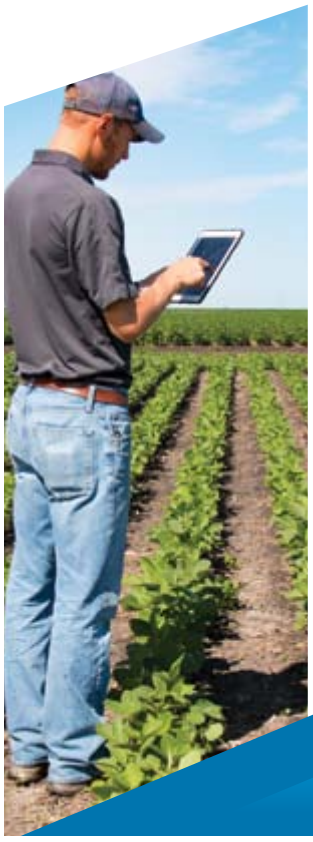
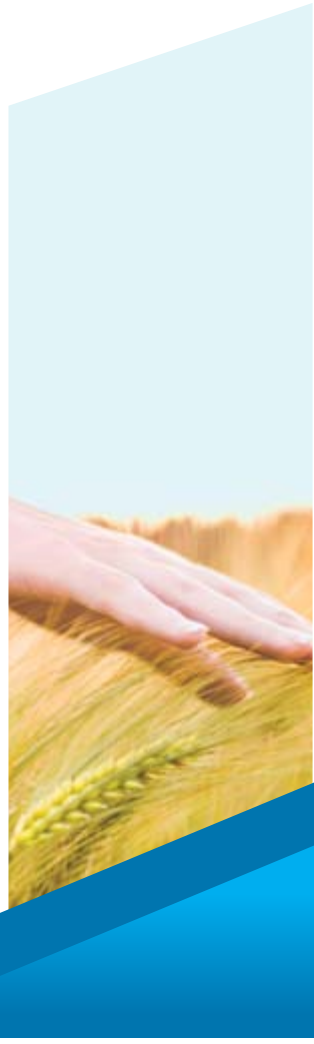
Australian Government

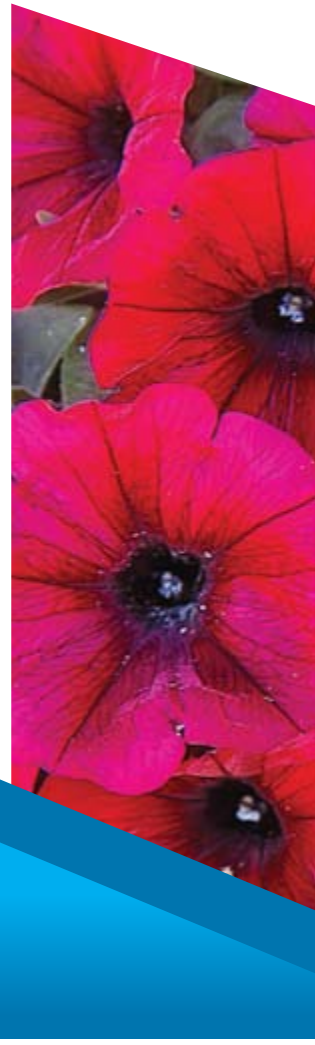
Department of Health

Office of the Gene Technology Regulator

ANNUAL REPORT 2016 2017







2016–17 HIGHLIGHTS

FOR THE OFFICE OF THE GENE TECHNOLOGY REGULATOR

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THE REGULATOR ISSUED NINE GMO LICENCES FOR RELEASE INTO THE ENVIRONMENT:

FIVE for field trials of genetically modified (GM) crop plants (wheat, potato, Indian mustard, banana and cotton)

ONE for a clinical trial of GM influenza vaccine

TWO for commercial releases of GM plants (two types of cotton)

ONE for a commercial release of a Dengue vaccine for human use

INCREASE IN THE NUMBER OF APPLICATIONS AND NOTIFICATIONS

+210 MORE APPLICATIONS

The total number of applications and notifications we received has increased by 210.

THE REGULATOR ISSUED TEN GMO LICENCES FOR WORK IN LABORATORIES OR PHYSICAL CONTAINMENT FACILITIES:

FIVE FOR **RESEARCH** INTO **HUMAN DISEASES**

FOUR FOR DEVELOPMENT OR TESTING OF **POTENTIAL TREATMENTS** FOR HUMAN DISEASES, INCLUDING TWO **CLINICAL TRIALS**

ONE FOR **RESEARCH** INTO FUNGAL DISEASE IN BANANAS

MONITORING AND COMPLIANCE ACTIVITIES

We inspected 43% of total **GM PLANT FIELD TRIAL SITES** to monitor compliance with licence conditions

We inspected 26% of **HIGHER LEVEL CONTAINMENT** facilities

MONITORED **INADVERTENT** DEALING licences for disposal of GM petunia

REGULATOR'S TECHNICAL REVIEW OF THE REGULATIONS

Published a discussion paper with options for how new technologies could be regulated

Stakeholders consulted broadly on options for regulation of new technologies

THE REGULATOR MADE 100% OF THE LICENCE DECISIONS WITHIN THE STATUTORY TIMEFRAMES

WE RECEIVED 817 LOW RISK DEALING NOTIFICATIONS

predominantly for research work in contained facilities. As at 30 June 2017 we received a total of 8674 notifications since the commencement of the regulatory scheme [includes expired NLRDs too].

TECHNICAL AND PROCEDURAL GUIDELINES ISSUED BY THE REGULATOR

GENERAL ADVICE ON LEGISLATIVE COVERAGE OF NEW TECHNOLOGIES

Guidance on regulatory requirements for contained research with **GMOs** containing engineered gene drives.

Consulted the regulated community on a revised Guidelines for certification of a Physical Containment Level 2 Large Scale Facility.

Initiated a review of the guidelines for certification of Physical containment Level 3 facilities.

Issued a new streamlined application form for the commercial release of GM plants Factsheet about GM petunias

THE REGULATOR ISSUED FIRST INADVERTENT DEALINGS LICENCES:

- four licences issued for the disposal of GM petunias inadvertently imported to Australia

These petunias were developed in Europe and unknowingly imported into various countries including Australia

INTERNATIONAL ENGAGEMENT

OECD working group on Harmonisation of Regulatory Oversight in Biotechnology

Input and advice on GMO regulation to other agencies to support engagement in the UN convention on Biological Diversity and UN Cartagena Protocol on Biosafety

Entry of Australian commercial approvals of GMOs into the OECD BioTrack Product database and the UN Biosafety clearing House

VISIT BY INTERNATIONAL DELEGATIONS:

KOREAN delegation, December 2016

INDIAN delegation, January 2017

Regulatory officials from **BURKINA FASO** and **NIGERIA** in April 2017

GMO RECORD:

We maintain a public record of GMO authorisations at: *http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmorec-index-1*

The Regulator ACCREDITED **3 organisations** with a total of 163 organisations accredited as at 30 June 2017: **SIXTY EIGHT PERCENT OF ORGANISATIONS ARE PUBLICLY FUNDED**

The Regulator **CERTIFIED 162 PHYSICAL CONTAINMENT FACILITIES** with a **TOTAL of 2042 facilities** certified as at 30 June 2017

ENGAGEMENT WITH STAKEHOLDERS

Meeting with non-government organisations in Nov 2016

IBC forum in May 2017

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Inquiries about the content of this report may be directed to the Regulatory Support Unit, Regulatory Practice and Compliance Branch, Office of the Gene Technology Regulator.

Australian Government
Department of Health
Office of the Gene Technology Regulator

LETTER OF TRANSMITTAL

The Hon. Dr David Gillespie MP
Assistant Minister for Health
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 2016 to 30 June 2017.

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 contained in Outcome 5 (Regulation, Safety and Protection) of the Department of Health Portfolio Budget Statements for the period 1 July 2016 to 30 June 2017.

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
6 October 2017

CONTENTS

ABOUT THIS REPORT

The report describes the roles and responsibilities of the Gene Technology Regulator (the Regulator) and the OGTR. It is a formal accountability document that summarises the performance of the OGTR against deliverables and key performance indicators contained in Outcome 5 (Regulation, Safety and Protection) of the 2016–17 *Department of Health Portfolio Budget Statements* (PBS).

Notes: The 2016–17 Annual Report of the Australian Government Department of Health also contains information about the OGTR. This includes the OGTR financial statements, which are consolidated into the department's financial statements.

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:

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

The report contains five chapters:

- Chapter 1: 'Gene Technology Regulator's overview'—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 Gene Technology Regulator's corporate and regulatory governance arrangements, including the structure of the OGTR and functions of its advisory committees.
- Chapter 3: 'Operational activities'—describes the functions, regulatory processes and operational performance of the OGTR, as well as achievements against the priorities for 2016–17. It summarises the types of GMO dealings, the processes for authorisations, and statutory timeframes. Deliverables and performance targets achieved for assessments and approvals, monitoring and compliance activities are reported. This chapter concludes with a summary of performance against the reporting structure published in the 2016–17 PBS.

- Chapter 4: ‘Engaging with stakeholders’—provides information on other activities relating to the Regulator’s statutory functions, including the technical review of the Regulations, 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.

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

CHAPTER 1

Gene Technology Regulator's overview

2016–17 has been another successful year for the OGTR. We continue to meet the objectives of Australia's national gene technology regulatory system, protecting the health and safety of people and the environment by regulating activities with genetically modified organisms, while delivering effective and efficient regulation.

Keeping pace with technology and achieving risk-based outcomes has been the key focus of our technical review of the *Gene Technology Regulations 2001* which commenced during the year. Communication with stakeholders through this process has been essential to gauge public interest in the advances in new technologies and to better understand future regulatory challenges that will face the OGTR.

To achieve the strategic outcomes set out for OGTR in the Department of Health Portfolio Budget Statements, we:

- achieved our targets for scientifically robust risk assessment and effective risk management of genetically modified organisms (GMOs)
- engaged actively in international activities so that our risk assessment methodologies remain best practice
- strengthened our relations with stakeholders and regulatory partners.

APPLICATIONS AND LICENCES: WHAT'S NEW?

The OGTR issued nine licences for release of genetically modified organisms GMOs into the environment. Of the GMO licences approved for release into the environment:

- five were for field trials of genetically modified (GM) crop plants (wheat, potato, Indian mustard, banana and cotton)
- one was for a clinical trial of a GM influenza vaccine
- two were for commercial releases of GM plants (two types of cotton)
- one was a commercial release of a dengue vaccine for human use.

In addition, ten GMO licences were issued for work in contained facilities based on the RARMPs. This is similar to previous years, with predominantly research into human disease and disease treatment, and one licence relating to plant disease research using GMOs. Of the GMO licences approved for work in contained facilities:

- five were for research into human diseases
- four were for development or testing of potential treatments for human diseases, including two clinical trials
- one was for research into fungal disease in bananas.

This year, for the first time in Australia, the OGTR issued four inadvertent dealings licences for disposal of unauthorised GMOs. These licences were issued in response

to the importation into Australia of petunias that were genetically modified for altered flower colour. These petunias had been developed in Europe and unknowingly imported into various countries, including Australia. GM petunias have not been approved for commercial release in Australia and it is an offense to knowingly plant or otherwise propagate them. Based on a risk assessment, we published appropriate methods for disposal of the GM petunia seed and plant materials. We worked with the Australian-based importers and suppliers to make it clear to businesses holding GM petunias that they are not authorised and must not be sold.

An action plan has been developed for monitoring inadvertent dealing licences that were issued for the disposal of unauthorised GM petunias. The OGTR inspectors visited the Australian-based importers and suppliers, to ensure nurseries were able to dispose of their seed stocks and plants appropriately, in accordance with the conditions of the licences. The action plan also includes further monitoring and working with industry in 2017–18 to minimise the persistence of GM petunias in Australia, such that these GMOs are not sold or propagated by wholesalers and their import and supply is ceased.

MONITORING ACTIVITIES: PREVENTION AND EDUCATION

The focus of our monitoring and compliance activities is prevention of adverse outcomes before they can arise. The OGTR strategy for prevention is based on cooperative compliance, which includes early engagement and communication with the regulated entities, information exchange, and educational activities to improve compliance with the legislation.

In 2016–17, OGTR inspected 43% of field trial sites to monitor compliance with licence conditions. Sites were inspected in New South Wales, Queensland, South Australia, Victoria and Western Australia. Crops inspected included GM banana, barley, canola, cotton, Indian mustard, safflower, sugarcane, wheat and white clover. In addition, the OGTR monitored 15 licences for GMO work in contained facilities. High levels of compliance by licence holders were reported.

The OGTR also inspected 26% of higher-level containment facilities to ensure compliance with certification conditions.

STAKEHOLDER ENGAGEMENT: TRANSPARENCY IN WHAT WE DO

Openness and transparency are the fundamental features of the gene technology regulatory scheme. We continued to consult with the general public, scientific experts (including the Gene Technology Technical Advisory Committee —GTTAC), regulated

organisations, other government regulatory agencies, and the states and territories on all licence applications for release of GMOs into the environment. The Department of Health Twitter account was used to notify the public about new applications for release of GMOs, opportunities to comment on consultation RARMPs, and licences issued for release of GMOs. The OGTR maintains a comprehensive website that provides extensive information on the regulatory system and the decisions made by the Regulator. This information includes copies of the full RARMPs for each licensed release of a GMO into the environment, and a number of fact sheets on relevant issues.

In November 2016, we held a stakeholder meeting in Canberra, primarily for the purpose of engaging with non-government organisations (NGOs) interested in gene technology. Members of the GTECCC and our colleagues from the Department of Health and Agriculture also attended the meeting. As the new Regulator, the meeting provided an opportunity for me to give stakeholders accurate information about the gene technology regulatory scheme and to let NGOs raise any issues or concerns. Presentations given on the day by the OGTR and a communiqué from the meeting are published on the OGTR website.

National Institutional Biosafety Committee Forum

In May 2017, we held the 7th National Institutional Biosafety Committee (IBC) Forum in Canberra. Representatives of IBCs and accredited organisations from most states and territories attended, with 150 delegates from 80 organisations. The forum was opened by Mr Mark Cormack, Deputy Secretary, Department of Health. The keynote address was given by Nobel Laureate Professor Brian Schmidt, Vice-Chancellor, Australian National University. Guest speakers and panel members from organisations and IBCs, together with OGTR staff, contributed to an engaging and well-received program. Major topics for discussion included current trends in gene technology, an update on the technical review of the Regulations and steps involved in the expected review of the scheme, including a workshop to canvas ideas from organisations and IBCs. There was also another workshop on clinical trials with relevant organisations and IBCs. The forum provided an important opportunity for feedback and exchange of information between IBCs and the OGTR, enhancing regulation of gene technology.

The OGTR actively participated in the Regulatory Science Network (RSN), including chairing RSN for the calendar year 2017. It provided excellent opportunities for information exchange and collaboration between Australian government agencies responsible for regulating chemicals and/or biological agents.

EFFICIENT AND EFFECTIVE REGULATION: CONTINUOUS IMPROVEMENT IN OUR WORK

A continued focus on improvement has ensured that our regulatory practices remain risk-based—that is, the level of regulatory oversight is proportionate to the level of risk posed by the activity. We also continuously reviewed our processes and guidance to regulated stakeholders to ensure our practices remain effective, efficient and timely within the constraints of the legislative scheme. We provided clarity around legislative coverage of new technologies while we are still conducting the technical review of the Regulations. Guidance on regulatory requirements for contained research with GMOs containing engineered gene drives was also published.

This year, we consulted the regulated community on a draft revised *Guidelines Certification Physical Containment Level 2 Large Scale Facility*. We also initiated a review of the *Guidelines Certification Physical Containment Level 3 Facilities*.

In September 2016, we issued a new streamlined application form for the commercial release of GM plants. This new form is the culmination of a significant amount of work in identifying relevant information required to underpin a rigorous risk assessment. It not only provides guidance for applicants on data requirements, but also aims to improve the process and reduce regulatory impacts for applicants.

Technical review of the Regulations

This year we continued to work on progressing the technical review of the Regulations. The purpose of the review is to ensure the Regulations provide clarity on the regulatory coverage of new technologies.

Advances in genetic modification techniques have been rapid over the last few years, in particular those techniques often referred to as genome editing (e.g. site-directed nuclease techniques utilising CRISPR/Cas9 and oligonucleotide-directed mutagenesis). To address how these new technologies should be regulated, the OGTR has published a discussion paper detailing four options and has consulted with a wide range of stakeholders. We received 741 submissions in response to the two month public submission period. Due to the complexity of the topic and significant community and stakeholder interest, the OGTR held follow-up discussions with a broad range of submitters.

In 2017–18, we will consider whether to recommend amendments to the Regulations based on a range of matters, including feedback from submissions, scientific understanding, potential risks, whether regulatory burden on stakeholders would be commensurate with risks and, also, the policy intent of the Act.

INTERNATIONAL HARMONISATION

Our active participation in international fora ensures that Australia's GMO regulatory scheme takes account of new developments in regulation and science. International engagement also informs best practice based on Australia's practical experience of administering efficient and effective GMO regulation. Our science-based approach to risk assessment is highly regarded internationally.

