 2020–21



Thirty-three (66%) of the current DIR licenses were issued to companies, 3 (6%) to government organisations, 6 (12%) to research institutes and 8 (16%) to universities (Figure 9). Two (4%) of the DIR licenses were held by organisations in the ACT, 2 (4%) in NSW, 19 (38%) in Qld, one (2%) in SA and 26 (52%) in Victoria (Figure 10).

Figure 9: Distribution of DIR licenses current as at 30 June 2021, by organisation type

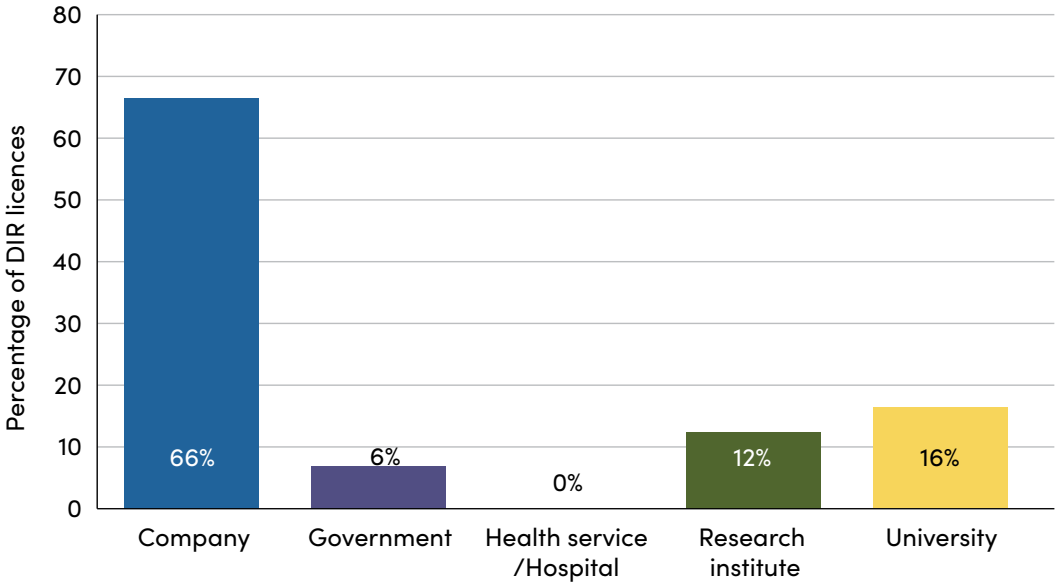
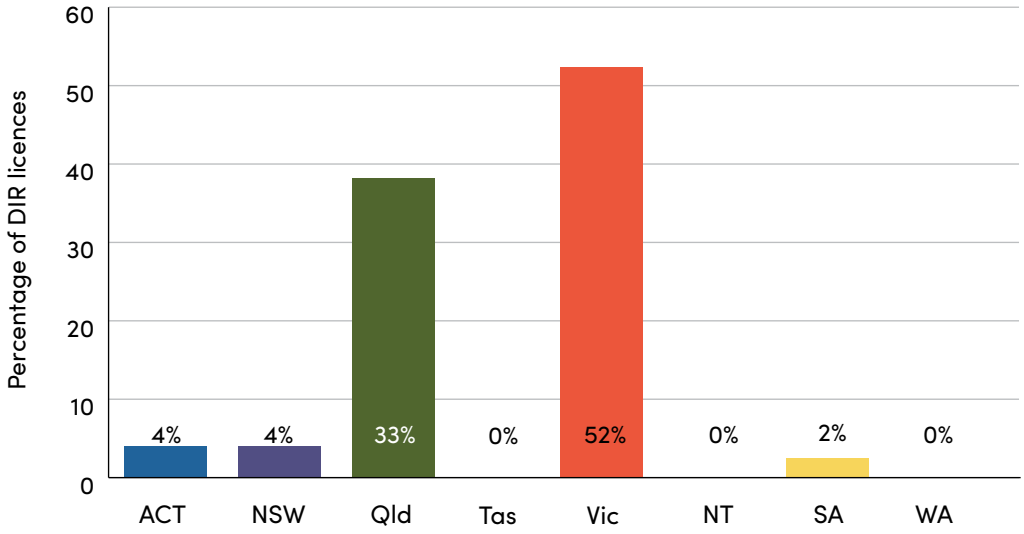


Figure 10: Distribution of DIR licenses current as at 30 June 2021, by state or territory



Licenses for dealings not involving intentional release of GMOs

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

In 2020–21, the Regulator issued 19 DNIR licenses (see Table 4). All decisions were made within the statutory timeframe of 90 days.

Only 4 DNIR licenses were issued in 2020–21 for laboratory-based research, with the majority being for clinical trials of GMOs.

Six of the DNIR licenses issued were for the manufacture or clinical trial of vaccines for COVID-19. A 5 further DNIR licenses were for clinical trials of gene therapies for inherited conditions such as haemophilia A (DNR-624) or phenylketonuria (DNIR-625). One of the DNIRs issued was for commercial supply of a gene therapy for patients with spinal muscular atrophy (Zolgensma; DNIR-621).

Table 4: DNIR licenses issued, 2020–21

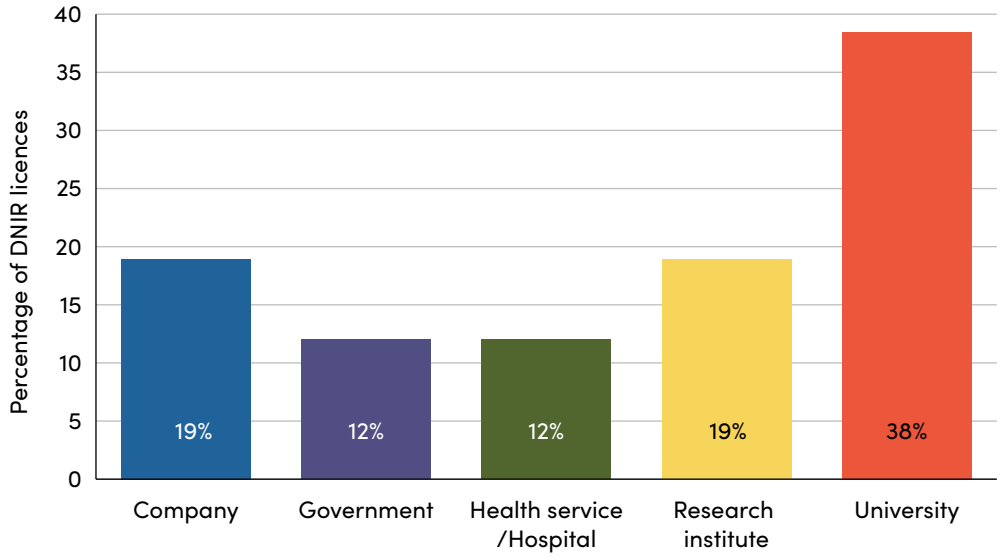
DNIR NO.	APPLICANT	TITLE	RECEIVED	ISSUED
DNIR-638	Avance Clinical Pty Ltd	Serotype 5 Based Recombinant Vector Encoding the Human CYP21A2 Gene to treat Congenital Adrenal Hyperplasia	01-Mar-21	30-Jun-21
DNIR-637	Janssen-Cilag Pty Ltd	A recombinant COVID-19 vaccine (Ad26. COV2.S) for use in clinical trials	24-Feb-21	05-May-21
DNIR-636	Avance Clinical Pty Ltd	Clinical trial to determine the safety and efficacy of SC-Ad6-1, an adenovirus based COVID-19 vaccine	15-Feb-21	15-Apr-21
DNIR-635	Novotech (Australia) Pty Limited	Clinical Trials with 4D-310 for the treatment of Fabry Disease	05-Feb-21	04-Jun-21
DNIR-634	The University of Queensland	Dissecting COVID-19 pathogenesis by advanced molecular technologies	29-Jan-21	10-Jun-21
DNIR-633	Murdoch Children's Research Institute	Administration of AVXS-101 to patients with genetically diagnosed spinal muscular atrophy	24-Nov-20	29-Mar-21
DNIR-632	Seqirus Pty Ltd	Formulation and Fill/Finish of a recombinant ChAdOx1 vector that expresses the spike protein of SARS-CoV-2	20-Nov-20	14-Dec-20
DNIR-631	Novotech (Australia) Pty Limited	SARS-CoV-2 prophylactic vaccine for use in clinical trials	13-Oct-20	28-Jan-21
DNIR-630	CSL Innovation Pty Ltd	Human Embryonic Kidney 293 cells containing recombinant ChAdOx1 vector expressing COVID-19 insert	06-Oct-20	02-Nov-20
DNIR-629	Novotech (Australia) Pty Limited	Clinical trial with ICM-203 for the treatment of arthritis	21-Sep-20	15-Jan-21
DNIR-628	The University of Melbourne	Identification of molecular factors that influence reassortment and pandemic potential of highly pathogenic avian influenza H5 viruses	04-Aug-20	30-Sep-20
DNIR-627	South Australian Health and Medical Research Institute	Generating mouse models with altered inheritance and sex bias	21-Jul-20	25-Sep-20
DNIR-626	Novotech (Australia) Pty Limited	Clinical Trials with a SARS-CoV-2 oral vaccine (bacTRL-Spike)	10-Jul-20	10-Aug-20
DNIR-625	BioMarin Pharmaceutical Australia Pty Ltd	Clinical trial to determine the safety and efficacy of BMN 307, an Adeno-associated virus vector-mediated gene transfer of human phenylalanine hydroxylase in patients with phenylketonuria	01-Jul-20	17-Sep-20
DNIR-624	Pfizer Australia Pty Ltd	A clinical trial to evaluate the efficacy and safety of PF-07055480 in adult male participants with moderately severe to severe haemophilia A	04-Jun-20	08-Oct-20

DNIR NO.	APPLICANT	TITLE	RECEIVED	ISSUED
DNIR-623	PPD Australia Pty Ltd	A Phase 1/2 Ascending Dose Study to Evaluate the Safety and Effects on Progranulin Levels of PR006 in Patients with Fronto-Temporal Dementia with Progranulin Mutations (FTD-GRN)	27-May-20	21-Sep-20
DNIR-621	Novartis Pharmaceuticals Australia Pty Limited	Supply of Zolgensma (Onasemnogene abeparvovec) for the treatment of patients with spinal muscular atrophy (SMA)	20-Apr-20	24-Aug-20
DNIR-619	Novotech (Australia) Pty Limited	CodaVax-H1N1, a live-attenuated vaccine for the use in clinical trials for breast cancer	01-Apr-20	28-Jul-20
DNIR-618	CSIRO	Genetic control strategies for plant pathogenic fungi	11-Mar-20	16-Jul-20

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

The types of organisations to which DNIR licenses have been issued since commencement of the scheme are shown in Figure 11. Of the 502 DNIR licenses issued to date, 95 (19%) have been to companies, 58 (12%) to government agencies, 60 (12%) to health services/hospitals, 96 (19%) to research institutes and 193 (38%) to universities.

Figure 11: Types of organisations issued with DNIR licenses since commencement of the Act



One hundred and forty seven (147) of the 502 DNIR licenses issued since the beginning of the scheme were current at 30 June 2021. Of these:

- 100 (68%) are medical, 39 (27%) for basic research, 5 (3%) for agriculture and 3 (2%) for veterinary (Figure 12)
- 34 (23%) are held by companies, 11 (7%) by government agencies, 7 (5%) by health services/ hospitals, 38 (26%) by research institutes, and 57 (39%) by universities (Figure 13)
- 4 (3%) of the current DNIR's are held in the ACT, 25 (17%) in NSW, 49 (33%) in Qld, 12 (8%) in SA, 52 (35%) in Vic and 5 (4%) in WA (Figure 14).

