Quarterly Report of the Gene Technology Regulator for the period 1 April to 30 June 2004

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Commonwealth Department of Health and Ageing

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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*, I am pleased to present to you the Quarterly Report of the Gene Technology Regulator, covering the period 1 April to 30 June 2004.

During this quarter, key achievements included the issuing of one licence for a dealing involving the intentional release of a genetically modified organism, six licences for dealings not involving intentional release of genetically modified organisms, one organisation was accredited and 35 contained facilities were certified.

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

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator
8 December 2004

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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
Breach	*see* 'Non-compliance'
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 an application evaluation is suspended – usually whilst awaiting further information from the applicant
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 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)
Non-compliance	A failure to comply with legislative requirements including licence, accreditation or certification 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	*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 April – June 2004 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, freedom of information requests received, and consultant contracts managed during this quarter.

Further information

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

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Key achievements during this quarter

The key achievements of the April – June 2004 quarter were:

Licences and other instruments

- 1 licence issued for a dealing involving the intentional release of a GMO into the environment (DIR licence).
- 6 licences issued for dealings not involving intentional release of GMOs into the environment (DNIR licences)
- 95 notifiable low risk dealing (NLRD) notifications received
- 1 organisation accredited
- 35 contained facilities certified
- 45 surrender of certifications processed
- 275 variations processed.

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

Monitoring and compliance

Approximately 48 per cent of current field trial sites and 20 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 of this report.

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.

Gene Technology Ministerial Council

The GTMC consists of one Minister from each State and Territory and one Minister from the Australian Government. Currently, the Ministerial Council comprises Ministers from a range of portfolios including health, agriculture, environment and innovation. The Council is chaired by Queensland.

The Ministerial Council did not meet this quarter.

Gene Technology Standing Committee

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

The Standing Committee did not meet this quarter.

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.[1]

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.

[1] Consultation is also required with State and Territory Governments, GTTAC, relevant local councils and, if the proposed dealing(s) may pose significant risk(s) to human health and safety and/or the environment, the public.

Once a RARMP is prepared, the Regulator again seeks comment on the RARMP from the same prescribed Australian Government authorities and agencies.[2]

In addition, comment is sought on each application and 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 one application for a DIR licence and two RARMPs.

Further information is set out in Part 2.

Public participation

During the quarter, the Regulator issued two invitations to the public to comment on RARMPs prepared for applications for a DIR licence. The invitations were 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 Australian* newspaper
- relevant regional press, such as the *Courier Mail*, *Northern Territory News*, *The West Australian* and rural press such as *Queensland Country Life, The Land* and *The Weekly Times*
- OGTR website www.ogtr.gov.au.

Further information is set out in Part 2.

[2] Consultation is also required with State and Territory Governments, GTTAC, relevant local councils and the public.

PART 2 Regulation of genetically modified organisms

Part 2 of the report outlines the regulatory activity undertaken during the April - June 2004 quarter. This includes information about applications for, and action taken with respect to, GMO licences and other instruments under the Act. It also includes details of monitoring activities and any breaches of conditions of a GMO licence that have come to the Regulator's attention. 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:

- **Dealing 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.

- **Dealing Not involving Intentional Release (DNIR) licences**

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

- **Accreditations of organisations**

  Licences may 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 assists to satisfy the Regulator that a facility which is proposed to be used to conduct a dealing 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.

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 April – 30 June 2004

Application type	Number received	Number approved[1]
DIR licence	2	1
DNIR licence	15	6
Accreditations	2	1
Certifications	70	35

1. Approvals reported in the current quarter mainly 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
- seeking comments from prescribed expert groups and key stakeholders (including the public) on the RARMP
- considering all comments relating to the protection of human health and safety and the environment in finalising the RARMP
- consideration of 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 9 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 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 status of applications for DIR licences that underwent evaluation during the quarter.

Status, as at 30 June 2004, of applications for a DIR licence subject to evaluation during the quarter

Application received	First round of consultation[1]	Second round of consultation	Withdrawn applications	Licence Issued
DIR 051/2004	DIR 045/2004[2]	DIR 047/2004		DIR 044/2004
DIR 052/2004	DIR 046/2004[2]	DIR 048/2004[4]		
	DIR 049/2004[3]			
	DIR 050/2004			

1. Includes posting of 'Early Bird' Notifications and summaries of applications on the OGTR website and to people on the OGTR mailing list.

