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

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 OCTOBER–31 DECEMBER 2007

The object of the *Gene Technology Act 2000* is:

'to protect the health and safety of people, and 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'

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Senator the Hon Jan McLucas
Parliamentary Secretary to the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

Dear Parliamentary Secretary

In accordance with section 136A of the *Gene Technology Act 2000* (the Act), I am pleased to present to you the Quarterly Report of the Operations of the Gene Technology Regulator, covering the period 1 October to 31 December 2007.

During this period I continued to discharge my statutory functions, including the issuing of one licence for a dealing involving the intentional release of genetically modified organisms (GMOs), six licences for dealings not involving intentional release of GMOs, and the certification of 69 physical containment facilities.

Routine monitoring activities for this quarter have exceeded the target rate and no significant risks to either human health or the environment were identified.

In addition, the *Risk Analysis Framework*, which provides guidance on the assessment to both applicants and evaluators, was updated to incorporate recent legislative changes arising from the *Gene Technology Amendment Act 2007*.

Yours sincerely

SD Meek

(Dr) Sue D Meek

Gene Technology Regulator

3 March 2008

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ABOUT THIS REPORT

Section 136 A (1) of the *Gene Technology Act 2000* (the Act) requires the Gene Technology Regulator (the Regulator) to prepare and give to the Minister after each quarter a report on the operations of the Regulator during that quarter. Section 136A(2) of the Act requires that the report include information on:

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

Its purpose is to inform the community of our roles and responsibilities and to provide a summary of our achievements over the past quarter.

This report has four key sections and appendices.

Gene Technology Regulatory System

Provides advice on the activities and outcomes achieved in relation to the implementation and management of the national regulatory system during the 1 October to 31 December 2007 quarter.

Regulation of genetically modified organisms

Provides details on the regulatory activity undertaken, including information about applications for, and action taken with respect to, GMO licences and other instruments under the Act. It also includes details of monitoring, auditing and compliance activities by the Regulator during this quarter.

Statutory Committee Operations

Reports on the activities of the three advisory committees established under the Act to assist the Regulator and the Gene Technology Ministerial Council.

Other activities of the Gene Technology Regulator

Describes other activities relating to the statutory functions of the Regulator that support the operations of the gene technology regulatory system.

Appendices

The appendices contain information on the number of Dealings Not involving Intentional Release (DNIR) licences issued and Communiqués for the statutory advisory committees.

SECTION 1

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 October to 31 December 2007 quarter were:

Licences and other instruments

- one licence issued for a dealing involving the intentional release (DIR) of GMOs into the environment
- six licences issued for DNIRs of GMOs into the environment
- 69 physical containment facilities certified
- surrenders of 11 certifications and 21 DNIRs processed
- 265 variations processed.

Further information on licences and other instruments is contained in Section 2 of this report.

Monitoring and Compliance

Approximately 26 percent of current field trial sites and 12 percent of post harvest field trial sites were subjected to routine monitoring during the quarter. This exceeds the target minimum rate of 5 percent per quarter.

Further information on monitoring and compliance is contained in Section 2 of this report.

Implementation of changes to the Gene Technology Legislation

An updated *Risk Analysis Framework* for genetically modified organisms was published during the quarter to incorporate changes resulting from amendments to the Act which commenced in July 2007.

The framework explains how the OGTR applies internationally recognised risk analysis practice to the evaluation of licence applications.

Further information is contained in Section 4 of this report.

Working collaboratively with States and Territories

Gene Technology Ministerial Council

The Gene Technology Ministerial Council (GTMC) oversees the implementation of the regulatory system and comprises one Minister from the Commonwealth and one Minister from each of the States and Territories. Currently, the GTMC includes Ministers from a range of portfolios including health, agriculture and environment.

State and Territory consultation

The Regulator must consult with State and Territory Governments and relevant local councils twice during the evaluation of applications for all DIR licences, except limited and controlled releases.

For each application for a DIR licence other than a limited and controlled release, the Regulator seeks advice on matters relevant to the preparation of the Risk Assessment and Risk Management Plan (RARMP) and comment on the RARMP itself once it is prepared. For each application for a limited and controlled release, the Regulator is only required to seek comment on the RARMP.

Further information is contained in Section 2 of this report.

Australian Government Agency liaison

The close relationship between the OGTR and other Australian Government authorities and agencies continued during this quarter.

Under the Act, the Regulator must seek advice from prescribed Australian Government authorities and agencies and the Australian Government Environment Minister on matters relevant to preparing the RARMP for each application for a DIR licence, except those that meet the criteria to be considered as a limited and controlled release.

The prescribed Australian Government authorities and agencies comprise:

- Australian Pesticides and Veterinary Medicines Authority
- Australian Quarantine and Inspection Service (AQIS)
- Food Standards Australia New Zealand
- National Industrial Chemicals Notification and Assessment Scheme
- Therapeutic Goods Administration.

Once a RARMP is prepared for any DIR licence application the Regulator is required to seek comment on the RARMP from the same prescribed Australian Government authorities and agencies.

In addition, comment is sought on each DIR RARMP from a range of other Australian Government agencies which, while not prescribed in the legislation, have maintained a strong interest in its implementation including the:

- Department of Agriculture, Fisheries and Forestry
- Department of Environment Water, Heritage and the Arts
- Department of Foreign Affairs and Trade
- Department of Innovation, Industry, Science and Research.

During the quarter, the Regulator did not seek advice and comment in respect of any RARMPs.

Further information on the processing of DIR applications is contained in Section 2 of this report.

Public participation

The Act requires the Regulator to consult the public on the RARMPs for all DIR licence applications. No invitations to the public to comment on RARMPs were issued during the quarter.

Further information on the processing of DIR applications is contained in Section 2 of this report.

SECTION 2

REGULATION OF GENETICALLY MODIFIED ORGANISMS

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of the report outlines the regulatory activity undertaken during the 1 October to 31 December 2007 quarter. This includes information about applications for GMO licences and other instruments under the Act. This section also details any EDDs made pursuant to the Act. It also includes details of monitoring activities and of alleged, admitted or self-reported non-compliances with the Act, or with the conditions imposed by the Regulator on GMO licences or other instruments issued pursuant to the Act. Summary reports on investigations completed during the quarter are supplied. Information on Confidential Commercial Information (CCI) applications has also been provided.

