Quarterly Report of the Gene Technology Regulator for the period 1 January to 31 March 2005

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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* (the Act), I am pleased to present to you the Quarterly Report of the Gene Technology Regulator, covering the period 1 January to 31 March 2005.

During this quarter, key achievements included the issuing of two licences for dealings involving the intentional release of genetically modified organisms, 18 licences for dealings not involving intentional release of genetically modified organisms, three organisations were accredited and 48 contained facilities were certified.

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

In addition, the OGTR concluded a comprehensive series of practice reviews with a representative sample of accredited organisations. The reviews established that accredited organisations and their Institutional Biosafety Committees had well developed and effective decision making, risk management and compliance systems for their activities under the Act and the *Gene Technology Regulations 2001*.

The revised *Risk Analysis Framework,* a guidance document for the assessment of licence applications to conduct dealings with genetically modified organisms, was also published during the quarter.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator
12 July 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 the statutory time limit for making a decision on an application is suspended – usually because evaluation cannot proceed until additional information requested from the applicant is received
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DIR	A dealing involving intentional release of a GMO into the environment (for example, field trial or commercial release)
DIR licence	A licence for a dealing involving intentional release of a GMO into the environment
DNIR	A contained dealing with a GMO not involving intentional release of the GMO into the environment (for example, experiments in a certified facility such as a laboratory)
DNIR licence	A licence for a dealing not involving intentional release of a GMO into the environment
Expert advisers	Advisers appointed by the Minister to give expert advice to either GTTAC or GTEC to assist them in the performance of their functions (expert advisers are not committee members)
FSANZ	Food Standards Australia New Zealand
GM	Genetically modified

GM product	A thing (other than a GMO) derived or produced from a GMO
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically modified organism
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
GTMC	Gene Technology Ministerial Council
GTSC	Gene Technology Standing Committee
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
Incident	A self-reported event which may constitute a non-compliance with regulatory requirements and a public health or environment risk
NLRD	Notifiable low risk dealing (e.g. plant or tissue culture work undertaken in a certified contained facilities)
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 January to March 2005 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 January – March 2005 quarter were:

Licences and other instruments

- 2 licences issued for a dealing involving the intentional release of GMOs into the environment (DIR licence).
- 18 licences issued for dealings not involving intentional release of GMOs into the environment (DNIR licences).
- 82 Notifiable Low Risk Dealing (NLRD) notifications received.
- 3 organisations accredited.
- 48 contained facilities certified.
- 11 surrenders of certifications processed.
- 2 DNIR licences surrended.
- 262 variations processed.

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

Monitoring and compliance

Approximately 14 per cent of current field trial sites and six 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 activities, including the conclusions of a comprehensive series of practice reviews with a representative sample of accredited organisations, is contained in Part 2 of this report.

Risk Analysis Framework

The revised *Risk Analysis Framework* for genetically modified organisms was published during the quarter.

The original document, published in January 2002, was developed in parallel with the Gene Technology Act and outlined the requirements of the Act in preparing Risk Assessment and Risk Management Plans. The revised framework explains how the OGTR applies internationally recognised risk analysis practice to the evaluation of licence applications.

It also incorporates a discussion of risk communication, and introduces standardised terminology to differentiate between various elements of the assessment process.

The review process involved consultation with the three gene technology advisory committees established by the Act (refer to Part 3 of this quarterly report for more information), State and Territory governments, previous applicants, accredited organisations and other key stakeholders, including the public. In addition, feedback was actively sought from equivalent international regulatory authorities.

The new document is available from the OGTR website www.ogtr.gov.au or by contacting the office directly.

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 Gene Technology Ministerial Council (Ministerial Council) comprises one Minister from the Commonwealth and one Minister from each of the States and Territories. Currently, the Ministerial Council includes Ministers from a range of portfolios including health, agriculture, environment and innovation.

The Ministerial Council met on 30 March 2005 to consider aspects of the independent review of *Gene Technology Act 2000*. The meeting was chaired by the Hon Tony McGrady, Queensland Minister for State Development and Innovation.

Gene Technology Standing Committee

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

The Standing Committee held several teleconferences to progress items for consideration at the 30 March 2005 Ministerial Council meeting.

Australian Government agency liaison

The close relationship between the OGTR and other Australian Government authorities and agencies continued during this quarter.

Under the Act, the Regulator must seek advice from prescribed Australian Government authorities and agencies and the Australian Government Environment Minister. Advice is sought on matters relevant to preparing the RARMP for each application made to the Regulator for a DIR licence.

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

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

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

In addition, comment is sought on each 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 four RARMPs.

Further information is set out in Part 2.

Public participation

During the quarter, the Regulator issued four 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 Weekend Australian* newspaper
- relevant regional press, such as *The Weekend Advertiser (* Wagga Wagga NSW)*, The Canberra Times, The West Australian*, and rural press such as *Queensland Country Life, The Countryman* and *The Land.*
- OGTR website www.ogtr.gov.au.

Further information is set out in Part 2.

PART 2 Regulation of genetically modified organisms

Part 2 of the report outlines the regulatory activity undertaken during the January to March 2005 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 January to 31 March 2005

Application type	Number received	Number approved[1]
DIR licence	1	2
DNIR licence	5	18
Accreditations	3	3
Certifications	38	48

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 the applicant's suitability, policy principles and any relevant policy guidelines.

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

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

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

The Act and the *Gene Technology Regulations 2001* (the Regulations) mandate minimum timeframes for the two rounds of consultation that the Regulator must undertake with prescribed expert groups and key stakeholders during the processing of each DIR application. However, longer periods 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 undergoing evaluation during the quarter.

Status, as at 31 March 2005, 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 045/2004[2] DIR 046/2004[2] DIR 056/2004[2] DIR 057/2005 DIR 058/2005	DIR 050/2004 DIR 053/2004[2] DIR 054/2004 DIR 055/2004		DIR 051/2004 DIR 052/2004

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 is stopped on these applications because further information was sought from the applicant

Applications received for DIR licences

The OGTR received one application for a DIR licence in the January to March 2005 quarter.

- DIR 058/2005 'Small Scale Field Trial of GM Insect Resistant (VIP) Cotton' (Deltapine Australia Pty Ltd)

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 057/2004 'Field trials of genetically modified herbicide tolerant hybrid *Brassica juncea*' (Bayer CropScience Pty Ltd)
- DIR 058/2005 'Small Scale Field Trial of GM Insect Resistant (VIP) Cotton' (Deltapine Australia Pty Ltd)

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 050/2004 'Vaccination of cattle with recombinant bovine herpesvirus vaccines' (Queensland Government Department of Primary Industries and Fisheries)
- DIR 051/2004 'Field trial of genetically modified (GM) sugarcane expressing sucrose isomerase' (University of Queensland)
- DIR 053/2004 'Field trial of genetically modified salt tolerant wheat on saline land' (Grain Biotech Australia Pty Ltd)
- DIR 054/2004 'Field trial of genetically modified wheat with altered grain starch' (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 Ltd)

Withdrawn applications for DIR licences

No DIR licence applications were withdrawn in this quarter.

Surrendered applications for DIR licences

No DIR licences were surrendered during this quarter.