Figure 12: Medical vs non-medical focus of DNIR licenses current as at 30 June 2021

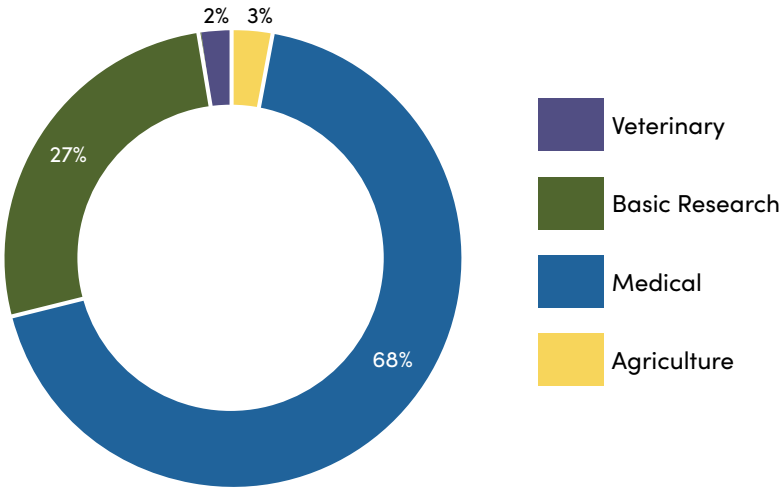


Figure 13: Distribution of DNIR licenses current as at 30 June 2021, by organisation type

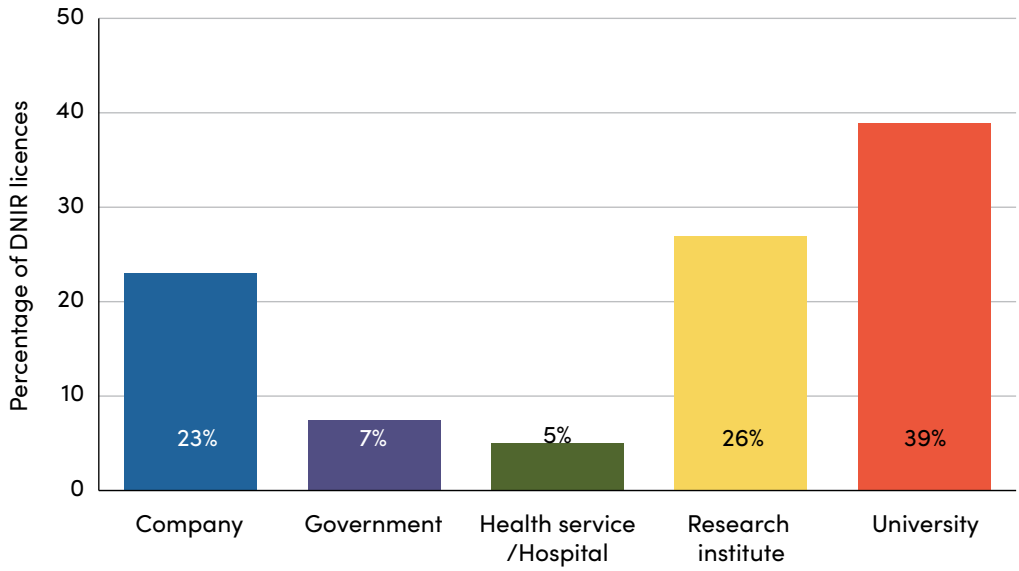
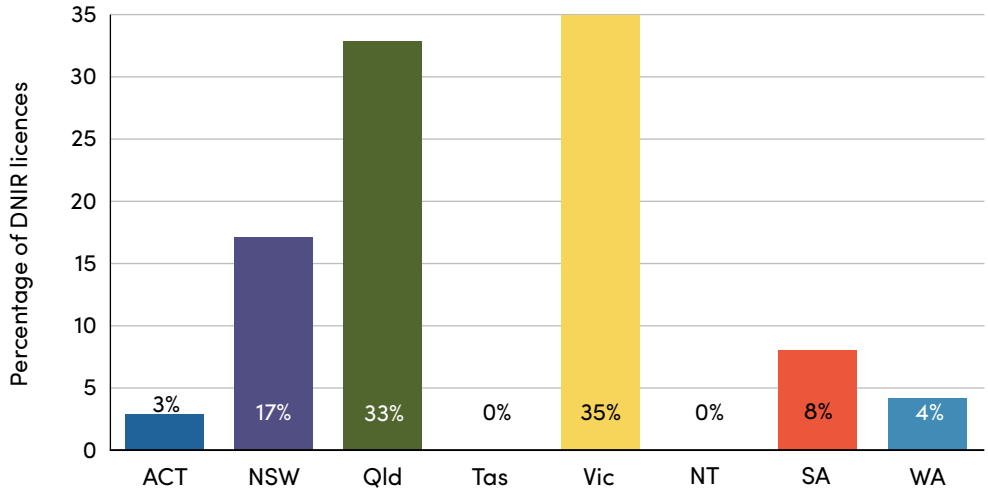
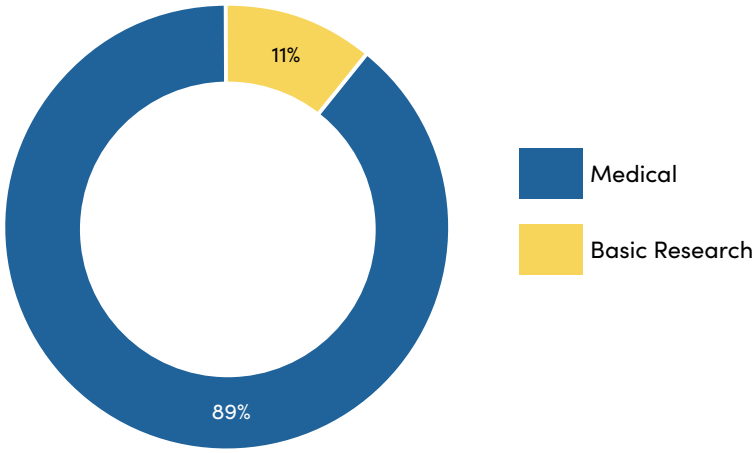


Figure 14: Distribution of DNIR licenses current as at 30 June 2021, by states and territories



Of the 19 DNIR licenses issued during 2020–21, 17 (89%) had a medical focus and the remaining 2 (11%) had a basic research focus (Figure 15). This shows a slight increase in medically focused work compared with all other current DNIR licenses.

Figure 15: Medical vs basic research focus of DNIR licenses issued during 2020–21



Notifiable low risk dealings

Notifiable low risk dealings (NLRDs) are GMO dealings that have been assessed, based on previous experience and current scientific knowledge, as posing low risk, provided certain criteria and risk management conditions are met. The criteria are published in Schedule 3, Parts 1 and 2 of the Gene Technology Regulations 2001. NLRDs can be conducted for a maximum of 5 years after which they expire and a new NLRD must be assessed by an institutional biosafety committee (IBC) in order for the dealings to continue.

During 2020–21, 770 NLRD notifications were received. As in past years, these were predominantly for research work. Figure 16 shows that there was a sizeable reduction in the number of NLRDs received for 2020–21 reporting period.

Figure 16: Number of NLRDs notified to the OGTR over the last 5 years

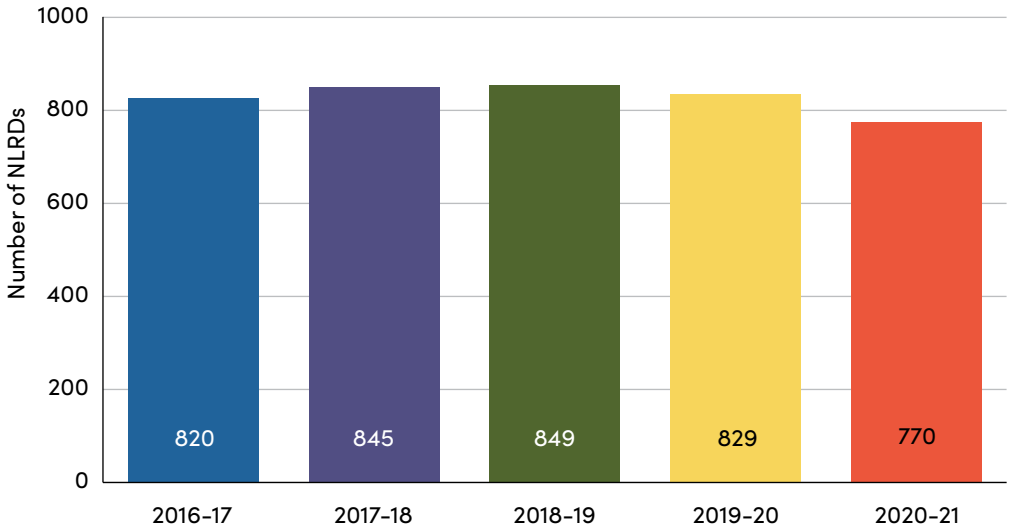
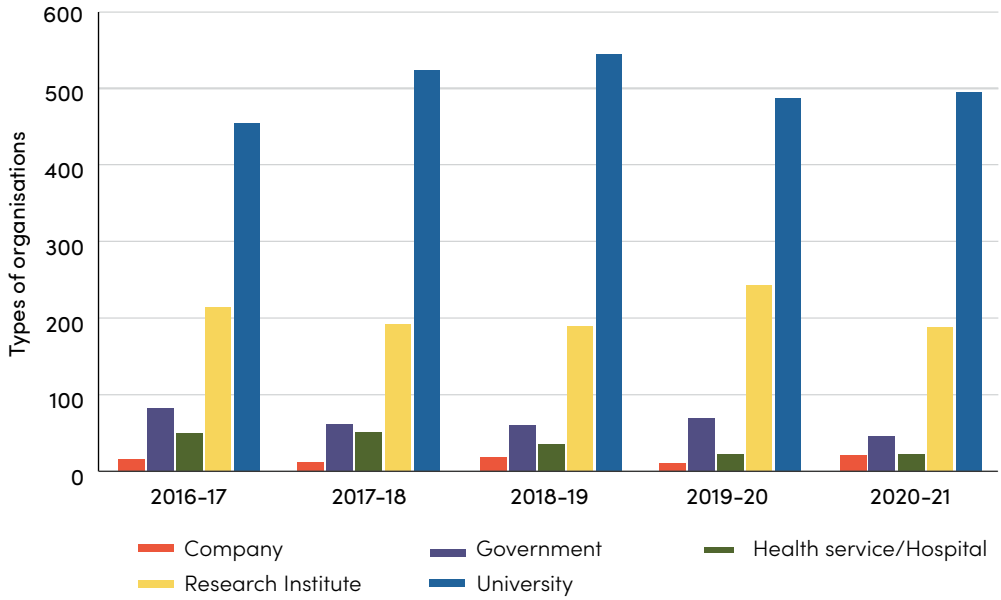


Figure 17 shows the types of organisations that reported NLRDs over the last 5 years. In 2019–20, when the outbreak of COVID-19 started, Figure 17 shows a reduction in the number of NLRDs submitted from Universities, Health service / Hospitals, and Companies, but an increase from Research Institutes and Government. In 2020–21 the number of NLRDs reported from Universities, Health service / Hospitals, and Companies remained largely the same as the previous year, but a sizeable reduction in Research Institutes and Government notifications can be seen, contributing to the overall reduction in NLRD's reported in 2020–21 as shown in Figure 16.

Many factors could impact the shifts in numbers that we have seen including the impact of the COVID-19 lock downs. Factors could include the strain on Health Services and Hospitals, the lack of University research activities as there was a shift to online learning and a reduction in International students, and the type of NLRD work being able to progress in the essential work environment.

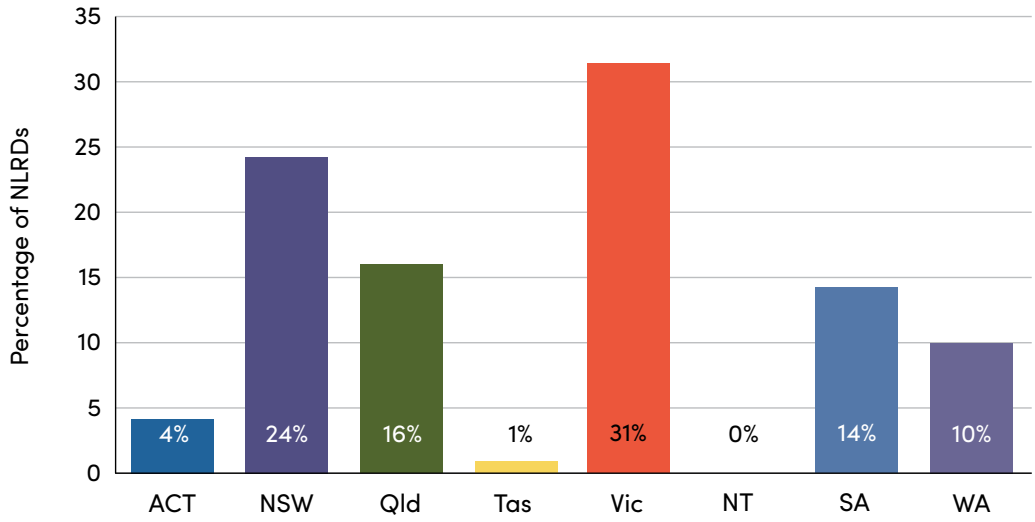
Figure 17: Types of organisations that notified to the OGTR over the last 5 years



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

The proportion of NLRDs notified in each state or territory which were current as at 30 June 2021 is shown in Figure 18.

Figure 18: Distribution of all current NLRDs as at 30 June 2021 by state or territory



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

During 2020–21, the Regulator received 2 requests for alternate facilities, with one being withdrawn by the applicant and one currently still under consideration. Eight alternate facility requests and 9 alternate transport, storage and disposal requests have been approved since the relevant provisions in Regulation 13 were introduced (September 2011).

Dealings placed on the GMO Register

The Regulator may determine that dealings with GMOs be included on the GMO Register provided they have previously been licensed, pose minimal risks to people or the environment, and are safe for anyone to undertake without the need for a licence. The determinations are legislative instruments that are not subject to disallowance, but the instrument must still be tabled in Parliament.

During 2020–21, the Regulator made a determination to include dealings with cut flowers of 3 GM carnation lines on the GMO Register in response to application REG002 from International Flower Developments Pty Ltd (IFD). The GM carnation lines, marketed as Moonaqua™, Moonberry™ and Moonvelvet™, have been modified to produce blue/purple coloured flowers. The determination came into effect on 17 July 2020. The dealings included on the GMO Register are import, transport and disposal of cut flowers from the GM carnations, enabling commercial distribution and sale of the cut flowers. The dealings had previously been authorised under the licence for DIR 134 since 2015.

Emergency dealing determinations

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

During 2020–21, the OGTR did not receive any requests for advice in relation to making emergency dealing determinations. No determinations were made, and none were in effect.

Licenses for inadvertent dealings

Part 5 of the Act allows the Regulator to grant inadvertent dealings licenses (a temporary licence of no longer than 12 months) to a person who has inadvertently come into possession of an unauthorised GMO so that they can safely dispose of the GMO.

During 2020–21, there were no new inadvertent dealings licenses issued, no applications were received and none were in effect.

Accreditation of organisations

Organisations may apply to the OGTR for accreditation under section 91 of the Act and the Regulator requires that organisations conducting licensed dealings with GMOs must remain accredited. To achieve and retain accreditation, the organisation must have access to a properly constituted and resourced institutional biosafety committee and must comply with other requirements of the Regulator's *Guidelines for Accreditation of Organisations*.