Types of Applications

Under the Act the Regulator is required to make decisions in relation to applications for the following instruments:

- **Dealings involving Intentional Release licences**

DIR licences authorise dealings ranging from limited and controlled releases (i.e. field trials) through to more extensive general or commercial releases of GMOs. DIR licence applications received after 1 July 2007 have a statutory timeframe of 255 working days for processing unless the Regulator determines the application is a limited and controlled release. Then the timeframe for making a decision is 150 working days, or 170 working days if the Regulator determines that the proposed dealings represent a significant risk to human health and the environment.

- **Dealings Not involving Intentional Release licences**

DNIR licences authorise contained dealings with GMOs carried out in laboratories and other containment facilities that are designed to prevent release of the GMO(s) into the environment. These licence applications have a statutory timeframe of 90 working days for processing.

- **Accreditations of organisations**

DIR and DNIR licences require organisations which conduct work with GMOs to be accredited. To achieve accreditation, the Regulator must usually be satisfied that the organisation has, or has access to, a properly constituted and resourced Institutional Biosafety Committee (IBC) and complies with the requirements of the Regulator's guidelines for accreditation. These applications have a statutory timeframe of 90 working days for processing.

- **Certifications of containment facilities**

Certification is required to satisfy the Regulator that a facility which is proposed to be used to conduct dealings with a GMO meets the guideline requirements for the particular level of physical containment specified. These applications have a statutory timeframe of 90 working days for processing.

GMO Register

The GMO Register is a list of dealings with GMOs that the Regulator is satisfied pose minimal risks to human health and safety and the environment and can therefore be undertaken by anyone, subject to any specified conditions, without the oversight of a licence holder. Under section 78 of the Act the Regulator may determine that dealings with a GMO previously authorised by a licence are to be included on the GMO Register. Such determinations are disallowable instruments.

New licences and other instruments

The following table describes the number and type of applications received for new licences and other instruments, as well as the approvals made by the Regulator in the quarter.

Application type	Number received	Number approved*
DIR licence	8	1
DNIR licence	8	6
Accreditations	2	0
Certifications	51	69

* *Approvals reported in the current quarter often relate to applications received in previous quarters.*

Processing of applications for Dealings involving Intentional Release licences

The key steps the Regulator takes when considering an application for a DIR licence are:

- initial screening of the application for completeness
- determining whether the application is a limited and controlled release
- consideration of the applicant's suitability against disclosure of relevant convictions and/or revocations and suspensions of related licences and permits
- seeking comments from prescribed experts, agencies and authorities on issues to consider in the RARMP for all DIR applications except limited and controlled releases
- preparing a consultation RARMP, including determining whether the proposed dealings may pose a significant risk and proposed licence conditions to manage risks to human health and safety and the environment
- seeking comments on the RARMP from prescribed experts, agencies and authorities and the public

- considering all comments relating to the protection of human health and safety and the environment in finalising the RARMP
- confirmation of the applicant's suitability, including capacity to meet licence conditions, and consideration of policy principles and any relevant policy guidelines.

Once these actions are completed, the Regulator can make a decision on whether or not to grant a licence and the conditions which are to be included in licence if issued.

The statutory timeframes for making a decision on DIR licences effectively extend over approximately twelve months, and eight or nine months for limited and controlled releases, as they exclude weekends and public holidays in the Australian Capital Territory.

This time limit may be extended, that is, the clock is stopped, if the decision-making process is unable to continue, for example, because of an unresolved application for declaration of CCI or because additional information is sought from the applicant.

The Act and the Gene Technology Regulations 2001 (the Regulations) mandate minimum 30 days timeframes for the one or two rounds of consultation that the Regulator must undertake with during the processing of each DIR application. However consultation periods longer than minimum timeframes are usually allowed to facilitate the provision of information and promote involvement in the decision-making process particularly by the community. An application for a DIR licence cannot normally be received and decided upon within the same three month reporting period.

The following table shows the progress of applications for DIR licences undergoing evaluation during the quarter.

Applications received	Notification of applications*	Withdrawn/ surrendered applications	Licence issued
DIR 076/2007	DIR 076/2007	DIR 012/2002	DIR 074/2007
DIR 077/2007	DIR 077/2007	DIR 022/2002	
DIR 078/2007		DIR 023/2002	
DIR 079/2007		DIR 056/2004	
DIR 080/2007		DIR 059/2005	
DIR 081/2007			
DIR 082/2007			
DIR 083/2007			

* *Although not required under the Act, all new DIR applications are notified on the OGTR website under 'What's New' and notified to all individuals and organistations on the OGTR mailing list.*

Applications received for Dealings involving Intentional Release licences

The Regulator received eight applications for a DIR licence in the quarter:

- DIR 076/2007 — Limited and controlled release of banana genetically modified for enhanced nutrition – Queensland University of Technology
- DIR 077/2007 — Limited and controlled release of wheat and barley genetically modified for enhanced tolerance to abiotic stresses or increased beta glucan — The University of Adelaide
- DIR 078/2007 — Limited and controlled release of sugarcane genetically modified for altered sugar production — The University of Queensland
- DIR 079/2007 — Limited and controlled release of banana genetically modified for disease resistance — Queensland University of Technology
- DIR 080/2007 — Limited and controlled release of wheat genetically modified for drought tolerance — Department of Primary Industries, Victoria
- DIR 081/2007 — Limited and controlled release of cotton genetically modified for enhanced water use efficiency — Monsanto Australia Limited
- DIR 082/2007 — Limited and controlled release of perennial ryegrass and tall fescue genetically modified for improved forage qualities — Department of Primary Industries, Victoria
- DIR 083/2007 — Limited and controlled release of waterlogging tolerant cotton — CSIRO.

Consultation on applications for Dealings involving Intentional Release licences

No consultations commenced on any DIR licence applications during this quarter as all under consideration were deemed by the Regulator to qualify as limited and controlled releases.

Although not required by the Act, the Regulator issued a 'Notification of Licence Application' for two DIR licence applications. These notifications were posted on the OGTR's website and sent to people and organisations on the OGTR mailing list to advise receipt of these applications and when the RARMPs are expected to be released for public comment.

Full copies of DIR applications can be obtained by contacting the OGTR. Summary information on DIR applications and consultation RARMPs, including proposed licence conditions, are available via the OGTR website or directly from the OGTR.