Clock stopped on four applications for DIR licences

The Regulations determine that a day on which the Regulator is unable to proceed with the decision-making process, or a related function, because information requested from the applicant has not been received, is not counted as part of the prescribed 170 day time-limit for a decision to be made on an application

This clock stop applied for some or all days in this quarter for the following applications:

- 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)
- DIR 053/2004 'Field trial of genetically modified salt tolerant wheat on saline land' (Grain Biotech Australia Pty Ltd)
- DIR056/2004 'Commercial release of herbicide tolerant cotton (LLCotton25)' (Bayer CropScience Pty Ltd)

Finalised applications for DIR licences

During the quarter, the Regulator issued two DIR licences:

- 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' (CSIRO)

Summary information on DIR applications and RARMPs, finalised RARMPs, and 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 18 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 82 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 January to March 2005 quarter.

Applications received and decisions made; existing licences and other instruments 1 January to 31 March 2005

Type	Number received	Number processed[1]
Surrender of certification	10	11
Surrender of DIR licence	0	0
Surrender of DNIR licence	1	2
Surrender of accreditation	1	0
Variation of certification[2]	117	230
Variation of accreditation	2	2

Variation of DIR licence[3]	5	9
Variation of DNIR licence[3]	17	21
Transfer of DNIR	2	6

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 one CCI application relating to a DIR application (DIR 058/2005). This application was subsequently withdrawn as the CCI was previously declared under DIR 036/2003.

The Regulator made no CCI declarations in relation to applications for a DNIR licence, and no CCI 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 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.

These inspections focus on the integrity of the physical structure of the facility and on the general laboratory practices followed in that facility, including those practices followed for dealings not involving intentional release (DNIRs), notifiable low risk dealings (NLRDs) and exempt dealings.

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored. During the January to March 2005 quarter, 12 field trial sites were subject to monitoring visits. Monitoring was carried out on two DIR licences and covered one plant type.

Current field trial sites monitored. Of the 43 sites current in the quarter, six were monitored. This represents a monitoring rate of 14 per cent of all current sites for the quarter.

Post-harvest field trial sites monitored. Of the 103 sites subject to post-harvest monitoring in the quarter, six were monitored. This represents a monitoring rate of six per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities. During the January to March 2005 quarter, monitoring in connection to contained dealings covered 10 organisations and 25 PC facilities. Monitoring of PC facilities encompassed PC2 laboratories (18 visited), PC2 animal containment facilities (two visited),

PC3 laboratory re-certifications (two visited), PC3 laboratory pre-certification inspections (one visited) and PC2 large scale pre-certification inspections (two visited).

Monitoring of contained dealings. During the January to March 2005 quarter, monitoring of the 10 accredited organisations, referred to above, also included assessment of the general procedures followed for dealings not involving intentional release (DNIRs), notifiable low risk dealings (NLRDs) and exempt dealings. In addition, compliance with the specific Licence conditions for one DNIR was examined.

Monitoring of dealings involving intentional releases

The following table shows the total monitoring coverage for field trial sites 1 January to 31 March 2005

Licensed Organisation Name	Licence Number	No. sites visited	Site status[1]	Crop type
CSIRO	DIR 038/2003	2	C	Cotton
		2	PHM	Cotton
Monsanto Australia Limited	DIR 035/2003	4	C	Cotton
		4	PHM	Cotton
Totals	2	12	C=6	1 type
			PHM=6	

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

Monitoring of dealings not involving intentional release (DNIR)

The following table shows the total monitoring coverage for DNIRs 1 January to 31 March 2005

Licensed Organisation Name	Licence Number
Western Australian Institute for Medical Research	DNIR 128/2002
Totals	1 DNIR licence

Monitoring of physical containment facilities

The organisations and the facility types the OGTR visited during this quarter are detailed in the following table. They included joint inspections with Contained Dealings Evaluation Section staff of two PC3 facilities and two PC2 Large scale

facilities. Inspections of these types of facilities are usually undertaken either prior to commissioning or when they are shutdown 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.

Organisation	Physical Containment (PC) facility	No. facilities visited
CSL Limited	PC2 Large scale+	2
Curtin University of Technology	PC2 Laboratory	3
Lions Eye Institute of Western Australia	PC2 Laboratory	4
Ludwig Institute for Cancer Research	PC2 Laboratory	4
Monash University	PC3 Laboratory+	1
Ozgene Pty Ltd	PC2 Laboratory	1
Peter MacCallum Cancer Institute	PC2 Insectary	1
	PC2 Laboratory	1
	PC2 Animal	2
Virax Holding Limited	PC2 Laboratory	1
Western Australian Institute for Medical Research	PC2 Laboratory	4
Western Sydney Area Health Service	PC3 Laboratory+	1
Totals	**5 Facility Types**	**25**

+ Joint inspection with Contained Dealing Evaluation Section

Monitoring findings

Dealings involving intentional release

During the quarter no non-compliances were identified during OGTR monitoring visits. However, three non-compliances were self-reported by licence holders as a result of monitoring activities conducted as a condition of their licences. All posed negligible risks to human health and safety and the environment.

Organisation	Monsanto Australia Ltd
Licence number and site	DIR 035/2003, Site 2
Summary of dealing	Licence relates to field trials of cotton (*Gossypium hirsutum*) genetically modified by introduction of genes to enhance tolerance to the herbicide glyphosate (Roundup Ready® MON 88913) and/or confer resistance to caterpillar pests (Roundup Ready® MON 88913/Bollgard® II or Bollgard® II). This site is in the post harvest phase.
Findings	This site was planted to GM cotton in October 2003 and harvested in May 2004. Monsanto Australia Ltd notified the OGTR that one flowering volunteer was observed during a routine post harvest monitoring inspection visit. The flowering volunteer was removed and destroyed immediately. However the Licence conditions for DIR 035/2003 state that the volunteer must be destroyed prior to flowering.
Risk assessment	As the volunteer had not yet set seed and was destroyed immediately upon detection there is negligible risk of persistence of the GMO at the site as a result of the non-compliance. The risk to human health and safety and the environment has therefore been assessed as negligible.
Risk management	Ongoing monitoring of the site is to take place according to the licence conditions of DIR035/2003 and volunteers are to be destroyed prior to flowering.

Organisation	Monsanto Australia Ltd
Licence number and site	DIR 012/2002, Sites 1,2,4,5,6 & 8
Summary of dealing	Licence relates to field trials of cotton (*Gossypium hirsutum*) genetically modified by introduction of two insecticidal genes and/or insecticidal genes in combination with a gene that confers tolerance to glyphosate, the active ingredient of Roundup® herbicide.
Findings	These sites were planted to GM cotton in March 2003 and harvested in September and October 2003. Monsanto Australia Ltd notified the OGTR that post harvest monitoring visits to these sites were not completed within 60 days of the previous monitoring inspection due to difficulty accessing the sites during the wet season.

	Licence conditions for DIR 012/2002 state that monitoring must occur within 60 days of the previous inspection.
Risk assessment	As the monitoring inspections continued at the required frequency after the missed inspection, and no volunteers reached maturity prior to the resumption of inspections and their removal, there is negligible risk of persistence of the GMO at the sites as a result of the non-compliance. The risk to human health and safety and the environment has therefore been assessed as negligible.
Risk management	Ongoing monitoring of the sites is to take place according to the licence conditions of DIR 012/2002.

