



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 JULY–30 SEPTEMBER 2006

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’



OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT
1 JULY–30 SEPTEMBER 2006



ISBN: 0-642-82639-0

Online ISBN: 0-642-82962-4

Print Copyright

© Commonwealth of Australia 2006

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, Canberra ACT 2600 or posted at <http://www.ag.gov.au/cca>

Online Copyright

© Commonwealth of Australia 2006

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, Canberra ACT 2600 or posted at <http://www.ag.gov.au/cca>

This report can be accessed through the Internet at <http://www.ogtr.gov.au>

Produced by:

Office of the Gene Technology Regulator
MDP 54 PO Box 100
WODEN ACT 2606

Email: ogtr@health.gov.au
Website: <http://www.ogtr.gov.au>
Telephone: 1800 181 030
Fax: (02) 6271 4202

Inquiries about the content of this report may be directed to the Policy, Communications and Secretariat Section of the Office of the Gene Technology Regulator.

Commonwealth Department of Health and Ageing

Publications Approval Number 3625

The Hon Christopher Pyne MP
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 Gene Technology Regulator, covering the period 1 July to 30 September 2006.

During this quarter, key achievements included the issuing of 2 licences for dealings involving the intentional release of genetically modified organisms (GMOs), 5 licences for dealings not involving intentional release of GMOs, and the certification of 37 physical containment facilities.

Routine monitoring activities for this quarter have again been well above the minimum target rate and no significant risks to either human health or the environment were identified.

The ongoing review of the guidelines for certification of contained facilities resulted in the issuing of new guidelines for Physical Containment Level 3 (PC3) laboratories, PC2 aquatic organism and PC2 arthropod facilities, and PC1 and 2 large scale production facilities on 1 September 2006.

Yours sincerely



(Dr) Sue D Meek
Gene Technology Regulator
12 December 2006

CONTENTS

GLOSSARY	vii
INTRODUCTION	1
Structure of this report	1
Further information	1
PART 1 NATIONAL REGULATORY SYSTEM	2
Key achievements during this quarter	4
Licences and other instruments	4
Monitoring and compliance	4
Working collaboratively with States and Territories	4
State and Territory consultation	4
Australian Government agency liaison	4
Public participation	5
PART 2 REGULATION OF GENETICALLY MODIFIED ORGANISMS	7
Applications received and decisions made	8
New licences and other instruments	9
Processing of applications for Dealings involving Intentional Release (DIR) licences	9
Applications received for DIR licences	10
Consultation on applications for DIR licences	10
Withdrawn applications for DIR licences	11
Surrendered applications for DIR licences	11
Clock stopped on DIR licence applications	11
Decisions on applications for DIR licences	12
Decisions on applications for Dealings Not involving Intentional Release (DNIR) licences	12
Notifications of notifiable low risk dealings (NLRD) received	12
Existing licences and other instruments	12
Confidential commercial information (CCI)	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 releases	15
Monitoring of physical containment facilities	16

Monitoring findings	17
Physical containment facilities	19
Practice Reviews	19
Audits	20
Investigations	20
PART 3 COMMITTEE OPERATIONS	21
Gene Technology Technical Advisory Committee	22
Gene Technology Community Consultative Committee	22
Gene Technology Ethics Committee	22
PART 4 OTHER ACTIVITIES	23
Reviews	24
International collaboration and coordination	24
Advice on gene technology regulation	24
Presentations	24
Meetings and workshops	24
Institutional Biosafety Committee (IBC) Training	25
National Strategy for Unintended Presence of Unapproved GMOs	25
OGTR website	25
OGTR email address and freecall number	26
Freedom of information	26
APPENDICES	
Appendix A: DNIR Licences issued July to September 2006	28
Appendix B: Gene Technology Community Consultative Committee	29
Appendix C: Gene Technology Ethics Committee	31

GLOSSARY

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 the statutory time limit for making a decision on an application is suspended — 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 <i>not</i> 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)
FSANZ	Food Standards Australia New Zealand
GM	Genetically modified
GM product	A thing (other than a GMO) derived or produced from a GMO
GMO	Genetically modified organism

GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics 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
NLRD	Notifiable low risk dealing (e.g. plant or tissue culture work undertaken in a certified containment facilities)
Non-compliance	An inconsistency between an event or state of affairs and the requirements imposed by licence conditions
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	<i>Gene Technology Regulations 2001</i>
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

INTRODUCTION

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:

- genetically modified organism (GMO) licences issued during the quarter
- any breaches of conditions of a GMO licence 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.

Structure of this report

This report is divided into four parts:

Part 1 outlines activities and outcomes achieved in relation to the implementation and management of the national regulatory system during the July to September 2006 quarter.