Withdrawn/surrendered applications for Dealings involving Intentional Release licences

No DIR licence applications were withdrawn during the quarter, but five were surrendered, following confirmation by the Monitoring Section that all licence conditions had been met:

- DIR 012/2002 — Commercial release of BollgardII and BollgardII/Roundup Ready® cotton — Monsanto Australia Limited

- DIR 022/2002 — Commercial release of insecticidal (INGARD®) cotton — Monsanto Australia Limited
- DIR 023/2002 — Commercial release of herbicide tolerant (Roundup Ready®) and herbicide tolerant/insect resistant (Roundup Ready®/INGARD®) cotton — Monsanto Australia Limited
- DIR 056/2004 — Field trial of herbicide tolerant (LLCotton25) and herbicide tolerant/insect resistant (LLCotton25/Bollgard II®) cottons — Bayer CropScience Pty Ltd
- DIR 059/2005 — Commercial release of herbicide tolerant (Roundup Ready Flex® MON 88913) and herbicide tolerant/insect resistant (Roundup Ready Flex® MON 88913/Bollgard II®) cotton south of latitude 22° South in Australia — Monsanto Australia Limited

Clock stopped on Dealings involving Intentional Release licence applications

The Regulations determine that a day on which the Regulator is unable to proceed with the decision-making process, or a related function, because information requested from the applicant has not been received, is not counted as part of the prescribed 170 day time-limit for a decision to be made on an application.

A request for further information was initiated in this quarter:

- DIR 078/2007 — Limited and controlled release of sugarcane genetically modified for altered sugar production — The University of Queensland

Decisions on applications for Dealings involving Intentional Release licences

During the quarter, the Regulator issued one DIR licence:

- DIR 074/2007 — Limited and controlled release of GM insect resistant and/or herbicide tolerant *Gossypium barbadense* cotton — Monsanto Australia Limited.

Summary information on DIR applications, finalised RARMPs and copies of licences are available from the OGTR website or can be obtained by contacting the OGTR directly.

Decisions on applications for Dealings Not involving Intentional Release licences

These dealings must be conducted in appropriate containment facilities and the dealings must not involve intentional release of a GMO into the environment.

During the quarter the Regulator issued two DNIR licences. More information about these licences is contained in Appendix 1 of this report.

A full listing of DNIR licence applications and their current status is available from the OGTR website.

Changes to existing licences and other instruments

The Regulator can, directly or upon application, vary an issued licence or other instrument. Variations involve changes to conditions applied to an instrument or a licence. For example, the Regulator can vary a licence to better manage risks if new information or data comes to light. The Regulator must not vary the licence unless she is satisfied that any risks posed by the dealings proposed to be authorised by the licence as varied are able to be managed in such a way as to protect the health and safety of people and the environment.

Most variations are made at the request of the instrument/licence holder and those applications have a statutory timeframe of 90 days for processing. Additionally, the Regulator can make a decision in relation to an application to transfer a licence to another person or consent to the surrender of a licence by a licence holder.

The following table describes the number and type of the applications received to change existing licences and other instruments, as well as the number of applications processed during the quarter.

Type	Number received	Number processed[1]
Surrender of certification	14	11
Surrender of DIR licence	1	5
Surrender of DNIR licence	6	21
Variation of certification[2]	326	225
Variation of DIR licence	3	9
Variation of DNIR licence[3]	21	31
Applications for CCI	4	1

1 *Numbers reported in this quarter often relate to applications received in previous quarters. For the purposes of this table, 'processed' means that action on the authorisation was completed.*

2 *Large number of applications to vary certifications of contained facilities in response to recent revisions to guidelines and often coincides with pending expiry of existing instruments.*

3 *Higher than average number of DNIR variations attributable to a number of factors including review of licences following legislative amendments to classification of dealings, changes to certified facilities following introduction of new guidelines, and some extensions*

Confidential Commercial Information

Under section 184 of the Act a person may apply to the Regulator in accordance with section 185 for specified information to be declared commercial confidential information (CCI). Specified information awaiting a decision on an application for CCI is treated as if it were CCI until a decision is made. If the Regulator declares information to be CCI the information is protected from disclosure. More information on the protection of CCI can be found in

Chapter 15 of the *Handbook on the Regulation of Gene Technology* which is available on the OGTR website.

During the quarter, the Regulator received four CCI applications in relation to four DIR licence applications. The Regulator also made one CCI declaration in relation to one DIR application.

Monitoring and Compliance

The aim of OGTR monitoring and compliance activities is to ensure dealings with GMOs comply with legislative obligations and are consistent with the object of the Act:

> *'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'.*

In particular, the Monitoring and Compliance Sections focus on management of dealings at field trial sites and within contained facilities certified by the Regulator to ensure:

- the dissemination of a GMO and its genetic material is minimised
- the persistence of a GMO in the environment is managed
- effective management of the GMO is maintained.

OGTR monitoring activities comprise the functions of routine monitoring including spot checks, assessment of monitoring findings and, where necessary, recommending corrective action and follow-up activities.

OGTR compliance activities comprise reviews of potential compliance risks, investigations, audits and related enforcement activities.

The Monitoring Section conducts routine monitoring visits of a minimum of 20 percent of field trial sites each year. To achieve this goal a minimum of five percent of current trial sites and five percent of trial sites subject to post-harvest monitoring are monitored each quarter.

Monitoring and Compliance Strategy

The purpose of routine monitoring of field trials is to ensure compliance with licence conditions and includes spot checks.

The OGTR strategy for conducting field trial monitoring draws on accumulated operational experience of risk profiling in relation to compliance.

For example, OGTR field trial monitoring coincides, where possible, with periods or circumstances when non-compliance with licence conditions designed to limit the spread and persistence of the GMOs is more likely to occur (for example, flowering and harvest of GM crops).

The monitoring program for contained dealings involves inspecting DNIRs and the facilities that those dealings are conducted in, as well as monitoring a minimum of 20 percent of PC4, PC3 and PC2 large-scale facilities per year.

These inspections focus on the integrity of the physical structure of the facility and on the general laboratory practices followed in that facility, including those practices followed for DNIRs and NLRDs.

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored: During the 1 October to 31 December 2007 quarter, nine field trial sites with GM plants were subjected to monitoring visits.

- **Current field trial sites:** Of the 19 sites current in the quarter, five were monitored. This represents a monitoring rate of 26 percent of all current sites for the quarter
- **Post-harvest field trial sites:** Of the 34 sites subject to post-harvest monitoring in the quarter, four were monitored. This represents a monitoring rate of 12 percent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection to contained dealings covered seven organisations and ten PC facilities. Monitoring of PC facilities encompassed PC2 laboratories (seven visited), PC3 laboratory (one visited) and PC2 animal containment facilities (two visited).

Monitoring of contained dealings: During the quarter, the monitoring of the ten PC facilities mentioned above included monitoring for compliance with the general practices that must be followed when undertaking dealings (e.g. DNIRs) that are required to be conducted within contained facilities.

Seven DNIRs were monitored during the quarter.