In 2020–21, 10 accreditations were issued, with a total of 186 organisations holding accreditation at 30 June 2021. Accredited organisations are located in all Australian states and territories (Figure 19). Over time, the profile of the types of organisations accredited by the Regulator has not changed significantly: a large proportion (60%) are primarily publicly funded, i.e. government, hospital/ health services, universities, and most research institutes. (Figure 20).

Figure 19: Organisations accredited as at 30 June 2021, by location of headquarters

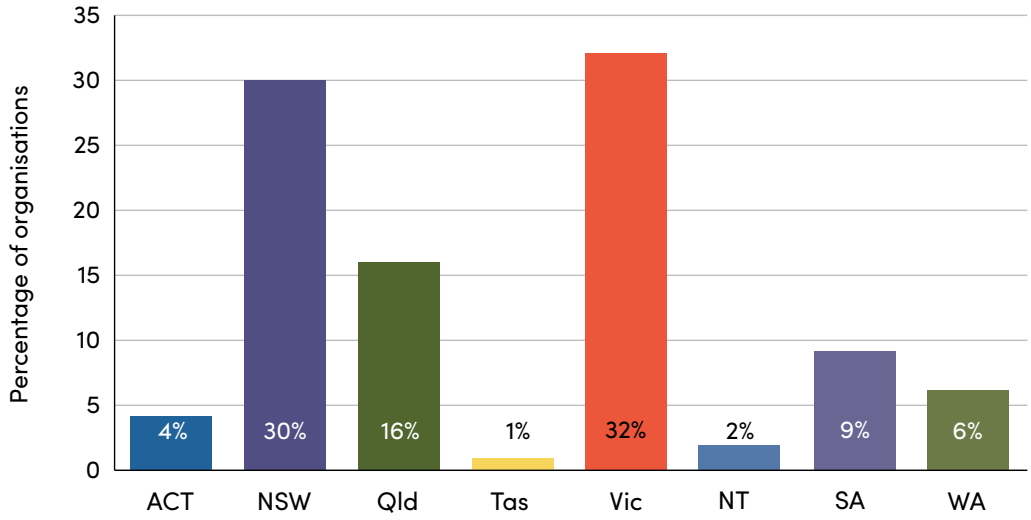
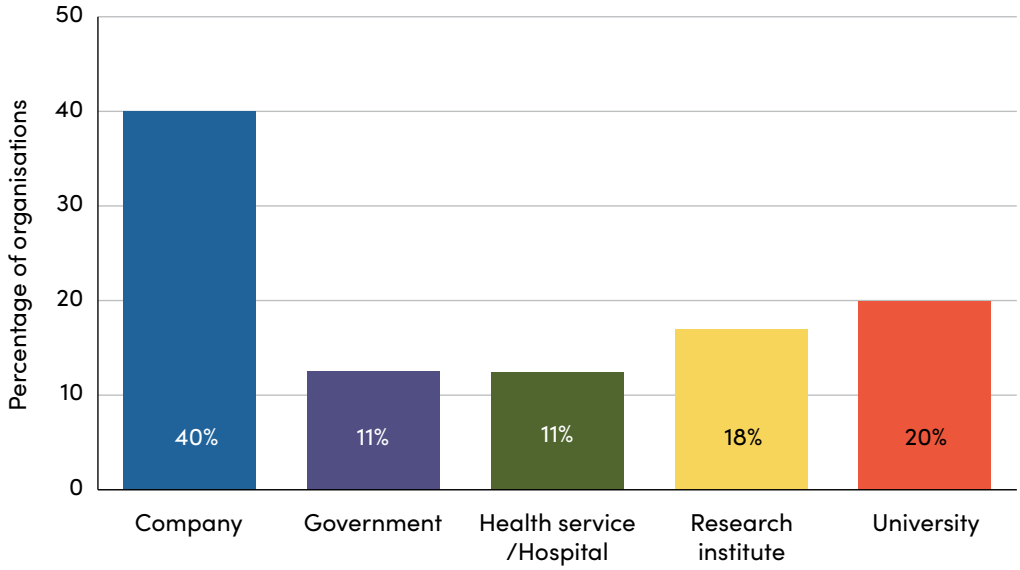


Figure 20: Types of organisations accredited as at 30 June 2020



Certification of physical containment facilities

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

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

During 2020–21, 101 new certifications for physical containment facilities were issued. There was one new high-level facility (PC3 laboratory) certified which was inspected by OGTR staff prior to certification.

High-level facilities (PC4, PC3 and PC2 large scale) are generally only certified for 3 years and require inspection by OGTR staff prior to re-certification. During 2020–21 OGTR staff inspected and re-certified 12 high level facilities. A further 12 facilities were unable to be inspected in person due to COVID-19 travel restrictions and were given short term extensions based on a desktop audit.

The number of OGTR-certified facilities at 30 June 2021 is listed by facility type and containment level in Table 5. PC2 laboratories are the most common type of facility certified by the Regulator (1742 PC2 laboratories).

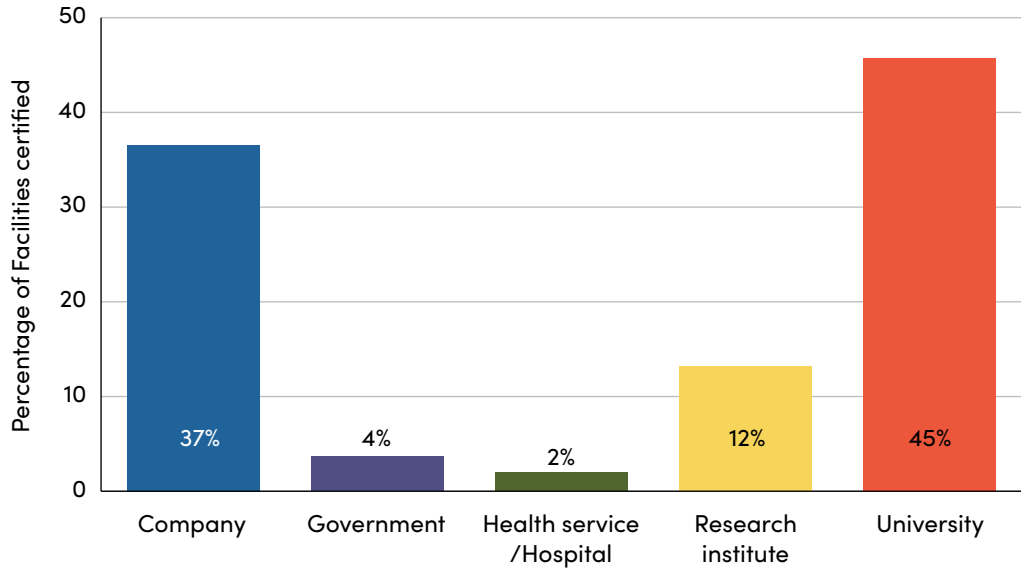
Table 5: Number of OGTR-certified facilities as at 30 June 2021*

FACILITY TYPE	PC1	PC2	PC3	PC4	TOTAL
Animal		236	6		242
Aquatic		31			31
Constant Temperature Room		41			41
Facility	304			4	308
Invertebrate		53	2		55
Laboratory		1178	24		1202
Large Grazing Animal		57			57
Large Scale		20			20
Plant		126			126
GRAND TOTAL	**304**	**1742**	**32**	**4**	**2082**

Note: PC = physical containment. PC1 and PC4 facilities are not categorised into types. This table excludes facilities for which the certifications were suspended (at the request of the certification holders) as at 30 June 2021

The types of organisations issued with new or renewed certifications in 2020–21 were predominantly universities with 46 (45%), companies 37 (37%), research institutes 12 (12%), government 4 (4%) and health service/hospitals 2 (2%) (Figure 21).

Figure 21: Facilities certified in 2020–21 by organisation type



The types of organisations currently holding certifications as at 30 June 2021 are predominantly universities with 1304 (58%), research institutes 381 (17%), and government agencies 285 (13%). Companies hold 153 (7%), with health service/hospitals 126 (5%). (Figure 22).

The distribution corresponds with the high number of authorisations for dealings requiring containment (DNIRs and NLRDs) held by universities and research institutes (see Figures 13 and 17). OGTR certified physical containment facilities are located in all Australian states and territories (Figure 23).

Figure 22: OGTR-certified facilities as at 30 June 2021, by organisation type

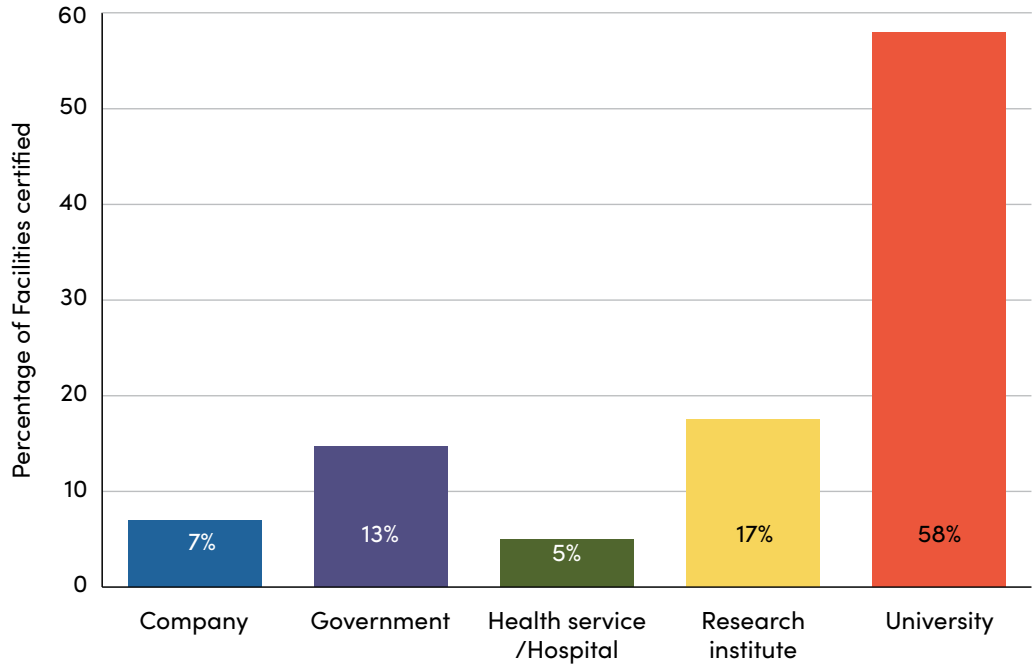
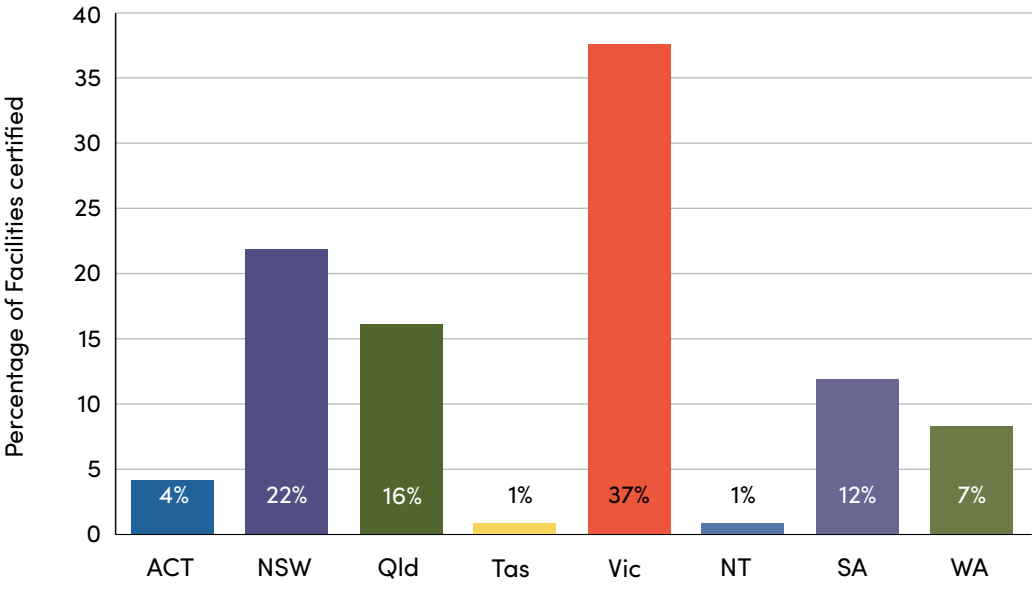


Figure 23: OGTR-certified facilities as at 30 June 2021, by location



Application trends

The numbers of most primary authorisation types issued during 2020–21 were similar to those in previous years (Table 6). However, there has been a drop in the number of new Certifications in the past 3 financial years and a large increase in the number of DNIRs over the last 2 financial years.