The OGTR actively participated in international efforts to harmonise regulatory oversight of work with GMOs. During the year, we were involved in a number of international meetings and provided ongoing input to the Organisation for Economic Co-operation and Development (OECD) Working Group on Harmonisation of Regulatory Oversight in Biotechnology and its Steering Group on Environmental Considerations. We also continued to contribute to Australia's engagement in the United Nations Convention on Biological Diversity and the United Nations Cartagena Protocol on Biosafety through our involvement as an expert, and in conjunction with the Department of Foreign Affairs and Trade and the Department of Agriculture and Water Resources.

The OGTR was invited to present to government agencies responsible for gene technology in Singapore and Vietnam on how we operate the gene technology regulatory scheme, including how we apply our process of risk analysis in the assessment of GMOs. Also, the OGTR continued to receive requests from regulators in other countries to visit Australia and learn about the Australian approach to GMO regulation. This represents a continuation of a trend over the past few years. Four visiting delegations were hosted by OGTR this year. Regulatory officials from Korea, India, Burkina Faso and Nigeria visited Australia to gain first-hand experience of the operation of the Australian gene technology scheme.

OUR PEOPLE

The ongoing commitment and dedication of OGTR staff has been essential in meeting our statutory timeframes and engaging effectively with our stakeholders. In recognition of this commitment, the Regulator's Achievement Award was presented to two staff members, Gillian Colebatch and Louisa Matthew, for their dedication to the work of the OGTR and for having worked tirelessly, and in good spirits, to achieve outcomes which were in the making over a period of several years.

Staff have enthusiastically embraced the Department of Health's Behaviours in Action policy, and this is reflected in staff survey results showing high levels of both participation and satisfaction. The OGTR also participated in communities of practice established jointly with the Therapeutic Goods Administration (TGA) and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which have increased collaboration and information sharing between the agencies.

CHALLENGES AHEAD

Looking ahead, the timing of the review of the gene technology scheme provides a unique opportunity to think about how the national system has had a good history of performance over time and how it may evolve to reflect best practice regulation of new technology. Australia is not alone in this endeavour, as our counterparts also consider how best to regulate new technologies that are changing the way we think about genetic modification and how our legal frameworks are established.

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), a description of the organisational structure of the Office of the Gene Technology Regulator (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 (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/state-territory-legislation) 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 Legislative and Governance Forum on Gene Technology (LGFGT). 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 (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/governance-1).

Although the Regulator must consider risks to human health and safety and the environment, relating to dealings with GMOs, other agencies have responsibility for regulating GMOs or genetically modified (GM) products as part of a broader or different legislative mandate. During development of the gene technology legislation, it was determined that the Regulator's activities should form part of an integrated legislative framework that includes a number of other existing regulatory authorities with complementary responsibilities and expertise (see http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/governance-1).

Conduct of 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 (APVMA), which is responsible for regulating all agricultural and veterinary chemicals, must register the insecticide product produced in the GM plant. It also approves application of herbicides to genetically modified 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 the decision-making processes to the extent that it is practicable within the limits of the relevant legislations.

CORPORATE GOVERNANCE ARRANGEMENTS

The Regulator is a statutory office holder with specific powers and functions under the Act (see http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/about-regulator-1). In exercising these functions, the Regulator is directly responsible to the Australian Parliament.

During 2016–17, the Assistant Minister for Health had portfolio responsibility for matters relating to the regulation of gene technology. Under section 133 of the *Gene Technology Act 2000*, the Secretary of the Australian Government Department of Health provides staff for administrative and scientific support to the Regulator. For administrative purposes, the staff and Regulator are collectively referred to as the Office of the Gene Technology Regulator (OGTR), and are administered as a separate division of the Department of Health and funded by the Gene Technology Special Account.

The OGTR has an ongoing head of agreement in place with the department to access a range of business management and reporting services directly through the Shared Services Centre. These services include information technology, financial reporting and accounting, human resources management, ministerial support and property management. The cost of these services is reviewed annually.

The *Public Governance, Performance and Accountability Act 2013* sets out the financial framework for OGTR governance. Integrity in financial reporting is maintained through internal audit arrangements as part of the head of agreement. The OGTR complies with the Commonwealth Fraud Control Guidelines 2011, as required by the department. More information is available in the 2016-17 Department of Health Annual Report. The OGTR maintains its own business risk management plan, against which senior OGTR staff report periodically.

The employment framework for the OGTR is the *Public Service Act 1999*. Staff are covered by the department's enterprise agreement, governance policies and practices. 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.

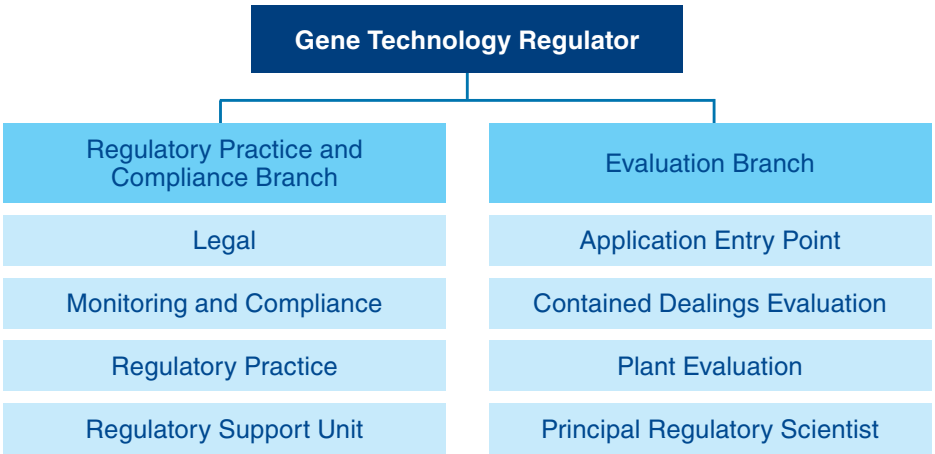
OGTR internal policies and practices cover the physical security and protection of confidential commercial information (CCI) received from applicants as required under the Act.

ORGANISATIONAL STRUCTURE

OGTR Executive

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 of the OGTR, 2016–17



GENE TECHNOLOGY REGULATOR

The Regulator is an independent statutory office holder who administers the nationally consistent scheme for regulating gene technology, comprising the Act and corresponding state and territory laws.[1] 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 genetically modified organisms GMOs.

Dr Raj Bhula commenced as Gene Technology Regulator on 18 July 2016.

Dr Bhula has a background of over 20 years' experience in the regulation of pesticides in Australia. She was the Executive Director of Scientific Assessment and Chemical Review at the APVMA and Program Manager, Pesticides at APVMA for almost 10 years. Dr Bhula has represented Australia at international expert committees, such as the Codex Committee on Pesticide Residues, and contributed to technical groups of the OECD Working Group on Pesticides. Much of this work included the development of technical policy and risk assessment methodologies. Before joining the Australian Public Service, Dr Bhula was a research associate and part-time lecturer at the Australian Defence Force Academy, University of New South Wales, in Canberra.

REGULATORY PRACTICE AND COMPLIANCE BRANCH

Mr Neil Ellis has been the acting Assistant Secretary, Regulatory Practice and Compliance Branch since December 2016. As acting Assistant Secretary he is responsible for regulatory practice policy, oversight of monitoring and compliance activities, corporate business and regulatory support, performance reporting, coordination of expert advisory committees, stakeholder communication and international cooperation activities.

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

The Legal Officer provides legal advice to the Regulator and the OGTR on the operation of Commonwealth, state and territory laws affecting their functions, including setting licence conditions and handling confidential commercial information. The Legal Officer is also responsible for training OGTR staff on legal issues and assists in responding to FOI requests.

1 *Gene Technology Act 2000*

The Monitoring and Compliance Section monitors and inspects dealings with GMOs conducted at field trial sites and within certified contained facilities. The aim of these activities is to ensure that dealings with GMOs comply with legislative obligations and are consistent with the object of the Act. Activities focus on monitoring compliance with conditions of licences or other instruments and restrictions, and managing risks in relation to any potential breach of conditions. Audits, reviews and investigations of organisations and individuals involved in GMO dealings (including self-reported incidents and allegations made by third parties) are conducted to ensure that any dealings are undertaken in accordance with the Act.

The branch's Regulatory Practice Section works collaboratively with the Best Practice Regulation Branch of the department. It delivers operational policies, provides technical support and coordinates the technical review of the Regulations. Secretariat services to the Gene Technology Ethics and Community Consultative Committee and the Gene Technology Technical Advisory Committee, coordination of ministerial correspondence and briefings, and contributions to international regulatory harmonisation activities also form part of the activities of this section. It serves as the contact point for other Australian Government agencies and national and international organisations involved in regulating GMOs.

In partnership with the department, the Regulatory Support Unit undertakes corporate and administrative functions, including performance and financial reporting, budget reporting, account processing, procurement, human resource management, staff training and coordination, accommodation, and property and asset management. It produces the annual report, staffs the freecall number (1800 181 030), coordinates responses to general email inquiries (to ogtr@health.gov.au) and manages the OGTR website. It has developed the Post Release Review Framework to guide ongoing oversight of GMOs that have been released commercially or as general releases.

EVALUATION BRANCH

Dr Michael Dornbusch has been Assistant Secretary of the Evaluation Branch since 2009. Dr Dornbusch's responsibilities encompass management of 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 Evaluation Branch is made up of the Application Entry Point, the Contained Dealings Evaluation Section, the Plant Evaluation Section and the Principal Regulatory Scientist.

All applications to OGTR are received and acknowledged through the Application Entry Point. Staff in this area also process accreditation applications, manage databases, provide trend and statistical analyses of application receipts and authorisations, report on workflows and undertake business improvement and efficiency initiatives. The team also supports the Evaluation Branch in sourcing scientific literature and manages a range of journal subscriptions for the office library.

The Contained Dealings Evaluation Section prepares risk assessment and risk management plans (RARMPs) in response to applications for dealings not involving intentional release of GMOs into the environment (DNIRs)—also known as 'contained dealings'—and applications for non-plant dealings involving intentional release (DIRs). The section also processes applications for certification of containment facilities. This includes inspecting high-level and large-scale facilities, reviewing certification guidelines, 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 genetically modified (GM) plants and prepares RARMPs for consultation with key stakeholders, including the public. The section gathers scientific data and publishes reference documents to inform the risk assessment process.

The Principal Regulatory Scientist provides advice on the risk assessment of GMOs, including in 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 two statutory committees to provide advice to the Gene Technology Regulator (the Regulator) and the Legislative and Governance Forum on Gene Technology (LGFGT). These are the:

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

Membership of the statutory committees is listed in Appendix 1.

Gene Technology Technical Advisory Committee

GTTAC's functions, as set out in section 101 of the Act, are to provide scientific and technical advice, at the request of the Regulator or the LGFGT, on GMOs; genetically modified (GM) products; applications made under the Act; the biosafety aspects of gene technology; and the need for policy principles, policy guidelines, codes of practice, and technical and procedural guidelines in relation to GMOs and GM products, and the content of such principles and codes.

The Regulator must seek GTTAC's advice on the risk assessment and risk management plan (RARMP) for all licence applications for dealings involving intentional release (DIR) and may seek advice on other applications. The Regulator must also seek GTTAC's advice during the preparation of the RARMP for all DIR applications that are not assessed as limited and controlled under section 50A of the Act.

The current members of GTTAC, including the Chair, Professor John Rasko AO, were appointed by the Assistant Minister for Health, the Hon Dr David Gillespie MP, for a three-year term that commenced on 1 February 2017.

GTTAC met four times during 2016–17: three times in face-to-face meetings and once by video conference. Communiqués from GTTAC meetings, which provide an overview of key matters discussed and resolutions, are published on the OGTR website (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gttaccomm-1).

Gene Technology Ethics and Community Consultative Committee

GTECCC's functions are set out in section 107 of the Act. They are to provide advice, at the request of the Regulator or the LGFGT, 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 policy principles, policy guidelines, codes of practice, and technical and procedural guidelines relating to GMOs and GM products, and the content of such principles and codes.

The current members of GTECCC, including the Chair, Ms Judith Jones, were appointed for the 2015–2018 triennium by the then Assistant Minister for Health, Senator the Hon Fiona Nash.

GTECCC met twice during 2016–17. Communiqués from GTECCC meetings, which provide an overview of key matters discussed and resolutions, are published on the OGTR website (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gteccc-comm-1).

GTECCC members also attended the OGTR's stakeholder engagement meeting held on 10 November 2016 (see 'Engagement with Stakeholders', Chapter 4), and the GTECCC Chair presented at the OGTR's 7th IBC Forum and participated in a public panel discussion held by the Australian Academy of Science on 'Next Generation Gene Technology'.

The first part of this chapter outlines 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. The second part of the chapter describes the operational performance in relation to the functions as required by the subsection 136(1A) of the Act and against the performance indicators in Outcome 5 (Regulation, Safety and Protection) of the *2016–17 Department of Health Portfolio Budget Statements* (PBS).

CHAPTER 3
Operational Activities

STATUTORY FUNCTIONS AND REGULATORY PROCESSES

Functions

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

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

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

GMOs, dealings and authorisations

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

Section 10 of the Act 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 http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/exemptdealclass-2
- a notifiable low risk dealing (NLRD) http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/nlrdclass-2
- licenced as:
  - a dealing not involving an intentional release (DNIR) of a GMO into the environment http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dnirclass-2
  - a dealing involving an intentional release (DIR) of a GMO into the environment http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dirclass-2
- an inadvertent dealing http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/inadvertentclass-2
- included on the GMO Register http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmoregister-1
- specified in an emergency dealing determination (EDD). http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/eddclass-2

For both DNIRs and DIRs, the legislation requires the Regulator to prepare a risk assessment and risk management plan (RARMP) 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 Minister for the Environment and Energy, 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 for emergency dealing determinations (EDDs) gives the Minister the power to expedite an approval of dealings with a GMO in an emergency (Part 5A of the Act).

Table 1 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 or 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.

More information on the various categories of GMO authorisations and their assessment processes is available at:
http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/authorisation-for-gmos and
http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/process-1

Accreditation of organisations and certification of physical containment facilities helps to manage risks that may be associated with GMO dealings (see http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/accred-org-responsibilities).

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

Table 1: 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	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 • 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

Category	Authorisation requirements	Controls
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	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 2. 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 2: 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

OPERATIONAL PERFORMANCE

This section describes the achievements and performance against Outcome 5 (Regulation, Safety and Protection) of the 2016–17 Department of Health PBS. 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.

Summary of assessments and approvals

Information on performance against deliverables and key performance indicators, as set out in the 2016–17 Department of Health PBS, is summarised in the second part of this chapter.

In 2016–17, the OGTR received 1781 applications and notifications, as defined under the Act (Table 3). 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.

Table 3: Applications and notifications, 2016–17

Application type	Received	Withdrawn	Approved[a]	Refused	Ceased consideration[b]	Under consideration[c]
Accreditation	5		3			2
CCI declaration for DIR licence	5		8			5
CCI declaration for DNIR licence			3			5
CCI declaration for other information	2	1				1
Certification	155	1	162			34
DIR licence	10		9			6
DNIR licence	7	2	10			1
Lifting suspension of certification[e]	49	1	46			4
NLRD notification	817	2[d]				

Application type	Received	Withdrawn	Approved[a]	Refused	Ceased consideration[b]	Under consideration[c]
Surrender of accreditation	1		1			
Surrender of certification	92	2	96			2
Surrender of DIR licence	3		5			
Surrender of DNIR licence	5	1	7			3
Suspension of accreditation[e]	3		3			
Suspension of certification[e]	68	1	66			1
Transfer of certification	8		6			2
Transfer of DIR licence			1			
Transfer of DNIR licence			1			
Variation of certification	501	14	380			181
Variation of DIR licence	8		8			
Variation of DNIR licence	42	6	30			15
Total	**1781**	**31**	**845**			**262**

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 2016–17 were received in the previous financial year.

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

c Under consideration at 30 June 2017.

d Withdrawals of NLRDs reported in 2016–2017 all resulted from administrative error.

e 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 2016–2017 were all requested by the applicant.

Licences for dealings involving intentional release of GMOs

The Regulator issued nine DIR licences during 2016–17 (Table 4) with a further six licence applications in progress as at 30 June 2017. Five of the DIR licences issued related to applications received before 1 July 2016.

Details of the traits introduced into the organisms for release are provided in Table 4.

All of the licence decisions were made within statutory timeframes (see 'Timeframes', Chapter 3). There were no appeals of decisions made under the gene technology legislation.

Six of the DIR licences issued in 2016–17 were for field trials or clinical trials (limited and controlled release) and three were for commercial releases.

The field trial licences were issued for GM wheat, potato, Indian mustard, banana and cotton with a variety of introduced traits. The commercial release licences were for two types of GM cotton. The other licences were for a commercial release of a dengue vaccine and a clinical trial for an influenza vaccine.