Monitoring of Dealings involving Intentional Releases

The following table summarises monitoring activities for field trials with GM crop plants for the period between 1 October to 31 December 2007.

Licensed Organisation Name	Licence Number	No. sites visited	Site status *	Crop type
Bayer CropScience Pty Ltd, Victoria	DIR 032/2003	1	PHM	Canola
Bayer CropScience Pty Ltd, Victoria	DIR 069/2006	2	C	Canola
Deltapine Australia Pty Ltd, Queensland	DIR 065/2006	1	PHM	Cotton
Department of Primary Industries, Victoria	DIR 071/2007	2	C	Wheat
Dow AgroSciences Australia Pty Ltd, New South Wales	DIR 044/2003	2	PHM	Cotton
Florigene Pty Ltd, Victoria	DIR 068/2006	1	C	Torenia
Totals	6 licences	9 sites	C = 5 PHM = 4	4 crop types

** C = current PHM = post-harvest monitoring.*

Monitoring of Dealings Not involving Intentional Release

The following table summarises monitoring activities for DNIRs for the period between 1 October to 31 December 2007.

Licensed Organisation Name	Licence Number
The Walter and Eliza Hall Institute of Medical Research, Victoria	DNIR 057/2002 DNIR 058/2002
Deakin University, Victoria	DNIR 112/2002
Ludwig Institute for Cancer Research, Victoria	DNIR 225/2003
Children, Youth and Women's Health Service, South Australia	DNIR 341/2004
Institute of Medical and Veterinary Science, South Australia	DNIR 135/2002 DNIR 151/2002
Total	7 DNIR licences

Monitoring of Physical Containment Facilities

The organisations and the facility types the OGTR visited during the 1 October to 31 December 2007 quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
Deakin University, Victoria	PC2 laboratory	1
	PC2 animal containment	1
The Walter and Eliza Hall Institute of Medical Research, Victoria	PC2 laboratory	2
Ludwig Institute for Cancer Research, Victoria	PC2 laboratory	1
Children, Youth and Women's Health Service, South Australia	PC2 laboratory	1
Institute of Medical and Veterinary Science, South Australia	PC2 laboratory	1
	PC2 animal containment	1
Melbourne Health, Victoria	PC2 laboratory	1
St Vincent's Hospital Sydney Ltd, New South Wales	PC3 laboratory *	1
Totals	3 facility types	10

** Joint inspection with Evaluation staff.*

Monitoring Findings

Findings for Dealings involving Intentional Release

The monitoring findings listed below indicate both the monitoring activities of the OGTR with respect to dealings with GMOs under this Act, in accordance with paragraph 136A(2)(c) of the Act, and the Regulator's response to those findings.

Findings by inspectors of inconsistencies between an event or state of affairs and the requirements imposed by licence or certification conditions are called non-compliances in this report. However, 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. The following aspects of the findings are taken into account as relevant:

- the extent of risk to the health and safety of people and the environment
- the severity of the issue or event involved in the finding
- the culpability of the licence holder or other relevant persons in bringing about the issue or event e.g. whether there was a bona fide mistake involved
- the types of mechanisms available to address the issue or event
- the compliance history of the licence holder or other relevant persons
- mitigating factors such as self-reporting or steps taken voluntarily by the licence holder to address the issue or event
- the need for deterrence.

After having regard to those matters, the OGTR has a range of options including additional investigation to determine if further action is warranted e.g. a recommendation of prosecution for an alleged breach of a licence condition or that a licence be suspended or cancelled. A proven breach of a licence condition will be reported in accordance with paragraph 136A(2)(b) of the Act.

In the case of all matters reported below it was decided that the findings of non-compliances with licence conditions were minor in nature, involved negligible or nil culpability, and could be resolved by reminders, education and/or cooperative compliance.

Findings for Dealings involving Intentional Release

There were no findings for DIRs for the 1 October to 31 December 2007 quarter.

Findings for Dealings Not involving Intentional Release

There was one finding for a DNIR for the 1 October to 31 December 2007 quarter.

Organisation	Ludwig Institute for Cancer Research
Licence number and site	DNIR225/2003
Summary of dealing	The permitted experiments include mouse models of colorectal cancer using a retroviral gene transfer system.
Findings	At the time of the inspection OGTR staff noted that some staff carrying out work under Licence DNIR 225/2003 had not signed a statement indicating that the licence holder had informed them of the conditions of the licence that apply to that person.
Assessment	While staff had been informed of the obligations imposed on them by the conditions of the licence, some had not signed appropriate acknowledgement statements. The compliance history of Ludwig Institute for Cancer Research is good and as a result of this finding systems were improved to ensure that acknowledgement forms were promptly signed as appropriate. No risks to human health and safety and the environment were identified.
Compliance management	Ludwig Institute for Cancer Research was reminded of the requirement to have signed statements from each person covered by this licence acknowledging that the licence holder has informed the person of the conditions of this licence that apply to that person.

Findings for Physical Containment Facilities

The OGTR's monitoring of certified PC facilities in the quarter found a small number of minor structural non-compliances with certification conditions. All were found to pose negligible risks to human health and safety and the environment.

	Non-Compliance Issue					
Number of PC Facilities inspected	Structure	PPE[1]	Equipment	Waste disposal	Work practices[2]	Transport
10	4	0	0	0	2	0

1 PPE = Personal Protective Equipment.

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

Monitoring of (Equine Influenza Vaccine) Emergency Dealing Determination

An Emergency Dealing Determination (EDD) is a legislative instrument made under the Act. EDDs are not made by the Regulator. Sections 72A–72E of the Act, which commenced on 1 July 2007, give the responsible Minister the power to expedite an approval of dealings with a GMO in an emergency. This recognises that situations may arise in which a rapid approval of a dealing with a GMO may be required. An EDD can only be made to have effect for up to six months but may be extended by the Minister. The emergency provisions further the object of the Act: to protect the health and safety of people and to protect the environment.

Dealings with a GM vaccine against Equine Influenza (EI) were authorised under *The Gene Technology (Equine Influenza Vaccine) Emergency Dealing Determination 2007* that was made by the responsible Minister in September 2007.

Dealings, including importation, transport and disposal of the GM vaccines, and their possession and supply in the course of these dealings, have been temporarily authorised under the EDD and are subject to the conditions of the EDD. The GM vaccines have been used in the containment and eradication of the outbreak of EI in Australia.

Import, supply and use of the GM vaccines have also been authorised by an Australian Quarantine and Inspection Service (AQIS) import permit and Australian Pesticides and Veterinary Medicines Authority (APVMA) emergency use permits. Administration of the vaccines to horses is authorised by the Australian Chief Veterinary Officer and the APVMA permit.

