

**Quarterly Report of  
the Gene Technology Regulator  
for the period  
1 April to 30 June 2006**

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Commonwealth Department of Health and Ageing

Publications Approval Number 3624



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

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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 2006.

During this quarter, key achievements included the issuing of 4 licences for dealings not involving the intentional release of genetically modified organisms (GMOs), and the certification of 36 physical containment facilities.

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

Yours sincerely

(Dr) Sue D Meek  
Gene Technology Regulator  
22 September 2006

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## Glossary

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Accredited organisation	An organisation that is accredited under section 92 of the Act
Act	<i>Gene Technology Act 2000</i>
APVMA	Australian Pesticides and Veterinary Medicines Authority
Breach of a licence condition	A breach of a licence condition which has been proven either in court or by way of admission following investigation
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 <u>not</u> 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 facility)
Non-compliance	An inconsistency between an event or state of affairs and the requirements imposed by licence 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	<i>Gene Technology Regulations 2001</i>
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

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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 2006 quarter.

**Part 2** details the regulatory activity undertaken, including information about applications for, and action taken with respect to, GMO licences and other instruments under the Act. It also includes details of monitoring, auditing and compliance activities by the Regulator during this quarter.

**Part 3** reports on the activities of the three advisory committees established under the Act to assist the Regulator and the Gene Technology Ministerial Council (GTMC).

**Part 4** summarises other activities undertaken by the Office of the Gene Technology Regulator (OGTR), including reviews and research, international collaboration and coordination, advice provided on gene technology regulation and freedom of information requests received.

## Further information

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

Office of the Gene Technology Regulator  
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Email: [ogtr@health.gov.au](mailto:ogtr@health.gov.au)  
Website: <http://www.ogtr.gov.au>  
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## **PART 1 National regulatory system**

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### **Key achievements during this quarter**

The key achievements of the April to June 2006 quarter were:

#### **Licences and other instruments**

- 4 licences issued for dealings not involving intentional release of GMOs into the environment (DNIR licences)
- 73 Notifiable Low Risk Dealing (NLRD) notifications received
- 36 containment facilities certified
- 49 surrenders of certifications processed
- 123 variations processed.

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

#### **Monitoring and compliance**

Approximately six percent of current field trial sites and ten percent of post harvest field trial sites were subjected to routine monitoring during the quarter. This exceeds the minimum target rate of five percent per quarter.

Further information on monitoring and compliance is contained in Part 2.

### **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.

#### **Australian Government agency liaison**

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

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

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

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

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

In addition, comment is sought on each DIR licence application and DIR RARMP from a range of other Australian Government agencies which, while not prescribed in the legislation, have maintained a strong interest in its implementation including the:

- Department of Agriculture, Fisheries and Forestry
- Department of Environment and Heritage
- Department of Foreign Affairs and Trade
- Department of Industry, Tourism and Resources.

During the quarter, the Regulator sought advice and comment in respect of four DIR applications and two DIR RARMPs.

Further information is set out in Part 2.

## **Public participation**

During the quarter, the Regulator issued two invitations to the public to comment on the RARMPs prepared in response to two DIR applications. The invitations were issued via email or post to people who have registered on the OGTR mailing list and via advertisements in:

- the *Australian Government Notices Gazette*
- The Australian newspaper
- relevant regional press such as
  - Queensland Country Life, The Northern Territory News, The Weekly Times, The Land, The West Australian, The Countryman, The Murray Pioneer and The Loxton News, and
- the OGTR website <http://www.ogtr.gov.au>

Further information is set out in Part 2

## **PART 2 Regulation of genetically modified organisms**

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Part 2 of the report outlines the regulatory activity undertaken during the April to June 2006 quarter. This includes information about applications for GMO licences and other instruments under the Act. It also includes details of monitoring activities and of alleged, admitted or self-reported non-compliances with the Act, or with the conditions imposed by the Regulator on GMO licences or other instruments issued pursuant to the Act. Summary reports on investigations completed during the quarter are supplied. Information on confidential commercial information (CCI) applications has also been provided.

### **Applications received and decisions made**

Under the Act the Regulator is required to make decisions in relation to applications for the following instruments:

- **Dealings involving Intentional Release (DIR) licences**

DIR licences authorise dealings ranging from limited and controlled releases (field trials) through to more extensive commercial releases of GMOs. These licence applications have a statutory timeframe of 170 working days for processing.
- **Dealings Not involving Intentional Release (DNIR) licences**

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

Licences require organisations which conduct work with GMOs to be accredited. In deciding whether to accredit an organisation, the Regulator must have regard to whether the organisation has, or has access to, a properly constituted and resourced Institutional Biosafety Committee (IBC) and complies with the requirements of the Regulator's guidelines for accreditation. These applications have a statutory timeframe of 90 working days for processing.
- **Certifications of contained facilities**

Certification is required to satisfy the Regulator that a facility which is proposed to be used to conduct dealings with a GMO meets the guideline requirements for the particular level of physical containment specified. These applications have a statutory timeframe of 90 working days for processing.

## GMO Register

The GMO Register is a list of dealings with GMOs that the Regulator is satisfied pose minimal risks to human health and safety and the environment and can therefore be undertaken by anyone, subject to any specified conditions, without the oversight of a licence holder. Under section 78 of the Act the Regulator may determine that dealings with a GMO previously authorised by a licence are to be included on the GMO Register. Such determinations are disallowable instruments.

## New licences and other instruments

The following table describes the number and type of applications received for new licences and other instruments, as well as the approvals made by the Regulator in the quarter.

