

**Quarterly Report of
the Gene Technology Regulator
for the period
1 October to 31 December 2005**

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This report can be accessed through the Internet at www.ogtr.gov.au.

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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 October to 31 December 2005.

During this quarter, key achievements included the issuing of one licence for dealings involving the intentional release of genetically modified organisms (GMOs), four licences for dealings not involving intentional release of genetically modified organisms (GMOs), and the certification of 41 physical containment facilities.

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.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator
28 April 2006

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Glossary

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
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 facilities)
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

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 October to December 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 October to December 2005 quarter were:

Licences and other instruments

- 1 licence issued for dealings involving the intentional release of GMOs into the environment (DIR licence).
- 4 licences issued for dealings not involving intentional release of GMOs into the environment (DNIR licences).
- 98 Notifiable Low Risk Dealing (NLRD) notifications received.
- 41 contained facilities certified.
- 52 surrenders of certifications processed.
- 252 variations processed.

More information on licences and other instruments including the first application to place a dealing on the GMO Register is contained in Part 2 of this report.

Monitoring and compliance

Approximately 28 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.

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 and environment.

The Independent Panel appointed by the Ministerial Council in June 2005 to undertake a review of the *Gene Technology Act 2000* (the Act) in accordance with section 186 conducted a series of public forums around Australia during the quarter (refer to Part 4 for more information). The forums were based upon the Terms of Reference and matters raised in five issues papers prepared in response to almost 200 submissions.

The Review panel is required to deliver its report to the Australian Parliament by 21 June 2006. Further information on the review process is available from the Gene Technology Ministerial Council website:

<http://www.health.gov.au/internet/wcms/publishing.nsf/Content/gtreview-1>

The Ministerial Council did not meet during the October to December 2005 Quarter. The next meeting of the Ministerial Council is scheduled for 27 April 2006.

Gene Technology Standing Committee

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

The GTSC met on 7 December 2005. The Chair of the Independent Panel appointed by the Ministerial Council to conduct a review of the Act provided members with a progress report, including an outline of outcomes of stakeholder consultations. The meeting also considered nominations for the Gene Technology Community Consultative Committee and received a briefing on the national strategy developed by the Biotechnology Ministerial Council for the unintended presence of unapproved GMOs in imports. The next meeting of the GTSC is scheduled for 27 February 2006.

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 three RARMPs.

Further information is set out in Part 2.

Public participation

During the quarter, the Regulator notified the receipt of the application DIR 061/2005 and issued three invitations to the public to comment on the RARMPs prepared in response to applications DIR 046/2003, DIR 059/2005 and DIR 060/2005. The invitation was 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 Northern Territory News*, *Yarra Ranges Journal* and rural press such as the *Weekly Times*, *Werribee Banner*, *The Countryman*, *The Land* and *Queensland Country Life*.
- 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 October to December 2005 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 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 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 October to 31 December 2005

Application type	Number received	Number approved¹
DIR licence	2	1
DNIR licence	8	4
Accreditations	1	2
Certifications	44	41
GMO Register	0	0

1. Approvals reported in the current quarter often 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 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 cannot normally be received and decided upon within the same three month reporting period.

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

Status, as at 31 December 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 062/2005	DIR 061/2005	DIR 060/2005		DIR 058/2005
DIR 063/2005		DIR 059/2005		
		DIR 046/2003		

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 two applications for DIR licences in the October to December 2005 quarter.

- DIR 062/2005 - Commercial release of herbicide tolerant Liberty Link® 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 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 061/2005 – Field testing of genetically modified salt tolerant wheat on saline land – Grain Biotech Australia 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 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 consultations on RARMPs for the following applications:

- DIR 046/2003 - Field Trial - Development of Fowl Adenovirus (FAV) Vaccine Vectors - Imugene Limited.
- DIR 059/2005 - Commercial release of herbicide tolerant (Roundup Ready Flex® MON 88913) and herbicide tolerant/ insect resistant (Roundup Ready Flex® MON 88913/ Bollgard II®) cotton south of latitude 22° South in Australia - Monsanto Australia Limited.
- DIR 060/2005 - Field Trial - Propagation and trial of imported GM rose varieties - Florigene Limited.

Withdrawn applications for DIR licences

No DIR licence application was withdrawn in this quarter.

Surrendered applications for DIR licences

No DIR licence was surrendered during this quarter.

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 no clock stop periods applied to any DIR licence applications in this quarter.

Decisions on applications for DIR licences

During the quarter, the Regulator issued one DIR licence:

- DIR 058/2005 - Small scale field trial of genetically modified insect resistant (VIP) Cotton – Deltapine Australia Pty Ltd.

