Quarterly Report of the Gene Technology Regulator for the period 1 January to 31 March 2006

ISBN 0 642 82637 4

Online ISBN: 0-642-82960-8

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

Produced by:

Office of the Gene Technology Regulator
MDP54 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 3623

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

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 January to 31 March 2006.

During this quarter, key achievements included the issuing of three licences for dealings involving the intentional release of genetically modified organisms (GMOs), four licences for dealings not involving intentional release of genetically modified organisms (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.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator
30 June 2006

Address: MDP 54 PO Box 100 Woden ACT 2606 Website: www.ogtr.gov.au
Telephone: 1800 181 030 Facsimile: 02 6271 4202

INTENTIONALLY LEFT BLANK

Contents

Glossary

Accredited organisation	An organisation that is accredited under section 92 of the Act
Act	*Gene Technology Act 2000*
APVMA	Australian Pesticides and Veterinary Medicines Authority
CCI	Confidential commercial information
Certified contained 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 not involving intentional release of the GMO into the environment (for example, experiments in a certified facility such as a laboratory)
DNIR licence	A licence for a dealing not involving intentional release of a GMO into the environment
Expert advisers	Advisers appointed by the Minister to give expert advice to either GTTAC or GTEC to assist them in the performance of their functions (expert advisers are not committee members)
FSANZ	Food Standards Australia New Zealand
GM	Genetically modified

GM product	A thing (other than a GMO) derived or produced from a GMO
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically modified organism
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
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 contained facilities)
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

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 January to March 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

INTENTIONALLY LEFT BLANK

PART 1 National regulatory system

Key achievements during this quarter

The key achievements of the January to March 2006 quarter were:

Licences and other instruments

- three licences issued for dealings involving the intentional release of GMOs into the environment (DIR licences).
- four licences issued for dealings not involving intentional release of GMOs into the environment (DNIR licences).
- 65 Notifiable Low Risk Dealing (NLRD) notifications received.
- 37 contained facilities certified.
- 44 surrenders of certifications processed.
- 74 variations processed.

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

Monitoring and compliance

Approximately 12 percent of current field trial sites and ten 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 Part 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.

As required by s194, the GTMC has commissioned an independent panel to conduct a review of the Act that is required to be tabled in the Australian Parliament by 21 June 2006.

The Gene Technology Standing Committee (GTSC) supports the work of the GTMC and comprises a senior government official from each jurisdiction with responsibility for coordinating gene technology issues.

The secretariat for the GTMC and the GTSC is provided by the Department of Health and Ageing.

Further information on the GTMC and the review is available from the Council website:

http://www.health.gov.au/internet/wcms/publishing.nsf/content/gene-gtmc.htm

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 one invitation to the public to comment on the RARMP prepared in response to application DIR 061/2005. The invitation was issued via email or post to people who have registered on the OGTR mailing list and via advertisements in:

- the *Australian Government Notices Gazette*
- *The Weekend Australian* newspaper
- relevant regional press such as *The West Australian, The Countryman* (WA) (rural newspaper), and *Narrogin Observer* (regional newspaper in the Corrigin area of Western Australia).
- OGTR website http://www.ogtr.gov.au.

Further information is set out in Part 2.

INTENTIONALLY LEFT BLANK

PART 2 Regulation of genetically modified organisms

Part 2 of the report outlines the regulatory activity undertaken during the January to March 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 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 contained 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 contained 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 January to 31 March 2006

Application type	Number received	Number approved[1]
DIR licence	3	3
DNIR licence	6	4
Accreditations	1	0
Certifications	38	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 it excludes weekends and public holidays in the Australian Capital Territory (ACT).

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

The Act and the *Gene Technology Regulations 2001* (the Regulations) mandate minimum 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
DIR 064/2006 DIR 065/2006 DIR 066/2006	DIR 062/2006 DIR 063/2006 DIR 064/2006	DIR 061/2005	None	DIR 046/2005 DIR 059/2005 DIR 060/2005

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 three applications for DIR licences in the January to March 2006 quarter.

