Quarterly Report of the Gene Technology Regulator for the period 1 April to 30 June 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 April to 30 June 2005.

During this quarter, key achievements included the issuing of five licences for dealings involving the intentional release of genetically modified organisms (GMOs), 11 licences for dealings not involving intentional release of GMOs, one organisation was accredited and 35 contained facilities were certified.

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

In April 2005 the OGTR hosted the inaugural National Institutional Biosafety Committee Forum at the National Museum. In addition, the static maps of GMO trial locations were replaced with an interactive, web-based Geographic Information System (GIS). The new maps display sites in relation to local landmarks (eg roads) and other land use activities such as agricultural production areas.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator
23 August 2005

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Contents

Glossary **vii**
Introduction **ix**
Structure of this report ix
Further information x
PART 1 National regulatory system **1**
Key achievements during this quarter 1
Licences and other instruments 1
Monitoring and compliance 1
National Institutional Biosafety Committee Forum 1
Maps of GMO Trial Locations 1
Working collaboratively with States and Territories 2
State and Territory consultation 2
Gene Technology Ministerial Council 2
Gene Technology Standing Committee 2
Australian Government agency liaison 2
Public participation 3
PART 2 Regulation of genetically modified organisms **4**
Applications received and decisions made 4
New licences and other instruments 5
Processing of applications for Dealings involving
Intentional Release (DIR) licences 5
Applications received for DIR licences 6
Consultation on applications for DIR licences 7
Withdrawn applications for DIR licences 7
Surrendered applications for DIR licences 7
Clock stopped on four applications for DIR licences 7
Finalised applications for DIR licences 8
Finalised applications for Dealings Not involving
Intentional Release (DNIR) licences 8

Notifications of notifiable low risk dealings received 8
Existing licences and other instruments 9
Confidential commercial information (CCI) 10
Monitoring and compliance 10
Monitoring and compliance strategy 10
Overview of monitoring and compliance for the reporting period 11
Monitoring of dealings involving intentional releases 11
Monitoring of dealings not involving intentional release (DNIR) 12
Monitoring of physical containment facilities 12
Monitoring findings 13
Physical containment facilities 18
Practice Reviews 19
Contained Dealings Practice Review 20
Audits 20
Investigations 20
PART 3 Committee operations **22**
Gene Technology Community Consultative Committee 22
Gene Technology Ethics Committee 22
Gene Technology Technical Advisory Committee 22
PART 4 Other activities **23**
Reviews 23
International collaboration and coordination 23
Advice on gene technology regulation 24
Presentations and meetings 24
Institutional Biosafety Committee Training 24
Consultants 24
Gene Technology Information Management System 25
OGTR website 26
OGTR email address and freecall number 26
Freedom of information 26

Appendix A **27**
DNIR Licences issued April – June 2005 27
Appendix B **29**
Gene Technology Technical Advisory Committee 29
Appendix C **40**
Gene Technology Ethics Committee Meeting 40

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
OECD	Organisation for Economic Cooperation and Development
OGTR	Office of the Gene Technology Regulator
PC1, PC2, PC3, PC4	Physical containment levels of facilities as certified by the Regulator
RARMP	Risk assessment and risk management plan
Regulations	*Gene Technology Regulations 2001*
Regulator	Gene Technology Regulator
Spot checks	Unannounced visits by the OGTR Monitoring and Compliance Section
Volunteer	Regrowth of plants from seed that has remained on a site after a trial has been completed

Introduction

The *Gene Technology Act 2000* (the Act) requires the Gene Technology Regulator (the Regulator) to prepare and give to the Minister after each quarter a report on the operations of the Regulator during that quarter. Section 136A(2) of the Act requires that the report include information on:

- genetically modified organism (GMO) licences issued during the quarter
- any breaches of conditions of a GMO licence that have come to the Regulator's attention during the quarter
- auditing and monitoring of dealings with GMOs under the Act by the Regulator or an inspector during the quarter.

Structure of this report

This report is divided into four parts:

Part 1 outlines activities and outcomes achieved in relation to the implementation and management of the national regulatory system during the April to June 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 April – June 2005 quarter were:

Licences and other instruments

- 5 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).
- 86 Notifiable Low Risk Dealing (NLRD) notifications received.
- 1 organisation accredited.
- 35 contained facilities certified.
- 43 surrenders of certifications processed.
- 235 variations processed.

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

Monitoring and compliance

Approximately 12 per cent of current field trial sites and 13 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.

National Institutional Biosafety Committee Forum

The inaugural National Institutional Biosafety Committee (IBC) Forum was held in Canberra on 14-15 April 2005. The aim of the forum was to enable the OGTR to hear the views of IBCs regarding their interactions with the regulatory system and the OGTR, and to provide briefings on new initiatives and developments. The forum was also an opportunity for IBCs to network with each other.

Further information on the IBC Forum is in Part 4 of this report.

Maps of GMO Trial Locations

The OGTR replaced static maps of GMO trial sites with a searchable, interactive web-based Geographic Information System (GIS) to better show the location of GMO field trials. The maps can be viewed at www.maps.ogtr.gov.au.

The website shows the location of all field trials involving the intentional release of GMOs into the environment under limited and controlled conditions that are subject to monitoring by the Gene Technology Regulator. The maps display their location in relation to local landmarks (eg roads) and other land use activities such as agricultural production areas and conservation areas. Information is available on both current and previous (post-harvest) trials.

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 did not meet during the April - June 2005 Quarter.

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 met by teleconference on 14 April regarding advice to the Ministerial Council on potential members of the independent panel, and other matters pertaining to the conduct of the review of the *Gene Technology Act 2000* (the Act) required by section 192 of the Act.

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 one RARMP.

Further information is set out in Part 2.