Summary information on DIR applications, executive summaries and finalised complete RARMPs and the licence conditions imposed, are available from the OGTR website at www.ogtr.gov.au, or can be obtained by contacting the OGTR directly. Full copies of DIR applications can be obtained by contacting the OGTR directly.

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 www.ogtr.gov.au.

Consultation on applications to include dealings with GMOs on the GMO Register

Although not required by the Act, during the quarter the Regulator consulted expert groups and key stakeholders, including the public, regarding matters relevant to risks to human health and safety and/or the environment in relation to the following application:

- Register 001/2004 – Proposal to include dealings with genetically modified blue carnations on the GMO Register - closed 19 October 2005.

Consultation on this application began in the previous quarter.

The GM carnation proposed for inclusion on the GMO Register is currently licensed for unrestricted commercial release under Licence No. DIR 030/2002. In order to assist her determination, the Regulator particularly sought any additional information to that contained in the RARMP prepared in connection with the licensing of those dealings. Information on the GMO Register and the application 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 98 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 October to December 2005 quarter.

Applications received and decisions made: existing licences and other instruments 1 October to 31 December 2005

Type	Number received	Number processed ¹
Surrender of certification	32	52
Surrender of DIR licence	0	0
Surrender of DNIR licence	1	0
Surrender of accreditation	2	1
Variation of certification	84	75
Variation of accreditation ²	152	149
Variation of DIR licence ³	11	14
Variation of DNIR licence ³	20	14

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 one-off increase in the number of variations to accreditations is due to the re-issuing, under the revised *Guidelines for Accreditation of Organisations*, 1 July 2005, of accreditations issued prior to July 2005.

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 two CCI applications relating to DIR applications.

The Regulator received one CCI application relating to a DNIR licence application that at the end of the quarter was still being processed.

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 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 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 per cent of physical containment PC4, 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 October to December 2005 quarter, 18 field trial sites were subjected to monitoring visits.

Current field trial sites monitored: Of the 25 sites current in the quarter, seven were monitored. This represents a monitoring rate of 28 per cent of all current sites for the quarter.

Post-harvest field trial sites monitored: Of the 83 sites subject to post-harvest monitoring in the quarter, 11 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 four organisations and 13 PC facilities. Monitoring of PC facilities encompassed PC2 laboratories (six visited), PC2 animal containment facilities (one visited), PC2 plant containment facilities (four visited) and PC2 large scale containment facilities (two visited).

Monitoring of contained dealings: During the October to December 2005 quarter, monitoring of the 13 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 October to 31 December 2005

Licensed Organisation Name	Licence Number	No. sites visited	Site status¹	Crop type
Bayer CropScience Pty Ltd	DIR 032/2002	2	PHM	Canola
	DIR 057/2004	2	C	Indian Mustard
CSIRO	DIR 017/2002	1	PHM	Field Pea ²
	DIR 031/2002	1	C	Grapevine
Monsanto Australia Limited	DIR 012/2002	7	PHM	Cotton
	DIR 055/2004	1	C	Cotton
Queensland Department of Primary Industries and Fisheries	DIR 028/2002	3	C	Pineapple
	DIR 028/2002	1	PHM	Pineapple
Total	7	18	C= 7 PHM= 11	6 types

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

2. The dealing 'Field evaluation of transgenic lines of peas with resistance to pea weevil', PR-105X2, was conducted under an advice to proceed issued by GMAC prior to 21 June 2001. The PHM conditions were included in CSIRO's licence DIR 017/2002.

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
CSIRO	PC2 Lab	1
	PC2 Plant Containment	2
CSL	PC2 Large Scale	2
James Cook University	PC2 Lab	3
	PC2 Animal Containment	1
Southern Cross University	PC2 Lab	2
	PC2 Plant Containment	2
Totals	4 Facility types	13

Monitoring findings

Dealings involving intentional release

During the quarter inspectors identified five acts or omissions which in the Regulator's view constituted non-compliance with the conditions of a DIR licence. Alleged, self-reported and admitted non-compliances are managed within the framework of the OGTR's Non-Compliance Protocol in order to achieve a proportional and consistent response by the Regulator. The Non-Compliance Protocol is available on the OGTR website:

<http://www.ogtr.gov.au/moncomp/protocol.htm>

In all instances, the risks to human health, safety and the environment were assessed as negligible and actions taken were commensurate with these findings.