- 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

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 applications:

- 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 - Field trial of GM cotton expressing natural plant genes for fungal control - Hexima Limited.
- DIR 064/2006 - Limited and controlled release of water-efficient GM cotton - Monsanto Australia 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 these applications and when the RARMPs are 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 application:

- DIR 061/2005 - Field Testing of genetically modified salt tolerant wheat on saline land - Grain Biotech Australia Pty Ltd.

Withdrawn applications for DIR licences

No DIR licence application was withdrawn this quarter

Surrendered applications for DIR licences

No DIR licence was 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 no clock stop periods that applied to any DIR licence applications during this quarter.

Decisions on applications for DIR licences

During the quarter, the Regulator issued three DIR licences:

- DIR 046/2003 – Limited and controlled release of GM fowl adenovirus (FAV) - Imugene Limited.
- DIR 059/2005 - Commercial release of herbicide tolerant (Roundup Ready Flex® MON 88913) and herbicide tolerant/ insect resistant (Roundup Ready Flex® MON 88913/ Bollgard II®) cotton south of latitude 22° South in Australia - Monsanto Australia Limited.
- DIR 060/2005 - Field Trial - Limited and controlled release of imported GM rose lines - Florigene Pty Ltd.

Summary information on DIR applications, finalised RARMPs and licence conditions imposed, are available from the OGTR website at http://www.ogtr.gov.au, or can be obtained by contacting the OGTR directly. Full copies of DIR applications can be obtained by contacting the OGTR directly.

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 four 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 at http://www.ogtr.gov.au.

Notifications of notifiable low risk dealings received

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

This category of dealings with GMOs 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 65 NLRD notifications in the quarter. A listing of NLRDs and their date of notification is available from the OGTR website at http://www.ogtr.gov.au.

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 January to March 2006 quarter.

Applications received and decisions made: existing licences and other instruments 1 January to 31 March 2006.

Type	Number received	Number processed[1]
Surrender of certification	77	44
Surrender of DIR licence	1	0
Surrender of DNIR licence	2	1
Surrender of accreditation	1	1
Variation of certification	42	45
Variation of accreditation	2	2
Variation of DIR licence	13	6
Variation of DNIR licence	25	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 two CCI applications relating to DIR applications and no CCI applications relating to DNIR Licence applications or NLRDs.

The Regulator made three declarations in relation to DIR applications, two declarations in relation to DNIR applications and one declaration in relation to an NLRD.

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 contained 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 percent of field trial sites each year.

A minimum of five percent of current trial sites and five percent 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 contained facilities involves inspecting and monitoring:

- a minimum of 20 percent 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, including those practices followed for dealings not involving intentional release (DNIRs), notifiable low risk dealings (NLRDs) and exempt dealings.

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored: During the January to March 2006 quarter, 16 field trial sites were subjected to monitoring visits.

Current field trial sites monitored: Of the 68 sites current in the quarter, eight were monitored. This represents a monitoring rate of 12 percent of all current sites for the quarter.

Post-harvest field trial sites monitored: Of the 84 sites subject to post-harvest monitoring in the quarter, eight were monitored. This represents a monitoring rate of ten percent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection to contained dealings covered two organisations and six PC facilities. Monitoring of PC facilities encompassed PC2 laboratories (four visited), PC2 animal containment facilities (one visited), and PC2 plant containment facilities (one visited).

Monitoring of contained dealings: During the January to March 2006 quarter, monitoring of the six 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.

Six DNIRs were monitored during this quarter.

Monitoring of dealings involving intentional releases

The following table shows the total monitoring coverage for field trial sites 1 January to 31 March 2006

Licensed Organisation Name	Licence Number	No. sites visited	Site status[1]	Crop type
Deltapine Australia Pty Ltd	DIR 058/2004	1	C	Cotton
Dow AgroSciences Australia Pty Ltd	DIR 044/2003	2	C	Cotton
		1	PHM	Cotton
Grain Biotech Australia Pty Ltd	DIR 053/2004	1	PHM	Wheat
Monsanto Australia Limited	DIR 035/2003	6	PHM	Cotton
	DIR 055/2004	5	C	Cotton
Totals	5	16	C=8	2 types
			PHM=8	

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
Murdoch University	PC2 Lab	1
	PC2 Plant Containment	1
The University of Western Australia	PC2 Lab	3
	PC2 Animal Containment	1
Totals	3 facility types	6

Monitoring findings

Dealings involving intentional release

During the quarter inspectors identified one act or omission which in the Regulator's view constituted non-compliance with the conditions of the relevant DIR licence.