Organisation	CSIRO
Licence number and site	DIR 038/2003, Site 7
Summary of dealing	Licence relates to field trials of cotton (*Gossypium hirsutum*) genetically modified by introduction of a bacterial herbicide tolerance gene (*bar*) that confers tolerance to the herbicide glufosinate ammonium. This site is in the post harvest monitoring phase.
Findings	This site was planted to GM cotton in November 2003 and harvested in February 2004. CSIRO notified the OGTR that 10 flowering volunteers were observed during a routine post-harvest monitoring inspection of the site. The flowering volunteers were removed and destroyed immediately. However, the Licence conditions for DIR 038/2003 state that volunteer plants must be destroyed prior to flowering.
Risk assessment	As the volunteers had not yet set seed and were destroyed immediately upon detection there is a negligible risk of persistence of the GMO at the site as a result of the non-compliance. The risk to human health and safety and the environment has therefore been assessed as negligible.
Risk management	Ongoing monitoring of the site is to take place according to the licence conditions of DIR038/2003 and volunteers are to be destroyed prior to flowering.

Dealings not Involving Intentional Release

During the quarter two non-compliances were identified as a result of monitoring activities of DNIR Licences. Neither posed risks to human health and safety or the environment.

Organisation	Western Australia Institute for Medical Research
Licence number and site	DNIR 128/2002
Summary of dealing	Expressing haemopoietic regulators in cells using amphotropic retroviruses. To gain a better understanding of haematopoitic cell development by using a replication defective retrovirus to transfer genes encoding intracellular signalling proteins into various mammalian cells
Findings	In contravention of OGTR's *Guidelines for Transport of GMO*, the secondary unbreakable container used for transporting GMOs from the facility was not appropriately labelled. In addition, some waste materials were decontaminated and destroyed by chemical sterilisation and incineration. The licence conditions of DNIR 128/2002 require that transport of GMOs must be in accordance with the transport guidelines that all GMO waste must be sterilised by autoclaving.
Risk assessment	The risk to human health and safety and the environment has been assessed as negligible for each non-compliance.
Risk management	Outer secondary containers are now labelled to indicate that they contain GM micro-organisms, and also include the telephone number of a person to contact should the waste container be lost or damaged. As the alternative waste treatment methods are approved by the Regulator, WAIMR have sought a variation to their Licence conditions to include destruction of waste by means other than autoclaving.

Note: These are breaches of specific DNIR licence conditions. Any breaches of Certification Guidelines for the facility/facilities in which the DNIR takes place are reported generically under non-compliances for physical containment facilities.

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.

The following table represents the number of non-compliances against Certification Guidelines in OGTR certified facilities inspected during 1 January to 31 March 2005.

Number of PC2 Facilities inspected	Structure	PPE	Equipment	Waste disposal	Work practices	Transport
25	9	2	15	-	1	14

PPE: Personal Protective Equipment

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, PC2 animal containment 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.

Practice Reviews

The Monitoring and Compliance Section may initiate Practice Reviews in response to observations made during monitoring activities, or follow up of incident reports that may relate to non-compliance by accredited organisations. Their objective is to determine if licence conditions can be, and are being, effectively implemented.

An accredited organisation may request a Practice Review to assess the effectiveness of systems used by IBCs to ensure that dealings are being conducted in accordance with the Act.

The primary focus of the review process is to determine whether practices being used pose potential human health or environmental risks that require management actions to be implemented. In certain instances, where a suspected non-compliance with the Act is identified, the issue may be referred for investigation.

A comprehensive series of Practice Reviews with a representative sample of 33 accredited organisations across Australia was concluded in this quarter. The reviews demonstrated a high level of compliance by accredited organisations with the requirements of the legislation and identified a number of examples of exemplary management practices.

Contained Dealings Practice Review

Practice Review Subject	The OGTR conducted practice reviews with Accredited Organisations and their Institutional Biosafety Committees (IBCs) to:- • better understand and validate IBC decision making processes, and risk and compliance management arrangements; • co-operatively identify strategies to assist compliance with regulatory requirements; and • provide input into the current review of the Gene Technology Regulations 2001 (the Regulations).	
Timeframe	April 2004 to March 2005	
Participants	***Organisation***	***State/Territory***
	BresaGen Limited	South Australia
	Institute of Medical and Veterinary Science	
	GroPep Limited	
	Children, Youth and Women's Health Service	
	The University of Adelaide	
	Flinders University	
	CSIRO Plant Industry	
	The University of Western Australia	Western Australia
	Animal Resources Centre	
	Telethon Institute for Child Health Research	
	Royal Perth Hospital	
	Cerylid Pty Ltd	Victoria
	AMRAD Operations Pty Ltd	
	Howard Florey Institute	
	Alpharma Animal Health Pty Ltd	
	The Walter and Eliza Hall Institute of Medical Research	

	The University of Melbourne	Victoria
	Peter MacCallum Cancer Centre	
	Ludwig Institute for Cancer Research	
	CSIRO Molecular Science	New South Wales
	University of New South Wales	
	The University of Sydney	
	Royal North Shore Hospital	
	The University of Queensland	Queensland
	Xenome Limited	
	Queensland University of Technology	
	Queensland Institute of Medical Research	
	Menzies School of Health Research	Northern Territory
	Royal Darwin Hospital	
	Charles Darwin University	
	Department of Business, Industry and Resource Development	
	University of Tasmania	Tasmania
	Tasmanian Alkaloids Pty Ltd	
Findings	The review established that the accredited organisations had well developed and effective decision making, risk management and compliance systems for their activities under the *Gene Technology Act 2000* and Regulations.	
Outcomes	The review informed the OGTR about current IBC practices and procedures, and difficulties experienced by accredited organisations relevant to different sizes and scales of operation. During the course of the reviews the OGTR provided practical advice to participants regarding the achievement of compliance with regulatory requirements. The review participants also put forward suggestions for consideration in the current review of the Regulations.	

Audits

Audits can be initiated by the OGTR or an accredited organisation, an audit can entail:

- 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
- suggest improvements to procedure and practices where appropriate.

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 the January to March 2005 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 following table is of an investigation finalised in the quarter 1 January to 31 March 2005

Type	Unintended GM tomato seed importation
Name	University of California (UC) Davis and University of Sydney
Current Status	Closed – Investigation Finalised.
Allegation	The investigation was instigated as a result of the information provided by the United States Department of Agriculture (USDA) concerning the mislabelling of GM tomato seeds that were sent from the University of California (UC) Davis to various researchers world wide.
Summary of Investigation	The OGTR conducted a thorough investigation and established the circumstances surrounding the importation, location and use of the seeds. Inquiries determined that a single shipment of 25 seeds was sent from UC Davis to researchers at the

	University of Sydney as part of a research project involving breeding conventional tomato under contained conditions. The researchers involved cooperated fully with the investigation. They were never in a position to know that they had inadvertently received GM tomato seeds and therefore had not breached the *Gene Technology Act 2000.*
Findings	The investigation determined that there was only one shipment of these seeds to Australia. Only 8 of the 25 seeds were planted as part of a PhD research program. The resulting 4 plants and 4 seeds that did not germinate were destroyed on site. The remaining 17 seeds were mailed by the researcher for analysis as requested by UC Davis after they became aware of the mislabelling. The tests subsequently confirmed the tomato seeds to be GM.
Risk Assessment and Management	The investigation determined that there was full control of the GM tomato seeds at all times whilst they were in Australia and the risk to human health and safety and the environment was assessed as negligible.