Organisation	Queensland Department of Primary Industry and Fisheries (QDPI&F)
Licence number and site	DIR028/2002, Site 2
Summary of dealing	Licence relates to field trial of pineapple (<i>Ananus comosus</i> var. <i>comosus</i>) genetically modified by introduction of a gene that reduces blackheart and/or a gene that controls flowering. All genetically modified pineapples also contain a bacterial herbicide tolerance gene used as a selectable marker.
Findings	<p>Monitoring at this site carried out in October 2005 determined that the following non-compliances against licence conditions had occurred at the site:</p> <ul style="list-style-type: none">• The sowing of GMOs at the site was not reported to the Regulator at least 7 days but not more than 30 days in advance of sowing taking place in May 2005.• The initiation of flowering at the site was not reported to the Regulator at least 7 days but not more than 30 days in advance of flowering taking place in October 2004.• GMOs were stored, contrary to storage requirements of the licence, in a cage at the site prior to planting.
Risk assessment	It was concluded that risks to human health and safety and environment as a result of this non-compliance were negligible.
Compliance management	QDPI&F were reminded of the requirement to ensure that notifications of planting and flowering at the site are provided to the OGTR within the timeframes specified by DIR028/2002. Storage of GM material is to be undertaken according to the requirements of the licence.

Organisation	Queensland Department of Primary Industry and Fisheries (QDPI&F)
Licence number and site	DIR028/2002, Site 3 and Site 4
Summary of dealing	Licence relates to field trials of pineapple (<i>Ananus comosus</i> var. <i>comosus</i>) genetically modified by introduction of a gene that reduces blackheart and/or a gene that controls flowering. All genetically modified pineapples also contain a bacterial herbicide tolerance gene used as a selectable marker. This site is a shadehouse area used to harden up the pineapples prior to planting in the open.
Findings	During routine OGTR monitoring of the site in October 2005 it was determined that GMOs had been housed at the site for periods of longer than 12 consecutive weeks between April and September 2005.
Risk assessment	It was concluded that risks to human health and safety and environment as a result of this non-compliance were negligible.
Compliance management	QDPI&F were reminded of the requirement to ensure that GMOs are not housed at the site for periods longer than 12 consecutive weeks, as required by DIR028/2002.

Organisation	CSIRO
Licence number and site	DIR 038/2003, Site 4
Summary of dealing	Licence relates to a field trial of cotton (<i>Gossypium hirsutum</i>) genetically modified by introduction of a bacterial herbicide tolerance gene that confers tolerance to and detoxifies the herbicide glufosinate ammonium (Liberty cotton). This site was planted in November 2003 and was harvested and cleaned in May 2004. This site is in the post harvest monitoring phase.
Findings	The OGTR was notified by CSIRO that this site had been sown to lucerne in September 2005. Planting of post harvest crops other than those stated in the licence require approval from the Regulator. Lucerne is not a permitted post harvest crop for this site.
Risk assessment	It was concluded that risks to human health and safety and the environment as a result of this non-compliance were negligible.
Compliance management	No additional risk treatment measures have been imposed for this site and CSIRO has requested a variation to DIR 038/2003 to allow lucerne as a post harvest crop. CSIRO was reminded of the requirement to comply with licence conditions with respect to post harvest crops.

Organisation	CSIRO
Licence number and site	DIR 038/2003, Site 9
Summary of dealing	Licence relates to a field trial of cotton (<i>Gossypium hirsutum</i>) genetically modified by introduction of a bacterial herbicide tolerance gene that confers tolerance to and detoxifies the herbicide glufosinate ammonium (Liberty Cotton). This site was sown in September 2004 and was harvested and cleaned in March 2005. This site is in the post harvest monitoring phase.
Findings	The OGTR was notified by CSIRO that this site had been planted to pigeon pea in early November 2005. Planting of post harvest crops other than those stated in the licence require approval from the Regulator. Pigeon pea is not a permitted post harvest crop for this site.
Risk assessment	It was concluded that risks to human health and safety and the environment as a result of this non-compliance were negligible.
Compliance management	As Bayer is the manager of this site and it now holds a licence for a dealing with the same GMO under DIR 056/2004, both Bayer and CSIRO requested that the site be transferred to the Bayer licence. The licence was varied to this effect and, at Bayer's request, to allow pigeon pea as a post harvest crop on this site. Bayer will continue post harvest monitoring of this site.