2. The clock was stopped on these applications.

3. First round consultation closed 4 June 2004

4. Second round consultation closed 25 June 2004

Applications received for DIR licences

The OGTR received two applications for DIR licences in the April – June 2004 quarter as follows:

- DIR 051/2004 'Field trial of genetically modified (GM) sugarcane expressing sucrose isomerase' (University of Queensland)
- DIR 052/2004 'Field trial of genetically modified rice (*Oryza sativa* L.) - functional characterisation of the rice genome'

All applications for DIR licences received in the April - June 2004 quarter were screened for completeness and the applicants notified of the receipt of their applications within the 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 applications:

- DIR 049/2004 'Field trial – Evaluation under field conditions of the cotton rubisco small subunit promoter driving a reporter gene' (CSIRO)
- DIR 050/2004 'Vaccination of cattle with recombinant bovine herpesvirus vaccines' (Queensland Government Department of Primary Industries and Fisheries).

Although not required to by the Act the Regulator also issued 'Early Bird Notifications' 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 second-round of consultations on RARMPs for the following applications:

- DIR 047/2003 'Field trial – Evaluation of GM white clover resistant to infection by *Alfalfa Mosaic Virus'* (Department of Primary Industries, Victoria)
- DIR 048/2003 'Field Trial – Field trail to assess transgenic cotton expressing natural plant genes for insect control' (Hexima Limited)

Withdrawn applications for DIR licences

No DIR licences where withdrawn in this quarter.

Clock stopped on two applications for DIR licences

The statutory timeframe of 170 days for assessing an application for a DIR licence can be suspended for several reasons. For example, the clock may stop on an application because of an unresolved application for CCI, or while further information is sought from the applicant.

The 'clock' remains stopped on the assessment of the following applications while further information is sought from the applicant:

- DIR 045/2003 - Vaccine Trial - Development of Porcine Adenovirus (PAV) Vaccine Vectors (Imugene Limited)
- DIR 046/2003 Vaccine Trial - Development of Fowl Adenovirus (FAV) Vaccine Vectors (Imugene Limited)

Finalised applications for DIR licences

During the quarter, the Regulator issued one DIR licence:

DIR 044/2003 'Field trial – Agronomic assessment and seed increase of transgenic cotton expressing insect tolerance genes from *Bacillus thuringiensis*' (Dow AgroSciences Australia Limited)

Summary information on DIR applications and RARMPs as well as the finalised RARMPs, including the licence conditions imposed are available from the OGTR website at 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.

Finalised 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 six 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 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 95 NLRD notifications in the quarter. A full listing of NLRDs and their date of notification is available from the OGTR website at 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. 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 vary existing licences and other instruments, as well as the number of applications processed during the April - June 2004 quarter.

Applications received and decisions made; existing licences and other instruments 1 April – 30 June 2004

Type	Number received	Number processed[1]
Surrender of certification	71	45
Surrender of DIR licence	1	1
Surrender of DNIR licence	1	1
Surrender of accreditation	0	1
Variation of certification[2]	681	248
Variation of accreditation	0	0
Variation of DIR licence[3]	8	10
Variation of DNIR licence[3]	27	17

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.
2. The increased volume of certification variation requests received in this quarter is due to the Guidelines being revised resulting in current holders of certifications progressively varying these to meet the new requirements.
3. The majority of variations are made at the request of the licence holder. Variations involve changes to licences where the Regulator is satisfied that the variation does not pose any additional risks to human health and safety and the environment that cannot be managed.

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

During the quarter, the Regulator received no CCI applications.

The Regulator made one CCI declaration in relation to an application for a DIR licence (DIR 050/2004), one declaration in relation to an application for a DNIR licence (DNIR 079/2002), and no declarations in relation to NLRDs.

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 risk of dissemination of a GMO and its genetic material is minimised
- the risk of 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 field trial monitoring strategy utilises risk profiling, which incorporates the accumulated operational experience of the office to date. OGTR field trial monitoring activity is scheduled, as far as possible, during inherently higher risk periods in dealings with gene technology (for example, flowering and harvest of GM crops) and to perform monitoring activities accordingly.

