



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 APRIL–30 JUNE 2009

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

‘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’



OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 APRIL–30 JUNE 2009

ISBN: 1-74186-954-4

Online ISBN: 1-74186-955-2

Publications Number P3-5564

Paper-based publications

© Commonwealth of Australia 2009

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Commonwealth. Requests and inquiries concerning reproduction and rights should be addressed to the Commonwealth Copyright Administration, Attorney-General's Department, Robert Garran Offices, National Circuit, Barton ACT 2600 or posted at <www.ag.gov.au/cca>

Internet sites

© Commonwealth of Australia 2009

This work is copyright. You may download, display, print and reproduce this material in unaltered form only (retaining this notice) for your personal, non-commercial use or use within your organisation. Apart from any use as permitted under the *Copyright Act 1968*, all other rights are reserved. Requests and inquiries concerning reproduction and rights should be addressed to Commonwealth Copyright Administration, Attorney-General's Department, Robert Garran Offices, National Circuit, Barton ACT 2600 or posted at <www.ag.gov.au/cca>

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

Email: ogtr@health.gov.au

Website: <www.ogtr.gov.au>

Telephone: 1800 181 030

Fax: (02) 6271 4202

Quarterly Report web page:

<www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1>

Inquiries about the content of this report may be directed to the Business Management and Communications Section, Regulatory Practice and Compliance Branch of the Office of the Gene Technology Regulator.

The Hon Mark Butler MP
Parliamentary Secretary for Health
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 April to 30 June 2009.

During this period three licences for dealings involving intentional release of genetically modified organisms (GMOs) and four licences for dealings not involving intentional release of GMOs were issued, and 37 physical containment facilities were certified.

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

This quarter saw the OGTR host the 3rd National Institutional Biosafety Committee forum at the Australian War Memorial in Canberra. The Forum provided a valuable opportunity for OGTR officers to meet with representatives from many of our accredited organisations to exchange information, receive feedback and discuss prospective changes to the Gene Technology Regulations 2001.

The Forum also provided an opportunity to officially launch the fourth version of the *Risk Analysis Framework*, a key strategic document for the OGTR.

Yours sincerely



Dr Joe Smith
Gene Technology Regulator

3 September 2009

CONTENTS

LETTER OF TRANSMITTAL	III
ABOUT THIS REPORT	1
NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM	4
Key achievements during this quarter	4
Licences and other instruments	4
Monitoring and Compliance	4
Working collaboratively with States and Territories	4
Gene Technology Ministerial Council	4
State and Territory consultation	5
Australian Government Agency liaison	5
Public participation	6
REGULATION OF GENETICALLY MODIFIED ORGANISMS	8
Types of Applications	8
GMO Register	9
New licences and other instruments	9
Processing of applications for Dealings involving Intentional Release licences	9
Applications received for Dealings involving Intentional Release licences	11
Consultation on applications for Dealings involving Intentional Release licences	11
Withdrawn applications and surrendered licences for Dealings involving Intentional Release licences	11
Clock stopped on Dealings involving Intentional Release licence applications	11
Decisions on applications for Dealings involving Intentional Release licences	12
Decisions on applications for Dealings Not involving Intentional Release licences	12
Changes to existing licences and other instruments	12
Emergency Dealing Determinations	13
Confidential Commercial Information	13
Monitoring and Compliance	13
Monitoring and Compliance Strategy	14
Overview of monitoring and compliance for the reporting period	14
Monitoring of Dealings involving Intentional Release	15
Monitoring of Dealings Not involving Intentional Release	16
Monitoring of Physical Containment Facilities	17
Monitoring Findings	18

Dealings involving Intentional Release	18
Findings for Dealings involving Intentional Release	19
Findings for Dealings Not involving Intentional Release	20
Findings for Physical Containment Facilities	21
Practice Reviews	22
Audits	22
Investigations	24
STATUTORY COMMITTEE OPERATIONS	26
Gene Technology Technical Advisory Committee	26
Gene Technology Ethics and Community Consultative Committee	26
OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR	28
International collaboration and coordination	28
Advice on gene technology regulation	28
Institutional Biosafety Committee Training	29
National Strategy for Unintended Presence of Unapproved GMOs	30
Reviews	30
Gene Technology Amendment Regulations 2009	30
OGTR website usage and statistics	31
Internet contacts and freecall number	32
OGTR email address and freecall number	32
Monitoring and compliance email inbox	33
Statutory Committee email inbox	33
Application and Licence Management email inbox	33
APPENDIX 1: DNIR LICENCES ISSUED 1 APRIL TO 30 JUNE 2009	36
APPENDIX 2: GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE COMMUNIQUE	38
GLOSSARY	42

ABOUT THIS REPORT

Sub-section 136A(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. Sub-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 Regulator's 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 April to 30 June 2009 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