Part 2 details 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.

Part 3 reports on the activities of the three advisory committees established under the Act to assist the Regulator and the Gene Technology Ministerial Council (GTMC).

Part 4 summarises other activities undertaken by the Office of the Gene Technology Regulator (OGTR), including reviews and research, international collaboration and coordination, advice provided on gene technology regulation and freedom of information requests received.

Further information

Further information about regulation of GMOs can be obtained by contacting:

Office of the Gene Technology Regulator
MDP 54 PO Box 100
WODEN ACT 2606

Email: ogtr@health.gov.au
Website: <http://www.ogtr.gov.au>
Telephone: 1800 181 030
Fax: (02) 6271 4202



PART 1

NATIONAL REGULATORY SYSTEM



Key achievements during this quarter

The key achievements of the July to September 2006 quarter were:

Licences and other instruments

- 2 licences issued for dealings involving the intentional release of GMOs into the environment (DIR licences).
- 5 licences issued for dealings not involving intentional release of GMOs into the environment (DNIR licences).
- 106 Notifiable Low Risk Dealing (NLRD) notifications received.
- 37 containment facilities certified.
- 18 surrenders of certifications processed.
- 73 variations processed.

More information on licences and other instruments is contained in Part 2 of this report.

Monitoring and compliance

Approximately 29 per cent of current field trial sites and 15 per cent of post harvest field trial sites were subjected to routine monitoring during the quarter. This exceeds the target minimum rate of five per cent per quarter.

Further information on monitoring and compliance is contained in Part 2.

Working collaboratively with States and Territories

State and Territory consultation

The Regulator must consult with State and Territory Governments and relevant local councils twice during the evaluation of applications for DIR licences.

For each application for a DIR licence, 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.

More information is contained in Part 2.

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. Advice is sought on matters relevant to preparing the RARMP for each application made to the Regulator for a DIR licence.

In this context, the Regulator consults with the following prescribed Australian Government authorities and agencies:

- Food Standards Australia New Zealand
- Australian Quarantine and Inspection Service
- National Health and Medical Research Council
- National Industrial Chemicals Notification and Assessment Scheme
- Australian Pesticides and Veterinary Medicines Authority
- Therapeutic Goods Administration.

Once a DIR RARMP is prepared, the Regulator again seeks comment on the RARMP from the same prescribed Australian Government authorities and agencies.

In addition, comment is sought on each DIR licence application and 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 and Heritage
- Department of Foreign Affairs and Trade
- Department of Industry, Tourism and Resources.

During the quarter, the Regulator sought advice and comment in respect of three applications for DIR licence and one RARMP.

Further information is set out in Part 2.

Public participation

During the quarter, the Regulator issued invitations to the public to comment on RARMPs prepared in response to four DIR licence applications. The invitations were issued via email or posted to people who have registered on the OGTR mailing list and via advertisements in:

- the *Australian Government Notices Gazette*
- The Australian and Weekend Australian
- relevant regional press such as
 - *The Land, Queensland Country Life, The Northern Territory News, The West Australian, Country Leader, The Courier, The Countryman, and The Weekly Times*
- OGTR website <http://www.ogtr.gov.au>

Further information is set out in Part 2.

A grayscale, high-magnification image of plant cells, showing a network of cell walls and internal structures. The cells are arranged in a somewhat regular pattern, with some larger, more rounded cells and some smaller, more elongated ones. The overall appearance is that of a cross-section of a plant stem or leaf, with the cell walls forming a complex, interconnected lattice.

PART 2

**REGULATION OF GENETICALLY
MODIFIED ORGANISMS**

Part 2 of the report outlines the regulatory activity undertaken during the July to September 2006 quarter. This includes information about applications for GMO licences and other instruments under 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 the number of confidential commercial information (CCI) applications has also been provided.

Applications received and decisions made

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

- **Dealings involving Intentional Release (DIR) licences**

DIR licences authorise dealings ranging from limited and controlled releases (field trials) through to more extensive commercial releases of GMOs. These licence applications have a statutory timeframe of 170 working days for processing.

- **Dealings Not involving Intentional Release (DNIR) 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**

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.

Applications received and decisions made, new licences and other instruments 1 July to 30 September 2006

Application type	Number received	Number approved ¹
DIR licence	0	2
DNIR licence	11	5
Accreditations	7	1
Certifications	50	37
GMO Register	0	0

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

Processing of applications for Dealings involving Intentional Release (DIR) 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 proposed dealings may pose a significant risk to human health and safety and the environment
- seeking comments from prescribed expert groups and key stakeholders (including the public if a significant risk is identified) on issues to consider in the RARMP
- preparing a consultation RARMP, including proposed licence conditions to manage risks to human health and safety and the environment
- considering all comments relating to the protection of human health and safety and the environment in finalising the RARMP
- consideration of the applicant's suitability, policy principles and any relevant policy guidelines.