The monitoring program for dealings conducted in contained facilities involves inspecting and monitoring:

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

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored. During the April - June 2004 quarter, 34 field trial sites were subject to monitoring visits. Monitoring was carried out on 10 DIR licences and covered two plant species.

Current field trial sites monitored. Of the 29 sites current in the quarter, 14 were monitored. This represents a monitoring rate of 48 per cent of all current sites for the quarter.

Post-harvest field trial sites monitored. Of the 101 sites subject to post-harvest monitoring in the quarter, 20 were monitored. This represents a monitoring rate of 20 per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of contained dealings. During the April-June 2004 quarter, monitoring in connection to contained dealings covered four organisations and 12 PC facilities. Monitoring of PC facilities encompassed PC2 laboratories (six visited), PC2 plant containment facilities (one visited), PC3 laboratory re-certifications (three visited), PC3 insectary re-certifications (one visited) and PC4 laboratory re-certifications (one visited). Recertification inspections are conducted prior to the extension of certification of high level facilities.

Monitoring of DIRs conducted

The total monitoring coverage for field trial sites during the April - June 2004 quarter is shown in the following table.

Licensed Organisation Name	Licence Number	No. sites visited	Site status[1]	Crop type
CSIRO	DIR 006/2001	2	PHM	Cotton
	DIR 017/2002	1	PHM	Cotton
	DIR 025/2002	1	PHM	Cotton
	DIR 036/2003	1	C	Cotton
	DIR 038/2003	2	C	Cotton
Department of Agriculture (Western Australia)	DIR 007/2001	1	PHM	Oilseed poppy
	DIR 008/2001	5	PHM	Cotton
	DIR 008/2001	8	PHM	Cotton
Dow AgroSciences	DIR 040/2003	2	C	Cotton
Monsanto Australia Limited	DIR 012/2002	8	C	Cotton
		2	PHM	Cotton
	DIR035/2003	1	C	Cotton
Totals	10	34	C=14	2 Species
			PHM=20	

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

Monitoring of DNIR conducted

No monitoring of DNIR licensed dealings was conducted in this quarter.

Monitoring of physical containment facilities conducted

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
EngeneIC Pty Ltd	PC2 Laboratory	1
Queensland Health Scientific Services	PC3 Laboratory[1]	2
	PC4 Laboratory[1]	1
	PC3 Insectary[1]	1
Royal Perth Hospital	PC3 Laboratory[1]	1
The University of Western Sydney	PC2 Laboratory	5
	PC2 Plant Containment Facility	1
Totals	5 facility types	12

1. Joint re-certification inspections with Contained Dealings Evaluation Section

Monitoring findings

Significant risk to human health or the environment

There were no non-compliances detected in this quarter that represented a significant risk to either human health or the environment

Other monitoring findings

Dealings involving intentional release

During the quarter, six non-compliances with licence conditions were identified as requiring further attention. A summary of each follows:

Organisation	CSIRO
Licence number and site	DIR 025/2002, Site 1
Summary of dealing	Licence relates to field trials of cotton (*Gossypium hirsutum* L.) genetically modified to express the insecticidal protein gene VIP3A. The site is in the post harvest monitoring phase.
Findings	DIR 025/2002 requires the results of monitoring activities be reported to the Regulator in writing within 14 days of any day on which monitoring occurs. OGTR staff were informed by the site manager that the site is regularly monitored and reports maintained, however, no monitoring reports had been provided to the Regulator at the time of the inspection.
Risk assessment	As a result of the management and monitoring activities being conducted at this site and the absence of volunteers no risks to human health and safety and the environment have been posed as a result of this non-compliance.
Risk management	On request, CSIRO submitted past monitoring reports for inspections carried out on this site since destruction of the GMO. CSIRO were reminded of their obligations under DIR 025/2002 to supply results of all monitoring activities undertaken at this site within 14 days of any day on which monitoring occurs.