Public participation

During the quarter, the Regulator issued one invitation to the public to comment on a RARMP prepared for application for a DIR licence. The invitation as 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 Age, The Advertiser, The Sydney Morning Herald* and rural press such as *The Land, The Weekly Times* and *The Stock Journal.*
- 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 April to June 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 April to 30 June 2005

Application type	Number received	Number approved[1]
DIR licence	1	5
DNIR licence	11	11
Accreditations	0	1
Certifications	39	35

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

Processing of applications for Dealings involving Intentional Release (DIR) licences

The key steps the Regulator takes when considering an application for a DIR licence are:

- initial screening of the application for completeness
- determining whether the proposed dealings may pose a significant risk to human health and safety and the environment
- seeking comments from prescribed expert groups and key stakeholders (including the public if a significant risk is identified) on issues to consider in the RARMP
- preparing a consultation RARMP, including proposed licence conditions to manage risks to human health and safety and the environment
- seeking comments from prescribed expert groups and key stakeholders (including the public) on the RARMP
- considering all comments relating to the protection of human health and safety and the environment in finalising the RARMP
- consideration of 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 30 June 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 059/2005	DIR 045/2004[2]			DIR 050/2004
	DIR 046/2004[2]			DIR 053/2004
	DIR 056/2004[2]			DIR 054/2004
	DIR 058/2005			DIR 055/2004
				DIR 057/2005

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 because further information was sought from the applicant

Applications received for DIR licences

The OGTR received one application for a DIR licence in the April – June 2005 quarter.

- DIR 059/2005 'Agricultural use of Roundup Ready Flex technology (MON 88913) in cotton' (Monsanto Australia 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 application:

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

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

The Regulator invited comment from expert groups and key stakeholders, including the public, as part of the second-round of consultations on RARMP for the following application:

- DIR 057/2004 'Field trials of genetically modified herbicide tolerant hybrid *Brassica juncea*' (Bayer CropScience Pty 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 DIR licence 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 056/2004 'Commercial release of herbicide tolerant cotton (LLCotton25)' (Bayer CropScience Pty Ltd). The clock was restarted on this application during the quarter, and Bayer CropScience Pty Ltd revised the scale of their application from a commercial release to a limited and controlled large scale field trial.

Finalised applications for DIR licences

During the quarter, the Regulator issued five DIR licences:

- DIR 050/2004 'Vaccination of cattle with recombinant bovine herpesvirus vaccines' (Queensland Government Department of Primary Industries and Fisheries)
- 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)
- DIR 057/2004 'Field trials of genetically modified herbicide tolerant hybrid *Brassica juncea*' (Bayer CropScience Pty Ltd)

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 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 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 86 NLRD notifications in the quarter. A full listing of NLRDs and their date of notification is available from the OGTR website at www.ogtr.gov.au.

Existing licences and other instruments

The Regulator can, directly or upon application, vary an issued licence or other instrument. For example, the Regulator can vary a licence to better manage risks if new information or data comes to light. Additionally, the Regulator can make a decision in relation to an application to transfer a licence to another person or consent to the surrender of a licence by a licence holder.

The following table describes the number and type of the applications received to vary existing licences and other instruments, as well as the number of applications processed during the April to June 2005 quarter.

Applications received and decisions made: existing licences and other instruments 1 April to 30 June 2005

Type	Number received	Number processed[1]
Surrender of certification	41	43
Surrender of DIR licence	1	0
Surrender of DNIR licence	0	0
Surrender of accreditation	0	0
Variation of certification[2]	113	205
Variation of accreditation	4	3
Variation of DIR licence[3]	14	9
Variation of DNIR licence[3]	20	18
Transfer of DNIR	0	0

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 059/2005). This application was also declared during the quarter.

The Regulator also received two CCI applications relating to NLRD applications and made one CCI declaration in relation to an NLRD.

Monitoring and compliance

The aim of OGTR monitoring and compliance activities is to ensure dealings with GMOs comply with legislative obligations and are consistent with the object of the Act:

> *To protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.*

In particular, the Monitoring and Compliance Section focuses on management of dealings at field trial sites and within contained facilities to ensure:

- the 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 April - June 2005 quarter, six field trial sites were subjected to monitoring visits.

Current field trial sites monitored: Of the 49 sites current in the quarter, six were monitored. This represents a monitoring rate of 12 per cent of all current sites for the quarter.

Post-harvest field trial sites monitored: Of the 69 sites subject to post-harvest monitoring in the quarter, nine were monitored. This represents a monitoring rate of 13 per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection to contained dealings covered 13 organisations and 26 PC facilities. Monitoring of PC facilities encompassed PC2 laboratories (16 visited), PC2 animal containment facilities (two visited), PC2 plant containment facilities (one visited), PC3 laboratory re-certifications (five visited).

PC1 large scale re-certification inspections (one visited) and PC3 animal containment facilities pre-certification inspections (one visited).

Monitoring of contained dealings: During the April – June 2005 quarter, monitoring of the 26 PC facilities mentioned above also included assessment of the general practices followed for dealings not involving intentional release (DNIRs), notifiable low risk dealings (NLRDs) and exempt dealings. In addition to these general practices, specific licence conditions for one DNIR were monitored.

Monitoring of dealings involving intentional releases

The following table shows the total monitoring coverage for field trial sites 1 April to 30 June 2005

Licensed Organisation Name	Licence Number	No. sites visited	Site status[1]	Crop type
BSES Limited	DIR 019/2001	1	C	Sugarcane
		1	PHM	Sugarcane
Dow AgroSciences Australia Pty Ltd	DIR 044/2003	1	PHM	Cotton
Monsanto Australia Limited	DIR 012/2002	2	C	Cotton
		5	PHM	Cotton
	DIR 012/2002 (PR89X2)	2	C	Cotton
	DIR 035/2003	1	PHM	Cotton
The University of Queensland	DIR 051/2004	1	C	Sugarcane
		1	PHM	Sugarcane
Totals	6	15	C=6	2 types
			PHM=9	

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 April to 30 June 2005

Licensed Organisation Name	Licence Number
Children, Youth and Women's Health Service	DNIR 236/2003
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 six PC3 facilities and one PC1 Large scale facility.