Office of The Gene Technology Regulator

Organisation	Monsanto Australia Limited
Licence number and site	DIR 055/2003, Site 34
Summary of dealing	Licence relates to a field trial of cotton (<i>Gossypium hirsutum</i>) genetically modified by introduction of genes to confer tolerance to the herbicide glyphosate (Roundup Ready Flex®) and/or confer resistance to caterpillar pests (Roundup Ready Flex®/Bollgard II® or Bolgard II®).
Findings	Monsanto notified the OGTR that a portion of the pollen trap along the western edge of the trial site was disturbed by earthmoving operations in the adjacent water supply channel. Approximately 10 metres of the 24 metre wide pollen trap was affected, leaving only 14 metres of pollen trap intact, 6 metres less than the amount required under the licence.
Risk assessment	It was concluded that risks to human health and safety and the environment as a result of this non-compliance were negligible.
Compliance management	To ensure that a minimum of 20 metres of pollen trap would be flowering at the same time as the remainder of the site Monsanto voluntarily removed 12 metres of GM RoundupReady Flex® cotton on the edge of the trial site where the pollen trap had been affected and replanted with a faster maturing Bollgard II® variety. Monsanto Australia Limited is to ensure that the area cultivated and resown to Bollgard II® is monitored weekly, with any emerging RoundupReady Flex® plants destroyed prior to flowering. In addition, if required the resown area is to be treated with growth regulators to ensure that the resown area flowers at the same time as the trial area and the remaining pollen trap plants.

Organisation	Monsanto Australia Limited
Licence number and site	DIR 055/2003, Site 6
Summary of dealing	Licence relates to field trial of cotton (<i>Gossypium hirsutum</i>) genetically modified by introduction of genes to confer tolerance to the herbicide glyphosate (Roundup Ready Flex®) and/or confer resistance to caterpillar pests (Roundup Ready Flex®/Bollgard II® or Bolgard II®).
Findings	Monsanto notified the OGTR that on October 7 the pollen trap was mistakenly planted using a Roundup Ready® cotton variety, which is not permitted under condition 18. On October 28 2005 Monsanto voluntarily destroyed the GMO trial plants and the pollen trap.
Risk assessment	It was concluded that risks to human health and safety and the environment as a result of this non-compliance were negligible.
Compliance management	The trial and pollen trap have been destroyed. The GMOs were replanted at the existing location and the pollen trap replanted with non GM cotton. Monsanto Australia Ltd has voluntarily agreed to monitor the site weekly and provide monitoring reports to the OGTR until further notice.

Organisation	Monsanto Australia Limited
Licence number and site	DIR 035/2002, Site 12
Summary of dealing	Licence relates to a field trial of cotton (<i>Gossypium hirsutum</i>) genetically modified by introduction of genes to confer tolerance to the herbicide glyphosate (Roundup Ready Flex®) and/or resistance to caterpillar pests (Roundup Ready Flex®/Bollgard II® or Bollgard II®). This site was planted in October 2004 and harvested in May 2005. The site is now in the post harvest monitoring stage.
Findings	Monsanto notified the OGTR that 2 flowering volunteers were observed during a post-harvest inspection of the site. The flowering volunteers were removed and destroyed immediately. However, the licence conditions for DIR 035/2002 state that volunteer plants must be destroyed prior to flowering.
Risk assessment	The risks to human health and safety and the environment were assessed as negligible. 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.
Compliance management	Monitoring of the site will continue as required by the licence and Monsanto is to ensure that volunteers are destroyed prior to flowering.

Physical containment facilities

OGTR's monitoring of certified PC facilities in the quarter found a number of acts or omissions which the Regulator regarded as minor 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	Equipment	Waste disposal	Work practices	Transport
13	4	0	0	4	3	7

PPE: Personal Protective Equipment

In addition monitoring staff were also involved in joint inspections (re-certification and pre-certification) of 2 PC2 large scale facilities with officers from the Contained Dealings Evaluation Section of the OGTR.

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 October to December 2005 quarter.

Audits

Audits can be initiated by the OGTR or an accredited organization. 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 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 October to December 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 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.

One investigation was completed in the October to December 2005 quarter.

Type	Unauthorised importation
Name	Genetically modified (GM) zebrafish (<i>Brachydanio rerio</i>)
Current Status	Investigation finalised.
Allegation	The investigation was instigated as a result of Australian Quarantine and Inspection Service (AQIS) referrals of instances of importation of zebrafish suspected to be GM.
Summary of Investigation	<p>GM zebrafish that have been modified to express fluorescent proteins which enhance their visual colour are known to be commercially available internationally.</p> <p>The genes that encode these proteins have been isolated from marine organisms including jellyfish and coral and include genes for green fluorescent protein (GFP), yellow fluorescent protein (YFP) and red fluorescent protein (RFP).</p> <p>The OGTR conducted an investigation to establish whether the referrals from AQIS regarding the importation of ornamental aquaria zebrafish involved fish that were GM.</p> <p>On the basis of advice provided by the overseas exporters it was concluded that ornamental aquaria zebrafish held by AQIS were GM and had been modified to express a fluorescent protein.</p> <p>The investigation also included a risk assessment to ascertain whether there were any risks to people or the environment associated with these instances of import into Australia of GM zebrafish expressing fluorescent</p>