**Applications received and decisions made, new licences and other instruments 1 April to 30 June 2006**

Application type	Number received	Number approved <sup>1</sup>
DIR licence	4	0
DNIR licence	6	5 <sup>2</sup>
Accreditations	3	1
Certifications	33	36
GMO Register	0	0

1. Approvals reported in the current quarter often relate to applications received in previous quarters.
2. Two applications were approved as one licence

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

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

- initial screening of the application for completeness
- determining whether the proposed dealings may pose a significant risk to human health and safety and the environment
- seeking comments from prescribed expert groups and key stakeholders (including the public if a significant risk is identified) on issues to consider in the RARMP
- preparing a consultation RARMP, including proposed licence conditions to manage risks to human health and safety and the environment

- considering all comments relating to the protection of human health and safety and the environment in finalising the RARMP
- consideration of the applicant's suitability, policy principles and any relevant policy guidelines.

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

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

This time limit may be extended, that is, the clock is stopped, if the decision-making process is unable to continue, for example, because essential additional information is sought from the applicant.

The Act mandates minimum timeframes for the two rounds of consultation that the Regulator must undertake with prescribed expert groups and key stakeholders during the processing of each DIR application. However, longer periods of consultation are usually allowed to facilitate the provision of information and promote involvement in the decision-making process particularly by the community. Therefore an application for a DIR licence would not normally be received and decided upon within the same three month reporting period.

The following table shows the progress of applications for DIR licences undergoing evaluation during the quarter.

**Applications for DIR licences subject to evaluation during the April to June 2006 quarter**

Application received	First round of consultation <sup>1</sup>	Second round of consultation	Withdrawn applications	Licence Issued
DIR 067/2006	DIR 065/2006	DIR 062/2005		
DIR 068/2006	DIR 066/2006	DIR 063/2005		
DIR 069/2006	DIR 067/2006			
DIR 070/2006	DIR 068/2006			

1. Includes posting of 'Early Bird' Notification and summary of application on the OGTR website and to people on the OGTR mailing list.

**Applications received for DIR licences**

The OGTR received four applications for DIR licences in the April to June 2006 quarter.

- DIR 067/2006 - Limited and controlled release of GM cotton lines with tolerance to waterlogging stress - CSIRO

- DIR 068/2006 - Limited and controlled release of GM torenia (an ornamental plant) with altered flower colour - Florigene Pty Ltd
- DIR 069/2006 - Limited and controlled release of hybrid, herbicide tolerant GM *Brassica napus* and hybrid *Brassica juncea* lines - Bayer CropScience Pty Ltd
- DIR 070/2006 - Limited and controlled release of GM sugarcane with altered plant architecture, drought tolerance and nitrogen use efficiency - BSES Limited

### **Consultation on applications for DIR licences**

In this quarter, consultations with expert groups and key stakeholders took place as part of first-round consultations to help identify risks to human health and safety and/or the environment to be considered in the RARMP for the following applications:

- DIR 065/2006 - Limited and controlled release of GM insect resistant (VIP3A and /or Cry1Ab) cotton - Deltapine Australia Pty Ltd
- DIR 066/2006 - Commercial release of GM herbicide tolerant and/or insect resistant cottons north of latitude 22° South - Monsanto Australia Limited
- DIR 067/2006 - Limited and controlled release of GM cotton lines with tolerance to waterlogging stress - CSIRO
- DIR 068/2006 - Limited and controlled release of genetically modified torenia with altered flower colour - Florigene Pty Ltd

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

The Regulator invited comment from expert groups and key stakeholders, including the public, as part of the consultations on RARMPs for the following applications:

- DIR 062/2005 - Commercial release of herbicide tolerant Liberty Link<sup>®</sup> Cotton for use in the Australian cropping system - Bayer CropScience Pty Ltd
- DIR 063/2005 - Field trial of GM cotton expressing natural plant genes for fungal control - Hexima Limited

### **Withdrawn applications for DIR licences**

No DIR licence applications were withdrawn during this quarter.

### **Surrendered applications for DIR licences**

One DIR licence was surrendered during this quarter.

- DIR 035/2003 - Field trials of herbicide tolerant (Roundup Ready<sup>®</sup> MON 88913) and herbicide tolerant/insect resistant (Roundup Ready<sup>®</sup> MON 88913/Bollgard II<sup>®</sup>) cotton - Monsanto Australia Limited

### **Clock stopped on DIR licence applications**

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

There were two clock stop periods that applied to DIR licence applications during this quarter.

- DIR 061/2005 - Field testing of genetically modified salt tolerant wheat on saline land - Grain Biotech Australia Pty Ltd
- DIR 069/2006 - Limited and controlled release of hybrid, herbicide tolerant GM *Brassica napus* and hybrid *Brassica juncea* lines - Bayer CropScience Pty Ltd

### **Decisions on applications for DIR licences**

During the quarter, the Regulator issued no DIR licences.

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

### **Decisions on applications for Dealings Not involving Intentional Release (DNIR) licences**

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

During the quarter the Regulator issued four DNIR licences. Further information about these licences is contained in Appendix A of this report.

A full listing of DNIR licence applications and their current status is available from the OGTR website at <http://www.ogtr.gov.au>

### **Notifications of Notifiable Low Risk Dealings (NLRD) 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 73 NLRD notifications in the quarter. A listing of NLRDs and their date of notification is available from the OGTR website at <http://www.ogtr.gov.au>

## Existing licences and other instruments

The Regulator can, directly or upon application, vary an issued licence or other instrument. For example, the Regulator can vary a licence to better manage risks if new information or data comes to light. Variations involve changes to conditions applied to an instrument or a licence. Most variations are made at the request of the instrument/licence holder. However, the Regulator must not vary the licence unless the Regulator is satisfied that any risks posed by the dealings proposed to be authorised by the licence as varied are able to be managed in such a way as to protect the health and safety of people and the environment.