Organisation	Physical Containment (PC) facility	No. facilities visited
Agen Biomedical	PC1 Large scale+	1
Bioproperties (Australia) Pty Ltd	PC2 Laboratory	1
Children, Youth and Women's Health Service	PC2 Laboratory	3
	PC2 Animal	1
Deltapine Australia Pty Ltd	PC2 Plant	1
James Cook University	PC3 Laboratory+	1
Mental Health Research Institute of Victoria	PC2 Laboratory	3
	PC2 Animal	1
National Measurements Institute	PC2 Laboratory	4
Queensland Government Department of Primary Industries and Fisheries	PC3 Animal+	1
Royal Children's Hospital and Health Service District	PC3 Laboratory+	2
Stem Cell Sciences	PC2 Laboratory	1
TGR Biosciences Pty Ltd	PC2 Laboratory	2
The University of Queensland	PC3 Laboratory+	2
University of Ballarat	PC2 Laboratory	2
Totals	**6 Facility Types**	**26**

+ Joint inspection with Contained Dealing Evaluation Section

Monitoring findings

Dealings involving intentional release

During the quarter four non-compliances were identified as a result of monitoring activities of DIR Licences. In all instances, the risks to human health, safety and the environment were assessed as negligible.

Organisation	CSIRO
Licence number and site	DIR 038/2003, Site 3
Summary of dealing	Licence relates to a field trial 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 under DIR 038/2003 in November 2003 and harvested in January 2005. On 27 May 2005, due to a reporting error, the OGTR was notified that 100-1000 flowering volunteers were observed during routine inspection of the site. Further inquires revealed the actual number of flowering volunteers was two. Licence conditions for DIR 038/2003 state that volunteer plants must be destroyed prior to flowering. The flowering volunteers were removed and destroyed immediately.
Risk assessment	The risks to human health and safety and the environment were assessed as negligible.
Risk management	As the volunteers had not yet set seed and were destroyed immediately upon detection there is no possibility for persistence as a result of this non-compliance.

Organisation	Monsanto Australia Ltd
Licence number and site	DIR 012/2002, Site 19
Summary of dealing	Licence relates to a field trial of cotton (*Gossypium hirsutum*) genetically modified by introduction of two insecticidal genes and/or insecticidal genes in combination with a gene that confers tolerance to the herbicide glyphosate, the active ingredient of Roundup®. The site is in the post harvest monitoring phase.
Findings	On 17 March 2005 Monsanto informed the OGTR that sugarcane had been planted on site 19. No licence variation request to allow this crop to be planted on this site had been submitted to the Regulator. The Regulator also found that Monsanto had not satisfactorily informed a person covered by the licence of their responsibilities.
Risk assessment	The risks to human health and safety and the environment were assessed as negligible.
Risk management	An application to the Regulator to vary DIR012/2002 to approve the growing of sugarcane on the site has been received. The variation will also increase the monitoring obligations for this site. Monsanto was advised to ensure it meets the increased monitoring obligations, and requested to provide revised policies and procedures to the Regulator that ensure persons covered by the licence are informed of the licence conditions.

Organisation	Monsanto Australia Ltd
Licence number and site	DIR 012/2002, Site 4
Summary of dealing	Licence relates to a field trial of cotton (*Gossypium hirsutum*) genetically modified by introduction of two insecticidal genes and/or insecticidal genes in combination with a gene that confers tolerance to the herbicide glyphosate, the active ingredient of Roundup®. The site is in the post harvest monitoring phase.
Findings	On 20 May 2005 Monsanto informed the OGTR that chickpea had been planted on site 4. No licence variation request to allow this crop to be planted on this site had been submitted to the Regulator. Monsanto's procedures for managing the site were not adequate.
Risk assessment	The risks to human health and safety and the environment were assessed as negligible.
Risk management	An application to the Regulator to vary DIR012/2002 to approve the growing of chickpea on the site and to sign off the site has been received. Monsanto agreed to revise its procedures for management of field trial sites and was requested to provide revised policies and documentation to the Regulator.

Organisation	Monsanto Australia Ltd
Licence number and site	DIR035/2003 site 10
Summary of dealing	Licence relates to a field trial of cotton (*Gossypium hirsutum*) genetically modified by introduction of genes to confer tolerance to the herbicide glyphosate (Roundup Ready® MON 88913) and/or resistance to caterpillar pests (Roundup Ready® MON 88913/Bollgard® II or Bollgard® II).
Findings	On 11 February 2005 Monsanto reported that during sowing of the trial site and pollen trap, seven rows of the pollen trap surrounding the site were accidentally sown to Roundup Ready Flex® cotton. This error occurred during seed packaging for sowing of the site, when a technician misunderstood the site plan.
Risk assessment	The risks to human health and safety and the environment were assessed as negligible.
Risk management	The dissemination of pollen from the Roundup Ready Flex® cotton was minimised by the application of a chemical that caused the shedding of flowers and bolls from the GM plants. Testing of seed from nearby crops found no gene flow from the Roundup Ready Flex®. Monsanto has indicated that sowing procedures have been reviewed and that accounting procedures will be implemented to prevent future occurrences of this sort. These procedures have been supplied to the OGTR.

Organisation	Monsanto Australia Ltd
Licence number and site	DIR 012/2002 site 28 & DIR035/2003 site 20
Summary of dealing	DIR 012/2002 Licence relates to a field trial of cotton (*Gossypium hirsutum*) genetically modified by introduction of two insecticidal genes (Bollgard® II) and/or insecticidal genes in combination with a gene that confers tolerance to the herbicide glyphosate, the active ingredient of Roundup® (Bollgard® II / Roundup Ready®). DIR 035/2003 Licence relates to a field trial of cotton (*Gossypium hirsutum*) genetically modified by introduction of two copies of the gene that confers tolerance to the herbicide glyphosate (Roundup Ready® MON 88913) and/or resistance to caterpillar pests (Roundup Ready® MON 88913/Bollgard® II or Bollgard® II). This site is in the post harvest phase.
Findings	Site 28 was planted to the GM cottons authorised under DIR 012/2002 on 4 April 2005. Additional planting of the GM cotton authorised by DIR 035/2003 on site 28 occurred on 20 April 2005. On 22 April 2005 Monsanto notified the OGTR of the additional planting, and requested that site 28 be transferred to DIR 035/2003 site 20. DIR 012/2002 and DIR 035/2003 licence conditions do not allow this to occur.
Risk assessment	The risks to human health and safety and the environment from the stacking of the genes introduced into these GMOs were assessed as negligible.
Risk management	Monsanto removed the DIR035/2003 plants on 19 May 2005. As the GMOs had not flowered, and were destroyed, there is no possibility for persistence as a result of this non-compliance.