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.

PART 3 Committee operations

The Act established three advisory committees:

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

Gene Technology Community Consultative Committee

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

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

Gene Technology Ethics Committee

The Gene Technology Ethics Committee (GTEC) held its eighth meeting in Canberra on 3 March 2005 with the new committee membership that has been appointed for a three year term. Members considered potential future projects and the direction of their ongoing papers. The next meeting for this Committee has been scheduled for 7 June 2005.

The 8th communiqué, outlining discussions held at this meeting is attached to this Quarterly Report (Appendix B).

Further information about the work of the GTEC and the new membership is available on the OGTR website www.ogtr.gov.au.

Gene Technology Technical Advisory Committee

The Gene Technology Technical Advisory Committee (GTTAC) held its 23rd meeting in Canberra on 7 and 8 March 2005 with the new committee membership that has been appointed for a three year term.

At this meeting, the Committee considered:

- Five applications for DIR licences
- Three RARMPS for DIR licences.

The Committee also received and discussed presentations on DIR and DNIR processes; horizontal gene transfer; and public perceptions of science and biotechnology.

In addition, Committee members were provided with an application for a DIR licence and were requested to provide comments out of session.

The 13th communiqué, outlining discussions held at the meetings of 22 July 2004 and 21 September 2004 is attached to this Quarterly Report (Appendix C).

The 14th communiqué, outlining discussions held at the meeting of 7 and 8 March 2005 will be provided in a subsequent report.

Further information about the work of the GTTAC and the new membership is available from the OGTR website www.ogtr.gov.au.

PART 4 Other activities

Reviews

The following reviews continued during this quarter:

- A review of the *Gene Technology Regulations 2001*.
- A review of the *Guidelines for the Certification of Facilities/Physical Containment Requirements* to address practical difficulties that have been encountered in their implementation. In this quarter drafting continued on revisions to the Certification Guidelines for PC3 laboratory facilities; the draft revised PC2 Drosophila facility guidelines were circulated to stakeholders for comment
- Draft revised Accreditation Guidelines were also circulated to accredited organisations for comment.

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:

- Conference on Plant-made Pharmaceuticals, (cPMP) 2005 and presentation entitled 'The Regulation of Plant Made Pharmaceuticals in Australia', 2 - 4 February 2005, Montreal, Canada.
- 15th meeting of the OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology, 23-25 February 2005, Paris, France.

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:

- University of Tasmania 'Australia's Regulatory System for GMOs' and Assessment of Licence applications for dealings involving intentional release of GMOs',14 January 2005, Hobart, Tasmania

- Participation in the Taralga Land Care Group meeting on GM Crops, 15 February 2005, Taralga, NSW
- CRC for Sugar Industry Innovation through Biotechnology 'Australian Gene Technology Regulation: Form and Function', 3 March 2005, Canberra, ACT
- Farmers for Choice: Plant Gene Technology Course 'Australian Gene Technology Regulation: Form and Function', 8 March 2005, Canberra, ACT

Institutional Biosafety Committee training sessions

The OGTR conducts a national program of training sessions for 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 $51,336. The table below lists the consultants, describes the purpose of the consultancy and the amount paid during the quarter.

Consultant	Amount paid (GST exclusive)	Purpose
CSIRO	$3,472	Provide report on the toxicity to *Diptera sp.* of the Cry2Ab insecticidal protein from GM cotton at the completion of research programme.
Dialog Information Technology	$47,864	Ongoing work on the Gene Technology Information Management System (GTIMS)
Total Consultants for quarter	$51,336	

Gene Technology Information Management System

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

State	Total Number of Organisations	Number Completed
ACT	8	6
TAS	2	2
NT	3	3
SA	13	7
WA	13	5

State	Total Number of Organisations	Number Completed
NSW	35	13
VIC	49	12
QLD	22	11
Total	145	58

OGTR website

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

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

The most popular downloaded documents were:

- 'The Biology & Ecology of Pineapple (*Ananas comosus var. comosus*) in Australia'
- 'The Biology and Ecology of cotton (*Gossypium hirsutum*) in Australia'
- 'The Biology and Ecology of White Clover (*Trifolium repens* L.) in Australia'
- 'The Biology and Ecology of Rice (*Oryza sativa* L.) in Australia'
- 'The Biology and Ecology of Papaya (paw paw), (*Carica papaya* L) in Australia'
- Handbook on the Regulation of Gene Technology in Australia

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

OGTR email address and freecall number

The 1800 number and the OGTR email address are points of contact for members of the public and other interested parties. Assistance with specific questions and additional mechanisms for public feedback are among some of the services provided by the 1800 line and email facilities.

The OGTR 1800 number and website received over 60 calls and 1273 emails in January 2005, 60 calls and 1420 emails in February 2005, and 135 calls and 1715 emails in March 2005.

Freedom of information

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

Appendix A

DNIR Licences issued January to March 2005

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 322/2004	4 January 2005	CSL Ltd, Victoria	Pilot scale fermentation and processing of merozoite surface proteins (MSP) expressed in recombinant *Escherichia coli*	The aim of this dealing is to produce pilot-scale quantities of merozoite surface proteins from *Plasmodium falciparum* for use in pre-clinical and clinical trials of a vaccine against malaria.
DNIR 323/2004	7 January 2005	University of Queensland	Development of novel gene therapy vectors for gene therapy	The aims are to develop new mechanisms and vectors for gene therapy of respiratory diseases and cancers.
DNIR 324/2004	7 January 2005	University of Queensland	Complementation of mutations to genes that play a role in virulence in intestinal and extraintestinal bacteria	This work will examine the processes important to adherence, colonisation, survival and pathogenesis employed by bacteria that cause enteric and urinary tract infections in humans.
DNIR 325/2004	7 January 2005	University of Queensland	Genetic analysis of *Xanthomonas albilineans*	This project explores the molecular basis for albicidin antibiotic biosynthesis and resistance in *Xanthomonas albilineans*
DNIR 327/2004	7 January 2005	Mater Medical Research Institute, Queensland	Retroviral expression of genes and small inhibitory RNA	This study aims to use retroviral vectors to generate stable and transient expression of human and rodent genes in human and rodent cell lines.
DNIR 328/2004	27 January 2005	Macfarlane Burnet Institute for Medical Research and Public Health, Victoria	Immunotherapy for Hepatitis C Virus (HCV) infection	The aim is to treat HCV-infected individuals who have failed conventional interferon-based therapy, with activated dendritic cells.
DNIR 329/2004	25 January 2005	The University of Melbourne, Victoria	Identification of virulence determinants of *Leptosphaeria maculans* and *Sclerotinia sclerotiorum.*	The purpose of this dealing is to identify, clone and characterize genes encoding pathogenicity determinants of the canola pathogens *Leptosphaeria maculans* and *Sclerotinia sclerotiorum*.