Additionally, the Regulator can make a decision in relation to an application to transfer a licence to another person or consent to the surrender of a licence by a licence holder.

The following table describes the number and type of the applications received to surrender or vary existing licences and other instruments, as well as the number of applications processed during the April to June 2006 quarter.

**Applications received and decisions made: existing licences and other instruments 1 April to 30 June 2006.**

Type	Number received	Number processed <sup>1</sup>
Surrender of accreditation	0	0
Surrender of certification	14	49
Surrender of DIR licence	0	1
Surrender of DNIR licence	3	2
Variation of certification	104	87
Variation of accreditation	0	2
Variation of DIR licence	7	13
Variation of DNIR licence	27	21

1. Numbers reported in this quarter often relate to applications received in previous quarters. For the purposes of this table, 'processed' means the action on the licence or instrument was completed.

## **Confidential Commercial Information (CCI)**

Under s.184 of the Act a person may apply to the Regulator in accordance with s.185 for specified information to be declared CCI. If the Regulator declares information to be CCI the information is protected from disclosure. More information on the protection of CCI can be found in Chapter 15 of the *Handbook on the Regulation of Gene Technology* which is available on the OGTR website at <http://www.ogtr.gov.au>

During the quarter, the Regulator received two CCI applications relating to DIR applications, one CCI application relating to an application for accreditation of an organisation and no CCI applications relating to DNIR Licence applications or NLRDs.

The Regulator made no declarations in relation to any CCI applications during this quarter.

## **Monitoring and compliance**

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

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

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

- the dissemination of a GMO and its genetic material is minimised
- the persistence of a GMO in the environment is managed
- effective management of the GMO is maintained.

## **Monitoring and compliance strategy**

OGTR monitoring and compliance activities comprise the functions of routine monitoring, reviews of potential risks, investigations and audits.

The OGTR conducts routine monitoring visits of a minimum of 20 percent of field trial sites each year.

A minimum of five percent of current trial sites and five percent of trial sites subject to post-harvest monitoring are monitored each quarter.

The purpose of routine monitoring of field trials is to ensure compliance with licence conditions and includes spot checks.

The OGTR strategy for conducting field trial monitoring draws on accumulated operational experience of risk profiling in relation to compliance.

For example, OGTR field trial monitoring coincides, where possible, with periods or circumstances when non-compliance with licence conditions designed to limit the spread and persistence of the GMOs is more likely to occur (for example, flowering and harvest of GM crops).

The monitoring program for contained facilities involves inspecting and monitoring:

- a minimum of 20 percent of physical containment PC4, PC3 and PC2 large-scale facilities per year
- selected PC2 and PC1 facilities.

These inspections focus on the integrity of the physical structure of the facility and on the general laboratory practices followed in that facility, including those practices followed for Dealings Not involving Intentional Release (DNIRs), Notifiable Low Risk Dealings (NLRDs) and Exempt dealings.

### **Overview of monitoring and compliance for the reporting period**

***Total field trial sites monitored:*** During the April to June 2006 quarter, ten field trial sites were subjected to monitoring visits.

***Current field trial sites monitored:*** Of the 33 sites current in the quarter, two were monitored. This represents a monitoring rate of six percent of all current sites for the quarter.

***Post-harvest field trial sites monitored:*** Of the 82 sites subject to post-harvest monitoring in the quarter, eight were monitored. This represents a monitoring rate of ten percent of all sites subject to post-harvest monitoring in this quarter.

***Monitoring of certified facilities:*** Monitoring in connection to contained dealings covered eight organisations and 39 PC facilities. Monitoring of PC facilities encompassed PC2 laboratories (24 visited), PC2 animal containment facilities (five visited), PC2 insectary facilities (three visited), PC2 plant containment facilities (three visited), PC2 aquatic facilities (one visited), PC2 constant temperature room (one visited), and PC2 large scale laboratories (two visited).

***Monitoring of contained dealings:*** During the April to June 2006 quarter, monitoring of the 39 PC facilities mentioned above also included monitoring for compliance with the general practices that must be followed when undertaking dealings that are required to be conducted in containment.

No DNIRs were monitored during this quarter.

## Monitoring of dealings involving intentional releases

The following table shows the total monitoring coverage for field trial sites  
1 April to 30 June 2006

Organisation	Licence Number	No. sites visited	Site status <sup>1</sup>	Crop type
CSIRO	DIR 017/2002	1	PHM	Clover
	DIR 018/2001	1	PHM	Poppy
	DIR 038/2003	1	C	Cotton
	DIR 052/2004	1	PHM	Rice
	DIR 054/2004	1	PHM	Wheat
Bayer CropScience	DIR 056/2004	2	C / PHM	Cotton
Dow AgroSciences	DIR 044/2003	1	PHM	Cotton
Bureau of Sugar Experiment Stations	DIR 019/2002	2	PHM	Sugarcane
Totals	8	10	C= 2 PHM= 8	6 types

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

## Monitoring of physical containment facilities

The organisations and the facility types the OGTR visited during this quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
Australian National University	PC2 Laboratory	1
	PC2 Animal Containment	1
	PC2 Insectary	1
CSIRO	PC2 Laboratory	5
	PC2 Plant Containment	2
Australian Stem Cell Centre	PC2 Laboratory	1
University of Melbourne	PC2 Laboratory	5

University of Melbourne	PC2 Animal Containment	3
	PC2 Insectary	2
Department of Primary Industries and Fisheries (Queensland)	PC2 Laboratory	1
University of Tasmania	PC2 Laboratory	4
	PC2 Animal Containment	1
University of Queensland	PC2 Laboratory	7
	PC2 Constant Temperature Room	1
	PC2 Plant Containment	1
	PC2 Aquatic	1
CSL	PC2 Large Scale Laboratory <sup>1</sup>	2
Totals	7 facility types	39

<sup>1</sup> Joint inspection with Contained Dealing Evaluation Section

## Monitoring findings

### Dealings involving intentional release

The Monitoring findings listed below are designed to indicate both the monitoring activities of the OGTR with respect to DIRs in accordance with paragraph 136A(2)(c) of the Act, and the Regulator's response to those findings.