Once these actions are completed, the Regulator can make a decision on whether to grant a licence and the conditions which are to be included in any licence.

The Regulator must make a decision on an application for a DIR licence within 170 working days of receiving the application. This timeframe effectively extends over approximately nine months as the statutory period excludes weekends and public holidays as observed in the Australian Capital Territory (ACT).

This time limit may be extended, that is, the application 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 minimum timeframes for the two rounds of consultation that the Regulator must undertake with prescribed expert groups and key stakeholders during the processing of each DIR application. However, longer periods of consultation are usually allowed to facilitate the provision of information and promote involvement in the decision-making process particularly by the community. Therefore 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 for DIR licences subject to evaluation during the quarter

Application received	First round of consultation ¹	Second round of consultation	Withdrawn applications	Licence Issued
Nil	DIR 070/2006	DIR 064/2006	Nil	DIR 062/2005
		DIR 065/2006		DIR 063/2005
		DIR 066/2006		
		DIR 067/2006		

1. Includes posting of 'Early Bird' Notification and summary of application on the OGTR website and to people on the OGTR mailing list.

Applications received for DIR licences

The OGTR received no applications for DIR licences in the July to September 2006 quarter.

Consultation on applications for DIR licences

In this quarter, consultations with expert groups and key stakeholders took place as part of first-round consultations to help identify risks to human health and safety and/or the environment to be considered in the RARMP for the following application:

- DIR 070/2006 — Limited and controlled release of GM sugarcane with altered plant architecture, drought tolerance and nitrogen use efficiency — BSES Limited

Although not required by the Act, the Regulator also issued an ‘Early Bird’ Notification to people and organisations on the OGTR’s mailing list to advise receipt of the application and when the RARMP is expected to be released for public comment.

The Regulator invited comment from expert groups and key stakeholders, including the public, as part of the consultations on a RARMP for the following applications:

- DIR 064/2006 — Limited and controlled release of water-efficient GM cotton — Monsanto Australia Limited
- DIR 065/2006 — Limited and controlled release of GM insect resistant (VIP3A and /or Cry1Ab) cotton — Deltapine Australia Pty Ltd
- DIR 066/2006 — Commercial release of GM herbicide tolerant and/or insect resistant cottons north of latitude 22° South — Monsanto Australia Limited
- DIR 067/2006 — Limited and controlled release of GM cotton lines with tolerance to waterlogging stress — CSIRO

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 applications for DIR licences

No DIR licence applications were withdrawn this quarter

Surrendered applications for DIR licences

No DIR licences were surrendered during this quarter.

Clock stopped on DIR 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.

There were two clock stop periods that applied to DIR licence applications during this quarter:

- DIR 061/2005 — Field testing of genetically modified salt tolerant wheat on saline land — Grain Biotech Australia Pty Ltd
- DIR 069/2006 — Field trial of herbicide tolerant GM hybrid *Brassica napus* and hybrid *Brassica juncea* lines — Bayer CropScience Pty Ltd

Decisions on applications for DIR licences

During the quarter, the Regulator issued two DIR licences:

- DIR 062/2005 — Commercial release of herbicide tolerant Liberty Link® Cotton for use in the Australian cropping system — Bayer CropScience Pty Ltd
- DIR 063/2005 — Limited and controlled release of fungal resistant GM cotton — Hexima Limited

Finalised RARMPs and copies of issued licences are available from the OGTR website or can be obtained by contacting the OGTR.

Decisions on applications for Dealings Not involving Intentional Release (DNIR) 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 five DNIR licences. Further information about these licences is contained in Appendix A of this report.

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

Notifications of notifiable low risk dealings (NLRD) received

The Act requires organisations to notify the Regulator when conducting NLRDs.

This category of dealings with GMOs is defined in the Gene Technology Regulations 2001 and has been assessed as posing low risks based on previous national and international experience. NLRDs must comply with certain risk management conditions and be contained in facilities deemed suitable by the Regulator.

NLRDs are assessed by the submitting organisation's Institutional Biosafety Committee (IBC) and do not require approval by the Regulator. The OGTR checks notifications for compliance with legislative requirements.

The Regulator received 106 NLRD notifications in the quarter. A listing of NLRDs and their date of notification is available from the OGTR website.

Existing licences and other instruments

The Regulator can, directly or upon application, vary an issued licence or other instrument. For example, the Regulator can vary a licence to better manage risks if new information or data comes to light. Variations involve changes to conditions applied to an instrument or a licence. Most variations are made at the request of the instrument/licence holder. However, the Regulator must not vary the licence unless the Regulator 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.