Organisation	CSIRO
Licence number and site	DIR 006/2001, Site 1
Summary of dealing	Licence relates to the agronomic assessment and seed increase of cotton (*Gossypium hirsutum* L.) modified for resistance to caterpillar pests through the Cry1Ac or Cry1Ac and Cry2Ab genes from *Bacillus thuringiensis* and modified for herbicide tolerance through the EPSPS gene from *Agrobacterium*. The site is in the post harvest monitoring phase.
Findings	DIR 006/2001 requires the results of monitoring activities be reported to the Regulator in writing within 14 days of any day on which monitoring occurs. OGTR staff were informed by the site manager that the site is regularly monitored and reports maintained, however, no monitoring reports had been provided to the Regulator at the time of the inspection. The original GPS coordinates supplied by CSIRO for DIR 006/2001 Site 1 and DIR 025/2002 Site 1 were identical, indicating that DIR 006/2001 Site 1 may have been re-planted with GM cotton within 12 months of harvest and cleaning. Licence conditions only permit the growing of cotton on DIR 006/2001 sites, 12 months after the GMO has been harvested and the site cleaned.
Risk assessment	On request, CSIRO submitted past monitoring reports for inspections carried out on DIR 006/2001 sites. Following these inspections, CSIRO provided evidence to show that the originally submitted GPS co-ordinates were in error, specifying the overall field location not the exact plot locations. DIR 006/2001 Site 1 and DIR 025/2002 Site 1 were spatially separate with only 29% of the field being used for DIR 006/2001 Site 1 in 2002 and the remaining 70% being sown to DIR 025/2002 Site 1 in 2003.
Risk management	CSIRO have submitted a licence variation request to amend the GPS coordinates for these sites to reflect their true locations.

Organisation	CSIRO
Licence number and site	DIR 006/2001, Site 7
Summary of dealing	Licence relates to the agronomic assessment and seed increase of cotton (*Gossypium hirsutum* L.) modified for resistance to caterpillar pests through the Cry1Ac or Cry1Ac and Cry2Ab from *Bacillus thuringiensis* and modified for herbicide tolerance through the EPSPS gene from *Agrobacterium*. The site is in the post harvest monitoring phase.
Findings	DIR 006/2001 requires that CSIRO provide the Regulator with monitoring reports within 14 days of the activity taking place. At the time of the inspections, the site manager advised OGTR staff that this site is regularly monitored and reports maintained, however, no monitoring reports had been provided to the Regulator. At the time of this inspection, the site manager informed OGTR staff that following the harvest and cleaning of DIR 006/2001 Site 7 in October 2002, the site had been re-sown to the same GM cotton under DIR 012/2002 in March 2003. DIR 006/2001 conditions only permit the growing of cotton on sites 12 months after the GMO has been harvested, cleaned and monitored for 12 months.
Risk assessment	Due to the management and monitoring activities being undertaken at this site under DIR 012/2002, no additional risks to human health and safety and the environment were posed by these issues.
Risk management	To ensure the continued management of this site, CSIRO have submitted an application to the Regulator to vary DIR 006/2001 and transfer the post-harvest monitoring requirements of Site 7 including a 12 month restriction of planting GM cotton onto DIR 012/2002. On request, CSIRO submitted all past monitoring reports for inspections carried out on DIR 006/2001 sites.

Organisation	Monsanto Australia Ltd
Licence number and site	DIR 012/2002, Site 1
Summary of dealing	Licence relates to field trials of cotton (*Gossypium hirsutum* L.) genetically modified to express the Cry1Ac and Cry2Ab genes that confers insect resistance and the EPSPS gene that confers tolerance to the herbicide glyphosate. This is a current field trial site for the second season plantings of GM cotton under the limited and controlled release conditions imposed by this licence
Findings	Records show that this site was planted to the same GM cotton in 2002 under licences held by Department of Agriculture, Western Australia (DIR 008/2001 and DIR 009/2001) and in 2003 and 2004 under DIR 012/2002. Licence conditions for DIR 012/2002 only permit two successive plantings of GM cotton at the same site. At the time of inspection, OGTR observed the trial site was also planted to strips of lablab, pigeon pea and melons. The licence does not permit the planting of these crops on the site without the prior approval of the Regulator.
Risk assessment	As a result of (1) the same GM cotton being planted and managed at the site, (2) the lablab, pigeon pea and melon crops not being planted on the areas of the site where the GM cotton was previously planted and (3) the absence of GM cotton volunteers in the lablab, pigeon pea or melon strips, the risk of dissemination of the GMO or its genetic material was negligible. Therefore, the risks to human health and safety and the environment posed by these issues were assessed as negligible.
Risk management	Monsanto were advised to ensure they meet their obligations under DIR 012/2002 with regard to the use and management of this trial site. An application to the Regulator to vary DIR 012/2002 to approve the growing of GM cotton on this site for the 2004 growing season has been received. An application to the Regulator to vary DIR 012/2002 to approve the growing of lablab, pigeon pea and melons on the site for the remainder of the 2004 growing season has been received.