	<p>proteins. This concluded that the risks posed by these incidents involving this type of GM zebrafish to people and the environment would be no greater than those posed by conventional (non-GM) zebrafish. However, action was taken to improve compliance with import requirements.</p>
Findings	<p>'Fluorescent' zebrafish imported to Australia were concluded to be GM. Dealings involving importation of GM fish for ornamental aquaria would require a licence under the Act.</p> <p>However the zebrafish were advertised by overseas exporters as 'fluorescent' and the two importers involved were unaware of their GM status.</p> <p>The GM zebrafish were not released from quarantine as the importers voluntarily surrendered them to AQIS inspectors for destruction</p>
Risk Assessment	<p>Risks to human health and safety or the environment from these instances of the importation of GM zebrafish expressing fluorescent proteins were assessed as negligible.</p>

Compliance

The GM zebrafish were voluntarily surrendered to AQIS for destruction and were not released from quarantine.

The OGTR requested the Pet Industry Association of Australia to advise members of the legislative requirements for GM fish.

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 held its tenth meeting on 15 November 2005 in Canberra. Members considered comments received from the public consultation process on the GTEC paper *National Framework for the Development of Ethical Principles in Gene Technology* which closed 28 October 2005. GTEC will revise the Framework in light of these comments and circulate it for another round of public consultation in early 2006.

The 10th communiqué summarising discussions held at this meeting is attached to this Quarterly Report (Appendix B).

In addition, during this quarter representatives of GTEC met with the Independent Panel carrying out the review of the Act. This discussion focused on GTEC's submission to the review and the issue papers prepared by the Panel.

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

Gene Technology Technical Advisory Committee

The Gene Technology Technical Advisory Committee (GTTAC) held its 26th meeting by teleconference on 6 December 2005. At this meeting GTTAC considered two DNIR applications and associated RARMPs, one DIR application and three DIR RARMPs. Members also received an update on the review of the Act and resolved to have a further meeting in January 2006 to discuss the review of the regulations.

The 16th communiqué summarising discussions held at this meeting is attached to this Quarterly Report (Appendix C).

In addition, during this quarter representatives of GTTAC met with the Independent Panel carrying out the review of the Act. This discussion focused on GTTAC's submission to the review and the issue papers prepared by the Panel.

Further information about the work of the GTTAC is available on the OGTR website www.ogtr.gov.au.

PART 4 Other activities

Reviews

During this quarter the review of the *Guidelines for the Certification of Facilities/Physical Containment Requirements* continued and analysis commenced of comments received in response to the consultation on draft revised guidelines for PC3 Laboratory facilities, and PC1 and PC2 Large Scale facilities.

In December 2005 OGTR met with the Australian Quarantine and Inspection Service, Standards Australia, the Australian Society for Microbiology, and the Public Health Laboratory Network to commence discussions on harmonisation of regulatory requirements for physical containment facilities.

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:

- 2005 China Australian Symposium. 9-12 October 2005, Beijing, China.
- 17th Session of the 'OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology'. 24-26 October 2005, Paris, France.
- Ad Hoc Technical Expert Group on 'Risk Assessment under the Cartagena Protocol on Biosafety'. 15-18 November 2005, Rome, Italy.

In addition discussions were held with various international government agencies and groups as part of ongoing efforts to raise awareness of Australia's regulatory system for gene technology and the monitoring of international practice. These included meetings with visitors to Canberra from:

- Hawaiian Agricultural Department, 5 October 2005
- New Zealand Environment Risk Management Authority officials, 17 October 2005.
- Brazilian cotton industry representatives, 19 October 2006.
- American Farm Bureau Federation, 25 and 27 October 2005.

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 to inform stakeholders, the Australian community and users about the regulatory system.

During the quarter, at the request of the Independent Review Panel, the OGTR gave presentations on the current regulatory system at public meetings conducted as part of the review of the Act.

Forums were held in both rural and urban centres: Canberra, Australian Capital Territory; Clare Valley and Adelaide, South Australia; Perth, Western Australia; Brisbane and Townsville, Queensland; Narrabri and Sydney, New South Wales; Melbourne and Horsham, Victoria; and Hobart, Tasmania.

In addition representatives from the OGTR participated in a workshop co-ordinated by the Australian Government Department of Environment and Heritage to consider environmental hazards that may be associated with the next generation of genetically modified plants.

Institutional Biosafety Committee Training

The OGTR conducts training sessions for accredited organisations and their IBCs. During the October to December quarter training sessions were conducted at the University of Queensland and Monash University.