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 surrender or vary existing licences and other instruments, as well as the number of applications processed during the July to September 2006 quarter.

**Applications received and decisions made — existing licences and other instruments
1 July to 30 September 2006.**

Type	Number received	Number processed ¹
Surrender of certification	20	18
Surrender of DIR licence	2	0
Surrender of DNIR licence	2	1
Surrender of accreditation	1	0
Variation of certification	110	49
Variation of accreditation	1	0
Variation of DIR licence	6	3
Variation of DNIR licence	12	21

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

Confidential commercial information (CCI)

Under s.184 of the Act a person may apply to the Regulator in accordance with s.185 for specified information to be declared CCI. 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 at <http://www.ogtr.gov.au>

During the quarter, the Regulator received and made a declaration concerning one CCI application relating to a DIR licence. The Regulator also received one CCI application relating to a DNIR licence 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 Section focuses on management of dealings at field trial sites and within containment facilities 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.

Monitoring and compliance strategy

OGTR monitoring and compliance activities comprise the functions of routine monitoring, reviews of potential risks, investigations and audits.

The OGTR conducts routine monitoring visits of a minimum of 20 per cent of field trial sites each year.

A minimum of five per cent of current trial sites and five per cent of trial sites subject to post-harvest monitoring are monitored each quarter.

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 containment facilities involves inspecting and monitoring:

- a minimum of 20 per cent of physical containment PC4, PC3 and PC2 large-scale facilities per year
- selected PC2 and PC1 facilities.

These inspections focus on the integrity of the physical structure of the facility and on the general laboratory practices followed in that facility.

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored: During the July to September 2006, 19 field trial sites were subjected to monitoring visits.

Current field trial sites monitored: Of the 21 sites current in the quarter, 6 were monitored. This represents a monitoring rate of 29 per cent of all current sites for the quarter.

Post-harvest field trial sites monitored: Of the 87 sites subject to post-harvest monitoring in the quarter, 13 were monitored. This represents a monitoring rate of 15 per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified containment facilities: Monitoring in connection to contained dealings covered 11 organisations and 32 PC facilities. Monitoring of PC facilities encompassed PC2 laboratories (18 visited), PC2 animal containment facilities (3 visited), and PC2 plant containment facilities (6 visited).

Monitoring of contained dealings: During the July to September 2006 quarter, monitoring of the 32 PC facilities mentioned above also included monitoring for compliance with the general practices that must be followed when undertaking dealings that are required to be conducted in containment, PC2 aquatic organism containment (one visited), PC3 laboratories (3 visited), and a PC3 insectary (1 visited).

Monitoring of dealings involving intentional releases

The following table shows the total monitoring coverage for field trial sites 1 July to 30 September 2006

Licensed Organisation Name	Licence Number	No. sites visited	Site status ¹	Crop type
Department of Primary Industries	DIR 047/2003	1	C	White Clover
Dow AgroSciences Australia Pty Ltd	DIR 044/2003	4	PHM	Cotton
Hexima Ltd	DIR 048/2003	2	PHM	Cotton
Monsanto Australia Ltd	DIR 012/2002	6	PHM	Cotton
		2	C	Cotton
		3	C	Cotton
	DIR 055/2004	1	PHM	Cotton
Totals	5	19	C= 6 PHM= 13	2 types

1. C = current, PHM = post-harvest monitoring

Monitoring of physical containment facilities

The organisations and the facility types the OGTR visited during this quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
University of Sydney	PC2 Laboratory	5
	PC2 Animal Containment	1
University of Wollongong	PC2 Laboratory	5
	PC2 Animal Containment	1
Victor Chang Cardiac Research Institute	PC2 Animal Containment	1
	PC2 Aquatic Organism Containment	1
Sydney-West Area Health Service Westmead Millenium Institute	PC2 Laboratory	4
Pacific Seeds Pty Ltd	PC2 Plant Containment	1
Monsanto Australia Limited	PC2 Plant Containment	1
University of Southern Queensland	PC2 Laboratory	1
	PC2 Plant Containment	1
Department of Primary Industries	PC2 Laboratory	1
	PC2 Plant Containment	3
University of Ballarat	PC2 Laboratory	2
Department of Primary Industry, Fisheries and Mines (NT) ²	PC3 Laboratory	2
	PC3 Insectary	1
Menzies School of Health Research ²	PC3 Laboratory	1
Totals	6 facility types	32

2. Inspections performed jointly with Contained Dealings Evaluation Section

Monitoring findings

Dealings involving intentional release

The Monitoring findings listed below are designed to indicate both the monitoring activities of the OGTR with respect to DIRs 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 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 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.