Table 6: Data for approval of main types of applications, 2016–17 to 2020–21

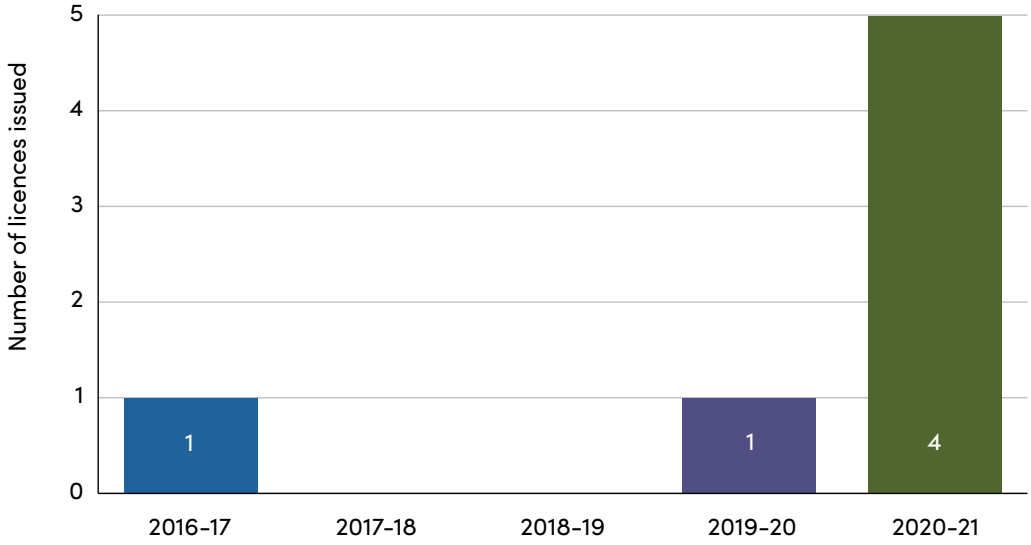
APPLICATION TYPE	2016–17	2017–18	2018–19	2019–2020	2020–2021
Accreditation	3	9	8	10	10
Certification	162	135	114[b]	100	101
DIR	9	9	6	3	9
DNIR[a]	10	9	11	20	19

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

a 'Approval' for DNIR refers to the number of licenses issued. This can differ from the total number of applications approved when 2 or more applications are integrated into a single licence.

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

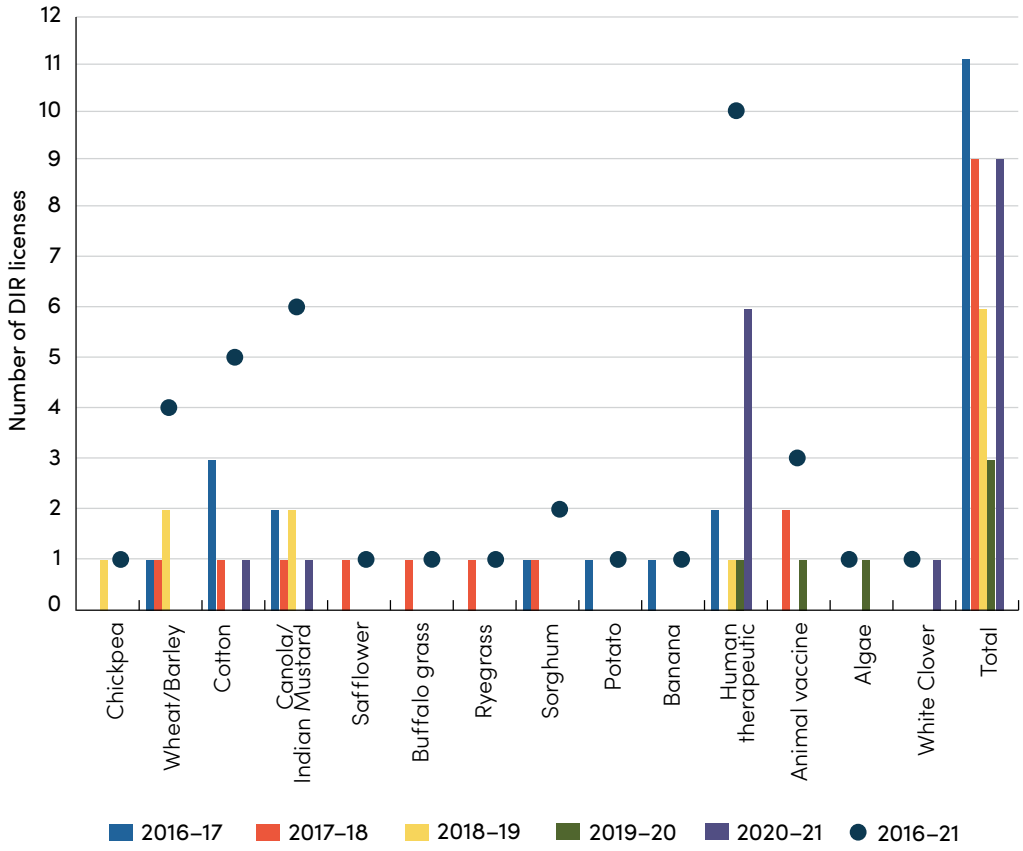
Figure 24: Commercial therapeutic GMO licenses issued, 2016–17 to 2020–21



There has been a large increase in the number of licenses issued for commercial GMO therapeutics in 2020–21, from one licence issued in 2016–17 and one in 2019–20 to 4 in 2020–21 (Figure 24). Over the past 20 years there have been 10 licenses issued for commercial GMO therapeutics, with 4 of those licenses in 2020–21 alone. These were 3 vaccines (2 for COVID-19 and one for cholera), and one gene therapy for the treatment of paediatric patients with spinal muscular atrophy.

Cotton, canola/Indian mustard, and wheat/barley have remained the most common crops for environmental release over the last 5 financial years (Figure 25). New crop licenses in the last 5 years include trials of sorghum, chickpea, potato and buffalo grass. There has also been a marked increase in human vaccines and therapeutics being trialled and commercially released. In 2020–21, 6 new licenses (limited and controlled or commercial release) were issued for GM therapeutics.

Figure 25: Focus of DIR licenses, 2016–17 to 2020–21

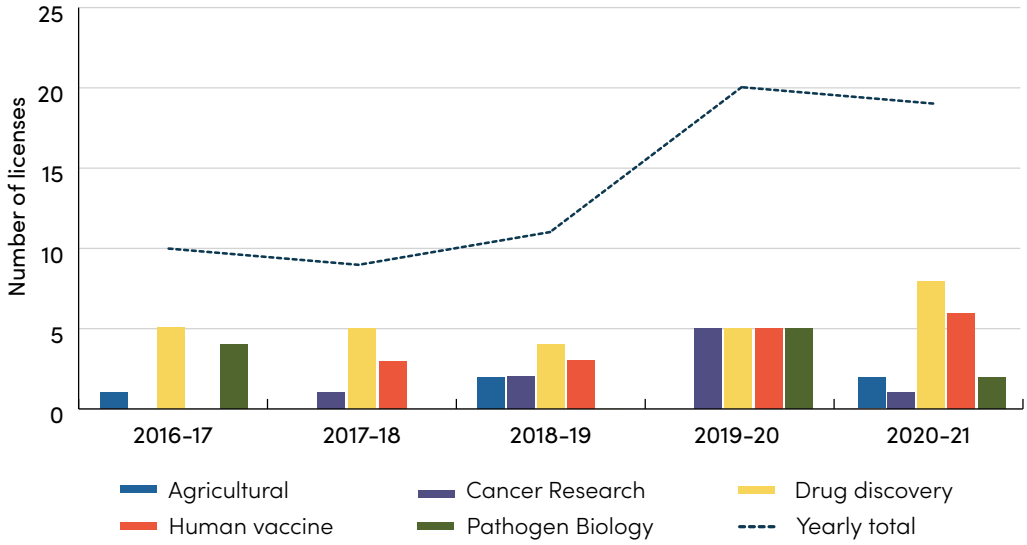


While there remains a higher than usual number of DNIR applications in 2020–21, there has also been a change in the character of DNIR licence applications received. There were more DNIR applications for human clinical trials of therapeutic GMOs than at any time in the previous 4 years (see Table 7). This continues the recent trend of increasing research interest and activity in the area of human therapeutic GMOs. There was also strong interest in vaccine development and drug delivery, and fewer licenses issued for cancer treatments or research into pathogen biology. 2020–21 also saw the issuing of 2 agriculturally focused DNIR licenses (Figure 26).

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

	2016–2017	2017–2018	2018–2019	2019–2020	2020–2021
Clinical trial DNIRs	1	6	9	10	12
Proportion of accreditation applications received from companies involved in clinical trials or human therapeutic GMO development	60%	57%	88%	60%	40%

Figure 26: Fields of research authorised under DNIR licenses, 2016–17 to 2020–21



Note: Agricultural include animal vaccines, importing grain for food or feed use, and studying the biology of plant and animal pathogens.
Cancer research involves both studying cancer mechanisms as well as developing and testing potential treatments.
Drug discovery involves identifying and testing possible new human therapeutics and delivery methods.
Human vaccines include both the development and testing of vaccines to be used in humans
Pathogen biology includes the study of human pathogens and any toxins they may produce.

Secondary applications

Confidential commercial information

Applications can be made to the Regulator under section 184 of the Act for specified information—that has not previously been made public—to be declared confidential commercial information (CCI). The extent of these claims can be the subject of considerable discussion with the applicant and may require the OGTR to independently verify what information is already in the public domain. The Act does not assign a statutory timeframe for the Regulator's decision on CCI applications, and the evaluation of a licence application may be paused if significant claims need to be resolved.

In 2020–21, the Regulator made 16 CCI declarations.

Surrenders

The surrender of licenses 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 91 surrender requests in 2020–21 and approved 76 for surrender of certifications of facilities, 8 for surrender of DIR licenses, 3 for surrender of a DNIR licence and 4 for surrender of accreditation.

Variations

Authorisation holders may apply to the Regulator for variations to instruments issued under the Act (licence, certification or accreditation), and the Regulator may also initiate variations. Variations range from minor administrative changes (such as a change to contact details in a licence or room numbers in a certification) to significant changes (such as extending the period of authorisation, growing a GM crop at a new site, new procedures for handling GMOs or changes to the area of a certified facility). In February 2019, the Regulator introduced application forms for DIR and DNIR licence variations to provide licence holders with guidance on the type of information to include in their application for a variation.

The Regulator approved 485 variation requests in 2020–21. Of these, 6 were for DIRs, 30 for DNIRs and 449 for certifications.

Monitoring dealings with genetically modified organisms

This section provides information on the OGTR's inspection activities during 2020–21. Due to the COVID-19 pandemic travel restrictions, some of the monitoring and compliance activities were conducted in a desktop capacity, comprising:

- 2 monitoring inspections of a DIR licence
- 4 monitoring inspections of DNIR licenses
- 23 monitoring inspections of certified facilities
- one Practice Review of a clinical trial.

The OGTR has received an increasing number of clinical trial applications, and therefore Monitoring and Compliance activities are commensurately focused on these activities to ensure compliance and to assist licence holders new to the gene technology scheme in achieving best practice. For further information see sections on 'Inspections of contained dealings' and also 'Practice Reviews'.

Inspections of DIR licenses

The Regulator's strategy for monitoring of trials for compliance with licence conditions draws on accumulated experience based on risk profiling and sampling of a range of dealings, locations where dealings are undertaken, and organisations who are conducting dealings.[9]

During 2020–21, there were 58 DIR licenses in force held by 27 accredited organisations. These comprised:

- 27 commercial release licenses (19 for plant crops, 7 for human clinical products and one animal vaccine product)
- 31 limited and controlled release licenses (19 for plant field trials, 8 human clinical trials, 3 animal vaccine trials and one for microalgae).

None of the commercial release licenses imposed conditions that necessitated site inspections. The OGTR inspected 5 of the 19 limited and controlled plant field trial licenses (which may have comprised multiple site visits per licence), and one human vaccine trial licence.

9 Details are in the Monitoring Protocol on the OGTR website

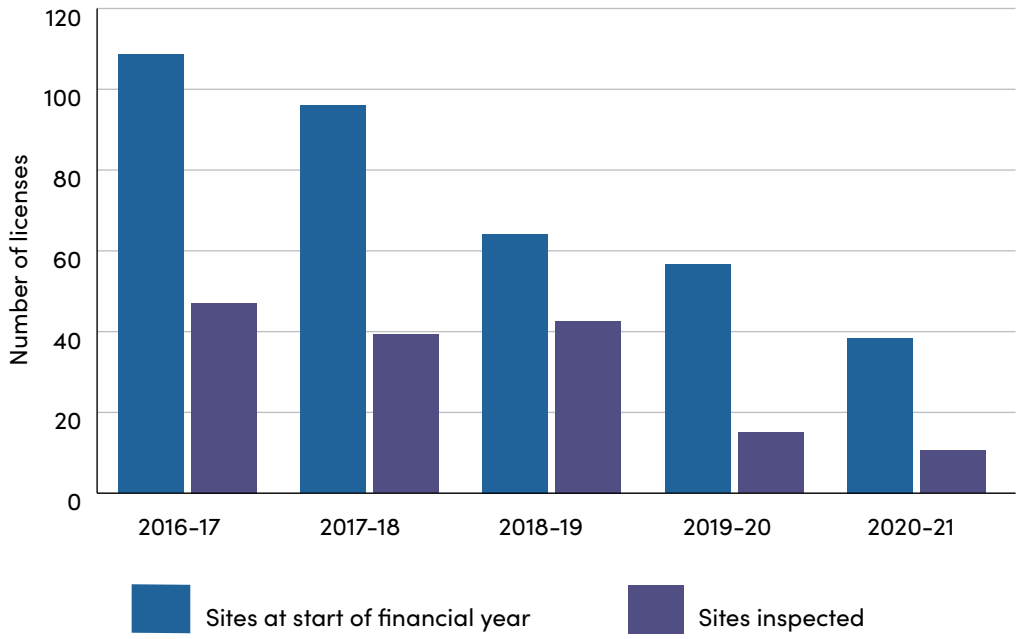
Outcome of inspection activities

The Regulator implements a risk-based selection process to identify limited and controlled release field sites and research or clinical trial sites for inspection. This process includes consideration of:

- the nature of the genetic modification and whether a site has reached a licence-specific milestone (that is, flowering, harvest or sign-off)
- reports of incidents of potential non-compliances at sites, or after adverse weather events such as storms, floods or cyclones
- the level of experience of the licence holder and the potential for inspection activities to assist in preventing the occurrence of non-compliance.