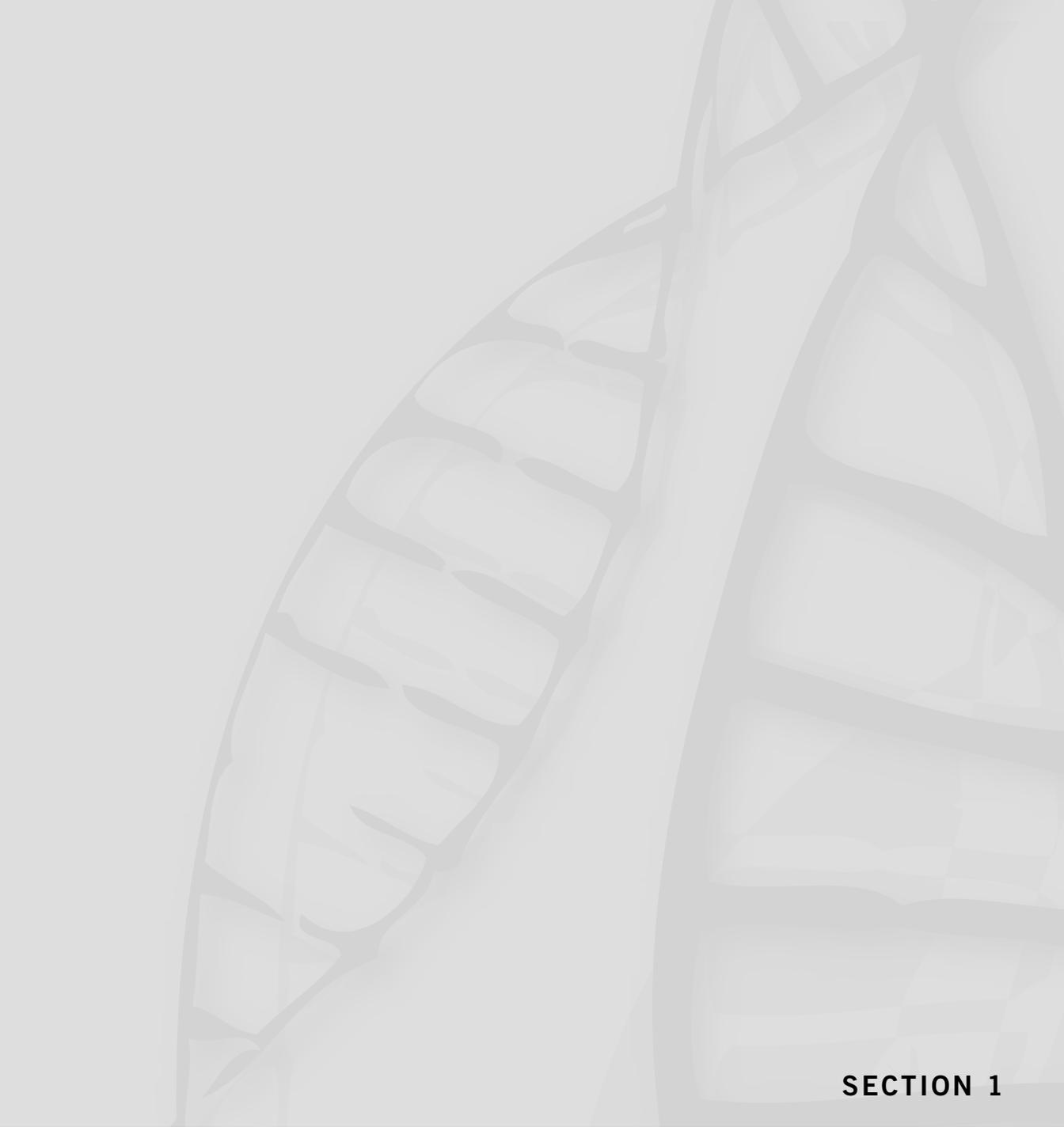
Reports on the activities of the two advisory committees established under the Act to assist the Regulator and the Gene Technology Ministerial Council.

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 April to 30 June 2009 quarter were:

Licences and other instruments

- 3 licences issued for Dealings involving the Intentional Release (DIR) of GMOs into the environment
- 4 licences issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- 37 physical containment facilities certified
- surrender of 44 certifications, 3 DNIR licences and 2 accreditations
- variation of 125 certifications, 11 DIR licences, 18 DNIR licences and 2 accreditations.

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

Monitoring and Compliance

Approximately 21 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 five percent per quarter.

Further information on monitoring and compliance is contained in Section 2 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 appropriate local councils during the evaluation of applications for all DIR licences.

For each application for a DIR licence other than a limited and controlled release, the Regulator is required to seek advice on matters relevant to the preparation of the Risk Assessment and Risk Management Plan (RARMP), and must also seek comment on the RARMP itself once it is prepared. For each application for a limited and controlled release, the Regulator is 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 the Australian Government Environment Minister, and prescribed Australian Government authorities and agencies, 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
- 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 the Environment, Water, Heritage and the Arts
- Department of Foreign Affairs and Trade.

During the quarter the Regulator sought advice in respect of two DIR 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. Two invitations to the public to comment on a RARMP 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 April to 30 June 2009 quarter. This includes information about applications for GMO licences and other instruments under the Act. This section 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 (eg field trials) through to more extensive general or commercial releases of GMOs. DIR licence applications have a statutory timeframe of 255 working days for processing unless the Regulator determines the application is a limited and controlled release application. 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 making a decision.

- **Accreditations of organisations**

DIR and DNIR licences require organisations which conduct work with GMOs to be accredited. To achieve accreditation, the Regulator must 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 making a decision.

- **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 making a decision.

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	2	3
DNIR licence	4	4
Accreditations	Nil	1
Certifications	37	37

* 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 or not the application is a limited and controlled release
- considering the applicant's suitability to hold a licence, having regard to relevant convictions, revocations and suspensions of related licences and permits, and ability to meet conditions of the licence
- 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 proposed licence conditions to manage risks to human health and safety and the environment, and determining whether the proposed dealings may pose a significant risk

- 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
- confirming the applicant's suitability, including their capacity to meet licence conditions, and considering 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 the licence if issued.

The statutory timeframes for making decisions 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 observed in the Australian Capital Territory.

This time limit may be extended, that is, the clock may be 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 a minimum 30 day timeframe for each of the one or two rounds of consultation that the Regulator must undertake 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*	Consultation on RARMP	Licences issued
DIR 096	DIR 096	DIR 094	DIR 090
DIR 097		DIR 095	DIR 092
			DIR 093

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

Applications received for Dealings involving Intentional Release licences

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

- DIR 096—Limited and controlled release of sugarcane genetically modified for herbicide tolerance—BSES Limited
- DIR 097—Limited and controlled release: Clinical trial of a candidate vaccine against Human respiratory syncytial virus and Human parainfluenza virus type 3—PPD Australia Pty Ltd.

Consultation on applications for Dealings involving Intentional Release licences

Although not required by the Act, the Regulator issued a 'Notification of Licence Application' for one DIR licence application. This notification was posted on the OGTR website and sent to people and organisations on the OGTR mailing list to advise receipt of this application and when the RARMP is expected to be released for public comment.

- DIR 096—Limited and controlled release of sugarcane genetically modified for herbicide tolerance—BSES Limited.

Two invitations to comment on a RARMP were issued during the quarter:

- DIR 094—Limited and controlled release of wheat and barley genetically modified for enhanced nutrient utilisation efficiency—CSIRO
- DIR 095—Limited and controlled release of sugarcane genetically modified for altered plant growth, enhanced drought tolerance, enhanced nitrogen use efficiency, altered sucrose accumulation, and improved cellulosic ethanol production from sugarcane biomass—BSES Limited.

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

Withdrawn applications and surrendered licences for Dealings involving Intentional Release licences

No DIR licence applications were withdrawn or surrendered during the quarter.

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 timeframe for making a decision on an application.

No requests for further information were initiated in this quarter.