Organisation	Monsanto Australia Ltd
Licence number and site	DIR 012/2002, Site 2
Summary of dealing	Licence relates to field trials of cotton (*Gossypium hirsutum* L.) genetically modified to express the Cry1Ac and Cry2Ab genes that confers insect resistance and the EPSPS gene that confers tolerance to the herbicide glyphosate. This site is a current filed trial for the second season plantings of GM cotton under the limited and controlled release conditions imposed by this licence.
Findings	At the time of inspection, it was observed that strips of lablab were sown as post harvest crops. The licence does not authorise this crop to be planted on this site and the prior approval of the Regulator should have been obtained for its use.
Risk assessment	As no GM cotton volunteers were observed in the lablab, there was a negligible risk of dissemination of the GMO or its genetic material. Therefore, the risks to human health, safety and environment posed by this non-compliance was assessed as negligible.
Risk management	Monsanto were advised to ensure they meet their obligations under DIR012/2002 with regard to the use and management of this trial site. An application to the Regulator to vary DIR 012/2002 to approve the growing of lablab on the site for the remainder of the 2004 growing season has been received.

Organisation	Monsanto Australia Ltd
Licence number and site	DIR 012/2002, Site 10
Summary of dealing	Licence relates to field trials of cotton (*Gossypium hirsutum* L.) genetically modified to express the Cry1Ac and Cry2Ab genes that confers insect resistance and the EPSPS gene that confers tolerance to the herbicide glyphosate. This site is a current field trial for the second season plantings of GM cotton on this site under the limited and contained release conditions imposed by this licence.
Findings	Records show that this site was planted to the same GM cotton in 2002 under a licence held by CSIRO (DIR 006/2001) and in 2003 and 2004 under DIR 012/2002. Licence conditions for DIR 012/2002 only permit two successive plantings of GM cotton at the same site.
Risk assessment	As a result of the same GM cotton being planted and managed at the site, risks to human health and safety and the environment were assessed as negligible.
Risk management	Monsanto were advised to ensure they meet their obligations under DIR 012/2002 with regard to use and management of the trial site. An application to the Regulator to vary DIR 012/2002 to approve the growing of GM cotton on this site for the 2004 growing season has been received.

Physical containment facilities

OGTR's monitoring of PC2 facilities in the quarter found a number of minor non-compliances and issues with certification instruments. Each observed non-compliance was assessed for risks posed to human health and safety and the environment. All issues observed posed negligible or no additional risk to human health and safety and the environment.

In most instances, issues observed arose from the imprecise wording of Version 1 of the *Guidelines for Certification of Facilities/Physical Containment Requirements* (the Guidelines) and did not jeopardise the secure containment of GMOs. The Guidelines are currently being revised and Version 2.2 of the requirements for PC2 laboratories and animal and plant containment facilities were issued on 7 August 2003. Holders of certification for these facilities are progressively varying their certificates to meet the new requirements.

Guidelines for the remaining facility types (PC1, PC2 aquatic, arthropod and large scale, PC3 and PC4) are undergoing review or are scheduled for review.

This quarter, monitoring staff also undertook joint inspections of five PC3 and PC4 facilities with officers from the Contained Dealings Evaluation Section of the OGTR. These inspections were required due the imminent expiry of the current certifications. These re-certification inspections are usually undertaken to coincide with when these facilities are shutdown, this enables safe examination of the physical structure of these facilities (including air ventilation systems). The inspections checked for compliance with procedural requirements, including training, maintenance documentation and waste management processes.