At the beginning of 2020–21, 38 licensed field trial sites were operating, 5 of which were current and 33 were subject to post-harvest monitoring conditions (Figure 27). Twenty-nine per cent of the plant field trial sites were inspected in the year.

Figure 27: Number of sites and number inspected each year, 2016-20



Types of GM crops inspected

OGTR inspected 5 plant species across 11 field trial sites during 2020–21 (Table 8). In 2020–21, the OGTR inspected field trial sites in all states and territories where field trials were being undertaken, except the Australian Capital Territory and South Australia. No trials were undertaken in Tasmania during 2020–21.

Table 8: Number of licensed GM plant DIR trial sites at beginning and end of 2020–21, and number inspected in 2020–21, by plant type

SPECIES	TRIAL SITES AS AT 1 JULY 2020	TRIAL SITES AS AT 30 JUNE 2021	TRIAL SITES INSPECTED DURING 2020–21
Banana	2	2	2
Barley, Wheat	4	1	1
Chickpea	1	1	0
Cotton	12	8	2
Perennial ryegrass	1	1	0
Sorghum	3	4	4
Wheat	15	5	2
TOTAL	**38**	**22**	**11**

PC plant facility

Inspection of a sorghum crop

Sorghum crop

Inspections of contained dealings

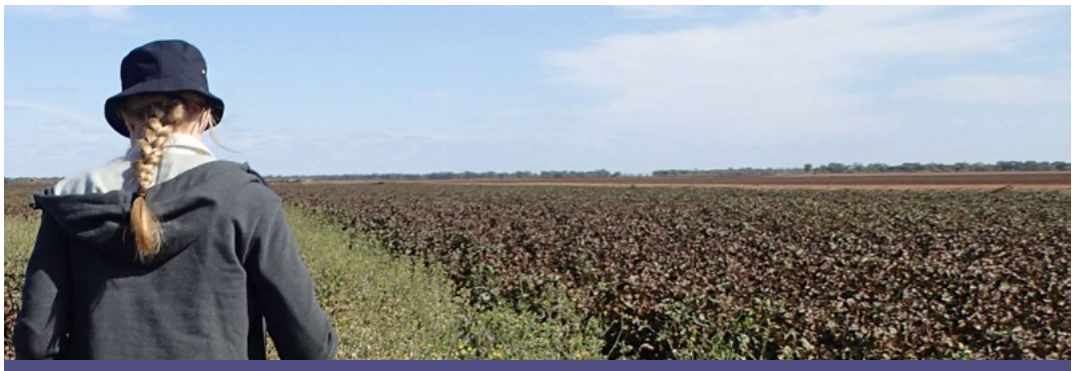
OGTRs monitoring program includes GMO dealings conducted in clinical facilities and certified containment facilities under DNIR licenses and NLRDs. For monitoring purposes, certified facilities are grouped into higher and lower containment types. These are designated by physical containment (PC) level. Accordingly, PC4, PC3 and PC2 large-scale laboratories are categorised as higher-level containment facilities and the remaining facility types are categorised as lower-level containment facilities. As well as examining the integrity of the physical structure of the facility, inspections cover the general work practices used in handling GMOs.

During 2020–21, 60 certified facilities were inspected across the range of facility types (Table 9); this includes 8 of the 55 higher-level containment facilities that had certification approvals in force at the beginning of 2020–21 (representing 15%).

In addition, 13 licenses for clinical trials or contained licenses were subject to monitoring inspections or practice reviews throughout 2020–21 (Table 10).

Table 9: Number of inspections of certified facilities (by type) conducted during 2020–21

CONTAINMENT TYPE	PC LEVEL AND FACILITY TYPE	INSPECTIONS
Lower level	PC1 Facility	0
	PC2 Animal	8
	PC2 Laboratory	40
	PC2 Plant	2
	PC2 Aquatic	0
	PC2 Large Grazing Animal	0
	PC2 Constant Temperature	0
	PC2 Invertebrate	2
Higher level	PC2 Large Scale	1
	PC3 Laboratory	3
	PC3 Animal	2
	PC3 Invertebrate	1
	PC4 Facility	1
TOTAL		**60**



Cotton field trial site

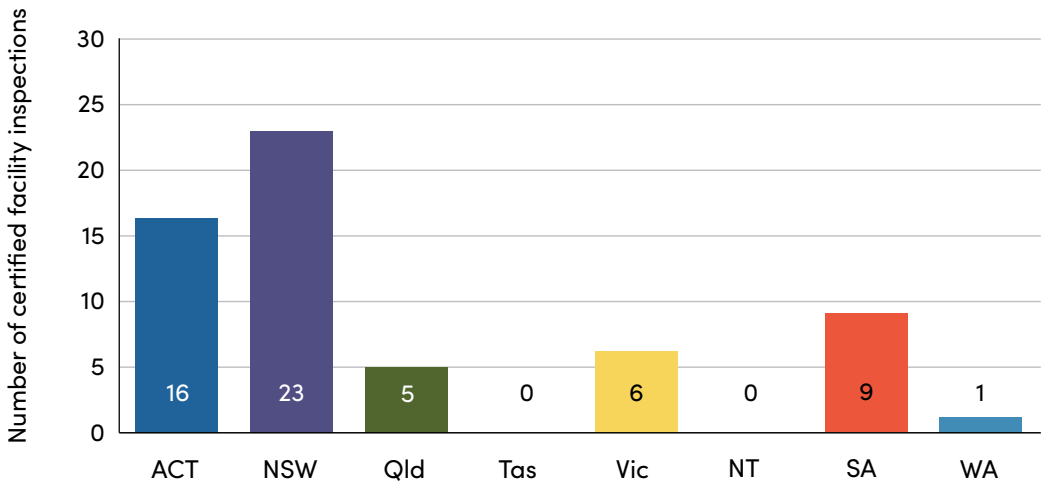
Table 10: Number of inspections or practice reviews of contained licenses and clinical trials conducted during 2020–21

ORGANISATION	STATE	LICENCE
Novotech Australia Pty Ltd	Qld	DIR-161
University of Wollongong	NSW	DNIR-081
The University of Adelaide	SA	DNIR-230
The University of Queensland	Qld	DNIR-472
University of Canberra	ACT	DNIR-478
CSIRO	ACT	DNIR-495
Western Sydney University	NSW	DNIR-552
Monash University	Vic	DNIR-556
The Children's Hospital at Westmead	NSW	DNIR-586
TheraVir Pty Ltd	SA	DNIR-602
Peter MacCallum Cancer Centre	Vic	DNIR-606
The University of Queensland	Qld	DNIR-634
Avance Clinical Pty Ltd	Qld	DNIR-636
TOTAL		13

Locations of facility inspections

Certified facilities are located in all Australian states and territories (Figure 23). In 2020–21, monitoring activities took place in each state and territory except the Northern Territory and Tasmania (Figure 28).

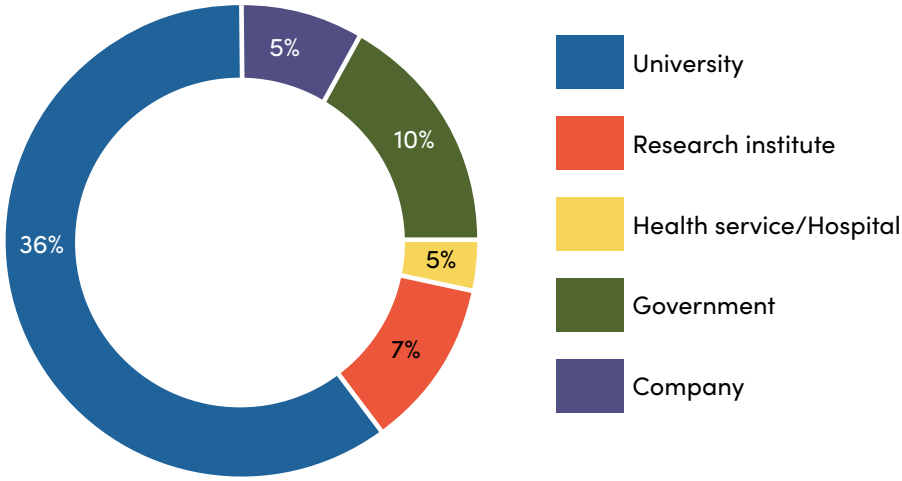
Figure 28: Number of certified facility inspections in 2020–21, by state and territory



Types of organisations inspected

Of the 5 categories of applicant organisations, universities held the largest number of certified facilities during 2020–21 (Figure 22). Figure 29 displays the distribution of inspections during 2020–21 by organisation type. Universities comprised the majority of inspections followed by government, research institutes, companies and health services/hospitals.

Figure 29: Certified facility inspections in 2020–21, by organisation type



Compliance with the Act

The monitoring activities of the OGTR with respect to dealings with GMOs, in accordance with section 136 (1A) of the Act, and the Regulator's response to those findings, are listed below.

Matters referred to as non-compliances in this report reflect situations where inspectors have found inconsistencies relating to requirements imposed by licence or certification conditions. Non-compliance is not regarded as a breach of the licence conditions unless proven to be so after investigation. Non-compliance with licence conditions is assessed against the OGTR Compliance and Enforcement Policy.[10]

During 2020–21, the regulated community continued to demonstrate a high level of compliance with the gene technology legislation.

Non-compliance findings for GMO dealings involving intentional release

In 2020–21, no DIR licence holders were found to be non-compliant.

Non-compliance findings for GMO dealings not involving intentional release

In 2020–21, no DNIR licence holders were found to be non-compliant.

Non-compliance findings for notifiable low risk dealings

In 2020–21, 3 NLRDs were found to be non-compliant against the Regulations, in that dealings were being undertaken in non-certified facilities.

Non-compliance findings for physical containment facilities

In 2020–21, 13 certified physical containment facilities were found to be non-compliant with a total of 18 certification conditions. These findings are summarised in Table 11.

10 The Compliance and Enforcement Policy is on the OGTR website

Table 11: Number of non-compliances identified in certified facilities during 2020–21, by non-compliance type

NATURE OF NON-COMPLIANCE	NUMBER
Equipment	3
Personal protective equipment	0
Structure	1
Transport	1
Waste disposal	0
Work practices	13

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

Compliance and enforcement mechanisms

Practice reviews

The OGTR may initiate practice reviews:

- to explore topics that could potentially pose compliance issues in the future
- to assess the effectiveness of systems used by licence holders and IBCs
- in response to observations made during monitoring activities
- to follow up incident reports, such as those that may relate to non-compliance with licence and certification conditions.

The overarching objective of practice reviews is to determine whether organisations have the ongoing capacity to comply with the gene technology legislation. Practice reviews may also have more focused objectives, specific to a particular matter or condition of a licence or certification instrument. In addition, an accredited organisation may request a practice review to assess the effectiveness of systems used by its institutional biosafety committee(s) to ensure that GMO dealings are being conducted in accordance with the Act.

Practice reviews have a significant education and awareness raising component. In certain instances where a suspected non-compliance with the Act is identified, findings may be referred for investigation.

The OGTR undertook 3 practice reviews with 3 organisations during this reporting period. Two were completed in the reporting period and the third review was still under consideration and the findings therefore will be included in the next reporting period. This year practice reviews covered one topic area and the findings for the reviews are outlined below. Included in the findings is a practice review from 2019–20, which was completed in 2020–21.

TOPIC	PREPAREDNESS OF ACCREDITED ORGANISATIONS TO UNDERTAKE LICENSED DEALINGS NOT INVOLVING INTENTIONAL RELEASE – HUMAN CLINICAL TRIALS
AIM	This is part of the OGTR's ongoing practice review program. The OGTR recognises that effective compliance is dependent on: • suitable arrangements to manage compliance for GMO dealings • suitable site selection and appropriate use of containment measures • staff training and provision of resources necessary to manage compliance obligations.
PARTICIPANTS	The review focused primarily on the organisation's preparedness to undertake clinical trials in humans and included: Peter MacCallum Cancer Centre and Avance Clinical Pty Ltd. The review assessed: • site selection and planning considerations for containment measures • the suitability of the organisations' arrangements to manage compliance risks, including training and oversight of staff, collaborating organisations and resourcing • any industry or other regulatory issues which could impinge on the organisations' effective compliance performance.
FINDINGS	The review found that the participating accredited organisations had considered and implemented effective measures in relation to site selection and planning for a licensed dealing not involving an intentional release.
OUTCOMES	The OGTR practice review program continued to assess vulnerabilities to containment and compliance with the *Gene Technology Act 2000*. Such information contributed to: • an overall understanding of compliance performance and emerging barriers to effective compliance • the continual improvement of compliance management processes • the prevention of practices and arrangements that could lead to non-compliance • compliance management and awareness activities.

TOPIC	PREPAREDNESS OF ACCREDITED ORGANISATIONS TO UNDERTAKE LICENSED DEALINGS INVOLVING INTENTIONAL RELEASE
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 CSIRO preparedness to undertake licensed dealings involving intentional release at the new research station at Boorowa NSW. The review assessed: • planning considerations for containment measures • the suitability of the organisations' arrangements to manage compliance risks, including training and oversight of staff, and resourcing • any industry or other regulatory issues which could impinge on the organisations' effective compliance performance.
FINDINGS	The review found that CSIRO had considered and implemented effective measures in relation to planning for a licensed dealing involving an intentional release.
OUTCOMES	The OGTR practice review program continued to assess vulnerabilities to containment and compliance with the *Gene Technology Act 2000*. Such information contributed to: • an overall understanding of compliance performance and emerging barriers to effective compliance • the continual improvement of compliance management processes • the prevention of practices and arrangements that could lead to non-compliance • compliance management and awareness activities.

Audits

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

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

These activities are conducted to:

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

Audits are an opportunity for organisations and the OGTR to share information to improve the risk management of dealings with GMOs under the Act. Audits may focus on a single dealing or issue, a range of dealings (e.g., dealings with a common host organism or dealings within a common climatic zone), the activity of an organisation across a range of dealings, or an activity common to a range of organisations.