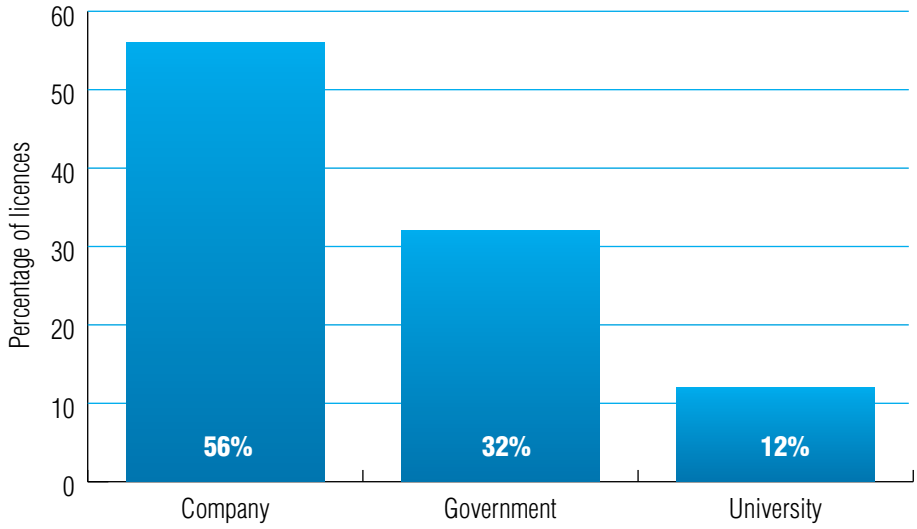
Of the nine DIR licences issued in 2016–17, six were issued to companies, one to a government agency and two to universities (Table 4). Of the 131 DIR licences issued since commencement of the Act, 73 (56%) have been to companies, 42 (32%) to government agencies and 16 (12%) to universities (Figure 3). Over the past six years, the number of DIR licence applications that the Regulator has received and approved has increased from five per year in 2011–12 to nine per year in both 2015–16 and 2016–17. In 2011–12 there were multiple applications for wheat/barley trials, as well as banana, canola and cotton.

Table 4: DIR licences issued, 2016–17

DIR no.	Applicant	Parent organism	Introduced trait	Type of release	Received	Issued
DIR-151	CSIRO	Wheat	Disease resistance, drought tolerance, altered oil content, altered grain composition	Limited and controlled	22-9-2016	1-5-2017
DIR-150	Queensland University of Technology	Potato	Disease resistance	Limited and controlled	20-7-2016	20-2-2017
DIR-149	Nuseed Pty Ltd	Indian mustard	Altered oil content	Limited and controlled	19-7-2016	14-2-2017
DIR-148	Sanofi-Aventis Australia Pty Ltd	Dengue vaccine	Attenuation	General and commercial	4-7-2016	27-6-2017
DIR-147	Monsanto Australia Limited	Cotton	Insect resistance	Limited and controlled	30-6-2016	23-1-2017
DIR-146	Queensland University of Technology	Banana	Disease resistance	Limited and controlled	16-6-2016	13-12-2016
DIR-145	Monsanto Australia Limited	Cotton	Herbicide tolerance and insect resistance	General and commercial	3-2-2016	20-12-2016
DIR-144	Clinical Network Services (CNS) Pty Ltd	Influenza virus	Attenuation, codon deoptimisation	Limited and controlled	22-12-2015	1-8-2016
DIR-143	Bayer CropScience Pty Ltd	Cotton	Herbicide tolerance and insect resistance	General and commercial	16-12-2015	8-12-2016

DIR = dealing involving intentional release of a genetically modified organism into the environment

Figure 3: Types of organisations issued with DIR licences since commencement of the *Gene Technology Act 2000*



Licences for dealings not involving intentional release of GMOs

DNIR licences authorise dealings with GMOs that are conducted in laboratories and other physical containment facilities and may pose risks that require management through specific licence conditions.

In 2016–17, 10 DNIR licences were approved (see Table 5). All approvals were made within the statutory time limit. One DNIR application was in progress at 30 June 2017.

Of the 10 DNIR licences issued in 2016–17, five were for research into human diseases, four were for development or testing of potential treatments for human diseases (including two clinical trials) and one was for research into a plant disease. This pattern is similar to previous years, with research predominating into human disease and disease treatment in DNIR licence applications, with other licences relating to either plant- or animal-disease research or production of therapeutic products using GMOs, such as vaccines.

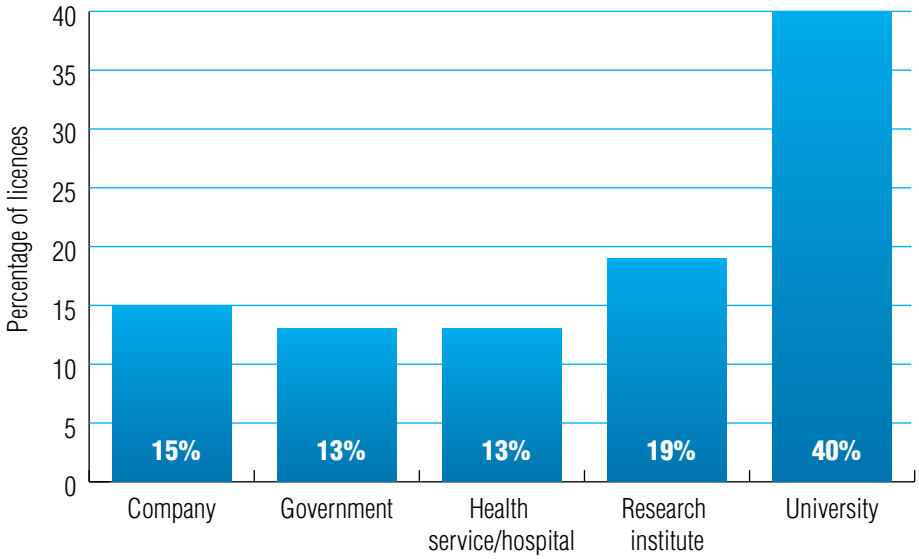
Table 5: DNIR licences issued, 2016–17

DNIR No.	Applicant	Title	Received	Issued
DNIR-575	The University of Sydney	Fine tuning transplantation tolerance with co-stimulatory molecules	20-2-2017	27-6-2017
DNIR-573	The University of Melbourne	Molecular biology of retroviral replication, pathogenesis and productive infection	4-1-2017	23-5-2017
DNIR-572	The Walter and Eliza Hall Institute of Medical Research	Analyses of gut and systemic infection with recombinant listeria	7-12-2016	13-4-2017
DNIR-571	Women's and Children's Health Network Incorporated	Phase I/II gene transfer clinical trial of scAAV9.U1a.hSGSH for mucopolysaccharidosis (MPS) IIIA	26-10-2016	14-3-2017
DNIR-570	CSIRO	Characterisation of the molecular determinants of host responses and pathogenicity of filoviruses	13-10-2016	1-3-2017
DNIR-569	PPD Australia Pty Ltd	Gene therapy, open-label, dose-escalation study of SPK-9001 (adeno-associated viral vector with human factor IX gene) in subjects with hemophilia B	19-4-2016	8-9-2016
DNIR-568	Queensland University of Technology	Development and use of a cucumber mosaic virus-based vector to investigate banana-Fusarium interactions	14-6-2016	29-9-2016
DNIR-567	Luina Bio Pty Ltd	Expression of PRS060 protein by recombinant Corynebacterium glutamicum	5-5-2016	1-9-2016
DNIR-566	Monash University	Biochemical studies of cholesterol-dependent cytolysin proteins	31-3-2016	5-8-2016
DNIR-565	Baker Heart and Diabetes Institute	Using adeno-associated virus vectors to study striated musculature and related tissues in vitro and in vivo	18-3-2016	21-7-2016

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

The types of organisations to which DNIR licences have been issued since commencement of the Act are shown in Figure 4.

Figure 4: Types of organisations issued with DNIR licences since commencement of the Act



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

Licences for inadvertent dealings

In 2016–17, the first inadvertent dealings (ID) licences were issued. These licences authorised the disposal of genetically modified (GM) petunias inadvertently imported to Australia.

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

In May 2017, Australia and other countries became aware that unauthorised GM petunias had entered the international and Australian markets. The GM petunias were genetically modified for altered flower colour. GM petunias have not been approved for commercial release in Australia and it is an offence to knowingly plant or otherwise propagate them. The Regulator worked with the Australian-based importers and suppliers to make it clear to businesses holding GM petunias that they are not authorised and must not be sold.

The Regulator performed a risk assessment, which concluded that the risks posed to human health and the environment from the GM petunias were negligible. The risk assessment also determined appropriate methods for disposal of the GM seed and plant material, which were included as licence conditions of the four ID licences issued for disposal of the GM petunias (Table 6). http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/id01

Table 6: Inadvertent dealings licences issued for disposal for GM petunias

Licence number	Licence holder	Date issued	Expiry date
ID01	Ball Australia Pty Ltd	1 June 2017	31 May 2018
ID02	Highsun Express Seeds Pty Ltd	2 June 2017	1 June 2018
ID03	Propagation Australia Pty Ltd	2 June 2017	1 June 2018
ID04	YoungPlants Pty Ltd	7 June 2017	6 June 2018

Notifiable low risk dealings

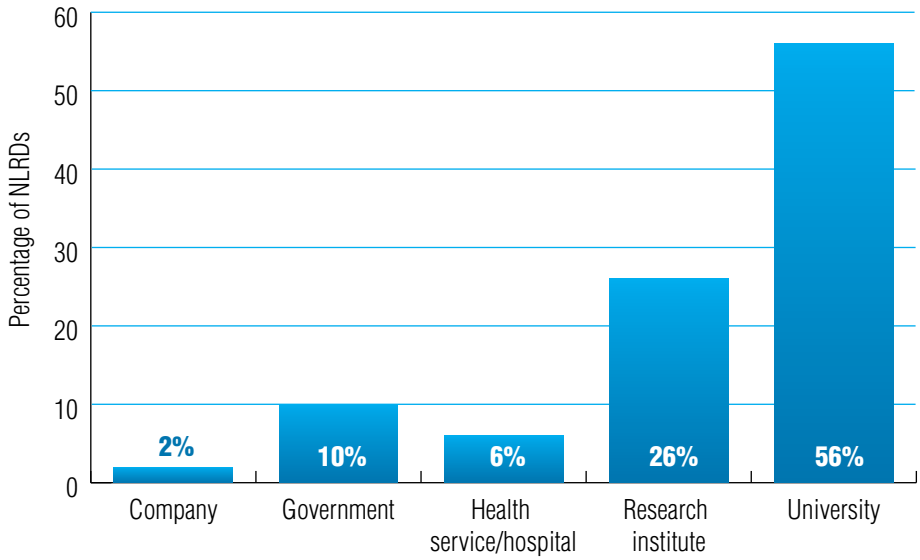
Notifiable low risk dealings are GMO dealings that have been assessed, based on previous experience and current scientific knowledge, as posing low risk, provided certain risk management conditions are met. Dealings with GMOs classified as NLRDs are listed in the Regulations under Schedule 3, Part 1 (NLRDs appropriate for PC1 facilities) and Schedule 3, Part 2 (NLRDs appropriate for PC2 [Part 2.1] and PC3 [Part 2.2] facilities).

Conduct of NLRDs does not require prior authorisation from the Regulator, but the dealings must have been assessed by an institutional biosafety committee (IBC) as meeting the NLRD classification, must be conducted in appropriate containment facilities 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.

During 2016–17, 817 NLRD notifications were received. As in past years, notified NLRDs were predominantly for research work. The types of organisations that notified NLRDs to the OGTR in 2016–17 are shown in Figure 5.

Inspection of a OGTR Certified PC2 Plant Facility in the ACT

Figure 5: Types of organisations that notified NLRDs in 2016–17



NLRD = notifiable low risk dealing

Dealings placed on the GMO Register

Dealings with GMOs may be placed 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. Such determinations are disallowable legislative instruments and must be tabled in parliament.

During 2016–17, there were no new listings on the register, and no applications were received to place dealings on the register.

Emergency dealing determinations

An EDD is a legislative instrument made by the Minister under section 72 of 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 EDD, including monitoring for compliance with any EDD conditions. Further information about EDDs are available at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/eddclass-2

During 2016–17, the OGTR did not receive any requests for advice in relation to making EDDs. No EDDs were made, and none were in effect.

Inspection of a current canola trial site in Victoria

Accreditation of organisations

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

In 2016–17, three accreditations were issued, with a total of 163 organisations holding accreditation at 30 June 2017. Accredited organisations are located in all Australian jurisdictions and one is based in the United States (Figure 6). The profile of the types of organisations accredited by the Regulator has not changed significantly: a large proportion (68%) are primarily publicly funded (Figure 7).

Figure 6: Organisations accredited at 30 June 2017, by location of headquarters

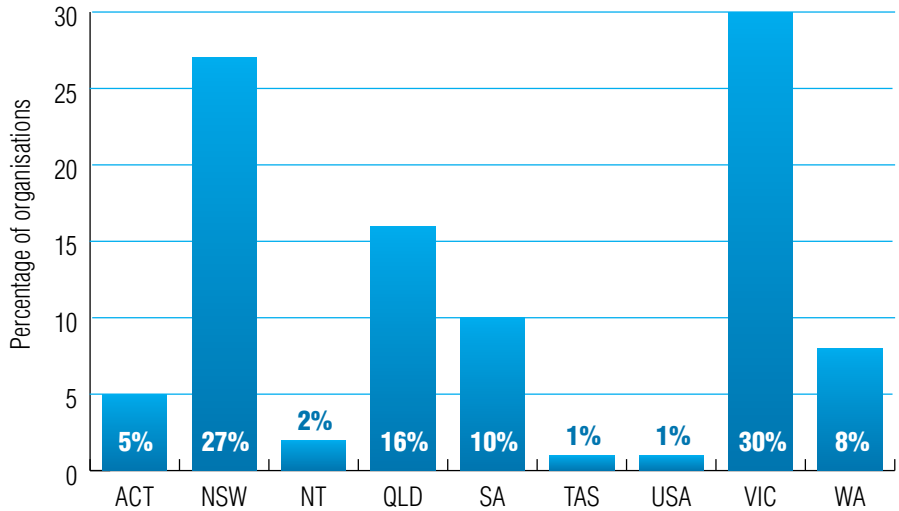
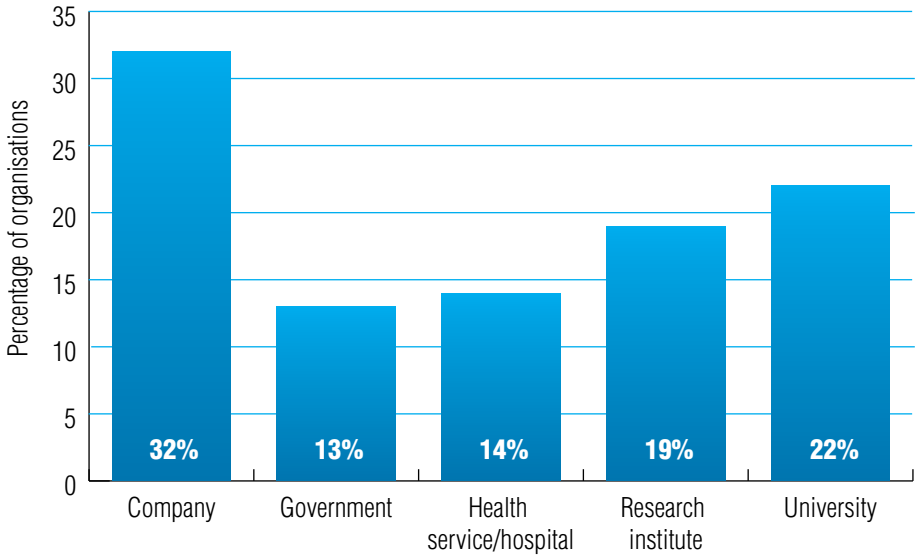


Figure 7: Organisations accredited at 30 June 2017, by type of organisation



Certification of physical containment facilities

Facilities may be certified by OGTR to particular containment levels under section 84 of the Act.

Physical containment facilities are classified according to how stringent the measures are for containing GMOs. 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. PC level 4 (PC4) facilities provide the most secure and stringent containment conditions.

During 2016–17, 162 certifications for physical containment facilities were approved (Table 4). The number of facilities certified at 30 June 2017 is listed in Table 7 by facility type and containment level.