Organisation	Monsanto Australia Limited
Licence number and site	DIR 012/2002, Site19
Summary of dealing	Licence relates to field trials of cotton (*Gossypium hirsutum*) genetically modified by introduction of two insecticidal genes and/or insecticidal genes in combination with a gene that confers tolerance to the herbicide glyphosate, the active ingredient of Roundup®. This site was planted in May 2004, was harvested in January 2005 and is now in the post harvest monitoring phase.
Findings	On 16 January 2006 Monsanto informed the OGTR that during inspection of the pollen trap and drains for site 19, three cotton volunteers approximately 50 cm tall with open bolls (seed set) were identified at the bottom of a large drain. The Licence requires that any regrowth of GMO plants must be destroyed before they flower.
Risk assessment	It was concluded that risks to human health and safety and the environment as a result of this non-compliance were negligible.
Compliance management	Monsanto Australia Limited has been reminded of its obligations to ensure that all regrowth of GMO plants are destroyed before flowering.

Dealings not Involving Intentional Release

During the quarter inspectors identified one act or omission that was assessed as a possible non-compliance with the conditions of the relevant DNIR Licence.

Organisation	The University of Western Australia
Licence number	DNIR 91/2002
Summary of dealing	To study the host response to cytomegalovirus and hepatitis C virus proteins to test for protective immune responses.
Findings	OGTR Inspectors identified a disjunction between a Licence condition and OH&S requirements. While licence conditions state that all manipulations must be carried out inside a Class II biological safety hood, UWA staff informed OGTR inspectors that certain procedures were carried out in a fume hood due to the use of phenol (a chemical which cannot be used safely in a Class II biological safety hood).
Risk assessment	The risks to human health and safety and the environment were assessed as negligible.
Compliance management	The OGTR has reviewed the conditions of the Licence to ensure that all safety requirements can be fulfilled.

The OGTR recognises that the wording of this Licence Condition presented problems for the organisation involved, as to adhere to the OGTR requirement would have been contrary to good laboratory practice. However the incident also highlights the importance of Licence Holders thoroughly informing

themselves of the relevant Licence Conditions and bringing potential compliance issues to the OGTR's attention.

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.

	Non-Compliance Issue					
Number of PC Facilities inspected	**Structure**	**PPE**[1]	**Equipment**	**Waste disposal**	**Work practices**	**Transport**
6	2	2	2	0	0	2

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 January to March 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 January to March 2006 quarter.

Investigations

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

There were no investigations completed in the January to March 2006 quarter.

PART 3 Committee operations

The Act established three advisory committees:

- The **Gene Technology Community Consultative Committee** (GTCCC)
  - 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** (GTEC)
  - provides advice on ethical issues relating to gene technology to the Regulator and the GTMC
- The **Gene Technology Technical Advisory Committee** (GTTAC)
  - provides scientific and technical advice to the Regulator and the GTMC.

Gene Technology Community Consultative Committee

The inaugural membership of the Gene Technology Community Consultative Committee (GTCCC) expired on 8 October 2004. The appointment process for new membership of the GTCCC was ongoing at the end of this quarter.

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

Gene Technology Ethics Committee

The Gene Technology Ethics Committee held its eleventh meeting on 30 March 2006 in Canberra. Members considered submissions received during the latest round of consultation on the *National Framework for the Development of Ethical Principles in Gene Technology* (which closed on 8 March 2006) and feedback from a presentation to GTTAC on 29 March 2006. GTEC will revise the Framework in light of the comments received.

GTEC also considered future projects which may be undertaken, including the development of a paper considering environmental ethics.