Findings by inspectors of inconsistencies between an event or state of affairs and the requirements imposed by licence conditions are called non-compliances in this report. However, non-compliances are not regarded as breaches of licence conditions unless proven to be so after investigation. Non-compliances are assessed against a number of considerations before determining the OGTR response. The following aspects of the findings are taken into account as relevant:

- The extent of risk to the health and safety of people and the environment
- The severity of the issue or event involved in the finding
- The culpability of the licence holder or other relevant persons in bringing about the issue or event e.g. whether there was a bona fide mistake involved

- The types of mechanisms available to address the issue or event
- The compliance history of the licence holder or other relevant persons
- Mitigating factors such as self-reporting or steps taken voluntarily by the licence holder to address the issue or event
- The need for deterrence.

After having regard to those matters, the OGTR has a range of options including additional investigation to determine if further action is warranted e.g. a recommendation of prosecution for an alleged breach of a licence condition or that a licence be suspended or cancelled. A proven breach of a licence condition will be reported in accordance with paragraph 136A(2)(b) of the Act.

In the case of all matters reported below it was decided that the findings of non-compliances with licence conditions were minor in nature, involved negligible or nil culpability, and could be resolved by reminders, education and/or cooperative compliance.

<b>Organisation</b>	Monsanto Australia Ltd (Monsanto)
<b>Licence number and site</b>	DIR 012/2002 sites 19 and 30
<b>Summary of dealing</b>	Licence relates to insect resistant and/or insect resistant and herbicide tolerant Bollgard II® and Bollgard II®/Roundup Ready® cotton (commercial release south of latitude 22° South). Herbicide tolerant INGARD®, Bollgard II® and/or Bollgard II®/Roundup Ready® (limited and controlled release north of latitude 22° South).
<b>Findings</b>	On 24 April 2006 Monsanto reported to the OGTR that one cotton volunteer with open bolls (seed set) was detected at each site during a routine monitoring inspection on 20 April 2006. DIR 012/2002 requires that any volunteer plants at sites north of 22° South be destroyed before setting seed. Both plants were removed and burnt.
<b>Assessment</b>	The volunteers were assessed to pose negligible risk to human health and safety and the environment, culpability was negligible, the incidents were self reported and were capable of being easily addressed by the removal of the volunteer.
<b>Compliance management</b>	Monsanto was reminded of their post harvest monitoring obligations to remove and destroy volunteers before flowering. No further action was taken.

<b>Organisation</b>	Monsanto Australia Ltd (Monsanto)
<b>Licence number and site</b>	DIR 012/2002 site 20
<b>Summary of dealing</b>	Licence relates to insect resistant and/or insect resistant and herbicide tolerant Bollgard II® and Bollgard II®/Roundup Ready® cotton (commercial release south of latitude 22° South). Herbicide tolerant INGARD®, Bollgard II® and/or Bollgard II®/Roundup Ready® (limited and controlled release north of latitude 22° South).

<b>Findings</b>	Monsanto failed to report the findings of its February 2006 monitoring of the site to the Regulator within 14 days of the inspection as required by the licence. It is important that licence holders report the findings of self monitoring to the OGTR in a timely fashion so that the OGTR can assess and, if necessary, respond to any adverse findings identified in that monitoring visit. On this occasion there were no adverse findings.
<b>Assessment</b>	As there were no adverse findings from the February 2006 monitoring conducted by Monsanto the risk to human health and safety and the environment was negligible. The non-reporting of the monitoring had been an oversight and not a deliberate action, therefore culpability was negligible.
<b>Compliance management</b>	Monsanto was reminded that reports of monitoring inspections are to be provided to the Regulator within 14 days. No further action was taken.

<b>Organisation</b>	Imugene Limited
<b>Licence number and site</b>	DIR 046/2003
<b>Summary of dealing</b>	Licence relates to the limited and controlled release of GM fowl adenovirus vaccine that has been modified by the insertion of the chicken interferon gamma (IFN- $\gamma$ ) gene to stimulate the immune system to provide protection against parasites/bacterial infections.
<b>Findings</b>	During an inspection of the dealing OGTR staff determined that some staff involved in the dealing did not properly understand the licence conditions relating to disposal of the GMOs at the completion of the trial. It was ascertained that these staff had not been properly informed of the conditions of the licence that applied to them, which is a requirement of the licence. Disposal of the GMOs had not yet occurred.
<b>Assessment</b>	Imugene's previous compliance record has been acceptable and the intended disposal method, whilst inconsistent with the licence conditions, would have been satisfactory for disposal of the GMOs. As disposal of the GMOs had not yet occurred there had been no breach of the disposal requirement, and the risks to human health and safety and the environment were negligible.
<b>Compliance management</b>	Imugene has applied for and has been granted a variation to the licence to enable disposal of the GMOs by a number of methods. Imugene has been reminded of its obligations under DIR 046/2003 to appropriately inform persons covered by the licence of the conditions that apply to them. Imugene has now advised that they have met this requirement. No further action was taken.