Under the Act, the Gene Technology Regulator has powers to monitor compliance with the conditions of the EDD. During the quarter monitoring was conducted in Queensland, Victoria, New South Wales and the Australian Capital Territory. The monitoring was structured so that the OGTR inspectors could observe operations at several points in the EI emergency management program.

Several organisations were inspected in each State including the relevant State department responsible for primary industries, relevant State regulatory authorities and the relevant equine industry organisations.

All the organisations were found to be compliant with the conditions of the EDD at the time of the inspections.

Organisations monitored:

Queensland:

Queensland Department of Primary Industries and Fisheries
Queensland Harness Racing
Queensland Racing Limited
Gympie Veterinary Service

Victoria:

Victoria Department of Primary Industries
Flemington Veterinary Clinic
Victoria Racing Limited

New South Wales:

NSW Department of Primary Industries
Racing NSW
NSW Greyhound and Harness Racing Regulatory Authority
Agnes Banks Equine Clinic
Cryosite

Australian Capital Territory:

ACT Veterinary Services

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. Their objective is to determine if 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 process is to determine whether practices being used pose potential human health or environmental risks that require management actions to be implemented. In certain instances, where a suspected non-compliance with the Act is identified, the issue may be referred for investigation.

There were no Practice Reviews completed in the 1 October to 31 December 2007 quarter.

Audits

Audits can be initiated by the OGTR or 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 accredited 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, 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.

There were no audits completed in the 1 October to 31 December 2007 quarter.

Investigations

An investigation is an inquiry into a suspected non-compliance with the Act and corresponding state laws with the aim of gathering evidence. Such investigations are not restricted to purely criminal aspects — in the wider context they may include advice on detected flaws and vulnerability in policies, practices and procedures. An investigation may be initiated as a consequence of monitoring by the OGTR, self-reporting by an accredited organisation or by third party reporting.

There were no investigations completed in the 1 October to 31 December 2007 quarter.

SECTION 3

STATUTORY COMMITTEE OPERATIONS

STATUTORY COMMITTEE OPERATIONS

The Act establishes three committees to provide advice to the Regulator and the Gene Technology Ministerial Council:

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

Gene Technology Technical Advisory Committee

As set out in section 101 of the Act, the functions of the Gene Technology Technical Advisory Committee (GTTAC) are to provide scientific and technical advice, on the request of the Regulator or the Ministerial Council, on gene technology, GMOs, GM products, applications made under the Act, the biosafety aspects of gene technology and the need for policy principles, policy guidelines, codes of practice, technical and procedural guidelines in relation to GMOs and GM products and the content of such principles and codes.

GTTAC held its 31st meeting on 4 December 2007 in Canberra. The Committee considered two DNIR applications, one request to vary a DNIR licence and reviewed eight biology documents prepared by the OGTR. These documents are based on the available scientific literature and serve as a key reference on the properties and characteristics of the unmodified parent organism. They provided a 'baseline' for comparison in the evaluation of GMOs.

The communiqué regarding the December GTTAC meeting is provided in Appendix 2.

The term of the current GTTAC membership expired on 8 December 2007 and an appointment process for the next triennum is underway.

Further information about the work of GTTAC, including its communiqués, is available from the OGTR website www.ogtr.gov.au/committee/gttac

Gene Technology Community Consultative Committee

As set out in section 107 of the Act, the functions of the Gene Technology Community Consultative Committee (GTCCC) are to provide advice on the request of the Regulator or the GTMC, on matters of general concern identified by the Regulator in relation to applications made under this Act, matters of general concern in relation to GMOs and the need for policy principles, policy guidelines, codes of practice, technical and procedural guidelines in relation to GMOs and GM products and the content of such principles and codes.

The term of the current GTCCC membership expired on 30 June 2007 and the appointment process for a new committee, the Gene Technology Ethics and Community Consultative Committee (GTECCC) established by the *Gene Technology Amendment Act 2007* is underway.

Further information about the work of GTCCC , including its communiqués is available from the OGTR website www.ogtr.gov.au/committee/gtccc

Gene Technology Ethics Committee

As set out in section 112 of the Act, the functions of the Gene Technology Ethics Committee (GTEC) are to provide advice on the request of the Regulator or the Ministerial Council, ethical issues relating to gene technology, the need for, and content of codes of practice in relation to ethics in respect of contained dealings with GMOs and the need for and content of policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons.

The GTEC held its 15th meeting in Canberra on 22 November 2007. Matters discussed included ethical issues arising from the modification of animals for aesthetic or ornamental purposes and working group papers on public consultation and environmental ethics.

The communiqué regarding the November GTEC meeting is provided in Appendix 3.

The term of the current GTEC membership expired on 8 December 2007. This committee will also be replaced by the GTECCC described above.

Further information about the work of GTEC, including its communiqués, is available from the OGTR website www.ogtr.gov.au/committee/gtec

SECTION 4

OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

Implementation of the *Gene Technology Amendment Act 2007* and the Gene Technology Amendment Regulations 2007

The *Gene Technology Amendment Act 2007* (the Amendment Act) and the Gene Technology Amendment Regulations 2007 commenced on 1 July 2007. These amendments implement legislative changes as agreed in the All Governments' response to the recommendations of an independent statutory review of the Act commissioned by the Gene Technology Ministerial Council.

Pursuant to preparatory work, including national IBC training and issuing of related guidelines, conducted in the previous quarter, the Regulator wrote to all accredited organisations to formally advise them of the commencement of the amended legislation. Over the quarter the OGTR responded to a range of queries from instrument holders and received approximately sixty applications for PC1 certified facilities and related changes to DNIR licences (see section 2).

The OGTR also continued to progress the nomination process for membership of the GTTAC and the new advisory committee created by the Amendment Act — the GTECCC. The GTECCC will combine the functions of the current GTEC and GTCCC and will commence from 1 January 2008.

An updated version of the *Risk Analysis Framework* was published in November 2007 which incorporates technical and procedural changes to the assessment of licence applications arising from the Amendment Act.

The updated document is available from the OGTR website www.ogtr.gov.au/pdf/public/raffinal3.pdf or by contacting the office directly.

International Collaboration and Coordination

Under the Act the Regulator's functions include:

- monitoring international practice in relation to regulation of GMOs
- maintaining links with international organisations that regulate GMOs in countries outside Australia
- promoting the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies.