Organisation	Dow AgroSciences Australia Pty Ltd
Licence number and site	DIR 044/2003, Site 6 & 16
Summary of dealing	Licence relates to field trial of cotton (<i>Gossypium hirsutum</i>) genetically modified by introduction of genes to confer tolerance to herbicide and/or resistance to insect pests.
Findings	At the time of the inspection OGTR staff observed that this site was on the Dalby Shire side of the Dalby–Wambo LGA boundary road (Ashmore Road). According to this licence, the GMOs may not be grown in Dalby Shire but may be grown in the Wambo Shire. Dalby Shire is completely surrounded by Wambo Shire. The sites were in post harvest monitoring phase.
Assessment	It was ascertained that Dow AgroSciences believed that sites 6 and 16 were located in Wambo Shire rather than Dalby Shire. This mistake occurred mainly because the sites were located in close proximity to the boundary between the Shires. Risks to human health and safety and the environment as a result of this non-compliance were negligible.
Compliance management	No immediate action was required (because no GMOs were present). The licence holder sought a variation to the Licence to allow further plantings at the sites. Dalby Shire was consulted regarding its inclusion as an approved planting area. A variation to the Licence to include Dalby Shire as a permitted growing area was made to allow further plantings at these locations.
Organisation	Monsanto Australia Ltd (Monsanto)
Licence number and site	DIR 012/2002 sites 27 and 36
Summary of dealing	Licence relates to commercial release of insect resistant Bollgard II® and insect resistant/ herbicide tolerant Bollgard II®/Roundup Ready® cotton south of latitude 22° South and limited and controlled release north of latitude 22° South.
Findings	On 29 September 2006 Monsanto reported to the OGTR that a notice of forecasted date of flowering at the field trial sites in northern Australia had not been provided to the Regulator within the required timeframe. The DIR 012/2002 licence requires notice at least 7 days prior to the forecasted date of flowering. Flowering occurred in late June and early July respectively for these sites.

Organisation	Dow AgroSciences Australia Pty Ltd
Assessment	The lack of notification had been an oversight and was not a deliberate omission. The risk to human health and safety and the environment was assessed as negligible.
Compliance management	Monsanto was reminded of its notification obligations. No further action was taken.

Dealings not involving intentional release

During the quarter no inspections were carried out against the conditions of any DNIR licence.

Physical containment facilities

OGTR's monitoring of certified PC facilities in the quarter found a number of acts or omissions which the Regulator regarded as minor non-compliances with certification conditions which are summarised in the table below. 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	Transport
32	8	0	0	6	1	12

1. PPE = Personal Protective Equipment

Practice Reviews

The Monitoring and Compliance Section 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 July to September 2006 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 (eg, 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 July to September 2006 quarter.

Investigations

An investigation is an inquiry into a suspected non-compliance with the Act and corresponding state and territory 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 one investigation completed in the July to September 2006 quarter.

The OGTR received a report from a member of the public alleging that a company was conducting dealings with GMOs in contravention of the *Gene Technology Act 2000*. The OGTR visited the company and determined the dealings were exempt dealings as classified under Schedule 2, Part 2 of the *Gene Technology Regulations 2001* and were being conducted as required in facilities that met criteria for a PC1 laboratory under the Australian/New Zealand Standard 2243.3:2002 Safety in Laboratories.

Such dealings do not require licensing or notice under the Act and the investigation concluded that the allegation was unsubstantiated.



PART 3

COMMITTEE OPERATIONS

The Act established three advisory committees:

- The **Gene Technology Technical Advisory Committee**
 - provides scientific and technical advice to the Regulator and the GTMC
- The **Gene Technology Community Consultative Committee**
 - provides advice on matters of general concern to the community, in relation to GMOs, to the Regulator and the GTMC
- The **Gene Technology Ethics Committee**
 - provides advice on ethical issues relating to gene technology to the Regulator and the GTMC

Gene Technology Technical Advisory Committee

The Gene Technology Technical Advisory Committee (GTTAC) held its 28th meeting on 19 September 2006 in Canberra. The Committee also considered items out-of-session in July 2006 and August 2006.

Further information about the work of the GTTAC including its communiqués, is available on the OGTR website <http://www.ogtr.gov.au>

Gene Technology Community Consultative Committee

The Gene Technology Community Consultative Committee (GTCCC) held its first meeting on 23 August 2006 in Canberra. The Committee established two working groups to look at the issues of community consultation processes and consultation with local government authorities.

The 9th GTCCC communiqué summarising discussion held at the August meeting is available in Appendix C.