Monitoring and compliance reviews

The Monitoring and Compliance Section carries out reviews of incidents or practices in dealings with GMOs that come to the notice of the section through monitoring activities or reports by accredited organisations. There are two types of reviews:

- ***incident reviews*** are initiated when an organisation reports a particular incident that may present a potential risk to human health and/or the environment and may be suspected to be a non-compliance with the Act and associated regulations
- ***practice reviews*** are initiated by the OGTR to determine if licence conditions can be, and are being, effectively implemented and include identification of potentially adverse effects of a GMO. This may be prompted by observations made during monitoring activities.

The primary focus of the review process is to determine whether the incident that has occurred, or practice being used, has a potential human health or environmental risk that requires management actions to be implemented. In certain instances where there has been a suspected non-compliance with the Act, the issue may be referred for investigation.

No incident or practice reviews were completed in this quarter.

Audits

An audit entails, depending on its scope:

- documentary evidence; and/or
- observations; and
- 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; and
- where appropriate suggest improvements to procedure 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.

No audits were completed in this 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.

The OGTR provides summarised accounts of investigations, once completed, in the relevant quarterly report. However, the OGTR does not release information about ongoing investigations because the information may:

- jeopardise current or future investigations
- be protected by legislation (for example, the *Privacy Act 1988*)
- contain confidential commercial information
- unfairly damage the reputation of third parties who have not themselves breached legislative requirements.

However, if there was an imminent risk to the health and safety of people and the environment, the Regulator would consider whether release of information may be appropriate.

No investigations were completed in this quarter.

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

At its 7th meeting, held in Melbourne on 29 April 2004, the current GTCCC working groups reported on their activities since the previous meeting and agreed on a new work strategy for each of the groups. Members were invited comment on the GTEC paper *Managing Risk Ethically* and also received presentations on the:

- *Biotechnology Public Awareness Survey 2003* from Biotechnology Australia; and
- OGTR review of its *Risk Analysis Framework*.

GTCCC is scheduled to meet late in 2004. Further information about the issues under consideration by GTCCC can be obtained from the April 2004 meeting communique attached to this Quarterly Report (Appendix B). Previous communiques can also be found on the OGTR website at www.ogtr.gov.au.ogtr.gov.au.

Gene Technology Ethics Committee

During the quarter GTEC continued its work on a range of agreed priority areas out of session. The working groups will report to GTEC on their progress at the next GTEC meeting in July 2004.

Further information about the issues under GTEC consideration can be obtained from previous meeting communiqués, on the OGTR website at www.ogtr.gov.au.

Gene Technology Technical Advisory Committee

During the quarter GTTAC held its 20th face-to-face/teleconference meeting in Canberra on 27 April 2004. At this meeting the Committee provided advice to the Regulator on:

- 1 application for a DIR licence
- 3 RARMPs for DIR licences; and
- 4 applications for DNIR licences and the associated RARMPs;

The Committee also discussed the GTEC paper on *Managing Risk Ethically* and received the following presentations:

- OGTR review of the *Risk Analysis Framework*: and
- Interactions between regulatory agencies.

In addition, on 30 April 2004, the Committee further considered, out of session one of the above three RARMPs for a DIR licence.

Information concerning discussions held at the above meeting will be made available in the next (12th) communique. GTTAC is scheduled to meet again on 22 July 2004.

Further information about the activities of GTTAC can be obtained from the communiques published on the OGTR website at www.ogtr.gov.au.

Reviews

The following reviews continued during this quarter:

- A review to develop a strategy to identify common data requirements for future applications for DIRs, particularly large-scale limited and controlled releases. This review is ongoing.
- A review of the OGTR's *Risk Analysis Framework*.
- A review of *Guidelines for the Certification of Facilities/Physical Containment Requirements* to address practical difficulties that have been encountered in the implementation. In this quarter:
    - drafting of revisions to guidelines for PC3 laboratory facilities, PC2 Aquatic and Anthropod facilities continued.