Decisions on applications for Dealings involving Intentional Release licences

Three DIR licence were issued during this quarter:

- DIR 090—Commercial release of rose genetically modified for altered flower colour—Florigene Pty Ltd
- DIR 092—Limited and controlled release of wheat genetically modified for altered grain composition—CSIRO
- DIR 093—Limited and controlled release of wheat and barley genetically modified for altered grain starch composition—CSIRO.

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 four 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 he 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. Applications for variation to licences have a statutory timeframe of 90 days for making a decision. Additionally, the Regulator can make a decision in relation to an application to transfer a licence/instrument to another person or consent to the surrender of a licence/instrument request by a licence/instrument holder.

The following table describes the number and type of applications for variation and surrender received in relation to existing licences and other instruments, as well as the number of variations and surrenders approved during the quarter.

Type	Number received	Number approved
Surrender of accreditation	Nil	2
Surrender of certification	48	44
Surrender of DIR licence	2	Nil
Surrender of DNIR licence	6	3
Variation of accreditation	2	2
Variation of certification	106	125
Variation of DIR licence	5	11
Variation of DNIR licence	26	18

¹ Numbers reported in this quarter often relate to applications received in previous quarters.

Emergency Dealing Determinations

During this quarter the Regulator did not receive any requests for advice in relation to the making of any Emergency Dealing Determinations (EDD) and no EDDs were in effect.

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 confidential commercial 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 is available on the OGTR website.

During the quarter, the Regulator received two CCI applications in relation to DIR licence applications. The Regulator also made four CCI declarations in relation to DIR applications.

Monitoring and Compliance

The aim of OGTR monitoring and compliance activities is to ensure that 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 PC2 large-scale, PC3 and PC4 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 April to 30 June 2009 quarter, 11 GM plant field trial sites under DIR licences were subjected to monitoring visits.

- **Current field trial sites:** Of the 28 sites current in the quarter, six were monitored. This represents a monitoring rate of 21 percent of all current sites for the quarter.
- **Post-harvest field trial sites:** Of the 39 sites subject to post-harvest monitoring in the quarter, five 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 eight organisations and 15 PC facilities. Monitoring of PC facilities encompassed eight PC2 laboratories, three PC2 animal containment facilities, one PC2 plant containment facility, one PC2 large scale facility and two PC3 laboratories.

Monitoring of contained dealings: During the quarter, the monitoring of the 15 PC facilities mentioned above included monitoring for compliance with the general practices that must be followed when undertaking dealings (eg DNIRs) that are required to be conducted within contained facilities.

Eight 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 April to 30 June 2009.

Licensed Organisation Name	Licence Number	No. sites visited	Site status*	Crop type
CSIRO, Australian Capital Territory	DIR 086/2008	1	Current	Maize
Monsanto Australia Limited, New South Wales	DIR 081/2007	2	PHM	Cotton
Monsanto Australia Limited, New South Wales	DIR 065/2006	1	PHM	Cotton
Monsanto Australia Limited, New South Wales	DIR074/2007	2	1 Current 1 PHM	Cotton
Florigene Pty Ltd, Victoria	DIR 084/2008	1	Current	Torenia
Queensland University of Technology, Queensland	DIR 076/2007	1	Current	Banana
	DIR 079/2007	1	Current	Banana
Hexima Ltd, New South Wales	DIR 063/2005	2	1 Current 1 PHM	Cotton
Totals		11	C = 6 PHM = 5	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 April to 30 June 2009.

Licensed Organisation Name	Licence Number
University of Technology, Sydney, New South Wales	DNIR 364/2005 DNIR 432/2007
Intervet Australia Pty Ltd, Victoria	DNIR 301/2004
University of Southern Queensland, Queensland	DNIR 027/2002 DNIR 028/2002
Centenary Institute of Cancer Medicine and Cell Biology, New South Wales	DNIR 079
The University of Sydney, New South Wales	DNIR 211/2003 DNIR 096/2002
Total	8 DNIR licences

Monitoring of Physical Containment Facilities

The organisations and the facility types the OGTR visited during the 1 April to 30 June 2009 quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
University of Technology, Sydney, New South Wales	PC2 laboratory	1
	PC2 animal containment	1
University of Southern Queensland, Queensland	PC2 animal containment	1
	PC2 plant containment	1
	PC2 laboratory	2
Centenary Institute of Cancer Medicine and Cell Biology, New South Wales	PC2 laboratory	2
Royal Prince Alfred Hospital, New South Wales	PC2 animal containment	1
The University of Sydney, New South Wales	PC2 laboratory	3
Avexa Limited, Victoria	PC3 laboratory	1
The University of Melbourne, Victoria	PC3 laboratory	1
Intervet Australia Pty Ltd, Victoria	PC2 large-scale	1
Total	5 facility types	15

Monitoring Findings

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 eg 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 eg 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 was one finding of non-compliance for DIRs for the 1 April to 30 June 2009 quarter.

Organisation	Hexima Ltd
Licence number and site	DIR 063/2005, Site 3
Summary of dealing	Field trial of GM cotton expressing natural plant genes for fungal control
Findings	<p>Hexima Ltd notified the OGTR that they had inadvertently planted a non-approved crop (soy beans) on the post-harvest GM cotton site.</p> <p>During an inspection of the post-harvest site, OGTR inspectors observed mature cotton Volunteers that had not been destroyed prior to flowering, as required under the licence.</p>
Assessment	<p>Hexima Ltd planted soy beans in the belief that this crop was permitted. Hexima Ltd informed OGTR as soon as they were aware of this mistake and voluntarily destroyed the soy crop. When Hexima Ltd was made aware of the mature Volunteers during the OGTR inspection, they immediately took steps to destroy the Volunteers.</p> <p>In addition to these corrective actions, Hexima Ltd undertook a voluntary review of their management strategy for this Site to minimise recurrence of this issue. This included increasing resources to the site and frequency of internal inspection activities, along with improved procedures regarding post-harvest crops on trial sites.</p> <p>Risks to human health, safety and environment were assessed as negligible.</p>
Compliance management	<p>Hexima Ltd were reminded of their obligation to ensure that only approved post-harvest crops are planted and that Volunteers must be destroyed prior to flowering.</p> <p>Given the voluntary corrective actions already taken by Hexima Ltd in addressing this non-compliance, no further action is required.</p>

Findings for Dealings Not involving Intentional Release

There were two findings of non-compliance for DNIRs for the 1 April to 30 June 2009 quarter.