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 331/2004	24 January 2005	The University of Melbourne, Victoria	Investigation of the virulence of *Klebsiella pneumoniae*: development of a vaccine and immunotherapeutics	The aims of the proposed dealings is to identify genes for *Klebsiella pneumoniae* virulence determinants and protective antigens and to investigate their function and potential as targets for vaccine development or immunotherapy.
DNIR 332/2004	27 January 2005	The University of Melbourne, Victoria	Identification of virulence-associated determinants and protective antigens in bacterial pathogens	The aim of this dealing is to identify novel virulence-associated determinants in several bacterial pathogens of humans and to investigate whether these factors can be used as targets for therapeutic or prophylactic vaccines.
DNIR 333/2004	28 January 2005	The University of Melbourne, Victoria	Manipulation of Influenza A viruses using reverse genetics to study both cellular, humoral and molecular characteristics of viral immunity	The aims are to use reverse genetics on Influenza A virus to determine the cellular, humoral and molecular characteristics of anti-viral immunity.
DNIR 334/2004	27 January 2005	University of New South Wales	Storage of GMOs that are a licensed dealing	The aim of this dealing is to store or dispose of pre-existing GMOs generated by several GMAC dealings.
DNIR 335/2004	27 January 2005	University of New South Wales	The role of quorum sensing in biofilm formation, virulence factor expression and environmental adaptation	The aims are to study the role of quorum sensing, quorum sensing genes and quorum sensing controlled factors in the processes of biofilm formation, environmental adaptation and infection
DNIR 336/2004	27 January 2005	Western Sydney Area Health Service, New South Wales	Use of wild type, gene knock-out, and transgenic mice, and recombinant viruses to study cytokine biology	The aims are to investigate the roles of immune cell activating proteins such as IL-15 in the immune response to virus infection.
DNIR 337/2004	28 January 2005	CSL Ltd, Victoria	Pilot scale fermentation and processing of Hepatitis C (HCV) polyprotein expressed in recombinant *Saccharomyces cerevisiae*	The aims are to produce pilot-scale quantities of Hepatitis C virus polyprotein from *S. cerevisiae* for purification and vaccine formulation.

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 339/2004	8 February 2005	The University of Melbourne, Victoria	Virulence genes of avian pathogenic *Escherichia coli*	The aims are to identify the genes responsible for virulence in avian pathogenic *E. coli* and to examine the efficacy of mutants with these genes deleted or disrupted as vaccine candidates.
DNIR 341/2004	24 February 2005	Women's and Children's Hospital, South Australia	Functional analysis of genes involved in T and epithelial cell differentiation and function by retroviral/lentiviral expression in human cells and cell lines	This project aims to investigate the function of various genes with regard to the normal and abnormal growth of human blood cells.
DNIR 342/2004	27 January 2005	Children's Hospital at Westmead, New South Wales	Use of wild type, gene knock-out, and transgenic, and recombinant viruses to study cytokine biology	The aims are to investigate the roles of immune cell activating proteins such as IL-15 in the immune response to virus infection.
DNIR 344/2004	30 March 2005	Western Australian Institute for Medical Research,	Studying gene regulation using amphotropic retroviruses	The aims of this project are to use replication defective amphotropic retroviruses to transfer genes into mammalian cell lines and primary cells.

Appendix B

Gene Technology Ethics Committee Meeting 3 March 2005, Canberra

COMMUNIQUE

The Gene Technology Ethics Committee (GTEC) held its eighth meeting in Canberra on 3 March 2005.

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').

On 8 October 2004 the membership term of the first triennium of GTEC expired. The newly appointed membership to serve on GTEC until 2007 held its first meeting on 3 March 2005. Details of the new membership are at Attachment A. The new members were welcomed to GTEC and were given a presentation on the operations and activities of the Office of the Gene Technology Regulator (OGTR).

GTEC's Work Plan

GTEC considered its ongoing projects from the previous triennium and potential new areas of interest.

Ethical Guidelines in Relation to Genetically Modified Organisms

The Committee discussed the direction of this paper in detail and considered comments received from a limited preliminary round of consultation with other ethics committees and government agencies. GTEC resolved to progress the paper in the direction of a general educational statement. The working group was reformed and will present a revised document at the next GTEC meeting.

Ethical Issues Associated with Trans-species Gene Transfer

The Committee discussed the final stages of development for this paper. Further consultation from the Gene Technology Technical Advisory Committee (GTTAC) will be sought. A working group for this paper was reformed.

The working group has agreed to invite a member of GTTAC to work with them in the final stages of preparation of the paper.

Further areas of interest

GTEC considered numerous additional areas which may result in developing GTEC papers in the future. Further information will be gathered on these items, which will be further discussed at future GTEC meetings.

GTEC and Relationships with Other Committees

GTEC will monitor the projects of relevant international ethics committees to increase awareness of the international environment regarding ethics and gene technology. GTEC also resolved to further develop relations with Australian ethics committees. GTEC will invite the Animal Welfare Committee to retain its observer status for the 2004-2007 triennium, and will respond to the invitations to comment on two joint works from the National Health and Medical Research Council, Australian Research Council, and the Australian Vice-Chancellors' Committee.

The Regulator reported on the operations of the OGTR. This information is publicly available in the Quarterly Report of the Gene Technology Regulator on the OGTR website, (www.ogtr.gov.au) or on request by phoning the number below.

Next Meeting

The next GTEC meeting will be held 7 June 2005.

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

Attachment A

Gene Technology Ethics Committee

Membership List

Dr Rachel Ankeny M.A Phil M.A. Med Eth. Ph.D

- Director and Senior Lecturer Unit for History and Philosophy of Science, Honorary Associate Faculty of Medicine (Centre for Values, Ethics and the Law in Medicine), University of Sydney

Associate Professor Gavin Ash BSc (Hons) Ph.D (NE)

- Associate Professor School of Agricultural and Veterinary Sciences, Charles Sturt University

Professor Donald Chalmers LL.B, LL.M

- Dean, Head of Faculty of Law and Professor of Law, University of Tasmania

Reverend Dr Brian Edgar BTh MTh Ph.D

- Director for Theology and Public Policy, The Australian Evangelical Alliance

Dr John Fleming BA Th.L (Hons) Ph.D

- President, Campion College, Sydney

Dr Neville Hicks BA (Hons) Ph.D

- Reader in Public Health, University of Adelaide

Dr Gordon Howarth BSc(Hons) Ph.D (Expert Adviser)

- Senior Research Scientist Women's and Children's Hospital

Dr Kees Hulsman BSc (Hons) Ph.D

- Senior Lecturer in Ecology, Australian School of Environmental Sciences, Griffith University

Ms Judy Jones BSc, LL.B

- Lecturer in Law, Australian Centre for Environmental Law, Faculty of Law, Australian National University

Dr Simon Longstaff Bed, M.Phil Ph.D

- Executive Director, St James Ethics Centre, Sydney

Dr Vaughan Monamy BSc(Murdoch) MSc(Tasmania) Ph.D(UNSW)

- Senior Lecturer in Environmental Science and Environmental Ethics

Dr Rosemary Robins BA (Hons) Ph.D

- Lecturer, Department of History and Philosophy of Science

Dr Wendy Rogers

- Associate Professor of Medical Ethics and Health Law, Department of Medical Education, Flinders University

Appendix C

Gene Technology Technical Advisory Committee

COMMUNIQUE
No. 13

This is the thirteenth communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the twenty first meeting of GTTAC, held on 22 July 2004, and the twenty second meeting of GTTAC, held on 21 September 2004 via teleconference.