One audit of CSIRO was undertaken in 2019–20, which was finalised in 2020–21 as outlined below.

AUDIT	CSIRO AUSTRALIAN CENTRE FOR DISEASE PREPAREDNESS (ACDP)
AIM	To provide advice to the Regulator with regards to ACDP's ongoing capacity to meet regulatory obligations
DETERMINATION	The audit found that CSIRO ACDP: • has a high level of management oversight with a strong organisational focus on biosafety • a demonstrated capacity to meet regulatory obligations • are responsive to challenges in the regulatory landscape.
ACTION	The OGTR proposed that: • ACDP continue to develop policies and procedures to aid regulatory compliance • there would be a continued oversight of ACDP regulatory compliance through routine monitoring • ACDP and OGTR will continue to explore new strategies to effectively manage regulatory risks.

Audits are also undertaken as part of the national strategy for unintended presence of unapproved GMOs in agricultural crops. OGTR is responsible for implementing a risk-based national strategy to manage the unintended presence of unapproved GMOs in seeds imported for sowing in Australia. The strategy was proposed and developed in 2005 under the then Australian Government Biotechnology Ministerial Council.

The strategy uses a risk management approach, with resources dedicated to the areas posing the highest likelihood of unintended presence of GMOs in agricultural crops. We have worked with the Australian Seed Federation (ASF) to develop a voluntary testing program of existing industry quality assurance measures.

In 2020–21, we continued to liaise with the seed industry to raise awareness about management of low-level presence of GMOs, and to ensure their ongoing voluntary cooperation and action regarding this issue. We continued to engage with other government departments, including the Australian Government Department of Agriculture, Water and the Environment, regarding low-level presence of unapproved GMOs in agricultural crops, and no incidents were identified in Australia.

Investigations

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

No investigations were undertaken in this reporting period.

Security Sensitive Biological Agents Regulatory Scheme

The *National Health Security Act 2007*, administered by the Department's Office of Health Protection and Response Division, provides for a scheme to regulate a List of Security Sensitive Biological Agents. Regulation 5A of the Gene Technology Regulations 2001 provides for OGTR inspectors to also be appointed as inspectors under the *National Health Security Act 2007*. Under a service level agreement, monitoring and compliance arrangements commenced early in 2009–10. During 2020–21, the OGTR continued to work with the Office of Health Protection and Response to operationalise these monitoring arrangements, however these activities were impacted by the implementation of COVID-19 response measures, including border closures, travel restrictions and physical distancing restrictions throughout 2020–21. Inspections continued in a desktop capacity during this time.

Performance against Portfolio Budget Statements targets

Our performance against the deliverables and key performance indicators set out in the Portfolio Budget Statements, which is also reported in the Department's 2020–21 annual report, is summarised below.

Our activities for 2020–21 are described under Program 5.1 in Outcome 5 (Regulation, Safety and Protection) of the 2020–21 Department of Health Portfolio Budget Statements.[11] The key objective of the subprogram relating to gene technology regulation is:

> ***Protecting the health and safety of people and the environment by regulating work with genetically modified organisms.***

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

Protect people and the environment through open, effective and transparent regulation of genetically modified organisms (GMOs).

2020–21 TARGET	2020–21 RESULT: MET
All decisions are made within the statutory timeframes, supported by scientific risk analysis.	100% of licensed dealings were made within statutory timeframes, with all decisions based on sound scientific analysis.
Continue to monitor regulated dealings with GMOs to ensure compliance with gene technology legislation.	Regulated dealings with GMOs were monitored through a combination of onsite visits and desktop audits.
No adverse effect on human health or environment from authorised GMOs.	There were no reports of adverse effects on human health or the environment from authorised GMOs.

The OGTR has skilled technical staff to conduct science-based risk assessments. There are project management structures in place for all licence applications, including timeframe and quality assurance reporting, with public consultation procedures built in to relevant decision making processes. The following licenses were issued during 2020–21:

- 5 licenses for trial of genetically modified (GM) vaccines for COVID-19
- 3 licenses for trial of GM cancer treatments
- 6 licenses for trial of GM therapeutics
- one licence for pre-clinical (in vitro and animal) research into understanding and treating human diseases
- one licence for the commercial supply of a GM therapy for an inherited condition
- 3 licenses for the commercial supply of vaccines against human diseases (including 2 COVID-19 vaccines)
- 2 licenses for the production of a COVID-19 vaccine
- 2 licenses for contained research on gene drives
- one licence for trial of GM crops
- 2 licenses for the commercial release of GM plants.

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

Monitoring and compliance desktop and onsite inspections showed a high level of compliance with licence and certification requirements. Stakeholders are continuing to work with inspectors using a cooperative compliance approach. As of June 2021, there were:

- 19 active clinical trial licenses for human therapeutics (2 for COVID-19-related therapeutics) and 2 active licenses for trials of animal therapeutics
- 12 licenses for the manufacture or commercial supply of human therapeutics (4 for COVID-19-related therapeutics) and 3 for animal therapeutics
- 14 licenses for GM plant field trials, with 22 active field trial sites for GM crops
- 18 licenses for the commercial release of GM plants and 5 licenses for the import of GM grain for processing
- 97 licenses for research using GMOs (one for COVID-19 related research)
- Over 2,000 facilities certified as appropriate for work with GMOs.

Chapter 4

Other Functions of the Gene Technology Regulator

This chapter describes achievements on other functions of the Regulator.

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

- developing draft policy principles and policy guidelines, as requested by the GTMM
- developing codes of practice
- issuing technical and procedural guidelines in relation to GMOs
- providing information and advice about GMOs and GM products to other regulatory agencies
- providing information and advice to the public about the regulation of GMOs
- providing advice to the GTMM about the:
  - operations of the Regulator and the GTTAC
  - effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation
- undertaking or commissioning research in relation to risk assessment and the biosafety of GMOs
- promoting the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies
- maintaining links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia
- performing such other functions as are conferred on the Regulator by the Act, the Regulations or any other law.

These functions maintain the OGTR's capacity to conduct high-quality risk analysis based on regulatory best practice and relevant scientific data.

Technical and procedural guidelines issued by the Regulator

In 2020–21, OGTR has continued reviewing the PC3 Certification Guidelines. This built on regulated stakeholder workshops held in 2018–19 in Melbourne, Sydney and Brisbane, and at the 2019 IBC Forum. Work in 2020–21 has focused on seeking advice from technical experts and further internal OGTR discussion of issues raised in consultation including key technical matters, the interaction with draft AS/NZS Standards and analysis of data collected during Monitoring visits.

2019 amendments to the Regulations

Amendments to the Gene Technology Regulations 2001 that resulted from the Regulator's most recent Technical Review, made by the Governor General in April 2019, are now fully in effect. The final schedule of the Gene Technology Amendment (2019 Measures No. 1) Regulations 2019 commenced on 8 October 2020, to repeal an item on the list of organisms that are not GMOs. The transitional arrangements that came into effect on 8 October 2019, for GMO dealings for which requirements were changing, also ended on that day. The Federal Register of Legislation compilation of the Regulations now incorporates all 3 schedules of amendments.

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

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

In 2020–2021, OGTR continued administrative implementation of the review recommendations. Streamlining initiatives to reduce regulatory burden included ongoing digital service delivery roll-out (online forms). OGTR has continued to provide technical and operational information to assist the Department of Health team leading the implementation of review recommendations. This included a series of consultation webinars where the OGTR team was responsible for presenting technical aspects and participating on the expert panel addressing audience questions, both live during the webinar and in writing for publication of FAQs. This work will continue into 2021–22.

Advice on GMOs and GM products

During 2020–21, the OGTR advised other regulatory agencies and the public on the regulation of GMOs and GM products.

Advice to other regulatory agencies

To facilitate reciprocal exchange of information with product regulators and other agencies on assessing and approving GMOs and GM products, the OGTR has developed memorandums of understanding (MOU) with Food Standards Australia New Zealand, Therapeutic Goods Administration and Australian Pesticides and Veterinary Medicines Authority.

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

The OGTR has provided advice regarding regulatory interfaces between the OGTR and the Australian Pesticides and Veterinary Medicines Authority to the 'Independent review of the pesticides and veterinary medicines regulatory system in Australia', and between the OGTR and Food Standards Australia and New Zealand to the '*Review of the Food Standards Australia and New Zealand Act 1991*'.

Inter-agency cooperation

The Regulatory Science Network (RSN) is a network of Australian government agencies responsible for regulating chemicals and/or biological agents. It aims to strengthen the regulation of these across government agencies. It also provides a forum for discussing regulatory and technical issues, and enhancing interagency cooperation.

OGTR's contributions to the 2020 RSN Annual Symposium on 'International Year of Plant Health' included a keynote presentation by Dr Alison Wardrop, and a session chaired by Dr Heidi Mitchell. The symposium was run in an online format and was well-attended by OGTR staff. OGTR continues to be active in the RSN and Dr Heidi Mitchell from OGTR is the 2021 chair of the RSN. This year, the RSN has introduced lunchtime webinars presented by representatives of the RSN agencies about their work and how it connects with the work of other RSN agencies.

Advice to the public

The Act requires the Regulator to maintain a record of approvals for GMO dealings (the GMO Record), which can be accessed by the public.[12] The GMO Record contains information on licenses issued, NLRDs notified, GMO dealings included on the Register, and emergency dealing determinations. During 2020–21, OGTR maintained the GMO Record and updated it with new authorisations.

Engagement with stakeholders

Digital service delivery for applications to the Regulator

As part of the ongoing development of digital service delivery, work on several forms has progressed during 2020–21 with the view to releasing these within the 2021–22 financial year. These forms include:

- Authorisation Guidance Tool
- Application for Accreditation of an Organisation
- Application to Transfer an Authorisation.

Enhancements of existing forms have also progressed to enable applications for "Surrender" of licenses to be included within the following forms. These updated forms should also be on track for release within the 2021–22 financial year:

- Application to Vary a DIR Licence
- Application to Vary a DNIR Licence.

Information on COVID-19

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

Meeting and conference attendance

During 2020–21, the Regulator and OGTR staff participated in a range of conferences and meetings on gene technology to inform users, the Australian community and stakeholders about the regulatory system. These included:

- Australasian College of Toxicology & Risk Assessment webinar series, 3 sessions in July, August and October 2020
- Beyond politics: Past, current and potential futures for GM regulation and oversight in Australia, Stretton Institute webinar, 24 July 2020
- Presentation to La Trobe University botany students on the Scheme, 19 August 2020
- ABSANZ annual general meeting, online 21 October 2020
- Regulatory Science Network Annual Symposium 2020: Regulating for Plant Health, online 3–5 November 2020
- 2020 Australian Longitudinal Study on Women's Health (ALSWH) symposium, online 23–27 November 2020

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

- ABSANZ Summit 2020: Biosafety – The New Norm, online 24–26 November 2020
- ABSANZ webinar series:
  - Security Sensitive Biological Agents Regulatory Scheme – 4 March 2021
  - Validation methodologies for different types of microbial decontamination – 15 April 2021
  - The Humble Autoclave – 25 May 2021
- APARS discussion: 'When is meat not meat?', online 17 March 2021
- The National Regulators Community of Practice, the Australia and New Zealand School of Government, and the Electoral Regulation Research Network Present: The Struggle to Regulate Integrity; Money and Politics Webinar, 19 April 2021
- Australian Society for Microbiology 2021, online 31 May–3 June 2021
- ARCS Australia 2021 Conference, online 7–9 June 2021

Research undertaken or commissioned by the Regulator

Documents to support the risk assessment of GMOs

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

During 2020–21, OGTR updated 2 biology documents:

- The Biology of *Triticum aestivum* L. (Bread Wheat)
- The Biology of *Trifolium repens* L. (White Clover)

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

Community attitudes survey

Since 2015, the Regulator has commissioned *community attitudes towards gene technology* surveys to gauge the state of Australian public awareness of gene technology, to identify knowledge gaps and to track changes in awareness and attitudes over time. A 2021 survey was commissioned in 2020–21 and is anticipated to be publicly available in late 2021. In addition to continuing to track community attitudes and behaviours, this survey will also consider the effect the COVID-19 pandemic may have had on attitudes.

IT systems modernisation project

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

Promoting harmonisation

The Regulator and OGTR continued to liaise with other regulatory and Australian Government agencies on relevant issues, but in a somewhat different format to usual during the latter quarter of 2020 due to the COVID-19 pandemic.

International regulatory liaison

Actively participating in international forums helps OGTR keep Australia's regulatory scheme up-to-date with developments in GMO regulation and science. International engagement also enables Australia to contribute to international best practice based on its practical experience of administering efficient and effective GMO regulation.

The OGTR continued to engage in international fora about harmonising risk assessment and regulation of GMOs. The OGTR leads Australian representation on, and coordinates Australian input to, the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology. The working group develops scientific guidance to support the risk assessment of GMOs. Feedback from meetings indicates a high regard for the Australian gene technology regulatory system.

The OGTR provides technical advice to support Australian engagement in activities under the United Nations Convention on Biological Diversity and Cartagena Protocol on Biosafety (the Protocol), such as submissions on the regulation of GMOs. We are the national focal point for the Protocol and for the Biosafety Clearing-House, and disseminate information to other agencies.