International collaboration and coordination activities undertaken during the quarter involved presentations to and/or participation in:

- Laboratories for The 21st Century Annual Conference — 1–4 October 2007, Charleston, South Carolina
- 50th Biological Safety Conference of the American Biological Safety Association — 4–10 October 2007, Nashville Tennessee, USA

- 20th Session of the Organisation for Economic Cooperation and Development Working Group on Harmonisation of Regulatory Oversight in Biotechnology — 24–26 October 2007, Paris, France
- European Food Safety Authority Scientific Forum and European Food Safety Summit, Experiences with Environmental Risk Assessment of Genetically Modified Plant: and meetings with senior representatives of the European Commission and key interest groups regarding GM regulation — 19–23 November 2007, Brussels, Belguim
- International Society for Risk Analysis Conference — Meta-uncertainty; its meaning and relevance to the risk assessment of dealings with GMOs; and Weed Risk Assessments in the Office of the Gene Technology Regulator, Australia — 9–12 December 2007, San Antonio, Texas, USA
- Meeting with technical officials from the Biotechnology Regulatory Services section of the United States Department of Agriculture, Agricultural Plant Health Inspection Service — 14 December 2007, Washington DC, USA.

Advice on Gene Technology Regulation

The Regulator and the OGTR endeavour to participate in events that inform stakeholders, the Australian community and/or users about the regulatory system.

During the 1 October to 31 December 2007 quarter the OGTR provided the following presentations:

- NSW Farmers-Cumberland Branch - Gene Technology: gene technology regulation and GM canola in Australia — 1–15 October 2007, Cumberland, New South Wales
- Cellular Therapies Advisory Committee — Role of the OGTR in regulating clinical trials with GMOs — 23 November 2007, Canberra, ACT
- Food Standards Australia and New Zealand Board. Overview of the Office of the Gene Technology Regulator — 28 November 2007, Canberra, ACT.

In addition a meeting with State and Territory technical contacts was held in Canberra on 27 November 2007. This bi-annual forum provides an opportunity to obtain feedback on the implementation of recent regulatory changes, and briefings on advances in risk assessment methodology and current DIR and DNIR applications.

National Strategy for Unintended Presence of Unapproved GMOs

The Australian Government Biotechnology Ministerial Council has endorsed a risk-based national strategy to manage the unintended presence of unapproved GMOs in imported seeds for sowing (the UP strategy). The strategy was developed by an interdepartmental working group chaired by Biotechnology Australia and comprised the then Department of Agriculture, Fisheries and Forestry; the Department of the Environment and Heritage; Department of Foreign Affairs and Trade; Department of Education, Science and Training; Department of Industry, Tourism and Resources; Department of Health and Ageing; FSANZ; and the OGTR.

The OGTR is responsible for implementing the UP strategy and has liaised closely with the Australian Seed Federation to develop a voluntary auditing and testing program of existing industry quality assurance measures. During the quarter, OGTR reviewed the quality assurance systems of one company (Syngenta Seeds Pty Ltd) and did not identify any issues of concern.

OGTR Website Usage and Statistics

The OGTR's website is a comprehensive source of information on activities of the office. The tables below provide information on the number of hits on the OGTR web site and the number of visitor sessions by month, and day of week pattern during the 1 October to 31 December 2007 quarter.

MONTH	HITS[1]	VISITORS[2]
October	1392548	35672
November	1342901	33258
December	1231265	29130

DAY OF THE WEEK PATTERN FOR THE QUARTER	HITS [1]	VISITORS[2]
Sunday	485756	12323
Monday	670168	16225
Tuesday	441275	15219
Wednesday	581527	15191
Thursday	594297	14369
Friday	571006	13446
Saturday	465246	11287

1 'A hit' is a request made to the server. Each file that is requested is counted as a hit

2 'Visitors' is the number of how many times the OGTR website has been visited.

The most popular pages viewed on the OGTR website during the period were:

- Index/Home
- What's New
- Search
- Handbook on the Regulation of Gene Technology in Australia
- GMO Record
- About the OGTR

- Intentional Release and Evaluation Processes
- Media Information
- Publications and Forms (Certification)
- Emergency Dealing Determinations

The most popular downloaded documents were:

- Risk Analysis Framework (2nd edition)
- Risk Analysis Framework (1st edition)
- The Biology & Ecology of White Clover (*Trifolium repens L.*) in Australia
- The Biology & Ecology of Wheat (*Triticum aestivum L.*) in Australia
- Handbook on the Regulation of Gene Technology in Australia
- The Biology & Ecology of Carnation (*Dianthus caryophyllus*) in Australia
- The Biology & Ecology of Carnation (*Gossypium hirsutum*) in Australia
- Annual Report 2006
- The Biology & Ecology of Pineapple (*Ananas comosus var. comosus*) in Australia
- OGTR Media Releases

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

Internet Contacts and Freecall Number

OGTR Email Address and Freecall Number

The OGTR's 1800 number and email address are points of contact for members of the public and other interested parties to obtain information about the regulation of GMOs. Assistance with specific questions and additional mechanisms for public feedback are among some of the services provided by the 1800 line and email facilities. The table below describes the activity of these facilities throughout the quarter.

MONTH	EMAILS	OGTR 1800 NUMBER
October	112	104
November	137	150
December	169	104

Monitoring and Compliance Email inbox

The OGTR maintains an email inbox to provide a central point for accredited organisations to contact the OGTR regarding queries, legislative notifications and self reporting of non-compliances. The email inbox ensures that all communications are answered efficiently whilst monitoring staff are away from the office. The inbox received 78 emails during the quarter.

Statutory Committee Email inbox

The Regulatory Practice and Secretariat Section maintain an email inbox to facilitate efficient communication between committee members and secretariat staff.

The inbox ensures that all communications are answered in a timely manner by secretariat staff. The inbox received 121 emails during the quarter.

Application and Licence Management Email inbox

During the quarter, the OGTR created a new mail inbox for correspondence and queries about applications received by the Application and Licence Management Section. This box provides a central, shared communications point to allow more efficient co-ordination of responses. The new inbox received 86 emails during the quarter.

APPENDICES

APPENDIX 1

DNIR Licences issued 1 October to 31 December 2007.