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 include:

- Participation in United States Food and Drug Administration forum on current and future regulatory policy initiatives at the United States Bioindustry Association Conference at BIO 2004 conference, San Francisco, USA (8 June).
- Conducted meetings with the United States Department of Agriculture's Animal Plant Health Inspection Service and Pew Foundation Initiative on Food and Biotechnology, Washington, USA (11 June).
- Attended the Canadian National Agriculture Biotechnology Council, 16th Annual General Meeting, 'Agricultural Biotechnology: Finding Common Agricultural Goals'. Guelph, Canada (13-14 June)
- Meetings with senior Government representatives from Health Canada, Industry Canada, Environment Canada, Canadian Food Inspection Agency and briefed the Biotechnology Assistant Deputy Ministers Coordinating Committee (BACC), Ottawa, Canada (15-17 June).
- Participation in the 15th session of the Organisation for Economic Co-operation and Development Working Group on Harmonisation of Regulatory Oversight in Biotechnology, Paris, France (16-18 June)

Advice on gene technology regulation

Presentations and meetings

The Gene Technology Regulator and the OGTR endeavour to participate in presentations and meetings on gene technology wherever possible to inform the community and users about the regulatory system. During the quarter the following presentations were given:

- Discussion on the regulation of GM Canola in Canada, National Farmers Union, Canberra, ACT on 2 April
- Discussion on the regulation of GMOs in Australia and Mongolia, Mongolian delegation, Canberra, ACT on 6 April
- "Risk Assessment and Issues relating to White Clover" (CSIRO) White Clover Reference Group, Canberra, ACT on 20 April
- "Regulation of Gene Technology in Australia" to the University of the Third Age, Canberra, ACT on 5 May
- Australian delegation presentation 'Australia's Regulatory System for Gene Technology', US Bioindustry Association Conference, at BIO 2004, San Francisco, 6 June

Institutional Biosafety Committee training sessions

The OGTR regularly provides training sessions to accredited organisations and their IBCs.

No training sessions were conducted in this quarter.

Consultants

During the reporting period, the OGTR managed three consultancy contracts worth a total of $62,814. The table below lists the consultants, describes the purpose of the consultancy and the amount paid during the quarter. The amount paid is nett of GST.

Consultant	Amount paid (GST exclusive)	Purpose
Acumen Alliance	$42,431	Development of an appropriate cost recovery model for the Office of the Gene Technology Regulator
CSIRO	$10,000	Potential for non-target impact of Cry2AB on Diptera
Dialog Information Technology	$10,383	Ongoing work on the Gene Technology Information System (GTIMS)
Total Consultants for quarter	$62,814	

Gene Technology Information Management System

The GTIMS rollout to date has migrated the following number of organizations to electronic application lodgment and tracking in each state.

State	Total Number of Organisations	Number Completed
ACT	11	6
TAS	2	2
NT	3	3
SA	14	7
WA	13	5
NSW	34	13
VIC	40	12
QLD	23	11
Total	140	59

OGTR website

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

- Maps of current field trial locations
- What's New
- Office of Gene Technology Handbook
- Media Releases
- About the OGTR
- Gene Technology Technical Advisory Committee Communiques

The most popular downloaded documents were:

- PR-152: Field test of pineapple plants modified for control of natural flowering *(Ananas comosus)* in Australia
- PR-95: Field test of pineapple plants modified to control flowering and ripening *(Ananas comosus)* in Australia
- PR-35: Planned release of transgenic rose (*Rosa x hybrida*) in Australia
- PR-26: Planned release of genetically modified tomatoes in Australia
- Handbook on the Regulation of Gene Technology in Australia
- GM products approved as food, food additives and processing aids in Australia
- Dealings involving GM products – therapeutics in Australia
- Risk Analysis Framework For Licence Applications to the Office of the Gene Technology Regulator

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 website received over 160 calls and 720 emails in April 2004, 200 calls and 850 emails in May 2004, and 50 calls and 830 emails in June 2004.

Freedom of information

The OGTR received no freedom of information requests during the quarter.

Appendix A

DNIR Licences issued April – June 2004

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 286/2004	22 April 2004	University of Queensland, Queensland	Retroviral expression of known and potential growth-regulatory genes in human and murine cell lines	The aim of this dealing is to understand how certain oncogenes actively cause or contribute to cancer and to identify new oncogenes involved in leukaemia and breast cancer.
DNIR 287/2004	28 May 2004	Monash University, Victoria	Subcellular trafficking of the *Dengue virus* NS5 protein	The aim of this research is to describe the localisation of the *Dengue virus* non-structural protein 5 (NS5) during infection of cultured mammalian and insect cells.
DNIR 288/2004	24 May 2004	AMRAD Operations Pty Ltd, Victoria	Cell lines expressing *Hepatitis B virus*	The aim of this dealing is to study the formation and release of lamivudine resistant and normal *Hepatitis B virus* in liver cells.