The OGTR is also responsible for entering Australian commercial approvals of GMOs into the OECD BioTrack Product Database[13] and the UN Biosafety Clearing-House.[14]

By participating in and presenting at international forums, the OGTR continued to interact with key regulatory counterparts in other countries during 2020–21, including:

- 2020 Innovations Dialogue: Life Sciences, International Security and Disarmament, online event 20–21 August 2020
- 4th International Workshop on Regulatory Approaches for Animal Biotechnology, online over several sessions, September– November 2020
- Applications of Genome Editing in Agriculture: CGIAR Focus on Livestock and Aquaculture, webinar 6 October 2020
- APEC High Level Policy Dialogue meeting on agricultural biotechnology, online 8 October 2020
- International Conference on Precision Crop Breeding, online 13 October 2020
- Global Low Level Presence Initiative, 4 sessions online, October and December 2020
- International Society for Cell and Gene Therapy Australia and New Zealand Region (ANZ) Regional Virtual Meeting, online 26 February 2021
- 35th Meeting of the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology, OECD Paris, online 1–3 March 2021
- Biotechnology Regulators Virtual Meeting with overseas regulators including USA, Canada, EU, UK, Argentina, Brazil and South Africa, online 13–14 April 2021
- Agriculture and Food Systems Institute webinar: 'Gene Edited Plants: Context and Communication for Plant Breeding Innovation', online (South Korea) 22 April 2021

13 The BioTrack Product Database is on the OECD website
14 The Biosafety Clearing-House is online

- Target Malaria teleconference, 28 April 2021
- Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) 24, online 31 May–9 June 2021
- Inter-American Institute for Cooperation on Agriculture: Conversation on Analysis Criteria and Opportunities for New Breeding Techniques, online 28 April 2021
- Agriculture & Food Systems Institute webinar & panel discussion, online 29 April 2021.

Chapter 5

Management and accountability

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

Human resources

The OGTR has a workforce of 44 employees at 30 June 2021. All permanent employees other than the Regulator are Australian public service staff employed by the Department of Health under the *Public Service Act 1999*.

The terms and conditions for non-Senior Executive Service staff at the OGTR are covered by the Department of Health Enterprise Agreement 2019–2022, which was made under section 172 of the *Fair Work Act 2009*. This is a principles-based agreement, with most of the detail on operation of conditions provided in supporting guidelines. It offers a range of non-salary benefits, listed in Table 12.

Table 12: Non-salary benefits

AGREEMENT	BENEFITS
Enterprise Agreement	• access to the employee assistance program • access to extended purchased leave • flexible working hours • flexible working locations, including, where appropriate, access to laptop computers, dial-in facilities and mobile phones • flex time • influenza vaccinations • leave for compelling reasons and exceptional circumstances • maternity and adoption leave • parental leave • pay-out of additional duty in certain circumstances • recognition of travel time • reimbursement of eyesight testing and eyewear costs prescribed specifically for use with screen-based equipment • study assistance • support for professional and personal development.
SES	• all of the above benefits, except flex time • airport lounge membership • car parking • private use of motor vehicles or an allowance in lieu (not all officers).

SES = Senior Executive Service

The OGTR continued to build a strong team culture in its 20th year of operation. A weekly all-staff Friday morning tea was a successful way of keeping staff up-to-date on major issues, and provided opportunities for input, participation and feedback. Friday morning tea had to be discontinued in late March 2020 due to COVID-19 restrictions, but was reinstated in March 2021. However, the OGTR explored other ways of staying in touch and informed using our online collaboration tools, as approved by the Department. Friday was also promoted as casual dress day, and staff who took up this option were encouraged to contribute a gold coin for donations to the Starlight Children's Foundation.

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

Regulator's Achievement Award

This year, the Regulator's Achievement Award recognised years of individual contribution to the work of the OGTR, as well as a team effort to meet the priorities of approvals for COVID-19 vaccines.

Dr Peter Thygesen was recognised for his many years of work at the OGTR and his representation and international involvement in the regulation of biotechnology and gene technology. Notably this year, Dr Thygesen was appointed Chair of the OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology (WGHROB). This has meant many late hours so that Australia could maintain international connections and remain engaged in international regulatory harmonisation activities. Dr Thygesen has a wealth of experience and passion for the work that has benefitted the OGTR over many years.

The Contained Dealings Evaluation Section received a team achievement award to recognise high quality delivered work within timeframes during an unusually demanding period involving significant uncertainty. The team has been a model for collaboration and flexible work arrangements. While expediting applications for COVID vaccine manufacture and commercial release and a number of COVID related clinical trials, team members worked together to continue to process the ongoing workload of DIRs, DNIR and certifications, including an increasing number of clinical trials.

Dr Peter Thygesen recipient of the Regulators achievement award

Training and development

OGTR staff undertook 636.5 hours of formal training during the year. This was in addition to orientation and induction training for all new starters.

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

The OGTR also supports the Department's graduate development program, providing placements for graduates during their second and third rotations. This allows graduates to gain experience working in a regulatory science environment. In return, we benefit from graduates' enthusiasm and fresh perspectives.

In 2020–21, refresher training was given to the emergency control team, which comprises 3 fire wardens and 2 first aid officers. Members of the emergency control team are self-nominated. On completion of the required training, they receive an allowance in accordance with the Enterprise Agreement.

During 2020–21, the OGTR Principal Legal Officer was to provide introductory and ongoing training for OGTR staff on legal issues (Table 13). Some of this training had to be put on hold due to the COVID-19 pandemic situation.

Table 13: Internal training presentations on legal issues, 2020–21

DATE	TOPIC
13 and 8 September 2020	Information Law – Confidentiality Obligations
17 and 22 September 2020	Giving Information and Advice
14 April 2021	Legal Fundamentals for Contractors and New Starters
4 May 2021	Privacy Awareness

During 2020–21, the OGTR Principal Regulatory Scientist provided training presentations for OGTR staff on risk analysis (Table 14).

Table 14: Internal training presentations on risk analysis, 2020–21

DATE	TOPIC
24 September and 13 October 2020	Introduction to Risk Analysis
27 April 2021	Risk Analysis at OGTR – introduction to concepts and terms
1 December 2020 and 20 May 2021	Overview of Risk Factors from Generic Risk Assessment Framework for Organisms

The OGTR Forum provides a venue where presentations are made by visiting experts, and staff share current information on scientific and risk assessment issues, summaries of recent conferences, and feedback from international meetings. Due to the COVID-19 pandemic, only one presentation was possible:

- 14 August – Natural gene drives – Chris Wanty.

Supportive working environment

OGTR staff have access to a range of departmental assistance measures, as part of providing a supportive working environment. These include financial support for eyesight testing, workstation assessments, problem resolution procedures and an employee assistance program. The employee assistance program is a free, short-term, professional and confidential counselling and advice service provided by Converge International. OGTR staff and their immediate family members can use the program.

As a family-friendly organisation, the OGTR has endeavoured to be responsive to employee needs and circumstances by providing flexible working arrangements, in recognition of the importance of work-life balance. We have a high proportion of staff on flexible work arrangements, mostly part-time. Staff have accessed the 48/52 provision, which provides additional unpaid leave while averaging salary payments during the year.

Work health and safety

The OGTR is committed to ensuring a safe and healthy work environment for all workers, including contractors and visitors, consistent with the legislative requirements of the *Work Health and Safety Act 2011* and the *Safety, Rehabilitation and Compensation Act 1988.*

The OGTR actively supports injured and ill employees in their return to work. We provide appropriate reasonable adjustment to working environments to achieve this, including flexible working arrangements. We support our commitment to providing rehabilitation assistance to injured and ill employees by medical examinations to determine fitness for duty and the need for workplace rehabilitation assistance.

COVID-19

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

Staff were encouraged to return to office in early 2021 and can use workplace agreements to continue to access remote working flexibility as appropriate. The Department transitioned all OGTR and health staff to laptops in 2020. All borrowed IT and ergonomic equipment has been returned to the office.

Initiatives to ensure workers' health, safety and welfare

The Department's Improving Wellness and Motivation in the Workplace: Reducing Unplanned Leave initiative supports a commitment to:

- create, promote and maintain a safe and healthy working environment
- encourage productive working relationships
- promote and encourage behaviours in staff and managers to help manage and reduce levels of unscheduled absence.

The initiative complements existing OGTR strategies and action plans aimed at promoting a positive work environment, increasing the health and wellbeing of staff, reducing rates of illness and injury, optimising performance, and managing workloads and work-life balance.

As part of the People Strategy Action Plan and the Enterprise Agreement, OGTR provided the option of influenza vaccinations, at no cost, to all staff.

In 2020–21, we conducted training for officers, workers, health and safety representatives, and a harassment contact officer. An e-learning module is available for all staff, including contractors and consultants, and an overview of the *Work Health and Safety Act 2011* is available on the Department's intranet site. We have incorporated strategies for identifying and managing work health and safety risks into business planning processes, as well as our performance reporting.

Other work health and safety support included training in first aid, emergency evacuation systems and fire safety systems.

Health and safety outcomes

Information on health and safety outcomes (including impacts on injury rates of workers) related to the initiatives mentioned above, or to previous initiatives, is incorporated into the Department's annual report.

Notifiable incidents

Statistics relating to any notifiable incidents that arose from the conduct of OGTR business or undertakings, which the OGTR became aware of during the year, are incorporated into the Department's annual report figures.

Investigations under Part 10 of the *Work Health and Safety Act 2011*

No directions, notices or enforceable undertakings under the *Occupational Health and Safety (Commonwealth Employment) Amendment Act 2006* or the *Work Health and Safety Act 2011* were served on the OGTR during the year.

Freedom of information

Entities subject to the *Freedom of Information Act 1982* (FOI Act) are required to publish information to the public as part of the Information Publication Scheme (IPS). Each agency must display on its website a plan showing what information it publishes in accordance with the IPS requirements.[15]

Freedom of information contact details and procedures

The OGTR received 4 requests for access under freedom of information legislation during the reporting period.

The FOI Act (section 11C) requires the Regulator to publish on the OGTR website a disclosure log listing information that has been released in response to a freedom of information request.[16]

15 The OGTR's Information Publication Scheme Agency Plan is on our website.
16 The OGTR's Freedom of Information Disclosure Log is on our website.

Presentations on gene technology in Australia

The Regulator and staff from the OGTR regularly attend and present papers to meetings, forums and conferences in Australia (Table 15).

Table 15: Presentations in Australia by the Regulator and OGTR staff, 2020–21

DATE	EVENT
21 July 2020	Stretton Institute Webinar presentation
19 August 2020	Presentation to La Trobe Uni Botany students
4 November 2020	Keynote 2: Genetically modified organisms RSN Annual Symposium
25 November 2020	Regulating outbreaks – how can regulation hinder and help in a crisis? ABSANZ conference
4 March 2021	Security Sensitive Biological Agents Regulatory Scheme Webinar
19 March 2021	Building Capacity for Small Exporters to Exploit 'new breeding technologies', Murdoch University
20 April 2021	Presentation to APVMA on new technologies in plant health

Stakeholder and public access to the OGTR

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

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

OGTR website

In 2020–21 the OGTR received funding from the Department to update the OGTR website to enable it to meet the Australian government Digital Service Standard.[17] The OGTR has worked with the department to improve the content and readability of the website. It is expected that the new OGTR website will go live in early 2021–22.

Website usage

Table 16 tracks monthly usage numbers for the OGTR website. The most requested online information sheets and website pages are listed below.

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

Table 16: Website activity, 2020–21

MONTH	SESSIONS [a]	USERS [b]
July	5,293	3,538
August	5,640	3,763
September	6,351	4,444
October	6,252	4,407
November	5,859	4,254
December	3,867	2,779
January	5,651	4,253
February	7,314	5,354
March	7,390	5,465
April	5,632	4,018
May	6,817	4,890
June	7,101	5,235

a A session is a period of active engagement with a website by a user.
b Includes both new and returning users

The most popular pages viewed on the OGTR website during 2020–21 were, in descending order:

1. Guidelines for Certification of Physical Containment 2 Facilities
2. Record of GMO Dealings
3. Fact sheets
4. Table of applications and authorisations for Dealings involving Intentional Release (DIR) into the environment
5. Application forms to work with GMOs
6. Application to certify facilities
7. DIR 180 – Commercial supply of a genetically modified COVID-19 vaccine – AstraZeneca Pty Ltd
8. Legislation
9. Guidelines for the Transport, Storage and Disposal of GMOs
10. About the Regulator.

The most popular downloaded documents in 2020–21 were:

1. Guidelines for Certification of a Physical Containment Level 2 Laboratory
2. Guidelines for the Transport, Storage and Disposal of GMOs
3. Fact Sheet – Genetically modified organisms in Australia
4. Guidelines for Certification of a Physical Containment Level 3 Laboratory
5. Types of Dealings with GMOs classified as exempt dealings – October 2019
6. Types of Dealings with GMOs classified as Notifiable Low Risk Dealings (NLRDs) – October 2019
7. List of NLRDs as notified to the Gene Technology Regulator – June 2020
8. Guidelines for Certification of a Physical Containment Level 1 Facility
9. Fact Sheet – What is gene technology?
10. Fact sheet – Genetically modified (GM) crops in Australia.

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 2020–21, use of the email address increased compared with the previous year (Table 17).

Table 17: Email activity, 2020–21 and 2019–20

MONTH	EMAILS	
	2020–21	2019–20
July	34	48
August	27	30
September	25	41
October	28	48
November	38	43
December	30	31
January	92	41
February	55	34
March	64	43
April	53	48
May	60	35
June	45	39
Total	551	481

Due to COVID-19 pandemic measures across states and territories, a dedicated email inbox was created in March 2020 for organisations to contact the OGTR if their organisation was unable, or foresees that it may become unable, to meet its obligations under Australia's gene technology legislation. Stakeholders were advised to address their COVID-19 related queries to OGTR.Alerts@health.gov.au. The inbox has received 48 emails during 2019–20 and closed in November 2020 but received 16 emails up to that time.

