Quarterly Report of the Gene Technology Regulator for the period 1 July to 30 September 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 July to 30 September 2004.

During this quarter, key achievements included the issuing of two licences for dealings involving the intentional release of genetically modified organisms, eleven licences for dealings not involving intentional release of genetically modified organisms, six organisations were accredited and 78 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 or adverse effects upon the environment were identified.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator
27 January 2005

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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 July - September 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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PART 1 National regulatory system

Key achievements during this quarter

The key achievements of the July – September 2004 quarter were:

Licences and other instruments

- 2 licences issued for dealings involving the intentional release of GMOs into the environment (DIR licences).
- 11 licences issued for dealings not involving intentional release of GMOs into the environment (DNIR licences)
- 135 notifiable low risk dealing (NLRD) notifications received
- 6 organisations accredited
- 78 contained facilities certified
- 49 surrender of certifications processed
- 1 surrender of DNIR processed.
- 4 surrenders of DIR processed.
- 349 variations processed.

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

Monitoring and compliance

Approximately 9 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 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 met once during this quarter on 18 August 2004.

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.[1]

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 three applications for a DIR licence and two RARMPs.

Further information is set out in Part 2.

Public participation

During the quarter, the Regulator issued three 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 *Melbourne Age, Geelong Advertiser* 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.

[1] 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 July - September 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 July – 30 September 2004

Application type	Number received	Number approved[1]
DIR licence	5	2
DNIR licence	34	11
Accreditations	4	6
Certifications	78	78

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 September 2004, of 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 053/2004	DIR 045/2004[2]	DIR 049/2004[4]		DIR 047/2004
DIR 054/2004	DIR 046/2004[2]			DIR 048/2004
DIR 055/2004	DIR 050/2004[2]			
DIR 056/2004	DIR 051/2004[3]			
DIR 057/2004	DIR 052/2004[3]			
	DIR 053/2004			
	DIR 054/2004			
	DIR 055/2004			

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 stopped on these applications

3. First round consultation closed 8 September 2004

4. Second round consultation closed 10 September 2004

Applications received for DIR licences

The OGTR received 5 applications for DIR licences in the July – September 2004 quarter as follows:

- DIR 053/2004 'Field testing of salt tolerant wheat on saline land' (Grain Biotech Australia)
- DIR 054/2004 'Alteration of grain starch in wheat' (CSIRO)
- DIR 055/2004 'Field trials of herbicide tolerant (Roundup Ready® Flex MON 88913) and herbicide tolerant /insect resistant (Roundup Ready® Flex MON 88913/Bollgard II®) cottons' (Monsanto Australia Limited)
- DIR 056/2004 'Commercial release of herbicide tolerant cotton (LLCotton25) for use in the Australian cropping system' (Bayer CropScience Ltd)
- DIR 057/2004 'Field trials of genetically modified herbicide tolerant hybrid *Brassica juncea*' (Bayer CropScience)

All applications for DIR licences received in the July - September 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 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 rice genome' (CSIRO)
- DIR 053/2004 'Field testing of salt tolerant wheat on saline land' (Grain Biotech Australia)
- DIR 054/2004 'Alteration of grain starch in wheat' (CSIRO)
- DIR 055/2004 'Field trials of herbicide tolerant (Roundup Ready® Flex MON 88913) and herbicide tolerant /insect resistant (Roundup Ready® Flex MON 88913/Bollgard II®) cottons' (Monsanto Australia Limited)

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 RARMP for the following application:

- DIR 049/2004 'Field trial – Evaluation under field conditions of the cotton rubisco small subunit promoter driving a reporter gene' (CSIRO)

Withdrawn applications for DIR licences

No DIR licences where withdrawn in this quarter.

Surrendered applications for DIR licences

Licences have been surrendered as field trials have finished, post harvet monitoring conditions have been met and the site has been signed off by the OGTR.