Organisation	Dow AgroSciences Australia Pty Ltd
Licence number and site	DIR044/2003 site 5
Summary of dealing	Licence relates to a field trial of cotton (*Gossypium hirsutum*) genetically modified by introduction of genes to confer tolerance to herbicide and/or resistance to pests.
Findings	On 27 April 2005 Dow AgroSciences Australia Pty Ltd reported that the pollen trap surrounding the GM cotton trial site was harvested at the same time as surrounding conventional cotton. The GM cotton trial was subsequently mulched and the module containing material from the pollen trap and conventional cotton was destroyed by burning. The containment of all pollen trap material in one module following harvest and subsequent destruction of that module prevented the dissemination of GM seed.

Risk assessment	The risks to human health and safety and the environment were assessed as negligible.
Risk management	The DIR 044/2003 licence will be varied to require post harvest monitoring of areas where pollen trap material may have been dispersed to prevent the persistence of the GMO at the site.

Organisation	Bureau of Sugar Experiment Stations (BSES)
Licence number and site	DIR019/2002 site 1
Summary of dealing	Licence relates to a filed trial of Sugarcane (*Saccharum*) genetically modified to express a reporter gene (*gfp*(S65T) encoding green fluorescent protein) and antibiotic resistance (*nptII*).
Findings	Monitoring at this site carried out in June 2005 identified the following non compliances with licence conditions: • The initiation of the flowering period was not reported to the Regulator within 7 days of occurrence • The site was not monitored daily during the flowering phase of the trial • Panicles were not removed from plants in the trial area prior to reaching maturity • The actual date of harvest of the site was not notified to the Regulator within 7 days of harvest • A period of more than 60 days passed between post harvest monitoring inspections at the site • Monitoring reports were not supplied to the Regulator within 30 days of monitoring taking place
Risk assessment	The risks to human health and safety and the environment were assessed as negligible.
Risk management	Post harvest monitoring of the site and all associated areas described by the licence will now be carried out at least once every 60 days, and monitoring reports containing all information required by the licence will be submitted to the Regulator within 30 days of each inspection. The actual date of harvest of the site has been notified in writing to the Regulator, and monitoring reports for monitoring already conducted at the site have been supplied to the Regulator.

Dealings not Involving Intentional Release

During the quarter one non-compliance was identified as a result of monitoring DNIR Licences. Risks to human health and safety and the environment were assessed as negligible.

Organisation	Children, Youth and Women's Health Service, South Australia
Licence number and site	DNIR 236/2003
Summary of dealing	Functional analysis of genes involved in haemopoiesis by retroviral expression in human cells and cell lines. The aim of this dealing is to study genes involved in the haemopoietic system to assess their effects on haemopoietic stem cell and progenitor cell differentiation.
Findings	In contravention of Condition 11 of DNIR 236/2003 (and Point B1 and B2 of Part B of the Guidelines for Transport of GMO), GMOs were being transported between certified contained facilities, Cert 1668/2003 and Cert 1669/2003, without being placed in an appropriately labelled secondary unbreakable container.
Risk assessment	The risks to human health and safety and the environment were assessed as negligible.
Risk management	Children, Youth and Women's Health Service has amended transport procedure to comply with relevant OGTR guidelines.

Note: This table refers to non-compliance with specific DNIR licence conditions. Any non-compliance with Certification Guidelines for the facility/facilities in which the DNIR takes place are reported generically under inspection of physical containment facilities.

Physical containment facilities

OGTR's monitoring of certified PC 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 risks to human health and safety and the environment.

The following table represents the number of non-compliances against the Regulator's Certification Guidelines in OGTR certified facilities inspected during 1 April to 30 June 2005. None posed risks to human health and safety or the environment.

Number of PC Facilities inspected	Structure	PPE	Equipment	Waste disposal	Work practices	Transport
26	10	7	12	0	18	6

PPE: Personal Protective Equipment

In most instances, issues observed arose from the 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.

Version 2.2 of the requirements for PC2 laboratories, PC2 animal containment and PC2 plant containment facilities were issued on 7 August 2003. The OGTR is managing a program where these facilities are being progressively re-certified according to the Version 2.2 Guidelines, and only a small number of facilities are still certified under Version 1 of the Guidelines.

This quarter, monitoring staff were also involved in joint inspections (re-certification and pre-certification) of six PC3 facilities and one PC1 large scale facility with officers from the Contained Dealings Evaluation Section of the OGTR. Inspections of these types of facilities are usually undertaken either prior to commissioning or when they 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.

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.

Contained Dealings Practice Review

Organisation	CSIRO Marine Research, Hobart, Tasmania
Issue	This Practice Review followed on from a self report by CSIRO (reported separately under Investigations) that a dealing conducted at CSIRO Marine Research, Hobart, may have exceeded the scope of the Notifiable Low Risk Dealing (NLRD) 1091/2003 "Development of daughterless carp technology".
Determination	The OGTR and CSIRO determined that there were some communication issues between researchers, located in Tasmania, and their Institutional Biosafety Committee (IBC), located in Melbourne.
Action	The IBC has enhanced communications with researchers in Hobart.