Organisation	The University of Technology Sydney (UTS)
Licence number	DNIR 364/2005
Summary of dealing	Generation and characterisation of poxvirus tumour necrosis factor receptor (TNF-R) homologues ORFs in subversion of cellular TNF-R signalling
Findings	At the time of inspection, OGTR staff noted that following the transfer of this licence from Sydney West Area Health Service (SWAHS) to UTS, new signed statements for persons covered by the licence had not been obtained by UTS, the new licence holder.
Assessment	The licence holder, UTS, had not obtained signed statements to demonstrate that persons covered by the licence had been informed of the modification to licence obligations following transfer of the licence to UTS. OGTR promptly received new signed statements from UTS. As the non-compliance was administrative in nature, the risks to human health and safety and the environment have been assessed as negligible.
Compliance management	UTS was reminded of the requirement for all persons covered by the licence to sign statements indicating an awareness of the licence conditions.

Organisation	The University of Sydney
Licence number	DNIR 211/2003
Summary of dealing	Construction and Manipulation of an Infectious cDNA clone of Enterovirus 71 and Coxsackievirus A16
Findings	At the time of the inspection, OGTR staff noted that the outermost containers that were used to transport GMOs or GM waste between buildings were not labelled with the name, address and contact details of the person responsible for the dealings.
Assessment	Staff had been trained in the obligations imposed on them by the conditions of the licence, had a comprehensive training and accountability system, and were willing to rectify the oversight. Furthermore the container did have biological hazard labels and the University of Sydney has a good compliance history. The risks to human health and safety and the environment have been assessed as negligible.
Compliance management	The University of Sydney was reminded of the requirement to transport GMOs and GM waste according to the Transport Guidelines

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.

Number of PC Facilities inspected	Non-Compliance Issue					
	Structure	PPE ¹	Equipment	Waste disposal	Work practices ²	Transport
15	1	0	2	0	0	3

¹ PPE = Personal Protective Equipment.

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

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 or not 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 was no practice review completed in the 1 April to 30 June 2009 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 or not 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 was one audit completed in the 1 April to 30 June 2009 quarter.

Audit	CSIRO
Issues	<p>This audit is part of the OGTR ongoing audit program and was conducted to:</p> <ul style="list-style-type: none"> • confirm that participating CSIRO licencees and organisations/IBCs have effective policies/governance-arrangements/practices in place to meet regulatory requirements • collect and transfer information on compliance performance risks arising from ongoing change • assess the degree of understanding of regulatory obligations and possible improvements to regulatory specification • assess/rectify CSIRO compliance performance arrangements for risks arising from the diversity and scale of their activities • contribute to understandings which confirm or otherwise the willingness and capabilities of regulated parties in our regulatory system • identify and raise awareness of effective compliance management approaches (ie capacity building).
Determination	<p>The audit recognised the CSIRO's capable coordination of compliance management arrangements for research institutes across Australia, under OGTR and other regulatory arrangements. The audit found that CSIRO compliance management arrangements (under the <i>Gene Technology Act 2000</i>) appear to:</p> <ul style="list-style-type: none"> • be well developed, adaptive, and comprehensive • comprise a number of compliance management mechanisms which could be drawn upon by the OGTR in developing effective compliance performance principles for future IBC Forums and other OGTR awareness activities • have the capacity to underpin CSIRO compliance against regulatory provisions/licence conditions.

Action

The audit team proposed a number of minor improvements to the CSIRO's compliance arrangements. The CSIRO made some improvements during the audit, with some further enhancements being considered as part of ongoing continual improvement activity.

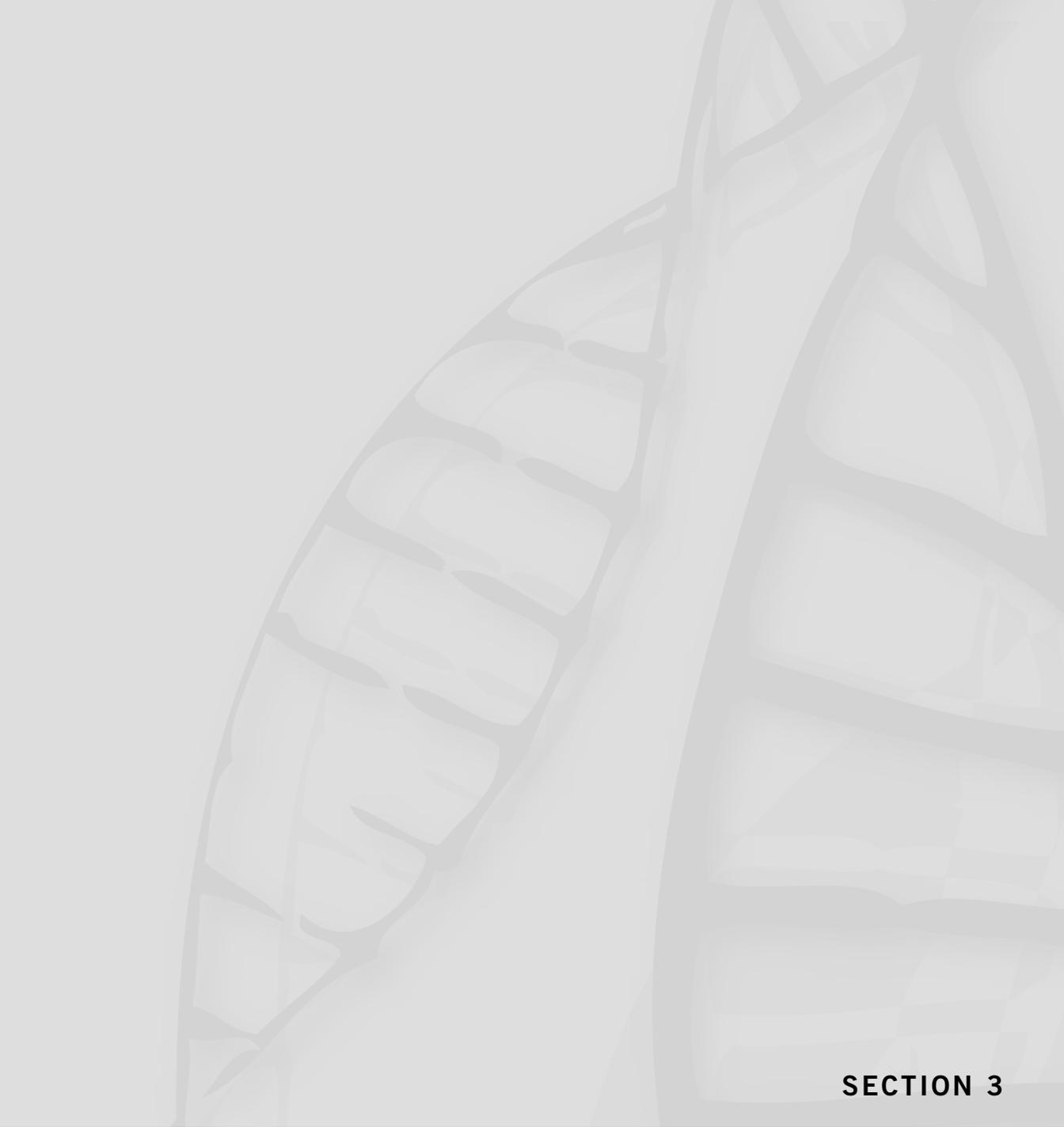
A number of CSIRO suggestions about improvements to regulatory specifications under the *Gene Technology Act 2000* are being considered as part of ongoing regulatory review and revision by the OGTR. Some of these issues together with the current regulatory revision program were further canvassed at the April 2009 IBC Forum held by the OGTR in Canberra.