Table 7: Number of facilities certified at 30 June 2017

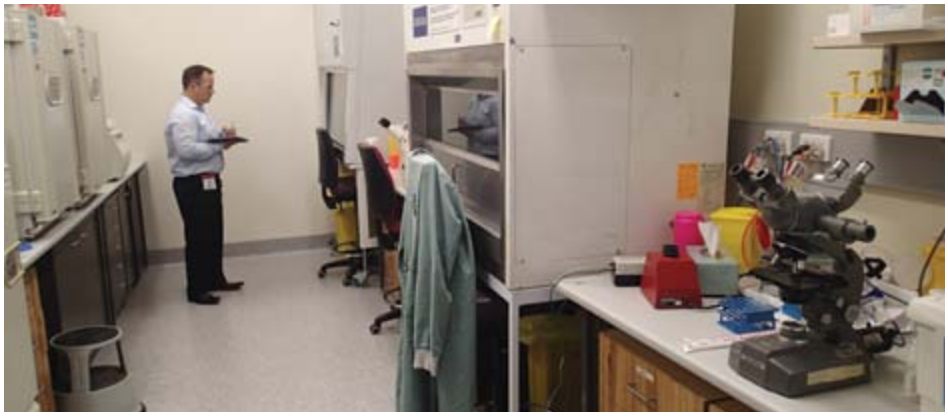
Facility type	PC1	PC2	PC3	PC4	Total
Animal		236	4		240
Aquatic		26			26
Constant temperature room		45			45
Facility	311			5	316
Invertebrate		53	2		55
Laboratory		1095	25		1120
Large grazing animal		52			52
Large scale facility		18			18
Plant		170			170
Grand total	**311**	**1695**	**31**	**5**	**2042**

PC = physical containment

a PC1 and PC4 facilities are not categorised into types.

Note: This table excludes facilities for which the certifications were suspended (at the request of the certification holders) as at 30 June 2017.

The types of organisations issued with certifications in 2016–17 were predominantly universities (72%) and government agencies (12%). The types of organisations that currently hold certifications as at 30 June 2017 were predominantly universities (55%), research institutes (18%) and government agencies (15%). This distribution reflects the research focus of these types of organisations, where most dealings require physical containment (NLRDs and DNIRs). OGTR-certified physical containment facilities are located in all Australian states and territories (Figure 9).



Inspection of an OGTR Certified PC 2 Laboratory in Queensland

Figure 8: Distribution of certified facilities at 30 June 2017, by organisation type

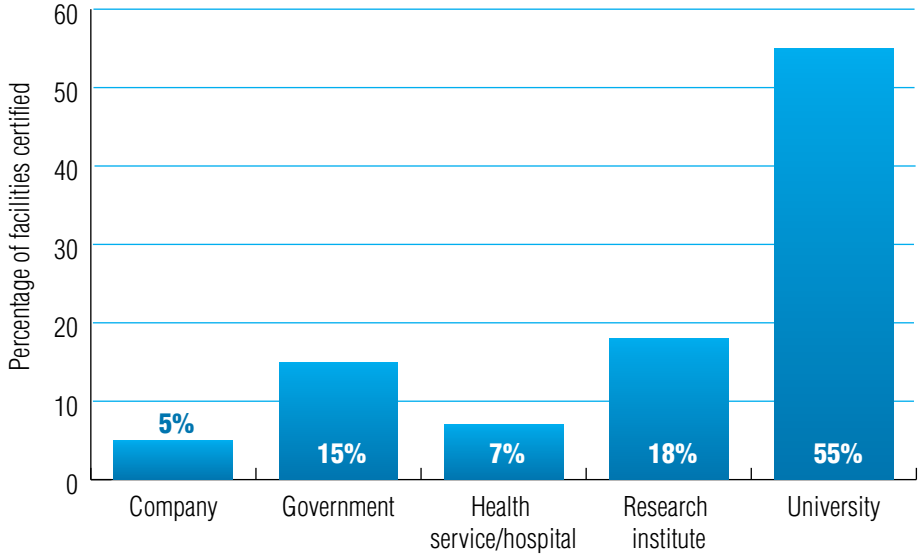
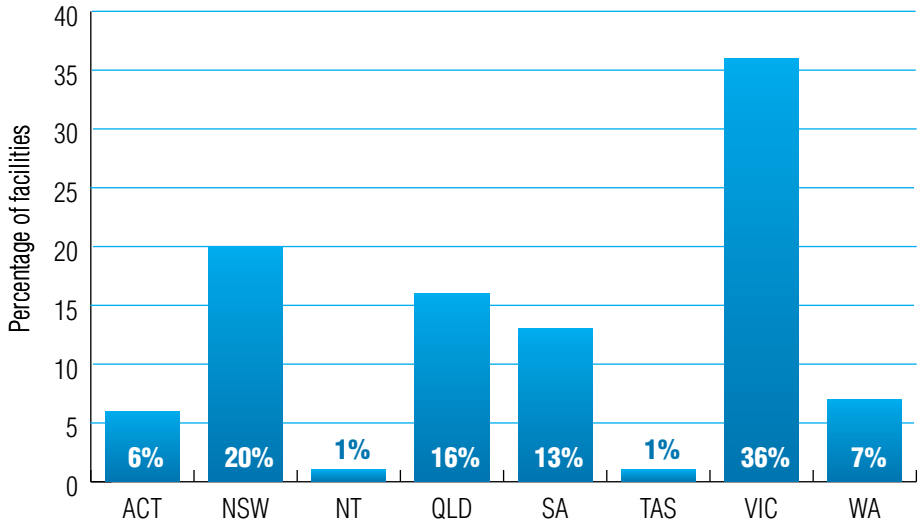


Figure 9: Physical containment facilities certified at 30 June 2017, by location



Trend data for approval of main types of applications

The numbers of authorisations issued during 2016–2017 were similar to those in previous years. Compared to 2015–2016, only numbers for new accreditations decreased slightly while approvals for other application types went up (Table 8).

Table 8: Trend data for approval of main types of applications, 2012–13 to 2016–17

Application type	2012–13	2013–14	2014–15	2015–16	2016–17
Accreditation	8	4	10	4	3
Certification	199	183	89	125	162
DIR	4	7	7	9	9
DNIR[a]	8[b]	10[c]	10[c]	7	10
NLRD	677	828	842	767[d]	817

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 licences issued. This can differ from the total number of applications approved when two or more applications are integrated into a single licence.

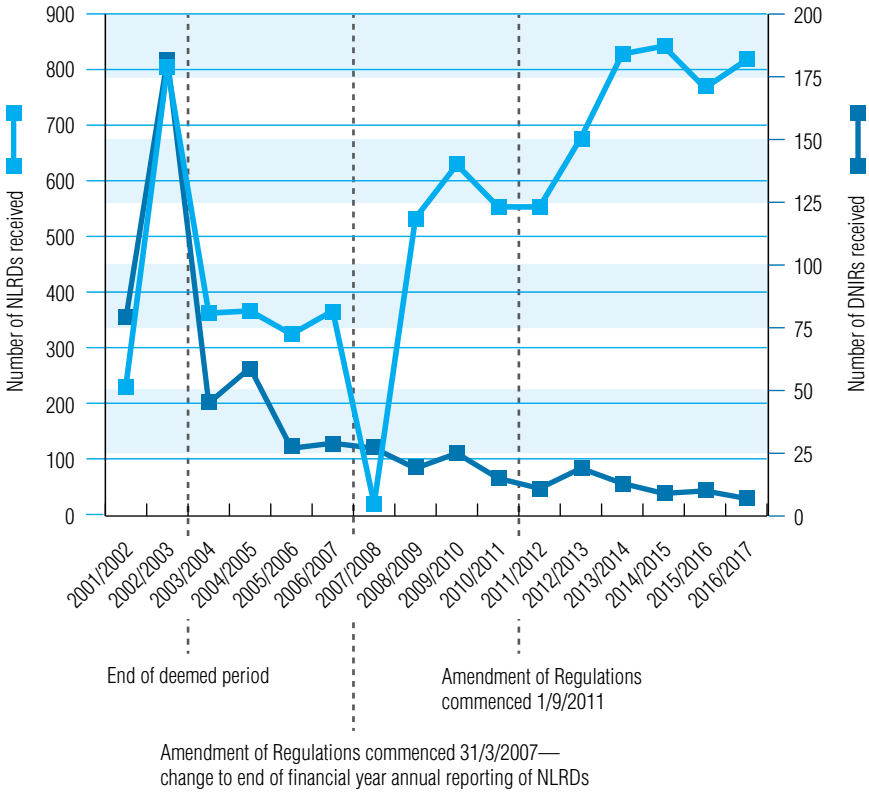
b Correction to the number (10) reported in the 2013–14 report. Three applications were approved and incorporated into a single licence.

c Two applications were approved and incorporated into a single licence.

d Correction to the number (750) reported in the 2015–2016 report. The complete set of data was not available at the time of the report.

Since the regulatory scheme commenced in 2001, there has been an increase in scientific knowledge and experience dealing with GMOs. Technical reviews of the Regulations have taken new scientific information into account to ensure that the classification of different types of dealing remains commensurate with the level of risk. Improved scientific understanding of risks associated with GMOs has generally resulted in dealings being reclassified as low risk, requiring an NLRD rather than a DNIR licence. This is reflected in the gradual decrease in the number of DNIR licence applications received and the concomitant increase in the number of NLRD notifications received. (Figure 10). The extremely small number of NLRDs received during the 2007–2008 financial year was due to a change from fortnightly reporting to annual.

Figure 10: Comparison trends for DNIRs and NLRDs



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 commercial confidential information (CCI). The extent of CCI 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 CCI claims need to be resolved.

In 2016–17, the Regulator made 11 CCI declarations. Decisions on a further 11 CCI applications were pending as at 30 June 2017.

Surrenders

Surrender of licences and certifications usually occurs when GMO dealings have concluded. Before 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 decommissioning of facilities has taken place.

The OGTR received 101 surrender requests in 2016–17 and approved 96 for surrender of certifications of facilities, five for surrender of DIR licences, seven for surrender of DNIR licences and one for surrender of accreditation.

Variations

Approval 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 to licences range from minor administrative changes (such as a change to contact details) to significant changes to dealings (such as a request to grow the GM crop at an additional or new site). Variations may also include evaluation of changes arising from renovations to a certified facility or new methods for handling GMOs.

The Regulator approved 418 variations in 2016–17 (see Table 3).

Monitoring dealings with genetically modified organisms

This section provides information on the OGTR's inspection activities during 2016–17.

Inspections of DIR licences

The OGTR strategy for field trial monitoring 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.[2]

During 2016–17, there were 54 active DIR licences held by 21 accredited organisations. These comprised 19 for commercial release of GMOs (14 for crops and five for vaccines), and 35 for limited and controlled release of GMOs (31 for crops and four for clinical trial of vaccines). None of the commercial release licences imposed conditions that necessitated monitoring. The OGTR inspected 12 of the 31 licences for limited and controlled field trials of GM crop varieties (which might include a number of trial sites for each licence). One limited and controlled vaccine trial (clinical trial) was inspected.

2 Details are in the Monitoring Protocol on the OGTR website at www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mc-protocols-1

Outcome of inspection activities

The OGTR's operational objective is to monitor at least 20% of all field trial sites of limited and controlled releases each year. A further target within this operational objective is to inspect a minimum of 5% of all field trial sites for limited and controlled releases during each quarter of the year.

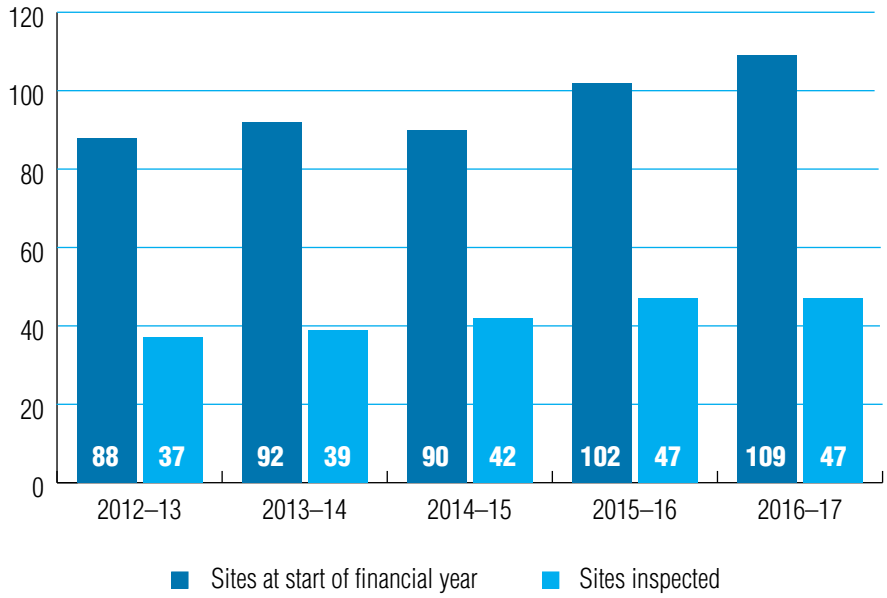
In 2016–17, the OGTR exceeded both its operational benchmark and its quarterly objective. At the beginning of 2016–17, 109 licensed field trial sites were operating, 42 of which were current and 67 of which were subject to post-harvest monitoring conditions. The OGTR inspected 47 sites in 2016–17 (17 current and 30 post-harvest monitoring sites), representing 43% of total sites as of 1 July 2016, thereby exceeding the target of 20% of field trial sites. A breakdown of the number and proportion of sites inspected in 2016–17 is in Table 9.

The numbers of current sites and of sites inspected over the past five years (2012–2017) are in Figure 11.

Table 9: Number and proportion of DIR field trial site inspections in each quarter of 2016–17

Number and proportion of sites inspected		
Quarter	**Current sites**	**Post-harvest monitoring sites**
July–September	5/42 (12%)	10/67 (15%)
October–December	5/44 (11%)	7/70 (10%)
January–March	4/30 (13%)	6/67 (9%)
April–June	3/19 (16%)	7/71 (10%)

Figure 11: Number of sites and number inspected each year, 2012–17



DIR = dealing involving intentional release of a genetically modified organism into the environment

Types of GM crops inspected

DIR licences authorised the limited and controlled release of the following range of GM plant species: banana, barley, canola, cotton, Indian mustard, potato, safflower, sorghum, sugarcane, wheat and white clover. Although licences were in force, planting has not occurred in all cases. Cotton and canola were the predominant GM crops grown, being trialled at 33 sites.

The OGTR inspected 47 field trial sites across nine plant species during 2016–17 (Table 10).

Table 10: Number of licensed DIR trial sites at beginning and end of 2016–17, and number inspected in 2016–17, by species

Species	Trial sites on 1 July 2016	Trial sites on 30 June 2017	Trial sites inspected
Banana	2	2	1
Barley	3	3	0
Barley, Wheat	9	11	7
Indian mustard	0	1	0
Canola	27	30	12
Cotton	30	3	10
Safflower	9	13	7
Sugarcane	20	19	6
Wheat	7	12	2
White clover	2	2	2

DIR = dealing involving intentional release of a genetically modified organism into the environment

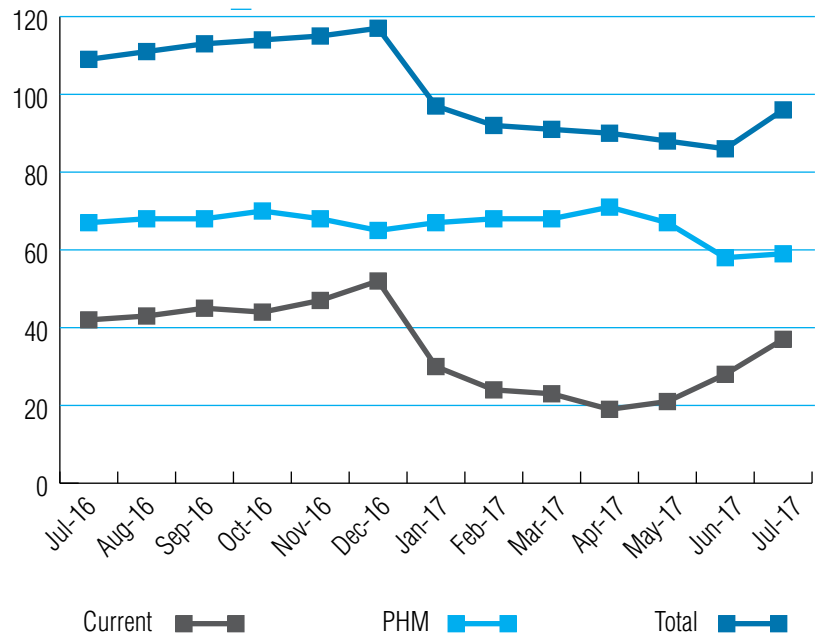
Note: Some DIR licences authorise trials with two similar crop species. In this table, trial sites authorised under such licences are listed separately from trial sites authorised under a licence for a single crop species.

Cycle and status of field trial sites

During the course of each year, a significant number of GM crop field trials undergo changes in status (i.e. moving from 'current' to 'post-harvest', through to 'signed-off'). A newly planted ('current') trial is subject to licence conditions to manage dissemination of the GMO from the trial site. These obligations continue until crop harvest and cleaning of the trial site is completed, changing the site status to 'post-harvest'. Trial sites are then subject to additional monitoring and reporting requirements, continuing until the OGTR is satisfied that no further inspections are required to manage persistence of the GMO. Sites may then become eligible for 'sign-off', subject to having completed all necessary licence obligations.

Figure 12 shows the change during 2016–17 in the numbers of current field trial sites and of field trial sites subject to post-harvest monitoring.