- DIR 007/2001 'Improved alkaloid production in oilseed poppy (*Papaver somniferum*)' (Department of Agriculture, Western Australia)
- DIR 015/2002 'Agronomic assessment and seed increase of transgenic cotton expressing tolerance to the herbicide glufosinate ammonium (CSIRO)
- DIR 016/2002 'Evaluation under field conditions of sub-clover stunt virus promoters driving an insect tolerance gene (Cry1Ab) from *Bacillus thuringiensis* (cotton) (CSIRO)
- DIR 025/2002 'Seed increase and efficacy studies in northern Australia of transgenic cotton expressing a new insecticidal protein gene (CSIRO)

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)

The ‘clock’ was stopped during this quarter on the following application:

- DIR 050/2004 ‘Vaccination of cattle with recombinant bovine herpesvirus vaccines’ (Queensland Department of Primary Industries and Fisheries)

Finalised applications for DIR licences

During the quarter, the Regulator issued two DIR licences:

- 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 trial to assess transgenic cotton expressing natural plant genes for insect control’ (Hexima Limited)

Summary information on DIR applications and RARMPs, as well as the finalised RARMPs, and 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 DNIR licences

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

During the quarter the Regulator issued 11 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 (NLRDs) 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 conducted in contained 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 135 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 applications received to vary existing licences and other instruments, as well as the number of applications processed during the July - September 2004 quarter.

Applications received and decisions made; existing licences and other instruments 1 July – 30 September 2004

Type	Number received	Number processed[1]
Surrender of certification	34	49
Surrender of DIR licence	4	4
Surrender of DNIR licence	1	1
Surrender of accreditation	0	0
Variation of certification[2]	304	315
Variation of accreditation	2	2
Variation of DIR licence[3]	17	10
Variation of DNIR licence[3]	22	22

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 for contained facilities 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

The following table describes the number of CCI applications received and declared during the July – September 2004 quarter.

CCI applications received and declarations made 1 July – 30 September 2004

Types of applications for which CCI was sought	Number received	Number declared[1]
DIRs	4	3
DNIRs	2	1
NLRDs	0	0

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

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 to a minimum of 20 per cent of field trial sites each year. A minimum of 5 per cent of current trial sites and 5 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 unannounced 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) 4, 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 July-September 2004 quarter, 27 field trial sites were subject to monitoring visits. Monitoring was carried out on 3 DIR licences held by two organisations and covered 3 plant types.

Current field trial sites monitored. Of the 22 sites current in the quarter, 2 were monitored. This represents a monitoring rate of 9 per cent of all current sites for the quarter.

Post-harvest field trial sites monitored. Of the 123 sites subject to post-harvest monitoring in the quarter, 25 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 July-September 2004 quarter, monitoring in connection to contained dealings covered 9 organisations, 22 PC facilities and 4 DNIR licences. Monitoring of PC facilities encompassed PC2 laboratories (19 visited), PC2 animal containment facilities (2 visited), PC3 laboratory facilities (1 visited), PC3 laboratory re-certifications (5 visited), PC3 animal containment facility re-certifications (1 visited), PC3 laboratory pre-certifications (2 visited) and PC2 laboratory large scale pre-certifications (2 visited).

Monitoring of DIRs

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

Licensed Organisation Name	Licence Number	No. sites visited	Site status[1]	Crop type
Bayer CropScience Pty Ltd	DIR 010/2001	12	PHM	Indian Mustard
		12	PHM	Canola
Bayer CropScience Pty Ltd	DIR 032/2003	2	C	Canola
CSIRO Plant Industry	DIR 018/2001	1	PHM	Poppy
Totals	3	27	C=2 PHM=25	3 types

1 C= current, PHM = post-harvest monitoring

Monitoring of DNIRs

Licensed Organisation Name	Licence Number
University of Queensland	DNIR 272/2003
The Prince Charles Hospital Health Service District	DNIR 215/2002
University of Canberra	DNIR 200/2003
Murdoch Children's Research Institute	DNIR 295/2004
Totals	4 DNIR licences

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
Princess Alexandra Hospital	PC2 Laboratory	2
	PC2 Animal House	1
John Hunter Hospital	PC2 Laboratory	3
Royal Children's Hospital	PC2 Laboratory	4
The Prince Charles Hospital Health Service District	PC2 Laboratory	1
University of Canberra	PC2 Laboratory	3
Austin Health	PC2 Laboratory	3
	PC2 Animal House	1
RMIT University	PC2 Laboratory	2
Melbourne Health	PC3 Laboratory[1]	1
Murdoch Children's Research Institute	PC2 Laboratory	1
Totals	3 Facility Types	22

1 Joint inspection with Contained Dealings Evaluation Section

Monitoring findings

DIRs

During the quarter, 4 non-compliances with licence conditions were identified as requiring further attention. A summary of each follows:

Organisation	Bayer CropScience Pty Ltd
Licence number and site	DIR 010/2001, PR-90X(3) Site 1
Summary of dealing	Licence relates to field trials of Indian mustard (*Brassica juncea*) genetically modified to express the *bar* gene that confers tolerance to the herbicide glufosinate ammonium. The site is in the post harvest monitoring phase.
Findings	At the time of inspection approximately 20 *B. juncea* volunteers were observed at the location. These volunteers had reached the flowering stage, with some plants also having early development of seed pods. A flowering wild radish (*Raphanus raphanistrum*) plant was observed within 10 metres of two flowering *B. juncea* volunteers.
Risk assessment	The OGTR determined the risk of gene dispersal and persistence of the GMO or its genetic material at the site was negligible, due to the *B. juncea* and *R. raphanistrum* plants being removed prior to seed set. Therefore, the risks to health, safety and the environment posed by this non-compliance were assessed as negligible.
Risk management	Immediate action was taken at the time of inspection to remove and destroy the *B. juncea* and *R. raphanistrum* plants. The licence holder was requested to conduct monitoring at fortnightly intervals, for the following month until the end of spring. The outcome of these additional inspections were provided to the Regulator within 5 working days of them taking place.

Organisation	Bayer CropScience Pty Ltd
Licence number and site	DIR 010/2001, PR-90X(2) Site 4
Summary of dealing	Licence relates to field trials of Indian mustard (*Brassica juncea*) genetically modified to express the *bar* gene that confers tolerance to the herbicide glufosinate ammonium. The site is in the post harvest monitoring phase.
Findings	At the time of inspection, it was observed that field peas were sown as post harvest crops. The licence does not permit this crop to be planted on the site without the prior approval of the Regulator.
Risk assessment	As no *B. juncea* volunteers were observed at the time of inspection, 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	The Regulator determined that Bayer had satisfied all their post harvest monitoring obligations at the site. A variation to DIR 010/2002 is being processed confirming that Bayer no longer has any further requirements to monitor or manage this site.

Organisation	CSIRO Plant Industry
Licence number and site	DIR 006/2001, Site 2
Summary of dealing	Licence relates to field trials of cotton (*Gossypium hirsutum*) genetically modified to express the *Cry1Ac* and *Cry2Ab* genes that confer insect resistance and the EPSPS gene that confers tolerance to the herbicide glyphosate. This site is in the post harvest monitoring phase.
Findings	This site was planted to GM cotton under DIR 006/2001 and harvested in November 2002. However, records show that the site was subsequently sown to GM cotton under DIR 012/2002 Site 8 in March 2003. Licence conditions for DIR 006/2001 only permit cotton being replanted at the location after a period of 12 months after harvesting the original GM cotton.
Risk assessment	As a result of (1) the same genetic modifications approved under DIR012/2002 being planted on this site, (2) the lack of propensity for cotton to establish a significant seed bank, and (3) the post harvest management to occur on the site following harvest of DIR 012/2002, 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	An application to the Regulator to vary DIR 006/2001 to transfer the site to DIR 012/2002 was received and accepted.

Organisation	Department of Agriculture, Western Australia
Licence number and site	DIR 009/2001, Site 1
Summary of dealing	Licence relates to field trials of cotton (*Gossypium hirsutum*) genetically modified to express the *Cry1Ac* and *Cry2Ab* genes that confer insect resistance. This site is in the post harvest monitoring phase.
Findings	This site was planted to GM cotton under DIR 009/2001 and harvested in November 2002. However, records show that the site was subsequently sown to GM cotton under DIR 012/2002 Site 1 in March 2003. Licence conditions for DIR 009/2001 only permit cotton being replanted at the location after a period of 12 months after harvesting the original cotton.
Risk assessment	As a result of (1) the same genetic modifications approved under DIR012/2002 being planted on this site, (2) the lack of propensity for cotton to establish a significant seed bank, and (3) the post harvest management to occur on the site following harvest of DIR 012/2002, 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	An application to the Regulator to vary DIR 009/2001 to transfer the site to DIR 012/2002 has been received.

Physical containment facilities

OGTR's monitoring of PC2 facilities and DNIR licences 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, the 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 PC2 animal and PC2 plant containment facilities were issued on 7 August 2003. Whilst the OGTR is managing a program where these facilities are being progressively re-certified according to the Version 2.2 Guidelines, some facilities are still certified under Version 1 of the Guidelines

Guidelines for the remaining facility types (PC1, PC2, aquatic, arthropod and large scale, PC3 and PC4) continue to be reviewed.