The OGTR audit program will continue to assess licensee compliance management arrangements and operational practices. Such information contributes to the continual improvement of OGTR compliance management processes, the prevention of practices and arrangements that could lead to non-compliance, and improved compliance capacity of organisations operating under the regulatory scheme.

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 was no investigations completed in the 1 April to 30 June 2009 quarter.



SECTION 3

STATUTORY COMMITTEE OPERATIONS

STATUTORY COMMITTEE OPERATIONS

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

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

Appointments to the two gene technology advisory committees were made by the then Parliamentary Secretary to the Minister for Health and Ageing, Senator the Hon Jan McLucas, in January 2008. Senator McLucas appointed Professor Brian Priestly as a member of GTTAC in November 2008.

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 met once during the quarter, on 18 April 2009. The communiqué is at Appendix 2.

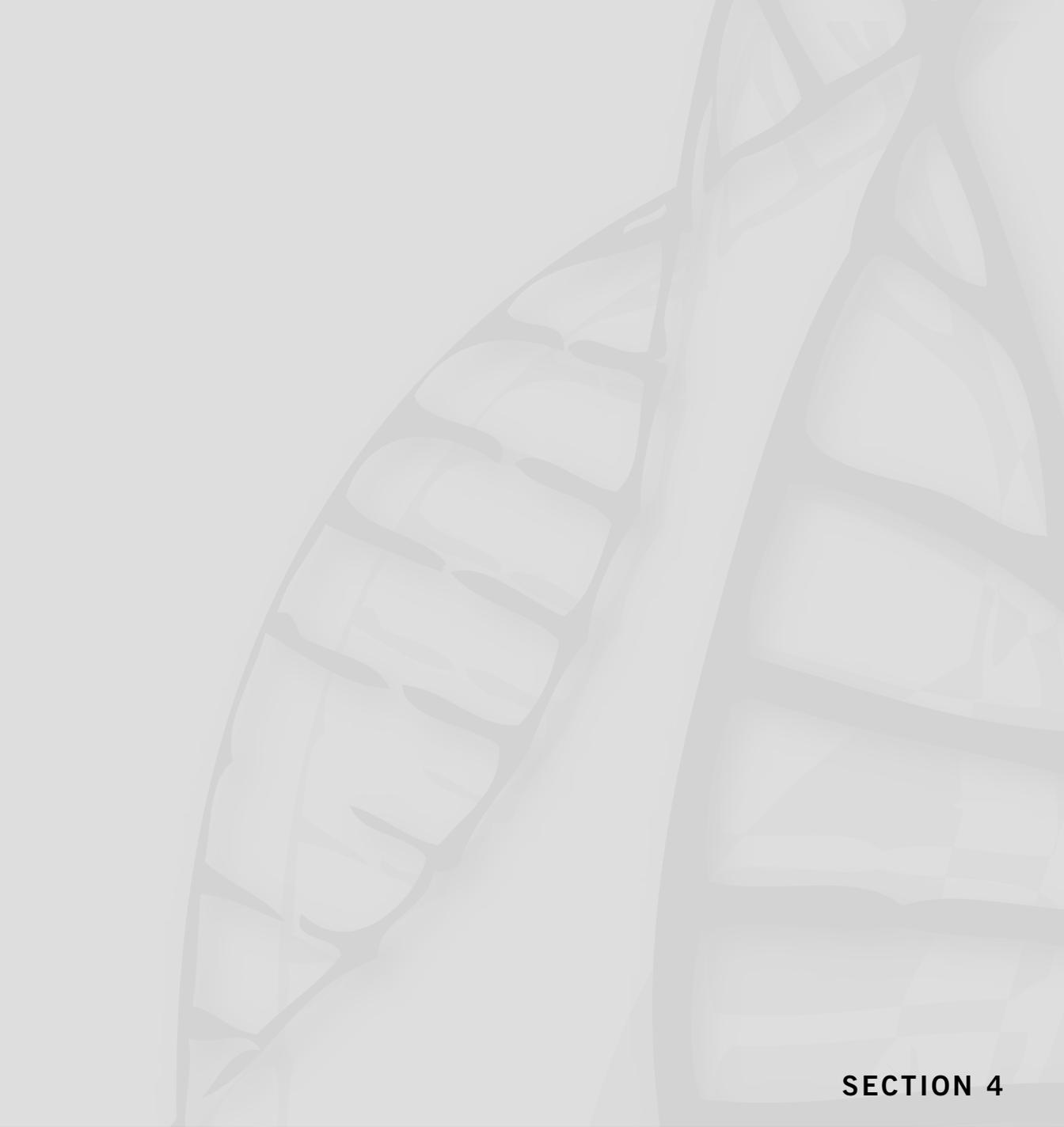
Further information about the work of GTTAC is available from the OGTR website <www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gttac-2>

Gene Technology Ethics and Community Consultative Committee

As set out in section 107 of the Act, the function of GTECCC is to provide advice on the request of the Regulator or the GTMC, on a number of matters, including ethical issues relating to gene technology, the need for and content of policy principles, policy guidelines, codes of practice, community consultation in respect of the process for applications for licences covering dealings involving the intentional release of a GMO into the environment, and risk communication matters in relation to those dealings. The appointment process for this new Committee was finalised in January 2008.

GTECCC did not meet during the quarter.