Further information about the work of the GTCCC is available from the OGTR website <http://www.ogtr.gov.au>

Gene Technology Ethics Committee

The Gene Technology Ethics Committee (GTEC) held a face-to-face meeting in Canberra on 25 July 2006. The Committee progressed the working group paper on 'Environmental Ethics and Gene Technology', and discussed the official, public launch of the *National Framework for the Development of Ethical Principles in Gene Technology*.

The 12th GTEC communiqué regarding the July meeting is available in Appendix D.

Further information about the work of the GTEC is available on the OGTR website <http://www.ogtr.gov.au>



PART 4

OTHER ACTIVITIES

Reviews

Review of the *Guidelines for the Certification of Facilities/Physical Containment Requirements* — the Regulator issued revised guidelines for PC3 Laboratory facilities, PC1 and PC2 Large Scale facilities, PC2 Aquatic Organism facilities, and PC2 Arthropod facilities (replacing PC2 Insectaries) on 1 September 2006.

Review of the *Guidelines for the Transport of GMOs* — during this quarter an OGTR working group was established to draft revisions to the transport guidelines.

International collaboration and coordination

Under the Act, two of the Regulator's functions are to monitor international practice in relation to regulation of GMOs, and to maintain links with international organisations that regulate GMOs in countries outside Australia.

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

- the International Association of Bioethics 2006, 8th World Congress of Bioethics, 6–9 August 2006, Beijing, China.
- the 9th International Symposium on Biosafety of GMOs, 24–29 September 2006, Jeju Island, South Korea.

Advice on gene technology regulation

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

Presentations

During the quarter, OGTR officers made presentations to:

- the Australian Society for Microbiology Conference, 2–7 July 2006, Gold Coast
- the Society for Risk Analysis Conference, 17–19 July 2006, Melbourne
- Biotechnology in Context — The Australian National University, 3 August 2006, Canberra
- the Australian and New Zealand Society for Laboratory Animal Science, 6–8 September 2006, Canberra

Meetings and workshops

OGTR officers hosted an information booth at the following conference:

- ComBio2006, 24–28 September 2006, Brisbane

Institutional Biosafety Committee (IBC) Training

The OGTR conducts training sessions for accredited organisations and their IBCs. During the quarter training sessions were provided to the Menzies School of Health IBC in Darwin.

National Strategy for Unintended Presence of Unapproved GMOs

An interdepartmental working group established by the Australian Government Biotechnology Ministerial Council and chaired by Biotechnology Australia has developed a risk based strategy for managing the unintended presence of unapproved GMOs. The OGTR has been asked to implement the strategy.

The OGTR is liaising closely with the Australian Seeds Federation on the development of a voluntary auditing and testing program of existing industry quality assurance measures. Agreement has been reached on the auditing and testing program, which will commence before the end of this year.

OGTR website

The most popular pages on the OGTR website during the quarter were:

- Home Page
- What's New
- Handbook on the Regulation of Gene Technology in Australia
- About the OGTR
- GMO Record
- Intentional Release and Evaluation Processes

The most popular downloads were:

- *Risk Analysis Framework*
- Handbook on the Regulation of Gene Technology in Australia
- The Biology and Ecology of Pineapple (*Ananas comosus var. comosus*) in Australia
- The Biology and Ecology of Carnation (*Dianthus caryophyllus*) in Australia
- OGTR Media Releases
- The Biology and Ecology of Wheat (*Triticum aestivum L.*) in Australia
- Consultation RARMP for DIR 066/2006 Commercial release of GM herbicide tolerant and/or insect resistant cotton lines north of latitude 22° South

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

OGTR email address and freecall number

The 1800 number and the OGTR email address are points of contact for members of the public and other interested parties. 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 OGTR email address received 117 emails in July 2006, 144 emails in August 2006, and 156 emails in September 2006.

Due to upgrading of the PABX system, the number of calls to the OGTR 1800 number for July and August are not available. In September 2006, 148 calls were received.

Freedom of information

No freedom of information requests were received by the OGTR during the quarter.