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; 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 the April to June 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 summarises an investigation finalised in the quarter 1 April to 30 June 2005

Organisation	CSIRO Marine Research, Hobart, Tasmania
Issue	On Wednesday 22 December 2004, the OGTR was notified by CSIRO, that a contained dealing conducted at CSIRO Marine Research, Hobart may have exceeded the scope of the Notifiable Low Risk Dealing (NLRD) 1091/2003: "Development of daughterless carp technology".
Determination	CSIRO and the OGTR Compliance Unit reviewed the circumstances surrounding the dealing and determined that whilst it could be categorised as a Notifiable Low Risk Dealing, it was not covered by NLRD 1091/2003.
Action	CSIRO has submitted a new NLRD 1649/2005 "Experimental studies on sexual differentiation and fertility in laboratory fish species" for this work. The Compliance Unit undertook a Practice Review of the circumstances surrounding the conduct of the dealing. The Practice Review is reported separately.

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 previous GTCCC is available from the OGTR website www.ogtr.gov.au

Gene Technology Ethics Committee

The Gene Technology Ethics Committee (GTEC) held its ninth meeting in Canberra on 7 June 2005. GTEC progressed work on its discussion papers entitled *National Framework Statement for the Development of Ethical Principles in Gene Technology* and *Ethical Issues Arising from Trans-species Gene Transfer* and established a working group to provide a submission to the review of the Act.

The 9th communiqué outlining discussions held at this meeting is attached to this Quarterly Report (Appendix C)

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 a teleconference on 31 May 2005 to discuss the review of the Regulations. GTTAC advised the Regulator on matters relating to the definitions used in the Regulations and exempt dealings. GTTAC also provided advice on a RARMP for a DIR licence application.

The 14th communiqué outlining discussions held at this meeting is attached to this Quarterly Report (Appendix B).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:

- Review of the *Gene Technology Regulations 2001*.
- Review of the *Guidelines for the Certification of Facilities/Physical Containment Requirements* continued to revise guidelines for PC3 Laboratory facilities and PC1 and PC2 Large Scale facilities.
- Revised Accreditation Guidelines were finalised.

International collaboration and coordination

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

International collaboration and coordination activities undertaken during the quarter involved participation in and/or presentation(s) to:

- Food Standards Australia New Zealand/AusAID Course 'Risk Analysis for Genetically Modified Foods' for representatives from SE Asian and Pacific nations. 4-8 April, Canberra ACT.
- OECD Conference 'Challenges and Opportunities in Agri-food Research - The role of regulation in the development & implementation of agrobiotechnology innovations involving gene technology'. 18 May, Rome Italy.
- Canadian Science Centre for Human and Animal Health 'International High Containment Biosafety Workshop'. 16-20 May, Winnipeg, Canada.
- Australian Delegation to the First meeting of the Ad Hoc Open-ended Working Group on Liability and Redress under the Cartagena Protocol on Biosafety. 25-27 May, Montreal, Canada
- Australian Delegation to the Second Meeting of the Parties to the Cartagena Protocol on Biosafety. 30 May to 3 June, Montreal, Canada.
- Environment Canada and Canadian Food Inspection Agency workshop on 'Containment Guidelines for Biotechnology-Derived Animals'. 4 June, Montreal, Canada.
- Biological and Toxin Weapons Convention - Annual Experts Group Meeting 'Statement on the ethical principles in gene technology, environmental ethics and the Biological Weapons Convention - is there a link?' 13- 24 June, Geneva, Switzerland.

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 stakeholders, the Australian community and users about the regulatory system. During the quarter one presentation was given:

- Department of Foreign Affairs and Trade Workshop on Domestic and International Law Regulation of Risk Analysis 'Regulation and Risk Analysis of Gene Technology in Australia', 10 May 2005, Canberra, ACT.

Institutional Biosafety Committee Training

On 14-15 April 2005 the OGTR hosted the inaugural Institutional Biosafety Committee (IBC) Forum in Canberra. Approximately 120 representatives of organisations from across Australia, together with OGTR staff attended the forum.

The IBC Forum was officially opened by the Parliamentary Secretary for the Department of Health and Ageing, the Hon. Christopher Pyne MP, who also officially launched the revised *Risk Analysis Framework*.

Delegates received briefings from OGTR staff on a range of current activities, including the outcomes of a comprehensive series of practice reviews of accredited organisations conducted across Australia, and progress on the reviews of guidelines for the certification of contained facilities and the Regulations.

IBCs presented examples of best practice identified during the review and feedback was sought from participants on issues of common interest. These included GMO transport requirements, laboratory signage, IBC training and the establishment of local networks between organisations.

OGTR staff were available for individual meetings and conducted a number of special interest group discussions, including the certification process for high level and large scale facilities and data requirement for DIR licences.

A key outcome from the forum was to include a new page on the OGTR website dedicated to the provision of information relevant to IBCs.

Consultants

During the reporting period, the OGTR managed two consultancy contracts worth a total of $32,001. The table below lists the consultants, describes the purpose of the consultancy and the amount paid during the quarter. The amount paid is net of GST.

Consultant	Amount paid (GST exclusive)	Purpose
PB&B Consulting	$3,680	Prepare risk assessment & incident response plan for GM soybean
Dialog Information Technology	$28,321	Ongoing work on the Gene Technology Information System (GTIMS)
Total Consultants for quarter	$32,001	

Gene Technology Information Management System

In June 2005 the OGTR applied a new security model, the Application Security List (ASL) to the Gene Technology Information Management System (GTIMS).

The ASL controls individual document security for NLRDs, DNIRs, DIRs and CCI applications by allowing the Primary Applicant to nominate who has access to their applications.

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
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:

- *Risk Analysis Framework*
- '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'
- 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 110 calls and 70 emails in April 2005, 90 calls and 60 emails in May 2005, and 140 calls and 70 emails in June 2005.