Further information about GTECCC is available from the OGTR website <www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gteccc-2>



SECTION 4

**OTHER ACTIVITIES OF THE
GENE TECHNOLOGY REGULATOR**



OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

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 deal with the regulation of gene technology and with agencies 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 participation in and presentation to:

- Meeting of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management under the UN Cartagena Protocol on Biosafety, 20–24 April 2009, Montreal, Canada
- The 8th International High Containment Biosafety Workshop, 10–15 May 2009, Winnipeg, Canada
- Institutional Biosafety Committee Workshop, 29 June–2 July 2009, Kuala Lumpur, Malaysia.

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 quarter the Regulator attended the following meetings:

- The Regulator attended a regulator's forum with the prescribed agency regulators who are involved in Australia's regulatory system for gene technology, 18 April 2009
- The Regulator attended a number of introductory meetings with the heads of various relevant stakeholder agencies, including the Therapeutic Goods Administration and Food Standards Australia New Zealand and the Australian Pesticides and Veterinary Medicines Authority. Meetings were also held with various stakeholders in the ACT and Victoria.

OGTR officers attended the following meetings/conferences:

- OGTR officers attended the Food Allergen Detection Workshop in Melbourne, hosted by the National Measurement Institute, 25–26 June 2009
- an OGTR officer participated in a teleconference for the Australian Weed Risk Management forum, 24 June 2009
- an OGTR officer attended the Australia/United States Chemical and Biological Global Knowledge Centre demonstration, 2 April 2009.

The OGTR also received visitors and presentations from:

- The former Parliamentary Secretary to the Minister for Health and Ageing, Senator the Hon Jan McLucas, visited the office, 12 May 2009.

Institutional Biosafety Committee Training

The 3rd National Institutional Biosafety Committee Forum (IBC Forum) was held in Canberra on 30 April–1 May 2009 at the Australian War Memorial. Representatives from all states and territories attended; 134 delegates representing 64 accredited organisations participated.

The IBC Forum facilitated exchange of information between IBCs and the OGTR and provided an arena in which to discuss prospective changes to the legislation regulating GMOs, in light of the review of the Regulations. The two-day meeting also provided an opportunity for organisations to discuss their specific regulatory issues with OGTR staff.

The IBC Forum was officially opened by the then Parliamentary Secretary for Health and Ageing, the Senator the Hon Jan McLucas, who also launched the fourth version of Risk Analysis Framework that was developed within the OGTR. The new Regulator, Dr Joe Smith, began the program with a comprehensive overview of the work of the OGTR; and a number of guest speakers from other Australian Government agencies and IBCs, as well as officers from several sections of the OGTR, gave presentations.

Feedback from delegates was strongly positive. There was unanimous support for the format of the program, and the topics covered were considered very valuable in helping IBCs fulfil their important role in the national regulatory system. From the OGTR's perspective, ongoing interaction with the IBCs is an important factor in maintaining the integrity of the regulatory scheme and fostering cooperative compliance.

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 of 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 (ASF) to develop a voluntary auditing and testing program of existing industry quality assurance measures. During the quarter the OGTR and the ASF continued development of the next stage which is to expand the program to involve additional companies and to broaden the reach of the program across additional segments of the industry.

Reviews

During this quarter, the program of review of Guidelines for Certification of Physical Containment Facilities continued, with draft revised PC3 Animal and PC3 Invertebrate guidelines being circulated, for targeted consultation, to organisations with experience or expertise with PC3 animal and invertebrate facilities.

Gene Technology Amendment Regulations 2009

The Gene Technology Amendment Regulations 2009 (Amendment Regulations 2009) were made by the Governor General on 30 April 2009 and commenced on 2 May 2009. The amendment confers on the Regulator the function of making available inspectors appointed under section 150 of the Act to be appointed as inspectors for the Security Sensitive Biological Agents (SSBA) Regulatory Scheme under Division 7 of Part 3 of the *National Health Security Act 2007* (NHS Act). This will allow inspectors from the existing Gene Technology Regulatory Scheme to monitor laboratories and facilities handling SSBA for compliance with the NHS Act. The Amendment Regulations 2009 only have effect at the Commonwealth level and do not change any gene technology regulation requirements and will not necessitate further amendment to State and Territory legislation.

OGTR website usage and statistics

The OGTR 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 website and the number of visitor sessions by month and day of week pattern during the 1 April to 30 June 2009 quarter.

MONTH	HITS ¹	VISITS ²
April	188,652	18,158
May	226,639	24,980
June	202,830	23,437

DAY OF THE WEEK PATTERN FOR THE QUARTER	HITS ¹	VISITS ²
Sunday	49,827	7,455
Monday	92,772	9,575
Tuesday	101,156	10,232
Wednesday	95,715	9,765
Thursday	101,253	10,115
Friday	116,036	9,399
Saturday	61,362	7,428

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

2 'Visits' is the number of times the OGTR website has been visited

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

- Home Page
- What's New
- Intentional Release and Evaluation Process
- Guidelines
- About the OGTR
- Publication and Forms—Certification of Physical Containment Facilities
- GMO Record

- IBC & Accredited Organisations Information
- Legislation
- Fact Sheets & Info Bulletins.

The most popular downloaded documents were:

- The Biology and Ecology of Cotton (*Gossypium hirsutum L.*) in Australia
- Risk Analysis Framework
- The Biology of *Carica papaya L.* (*papaya, papaw, paw paw*) in Australia
- The Biology of the Sugarcane (*Saccharum spp.*) in Australia
- The Biology and Ecology of Rice (*Oryza sativa L.*) in Australia
- The Biology and Ecology of Pineapple (*Ananas comosus var. comosus*) in Australia
- The Biology and Ecology of *Torenia spp. (torenia)* in Australia
- The Biology and Ecology of Carnation (*Dianthus caryophyllus L.*) in Australia
- DIR 093 Risk Assessment and Risk Management Plan for limited and controlled release of wheat and barley genetically modified for altered grain starch composition

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
April	93	132
May	129	108
June	159	107

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 while monitoring staff are away from the office. The inbox received 121 emails during the quarter.

Statutory Committee email inbox

The Regulatory Practice and Secretariat Section maintains 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 172 emails during the quarter.

Application and Licence Management email inbox

This electronic mail inbox provides a central, shared communication point to allow efficient coordination of responses for correspondence and queries about applications received by the Application and Licence Management Section. The inbox received 535 emails during the quarter.