APPENDICES

APPENDIX A

DNIR Licences issued July to September 2006

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 387/2006	21 July 2006	CSIRO (AAHL), Victoria	Identification of virulence factors for infectious bursal disease virus (IBDV)	Recombinant strains of infectious bursal disease virus (IBDV) will be used to identify the virulence factors that make IBDV pathogenic to chickens.
DNIR 386/2006	24 July 2006	Institute of Drug Technology Australia Ltd, South Australia	Clinical trials to determine the safety, immunogenicity/efficacy and tolerability of ChimeriVax™ Dengue tetra-valent vaccine	The purpose of this dealing is to conduct a Phase IIa clinical trial of ChimeriVax™-DEN, a tetravalent, live, attenuated, chimeric, genetically modified vaccine against dengue virus.
DNIR 388/2006	1 September 2006	Baker Heart Research Institute, Victoria	Virus-mediated approaches to examine cardiovascular disease <i>in vitro</i> and <i>in vivo</i>	This project utilises virus-based gene delivery to examine the processes that control the function of the heart and circulation in health and disease.
DNIR 389/2006	1 September 2006	University of Canberra, Australian Capital Territory	Mechanisms of Ross River viral disease	The aim of the proposed dealings is to study the pathogenesis of Ross River virus-induced polyarthritis in a mouse model.
DNIR 400/2006	22 September 2006	Cargill Australia Limited, New South Wales	Canadian canola seed import for further processing at Newcastle	The aim of the dealing is to import Canadian canola seed into Newcastle, NSW, Australia, for crushing in order to supply domestic oil and meal demands.

APPENDIX B

Gene Technology Community Consultative Committee Meeting

23 August 2006, Canberra

COMMUNIQUÉ

The Gene Technology Community Consultative Committee (GTCCC) held its ninth meeting in Canberra on 23 August 2006.

GTCCC 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 hold office on a part-time basis.

The new membership of GTCCC was appointed by the Parliamentary Secretary to the Minister for Health and Ageing, the Hon Christopher Pyne, for the term from 1 July 2006 to 30 June 2007. The new membership of the Committee held its first meeting on 23 August 2006. The new members were welcomed to GTCCC and gave introductory statements about themselves. The members received reports on the operations and activities of the Office of the Gene Technology Regulator (OGTR), and on the financial procedures and operating procedures of the Committee. The members also received a presentation on public perceptions of gene technology from a representative of Biotechnology Australia.

GTCCC's Work Plan

Community Consultation and Participation

Members considered the discussion paper on *Community Consultation and Participation*, which was prepared by the previous GTCCC membership. The Committee resolved to form a working group to consider the recommendations of the paper and ways in which they may be put into practice.

Consultation with Local Government Authorities

As part of discussion about potential projects for the new Committee to undertake, members identified consultation with Local Government Authorities (LGAs) about gene technology issues as a priority area. The Committee resolved to form a working group to develop a strategy for enhancing communication between the OGTR and LGAs.

Review of the Gene Technology Act 2000

The Committee discussed the recommendations of the *Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement**. The Committee discussed in particular the recommendation that GTCCC and the Gene Technology Ethics Committee (GTEC) be combined. The Committee resolved to discuss this recommendation in more detail at the next meeting and consider drawing up a statement about the work it would like to see continued if the recommendation is approved by the Government and implemented.

* More information about the Review is available on the Gene Technology Ministerial Council's website at <http://www.health.gov.au/internet/wcms/publishing.nsf/content/gene-gtmc.htm>

GTEC and Relationships with Other Committees

The Committee received reports from the Chair, the Gene Technology Regulator, the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics Committee (GTEC).

Next Meeting

The next GTCCC meeting will be held early in 2007.

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

APPENDIX C

Gene Technology Ethics Committee Meeting

25 July 2006, Canberra

COMMUNIQUÉ

The Gene Technology Ethics Committee (GTEC) held its twelfth meeting in Canberra on 25 July 2006.

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').

At its July 2006 meeting, the GTEC Working Group developing the draft paper on 'Environmental Ethics and Gene Technology' reported on its activities since the previous meeting and received feedback and suggestions to further develop the project. Members received presentations on applicant suitability, biosecurity and genetics. Members discussed the recommendations of the *Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement*, and were informed of relevant work from other national committees via cross-member reports. In addition, members received reports on the general operations of the OGTR and the OGTR's international liaison activities.

Key outcomes from the twelfth meeting are reported below.

GTEC's Work Plan

National Framework for the Development of Ethical Principles in Gene Technology

Members were presented with final copies of the Framework and discussed options for the official public launch of the document. The Committee resolved to launch the Framework at the OGTR Institutional Biosafety Committee Forum in November 2006.

Environmental Ethics and Gene Technology

The Working Group presented the Committee with a revised version of the draft discussion paper on environmental ethics and the implications for gene technology, and highlighted changes made to the second part of the paper, which explores the boundaries and scope of the paper. The Committee discussed different approaches which could be taken and the target audience for the paper. A number of editorial changes were identified.

The Committee resolved to develop the paper further, taking into consideration the changes suggested at the meeting. The Committee also resolved to expand the existing Working Group.

Review of the Gene Technology Act 2000

The Committee discussed the recommendations of the Statutory Review of the *Gene Technology Act 2000* and the Gene Technology Agreement*. The Committee noted that several of the recommendations were in line with recommendations it made in its submission to the Review. The Committee discussed in particular the recommendation that GTEC and the Gene Technology Community Consultative Committee (GTCCC) be combined. In light of this recommendation and the recent appointment of the new GTCCC, the Committee resolved to approach the GTCCC and propose the establishment of a collaborative project between the two Committees.