National Strategy for Unintended Presence of Unapproved GMOs

An interdepartmental working group established by the Biotechnology Ministerial Council and chaired by Biotechnology Australia has developed a risk based strategy for managing the unintended presence of unapproved GMOs. Imported seeds for sowing have been identified as the most likely source and the OGTR has been asked to implement the strategy. In this quarter the OGTR commenced liaison with industry bodies regarding the provision of advice on industry quality assurance and testing regimes.

Consultants

No consultants were contracted by the OGTR during the reporting period.

Gene Technology Information Management System

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

State	Total Number of Organisations	Number Completed
ACT	8	6
TAS	2	2
NT	3	3
SA	13	7
WA	13	5
NSW	35	13
VIC	49	12
QLD	22	11
Total	145	59

OGTR website

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

- Maps of current field trial locations
- What's New
- 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 120 calls and 115 emails in October 2005, 140 calls and 60 emails in November 2005, and 120 calls and 30 emails in December 2005.

Freedom of information

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

Appendix A

DNIR Licences issued October to December 2005

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 360/2005	7 October 2005	University of Queensland	Identification of virulence determinants of encephalitic flaviviruses	The aims of this research are to investigate the role of flaviviral genes and untranslated genomic regions in the virulence and pathogenicity of encephalitic flaviviruses.
DNIR 364/2005	25 October 2005	Sydney-West Area Health Service, New South Wales	Generation and characterisation of poxvirus Tumour Necrosis Factor Receptor (TNF-R) homologues ORFs in subversion of cellular TNF-R signalling	The aims of this research are to investigate how poxvirus tumour necrosis factor receptor-like proteins are able to inhibit the death of infected cells.
DNIR 367/2005	30 November 2005	University of Sydney, New South Wales	Molecular characterisation of the biogenesis and action of cholera toxin and related enterotoxins	The purpose of this dealing is to clone and express the cholera toxin of <i>Vibrio cholerae</i> and related enterotoxins of <i>Escherichia coli</i> , and to analyse their interactions with mammalian cells, for potential use in therapeutics.
DNIR 368/2005	6 December 2005	Monash University, Victoria	Measurement of cell entry mediated by HIV-1 particles pseudotyped with <i>Hepatitis C virus</i> (HCV) envelope proteins	The aims of this dealing is to investigate the entry into human liver cells <i>in vitro</i> of HIV-1 particles pseudotyped with <i>Hepatitis C virus</i> (HCV) envelope proteins.

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Appendix B

Gene Technology Ethics Committee Meeting 15 November 2005, Canberra

COMMUNIQUE

The Gene Technology Ethics Committee (GTEC) held its tenth meeting in Canberra on the 15 November 2005.

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

At its November 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 a presentation by a guest from Biotechnology Australia on the bioethics survey series and were informed of relevant work from other national committees via cross-member reports. In addition, members received a report from the Gene Technology Regulator on the operations of the Office of the Gene Technology Regulator (OGTR).

Key outcomes from the tenth meeting are reported below.

GTEC's Work Plan

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

National Framework for the Development of Ethical Principles in Gene Technology

The working group presented an overview of the development of the Framework noting a number of issues raised during the public consultation. Based on the consultation, the working group suggested a number of changes to improve and clarify the Framework.

The Committee resolved that the working group should hold a face to face meeting to revise the document, taking into account comments provided by GTEC at this meeting and the comments received from the consultation process. The Committee will then conduct another round of public consultation, including specifically inviting comments from those who previously commented on the Framework.

Ethical Issues Associated with Trans-species Gene Transfer

The working group presented the revised document for GTEC's consideration. The Committee identified some editorial changes and agreed that, subject to the editorial changes, the document is ready for finalisation.

Future Projects

The Committee considered a number of possible avenues for future work. The Committee agreed to form a working group to explore how the inclusion of the environment in ethical considerations differentiates GTEC's work from other ethics committees. The committee agreed that the working group should develop a position paper on this matter.

In relation to other matters, GTEC agreed to examine the issue of biodiversity and resolved to maintain a watching brief on plant-made and animal-made pharmaceuticals.

Review of the Gene Technology Act 2000

The Committee considered the issues papers published in October 2005 by the Review Panel. Members discussed the option of possibly combining the functions of GTEC and the Gene Technology Community Consultative Committee and noted some concerns about the effective functioning of a combined Committee. The Committee also considered the suggestion that social, cultural, economic and trade matters should be incorporated into the Act noting that they are not precluded from considering such matters.