Figure 12: Number of DIR field trial sites and their status during 2016–17



DIR = dealing involving intentional release of a genetically modified organism into the environment

PHM = post-harvest monitoring

Locations of field trial site inspections

In 2016–17, the OGTR inspected field trial sites in all states and territories where field trials were undertaken, except in the Australian Capital Territory and the Northern Territory (Table 11).

A canola post-harvest trial site planted with wheat in Victoria

Table 11: Number of DIR field trial sites and OGTR inspections in 2016–17, by state and territory

Jurisdiction	Trial sites at 1 July 2016	Site inspections
Australian Capital Territory	4	0
New South Wales	22	10
Northern Territory	0	0
Queensland	32	11
South Australia	3	2
Tasmania	0	0
Victoria	35	18
Western Australia	13	6

DIR = dealing involving intentional release of a genetically modified organism into the environment

Inspections of contained dealings

The monitoring program also encompasses dealings conducted in certified containment facilities under DNIR licences and NLRDs. For monitoring purposes, certified facilities are grouped into higher and lower containment types. These are designated by physical containment (PC) level. Accordingly, PC4, PC3 and PC2 large-scale laboratories are categorised as higher-level containment facilities and the remaining facility types are categorised as lower-level containment facilities. At least 20% of higher-level physical containment facilities are monitored annually. As well as examining the integrity of the physical structure of the facility, inspections cover the general work practices used in handling GMOs.

At 30 June 2017, 142 organisations held 2042 certification instruments for containment facilities. During 2016–17, the OGTR inspected 68 facilities across the range of facility types (Table 12). Of the 54 higher-level containment facilities that had certification instruments in force at the beginning of 2016–17, 14 were inspected. This figure represents 26% of higher-level containment facilities and exceeds the minimum target of inspecting 20% of such facilities each year.

In addition, 15 DNIR licences in force during 2016–17 were monitored.

Table 12: Number of inspections of certified facilities (by type) conducted during 2016–17

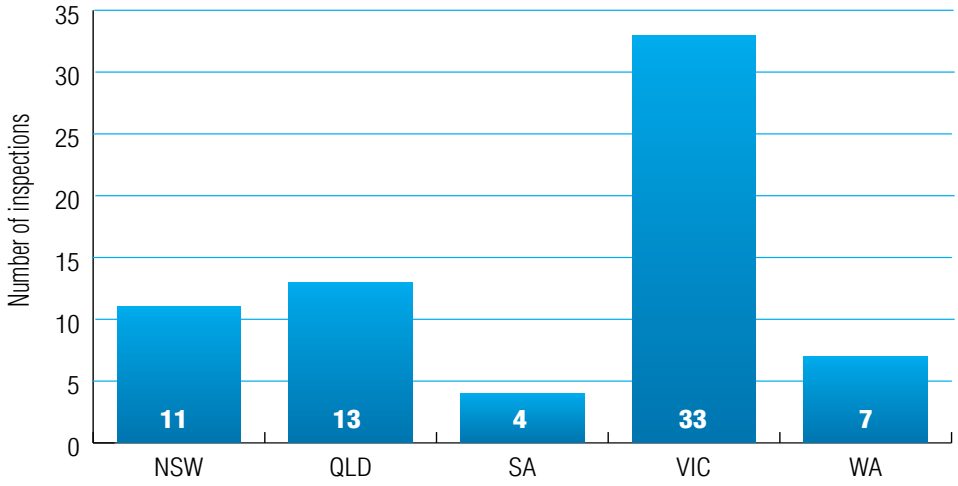
Containment type	PC level and facility type	Inspections
Lower level	PC1 facility	1
	PC2 Animal	4
	PC2 Laboratory	41
	PC2 Plant	8
Higher level	PC2 Large scale	7
	PC3 Laboratory	7
Total		**68**

PC = physical containment

Locations of facility inspections

Certified facilities are located in all Australian states and territories (Figure 9. In 2016–17, monitoring activities took place in each state and territory except the Australian Capital Territory and the Northern Territory (Figure 13).

Figure 13: Number of certified facility inspections in 2016–17, by state and territory



Types of organisations inspected

Of the five categories of applicant organisations, universities held the largest number of certifications during 2016–17 (Figure 14). The number of inspections of facilities

(Figure 15), as far as practicable, were proportional to the number of facilities in each organisation category.

Figure 14: Distribution of certified facilities at 30 June 2017, by organisation type

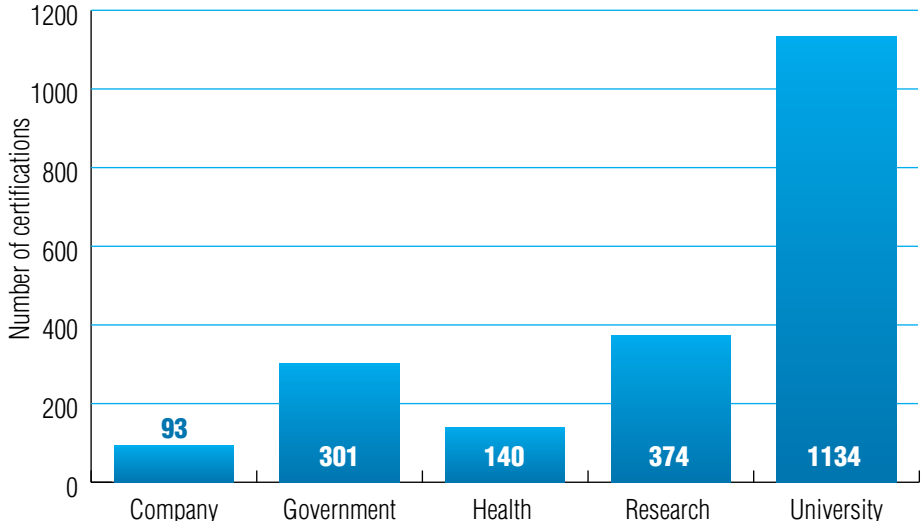
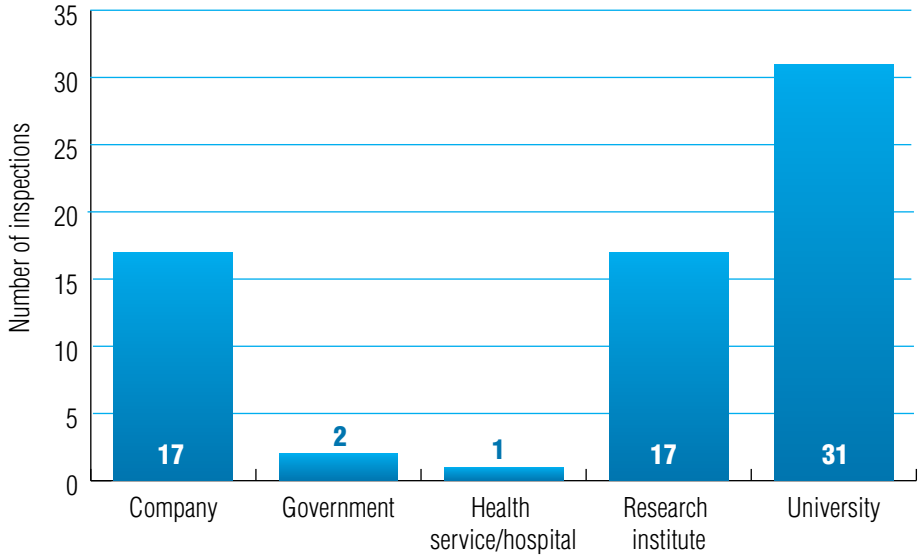


Figure 15: Number of certified facility inspections in 2016–17, by organisation type



Compliance with the Act

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

Matters referred to as non-compliances in this report reflect situations where inspectors have found inconsistencies relating to requirements imposed by licence or certification conditions. Non-compliances are not regarded as breaches of licence conditions unless proven to be so after investigation. Non-compliances with licence conditions are assessed against a number of considerations before determining the OGTR response, as described under the OGTR Compliance and Enforcement Policy.[3]

During 2016–17, the regulated community demonstrated a high level of compliance with the gene technology legislation.

Non-compliance findings for GMO dealings involving intentional release

In 2016–17, four licence holders of DIR licences were found to be non-compliant. These findings are outlined below.

Organisation	**Monsanto Australia Limited**
Licence number and site	DIR 120 Site 7
Summary of dealing	The purpose of the trial is to assess the agronomic performance of the GM cotton under Australian field conditions and generate data for possible future commercial release.
Findings	On 29 October 2016, Monsanto self-reported the planting of a non-permitted crop (commercial cotton) on Site 7 at Cecil Plains (Queensland), a post-harvest site. DIR-120 licence conditions state that no plants may be intentionally grown in the area unless the plants are: • the GMOs, non-GM cotton, or commercially approved GM cotton planted in accordance with the conditions of DIR 120 licence; or • listed as post-harvest crops permitted for GM cotton field trial sites in the OGTR Policy on Post-Harvest Crops as current at the time of planting; or • agreed to in writing by the Regulator. Commercial cotton is not a permitted post-harvest crop, and this planting was not in accordance with DIR 120 licence conditions. Monsanto stated the grower responsible for Site 7 had planted commercial cotton because he wanted to take advantage of recent rains; this was despite being trained and aware that this planting was not approved.

3 http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mc-protocols-1 is on the OGTR website

Assessment	This was the second time in 2016 that a non-permitted post-harvest crop was planted by the grower at DIR 120 Site 7; in January 2016 a non-permitted soybean crop was planted. Following that incident, the grower was re-trained by Monsanto with regard to post-harvest crop management. The planting of non-permitted post-harvest plants can hinder the detection of volunteers. The non-permitted post-harvest commercial cotton was destroyed by Monsanto and all cotton volunteers at this site will be managed as GM cotton. The risk posed by this non-compliance to human health and safety and the environment was assessed as negligible.
Compliance management	In consultation with the OGTR, Monsanto has implemented the following strategies at the site: • Destroyed the cotton at Site 7 • Continued to ensure that all volunteers are destroyed prior to flowering • Updated grower training with more emphasis on post-harvest management.

Organisation	**Nuseed Pty Ltd**
Licence number and site	DIR 123 Site 28
Summary of dealing	Limited and controlled release of canola genetically modified for altered oil content.
Findings	During a routine monitoring inspection conducted on 29 March 2017, OGTR inspectors found several (approximately 10-12) plants of a related species growing amongst the GM trial plants. Some of these plants were flowering and had also developed seed pods. This finding is not consistent with licence condition 34 of DIR 123. OGTR inspectors concluded that despite conducting routine monitoring, Nuseed Pty Ltd did not identify (and destroy) the related species within the trial site, before flowering.
Assessment	The risk assessment and risk management plan for DIR 123 determined risks were negligible within the context of the proposed release, which included that related species would not be allowed to flower. The presence of flowering related species with seed pods within the canola trial site provides greater opportunity for outcrossing, production of viable hybrid offspring and the persistence of volunteer GM hybrids. The GM trait is unlikely to enhance survival and persistence of the GM hybrids, thus risks to human health and safety and the environment remain negligible.

Compliance management	In consultation with the OGTR, Nuseed Pty Ltd: • elected to voluntarily destroy the GM canola trial crop at the site by herbicide application • would review their procedures and training for inspection of trial sites for volunteers (including related species) and destroy them prior to flowering. At the end of the reporting period, the trial site was under the post-harvest monitoring phase. As part of the post-harvest inspection requirements (licence condition 47), Nuseed Pty Ltd must inspect for volunteers and inspect for related species, and destroy both volunteers and related species prior to flowering.

Organisation	**Sugar Research Australia Ltd (SRA)**
Licence number and site	DIR 129 Site 7
Summary of dealing	The purpose of the release is to evaluate the field performance of GM herbicide tolerant sugarcane and to conduct breeding to develop commercially useful GM herbicide tolerant sugarcane clones.
Findings	The OGTR identified that a notice of cleaning was not provided for Site 7 following final harvest. Upon request, SRA provided the notice which identified that cleaning was done outside the 14 day period following final harvest, contrary to the licence conditions.
Assessment	Prior to OGTR identifying the issue, SRA had commenced cleaning of Site 7 by herbicide application. The herbicide was applied more than 14 days following final harvest, and the OGTR had not been notified. SRA stated that the cleaning was delayed in line with commercial sugarcane practices in the Bundaberg region. SRA also did not consider cleaning to be complete until the site was rotary hoed. Consequently, SRA stated that this is why the OGTR was not notified in this instance. SRA already has appropriate procedures in place for the cleaning of sites and providing notification to the OGTR. Prior to this incident, SRA had trained all relevant personnel. The risk posed by this non-compliance to human health and safety and the environment was assessed as negligible.
Compliance management	In consultation with the OGTR, SRA would: • ensure that future cleaning was conducted within the 14 day timeframe outlined in the licence • re-train personnel involved in relevant licence conditions.

Organisation	GO Resources Pty Ltd
Licence number and site	DIR 131 Sites 8 and 11
Summary of dealing	Limited and controlled release of safflower genetically modified for high oleic acid composition.
Findings	Two days before the scheduled routine monitoring inspection on 28 June 2017, a GO Resources representative informed OGTR inspectors that chickpeas were inadvertently sown over post-harvest phase Sites 8 and 11. During inspection, inspectors confirmed that this was the case. Chickpeas are not a permitted post-harvest crop. Further discussions with the GO Resources representative revealed that the farmhands did not properly understand the instructions regarding permitted post-harvest crop provided by the trial coordinator and the land owner. This resulted in inadvertent sowings over the trial sites. OGTR inspectors concluded that despite effective communication strategies in place between GO Resources, the trial coordinator and the landowner, a miscommunication occurred on this occasion. The sowing of chickpeas over post-harvest trial sites is not consistent with licence condition 48b of DIR 131.
Assessment	Chickpeas and safflower are members of two separate families that do not cross or hybridise. The GO Resources representative informed OGTR inspectors that they would elect to destroy the chickpeas soon after active emergence. Risks to human health and safety and the environment were assessed as negligible.
Compliance management	In consultation with the OGTR, GO Resources: • elected to destroy the chickpeas soon after active emergence • would, as part of the post-harvest inspections, continue to inspect for safflower volunteers and destroy them before flowering • would review its procedures and training with regards to effective communication between its staff, the trial coordinator and the landowner, inclusive of farm hands.

Non-compliance findings for GMO dealings not involving intentional release

In 2016–17, three DNIR licences were found to be non-compliant, as outlined below.

Organisation	PPD Australia Pty Ltd
Licence number	DNIR 569

Summary of dealing	This trial aims to assess the safety and tolerability of gene therapy treatment using a genetically modified adeno-associated viral vector encoding human Factor IX in patients with severe hemophilia B.
Findings	PPD Australia self-reported that a qualified person performed an intravenous infusion with a GMO without training in the licence conditions, and who had also not signed a statement indicating that they had been informed of licence conditions and had understood and agreed to be bound by the licence conditions.
Assessment	At the time of the intravenous infusion, the person was supervised by another person appropriately trained in the licence conditions. Following the infusion, the supervising person dealt with transport and storage of all the materials as per the licence conditions. As such, no additional risks were identified.
Compliance management	PPD Australia was reminded that prior to permitting persons to commence work with a GMO they must: • inform all persons covered by a licence of the conditions that apply to them • obtain a signed statement from each person covered by the licence acknowledging that the licence holder had informed the person of the conditions of the licence, or variations to those conditions, that apply to that person.

Organisation	**Deakin University**
Licence number(s)	DNIR-512
Summary of dealing	The aim of the dealing is to generate replication defective (RD) GM HIV-1 viral particles pseudotyped with envelope proteins of different viruses and use them for in vitro studies to investigate how these GM viruses gain entry into cells.
Findings	Deakin University did not inform (or adequately inform) persons undertaking licensed dealings of the conditions that applied to them. Deakin University self-identified that licensed dealings (i.e. experimentation, storage and disposal) were undertaken in facilities not listed on the licence. DNIR-512 requires that all dealings must be conducted in specific facilities certified to at least PC3. At the time of inspection, it was identified that, although prohibited by the licence, transport of GMOs between certified facilities routinely occurred. It was also identified that the manner of transport was not consistent with licence conditions. The personal protective equipment (PPE) worn by persons undertaking dealings (to minimise potential exposure to the GMO) did not include face masks, as required by the licence.

Assessment	As dealings were undertaken in certified, high-containment facilities, the risks to human health and safety were assessed as low. The unauthorised facilities where they conducted licensed dealings were equivalent to and certified at the same containment level as those listed on the licence. As such, no additional risks were identified. GMOs were contained at all times during transport and no spills were identified. No additional risks were identified. Although exposure to the GMO poses risks to human health, there was no evidence to suggest that any incident had occurred where the failure to wear the required PPE had exposed anyone undertaking a dealing to additional risks.
Compliance management	Deakin University agreed to: • develop and implement a re-training program to ensure that all persons undertaking dealings with the GMOs are aware of applicable licence conditions • cease undertaking licensed dealings in unauthorised facilities • transport GMOs only when authorised by the Regulator, and in a manner consistent with licence conditions • ensure that face masks are worn by persons undertaking dealings with the GMO.