GTEC and Relationships with Other Committees

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

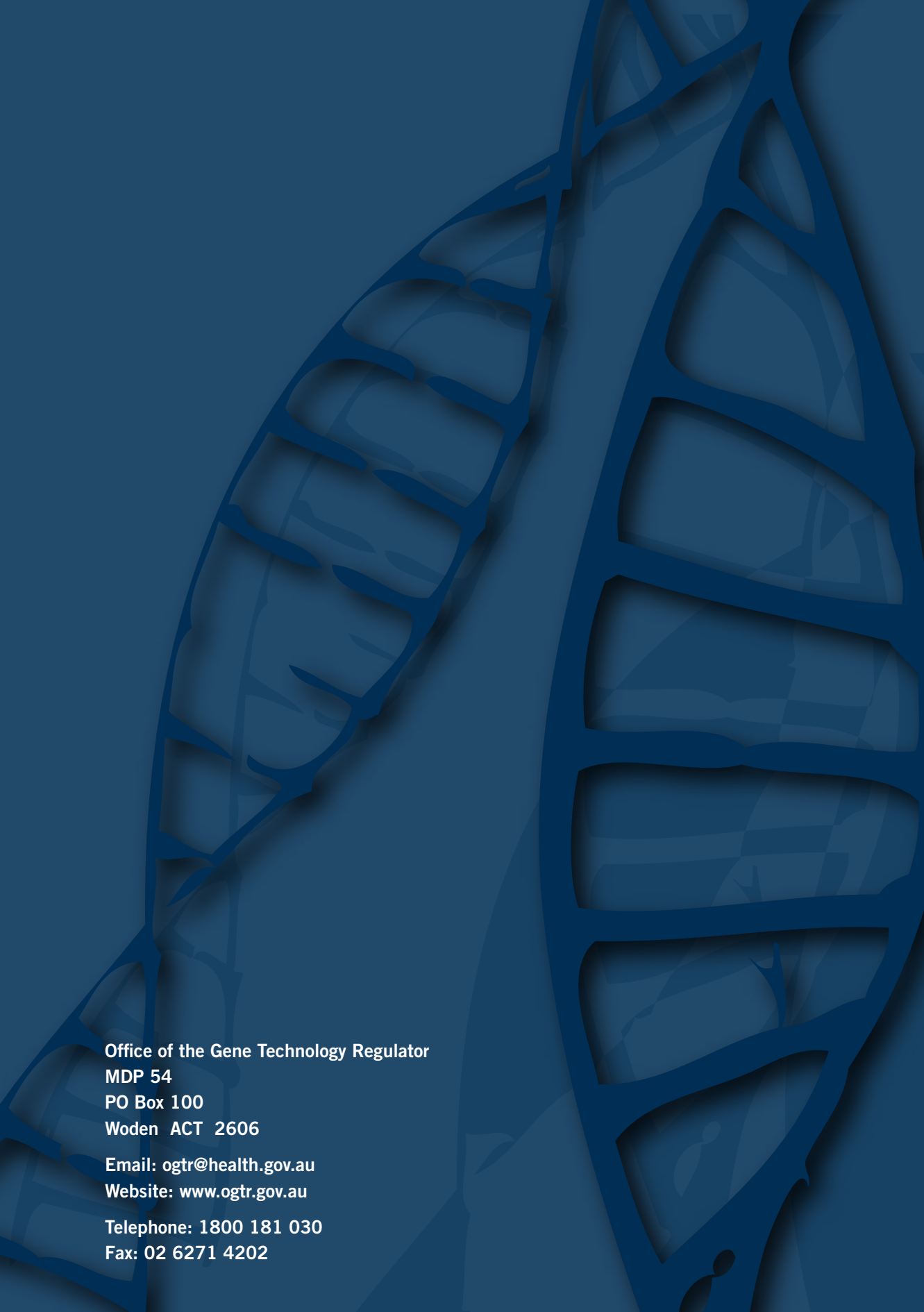
The Committee noted the appointment of the new Australian Health Ethics Committee (AHEC) and resolved to send a letter of congratulations to the incoming Chair.

Next Meeting

The next GTEC meeting will be held in November 2006.

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

* *More information about the Review is available on the Gene Technology Ministerial Council's website at <http://www.health.gov.au/internet/wcms/publishing.nsf/content/gene-gtmc.htm>*



Office of the Gene Technology Regulator
MDP 54
PO Box 100
Woden ACT 2606

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

Telephone: 1800 181 030
Fax: 02 6271 4202