The 11th Communiqué summarising discussions held at this meeting is attached to this Quarterly Report (Appendix B).

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

Gene Technology Technical Advisory Committee

As agreed at its 26th meeting, a number of Gene Technology Technical Advisory Committee (GTTAC) members met with the OGTR on 17 January 2006 for further consultation on the review of the Regulator's review of the Regulations.

GTTAC held its 27th meeting in Canberra on 29 March 2006. At this meeting GTTAC considered one DIR RARMP, five DIR applications and a variation to a DNIR licence.

Members also received presentations on genetic analysis software, developments regarding a new synthetic drug treatment (morpholinos) for inherited genetic diseases and GTEC's draft *National Framework for the Development of Ethical Principles in Gene Technology*.

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

PART 4 Other activities

Reviews

The review of the *Guidelines for the Certification of Facilities/Physical Containment (PC) Requirements* continued during this quarter. The OGTR progressed the revised guidelines for PC1 and PC2 Large Scale facilities and PC3 Laboratory facilities to near-completion, focusing on several technical issues raised during consultations. Work also commenced on re-formatting all current certification guideline documents to align them with the structure adopted for the revised *Guidelines for Accreditation of Organisations* issued by the Regulator on 1 July 2005.

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:

- Asia Pacific Economic Cooperation (APEC) Conference on Biosafety policy options for APEC economies, 'Australia's experience with the development and implementation of gene technology regulation'. 16-18 January 2006, Manila, Philippines.
- Australian Delegation to the Third Meeting of the Parties (MOP3) to the Cartagena Protocol on Biosafety. 13-17 March 2006, Curitiba, Brazil.

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

Grains Research and Development Corporation review of WA Herbicide Resistance Initiative, 'Patterns of gene technology regulation'. 13-14 March 2006, Perth.

Meetings and workshops

During the quarter, at the request of the independent panel conducting the review of the Act (refer section 1), the Regulator provided advice on the operation of the regulatory system.

In addition a briefing on the OGTR's role in certifying contained facilities was provided to the Productivity Commission's review of the Australian Government's relationship with Australian Standards Ltd and the National Association of Testing Authorities.

A combined briefing on the integrated regulatory framework for GMOs and GM products was provided to the WA Parliamentary Secretary for Agriculture by the OGTR, FSANZ and the APVMA.

The OGTR also participated in an AQIS workshop for assessors, a CSIRO gene technology course and briefing of ACT government officials, and a Standards Australia subcommittee meeting on microbiological containment standards.

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. Imported seeds for sowing have been identified as the most likely source and the OGTR has been asked to implement the strategy. In this quarter the OGTR advanced liaison with industry bodies regarding the provision of advice on industry quality assurance and testing regimes.

OGTR website

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

- What's New
- Maps of current field trial locations
- Handbook on the Regulation of Gene Technology in Australia
- About the OGTR
- Intentional Release
- GMO Record

The most popular downloaded documents were:

- *Risk Analysis Framework*
- Handbook on the Regulation of Gene Technology in Australia
- 'The Biology & Ecology of pineapple (*Ananas comosus var. comosus*) in Australia'
- 'The Biology and Ecology of cotton (*Gossypium hirsutum*) in Australia'
- The Biology and Ecology of bread wheat (Triticum aestivum L. em Thell.) in Australia
- The Biology and Ecology of carnation (Dianthus caryophyllus L.)

- 'The Biology and Ecology of white clover (*Trifolium repens* L.) in Australia'

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 1800 number and email address received 36 calls and 70 emails in January 2006, 66 calls and 86 emails in February 2006, and 75 calls and 85 emails in March 2006.

Freedom of information

The OGTR received one freedom of information request during the quarter.