This quarter, monitoring staff were also involved in one joint re-certification inspection of a PC3 facilities facility with officers from the Contained Dealings Evaluation Section of the OGTR. These re-certification inspections are usually undertaken when these facilities are shut down which enables safe examination of the physical structure of these facilities (including air ventilation systems) as well as inspection 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.

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

GTCCC held its 8th meeting in Melbourne on 4 August 2004, the current GTCCC working groups reported on their activities since the previous meeting. Members received presentations from:

- the Faculty of Law of the Australian National University regarding the precautionary principle; and
- the OGTR on the review of the *Risk Analysis Framework*.

Further information about the issues under consideration by GTCCC can be obtained from the communiqué attached to this Quarterly Report (Appendix B). Previous communiqués can also be found on the OGTR website at www.ogtr.gov.au.

Gene Technology Ethics Committee

GTEC held its 7th meeting in Canberra on 19-20 July 2004. The current GTEC working groups discussed and outlined future progress on their projects and Members received presentations from:

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

GTEC were also invited to comment on the following two GTCCC papers:

- *Community Consultation and Participation*; and
- *Incorporating public understanding into the regulation of gene technology.*

Further information about the issues under GTEC consideration can be obtained from meeting communiqués, attached to this Quarterly report (Appendix C) or from the OGTR website at www.ogtr.gov.au.

Gene Technology Technical Advisory Committee

GTTAC held its 21st meeting in Canberra on 22 July 2004. At this meeting the Committee provided advice to the Regulator on:

- 3 applications for a DIR licence;
- 1 RARMP for a DIR licence; and
- 7 applications for DNIR licences and the associated RARMPs.

Members received a presentation from the OGTR on the "Cotton Research Program". The Committee also discussed the OGTR review of the *Gene Technology Regulations 2001.*

GTTAC also held its 22nd meeting on 21 September 2004 by teleconference. At this meeting the Committee provided advice to the Regulator on:

- 4 applications for a DIR licence;
- 1 RARMP for a DIR licence; and
- 2 applications for DNIR licences and the associated RARMPs.

The Committee also discussed the OGTR reviews of the *Risk Analysis Framework* and the *Gene Technology Regulations 2001.*

Information concerning discussions held at the above meeting will be made available in the next (13th) communiqué. GTTAC is scheduled to meet again in the first quarter of 2005.

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

PART 4 Other activities

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 the *Gene Technology Regulations 2001.*
- 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 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 the 4th ASEAN-ILSI Training Workshop on Safety Assessment of Agriculture –Related GMOs, Jakarta, Indonesia (31 August – 2 September 2004)

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[1]:

[1] Unless otherwise indicated, the location was Canberra.

- CRC for Molecular Plant Breeding, "Regulatory Environment for GMOs in Australia", 7 July 2004
- AVCC Deputy & Pro-Vice-Chancellors (Research) Committee meeting, "Gene Technology Regulation and Australian Universities", 16 July 2004
- States and Territories Technical Committee meeting, "Cotton Research Program", 19 August 2004
- 14th Australian Weeds Conference, "Gene Technology Regulation in Australia": "Assessing and Managing the Weediness of GM Plants", Wagga Wagga, NSW, 16 September 2004
- "Regulation of Gene Technology in Australia" at the 4th ASEAN-ILSI Training Workshop on Safety Assessment of Agriculture – Related GMOs, Jakarta, Indonesia, 2 September 2004
- Australasian Research Management Society, ARMS 2004 Conference, , "Compliance considerations in the regulation of gene technology in Australia", 17 September 2004
- Royal Australia Chemical Institute Cereal Chemistry Division and the Wheat Breeders Assembly "Regulatory Environment for GMOs in Australia", 21 September 2004
- Griffith University - Gold Coast, "Regulation of Gene Technology", 26 September 2004
- Griffith University - Nathan (Brisbane), "Regulation of Gene Technology" 27 September 2004

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 two consultancy contracts worth a total of $47,727. 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	$35,905	Development of an appropriate cost recovery model for the Office of the Gene Technology Regulator
Dialog Information Technology	$11,822	Ongoing work on the Gene Technology Information System (GTIMS)
Total Consultants for quarter	$47,727	