<b>Organisation</b>	Dow AgroSciences
<b>Licence number and site</b>	DIR 044/2003 Site 8
<b>Summary of dealing</b>	Licence relates to field trial of cotton ( <i>Gossypium hirsutum</i> ) genetically

<b>Summary of dealing continued</b>	modified by introduction of genes to confer tolerance to herbicide and/or resistance to insect pests.
<b>Findings</b>	At the time of the inspection OGTR staff observed several instances where viable cotton plants had been left on the site following harvest. There were three mature cotton plants with open bolls (seed set) on the site and five mature cotton plants with open bolls (seed set) in the main drain, parallel to the tail ditch, adjacent to the site.
<b>Assessment</b>	The volunteers were assessed to pose negligible risks to human health and safety and the environment, and Dow AgroSciences voluntarily took appropriate action to remove the volunteers. It was determined that Dow AgroSciences misinterpreted the exact area to be monitored around the site. Culpability on this occasion was negligible and Dow AgroSciences previous compliance history has been good.
<b>Compliance management</b>	Discussions with Dow AgroSciences have clarified the areas which should be monitored under post harvest monitoring licence conditions. No further action was taken.

<b>Organisation</b>	Bureau of Sugar Experiment Stations
<b>Licence number and site</b>	DIR 019/2002
<b>Summary of dealing</b>	Licence relates to a field trial of Sugarcane ( <i>Saccharum interspecific hybrid</i> ) genetically modified to express a reporter gene ( <i>gfp</i> (S65T) encoding green fluorescent protein) and antibiotic resistance ( <i>nptII</i> ).
<b>Findings</b>	During an inspection of the dealing OGTR staff determined that a period of more than 60 days had passed between post harvest monitoring inspections at the site which is inconsistent with the licence conditions. The inspection due in November 2005 was not conducted. Monitoring of the site and all associated areas described by the licence was carried out at least once every 60 days from January 2006. The licence requires that monitoring should occur every 60 days to ensure that any regrowth of the GM plants is identified and destroyed.
<b>Assessment</b>	Whilst monitoring had not occurred at the required interval no additional regrowth (volunteers) were noted at later inspections and the risks to human health and safety and the environment were assessed as negligible. Culpability on this occasion was negligible and all subsequent inspections had been carried out within the required timeframe.
<b>Compliance management</b>	BSES was reminded of its post harvest monitoring obligations. No further action required.

### Dealings not Involving Intentional Release

No DNIRs were monitored during this quarter.

## Physical containment facilities

OGTR's monitoring of certified PC facilities in the quarter found a number of non-compliances with certification conditions which are summarised in the table below. All were found to pose negligible risks to human health and safety and the environment.

Number of PC Facilities inspected	Non-compliance Issue					
	Structure	PPE <sup>1</sup>	Equipment	Waste disposal	Work practices	Transport
39	19	4	1	5	8	4

1. PPE = Personal Protective Equipment

## Practice Reviews

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

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

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

There were no practice reviews completed in the April to June 2006 quarter.

## Audits

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

- documentary evidence
- observations
- assessments of procedures and practices.

These activities are conducted to:

- verify that an accredited organisation has relevant and effective management procedures and practices to meet requirements under the Act, including accreditation requirements, guidelines and any licence conditions applicable to a dealing under the Act

- assess whether procedures and practices provide mechanisms to identify and resolve emerging risks
- where appropriate suggest improvements to procedures and practices.

Audits are an opportunity for accredited organisations and the OGTR to share information to improve the risk management of dealings with GMOs under the Act. Audits may focus on a single dealing, a range of dealings (eg, dealings with a common host organism or dealings within a common climatic zone), the activity of an organisation across a range of dealings, or an activity common to a range of organisations.

There were no audits completed in the April to June 2006 quarter.

## Investigations

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

There was one investigation completed in the April to June quarter.

<b>Issue</b>	The Sydney West Area Health Service (SWAHS) self-reported an incident involving DNIR 264/2003 (Liver cell biology and liver injury, metabolic liver disease and mitochondrial dysfunction in drug-induced liver disease). The incident involved researchers injecting mice with an adenoviral vector in a PC1 facility, not within a PC2 facility as required by the licence conditions.
<b>Findings</b>	The incident was identified by the SWAHS IBC who immediately suspended the dealing and assisted the OGTR compliance staff with the subsequent investigation. The investigation established that: <ul style="list-style-type: none"> <li>• there had been a failure in communication between the licence holder, the project supervisor and the researchers involved;</li> <li>• the communication breakdown was evident from differing versions and accounts regarding supervisory authorisations and relevant personnel not having knowledge of the conditions attached to the approved dealing;</li> <li>• the licence holder could not provide the OGTR with signed statements that the researchers were aware and informed of the licence conditions of DNIR 264/2003; and</li> <li>• the primary researcher stated that there was no intent to act without authorisation and was remorseful for the resulting incident.</li> </ul>
<b>Risk assessment</b>	It was concluded that risks to human health and safety and the environment as a result of this incident were negligible.
<b>Action</b>	A warning letter was issued to the licence holder, Sydney West Area Health Service, emphasising that all persons covered under the licence must be fully informed of the licence conditions.

<b>Action continued</b>	The licence holder has agreed to ensure that: <ul style="list-style-type: none"><li>• each person covered by a DNIR licence is informed of the obligations imposed on them by that particular licence and</li><li>• signed statements are obtained from each person covered by a DNIR licence confirming that they have been informed of their obligations for that particular licence.</li></ul>
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## **PART 3 Committee operations**

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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 Gene Technology Community Consultative Committee was appointed by the Parliamentary Secretary Christopher Pyne on 14 June 2006. The twelve month appointments begin on 1 July 2006. The GTCCC consists of a mix of continuing members from the inaugural GTCCC and new members, providing a balance between new ideas and an understanding of the GTCCC's role and function to facilitate a productive term.