Organisation	**Intervet Australia Pty Ltd**
Licence number(s)	DNIR 301
Summary of dealing	The aim of this dealing is to produce large-scale quantities of recombinant *M. haemolytica* for use in an inactivated veterinary vaccine.
Findings	Intervet Australia Pty Ltd did not inform persons covered by the licence of relevant licence conditions that applied to them and, therefore, records of signed statements from staff were not available. Also, copies of licence conditions were not available in authorised facilities for staff to access, as required by licence conditions. Dealings with GMOs were undertaken in a facility not authorised by the licence and there was also unauthorised transportation of GMOs into that facility. Personal protective equipment (PPE) was not decontaminated prior to laundering, as was required by licence conditions.

Assessment	The above-mentioned issues are the direct result of the licence holder not meeting their obligation to inform staff of applicable licence conditions. The risks to human health and safety and the environment were assessed as low. The unauthorised facility where licensed dealings had occurred was equivalent to and certified at the same containment level as other facilities listed on the licence. Transport to this facility, though unauthorised, was undertaken in a manner consistent with the OGTR's transport requirements and no spills were identified as having occurred. As such, no additional risks were identified. Although exposure to the GMO (as a result of failure to decontaminate PPE prior to laundering) poses risks to human health and the environment, there was no evidence to suggest that this had occurred.
Compliance management	Intervet Australia Pty Ltd agreed to: • develop and implement a training program to ensure that all persons undertaking dealings with the GMOs are aware of applicable licence conditions • ensure copies of the licence are available to staff • ensure all required records are kept, including signed statements • cease undertaking licensed dealings in unauthorised facilities or using unauthorised transport • ensure that any PPE used during dealings with the GMO is decontaminated prior to laundering.

Non-compliance findings for notifiable low risk dealings

There were no non-compliance findings for notifiable low risk dealings.

Non-compliance findings for physical containment facilities

In 2016–17, 10 certified physical containment facilities were found to be non-compliant with 13 certification conditions. These findings are summarised in Table 13.

Table 13: Number of minor non-compliances identified in certified facilities during 2016–17, by non-compliance type

Nature of non-compliance	Number
Equipment	2
Personal protective equipment	0
Structure	4
Transport	1
Waste disposal	0
Work practices[1]	6

1 Work practices include personnel training, record keeping or other actions affecting compliance with certification instruments.

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 non-compliances were resolved by reminders, education and/or cooperative compliance.

Compliance and enforcement mechanisms

Practice reviews

The OGTR may initiate practice reviews in response to observations made during monitoring activities, or to follow up incident reports that may relate to non-compliance with licence conditions by accredited organisations. The objective of practice reviews is to determine whether licence conditions can be, and are being, effectively implemented.

An accredited organisation may request a practice review to assess the effectiveness of systems used by its IBC(s) to ensure that dealings are being conducted in accordance with the Act.

The primary focus of the review is to determine whether practices being used pose potential human health or environmental risks that require implementation of any management actions. In certain instances where a suspected non-compliance with the Act is identified, the issue may be referred for investigation.

The OGTR initiated and completed the following two practice reviews during this reporting period.

	Transport storage and disposal (TSD) practice review
Aim	This is part of the OGTR's ongoing practice review program. The OGTR recognises that effective compliance is dependent on: • suitable arrangements to manage compliance of dealings with GMOs • the appropriate use of specified equipment and service providers • the availability of appropriate services.
Participants	The review included assessments of the practices of the following two accredited organisations: Westmead Millennium Institute for Medical Research and the Children's Medical Research Institute. The review assessed: • the operational practices for managing the TSD compliance requirements • the suitability of the organisations' arrangements to manage compliance risks for TSD • any industry or other regulatory issues which could impinge on the organisations' effective compliance performance.
Findings	The review found that: • the participating accredited organisations were found to have efficient tailored arrangements to comply and manage TSD guidelines.
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.
	DIR 120 Site 15 dryland cotton trial practice review
Aim	This review was initiated as part of the OGTR educational and knowledge-building exercise in relation to Monsanto's GM dryland (unirrigated) cotton trial, with special reference to skip row planting of pollen trap and the effectiveness of it in meeting licence condition 27 under dryland conditions.

Participants	Monsanto Australia Ltd senior staff assisted the OGTR during the review and the three visits which were made to the sites. The review was initiated after the first inspection of the trial site in late November 2016 to assess the density and pace of growth of non-GM cotton plants as an effective pollen trap in dryland cropping conditions. OGTR staff further visited the trial site twice in mid-December 2016 and again in mid-January 2017, to assess the recovery and performance of the pollen trap plants.
Findings	The review found that: • Monsanto was fully effective in managing the requirements of licence conditions at various stages, although abiotic factors, such as rainfall, presented challenges • the pollen trap plants improved in relation to pace of growth and size • prior to flowering, the plants had recovered to function as a pollen trap • the information gathered during the review was valuable for the OGTR in raising awareness and improving capacity to assess dryland GM cotton trials.
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.

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

The strategy uses a risk management approach, with resources dedicated to the areas posing the highest likelihood of unintended presence of GMOs. The OGTR has worked with the Australian Seed Federation (ASF) to develop a voluntary testing program of existing industry quality assurance measures. Further information about the strategy is available at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mon-unintended-1

In 2016–17, the OGTR continued to liaise with the ASF and the seed industry, presenting at the annual ASF Convention to raise awareness amongst their membership about management of low-level presence of GMOs, and to ensure their ongoing voluntary cooperation and action regarding this issue.

The OGTR also visited five seed breeding organisations (Advanta Seeds Pty Ltd, Pioneer Hi-Bred Australia Pty Ltd, Heritage Seeds Pty Ltd, Pasture Genetics and Seed Genetics International Pty Ltd) to audit their quality assurance systems, and did not identify any issues of concern. The OGTR continued to engage with other government departments, including the Australian Government Department of Agriculture and Water Resources, regarding low-level presence of unapproved GMOs.

Investigations

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

There were no investigations completed in this reporting period.

Monitoring of GM petunia inadvertent dealings licences

During 2017, the Gene Technology Regulator issued four inadvertent dealings licences for dealings with GM petunia varieties that unintentionally entered the Australian market without approval. These petunia varieties were genetically modified to produce a pigment found naturally in other flowering plants, leading to a range of colours.

The inadvertent dealings licences were issued to allow appropriate disposal of these GMOs by any organisations inadvertently in possession of them. This was supported by risk assessments which concluded that the GM petunias are considered to pose negligible risks to human health and safety and the environment.

OGTR inspectors engaged industry groups to clarify which GM petunias were present in Australia and also visited those importing nurseries (holders of inadvertent dealings licences) who were inadvertently in possession of GM petunia varieties to ensure that they were able to dispose of their stock in an appropriate manner. The OGTR worked with the industry, including the peak association, to manage the persistence of GM petunias in Australia, with an emphasis on ensuring that these GMOs are not sold or propagated by wholesalers/retailers and that supply is ceased.

More information can be found on the OGTR website:
http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/id01

Security Sensitive Biological Agents Regulatory Scheme

The *National Health Security Act 2007*, which is administered by the department's Office of Health Protection (OHP), provides for a scheme for regulating security sensitive biological agents (SSBAs). 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*. The OGTR has worked with the OHP to develop operational monitoring requirements. Under a service level agreement between OGTR and OHP, SSBA inspection activities commenced early in 2009–10. These activities continued during 2016–17.

PERFORMANCE AGAINST PBS TARGETS

The OGTR's performance against the deliverables and key performance indicators set out in the PBS, which is also reported in the department's 2016–17 annual report, is summarised below.

The OGTR's activities for 2016–17 are described under Program 5.1 in Outcome 5 (Regulation, Safety and Protection) of the 2016–17 Department of Health PBS.[4] 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 technical review of the *Gene Technology Regulations 2001*

2016–17 target	2016–17 result: Not met
Draft amendment regulations, informed by stakeholder submissions, will be prepared in 2016. Consultation on proposed amendments will be undertaken in 2016–17.	Stakeholder consultation on proposed amendments will commence in 2017–18.

OGTR consulted with a wide range of stakeholders on regulatory options to address new technologies, outlined in a discussion paper. The OGTR received 741 submissions in response to the two-month public submission period. Due to the complexity of the topic and significant community and stakeholder interest, the OGTR held follow-up discussions from April through to June with a broad range of submitters.

Provide open, effective and transparent regulation of GMOs

2016–17 target	2016–17 result: Met
Risk assessments and risk management plans prepared for 100% of applications for licensed dealings. Stakeholders, including the public, consulted on all assessments for proposed release of GMOs into the environment.	Risk assessments and risk management plans were prepared for 100% of applications for release of GMOs into the environment in 2016–17. Stakeholders, including the public, were consulted on the assessments of these applications.

In 2016–17, stakeholders, including the public, were consulted on 11 risk assessment and risk management plans in response to licence applications for field trials of GM banana, cotton, Indian mustard, potato, wheat, barley, sorghum and a vaccine for chickens, and commercial releases of two types of GM cotton and a dengue vaccine.

4 Available at: http://www.health.gov.au/internet/budget/publishing.nsf/Content/2015-2016_Health_PBS

Protect people and the environment through identification and management of risks from GMOs

2016–17 target	2016–17 result: Met
Scientifically robust risk assessment and effective risk management of GMOs. A high level of compliance with the gene technology legislation and no adverse effect on human health or the environment from authorised GMOs.	Scientifically robust risk assessments were prepared and all the risks identified for GMOs were effectively managed. The regulated entities reported high levels of compliance with the gene technology legislation and no adverse effects on Australian people or the environment from the approved GMOs.

In 2016–17, there were no adverse effects on human health or the environment from authorised GMOs. A high level of compliance with the gene technology legislation continued, with no enforcement action required. Risk assessment and risk management plans for the release of GMOs are available online.[5]

Facilitate cooperation and provision of advice between relevant regulatory agencies with responsibilities for GMOs and/or genetically modified products

2016–17 target	2016–17 result: Met
A high degree of cooperation with relevant regulatory agencies and timely provision of advice, including supporting engagement in international fora.	A high degree of cooperation was maintained with relevant regulatory agencies, with timely advice provided, as required.

OGTR engaged with international fora relevant to GMO regulation, including the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology. Regulators from other countries continued to seek input from the OGTR because the Australian scheme is considered a model for robust, practical and efficient regulation of GMOs. The OGTR also provided technical support to Australian engagement in meetings under the United Nations Convention on Biological Diversity and Cartagena Protocol on Biosafety.

5 Available at: www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1

Percentage of field trial sites and higher-level containment facilities inspected

2016–17 target	2016–17 result: Met	2015–16	2014–15	2013–14	2012–13
≥20%	43% of field trial sites	46%	44%	40%	42%
	26% of higher-level containment facilities	21%	26%	25%	25%

In 2016–17, OGTR inspectors exceeded operational targets by inspecting 43% of field trial sites to monitor compliance with licence conditions. Sites were inspected in New South Wales, Queensland, Victoria and Western Australia. Crops inspected included GM canola, wheat, barley, cotton, sugarcane, white clover and safflower.

OGTR also inspected 26% of higher-level containment facilities to ensure compliance with certification conditions. These inspections focused on the integrity of the physical structure of the facility and on the general laboratory practices followed.

Percentage of licence decisions made within statutory timeframes

2016–17 target	2016–17 result: Met	2015–16	2014–15	2013–14	2012–13
100%	100%	100%	95%	100%	100%

In 2016–17, 100% of the licence decisions were made within the statutory timeframes. From these:

- six licences were issued for field trials of GM banana, cotton, Indian mustard, potato, wheat and a clinical trial of influenza vaccine
- three commercial release licences were issued for two types of GM cotton and a dengue vaccine
- ten licences were issued for work with GMOs in high-level contained laboratory facilities.

CHAPTER 4
Engaging with stakeholders

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 LGFGT
- 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 LGFGT 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 assessments based on regulatory best practice and relevant scientific data.

TECHNICAL AND PROCEDURAL GUIDELINES ISSUED BY THE REGULATOR

During 2016–17, the OGTR progressed a revision of the *Guidelines For Certification Of a Physical Containment Level 2 Large Scale Facility*, and consulted on a draft revised guideline in February–March 2017. A review of the *Guidelines For Certification Of a Physical Containment Level 3 Facilities* (including animal, aquatic and laboratory facilities) was also initiated in 2016–17.

In September 2016, the Regulator issued a new application form specifically for the commercial release of GM plants: *Application for a licence for dealings involving intentional release (DIR) of GM plants into the environment—commercial release*.

Development of this new form allowed the science-related questions to be tailored to the specific information required for a risk analysis of commercial releases of GM plants. Additionally, the new form has links to example answers which assist in the completion of the form and illustrate the kind of information required. This form complements the application form for field trials of GM plants and was developed following extensive stakeholder consultation. The form is available on the OGTR website at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/apps-for-gmo

Gene technology is a rapidly developing field of science and the OGTR is aware of differences of opinion among regulated stakeholders as to whether organisms modified using some new technologies are subject to regulation as GMOs. To provide clarity around regulatory capture of new technologies, the Regulator issued a general guidance while continuing with the technical review of the Regulations. The Regulator also provided guidance on regulatory requirements for contained research with GMOs containing engineered gene drives.

TECHNICAL REVIEW OF THE REGULATIONS

The Regulator periodically reviews the Regulations in order to advise the LGFGT about the effectiveness of the legislative framework, including in relation to possible amendments to the Regulations. These technical reviews address the interface between science and regulation, which needs to be kept up-to-date with current understanding and technology in this rapidly developing field. The Regulator's technical reviews of the Regulations are limited to issues that do not affect the policy settings of the regulatory scheme.

The Regulator initiated a technical review of the Regulations in 2015–16 to provide clarity about whether organisms developed using a range of new technologies are subject to regulation as GMOs and to ensure that new technologies are regulated in a manner commensurate with the risks they pose. This review was progressed in 2016–17.

New technologies

Since the 2011 technical review of the Regulations, several technologies have developed rapidly—in particular, those techniques often referred to as genome editing. This includes site-directed nuclease techniques (e.g. utilising CRISPR/Cas9) and oligonucleotide-directed mutagenesis.

The Regulations contain a list of organisms that are not GMOs (Schedule 1), some items of which remain unchanged from the original Regulations published in 2001.

The existing wording in the Schedule now raises uncertainty about whether or not organisms developed using some new technologies meet the definition of 'genetically modified organisms' in the Act. The technical review aims to clarify this uncertainty and bring the wording up-to-date with current technology and scientific knowledge.

Consultation on options

On 17 October 2016, the Regulator published a discussion paper[6] detailing four options for how new technologies could be regulated. A call for submissions was published on the OGTR website, the *Australian Government Gazette* and in *The Australian* newspaper, and circulated to accredited organisations, institutional biosafety committees, subscribers to *OGTR News*, relevant Australian Government agencies, and states and territories. Submissions closed on 16 December 2017.

OGTR directly received 126 submissions from individuals, state government and Australian Government agencies, research organisations, companies, and industry and community groups. A total of 615 submissions were also received through a form on the Do Gooder website, initiated by Friends of the Earth Australia. Submissions are available on the OGTR website[7].

Three of the four options for how new technologies could be regulated received substantial support from submitters. Submissions raised a variety of complex issues which OGTR further explored through targeted discussions with submitters.

Next steps

The Regulator is considering whether to recommend amendments to the Regulations. In making this decision, the Regulator will consider scientific understanding, potential risks, the regulatory burden implications for stakeholders, whether regulatory burden would be commensurate with risks, and also the policy intent of the Act.

If the amendments to the Regulations are recommended, the Regulator will publicly consult on draft amendments in 2016–17. In accordance with the requirements of the Office of Best Practice Regulation, the change in regulatory burden that might result from any proposed changes would also be examined.

Any amendments to the legislation forming the scheme, including the Commonwealth Regulations, must be formally agreed by a majority of states and territories through the LGFGT. The Regulator would seek this agreement after proposed amendment regulations are finalised.

6 Available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewdiscussionpaper-htm
7 Available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewsubmissions-htm

ADVICE ON GMOS AND GM PRODUCTS

During 2016–17, the OGTR provided advice on the regulation of GMOs and GM products to other regulatory agencies and the public.

Advice to other regulatory agencies

To facilitate reciprocal exchange of information with other product regulatory agencies on assessment and approval of GMOs and GM products, the OGTR has developed memoranda of understanding (MOUs) with Food Standards Australia New Zealand (FSANZ), the Therapeutic Goods Administration (TGA) and the Australian Pesticides and Veterinary Medicines Authority (APVMA). In 2016–17, the OGTR, in conjunction with the relevant agencies, commenced reviews of its MOUs with FSANZ and APVMA. The OGTR also has an MOU with the Department of the Environment and Energy in relation to consultation with the Minister for the Environment and Energy on DIR licence applications, as prescribed by the *Gene Technology Act 2000*. OGTR is working with the Department of Agriculture and Water Resources (DAWR) to develop a schedule to the MOU between the Department of Health and DAWR detailing interactions between OGTR and DAWR.

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 regulatory science across government agencies and provides a forum for the discussion of regulatory and technical issues, and enhancing inter-agency cooperation.