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 426/2007	21 December 2007	Griffith University, Queensland	Characterising virulence in enteric pathogens	The purpose of these dealings is to study the function of bacterial molecules that enter into and alter host cells in order to understand disease progression and identify targets for therapeutics
DNIR 425/2007	16 November 2007	CSL Limited, Victoria	Reverse genetics of Influenza	The aim of the dealing is to construct influenza viruses by reverse genetics for research purposes
DNIR 424/2007	16 November 2007	Children, Youth and Women's Health Service, South Australia	Evolution and selection of complement-resistant VSV-G variants	The purpose of this dealing is to isolate a complement-resistant variant of the Vesicular stomatitis virus (VSV)-G glycoprotein that can be used to pseudotype lentiviral vectors

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 423/2007	16 November 2007	Queensland Institute of Medical Research, Queensland	The biology of arbovirus fitness in arthropod hosts	The purpose of this dealing is to study the replication of genetically modified Ross River virus strains in mosquitoes
DNIR 422/2007	8 November 2007	Sydney-West Area Health Service, New South Wales	Pathogenesis of hepatitis C virus	The aim of the project is to understand how hepatitis C virus causes disease in infected people, including fatty liver, inflammation and scarring of the liver, liver failure and liver cancer
DNIR 420/2007	5 October 2007	Institute of Medical and Veterinary Science, South Australia	Determining the relative packaging efficiency of HIV-1 and HIV-1 derived vector genomes	The purpose of the dealing is to determine the relative packaging efficiencies of wild-type HIV-1 genomic RNA and the genomic RNA of attenuated HIV-1 derived gene vectors

APPENDIX 2

Gene Technology Technical Advisory Committee
4 December 2007, Canberra
COMMUNIQUÉ FOR THE 31ST MEETING

This is the 21st communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 31st meeting of GTTAC, held on 4 December 2007 and matters considered out of session in July and September 2007.

GTTAC is a statutory advisory committee to the Gene Technology Regulator (the Regulator) and the Gene Technology Ministerial Council. All Committee members and expert advisers hold office on a part-time basis.

The Regulator receives input from GTTAC on applications for licences to conduct dealings with genetically modified organisms (GMOs), as well as comments on the Risk Assessment and Risk Management Plan (RARMP) that is prepared for each of these applications.

The purpose of this Communiqué is to provide a brief overview of the applications and RARMPs considered by GTTAC and the advice the Committee has provided to the Regulator with regard to those applications and RARMPs.

The Communiqué also summarises other major issues discussed by GTTAC.

Advice on RARMPs

Advice on DNIR 179/2003 Variation RARMP

GTTAC considered the RARMP prepared in response to the following application:

- DNIR 179/2003 — *Ex vivo* retroviral transduction of CD34 selected haematopoietic stem cells for clinical gene therapy — variation to original application

DNIR 179/2003, issued to The Children's Hospital at Westmead in June 2003, licenced the laboratory component of the trial. The licence holder has applied for a variation to the licence conditions to enable the clinical trial to proceed.

The aim of the clinical trial is to introduce genes into CD34 haematopoietic stem cells to treat patients with X-linked Severe Combined Immunodeficiency and to provide resistance to alkylating drugs used in cancer therapy. The proposed dealings involve the *ex vivo* transduction of CD34+ cells from patients who are undergoing chemotherapy with a replication defective vector, followed by *in vivo* administration of the transduced cells to the patient from whom they were originally isolated. Authorisation from the TGA would also be required before administration to patients in a clinical trial could proceed.

GTTAC discussed the application and advised the Regulator that:

- Further information regarding the methodologies and the results of similar clinical trials carried out overseas should be requested.
- Comment should also be sought from the Cellular Therapies Advisory Committee of the NH&MRC

Advice on Applications

- Molecular identification & characterisation of the virulence and host range determinants of SARS and SARS-like *Coronaviruses* (DNIR 427/2007)
- Identification of virulence factors for *Henipaviruses* (DNIR 428/2007)

The Committee discussed two licence applications from CSIRO Livestock Industries, Geelong, involving the generation of genetically modified viruses. Both applications seek to generate mutant and chimeric viruses, to characterise viral infectivity in mammalian tissue culture cells and to examine changes in viral pathogenesis and tissue tropism by infecting animals (ferrets or bats). The dealings are proposed to occur at the Australian Animal Health Laboratories in Geelong, in PC3 and PC4 containment facilities.

GTTAC advised the Regulator that additional information on the sequence of planned experiments would be useful in preparing the RARMP.

Review of Biology Documents

GTTAC reviewed a number of Biology Documents prepared by the OGTR. The documents are based on the available scientific literature and serve as a key reference on the properties and characteristics of the unmodified parent organism, providing a 'baseline' for comparison in the conduct of risk assessments for GMOs. The existing Biology Documents for cotton, canola, wheat, sugarcane, papaya and pineapple have been updated. New documents have been developed for banana and zebrafish. Feedback from GTTAC will be incorporated into the documents before they are published on the OGTR website.

Committee members commented favourably on the documents and encouraged the Regulator to make these documents as widely available as possible.

Presentation

An information paper on the number of volunteer plants found during the post-harvest monitoring period for limited and controlled releases of GM canola and cotton was presented to GTTAC.

Enquiries and Risk Assessment and Risk Management Plans

For all enquiries and to obtain copies of applications or RARMPs for dealings involving the intentional release of GMOs into the environment, please phone the OGTR on 1800 181 030. The RARMPs are also available electronically from our website at http://www.ogtr.gov.au

APPENDIX 3

Gene Technology Ethics Committee Meeting 22 November 2007, Canberra COMMUNIQUE

The Gene Technology Ethics Committee (GTEC) held its fifteenth meeting in Canberra on 22 November 2007.

GTEC was established by the *Gene Technology Act 2000* (the Act) as a statutory advisory committee to the Gene Technology Regulator (the Regulator) and the Gene Technology Ministerial Council. All committee members and expert advisers hold office on a part-time basis. (A reference to 'members' in the communiqué includes 'expert advisers').

This was the final meeting of the Committee, which will be replaced by the new Gene Technology Ethics and Community Consultative Committee (GTECCC) from 2008.

The main items discussed were:

- Ethical issues arising from the modification of animals for aesthetic or ornamental purposes.
- Response to the National Framework for the Development of Ethical Principles in Gene Technology.
- Working group papers:
  - Public Consultation: Community & Stakeholders (this paper was initiated by the Gene Technology Community Consultative Committee (GTCCC) and considered jointly with GTEC at their combined meeting on 15 March 2007)
  - Environmental Ethics and Gene Technology

Members of the Committee also received a report from the Chair regarding relevant events he had attended since the last GTEC meeting, and from the Regulator regarding the ongoing and completed work of the Office. Members were informed of relevant work from other national committees via cross-member reports.

GTEC's Work Plan

The Committee agreed to refer projects still in development to the new GTECCC and provided some guidance on the key issues that the new Committee might consider in finalising them.

GTEC and Relationships with Other Committees

The Committee received reports from the Chair, the Gene Technology Regulator, the Gene Technology Technical Advisory Committee (GTTAC), the Australian Health Ethics Committee (AHEC) and the Animal Welfare Committee (AWC).