INTENTIONALLY LEFT BLANK

Appendix A

DNIR Licences issued January to March 2006

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 369/2005	6 February 2006	St Vincent's Hospital, Sydney, New South Wales	A phase 2 study to evaluate the efficacy & safety of Merck Adenovirus serotype 5 HIV-1 vaccine in adults at high risk of HIV-1 infection.	The aims of the dealing are to test the safety, efficacy and tolerability of a recombinant adenovirus vaccine containing genes from HIV-1 to act as a prophylactic vaccine to prevent HIV-1 infection of HIV-1 seronegative individuals.
DNIR 370/2005	6 February 2006	St Vincent's Hospital, Sydney, New South Wales	A randomised study of therapeutic immunization and treatment interruption among subjects diagnosed with acute or recent HIV infection.	The aims of the dealing are to test the safety, efficacy and tolerability of a recombinant adenovirus containing genes from HIV-1 as a therapeutic vaccine to suppress viral replication and lower the viral load in patients who have been diagnosed with acute or recent HIV-1 infection and who have been receiving antiretroviral therapy.
DNIR 372/2005	9 February 2006	Melbourne Health, Victoria	The effect of Hepatitis B virus surface antigen mutations on Hepatitis Delta virus assembly and release.	The aims of this research are to study the effect of mutations encoded by the Hepatitis B virus envelope genes on the assembly and release of Hepatitis delta virus.
DNIR 374/2005	20 February 2006	CSL Limited, Victoria	Fermentation and processing of a recombinant antibody expressed in recombinant Chinese Hamster Ovary cells.	The purpose of this dealing is to produce and purify pilot-scale quantities of recombinant, chimeric anti-cancer antibodies from Chinese Hamster Ovary cells.

INTENTIONALLY LEFT BLANK

Appendix B

Gene Technology Ethics Committee Meeting 30 March 2006, Canberra

COMMUNIQUE

The Gene Technology Ethics Committee (GTEC) held its eleventh meeting in Canberra on 30 March 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 March 2006 meeting, the current GTEC Working Groups reported on their activities since the previous meeting and received feedback and suggestions to further develop their projects. Members received a presentation by a guest from the Office of the Gene Technology Regulator (OGTR) on horizontal gene transfer. In addition, members were informed of relevant work from other national committees via cross-member reports and received a report on the operations of the OGTR. Relevant members reported back to the Committee about the Working Group meeting with the Independent Review Panel and the Victorian Biotechnology Ethics Advisory Committee launch of the *Statement of Ethical Principles for Biotechnology in Victoria*. Key outcomes from the meeting are reported below.

GTEC's Work Plan

Details of the current GTEC working group projects are provided below for information.

National Framework for the Development of Ethical Principles in Gene Technology

The Working Group presented an overview of the development of the Framework, noting a number of issues raised during the latest round of consultation and the presentation on the Framework given to the Gene Technology Technical Advisory Committee (GTTAC). The Working Group suggested a number of changes to improve and clarify the Framework and discussed options for publication and ongoing development of the document.

The Committee resolved that the Working Group should edit the Framework in light of the comments received during the consultation and from GTTAC, and explore options for publication, prior to finalising the Framework and referring it to the Regulator.

Ethical Issues Associated with Trans-species Gene Transfer

The Working Group presented the revised document for GTEC's consideration. The Committee identified some minor editorial changes and agreed that, subject to the editorial changes, the document is ready to be finalised.

Environmental Ethics and Gene Technology

The Working Group presented the Committee with a preliminary draft discussion paper on environmental ethics and the implications for gene technology. The Committee discussed the ways that different environmental philosophies and the specifications of the Act influence its deliberations.

The Committee resolved to develop the paper further, taking into consideration differing viewpoints and the context provided by the Act. The Working Group was invited to develop a map of issues which warrant further discussion.

Future Projects

The Committee considered a number of subjects as possible future working group projects. These included applicant suitability, possible dual or malevolent uses of gene technology and the current state of knowledge of gene technology. The Committee decided to invite guest speakers on each of these topics to the next meeting to provide members with further information.

GTEC and Relationships with Other Committees

The Committee received reports from the Chair, the Gene Technology Regulator, GTTAC and the Animal Welfare Committee (AWC). A written report from the Australian Health and Ethics Committee was also received and tabled.

The Committee agreed to consider and comment on the AWC's draft paper *Minimising pain, distress and suffering in animals in research*.

Next Meeting

The next GTEC meeting will be held in July 2006.

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