OGTR continued to participate in the RSN in 2016–17, including chairing the RSN for the 2017 calendar year. OGTR participated in an RSN meeting on 8 August 2016, and arranged and hosted meetings on 20 March 2017 and 30 June 2017.

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.[8] The GMO Record contains information on licences issued, NLRDs, GMO dealings included on the GMO Register, and EDDs. During 2016–17, the GMO Record was maintained and updated with new authorisations.

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

ENGAGEMENT WITH STAKEHOLDERS

The Regulator held a stakeholder engagement meeting on 10 November 2016 to engage with non-government organisations (NGOs) interested in gene technology. Three NGOs attended, along with members and the Chair of GTECCC, and staff from the OGTR, the Department of Health, and the Department of Agriculture and Water Resources. Presentations given on the day by the OGTR, and a communiqué from the meeting, are available on the OGTR website (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/our-view).

On 21 June 2017, the Regulator participated in a public panel discussion held by the Australian Academy of Science on 'Next Generation Gene Technology'.

During 2016–17, the Regulator and the OGTR participated in a range of presentations and meetings on gene technology to inform users, the Australian community and stakeholders about the regulatory system.

The OGTR participated in the following meetings:

- ARCS Scientific Congress, August 2016, Canberra
- WA Department of Parks and Wildlife Workshop: Gene Drive and Invasive Species Control, August 2016, Perth
- Society for Risk Analysis
- Australia New Zealand Conference, November 2016, Adelaide
- ANU Lecture, August 2016
- Australasian College of Toxicology & Risk Assessment (ACTRA) workshop, July 2016, Canberra
- Australian Cotton Conference, August 2016, Gold Coast
- Ag and Foodtech Conference, August 2016, Brisbane
- International Biotechnology Symposium 2016, October 2016, Melbourne
- AgCatalyst, December 2016, Sydney
- 20th Australasian Weeds Conference, September 2016, Perth
- ComBio 2016, October 2016, Brisbane
- Australian Seed Federation Seed Business Convention, Melbourne, August 2016
- Association of Biosafety for Australia & New Zealand 6th Annual Conference, Melbourne, November 2016.

National Institutional Biosafety Committee Forum

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

The 7th National IBC Forum was held in Canberra on 4–5 May 2017 at the National Gallery of Australia. Representatives of IBCs and accredited organisations from most states and territories attended, with 150 delegates from 80 organisations. The forum was opened by Mr Mark Cormack, Deputy Secretary, Department of Health. The keynote address was given by Nobel Laureate Professor Brian Schmidt, Vice-Chancellor, Australian National University. Guest speakers and panel members from organisations and IBCs, together with OGTR staff, contributed to an engaging and well-received program. Major topics for discussion included current trends in gene technology, biohacking, an update on the technical review of the Regulations, and steps involved in the review of the Scheme, including a workshop to canvas ideas from organisations and IBCs. There was also another workshop on clinical trials with relevant organisations and IBCs. The forum provided an important opportunity for feedback and exchange of information between IBCs and the OGTR, enhancing regulation of gene technology.

Chair of GTECCC, Judy Jones speaking at the IBC Forum 2017

RESEARCH UNDERTAKEN OR COMMISSIONED BY THE REGULATOR

As part of an ongoing information-gathering project on public attitudes towards GMOs, the OGTR commissioned Instinct and Reason to conduct a survey to:

- explore current awareness, attitudes and understanding towards general science and technology, specific biotechnology issues and specific applications and controllers of the technology
- explore differences in awareness, perceptions and attitudes according to key demographic variables, such as age, gender, location and education and, in terms of mindsets, to determine segments in the community.

The final report highlights that both awareness and support for gene technologies in Australia has held steady since 2015. Australians are still more in support of genetically modified organisms than opposed, although this depends on the application of the technology. For example, support is greater for medical and industrial uses than for using the technology in food and crops. The report also shows that most support or rejection of genetically modified foods is conditional, and is likely to move based on knowledge of regulation or scientific evidence of safety.

PROMOTING HARMONISATION

The OGTR has continued to liaise with other regulatory agencies and other Australian Government agencies on relevant issues. Regulatory harmonisation and the need to address regulation of new and emerging technologies has been a focus both nationally and internationally.

International regulatory liaison

Active participation in international forums ensures that Australia's regulatory scheme takes account of developments in GMO regulation and science. Feedback from meetings continues to indicate that the Australian gene technology regulatory system is highly regarded. International engagement also enables Australia to inform international best practice based on its practical experience of administering efficient and effective GMO regulation.

The OGTR provides input and advice on GMO regulation to other Australian agencies to support their international engagement—for example, responses to notifications by other countries about changes to regulation (including GMO regulation) under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures, and engagement in the UN Convention on Biological Diversity and the UN Cartagena Protocol on Biosafety.

OGTR staff with Indian delegation

The OGTR continued to engage in international fora relevant to the harmonisation of 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 (WGHROB). The WGHROB develops scientific guidance to support the risk assessment of GMOs.

The OGTR is responsible for entering Australian commercial approvals of GMOs into the OECD BioTrack Product Database[9] and the UN Biosafety Clearing-House.[10] The OGTR provides technical advice to support Australian engagement in activities under the protocol, such as submissions on particular issues.

The OGTR is the national focal point for the UN Cartagena Protocol on Biosafety and for the Biosafety Clearing-House, and disseminates information to other agencies.

The OGTR interacted with key regulatory counterparts in other countries through participation in international forums in 2016–17, including:

- UN Convention on Biological Diversity, Open-ended Online Forum on Synthetic Biology, June/July 2016
- OECD Co-operative Research Programme Funded Workshop: Environmental Release of Engineered Pests: Building an International Governance Framework, 5–6 October 2016, Raleigh, North Carolina, USA. Contribution to paper on Australian gene technology regulation.
- OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology (WGHROB) 6th Steering Group on Environmental Considerations for Transgenic Plants, 18–20 October 2016, Ottawa, Canada
- 13th Conference of the Parties to the UN Convention on Biological Diversity and 8th Meeting of the Parties to the UN Cartagena Protocol on Biosafety, 4–17 December 2016, Cancun, Mexico
- A meeting of Australian Government officials with a delegation of Japanese House of Representatives researchers, 17 January 2017, Canberra
- Genetic Modification Advisory Committee (GMAC) of Singapore, Strategic Retreat, 17 May 2017, Singapore
- 14th International Symposium on the Biosafety of Genetically Modified Organisms, 4–8 June 2017, Guadalajara, Mexico
- The Third International Workshop on the Regulation of Animal Biotechnologies, 26–30 June 2017, Charlottesville VA, USA

9 The BioTrack Product Database is on the OECD website http://www.oecd.org/science/biotrack/
10 The Biosafety Clearing-House is online https://bch.cbd.int/

- The 5th Meeting of the Global Low Level Presence Initiative, 14–15 June 2017, Rome, Italy.

In 2016–17, the OGTR continued to receive requests from regulators in other countries to visit Australia and learn about the Australian approach to GMO regulation. This represents continuation of a trend over the past few years. Feedback from these visits indicates that the OGTR's approach to risk analysis and regulation is held in high regard as scientifically rigorous, practical and effective.

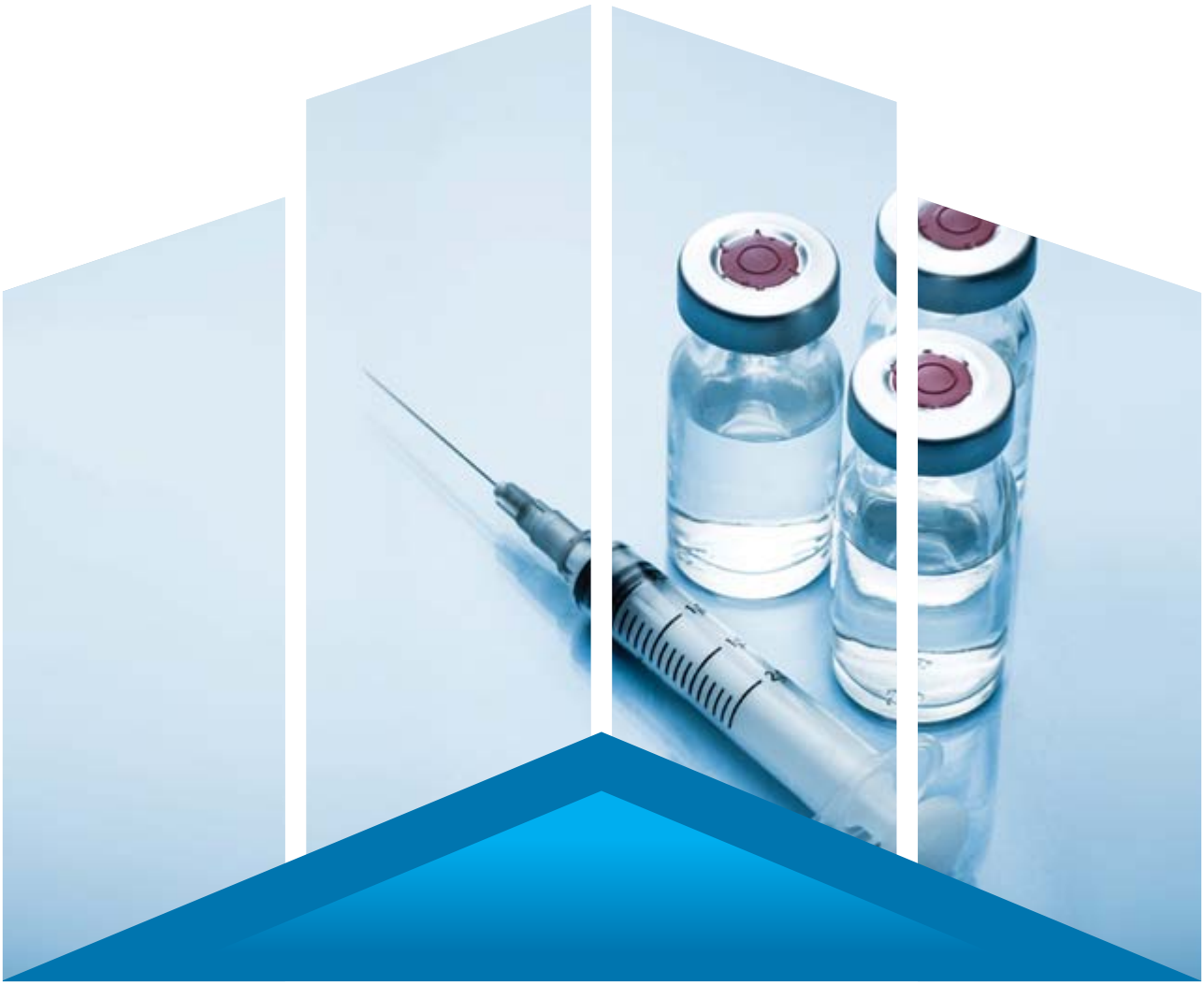
Visits by international delegations to the OGTR regarding GMO regulation in 2016–17 were:

- Korean delegation, December 2016
- Indian delegation, January 2017
- Regulatory officials from Burkina Faso and Nigeria, supported by the UN International Centre for Genetic Engineering & Biotechnology, April 2017.

The management and accountability practices of the Office of the Gene Technology Regulator encompass 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 Gene Technology Regulator reports to parliament annually, as required by legislation.

CHAPTER 5

Management and accountability



HUMAN RESOURCES

The OGTR has a workforce of 50 employees. The terms and conditions for non–Senior Executive Service staff at the OGTR are covered by the Department of Health Enterprise Agreement 2016–19, 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 14.

Table 14: Non-salary benefits

Agreement	Benefits
Enterprise Agreement	• Access to negotiated discount registration or membership fees to join a fitness or health club • 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 and hepatitis B vaccinations for staff who are required to come into regular contact with members of the community who have increased risk of exposure to influenza • 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 • Home office equipment • 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 16th 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 was also promoted as casual dress day, and staff who took up this option were encouraged to contribute a gold coin for donations to:

- Hat Day for Mental Health
- Movember
- OzHarvest Canberra
- Queensland Flood Appeal.

The OGTR implemented measures to maintain staff skills and motivation through appropriate training and development, and to ensure that recruitment occurred in a timely manner.

Regulator's Achievement Award

Regulator's Achievement Award recipients

Staff nominations for the Regulator's Achievement Award this year reflected the qualities of professionalism, perseverance, excellent communication and engaging with respect. The two recipients, Gillian Colebatch and Louisa Matthew, were acknowledged by their colleagues for their dedication to the work of the OGTR and for having worked tirelessly, and in good spirit, to achieve outcomes which were in the making over a period of years.

Gillian Colebatch was primarily responsible for managing the nomination and appointment process for the two statutory advisory committees—the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics and Community Consultative Committee (GTECCC) —over the past two years. The committees provide valuable advice which is integral to the functions of the Regulator and the work of the OGTR. Gillian was diligent in her communication and stakeholder management with the Minister's Office and colleagues. She also kept nominees updated and interested while maintaining the integrity of the process. Gillian was cheerful, persistent and efficient in dealing with many externalities which were outside her, or the OGTR's, control. Over this time, she has won the respect of the committee Chairs and members.

Louisa Matthew has been instrumental in managing the technical review of the *Gene Technology Regulations 2001*. Over the course of the last few years, Louisa gained an incredible amount of knowledge about the relevant new technologies and how they are being considered in other jurisdictions. She formed networks with many national and international colleagues, which allowed her to stay on top of developments in the field. She managed the administrative process of the regulatory review, engaging with relevant stakeholders. This involved organising meetings, giving presentations and

responding to public and ministerial questions. Louisa has made a very significant intellectual contribution over many years to OGTR's understanding and approach to new technologies and the legislation.

Staff profile, training and development activities

This section provides information on Australian Public Service staff employed by the Office of the Gene Technology Regulator (OGTR) in 2016–17 under the *Public Service Act 1999*.

Tables 25 to 27 provide details on staff numbers, and aggregated information on salary, performance pay and non-salary benefits provided to staff during 2016–17 under the Department of Health Enterprise Agreement 2011–14 and individual flexibility arrangements.

Training and development

OGTR staff undertook 48 days 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.

In 2016–17, refresher training was given to the emergency control team, which comprises a floor warden and two fire wardens. 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 2016–17, the OGTR Legal Officer conducted introductory and ongoing training for OGTR staff on legal issues (Table 15).

Table 15: Internal training presentations on legal issues, 2016–17

October 2016	Confidential commercial information
November 2016	Conflicts of interest
March 2017	Introduction to the Australian legal system
March 2017	Information disclosure
March 2017	Who are the regulators?

May 2017	The Commonwealth public interest disclosure scheme
June 2017	Complaint handling and the Commonwealth Ombudsman

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. A range of OGTR staff and guest speakers made presentations at the OGTR Forum in 2016–17 (Table 16).

Table 16: Presentations at the OGTR Forum, 2016–17

July 2016	Evidence for decision-making and risk analysis. Dr Michael Dornbusch
July 2016	Communication—writing reports and other documents. Dr Michael Dornbusch
August 2016	Assessment endpoints—what are they and where do we get them? Dr Michael Dornbusch
August 2016	The carrot and stick approach to regulating medicines manufacture. Dr Harry Rothenfluh, Therapeutic Goods Administration
October 2016	Regulation by the APVMA. Dr Raj Bhula
November 2016	Improving sorghum for various end-uses with genomic-informed genetic technologies. Professor Ian Godwin, University of Queensland
February 2017	Indian biosafety regulatory framework and knowledge products. Shri Gyanesh Bharti, Ministry of Environment, Forest and Climate Change, Government of India Strengthening environmental risk assessment in Indian biosafety regulation. Professor K. Veluthambi, Madurai Kamaraj University, India
February 2017	Key outcomes from UN Biodiversity Conference COP-MOP 8. Dr Michael Dornbusch
March 2017	Impacts of invasive plants—adaptive management, risk and uncertainty. Professor Paul Downey, University of Canberra
April 2017	Overview of GMO regulation in Burkina Faso. Professor Chantal Kabore, Director, Burkina Faso National Biosafety Agency, Ministry of Scientific Research and Innovation

April 2017	Overview of GMO regulation in Nigeria. Ms Blessing Oligwekwe, Senior Scientific Officer, National Biosafety Management Agency, Nigeria
May 2017	Regulatory impact analysis. Mr Joshua Saunders, Office of Best Practice Regulation, Department of Prime Minister and Cabinet
May 2017	OECD work on GMO risk assessment—update and observations. Feedback on the 31st meeting of the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology • Peter Thygesen

Supportive working environment

In keeping with the OGTR's objective of providing a supportive working environment, staff have access to departmental assistance measures. 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. Staff have accessed extended maternity leave on half pay, and the 48/52 provision, which provides additional unpaid leave while averaging salary payments during the year.

Feedback from the department's annual staff survey again indicated high overall job satisfaction among OGTR staff. Survey feedback was used to inform the OGTR People Strategy Action Plan for 2016–17.

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, and provides appropriate reasonable adjustment to working environments to achieve this, including flexible working arrangements. The commitment to providing rehabilitation assistance to injured and ill employees is supported by medical examinations to determine fitness for duty and the need for workplace rehabilitation assistance.