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	39	12
QLD	23	11
Total	139	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 Communiqués

The most popular downloaded documents were:

- Draft *Risk Analysis Framework*
- GTEC Submission on the National Health and Medical Research Committee's Draft Guidelines on Xenotransplantation Research
- PR-26: Planned release of genetically modified tomatoes in Australia (authorised under the former voluntary system by the Genetic Manipulation Advisory Committee (GMAC))
- DIR 20/2002 Risk Assessment and Risk Management Plan Final Version

  "General Release of Roundup Ready® canola (*Brassica napus*) in Australia"
- PR-35 Planned release of transgenic rose (Rosa x hybrida) containing kanamycin or chlorsulfuron resistance gene and 'blue' gene (flavonoid 3'5'hydroxylase) (also authorised by GMAC)

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 207 calls and 870 emails in July 2004, 196 calls and 1010 emails in August 2004, and 115 calls and 980 emails in September 2004.

Freedom of information

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

Appendix A

DNIR Licences issued July - September 2004

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 290/2004	26 July 2004	Australian National University, Australian Capital Territory	Temporary storage of *Ross River virus* mutants	The proponents intend to store *Ross River virus* mutants for future use.
DNIR 292/2004	18 August 2004	Queensland Institute of Medical Research, Queensland	Kunjin replicon virus like particles for delivery of cytokines into mice	The proponents intend to deliver immune response modulating genes into mice using Kunjin replicons with the aim of effecting tumour regression and preventing transplant rejection.
DNIR 293/2004	30 July 2004	University of Queensland, Queensland	Viral delivery of genes or siRNA involved in adipogenesis or insulin signalling cells	The aim of this dealing is to examine the effect of increasing or reducing the expression of factors involved in the body's response to insulin and in human fat tissue development in mammalian cells.

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 295/2004	30 July 2004	Murdoch Children's Research Institute, Victoria	Somatic cell genetic studies of mitochondrial chain disorders	The aim of this dealing is to determine the genetic basis of human diseases caused by mitochondrial energy generation disorders.
DNIR 297/2004	10 August 2004	Australian Army Malaria Institute, Queensland	Development of *in vitro* liver stage drug susceptibility assays for *Plasmodium vivax*, *P.falciparum, P.yoelii* and *P.cynomolgi*	The aim of this dealing is to develop an *in vitro* assay for evaluating the effectiveness of new drugs and vaccines against the liver stage of malarial parasites.
DNIR 298/2004	23 September 2004	CSIRO – Molecular Science, New South Wales	A Phase I/IIa two centre, open label, dose escalation study to assess the safety, tolerability and efficacy of FP253 in combination with fludarabine phosphate	The aim of this dealing is to conduct a clinical trail to assess the safety, tolerability and efficacy of a new therapy for prostate cancer.

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 299/2004	22 September 2004	Monash University, Victoria	Characterisation of replication competent *Hepatitis B viruses*	The aim of this dealing is to characterize *Hepatitis B viral* DNA sequences present in blood samples from different animal species.
DNIR 302/2004	3 September 2004	AMRAD Operations Pty Limited, Victoria	Generation of stable cell lines expressing *Hepatitis B virus* using the ViraPaower™ lentiviral expression system	The aim of this dealing is to generate recombinant liver cells that express *Hepatitus B virus*.

Appendix B

Gene Technology Community Consultative Committee

4 August 2004, Melbourne

COMMUNIQUE

The Gene Technology Community Consultative Committee (GTCCC) held its eighth meeting in Melbourne on 4 August 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 eighth meeting, the current GTCCC working groups reported on their activities since the previous meeting. GTCCC were informed of the other Gene Technology Advisory Committees' activities through cross-member reports and received a report on the activities of the Office of the Gene Technology Regulator (OGTR). Members also received a presentation on the review process of the Risk Analysis Framework and a presentation on the precautionary principle from the cross-member for the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics Committee (GTEC). As this was the final meeting for the current membership of the GTCCC, members reflected on the inaugural triennium of the GTCCC and made recommendations for consideration by the new GTCCC membership.

GTCCC's Work Plan

GTCCC's first communiqué 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 applicant to be issues a licence

Since the previous GTCCC meeting, the paper had been provided to GTTAC and GTEC for their consideration and comment. GTCCC members discussed these comments in detail. The paper will be considered further at the next GTCCC meeting.