Further information about the work of the GTCCC is available from <http://www.ogtr.gov.au/committee/gtccc.htm>

### **Gene Technology Ethics Committee**

The Gene Technology Ethics Committee (GTEC) members progressed their working group papers this quarter, including the *National Framework for the Development of Ethical Principles in Gene Technology*. GTEC are scheduled to next meet on 25 July 2006 in Canberra.

Further information about the work of the GTEC is available from <http://www.ogtr.gov.au/committee/gtec.htm>

### **Gene Technology Technical Advisory Committee**

The Gene Technology Technical Advisory Committee did not meet this quarter. GTTAC will consider items out of session in July 2006 and are scheduled to next meet in Canberra on 19 September 2006.

The 17<sup>th</sup> GTTAC communiqué covering the March 2006 meeting is available in Appendix B.

Further information about the work of the GTTAC is available from <http://www.ogtr.gov.au/committee/gttac.htm>

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## **PART 4 Other activities**

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### **Reviews**

The review of the *Guidelines for the Certification of Facilities/Physical Containment Requirements* continued during this quarter. Technical consultations on the guidelines for PC3 Laboratory facilities were finalised. Revisions to the guidelines for PC1 and PC2 Large Scale facilities, PC2 Aquatic Organism and PC2 Arthropod (replacing Insectary) facilities were also progressed to take into account consultation comments and additional technical advice.

Work continued on re-structuring all existing certification guidelines to align them with the model developed in the revised *Guidelines for Accreditation of Organisations* issued by the Regulator on 1 July 2005.

### **International collaboration and coordination**

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

International collaboration and coordination activities undertaken during the quarter involved participation in and/or presentations to:

- The 18th Session of the OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology, held in Bern Switzerland, in June 2006.

### **Advice on gene technology regulation**

The Regulator and the OGTR participate in presentations and meetings on gene technology to inform stakeholders, users of the technology and the Australian community about the regulatory system.

### **Presentations**

During the quarter OGTR officers made presentations to:

- the University of the 3rd Age on the regulation of gene technology in Australia and
- the Australasian Controlled Environment Working Group on the regulation of contained facilities and working with the OGTR Guidelines.

### **Meetings and workshops**

During the April to June quarter the OGTR participated in the Victorian Biotechnology Ethics Advisory Committee's (VBEAC) Victorian Institutional

Biosafety Committees roundtable 'Ethics and the national gene technology regulatory system'.

### **Institutional Biosafety Committee (IBC) Training**

Officers from the OGTR presented information and provided training on the national regulatory system and the role of the OGTR to:

- South Australian and Northern Territory based IBCs
- Johnson & Johnson Research Pty Ltd IBC and
- the Queensland Department of Primary Industries and Fisheries.

### **National Strategy for Unintended Presence of Unapproved GMOs**

An interdepartmental working group established by the Australian Government Biotechnology Ministerial Council and chaired by Biotechnology Australia has developed a risk based strategy for managing the unintended presence of unapproved GMOs on an ongoing basis. The OGTR has been asked to implement the strategy.

As part of this work, the OGTR is liaising closely with the Australian Seeds Federation (ASF) on the development of a voluntary auditing and testing program of existing industry quality assurance measures. In May the OGTR and the ASF met to develop the final stages of the program. Agreement is expected in the coming months and the program will commence before the end of this year.

### **OGTR website**

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

- Home Page
- What's new
- Search
- Handbook on the Regulation of Gene Technology in Australia
- About the OGTR
- Maps of Trial Sites

The most popular downloaded documents were:

- Risk Analysis Framework
- Handbook on the Regulation of Gene Technology in Australia
- The Biology and Ecology of Pineapple
- The Biology and Ecology of Cotton
- The Biology and Ecology of Wheat
- The Biology and Ecology of Carnation

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

### **OGTR freecall number and email address**

The OGTR freecall number (1800 181 030) and the OGTR email address (ogtr@health.gov.au) 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 freecall number and email address received 45 calls and 117 emails in April 2006, 179 calls and 125 emails in May 2006, and 167 calls and 169 emails in June 2006.

### **Freedom of information**

The OGTR received no freedom of information requests during the March to June 2006 quarter.

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## Appendix A

### DNIR Licences issued April to June 2006

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 384/2006	31 May 2006	Ludwig Institute for Cancer Research, Victoria	Analysis of molecular signalling for growth of blood vessels and lymphatic vessels using adenoviral gene transfer	The purpose of this dealing is to transfer genes using adenoviral vectors and to analyse the expressed proteins for growth of blood and lymphatic vessels in cultured mammalian cells and mice.
DNIR 381/2006, 382/2006	16 May 2006	The University of Melbourne, Victoria	Biological requirements of prion formation	The aims of this research are to express isoforms of human, mouse and hamster prion proteins to identify regions of the protein that modulate the infection process.
DNIR 380/2005	9 May 2006	The University of Queensland	Engineering anaerobic bacteria for multimodal cancer therapy	The aims of this study are to investigate the potential of utilising anaerobic bacteria that express recombinant immunotoxins as treatments for solid tumours in animal models.
DNIR 376/2005	10 April 2006	The University of Sydney, New South Wales	RCAS gene transmission to TVA transgenic mice and cells	This study aims to identify human and mouse genes that are responsible for maintaining a normal differentiation program in keratinocytes.