GTEC provided a submission in response to the Review Panel's call for submissions. The Committee noted that GTEC representatives would meet with the Review Panel to discuss GTEC's submission and the Issue Papers on 13 December 2005. Further information about the review process is available from the Gene Technology Ministerial Council website:

<http://www.health.gov.au/internet/wcms/publishing.nsf/Content/qtreview>

GTEC and Relationships with Other Committees

The Committee received reports from the Chair, the Gene Technology Regulator and GTTAC. A written report from the Australian Health and Ethics Committee was also received and tabled.

The Committee agreed to consider and comment on the draft *Guidelines for the creation, breeding and use of genetically modified and cloned animals for scientific purposes* prepared by the Animal Welfare Committee.

Next Meeting

The next GTEC meeting will be held on 30 March 2006.

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

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Appendix C

Gene Technology Technical Advisory Committee

COMMUNIQUE No. 16

This is the sixteenth communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the twenty-sixth meeting of GTTAC, held on 6 December 2005, and matters considered out of session in August 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 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 Not Involving the Intentional Release of Genetically Modified Organisms (DNIRs)

DNIRs are dealings that are undertaken within a physical containment facility. DNIRs do not involve the release of a GMO into the environment.

A Risk Assessment and Risk Management Plan (RARMP) is prepared in respect of every licence application for a DNIR licence. GTTAC is consulted on DNIRs which involve novel GMOs or clinical trials, or which are likely to be contentious.

Advice on RARMPs

Advice on Genetically Modified (GM) Vaccine

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

DNIR 369/2005 – A phase 2 study to evaluate the efficacy and safety of Merck Adenovirus serotype 5 HIV-1 vaccine in adults at high risk of HIV-1 infection

DNIR 370/2005 – A randomised study of therapeutic immunisation and treatment interruption among subjects diagnosed with acute or recent HIV infection

The OGTR has received two applications from St Vincent's Hospital, Sydney, to conduct clinical trials of a human adenovirus vaccine in a clinical facility.

The aim of the proposed dealings, which utilise the same GMO, is to conduct a three dose multi-centre randomised placebo-controlled clinical trial to test the safety, efficacy and tolerability of a recombinant HIV-1 vaccine based on the human Ad5 serotype adenovirus.

DNIR 369/2005 would test the ability of the vaccine to decrease the HIV-1 viral load of trial subjects who are inoculated with the vaccine and who subsequently become infected with HIV-1.

Under DNIR 370/2005, a therapeutic trial would be conducted to determine whether the vaccine can prime the immune system to suppress HIV replication and decrease viral load following interruption of anti-retroviral therapy.

Aspects of the genetic modification proposed by this application are protected by a declaration of confidential commercial information, but were made available to GTTAC.

GTTAC discussed these applications from St Vincent's Hospital (Sydney) and advised the Regulator that:

- the risk assessment identifies all risks associated with the use of the GMO; and
- the Committee agrees with the proposed licence conditions.

GTTAC also advised the following:

- The Committee is to be notified of the number of Australians to be involved in the trials.

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 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

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

Advice on GM Fowl Adenovirus

DIR 046/2003 – Limited and controlled release of GM fowl adenovirus (FAV)

Imugene Ltd has applied for a licence to trial a GM fowl adenovirus (FAV). The proposed trial involves the limited and controlled release of a GM fowl adenovirus at an animal containment facility in Werribee, Victoria.

The purpose of the proposed release is to investigate the ability of GM FAV8 to boost the immune system of inoculated chickens and to provide information on the shedding and spread of the GM virus. The adenovirus contains the chicken interferon gamma (Ch IFN- γ) gene which produces the Ch IFN- γ protein. Imugene anticipates that expression of Ch IFN- γ protein in inoculated chickens

will stimulate their immune system and assist them to use food more efficiently, thereby increasing their rate of weight gain.

The proposed trial would involve the inoculation of up to 1500 chickens with the GM FAV8 between 1 February 2006 and 30 April 2006. Chickens used in the trial would be obtained from commercial flocks and would have already been vaccinated against several other viruses. Sentinel animals would be used to confirm that GM FAV8 cannot be transmitted to animals outside the known host range of the virus.

The applicant proposes to run the trial for a period of 49 days, after which all animals involved in the trial would be euthanased and incinerated following the removal of tissue samples for analysis. At the completion of the study, all litter would be incinerated and the facility would be decontaminated and monitored.

GTTAC advised the Regulator that:

- The risk assessment identifies all risks associated with the release.
- The Committee agrees with the proposed licence conditions, however, it was noted that monitoring of the site after decontamination is demonstrated to be complete and the inclusion of sheep as sentinel animals are not necessary.