Freedom of information

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

Appendix A

DNIR Licences issued April – June 2005

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 345/2005	6 Apr 05	University of Sydney, New South Wales	Function of *Dichelobacter nodosus* genes and production of recombinant antigens.	The purpose of the dealings is to investigate the function of potential virulence genes in *Dichelobacter nododus*, the causative agent of footrot, and to produce recombinant antigens.
DNIR 346/2005	4 May 05	South Eastern Sydney Area Health Service, New South Wales	Cellular antiviral immunity (including HIV and HCV)	The aim of this dealing is to study cellular immunity of peripheral blood mononuclear cells to *Human immunodeficiency virus* (HIV) and *Hepatitis C virus* (HCV) be expressing HIV and HCV antigens using *Vaccinia virus* recombinant vectors and conducting *in vitro* assays that measure cytotoxic T cell activity, lymphoproliferative activity and cytokine production.
DNIR 347/2005	5 May 05	University of Wollongong, New South Wales	Storage of GMOs that are GMAC, NLRD and DNIR dealings	The purpose of this dealing is to store GMOs that were produced under GMAC, NLRDs and DNIRs dealings.
DNIR 348/2005	4 Apr 05	CSIRO Molecular Science, Victoria	Production of anti-CD59 antibody Fab fragments using recombinant *E. coli*	The purpose of this dealing is to produce large-scale quantities of recombinant *Escherichia coli* expressing anti-CD59 antibody fragments and to purify the recombinant protein.
DNIR 349/2005	12 May 05	University of Queensland	Investigations into the role of novel genes at the level of the cell and animal	The purpose of this dealing is to understand the role of genes of interest in disease specifically inflammation, tissue regeneration and congenital abnormalities.

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 350/2005	27 May 05	University of Technology, Sydney, New South Wales	Development of Chimeric and humanized forms of a mouse monoclonal antibody	The aims of this dealing are to produce large-scale quantities of chimeric and humanised forms of the murine monoclonal antibody mKap.
DNIR 351/2005	27 June 05	The University of Melbourne, Victoria	Cell wall metabolism in mycobacteria	The aim of this dealing is to investigate the cell wall metabolism of *Mycobacterium tuberculosis*, the causative agent of tuberculosis.
DNIR 352/2005	6 Apr 05	CSL Ltd, Victoria	Preparation of trial batches of inactivated human influenza vaccine from strains of attenuated avian influenza.	The aim of the dealing is to prepare batches of inactivated human influenza vaccine from strains of attenuated avian influenza.
DNIR 355/2005	3 June 05	NSW Department of Primary Industries	Function of *Dichelobacter nodosus* genes	The purpose of this dealing is to examine the function of potential virulence genes in *Dichelobacter nodosus*, the causative agent of footrot, through *in vivo* testing on sheep (*Ovis aries*).
DNIR 358/2005	30 June 05	CSIRO Entomology, Australian Capital Territory	Immunocontraceptive effects of recombinant murine cytomegaloviruses expressing mouse zona pellucida subunit 3 protein	The purpose of this dealing is to test the efficacy and safety of recombinant Murine cytomegalovirus expressing immunocontraceptive proteins.
DNIR 359/2005	30 June 05	CSIRO Entomology, Australian Capital Territory	Storage of GMOs that are a licensed dealing	The purpose of this dealing is to store GM cell lines that are no longer being worked on but for which the researchers wish to maintain stocks.

Appendix B

Gene Technology Technical Advisory Committee

COMMUNIQUE
No. 14

This is the fourteenth communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the twenty third meeting of GTTAC, held on 7 & 8 March 2005 and at a teleconference on 31 May 2005 as well as matters considered by GTTAC out-of-session in January 2005.

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 Involving the Intentional Release of Genetically Modified Organisms

Dealings Involving the Intentional Release of GMOs (DIRs) are dealings that are undertaken outside of a certified physical containment facility. DIRs involve

the limited and controlled release (field trial) of a GMO or a commercial (general) release of a GMO.

A Risk Assessment and Risk Management Plan (RARMP) is prepared in respect of every licence application for a DIR licence and 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 GM Bovine herpesvirus vaccine

GTTAC considered the RARMP prepared in response to the following application:

Vaccine trial – vaccination of cattle with recombinant Bovine herpesvirus vaccines (DIR 050/2004)

The OGTR has received an application from the Queensland Government Department of Primary Industries and Fisheries (QDPIF) for the limited and controlled release of up to 19 genetically modified (GM) *Bovine herpesvirus* (BoHV-1) vaccines into the environment. The aim of the trial is to evaluate the safety and efficacy of the GM vaccines to protect cattle from primary infection from BoHV-1 and *Bovine viral diarrhoea virus* (BVDV).

The trial will be conducted in Queensland and will involve the inoculation of up to 180 cattle, aged between 4 to 6 months with the approved GM vaccines administered via a nasal drip. Groups of cattle will be inoculated with the GM vaccines and held in the PC1 animal containment facility for 6-8 weeks. During this time their immune response to the vaccines will be tested. The cattle will shed GM virus for up to 8 days following inoculation and after that time they will be latently infected with the GMOs.

At the end of the test period the cattle will be euthanased in a post-mortem room on site except for 1 or 2 of the groups of cattle that will be moved from the PC1 animal containment facility to designated paddocks on site for a period of 3 weeks before being euthanased.

The GM vaccines will be produced by the insertion of one or more of 19 gene constructs that encode either of the envelope (E) glycoproteins2 E0 and E2 from BVDV into an existing, conventional BoHV-1 vaccine strain V155. This existing vaccine has been used in over 2 million feedlot cattle with no adverse effects to human health and safety or to the environment being recorded.

[2] *Envelope glycoprotein* - a glycosylated protein that is located in the envelope of a virus and that is capable of stimulating an immune response.

While there have been no previous releases of these GM vaccines in Australia, a field trial with a similar vaccine was conducted under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee (GMAC). There have been no reports of adverse effects on human health or the environment resulting from this release.

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

- the Committee agrees with the assessment made by the OGTR on risk of toxicity, allergenicity and transmission of the GMOs;
- the risk assessment identifies all risks associated with the release; and
- the Committee agrees with the proposed licence conditions and recommends the use of sentinel sheep.

Advice on GM Wheat

GTTAC considered the RARMPs prepared in response to the following applications:

Field trial of genetically modified salt tolerant wheat on saline land (DIR 053/2004)

The OGTR has received an application from Grain Biotech Australia to carry out a small scale field trial of GM wheat on a single site in the Corrigin Shire, Western Australia, covering an area of up to 0.45 hectares from April 2005 to January 2006.