GTTAC is 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.

The Regulator receives input from GTTAC on applications for licences to conduct dealings with genetically modified organisms (GMOs), as well as comments on the Risk Assessment and Risk Management Plan (RARMP) that is prepared for each of these applications.

The purpose of this Communique is to provide a brief overview of the applications and RARMPs considered by GTTAC and the advice the Committee has provided to the Regulator with regard to those applications and RARMPs.

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

Dealings Not Involving the Intentional Release of Genetically Modified Organisms

Dealings Not Involving the Intentional Release of GMOs (DNIRs) are dealings that are usually undertaken within a certified facility (so that the organism is physically contained) and where the personnel involved in the dealing have been assessed as having adequate training and experience for the task. These are typically laboratory-based projects.

Applications and RARMPs for the following DNIRs were considered:

Application Number and Title	Project Description
DNIR 292/2004 Kunjin replicon virus like particles for delivery of cytokines into mice.	The aim of this project is to determine whether Kunjin replicon virus-like particles (KUN VLPs) can be used to deliver immuno-modulatory genes as a potential treatment for cancer or to prevent transplant rejection.
DNIR 293/2004 Viral delivery of genes or siRNA involved in adipogenesis or insulin signalling to cells.	The aim of this project 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.
DNIR 295/2004 Somatic cell genetic studies of mitochondrial respiratory chain disorders.	The aim of this project is to extend the lifespan of cultured human fibroblasts and introduce individual chromosomes into the fibroblasts in order to map the chromosomal location of genes involved in respiratory chain disorders.
DNIR 297/2004 Development of in vitro liver stage drug susceptibility assays for *Plasmodium vivax, P. falciparum, P. yoelii* and *P. cynomogli.*	The aim of this dealing is to develop *in vitro* liver stage drug susceptibility assays for malaria parasites.
DNIR 298/2004 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 project is to assess the safety, tolerability and efficacy of a candidate cancer therapeutic in a Phase I/IIa clinical trial in prostate cancer patients
DNIR 299/2004 Characterisation of replication competent hepatitis B viruses (HBV).	The aim of this project is to express complele genomes of cloned hepatitis B viruses (HBVs) from penguins and bats in cultured eukaryotic cells *in vitro* to test viral replication, and to test the ability of resulting HBV particles to infect primary host cells in cell culture.
DNIR 302/2004 Generation of stable cell lines expressing Hepatitis B Virus using the ViraPower lentiviral expression system.	The aim of this study is to express the human Hepatitis B virus (HBV) genome in human cultured cells using a HIV-1-based lentiviral expression system and to characterise HBV synthesis in stable human cell cultures.
DNIR 305/2004 Wnt/FZSD in human cancer	The proposed dealings aim to determine the role of FZD and Wnt genes, in particular FZD7 (frizzled Drosophila homolog 7), in the morphological changes that lead to metastasis of colon tumour cells.
DNIR 307/2004 Molecular studies of human immunodeficiency virus (HIV-1) and hepatitis C virus (HCV)	The proposed dealings aim to study the fusion and entry of HIV-1 and (HCV) in human cell lines in order to develop antiviral therapeutics and vaccines targeting virus-cell interactions.

GTTAC agreed that the risk assessments for the proposed dealings identified all risks associated with human health and safety and the environment, and that the measures proposed in the risk management plan are adequate to deal with the identified risks.

The Committee further agreed that, in relation to DNIR 305/2004, caution should be used by those conducting the dealings when handling sharps.

Dealings Involving the Intentional Release of Genetically Modified Organisms

Dealings Involving the Intentional Release of GMOs (DIRs) are dealings that are undertaken outside of a contained facility. DIRs include limited and controlled releases (eg: field trials) and commercial releases of GMOs.

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

Advice on RARMPs

Advice on genetically modified cotton

GTTAC considered the RARMPs prepared in response to the following applications concerning the release of transgenic cotton in Australia.

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

The OGTR has received an application from CSIRO for the intentional release of genetically modified (GM) cottons into the environment, on a limited scale and under controlled conditions. CSIRO proposes to conduct a small scale, limited and controlled release of 60 GM cotton lines on one site covering an area of up to 0.1 hectares in each summer growing season at the Australian Cotton Research Institute (ACRI) in the Shire of Narrabri, NSW. The release is planned for October 2004 to May 2006 and encompasses two summer growing seasons.

The aim of the proposed release is to evaluate the efficacy of the rubisco small subunit (rbcS) promoter, compared to the 35S viral promoter in controlling the expression of the uidA reporter gene in the GM cotton lines under Australian field conditions.

The GM cotton lines covered by this application are for research purposes only and are still in the early development stages.

The antibiotic resistance marker genes (nptII and hph), the reporter gene (uidA), the viral promoter (35S) have been used in a number of GM cottons that have previously been approved for intentional release (see below).

Introduced Genes	**DIR reference**	**Applicant**	**Type of release**
35S/uidA/nptII	005/2001 006/2001 009/2001 012/2001	Cotton Seed Distributors Ltd CSIRO Department of Agriculture WA Monsanto	Limited and controlled Limited and controlled Limited and controlled Commercial
nptII	008/2001 022/2002 023/2002	Department of Agriculture WA Monsanto Monsanto	Limited and controlled Commercial Commercial
hph	017/2002 025/2002 034/2003 036/2003	CSIRO CSIRO Syngenta CSIRO	Limited and controlled Limited and controlled Limited and controlled Limited and controlled

However, this is the first application for a licence involving the expression of an introduced gene under the control of the rbcS promoter from cotton.

GTTAC discussed this application from CSIRO and advised the Regulator that:

- GTTAC agreed with the assessment made by the OGTR on risk of toxicity, allergenicity, weediness and gene transfer; and
- GTTAC agreed with the proposed licence conditions.

Advice on Applications

Advice on genetically modified bovine herpesvirus 1 vaccine

Vaccination of cattle with recombinant bovine herpesvirus 1 vaccines (DIR 050/2004)

The OGTR has received an application from the Queensland Department of Primary Industries and Fisheries for a licence for the intentional release of genetically modified (GM) BoHV-1 vaccines into the environment on a limited scale and under controlled conditions within Physical Containment Level 1 (PC1) animal containment facilities which are sufficient to contain cattle. The applicant has proposed that the releases take place between October 2004 and 2009. The unmodified BoHV-1 (serotype 1.2b) is found in cattle and buffalo populations all over the world, including Australia. BoHV-1 serotype 1.2b is the only BoHV-1 serotype that has been found in Australia. Up to 180 cattle will be involved in this trial.