APPENDICES

APPENDIX 1:

DNIR licences issued 1 April to 30 June 2009

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR-453	19 April 2009	The University of Queensland, QLD	Investigations into the role of novel genes at the level of the cell and animal	The purpose of this dealing is to use replication defective lentiviral vectors in vitro and in vivo as a tool to investigate the function of genes involved in eukaryotic tissue, organ and organism development.
DNIR-458	6 April 2009	CSIRO, Victoria	Pathogenicity of J paramyxovirus (JPV) and Beilong paramyxovirus (BeiPV)	The purpose of this dealing is to generate recombinant J Paramyxovirus and Beilong Paramyxovirus including changes in viral genes or non-coding regions to determine their influence on pathogenicity

DNIR-459	14 April 2009	Children, Youth and Women's Health Service, South Australia	Molecular mechanisms of bone growth	The purpose of this dealing is to use replication defective lentiviral vectors in vitro and in vivo as a tool to investigate the function of genes involved in bone growth or repair.
DNIR-461	26 June 2009	PPD Australia Pty Ltd, Victoria	A randomized phase 3 clinical trial to evaluate the efficacy and safety of treatment with OncoVEX compared to subcutaneously administered GM-CSF in previously treated melanoma patients with unresectable stage IIIb, IIIc and IV disease	The purpose of the dealings is to undertake the Australian arm of a multi-national, phase III clinical trial in melanoma patients with unresectable disease.

APPENDIX 2:

Gene Technology Technical Advisory Committee COMMUNIQUÉ 22 April 2009, Canberra

This is the 25th communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 35th meeting of GTTAC, held on 22 April 2009.

GTTAC is a statutory advisory committee established under the *Gene Technology Act 2000* (the Act) to provide scientific and technical advice 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 advice from GTTAC on Risk Assessment and Risk Management Plans (RARMPs) prepared in respect of applications for licences to conduct dealings with genetically modified organisms (GMOs).

The purpose of this Communiqué is to provide a brief overview of the applications and RARMPs considered by GTTAC and, in accordance with Regulation 29 of the Gene Technology Regulations 2001, any resolutions the Committee has provided to the Regulator with regard to those applications and RARMPs.

The Communiqué also provides an overview of any other major issues discussed by GTTAC.

Dealings Involving the Intentional Release of Genetically Modified Organisms

Dealings Involving the Intentional Release of GMOs (DIRs) involve the limited and controlled release (field trial) of a GMO or a commercial (general) release of a GMO.

The RARMP for every DIR licence application is released for public comment as part of the consultation process. Information on how to obtain copies of applications and RARMPs for DIRs is provided at the end of this document.

GTTAC Advice

The Regulator must seek GTTAC advice on RARMPs prepared in respect of all DIR applications.

The Regulator must also seek GTTAC advice during the preparation of the RARMP for all DIR applications which are not assessed as 'limited and controlled' under Section 50A of the Act.

Advice on Consultation RARMP—Commercial Release

GTTAC considered the consultation RARMP prepared in response to the following commercial release application:

DIR 090—Commercial release of rose genetically modified for altered flower colour

The application, from Florigene Pty Ltd, involves the commercial release of a Hybrid Tea Rose genetically modified to alter flower colour from pink to purple/blue. When GTTAC's advice was sought during the preparation of the RARMP they advised that the risk assessment should be done on the assumption that, if released commercially, the GM rose would be widely grown in home gardens. The committee also advised that there is potential for exposure of humans and animals to products derived from the GM flowers, but that no issues were identified which might give rise to adverse outcomes. The committee noted that these points had been included in the consultation RARMP.

RESOLUTION: *GTTAC advised the Regulator that the RARMP for DIR 090 adequately identifies and addresses risks to people and to the environment and that they had nothing to add to the advice given at their previous meeting (Meeting 34, 15 October 2008)*

Advice on Consultation RARMPs—Limited and Controlled Release

GTTAC considered the Consultation RARMPs prepared in response to the following applications for limited and controlled releases:

DIR 092—Limited and controlled release of wheat genetically modified for altered grain composition

The application, from CSIRO, involves the release of 16 lines of wheat which have been genetically modified for altered grain composition, on a limited scale and under controlled conditions. The trial is proposed to take place at one site in the Australian Capital Territory. GTTAC agreed that the RARMP for DIR 092 adequately identifies and addresses risks to people and the environment.

RESOLUTION: *GTTAC advised the Regulator that the following items should be considered when finalising the Risk Assessment and Risk Management Plan:*

- *Consider how best to ensure conditions that would adequately stimulate the germination of volunteers in the last six months of the monitoring period; and*
- *Consider defining the amount of soil moisture necessary to promote germination of volunteers post-harvest.*

DIR 093—Limited and Controlled Release of wheat and barley genetically modified for altered grain starch composition

This application, also from CSIRO, involves the release of three lines of wheat and one line of barley, genetically modified for altered grain starch composition, on a limited scale and under controlled conditions. The trial is proposed to take place at one site in the Australian Capital Territory. GTTAC noted that the application includes proposed human nutritional trials, which would require approval from a Human Research Ethics Committee (HREC). GTTAC agreed that the RARMP for DIR 093 adequately identifies and addresses risks to human health and safety and risks to the environment from the proposed release.

RESOLUTION: GTTAC advised the Regulator that the following items should be considered when finalising the Risk Assessment and Risk Management Plan:

- *Consider how to ensure conditions that would adequately stimulate the germination of volunteers in the last six months of the monitoring period;*
- *Consider requiring that proposed human nutritional trials be endorsed by an independent HREC; and*
- *Consider defining the amount of soil moisture necessary to promote germination of volunteers post-harvest.*

OTHER ADVICE

Dealings Not Involving the Intentional Release of Genetically Modified Organisms

Dealings not involving the intentional release of GMOs (DNIRs) are dealings that are usually undertaken within a facility where the organism is physically contained.

DNIR 461—Phase 3 clinical trial with Oncovex^{GM-CSF} compared to subcutaneously administered GM-CSF.