The aim of the proposed release is to evaluate tolerance to saline soil and to evaluate agronomic performance of the GM wheats under Australian field conditions.

The GM salt tolerant wheat has been genetically modified to contain the ornithine amino transferase gene (*oat*) isolated from *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 GM wheat and pollen trap plants from the trial, or their by-products will be used for human food or animal feed.

There have been no previous releases of the proposed GM wheats. However, five field releases of other GM wheats were approved under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee (GMAC).

GTTAC discussed this application from Grain Biotech Australia and advised the Regulator that:

- the risk assessment identifies all risks associated with the release;
- the terminology used in the RARMP to describe allergenicity, toxicity and the risk management of rodents and birds should be adjusted; and
- the Committee agrees with the proposed licence conditions and recommended the use of bird netting on the proposed trial site.

Field trial of genetically modified wheat with altered grain starch (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 0.25 ha in the Australian Capital Territory (ACT) from May 2005 to December 2006.

The GM wheats proposed for release have been genetically modified with a gene silencing construct designed to prevent the expression of either starch enzymes (SE) I or II which influence starch metabolism in wheat. The SE sequences in the silencing constructs and the high molecular weight (HMW) glutenin promoter (endosperm specific) were both derived from wheat. The effect of the gene silencing is to increase the proportion of amylose as opposed to amylopectin stored in the wheat grain. The transformation construct also contains the neomycin phosphotransferase (*nptII*) gene, derived from *Escherichia coli*, as a selectable marker.

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 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.

None of the material harvested from the trial will be used for human food or stock feed and any material not used for further research will be destroyed. This GM wheat would require approval by Food Standards Australia New Zealand (FSANZ) before it could be used for human consumption.

There have been no previous releases of the proposed GMO under the Gene Technology Act 2000.

However, five field releases of other GM wheats were approved under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee (GMAC).

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

- the Committee agrees with the assessment made by the OGTR on risk of toxicity, allergenicity, weediness and gene transfer;
- the risk assessment identifies all risks associated with the release; and
- the Committee agrees with the proposed licence conditions and recommends that the monitoring should be carried out for a period of 24 months.

Advice on Cotton

GTTAC considered the RARMP prepared in response to the following application:

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

Monsanto proposes to conduct a field trial on 91 sites covering a maximum total area of 1811 hectares, over two planting seasons, the southern summer growing season and the northern winter growing season, between September 2005 and November 2006. The summer trial sites (maximum of 1767 hectares) would be in the cotton growing regions of New South Wales and southern Queensland, and the winter trial sites (maximum of 42 hectares) would be in northern Western Australia, the Northern Territory and northern Queensland.

The aims of the proposed release are to:

- transfer the Roundup Ready® Flex herbicide tolerant trait into elite cotton varieties suitable for use under Australian conditions;
- test agronomic performance including disease resistance (bacterial blight and fusarium and verticillium wilts);
- produce seed for future releases (which would require separate applications and approval processes);
- 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 Food Standards Australia New Zealand (FSANZ)) and data on the GM cottons' tolerance to glyphosate, weed control effectiveness and glyphosate residue levels (required by the Australian Pesticides and Veterinary Medicines Authority).

Roundup Ready® Flex MON 88913 cotton, contains two copies of a gene, *cp4 epsps*, derived from *Agrobacterium* sp. strain CP4, conferring tolerance to glyphosate, the active ingredient in Roundup® herbicides. The proposed release will also include some lines containing the RR Flex trait in combination with Bollgard II® cotton (containing two insecticidal genes, a reporter gene and an antibiotic resistance marker gene).

It was noted that GTTAC had considered and provided advice on this proposal at its previous meeting on 21 September 2004 and that the risks posed under this proposal are similar to those for DIRs 005, 006, 009, 012, 023 and 035.

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 Committee agrees with the assessment made by the OGTR on risk of toxicity, allergenicity and gene transfer;
- the terminology in the RARMP should be reviewed to ensure the clear differentiation of hazards and risks;
- the risk assessment identifies all risks associated with the release;
- the RARMP should address the risk of visitors to the site accidentally removing material from the trial site; and
- the Committee agrees with the proposed licence conditions.

Advice on Applications

Advice on Indian Mustard

Field trial to allow controlled release of genetically modified, herbicide tolerant hybrid Indian Mustard (*Brassica juncea*) (DIR 057/2004)

The OGTR has received an application from Bayer CropScience Pty Ltd (Bayer) for a licence to allow the intentional release of GM Indian mustard (*Brassica juncea*) into the environment on a limited scale and under controlled conditions. The proposed release would take place at four sites each in the winter and summer growing seasons of 2005-2008, on a maximum area of four hectares per site, in up to 17 shires in New South Wales, South Australia and Victoria.

The main aims of the proposed release are to: evaluate the effectiveness of the introduced herbicide tolerance trait in the field; assess the agronomic performance of GM Indian mustard lines in Australia, including comparisons with GM and conventional canola and conventional Indian mustard; and to produce seed for further evaluation overseas and in Australia.

The GM Indian mustard incorporates the *barnase-barstar* hybrid breeding system and a herbicide tolerance gene. Both these traits in canola (*Brassica napus*) were approved in 2004 for field trials under licence DIR 032/2002. The GM Indian mustard proposed for release has been derived by conventional breeding conducted overseas between GM canola approved under licence DIR 032/2002 and Indian mustard. The F1 hybrid was then further backcrossed to Indian mustard. The barnase-barstar hybrid breeding system is also present in InVigor® canola approved for commercial release under licence DIR 021/2002.

The *barnase* (male sterility) and *barstar* (fertility restorer) genes are derived from the bacterium *Bacillus amyloliquefaciens*. Bayer sought and received approval to have information relating to the introduced herbicide tolerance gene, regulatory elements, gene constructs including plasmid maps, precise arrangement of the genetic elements and data on molecular characterisation of the GM Indian mustard (derived from the GM canola under licence DIR 032/2002) declared as Confidential Commercial Information (CCI).