The Monitoring and Compliance Section maintains an email inbox to facilitate efficient communication with accredited organisations. The inbox provides a central point through which accredited organisations can contact OGTR with queries, legislative notifications and self-reporting of non-compliances. The inbox ensures that all communications are answered efficiently while staff are away from the office. The inbox received 665 emails during 2020–21 (compared to 804 in 2019–20).

The Contained Dealings Evaluation Section maintains an email inbox to efficiently coordinate responses to queries on classifying GMO dealings, certification requirements and GMO licenses. The inbox received 439 emails during 2020–21 (compared to 644 in 2019–20).

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 5,113 emails during 2020–21 (compared to 2,438 in 2019–20).

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

Appendices

Appendix 1
Appendix 2

Appendix 1 – Membership of statutory committees

Table 18: Gene Technology Technical Advisory Committee members 2020–23

MEMBER	POSITION
Professor John Rasko AO (Chair)	Director, Cell and Molecular Therapies, Royal Prince Alfred Hospital; Program Head, Centenary Institute, University of Sydney (NSW)
Dr Graham Bonnett	Lead Drought Resilience Mission, CSIRO Agriculture and Food (Qld)
Honorary Professor Fiona Cameron	Honorary Professor, ANU College of Science (ACT)
Associate Professor Michael Considine	Australian Research Council Future Fellow, University of Western Australia (WA)
Dr Paul Downey	CEO/Principal Consultant – environmental management, Paul Downey Consulting (NSW)
Dr Tessa Gargett	Postdoctoral Research Officer, Royal Adelaide Hospital and Centre for Cancer Biology (SA)
Dr Grant Logan	Senior Scientist, Gene Therapy Research Unit, Children's Medical Research Institute (NSW)
Associate Professor Michael Michael	Medical Scientist, Department of Gastroenterology and Hepatology, Flinders Medical Centre (SA) Program Lead, Cancer Research, Flinders Health and Medical Research Institute, Flinders University (SA)
Professor Geraldine O'Neill	Head, Children's Cancer Research Unit, The Children's Hospital at Westmead & Conjoint Professor of Cancer Cell Biology, University of Sydney (NSW)
Dr Gabrielle O'Sullivan (GTECCC cross-member)	Executive Officer and Member, Institutional Biosafety Committee, Royal Prince Alfred Hospital (NSW)
Dr Kelly Pearce (layperson)	Director and Founder, Wheatbelt Science Pty Ltd (WA)
Dr Jason Smythe	Chief Operating Officer, The Monash Institute of Medical Engineering, Monash University (Vic)
Professor Jane Visvader	Joint Head, Breast Cancer Laboratory and Cancer Biology and Stem Cells Division, Walter and Eliza Hall Institute of Medical Research (Vic)
Professor Calum Wilson	Professor (Plant Pathology), University of Tasmania (Tas)
Professor Paul Young	Head of School and Professor of Virology, School of Chemistry & Molecular Biosciences, Australian Infectious Diseases Research Centre, 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 19: Gene Technology Ethics and Community Consultative Committee members 2020–23

MEMBER	POSITION/COMMENT
Associate Professor Judith Jones (Chair)	Associate Professor, College of Law, The Australian National University (ACT)
Professor Rachel Ankeny	Professor, School of Humanities, University of Adelaide (SA)
Dr Deborah Cleland	Resigned February 2021
Dr Paul Downey	CEO/Principal Consultant – environmental management, Paul Downey Consulting (NSW)
Ms Paula Fitzgerald	Chief Executive Officer, Australian Fodder Industry Association (Vic)
Dr Jaden Hastings (expert adviser)	Founder/Director, Alpha Space Pty Ltd
Rabbi Dr Aviva Kipen	Membership expired June 2021
Dr Rachel Nowak	Director, Research Marketing and Communications, University of Melbourne (Vic)
Dr Gabrielle O'Sullivan (GTTAC cross-member)	Executive Officer and Member, Institutional Biosafety Committee, Royal Prince Alfred Hospital (NSW)
Dr Kelly Pearce	Director and Founder, Wheatbelt Science Pty Ltd (WA)
Professor Stephen Robson	Professor in Reproductive Medicine, The Australian National University (ACT)
Dr Robert Sward AM	Director, BioBotanicals Consulting (Vic)
Dr Lynn Woodward	Senior Lecturer – College of Medicine & Dentistry, James Cook University (Qld)

Note: Members are appointed as individuals, not as representatives of any organisation. Occupation and employment information is included to demonstrate experience and qualifications relevant to their appointment.

Appendix 2 – Statutory functions and regulatory processes

Functions

In administering the gene technology regulatory system, the Regulator has specific responsibility to protect the health and safety of people, and to protect the environment, by identifying risks posed by, or as a result of, gene technology, and by managing those risks through regulating certain dealings with GMOs.

Section 27 of the Act sets out the functions of the Regulator to:

- perform functions in relation to GMO licenses, as set out in the Act (Part 5)
- develop draft policy principles, policy guidelines and codes of practice, as requested by the GTMM
- issue technical and procedural guidelines in relation to GMOs
- provide information and advice to other regulatory agencies about GMOs and GM products
- provide information and advice to the public about the regulation of GMOs
- provide advice to the GTMM about the:
  - operations of the Regulator and the Gene Technology Technical Advisory Committee
  - effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation
- undertake or commission research in relation to risk assessment and the biosafety of GMOs
- promote the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies
- maintain links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia
- perform such other functions as are conferred on the Regulator by the Act, the Regulations or any other law.

GMOs, dealings and authorisations

The Act defines a GMO as any organism that has been modified by gene technology, offspring derived from such an organism, or anything declared as a GMO in the Regulations (the full definition is in section 10 of the Act).

Section 10 of the Act defines 'deal with', in relation to a GMO, as the following:

(a) conduct experiments with the GMO

(b) make, develop, produce or manufacture the GMO

(c) breed the GMO

(d) propagate the GMO

(e) use the GMO in the course of manufacture of a thing that is not the GMO

(f) grow, raise or culture the GMO

(g) import the GMO

(h) transport the GMO

(i) dispose of the GMO

and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (i).

The Act forms the basis of a prohibitory scheme that makes dealing with a GMO a criminal offence unless, as outlined in section 31, the dealing is:

- an exempt dealing
- a notifiable low risk dealing (NLRD)
- licensed as:
  - a dealing not involving an intentional release (DNIR) of a GMO into the environment
  - a dealing involving an intentional release (DIR) of a GMO into the environment
- an inadvertent dealing
- included on the GMO Register
- specified in an emergency dealing determination (EDD).

For both DNIRs and DIRs, the legislation requires the Regulator to prepare a risk assessment and risk management plan as part of the process of making a decision on whether to issue or refuse a licence (sections 47 and 50 of the Act, respectively). The licensing system is centred on a rigorous process of risk assessment based on scientific evidence. For DIRs, the legislation requires consultation with a wide range of experts, agencies and authorities, as well as the public. These include the Gene Technology Technical Advisory Committee, state and territory governments, Australian Government agencies prescribed in the Regulations, the Commonwealth Environment Minister, and relevant local councils.

Part 5 of the Act also allows the Regulator to grant a temporary licence (no longer than 12 months) to a person who finds that they are inadvertently dealing with an unlicensed GMO, so that they can safely dispose of the GMO.

To be included on the GMO Register, the dealings with the GMO must first have been licensed by the Regulator. The Regulator must be satisfied that the risks associated with the dealings are minimal and that it is no longer necessary for people undertaking the dealings to be covered by a licence.

The provision to make emergency dealing determinations gives the Minister the power to expedite an approval of dealings with a GMO in an emergency (Part 5A of the Act).

Table 20 summarises the categories of GMO authorisations, their authorisation requirements and the extent of containment required to conduct the dealings.

The Regulator may, directly or on application, vary an issued licence, GMO Register entry or other instrument. Variations may involve changes to conditions applied to a licence or to the GMO Register entry or other instrument. The Regulator must not vary a licence unless satisfied that any risks posed by the dealings to be varied are able to be managed to protect the health and safety of people and the environment. The Regulator cannot vary a DNIR licence to authorise dealings for intentional release of a GMO into the environment.

Dealings with GMOs classified as NLRDs are listed in the Regulations under Schedule 3, Part 1 (NLRDs appropriate for PC1 facilities) and Schedule 3, Part 2 (NLRDs appropriate for PC2 [Part 2.1] and PC3 [Part 2.2] facilities).

Conducting NLRDs does not require prior authorisation from the Regulator, but the dealings must have been assessed by an institutional biosafety committee as meeting the NLRD classification, must be conducted in appropriate containment facilities (usually facilities certified by the Regulator) and must comply with other requirements specified in the Regulations. NLRDs must be notified to the Regulator annually. Authority to conduct an NLRD has a five-year time limit.

More information on the various categories of GMO authorisations and their assessment processes are available on the OGTR website.

Accreditation of organisations and certification of physical containment facilities helps to manage risks that may be associated with GMO dealings.

Conditions of most licenses for GMO dealings include a requirement for the organisation conducting the dealings to maintain accreditation.

Table 20: Categories of authorisations for GMO dealings under the *Gene Technology Act 2000*

CATEGORY	AUTHORISATION REQUIREMENTS	CONTROLS
DIR (except for limited and controlled releases)	Licence required Review of applications by IBC Consultation on application Preparation of RARMP Consultation on RARMP and licence Decision by Regulator	Controls may be required, determined case by case, and other licence conditions will apply
DIR (limited and controlled releases)	Licence required Review of applications by IBC Preparation of RARMP Consultation on RARMP and licence Decision by Regulator	Controls will be required, based on size and scope of release sought by applicant, and other licence conditions will apply
DNIR	Licence required Review of applications by IBC Preparation of RARMP Licence decision by Regulator	No intentional release to the environment Usually PC2 (or higher) certified physical containment facilities
EDD	Licence not required Determination by minister, subject to advice of threat and utility of GMO from competent authorities, and risk assessment advice from Regulator Legislative instrument	Containment measures may be included in EDD conditions
Exempt	Licence not required GMO dealings classified as exempt are scheduled in the Regulations	No intentional release to the environment
GMO Register	Licence not required GMO dealings must have been previously licensed Review of relevant information by Regulator Legislative instrument	Controls may be required
Inadvertent dealings	Licence required Licence decision by Regulator only for the purposes of disposal of the GMO	Controls and/or disposal measures will apply
NLRD	Licence not required GMO dealings classified as NLRDs are scheduled in Regulations Conduct of NLRDs requires prior assessment by IBC to confirm proper classification Notified in annual report to Regulator	No intentional release to the environment Usually PC1- or PC2-certified physical containment facilities

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

Timeframes

Under section 43(3) of the Act, the Regulator must issue, or refuse to issue, a licence within a time limit prescribed by the Regulations. The Regulations also prescribe a timeframe for consideration of applications to accredit organisations and to certify facilities. These statutory timeframes are shown in Table 21. 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 21: Prescribed timeframes for applications

CATEGORY	TIMEFRAME (WORKING DAYS)
Accreditation	90 (r. 16)
Certification	90 (r. 14)
DIR—limited and controlled, no significant risk	150 (r. 8)
DIR—limited and controlled, significant risk	170 (r. 8)
DIR—except for limited and controlled releases	255 (r. 8)
DNIR	90 (r. 8)
Licence variation	90 (r. 11A)

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

Glossary

Glossary and shortened forms

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

TERM	DESCRIPTION
Accredited organisation	An organisation that is accredited under section 92 of the *Gene Technology Act 2000*
Act	*Gene Technology Act 2000*
APVMA	Australian Pesticides and Veterinary Medicines Authority
CCI	Confidential commercial information declared under section 185 of the *Gene Technology Act 2000*
Contained dealing	See DNIR
CSIRO	Commonwealth Scientific and Industrial Research Organisation
Dealing	To 'deal with' a GMO is defined in section 10 of the *Gene Technology Act 2000*. It includes to experiment with, manufacture, breed, propagate, grow, culture, import, transport and dispose of a GMO, and to possess, supply or use a GMO in the course of any of these activities.
Department	Australian Government Department of Health
DIR	A dealing involving intentional release of a GMO into the environment (e.g., field trial or commercial release of a GM plant or animal vaccine)
DNIR	A dealing not involving intentional release of the GMO into the environment (e.g., experiments with GMOs in a certified facility such as a laboratory or manufacture of a commercial therapeutic from a GMO in a large scale facility)
EDD	Emergency dealing determination
Gene Technology Agreement	An intergovernmental agreement that all Australian jurisdictions signed in 2001, which underpins the nationally consistent regulatory framework for gene technology
GM	Genetically modified
GM product	A thing (other than a GMO) derived or produced from a GMO
GMO	Genetically modified organism
GMO Record	Record of GMO dealings
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional biosafety committee
Incident	A self-reported event that may constitute a non-compliance with regulatory requirements and a risk to public health or the environment
GTMM	Gene Technology Ministers' Meeting
MOU	Memorandum of understanding

TERM	DESCRIPTION
NLRD	Notifiable low risk dealing (e.g. plant or tissue culture work undertaken in a certified physical containment facility)
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator
PBS	Portfolio Budget Statements
PC1, PC2, PC3, PC4	Physical containment levels of facilities certified by the Regulator
Physical containment facility	A building or place certified by the Regulator to a specified containment level under section 84 of the *Gene Technology Act 2000*
RARMP	Risk assessment and risk management plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator
RSN	Regulatory Science Network

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136(1A)(b)	46–49	Any breaches of conditions of a GMO licence that have come to the Regulator's attention during the financial year
136(1A)(c)	33	Emergency dealing determinations made by the Minister during the financial year
136(1A)(d)	33	Any breaches of conditions of an emergency dealing determination that have come to the Regulator's attention during the financial year
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