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## **Appendix B**

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### **Gene Technology Technical Advisory Committee**

#### **Communiqué**

#### **No.17**

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*This is the seventeenth Communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the twenty-seventh meeting of GTTAC, held on 29 March 2006.*

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

## **Dealings Involving the Intentional Release of Genetically Modified Organisms (DIRs)**

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 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**

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

### **Advice on GM Wheat**

#### **DIR 061/2005 – Field testing of genetically modified salt tolerant wheat on saline land**

Grain Biotech Australia Pty Ltd has submitted an application for a licence for a small scale field trial of up to 20 lines of GM salt tolerant wheat plants. The trial would take place on a farm site in the Corrigin Shire, Western Australia, and cover an area of 0.45 hectares.

Under the proposed trial, the wheat lines will be planted in soil with a salinity gradient and evaluated for salt tolerance and agronomic performance.

The GM wheat lines have been modified to contain one or more copies of the ornithine aminotransferase (*oat*) gene, which is derived from the common plant *Arabidopsis thaliana*. The *oat* gene leads to increased production of proline, an osmoprotectant, which is a molecule that can protect plant proteins and membranes against the effects of high salt concentrations and enable plants to grow in saline soils.

The GM wheat lines also contain either the *cah* selectable marker gene, which provides resistance to the herbicide cyanamide, or the *nptII* selectable marker gene, which provides resistance to antibiotics such as neomycin and kanamycin.

None of the material harvested from the trial, including the seed, would be used for food for either humans or animals. Any material which is not used for research would be destroyed.

GTTAC advised the Regulator that:

- GTTAC agrees with the assessment made by the OGTR;

- GTTAC agrees with the proposed licence conditions except that monitoring should be continued for 12 months after the last volunteer, rather than a non-qualified 2 years;
- It should be clarified that livestock would not have access to the site until after the monitoring period;
- Containment measures proposed by the applicant should be distinguished from the licence conditions proposed by the Regulator; and
- The risk assessment identifies all the events by which the proposed release could potentially give rise to adverse outcomes to the health and safety of people or the environment posed by or as a result of gene technology.

## **Advice on Applications**

### **Advice on GM Cotton**

#### **Commercial Release of Herbicide Tolerant Liberty Link<sup>®</sup> Cotton for use in the Australian Cropping System**

##### **(DIR 062/2005)**

Bayer CropScience (Bayer) has submitted an application seeking approval to commercially release GM herbicide tolerant Liberty Link<sup>®</sup> Cotton in Australia. Bayer has predicted that the most substantial adoption of the GM cotton will occur initially in the existing cotton growing regions of New South Wales and Queensland, followed by uptake in other areas where environmental conditions are suitable for cotton cultivation.

Liberty Link<sup>®</sup> Cotton contains the *bar* gene which confers tolerance to glufosinate ammonium, the active ingredient in several herbicides including Liberty<sup>®</sup>. Liberty Link<sup>®</sup> Cotton can be sprayed with glufosinate ammonium to kill weeds without damaging the crop itself.

Bayer proposes that the GM cotton plants and their products be used in the same manner as conventional and other commercially approved GM cottons – which includes use in human food and stockfeed, transportation, sale of lint and exporting seed.

Liberty Link<sup>®</sup> Cotton was previously assessed under DIR 056/2004.

GTTAC advised the Regulator that the following issues should be considered in preparation of the RARMP:

- The impact of removing all containment measures;
- Specific issues relating to the unrestricted use of the GM cotton in northern areas of Australia including planting, stock feeding and transportation; and
- Specific issues relating to consequences of stacking with other commercially released GM cottons.

In addition GTTAC recommended that advice provided in relation to previous assessments of this GM cotton and other herbicide tolerant GM cottons should be considered when drafting the RARMP.

### **Field trial of GM cotton (*Gossypium hirsutum*) expressing natural plant genes for fungal control**

**(DIR 063/2005)**

The Regulator has received an application from Hexima Limited which proposes a small scale field trial of GM Cotton lines on two sites in the Pittsworth Shire, Queensland, and one site in the Narrabri or Moree Plains Shire, New South Wales. The trial would cover an area of up to one hectare per season for three growing seasons from 2006 to 2009.

The GM cotton lines contain the commonly used antibiotic resistance gene neomycin phosphotransferase (*nptII*) gene and a fungal resistance gene (*NaD1*). The *NaD1* gene encodes a plant defensin protein which enhances resistance to major fungal diseases of cotton, including Fusarium wilt, black root rot and Verticillium wilt.

The aims of the proposed limited and controlled release are to: evaluate the three GM cotton lines for enhanced resistance to fungal diseases compared with non-GM cotton lines; assess agronomic performance under field conditions; measure the expression levels of the defensin protein; and test for adverse impacts on selected beneficial microorganisms (mycorrhiza).

No products from the release would be used for human food or animal feed.

GTTAC advises the Regulator that the following issues should be assessed in the RARMP:

- Potential for toxicity/allergenicity of NAD1 proteins in the GM cotton line to humans and other organisms including beneficial soil microorganisms; and
- Potential for the GM cotton lines to be harmful to the environment arising from potential for increased weediness.

### **GM Cotton Field Trial – Limited and controlled release of water efficient GM cotton**

**(DIR 064/2006)**

Monsanto Australia Limited has applied for approval for a limited and controlled release of GM cotton lines which have been modified for increased water efficiency.

Up to 24 GM cotton lines are proposed for release in ten sites in New South Wales. Each line contains 1 of 24 different genes derived from the plants *Arabidopsis thaliana* (thale cress), *Zea mays* (corn), *Glycine max* (soybean),

*Oryza sativa* (rice) and *Gossypium hirsutum* (cotton). The introduced genes encode proteins that are intended to confer enhanced water use efficiency by regulating expression of endogenous genes or modulating biochemical pathways in the cotton plants.

The purpose of the trial is to evaluate the agronomic characteristics, water use efficiency, yield and fibre quality of the GM cotton lines under optimum watering and water stress treatments. Seed will be collected for further studies including possible future releases (subject to additional assessments and approvals).