WORKING GROUP 2:

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

Since the previous GTCCC meeting, the paper had been provided to GTTAC and GTEC for their consideration. The Committee discussed the comments received and the additional comments put forward by members. The Committee finalised the document at the meeting and referred it to the Regulator.

Presentation on the precautionary principle

Members received a presentation from the cross-member for GTTAC and GTEC, providing an overview of the precautionary principle. The presentation described how a statement on precaution included in the Act is based on the *Rio Declaration on Environment and Development (1992)*.

Risk Analysis Framework

A representative from the OGTR gave a presentation on the review of the Risk Analysis Framework (RAF) to update members on the review process currently under way. The RAF provides guidance on how the OGTR conducts its risk assessments. The Committee was advised that comments on the draft revised RAF will be sought from members, Australian Government agencies and the public in August 2004.

Next Meeting

The next GTCCC meeting is scheduled later in 2004.

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

Appendix C

Gene Technology Ethics Committee Meeting

19-20 July 2004, Canberra

COMMUNIQUE

The Gene Technology Ethics Committee (GTEC) held its seventh meeting in Canberra on the 19th and 20th of July 2004.

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

At its July 2004 meeting, the current GTEC working groups reported on their progress since the previous GTEC meeting. In addition, members received presentations from Biotechnology Australia and the Office on of the Gene Technology Regulator (OGTR). Members were also informed of relevant work of other Gene Technology Advisory Committees via cross-members reports, and received reports from the Animal Welfare Committee (AWC) and the Australian Health Ethics Committee (AHEC). A Chair's activity report and a report from the Gene Technology Regulator on activities of the OGTR were also provided to members for their information. Key outcomes from the meeting are reported below.

GTEC's Work Plan

GTEC's first communiqué from its inaugural meeting in December 2001 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 status of a number of the current working groups are provided below for information.

Ethical Guidelines in Relation to Genetically Modified Organisms

The working group presented a revised report which had been amended out-of-session to incorporate comments from the previous GTEC meeting. The Committee recommended a number of amendments to the working group. The working group informed the Committee that the guidelines are of interest to other government agencies. The working group will circulate a revised version of the guidelines to the Committee out-of-session later this year.

Ethical Issues Associated with Trans-species Gene Transfer[1]

Since the previous GTEC meeting, GTEC sought further comment from the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Community Consultative Committee (GTCCC). GTTAC and GTCCC first commented on the paper in November 2003 and December 2003 respectively. GTEC valued these additional comments and resolved to incorporate them where possible. A revised draft paper will be considered by GTEC out-of-session later this year.

Once finalised, the paper will be published on the Committee's page on the OGTR website.

Managing Risk Ethically

GTEC considered comments received from GTTAC and GTCCC. GTEC resolved to make minor amendments to the paper in light of these comments. GTEC also resolved to refer the paper to the OGTR as part of the review of the Risk Analysis Framework. Once finalised, the *Managing Risk Ethically* paper will be available on the OGTR website.

GMOs, Lay Understandings and Civic Ethics (A History of Ideas about Environmental Precautions)

This paper was discussed in detail by the Committee and several amendments were suggested to the working group. The Committee noted the paper would provide further background information to other GTEC papers. The working group will revise the paper and it will be considered by GTEC again later this year.

[1] Previously titled *Ethical Issues Associated with Transkingdom Gene Transfer.* 'Trans-species' more accurately reflects the matters discussed in the paper.

GTEC and Relationships with Other Committees

The Committee welcomed an observer from the AWC who provided a report on relevant AWC activities. GTEC also heard a report from the AHEC, including a discussion of the progress of the development of animal-to-human transplant guidelines to which GTEC provided two submissions.

A representative from Biotechnology Australia presented the outcomes of the third stage of a tracking study titled *Biotechnology Public Awareness Survey 2003.* The study aims 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.

GTEC also received a presentation from a representative of the OGTR updating members on the progress of the review of the Risk Analysis Framework. GTEC was advised that its members, Australian Government agencies and the public would be invited to comment on the revised draft in August 2004.

GTEC provided comment on two draft papers from the GTCCC. Further information about the activities of the GTCCC is available from the OGTR website.

The Regulator reported on the operations of the OGTR. This information is publicly available in the Quarterly Reports of the Gene Technology Regulator on the OGTR website, or by request by phoning the number below.

Next Meeting

The next GTEC meeting is scheduled for late 2004.

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