The proposed trial involves the use of four GMOs based on BoHV-1 that have been modified by the addition of full length (E2) or truncated (E0) genes from bovine viral diarrhoea virus (BVDV)and/or by the addition of a gene encoding the GFP marker gene (see Table 1). The inserted genes will be under the control of the human cytomegalovirus immediate early (hCMV ie) promoter. The BVDV E2 gene encodes the major target of neutralising antibodies against BVDV infection. E2, in conjunction with E0 and other BVDV proteins that will not be used in this dealing, are the determinants of BVDV host range. Green fluorescent protein (GFP) will also used in the constructs as a novel foreign antigen to allow serological differentiation of vaccinated animals from those with a natural BoHV-1 infection.

Immunisation with the GM vaccines will be used to determine:

- the immune response of the vaccinated cattle to the BoHV-1, BVDV and GFP antigens;
- the ability of the GM vaccines to protect cattle from a challenge with BoHV-1 or BVDV or a bacterial pathogen; and
- the influence of pre-existing immunity to BoHV-1 and BVDV on the efficacy of the BoHV 1 vaccines.

Table 1 GMOs proposed for release under DIR 050/2004

GMO	Parent virus	Promoter	Gene inserted	Poly-A
1	BoHV-1	hCMV-ie	GFP	Rabbit β-globin poly-A
2	BoHV-1	hCMV-ie	E2	Rabbit β-globin poly-A
3	BoHV-1	hCMV-ie	E0-GFP	Rabbit β-globin poly-A
4	BoHV-1	hCMV-ie	E2 + E0-GFP	Rabbit β-globin poly-A

The applicant sought approval to declare details of the insertion sites of the BVDV antigens as confidential commercial information (CCI). This information has been declared CCI.

GTTAC discussed this application and advised the Regulator that the following issues should be considered:

- the species specificity of the parent virus;
- the role that the inserted genes may play in the host range of the recombinant virus;
- the potential for the GM BoHV-1 to be more toxic or allergenic to cattle than the parent organism;
- any effect that the inserted genes may have on the lifecycle of the GM virus including the ability to be re-activated following a latent infection;
- whether the proposed containment is adequate; and
- whether Food Standards Australian New Zealand (FSANZ) has approved any products containing GFP for human consumption.

The OGTR advised GTTAC at their 22nd meeting that the clock has been stopped on this application since the applicant has advised that other BoHV-1 GMOs are likely to be added to the application and that the use of GFP as a marker is being reviewed.

Advice on genetically modified sugarcane

Field trial of sugarcane expressing sucrose isomerase (DIR 051/2004)

The OGTR has received an application from the University of Queensland for a licence for the intentional release of genetically modified (GM) sugarcane into the environment on a limited scale and under controlled conditions at 2 sites covering maximum total area of 3.55 ha in the Burdekin Shire, Queensland. The applicant has proposed that the release will occur between early 2005 and late 2010. Plantings are proposed to take place during March-May and August-October in each of 2005, 2006 and 2007.

The proposed trials involve up to 120 transgenic lines of GM sugarcane containing the sucrose isomerase (si) gene isolated from the bacterium Panthoea dispersa and the aminoglycoside resistance gene (aphA or nptII) from the bacterium Escherichia coli as a selectable marker. The si gene transferred into the GM sugarcane confers upon the plant the ability to express the sucrose isomerase enzyme which converts sucrose into its isomer isomaltulose.

The aims of the proposed release are to:

- determine the agronomic performance of the GM sugarcane lines under field conditions including concentrations of different sugars in various tissues over the growing season; and
- observe the presence of any indirect effects caused by the genetic modifications eg. alteration of sensitivity to environment and biological stress.

The results will be used to guide the experimental adjustment of parameters such as timing and strength of expression of the introduced genes, for optimal beneficial effects in sugarcane improvement.

GTTAC discussed this application and advised the Regulator that the following issues should be considered in relation to this application:

- potential for toxicity/allergenicity of GM sugarcane to humans and other organisms;
- the potential for GM sugarcane to be harmful to the environment because of an increased potential for weediness;
- potential for gene transfer posed by the release of these GMOs and its consequences; and
- obtain further useful information from the Bureau of Sugarcane Experiment Stations (BSES) and sugarcane experts regarding destruction of sugarcane after harvest.

Advice on genetically modified rice

Phenotyping of T-DNA and/or transposon Ds insertion line of rice (Oryza sativa L.) under field conditions (DIR 052/2004)

The OGTR has received an application from CSIRO for a licence for the intentional release of genetically modified (GM) rice (Oryza sativa L. cv Nipponbare) into the environment, on a limited scale and under controlled conditions.

CSIRO proposes to carry out the release at one site in the local government area of Wagga Wagga City Council, NSW over three growing seasons between October 2004 and May 2008, including provision for one fallow season if required. However, the statutory timeframe for consideration of the application extends until February 2005. Therefore if a licence were to be issued it would be likely to cover the growing seasons between 2005 and 2009.

The aims of the proposed release are:

- to identify rice genes influencing traits of biological or agronomic interest by observing alterations in the visible characteristics (phenotypes) of GM rice lines which were generated under contained (laboratory and glasshouse) conditions; and
- to characterise gene flow in rice under Australian field conditions.

The proposed trial involves the planting of approximately 1500 different GM rice lines (usually 30 plants of each line). The lines contain various combinations of commonly used reporter genes and antibiotic resistance and herbicide tolerance genes as selectable markers, as well as transposable Ds elements and 'plasmid rescue' elements.

GTTAC discussed this application from CSIRO and advised the Regulator that the following issues should be considered:

- the potential for GM rice to be harmful to humans or other organisms because it may be toxic or allergenic;
- the potential for GM rice to be harmful to the environment because of inherent weediness or increased potential for weediness and the potential for 'shattering' to lead to a persistent seedbank;
- the potential for the new genes introduced into the GM rice to transfer to other organisms with adverse consequences;
- whether the 150m isolation zone was sufficient, considering seed movement by rodents;
- seek further information from the applicant concerning the proposed 2km distance from breeding lines; and
- monitoring of the proposal at the end of three plantings.

Advice on genetically modified wheat

Field testing of salt tolerant wheat on saline land (DIR 053/2004)

The OGTR has received an application from Grain Biotech Australia Pty Ltd (GBA) for a licence to intentionally release genetically modified (GM) salt tolerant wheat (Triticum aestivum L.) on a limited scale under controlled conditions. The proposed release would take place in Corrigin shire, Western Australia on 0.45 ha from April 2005 to April 2006. The aim of the proposed release is to evaluate the salt tolerance and agronomic performance of GM salt-tolerant wheat in a field affected by different levels of salinity.

The GM salt tolerant wheat has been genetically modified to contain the ornithine amino transferase gene (oat) isolated from a common plant, Arabidopsis thaliana. The oat gene produces the enzyme, ornithine amino transferase enzyme (OAT). Over-expression of this enzyme can increase proline levels in the plant. The GM wheat also contains the selective marker gene, cyanamide hydratase (cah) isolated from the soil fungus Myrothecium verrucaria. The cah gene produces the enzyme cyanamide hydratase (CAH) that confers cyanamide resistance by hydrating the nitrile group of cyanamide to produce urea.

The proposed release would consist of the GM wheat, non-GM bread wheat, a non-GM barley, a non-GM durum wheat and non-GM salt adapted bread wheat. None of the material harvested from the trial, including seed will be used for human food or animal feed. Any material not used for research will be destroyed.