The Committee considers that for future larger scale releases more data on the effects of the virus on the host are needed and the ability of the virus to infect other bird species needs to be further investigated.

Advice on GM Cotton

DIR 059/2005 – Commercial release of herbicide tolerant (Roundup Ready Flex[®] MON 88913) and herbicide tolerant/insect resistant (Roundup Ready Flex[®] MON 88913/Bollgard II[®]) cotton south of latitude 22° South in Australia

The OGTR has received an application from Monsanto Australia Ltd for commercial release of GM Roundup Ready Flex[®] (herbicide tolerant) and Roundup Ready Flex[®]/Bollgard II[®] (herbicide tolerant/insect resistant) cotton. The proposed release would involve a phased introduction commencing with up to 20,000 hectares in cotton growing regions of New South Wales and southern Queensland south of latitude 22° South. If approved, planting is anticipated to commence in spring 2006, and planting in subsequent years may extend to other areas south of latitude 22° South.

The applicant has also proposed to transport cotton seed from the release to areas north of latitude 22° South for use as stockfeed.

Roundup Ready Flex[®] cotton contains two copies of a gene which provides tolerance to glyphosate, the active ingredient in Roundup Ready[®] herbicide. It differs from the previously released Roundup Ready[®] cotton in that tolerance to Roundup Ready[®] herbicide is prolonged beyond the four leaf growth stage, offering farmers a greater window during which the herbicide can be applied.

Monsanto has also submitted an application to the Australian Pesticides and Veterinary Medicines Authority to allow the use of Roundup Ready[®] herbicide on GM cotton beyond the four leaf stage.

GTTAC advised the Regulator that:

- The risk assessment identifies all risks associated with the commercial release.
- The Committee agrees to the proposed licence conditions.

Advice on GM Roses

DIR 060/2005 Field Trial - Propagation and trial of imported GM rose varieties

Florigene Ltd is seeking approval for the limited and controlled release of three GM rose lines. The imported rose lines are of Hybrid Tea and Floribunda varieties and have been genetically modified to alter the flower colour and produce blue pigments.

The aims of the proposed release are to: evaluate the productivity, morphology and viability of the GM rose lines in an Australian green house facility; conduct limited propagation; and generate data to support a possible future application for large scale release.

The three rose lines would be grown in pots in an enclosed, insect-proof greenhouse in the Yarra Ranges Shire, Victoria. Approximately 100 plants of each GM rose line are proposed for release, along with 100 plants each of the two non-GM parental rose varieties, and 10 plants each of two other non-GM rose varieties.

GTTAC advised the Regulator that:

- the risk assessment identifies all risks associated with the release; and
- the Committee agrees with the proposed licence conditions.

Advice on Applications

Advice on Wheat

Intentional release of Genetically Modified Wheat (DIR 061/2005)

The OGTR has received an application from Grain Biotech Australia Pty Ltd for a limited and controlled release 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 a maximum area of 0.45 hectares.

The purpose of the proposed trial is to evaluate the wheat lines for salt tolerance and agronomic performance. The GM wheat lines, along with controls of non-GM wheat lines, would be planted in soil with a salinity gradient. The trial would run for one season, from April 2006 to December 2006.

The GM wheat lines have been genetically modified to contain an additional copy of the *oat* gene, which enhances synthesis of the enzyme ornithine amino transferase and leads to increased production of proline. Proline is an osmoprotectant, a molecule which can protect plant proteins and membranes from 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 discussed this application and advised the Regulator that:

- issues relating to containment, seed dormancy and reproductive isolation need to be considered.

GTTAC also noted that the application is very similar to DIR 053/2004.

Other Advice

The OGTR sought GTTAC advice on the RARMP for the following DIR application in an out-of-session package in August 2005.

DIR 058/2005 – Limited and controlled release of insect resistant (VIP) GM cotton

Deltapine Australia Pty Ltd is seeking approval for the intentional release of three GM insect resistant (VIP) cotton lines into the environment, on a limited scale and under controlled conditions.

The cotton lines have been modified to contain the *vip3A* gene from the bacterium *Bacillus thuringiensis*, for insect resistance, and the *aph4* gene from *Escherichia coli* for antibiotic resistance.

Deltapine proposes to conduct the release on up to two sites in the Narrabri Shire, New South Wales, and/or the Emerald Shire, Queensland. The total area of the release would be up to 1 hectare, and the trial would take place over the 2005-06 cotton growing season.

The aim of the proposed release is to produce seed for future releases, which would be subject to future assessments and approvals.

GTTAC advised the Regulator that:

- the risks posed by the proposed dealings under DIR 058 are negligible; and
- the Committee agrees with the proposed licence conditions.

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>