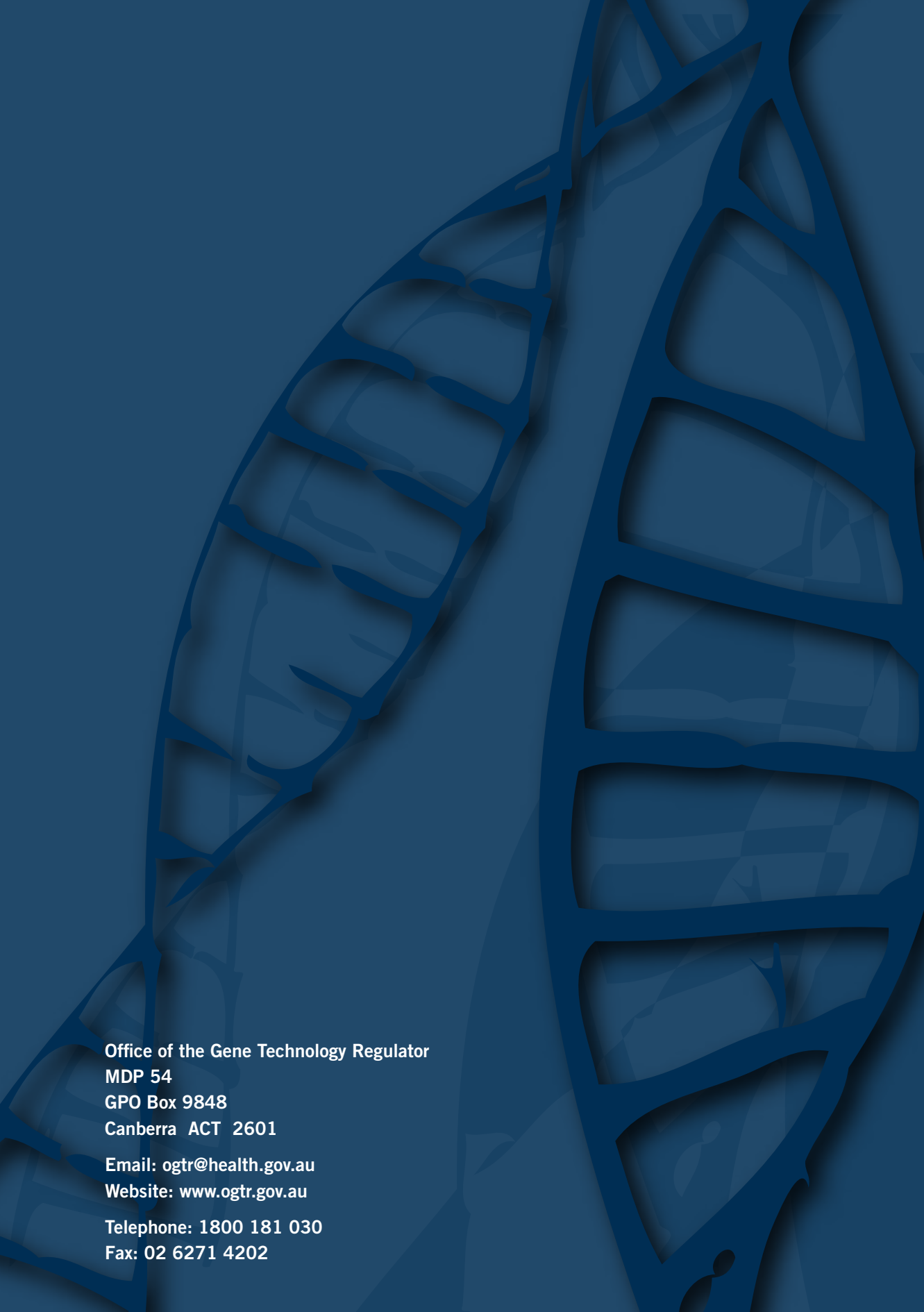
For all inquiries, please contact the Office of the Gene Technology Regulator on 1800 181 030 (free-call)

GLOSSARY

This section contains a brief description of terms relevant to an understanding of this quarterly report. They do not substitute for definitions of terms relevant to the operation of the gene technology regulatory system that are contained in section 10 of the *Gene Technology Act 2000*.

Accredited organisation	An organisation that is accredited under section 92 of the Act
Act	*Gene Technology Act 2000*
APVMA	Australian Pesticides and Veterinary Medicines Authority
Breach of a licence condition	A breach of a licence condition which has been proven either in court or by way of admission following investigation
CCI	Confidential commercial information
Certified containment facility	A building or place certified by the Regulator to a specified containment level under section 84 of the Act
Clock stop	The period during which time does not run for purposes of the statutory time limit for making a decision — usually because evaluation cannot proceed until additional information requested from the applicant is received
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DIR	A dealing involving intentional release of a GMO into the environment (for example, field trial or commercial release)
DIR licence	A licence for a dealing involving intentional release of a GMO into the environment
DNIR	A contained dealing with a GMO not involving intentional release of the GMO into the environment (for example, experiments in a certified facility such as a laboratory)
DNIR licence	A licence for a dealing not involving intentional release of a GMO into the environment
Expert advisers	Advisers appointed by the Minister to give expert advice to either GTTAC or GTEC to assist them in the performance of their functions (expert advisers are not committee members)
EDD	Emergency Dealing Determination
FSANZ	Food Standards Australia New Zealand
GM	Genetically modified
GM product	A thing (other than a GMO) derived or produced from a GMO
GMAC	Genetic Manipulation Advisory Committee

GMO	Genetically modified organism
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTMC	Gene Technology Ministerial Council
GTSC	Gene Technology Standing Committee
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
Incident	A self-reported event which may constitute a non-compliance with regulatory requirements and a public health or environment risk
Limited and controlled release	A type of DIR which meets certain criteria relating to limiting and controlling the dealings with the GMO (eg a field trial)
NLRD	Notifiable low risk dealing (work with transgenic plants, animals or microorganisms undertaken in certified contained facilities)
Non-compliance	An inconsistency between an event or state of affairs and the requirements imposed by licence accreditation or certification conditions, or any of the requirements of the Act or Regulations
OGTR	Office of the Gene Technology Regulator
PC1, PC2, PC3, PC4	Physical containment levels of facilities as certified by the Regulator
RARMP	Risk assessment and risk management plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator
Spot checks	Unannounced visits by the OGTR Monitoring and Compliance Section
Volunteer	Regrowth of plants from seed that has remained on a site after a trial has been completed



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