Initiatives to ensure workers' health, safety and welfare

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

- creating, promoting and maintaining a safe and healthy working environment
- encouraging productive working relationships
- promoting and encouraging behaviours in staff and managers which assist in the management and reduction of 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.

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

In 2016–17, training was conducted 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. Strategies for identification and management of work health and safety risks have been incorporated into business planning processes.

Staff of the Contained Dealings Evaluation Section undertook driver training, as they are required to drive in capital cities when inspecting facilities. Staff of the Monitoring and Compliance Section also undertook this training, as well as four-wheel-drive training. Staff from this section are required to drive in all states and territories of Australia, including in country areas, on unfamiliar roads (tar and gravel) and under a range of conditions (such as rain and low visibility).

Other work health and safety support included provision of 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 business or undertakings by the OGTR, 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.

Regular work health and safety inspections were undertaken at the OGTR premises in Barton during 2016–17. No major health or safety issues were identified.

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). This requirement is in Part II of the FOI Act and has replaced the former requirement to publish a section 8 statement in an annual report. Each agency must display on its website a plan showing what information it publishes in accordance with the IPS requirements.[11]

11 The OGTR's Information Publication Scheme Agency Plan is on our website - http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ips-plan

Freedom of information procedures

From 1 November 2010, a number of changes arising from the *Australian Information Commissioner Act 2010* and the *Freedom of Information Amendment (Reform) Act 2010* were implemented, including removal of an application fee, and no cost for the first hour of decision-making.

To enable a prompt response and to help the OGTR meet its obligations under the FOI Act, applicants should provide as much information as possible about the documents they are seeking. A telephone number or an email address should also be included, in case OGTR officers need clarification.

Freedom of information contact details

Inquiries about submitting a formal request under the FOI Act should initially be directed to the Freedom of Information Coordinator on (freecall) 1800 181 030.

Formal requests should be sent to:

Freedom of Information Coordinator
Office of the Gene Technology Regulator
MDP 54
GPO Box 9848
Canberra ACT 2601

For the purposes of section 15(2A)(c) of the *Freedom of Information Act 1982*, freedom of information requests by electronic communication must be emailed to ogtr@health.gov.au.

The OGTR received six requests for access under freedom of information legislation during the reporting period. Five of the six requests were finalised within the statutory timeframes in 2016–17 and the sixth is still pending.

The Regulator is required by the FOI Act (section 11C) to publish on the OGTR website a disclosure log listing information that has been released in response to a freedom of information request.[12]

12 The OGTR's Freedom of Information Disclosure Log is on our website - http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/foi-disclosure2-htm

FEEDBACK RECEIVED

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

During 2016–17, the regulated entities and non-government organisations provided positive feedback about engagement with OGTR. Specifically appreciated was our professionalism, responsiveness to queries and cordial approach in meetings. For example:

> *"Many thanks for your cordial and very productive meeting … It was good to have more clarity about how we can contribute constructively to your project."*
>
> *"Thanks a lot for welcoming us to your meeting … The presentations were very informative and helpful … Thanks to you and your team for also engaging with our comments …"*
>
> *"Thanks too for the opportunity to brief you …"*
>
> *"The discussions throughout the day were robust, professional and productive …"*

OGTR also received the following feedback from overseas regulatory agencies:

> *"Many thanks for sharing the info and links below. Your visit was of great value to us as we move forward in our deliberations …"*
>
> *"… we would like to express our sincere appreciation for your time to share your experience and knowledge in crop protection regulations and in the area of plant breeding innovation."*
>
> *"My thanks and appreciation to everyone who assisted with this visit at all … levels."*

PRESENTATIONS AND MEETINGS ON GENE TECHNOLOGY IN AUSTRALIA

The Regulator and staff from the Office of the Gene Technology Regulator regularly attend and present papers to meetings, forums and conferences in Australia (Table 17).

Table 17: Presentations and representations in Australia by the Regulator and OGTR staff, 2016–17

Date	Event	Location
August 2016	Regulation of GMO therapeutics by the Gene Technology Regulator, ARCS Scientific Congress	Canberra
August 2016	Regulation of gene technology and GMOs: Australian framework and operation, West Australian Department of Parks and Wildlife, Gene Drive Workshop	Perth
August 2016	Gene technology, ethics and the Office of the Gene Technology Regulator, Biology, Society and Ethics undergraduate course (BIOL3191)	Canberra
August 2016	Ag and Foodtech Conference	Brisbane
November 2016	Regulatory science vs research science: decision-making for environmental release of GM plants, Society for Risk Analysis Australia–New Zealand Conference	Adelaide
November 2016	Development of a genetic risk assessment framework for organisms, Society for Risk Analysis Australia–New Zealand Conference	Adelaide
November 2016	NGO meeting presentations	Canberra

STAKEHOLDER AND PUBLIC ACCESS TO THE OGTR

The Office of the Gene Technology Regulator (OGTR) facilitates access by accredited agencies, stakeholders and the public to its services through a website, an email address and a freecall 1800 number.

Website usage

Table 18 tracks usage numbers for the OGTR website month by month. The most requested online information sheets and website pages are listed below.

Table 18: Website activity, 2016–17

Month	Sessions[a]	Users[b]
July	4249	2831
August	5775	3865
September	5293	3558
October	5266	3600
November	5822	3968
December	5598	4252
January	4806	3629
February	6129	4214
March	6676	4592
April	4967	3630
May	6515	4501
June	5450	3813

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 2016–17 were, in descending order:

1. Table of applications and authorisations for dealings involving intentional release (DIR) into the environment
2. Record of GMO dealings
3. *Guidelines For Certification Of Physical Containment Level 2 Facilities*
4. Application to certify facilities
5. Legislation
6. Genetically modified product approvals
7. About the Regulator
8. Previous reviews of gene technology legislation
9. Application forms to work with GMOs
10. *Guidelines For Certification Of Physical Containment Level 2 Laboratory.*

The most popular downloaded documents in 2016–17 were:

1. *Guidelines For Certification Of A Physical Containment Level 2 Laboratory.*
2. *Guidelines for the transport, storage and disposal of GMOs*
3. 2016–17 Technical Review of the *Gene Technology Regulations 2001* —discussion paper
4. Types of dealings with GMOs classified as notifiable low risk dealings (NLRDs)
5. What dealings with GMOs are classified as exempt dealings?
6. *Guidelines For Certification Of A Physical Containment Level 2 Animal Facility*
7. *Guidelines For Certification Of A Physical Containment Level 1 Facility*
8. Risk Analysis Framework 2013
9. *Guidelines For Certification Of A Physical Containment Level 3 Laboratory*
10. Annual inspection checklist for PC2 laboratories

EMAIL ADDRESS AND FREECALL NUMBER

The 1800 number and the OGTR email address (ogtr@health.gov.au) are points of contact for members of the public and other interested parties. Assistance with specific questions and advice on additional mechanisms for public feedback are among the services that the 1800 line and email facilities provide (Table 19).

Table 19: Email and freecall 1800 number activity, 2016–17 and 2015–16

Month	Emails		1800 number	
	2016–17	2015–16	2016–17	2015–16
July	39	42	63	43
August	30	52	65	53
September	35	66	75	63
October	240	31	60	35
November	98	41	67	38
December	590	48	59	43
January	68	40	63	35
February	110	42	35	40
March	120	52	81	46
April	140	56	75	50
May	125	58	64	55
June	81	50	63	45
Total	**1676**	**578**	**770**	**546**

The Monitoring and Compliance Section maintains an email inbox to facilitate efficient communication with accredited organisations. The inbox provides a central point through which accredited organisations can contact the section 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 1203 emails during 2016–17 (1115 in 2015–16).

The Regulatory Practice Section maintains an email inbox to facilitate efficient communication between advisory committee members and secretariat staff. The inbox ensures that secretariat staff answer all communications in a timely manner. The inbox received 1653 emails during 2016–17 (790 in 2015–16).

The Contained Dealings Evaluation Section maintains an email inbox to provide efficient coordination of responses to queries relating to classification of GMO dealings, certification requirements and GMO licences. The inbox received 471 emails during 2016–17 (444 in 2015–16).

The Application Entry Point maintains an email inbox to provide a central, shared communication point, allowing efficient coordination of responses to correspondence and queries about applications the section has received. The inbox received 1658 emails during 2016–17 (1427 in 2015–16).

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

APPENDIX 1

Membership of statutory committees

Table 25: GTTAC members 2017–20

Member	Position
Professor John Rasko AO (Chair)	Director, Cell and Molecular Therapies, Royal Prince Alfred Hospital; Program Head, Centenary Institute (New South Wales)
Dr Graham Bonnett	Research Director, CSIRO Agriculture and Food (Queensland)
Dr Orin Chisholm	Program Director, Pharmaceutical Medicine, and Senior Lecturer, UNSW (New South Wales)
Ms Laura Fell	Egg Farmer, McLaren Vale (South Australia)
Dr Tessa Gargett	Research Scientist, Royal Adelaide Hospital (South Australia)
Dr Richard Gordon	Senior Research Fellow, School of Biomedical Sciences, University of Queensland (Queensland)
Professor John Hayball	School of Pharmacy and Medical Sciences, University of South Australia (South Australia)
Professor Robert Henry	Professor of Innovation in Agriculture, and Director, Queensland Alliance for Agriculture and Food Innovation (Queensland)
Dr TJ Higgins, AO	Honorary Fellow, CSIRO Agriculture and Food (Australian Capital Territory)
Dr Danny Llewellyn	Chief Research Scientist, CSIRO Agriculture and Food (Australian Capital Territory)
Dr Rebecca McCrackan	Senior Intellectual Property Advisor; Patent and Trade Marks Attorney (Western Australia)
Dr Michael Michael	Laboratory Head, Flinders Centre for Innovation in Cancer, Flinders Medical Centre (South Australia)
Dr Gabrielle O'Sullivan (GTECCC cross-member)	Executive Officer and Member, Institutional Biosafety Committee, Royal Prince Alfred Hospital (New South Wales)
Associate Professor Jason Smythe	Senior Business Development Manager, Faculty of Medicine, Monash University; Adjunct Associate Professor, Faculty of Science and Engineering, La Trobe University (Victoria)
Dr Robert Sward (GTECCC cross-member)	Director, BioBotanicals Consulting (Victoria)
Professor Paul Young	Professor of Virology and Head of School, School of Chemistry and Molecular Biosciences, University of Queensland (Queensland)

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 26: GTECCC members 2015–18

Member	Position
Ms Judith Jones (Chair)	Senior Lecturer, Australian National University College of Law (Australian Capital Territory)
Ms Paula Fitzgerald	Agricultural advocate and consultant (Victoria)
Dr Vaughan Monamy	Associate Professor of Environmental Science and Environmental Ethics, Australian Catholic University (New South Wales)
Professor Dianne Nicol (AHEC cross-member)	Director, Centre for Law and Genetics; Professor of Law, University of Tasmania
Dr Rachel Nowak	Principal, Rachel Nowak and Associates (Victoria)
Dr Gabrielle O'Sullivan (GTTAC cross-member)	Executive Officer, Institutional Biosafety Committee, Royal Prince Alfred Hospital (New South Wales)
Ms Meg Parkinson	Free range Egg Farmer (Victoria)
Dr Gregory Pike	Founding Director of the Adelaide Centre for Bioethics and Culture (South Australia)
Mr Hugh Roberts	Farmer and a Director of the Australian Seed Authority and the Australian Crop Accreditation System (New South Wales)
Dr Frances Shapter	Project Officer, School of Veterinary Science, University of Queensland (Queensland)
Dr Robert Sward (GTTAC cross-member)	Director, BioBotanicals Consulting (Victoria)
Mrs Emma Thomas	Farmer and agricultural consultant (New South Wales)

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.

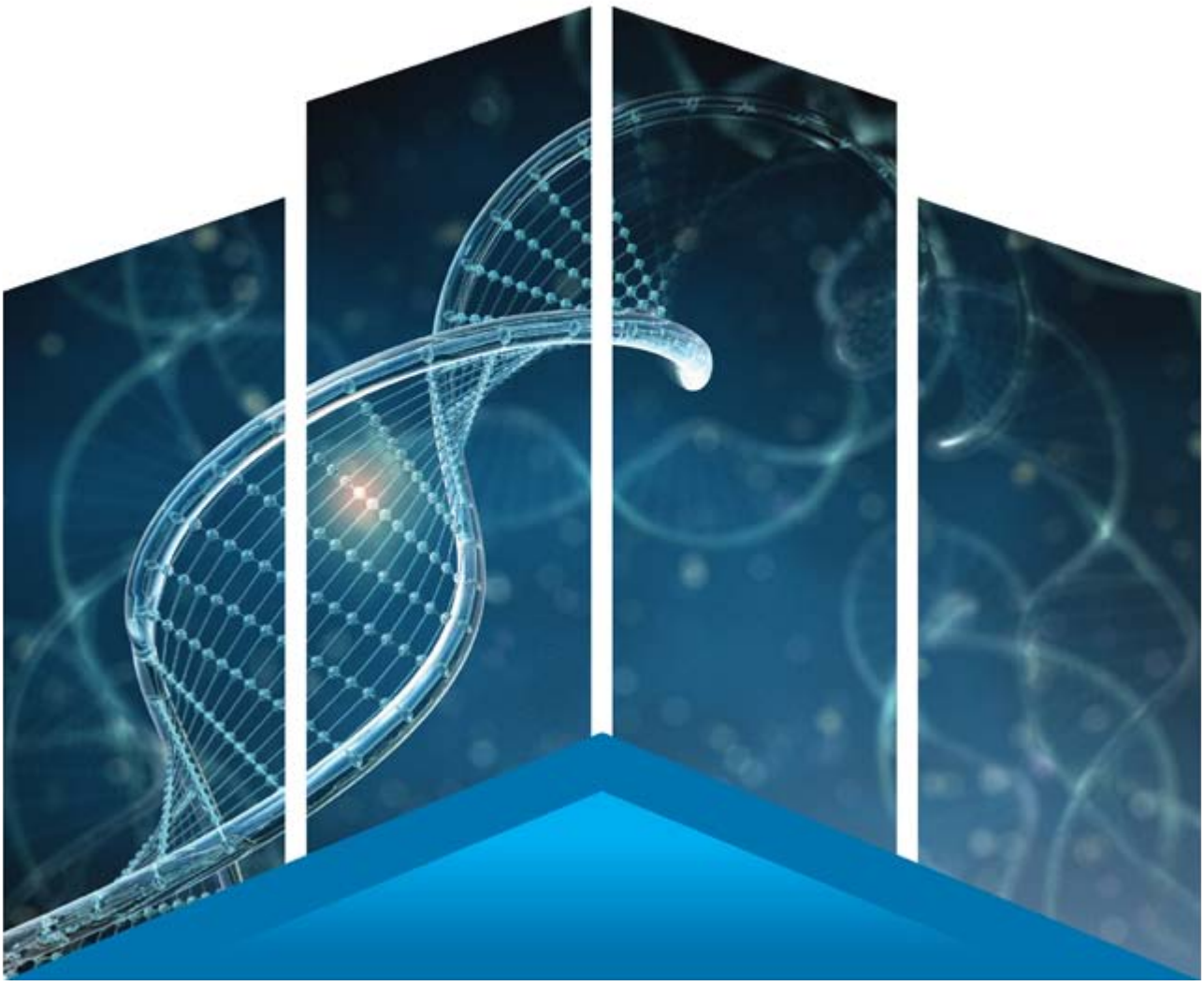
GLOSSARY AND SHORTENED FORMS

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.

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.
DAWR	Department of Agriculture and Water Resources
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)
DNIR	A contained dealing with a GMO not involving intentional release of the GMO into the environment (e.g. experiments in a certified facility such as a laboratory)
EDD	Emergency dealing determination
FSANZ	Food Standards Australia New Zealand
Gene Technology Agreement	An intergovernmental agreement that all Australian jurisdictions signed in 2001, which underpins the nationally consistent regulatory framework for gene technology
GM	Genetically modified
GM product	A thing (other than a GMO) derived or produced from a GMO
GMO	Genetically modified organism
GMO Record	Record of GMO dealings
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTTAC	Gene Technology Technical Advisory Committee

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
LGFGT	Legislative and Governance Forum on Gene Technology
MOU	Memorandum of understanding
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
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
SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice (United Nations Convention on Biological Diversity)
TGA	Therapeutic Goods Administration
UN	United Nations

LIST OF REQUIREMENTS



Gene Technology Act 2000 reference	Part of report	Description
136(1A)(a)	27–31	GMO licences issued during the financial year
136(1A)(b)	47	Any breaches of conditions of a GMO licence that have come to the Regulator's attention during the financial year
136(1A)(c)		Emergency dealing determinations made by the Minister during the financial year
136(1A)(d)		Any breaches of conditions of an emergency dealing determination that have come to the Regulator's attention during the financial year
136(1A)(e)	20, 15, 54–55, 103	Auditing and monitoring of dealings with GMOs under this Act by the Regulator or an inspector during the financial year

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