Aspects of the genetic modification are pending a decision for an application to declare them confidential commercial information, but were made available to GTTAC.

GTTAC advised the Regulator that:

- The potential for toxicity/allergenicity of the GM cotton lines to humans and other organisms should be assessed; and
- The potential for the GM cotton to be harmful to the environment because of an increased potential for weediness should be assessed.

### **GM Cotton Field Trial – Limited and controlled release of GM insect resistant (*VIP3A* and/or *Cry1Ab*) Cotton**

#### **(DIR 065/2006)**

Deltapine Australia Pty Ltd is seeking approval for a small scale field trial of GM cotton (*Gossypium hirsutum* L). The trial proposes using 11 GM cotton lines, containing one or two insect resistance genes (*vip3A* and/or *cry1Ab*). These insect resistant genes are toxic to the major lepidopteran caterpillar pests of cotton.

The aim of the trial is to produce seed for future GM cotton trials and Deltapine proposes to conduct the trial at a site in Narrabri, New South Wales.

These insect resistance genes have been involved in previous limited releases on an individual basis. This is the first time that the combination of these two genes will be assessed.

GTTAC advised the Regulator that:

- The potential for toxicity/allergenicity of the GM cotton lines to human be assessed;
- The potential for toxicity for the GM cotton lines to non-target organisms, including predators of the target pests, be assessed; and
- The potential for the GM cotton lines to be harmful to the environment because of an increased potential for weediness be assessed.

## **Commercial release of GM herbicide tolerant and/or insect resistant cottons north of latitude 22° South**

**(DIR 066/2006)**

Monsanto Australia Limited has applied for approval of the general release of five types of herbicide tolerant and/or insect resistant GM cotton lines north of latitude 22° South.

The five types of GM cottons are:

- insect resistant Bollgard II<sup>®</sup> cotton (MON15985)
- herbicide tolerant Roundup Ready<sup>®</sup> cotton (MON1445)
- herbicide tolerant Roundup Ready Flex<sup>®</sup> cotton (MON88913)
- herbicide tolerant/insect resistant Roundup Ready<sup>®</sup>/Bollgard II<sup>®</sup> cotton (MON1445/MON15985)
- herbicide tolerant/insect resistant Roundup Ready Flex<sup>®</sup>/Bollgard II<sup>®</sup> cotton (MON88913/MON15985).

Bollgard II<sup>®</sup> cotton contains two insecticidal genes (*cry1Ac* and *cry2Ab*), which confer resistance to the major lepidopteran caterpillar pests of cotton. Roundup Ready<sup>®</sup> cotton contains one copy of the *cps4 epsps* gene conferring tolerance to glyphosate up to the four-leaf stage of growth. Roundup Ready Flex<sup>®</sup> cotton contains two copies of the *cps4 epsps* gene, which confers tolerance to glyphosate throughout the growing season. The stacked GM cottons (Roundup Ready<sup>®</sup>/Bollgard II<sup>®</sup> and Roundup Ready Flex<sup>®</sup>/Bollgard II<sup>®</sup>) contain all the genes introduced into each of the parent GMOs.

The applicant has proposed that the GM cotton be used in the same manner as conventional and other commercially approved GM cottons. This includes use in human food and stockfeed, transportation, sale of lint and export of seed.

GTTAC advised the Regulator that:

- The impact of unrestricted dealings with the GM cottons in northern areas of Australia including planting, stock feeding and transportation should be assessed;
- The impact of removing all containment measures should be assessed; and
- The impact of stacking these cottons with GM Liberty Link<sup>®</sup> Cotton (tolerant to glufosinate ammonium) which is currently subject to assessment (DIR 62/2005) should be assessed.

## **Other Advice**

### **DNIR 275/2004 – VARIATION: Viral protein gene function in whole virus for screening anti-viral compounds**

Biotron is a biotechnology company currently conducting research into the development of novel antiviral therapeutic agents. To facilitate the screening and identification of antiviral agents, Biotron applied for, and was granted a DNIR licence permitting the construction of live viruses with a range of specific genetic modifications. Aspects of this licence, including the specifics of the genetic modifications are protected by a declaration of confidential commercial information (CCI).

In order to further this research, Biotron has requested a variation to their licence to broaden the source of genetic material used for the genetic modifications and alter their methodology. The specifics of this variation are also covered by a CCI declaration but were made fully available to GTTAC.

GTTAC advised the Regulator that:

- The variation as proposed may pose increased risks that would not be managed by the original risk assessment and risk management plan;
- Work involving GM viruses in which the proposed modifications have been carried out *in trans* may require Physical Containment Level PC2 to adequately manage the risks to human health and the environment; and
- Work involving GM viruses in which the proposed modifications have been carried out *in cis* may require PC3 to adequately manage the risks to human health and the environment.

## **Presentations**

The following presentations were made to GTTAC:

- Overview of the GeneAIEx software package, which is used to analyse population genetics data.
- Information about morpholino oligos, which are key molecules in an antisense technology being used in emerging therapies for sufferers of Duchenne Muscular Dystrophy.
- An overview of the developments in the *National Framework for the Development of Ethical Principles in Gene Technology*, which is being produced by the Gene Technology Ethics Committee.

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

GTTAC was provided with an update on the Review of the Regulations. A representative of the OGTR outlined changes which had been made to the Amendment Regulations since the previous GTTAC meeting, and the timeframes and processes outstanding for the finalisation of the draft amendments.

A number of members attended a meeting on 17 January 2006 to discuss the Review of the Regulations with the OGTR. A report was given to the full Committee detailing the outcomes of this meeting.

## **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 the OGTR website at <http://www.ogtr.gov.au>