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 289/2004	25 May 2004	Flinders University, South Australia	Asexual genetic exchange in *Rhynchosporium secalis*, the causal agent of barley scald	The aim of this dealing is to investigate whether genes can be exchanged between isolates of *R. secalis* in the absence of a sexual cycle.
DNIR 291/2004	26 May 2004	South East Sydney Area Health Service, New South Wales	Analysis of *Cytomegalovirus* (CMV) genes involved in antiviral susceptibility, replication and cell tropism	The aim of this dealing is to determine the role of different gene regions of CMV in infection and growth of the virus and inhibition of growth by antiviral drugs, focussing on the DNA polymerase and protein kinase mutations.
DNIR 301/2004	27 Jun 2004	Intervet Australia Pty Limited, Victoria	Fermentation, processing and inactivation of *M. haemolytica* cultures	The aim of this dealing to produce large-scale quantities of recombinant *M. haemolytica* for use in an inactivated veterinary vaccine.

Appendix B

Gene Technology Community Consultative Committee

Melbourne, Victoria

29 April 2004

Communique

The Gene Technology Community Consultative Committee (GTCCC) held its seventh meeting in Melbourne, Victoria on 29 April 2004

The 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.

At its seventh meeting, the current GTCCC working groups reported on their activities since the previous meeting. The Committee received a presentation from Biotechnology Australia concerning a survey on biotechnology. There were also two presentations from the Office of the Gene Technology Regulator (OGTR) covering the Risk Analysis Framework and the assessment process of applications for the declaration of Confidential Commercial Information.

GTCCC's Work Plan

GTCCC's first communique from its meetings of April and July 2002 detailed a number of priority areas that would form the basis of the Committee's future work plan and result in the provision of advice to the Regulator. Since that time the working groups have been developing and refining their ideas out-of session and at each subsequent meeting of the Committee. Details of the current working groups are provided below.

WORKING GROUP 1:

Review of processes by which the OGTR can improve community consultation and participation including review of the effectiveness of information and communication provided to the community in general and to the regions involved in limited and controlled releases and the processes used to assess the fitness of applicants to be issued a licence

The working group provided members with the revised draft paper on community consultation which incorporated the Committee's comments from the previous GTCCC meeting. The Committee discussed the paper comprehensively and additional amendments were made. The draft paper will be provided to the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics Committee (GTEC) for consideration and comment.

The Committee thanked the working group for the report on applicant fitness and recommended that the OGTR give consideration to reporting the assessment of applicant fitness more comprehensively.

WORKING GROUP 2:

Consider issues associated with public understanding of science, risk and public perceptions of gene technology

The working group presented to the Committee the revised paper on incorporating public understanding into the regulation of gene technology. The working group highlighted developments that resulted from comments received at the previous GTCCC meeting. The Committee discussed the paper and proposed a number of amendments. The paper will be circulated to the Committee for out-of-session consideration and will then be forwarded to GTTAC and GTEC for consideration and comment.

Biotechnology Australia: Results of public survey on Biotechnology

A representative from Biotechnology Australia presented the outcomes of the third stage of a tracking studying, *Biotechnology Public Awareness Survey 2003,* to determine the level of knowledge in the community regarding gene technology and attitudes towards this technology. Further information about Biotechnology Australia and the survey is available from the Biotechnology Australia website www.biotechnology.gov.au.

Risk Analysis Framework

A representative from the OGTR gave a presentation on the OGTR's Risk Analysis Framework (RAF) to update members on the RAF review process currently under way. The RAF provides guidance on how the OGTR conducts its risk assessments.

GTEC paper on managing risk ethically

The GTEC paper Managing Risk Ethically was provided to the Committee for consideration. Members undertook to provide comments to GTEC on the paper. Information on GTEC is available from the OGTR website www.ogtr.gov.au.

For all inquiries, please contact the Office of the Gene Technology Regulator on

1800 181 030 (free-call)