GTTAC considered the RARMP prepared by the Regulator in response to an application from PPD Australia Pty Ltd. The application concerns a randomised phase 3 clinical trial to evaluate the efficacy and safety of treatment of melanoma with a genetically modified human herpesvirus 1 JS1 strain (Oncovex^{GM-CSF}). Treatment with the GM virus will be compared with subcutaneously administered Granulocyte Macrophage Colony Stimulating Factor (GM-CSF). The trial will involve previously treated melanoma patients with unresectable Stage IIIb, IIIc and IV disease. GTTAC discussed possible risks to health and safety of clinical staff administering the GMO and noted that the GM virus would be severely weakened and would be unlikely to cause infection in healthy people

RESOLUTION: *In relation to the RARMP for DNIR 461 GTTAC advised that the Regulator:*

- *Should seek further information from the applicant regarding the capacity of the GM virus for replication; and*
- *Should consider the risk to health and safety of clinical staff administering the GMO as low rather than negligible*

GTTAC also advised that consideration be given to recommending:

- *double gloving for persons administering the GM virus;*
- *a training log to be kept for approved personnel;*
- *prophylactic treatment (acyclovir) to be immediately available to clinical staff in the event of exposure to the GM virus; and*
- *treated trial subjects to be advised to avoid contact with the aged and newborns*

NB: Safety issues related to participants form part of the ethical and scientific review of clinical trials conducted by Human Research Ethics Committees prior to endorsement. In addition, the TGA may seek additional information and clarification about safety or other aspects of clinical trials that are notified as part of the CTN/CTX process.

REVIEW OF THE GENE TECHNOLOGY REGULATIONS 2001

GTTAC received a report on progress in the review of the Gene Technology Regulations 2001, including an analysis of submissions from the regulated community on potential areas of amendment. GTTAC noted that an Out of Session package seeking advice on proposals for amendments being considered would be sent to members before the next meeting. The committee also noted that, following feedback from GTTAC and policy approval by the Gene Technology Ministerial Council (GTMC), detailed drafting instructions will be provided to the Office of Legislative Publishing and Drafting in the Attorney-General's Department. GTTAC will be consulted on the draft amendment regulations when ready.

RESOLUTION: *GTTAC advised the Regulator that they strongly supported the proposed clarification of language describing pathogenicity and pathogenic characteristics of hosts and vectors in Schedules 2 and 3 of the Regulations.*

ENQUIRIES AND RISK ASSESSMENT AND RISK MANAGEMENT PLANS

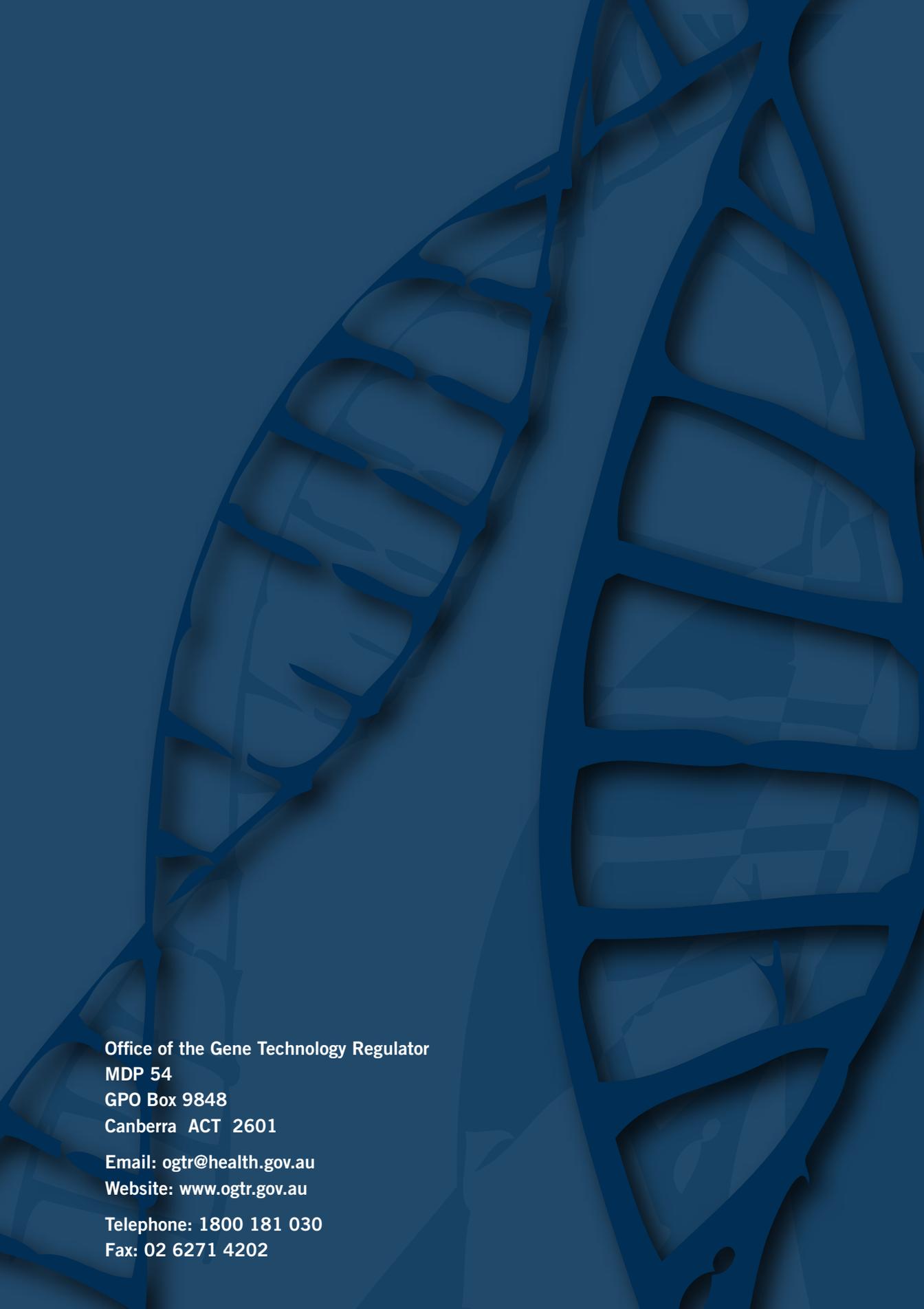
For all enquiries and to obtain copies of applications or RARMPs for dealings involving the intentional release of GMOs into the environment, please phone the OGTR on 1800 181 030. The RARMPs are also available electronically from our website at <http://www.ogtr.gov.au>

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	<i>Gene Technology Act 2000</i>
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 (e.g. 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 <u>not</u> involving intentional release of the GMO into the environment (e.g. 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 GTECCC 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
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 (e.g. 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



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

Email: ogtr@health.gov.au
Website: www.ogtr.gov.au

Telephone: 1800 181 030
Fax: 02 6271 4202