None of the GM *B. juncea* plants from the release, or their by-products would be used for stock feed or human food. An approval from FSANZ would be required before oil from the GM *B. juncea* lines could be used for human consumption.

GTTAC discussed this application from Bayer CropScience Pty Ltd and advised the Regulator that:

- The Committee would like further information from the applicant concerning the location, containment and fate of bees;
- The Committee recommended a more structured representation of the trial objectives
- A GTTAC working group was established to consider further information provided by the applicant regarding bees and weediness for preparation of the RARMP.

Other Advice

DIR 051/2004 – Field trial of sugarcane expressing sucrose isomerase (University of Queensland); and

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

The OGTR sought GTTAC advice on RARMPs for the above DIR applications in an out of session package in January 2005 due to legislative time constraints which prevented their consideration at the 7/8 March 2005 GTTAC meeting.

These DIR applications were previously considered by GTTAC at the 22 July 2004 meeting and by individual GTTAC members in December 2004. Details of that meeting are documented in GTTAC Communiqué 13 which is available from the OGTR website.

At the 23rd GTTAC Meeting (March 2005) members were briefed on the decisions on these licence applications.

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

This proposed dealing involves 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 environmental and biological stress.

GTTAC considered the RARMP for DIR 051/2004 and advised the Regulator that:

- the risk assessment identifies all risks associated with the release and recommends that the risk of weediness, allergenicity and toxicity may be better classified as 'negligible'; and
- the Committee agrees with the proposed licence conditions and recommends that the monitoring period for this perennial species should be greater than 12 months.

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

The proposed dealing involves 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 considered the RARMP for DIR 052/2004 and advised the Regulator that:

- the risk assessment identifies all risks associated with the release;
- the risk of weediness should be negligible rather than low;
- no additional data needs to be collected apart from gene flow data. Replication of previous work on the field biology of rice should not be required; and
- the Committee agrees with the proposed licence conditions and recommends that:
    - site 2 should be surrounded by 40 cm high earth banks; and
    - the edges of the cage covering the sites should be required to be in contact with the ground around its entire perimeter;

Presentations

The following presentations were made to GTTAC:

- Introduction to the assessment process for Dealings Involving the Intentional Release of GMOs into the environment (DIRs) (OGTR);
- Introduction to the assessment for Dealings Not involving Intentional Release of GMOs into the environment (DNIRs) (OGTR);
- Risk Analysis Framework (OGTR);
- Horizontal Gene Transfer (OGTR); and
- Public Perceptions of Science and Biotechnology (Biotechnology Australia).

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

GTTAC members met by teleconference on 31 May 2005 and discussed the following documents regarding the review of the Regulations:

- Consideration of exempt dealings with respect to transgenic mice and rats and the review of the *Gene Technology Regulations 2001*
- Consideration of the review of the *Gene Technology Regulations 2001*

The draft revised Regulations will be made available for public comment later in the year.

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

Appendix C

Gene Technology Ethics Committee Meeting
7 June 2005, Canberra

COMMUNIQUE

The Gene Technology Ethics Committee (GTEC) held its ninth meeting in Canberra on 7 June 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 communique includes 'expert advisers').

At its June 2005 meeting, the current GTEC working groups reported on their activities since the previous meeting and received feedback and suggestions to further develop their projects. Members received four presentations by invited guests and were informed of relevant work from other national committees via cross-member reports. In addition, members received a report from the Office of the Gene Technology Regulator (OGTR) on the recent Institutional Biosafety Committee forum and a report from the Regulator on activities undertaken by the OGTR since the eighth meeting held in March 2005. Key outcomes from the meeting are reported below.

GTEC's Work Plan

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

Ethical Issues Associated with Transpecies Gene Transfer

The working group presented the revised document and responses to comments that had been received from the Gene Technology Technical Advisory Committee (GTTAC). GTEC agreed that it is worth progressing this paper further and that additional collaboration with GTTAC should be sought.

The Committee suggested a number of ways to improve the readability and to clarify the purpose and audience of this paper.

Ethical Statement in relation to Genetically Modified Organisms

The working group presented an update on the progress of the ethical statement. GTEC discussed the importance of ensuring that the purpose of the document is applicable across a broad range of audiences and ways of clarifying the values and principles expressed in the document. Once the revised document has been considered by GTEC, it will be circulated to key organisations, industry and international organisations for consultation, as part of a staggered public consultation.

GTEC and Relationships with Other Committees

The Committee welcomed a new observer from the Animal Welfare Committee (AWC) to the meeting who gave an overview of the operations of the AWC and how it operated within the National Health and Medical Research Council (NHMRC).

GTEC also welcomed invited guests representing the following organisations:

- Biotechnology Australia; presented an overview of the organisation including information about the Biotechnology Liaison Committee and ongoing surveys to monitor public opinions about gene technology.

- Department of the Environment and Heritage; presented an introductory overview to the concept of benefit sharing.

- Victorian Biotechnology Ethics Advisory Committee (VBEAC); VBEAC is currently developing an ethical code and a map detailing existing codes and guidelines. GTEC previously provided comments on a draft version of these documents.

- Victorian Department of Health; presented a report on the meeting of the United National Educational, Scientific and Cultural Organisation Commission on the Ethics of Scientific Knowledge and Technology (COMEST), held in Thailand 23-25 March 2005.

The OGTR provided an overview of how the new *Risk Analysis Framework* (RAF) will change the risk assessment process. The risk assessment process is currently going through a stage of transition in the OGTR to conform to the new RAF. The RAF is available on the OGTR website or on request by phoning the number below.

The Biological and Toxin Weapons Convention (BWC) was introduced to GTEC and advice was sought in relation to a paper that will be presented to a meeting of technical experts on the BWC, regarding links between gene technology, environmental ethics and the biological weapons.

As a standing item at every GTEC meeting, the Committee receives verbal reports on activities from the cross-members with the Australian Health Ethics Committee, GTTAC and the GTCCC. Communiques covering meetings for all gene technology advisory committees are publicly available from the OGTR website.

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

Next Meeting

The next GTEC meeting will be held in November 2005.

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