GTTAC discussed this application from Grain Biotech Australia and advised the Regulator that the following issues should be considered:

- The potential for toxicity/allergenicity of GM wheat to humans and other organisms;
- The potential for GM wheat to be harmful to the environment because of an increased potential for weediness; and
- The potential for gene transfer posed by the release of these GMOs and the consequences of such gene transfer.

Field trial – Alteration of grain starch in wheat (DIR 054/2004)

The OGTR has received an application from CSIRO Plant Industry (CSIRO) for a licence to allow the intentional release of genetically modified (GM) wheat into the environment on a limited scale and under controlled conditions. The release

is proposed to take place at one site covering a maximum total area of 0.05 ha in the Australian Capital Territory (ACT) from May 2005 to December 2006. The aim of the proposed release is to assess the field performance of GM wheat with altered starch characteristics and to generate seed stocks of the wheat lines for future research.

CSIRO has sought and received approval to have details of the gene constructs, sequence information, and precise identification of the genes involved declared as confidential commercial information (CCI).

The proposed trial involves six transgenic lines of the GM starch-altered wheat. Gene silencing (RNAi) has been used to knockout the expression of two 'starch enzymes' (SE). The sixth line represents a vector-only transformed line as a control. All SE sequences were derived from wheat (Triticum aestivum L.). All lines proposed for release also contain the commonly used bacterial selectable marker gene neomycin phosphotransferase (nptII) from Escherichia coli that confers resistance to antibiotic karamycin.

GTTAC discussed this application from CSIRO Plant Industry and advised the Regulator that the following issues should be considered:

- The potential for toxicity/allergenicity of GM wheat to humans and other organisms;
- The potential for GM wheat to be harmful to the environment because of an increased potential for weediness; and
- The potential for gene transfer posed by the release of these GMOs and the consequences of such gene transfer.

Advice on genetically modified cotton

Field trials of herbicide tolerant (Roundup Ready® Mon 88913) and herbicide tolerant/insect resistant (Roundup Ready® Mon 88913/Bollgard II®) cotton (DIR 055/2004)

The OGTR has received an application from Monsanto Australia Limited (Monsanto) for a licence for the intentional release of genetically modified (GM) herbicide tolerant cotton (Roundup Ready® Flex MON 88913) and herbicide tolerant/insect resistant cotton (Roundup Ready® Flex MON 88913/Bollgard II®) into the environment, under limited and controlled conditions.

Monsanto proposes to carry out field trials covering an area of up to 2011 hectares over two planting seasons, the southern summer growing season and the northern winter growing season, between September 2005 and November 2006. The summer trials would be conducted in the cotton growing regions of NSW and southern Qld, and the winter trials in northern WA, the NT and northern Qld.

The aims of the proposed release are to:

- incorporate the Roundup Ready® Flex MON 88913 (RR Flex cotton) trait into elite cotton varieties suitable for use under Australian conditions;
- test agronomic performance including disease resistance (bacterial blight, fusarium and verticillium wilt);
- produce seed for future release;
- set up demonstration sites for industry, government, researchers and the wider community; and
- collect data required for future applications to the OGTR and other regulators for commercial release such as levels of novel protein expression and seed composition (required by the OGTR and FSANZ) and data on the GM cottons' tolerance to glyphosate, weed control and glyphosate residue levels (required by the Australian Pesticides and Veterinary Medicines Authority (APVMA)).

None of the cotton plants from the release, or their by-products, would be used for animal and human food. The applicant proposes to sell lint from the release for use as fibre in the textile industry. Lint does not contain genetic material or protein.

Details of the gene construct, including the plasmid map and some of the regulatory sequences have previously been declared as Confidential Commercial Information (CCI) under section 185 of the Act, in connection with licence application DIR 035/2003.

GTTAC discussed this application from Monsanto Australia Ltd and advised the Regulator that the following issues should be considered:

- the risks posed by the proposed release under DIR 055/2004 are similar to those posed by the previous RR Flex and RR Flex/Bollgard II® cotton application (DIR 035/2003);
- the risks posed by the proposed release are also similar to those posed by the previous Roundup Ready® and Roundup Ready®/Bollgard II® cotton applications (DIR 012/2002 and DIR 023/2002); and
- advice provided in relation to the same GMOs previously assessed under DIR 035/2003 and to similar previously assessed GM cottons (Bollgard II® and Roundup Ready® cottons) should be considered in the preparation of the RARMP for DIR 055/2004.
- Commercial release of herbicide tolerant (glufosinate ammonium) cotton (DIR 056/2004)

The OGTR has received an application from Bayer CropScience Pty Ltd (Bayer) for a licence to intentionally release genetically modified (GM) herbicide tolerant cotton (LLCotton25) into the environment. The aim of the proposed release is to commercially release LLCotton25 into the Australian agricultural system, and undertake ongoing product research and development.

No specific containment measures have been proposed and Bayer intends that the GM cotton plants and their products would be used in the same manner as conventional and other GM cotton. Hence, the dealings would include use in human food (subject to approval by FSANZ), transportation and use as stockfeed anywhere in Australia, sale of lint and exporting seed. LLCotton25 contains the bar gene which confers tolerance to the herbicide glufosinate ammonium (also called phosphinothricin), the active constituent of the herbicides Basta®, Finale®, Buster® and Liberty®. LLCotton25 plants can be sprayed with glufosinate ammonium to kill problem weeds without damaging the crop itself.

Bayer requests approval to commercially plant LLCotton25 wherever conditions are suitable for cotton cultivation. The applicant anticipates a phased introduction over 3 years, involving large scale grower evaluations and seed increases, and the development of additional lines adapted for particular regional conditions.

Initially, Bayer expects the most substantial adoption of the GM cotton to occur in the existing cotton growing regions of New South Wales and Queensland, followed by uptake in potential future cotton growing areas in these states, the Northern Territory, four shires in Western Australia, and two shires close to the NSW border in both South Australia and Victoria. Small scale use for demonstrations and educational purposes is also proposed outside these areas.

Bayer currently has a research permit from the Australian Pesticides and Veterinary Medicines Authority (APVMA) for small scale use of glufosinate ammonium on the GM cotton, and intends to submit an application to the APVMA to register the herbicide for commercial scale use.
GTTAC discussed this application from Bayer CropScience Pty Ltd and advised the Regulator that the following issues should be considered:

- the risks associated with toxicity, allergenicity, weediness or gene flow in relation to commercial scale release of LLCotton25 are negligible; and
- advice provided in relation to previously assessed GM cottons should be considered in the preparation of the RARMP for DIR 056/2004.

Presentations

The following presentations were made to GTTAC:

- Review of the Risk Analysis Framework; and
- Update on the research project on the environmental impact of GM cotton.

Review of the *Gene Technology Regulations 2001* (the Regulations)

The Committee was advised that the review of the Regulations was progressing. The Committee noted the progress and agreed to forward comments on this matter to OGTR.
Enquiries and Risk Assessment and Risk Management Plans
For all enquiries and to obtain copies of applications or RARMPs for dealings involving the intentional release of GMOs into the environment, please phone the OGTR Free-call hotline on 1800 181 030. The RARMPs are also available electronically from our website at www.ogtr.gov.au.