Quarterly Report of the Gene Technology Regulator for the period 1 July to 30 September 2005

ISBN 0 642 82639 0

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

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Commonwealth Department of Health and Ageing

Publications Approval Number 3625

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 July to 30 September 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 59 contained facilities were certified.

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

On 2 August 2005 my office hosted a Science Forum on risk assessment attended by representatives from ten Australian Government regulatory and policy agencies.

On the 24 August I issued an invitation to comment on the first application for a dealing to be included on the GMO Register.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator
22 December 2005

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Glossary

Accredited organisation	An organisation that is accredited under section 92 of the Act
Act	*Gene Technology Act 2000*
APVMA	Australian Pesticides and Veterinary Medicines Authority
CCI	Confidential commercial information
Certified contained facility	A building or place certified by the Regulator to a specified containment level under section 84 of the Act
Clock stop	The period during which the statutory time limit for making a decision on an application is suspended – usually because evaluation cannot proceed until additional information requested from the applicant is received
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DIR	A dealing involving intentional release of a GMO into the environment (for example, field trial or commercial release)
DIR licence	A licence for a dealing involving intentional release of a GMO into the environment
DNIR	A contained dealing with a GMO not involving intentional release of the GMO into the environment (for example, experiments in a certified facility such as a laboratory)
DNIR licence	A licence for a dealing not involving intentional release of a GMO into the environment
Expert advisers	Advisers appointed by the Minister to give expert advice to either GTTAC or GTEC to assist them in the performance of their functions (expert advisers are not committee members)
FSANZ	Food Standards Australia New Zealand
GM	Genetically modified

GM product	A thing (other than a GMO) derived or produced from a GMO
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically modified organism
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
GTMC	Gene Technology Ministerial Council
GTSC	Gene Technology Standing Committee
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
Incident	A self-reported event which may constitute a non-compliance with regulatory requirements and a public health or environment risk
NLRD	Notifiable low risk dealing (e.g. plant or tissue culture work undertaken in a certified contained facilities)
OGTR	Office of the Gene Technology Regulator
PC1, PC2, PC3, PC4	Physical containment levels of facilities as certified by the Regulator
RARMP	Risk assessment and risk management plan
Regulations	*Gene Technology Regulations 2001*
Regulator	Gene Technology Regulator
Spot checks	Unannounced visits by the OGTR Monitoring and Compliance Section
Volunteer	Regrowth of plants from seed that has remained on a site after a trial has been completed

Introduction

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

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

Structure of this report

This report is divided into four parts:

Part 1 outlines activities and outcomes achieved in relation to the implementation and management of the national regulatory system during the July to September 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 July to September 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).
- 88 Notifiable Low Risk Dealing (NLRD) notifications received.
- 59 contained facilities certified.
- 25 surrenders of certifications processed.
- 8 DNIR licences surrendered.
- 98 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 13 per cent of current field trial sites and 14 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.

Science Forum

On 2 August 2005 the OGTR hosted the fourth inter agency Science Forum to consider new statistical tools and approaches for health and environmental risk assessments. The Forum was attended by approximately 60 representatives from ten Australian Government regulatory and policy agencies and included presentations on a number of case studies on emerging technologies. The keynote speaker was Dr Scott Ferson of Applied Biomathematics, New York, who is at the forefront of developing broadly applicable statistical concepts for addressing uncertainty.

Working collaboratively with States and Territories

State and Territory consultation

The Regulator must consult with State and Territory Governments and relevant local councils twice during the evaluation of applications for DIR licences.

For each application for a DIR licence, the Regulator seeks advice on matters relevant to the preparation of the Risk Assessment and Risk Management Plan (RARMP) and comment on the RARMP itself once it is prepared.

More information is contained in Part 2.

Gene Technology Ministerial Council

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

The Ministerial Council did not meet during the July to September 2005 Quarter.

Gene Technology Standing Committee

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

The GTSC met during the reporting period on 9 August 2005.

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 two applications for DIR licences and two RARMPs.

Further information is set out in Part 2.

Public participation

During the quarter, the Regulator issued one invitation to the public to comment on a RARMP prepared in response to application DIR58 (Deltapine VIP cotton field trial). 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 rural press such as *The Land and Queensland Country Life.*
- OGTR website www.ogtr.gov.au.

Further information is set out in Part 2.

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PART 2 Regulation of genetically modified organisms

Part 2 of the report outlines the regulatory activity undertaken during the July to September 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:

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

  DIR licences authorise dealings ranging from limited and controlled releases (field trials) through to more extensive commercial releases of GMOs. These licence applications have a statutory timeframe of 170 working days for processing.

- **Dealing Not involving Intentional Release (DNIR) licences**

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

- **Accreditations of organisations**

  Licences may require organisations which conduct work with GMOs to be accredited. To achieve accreditation, the Regulator must usually be satisfied that the organisation has, or has access to, a properly constituted and resourced Institutional Biosafety Committee (IBC) and complies with the requirements of the Regulator's guidelines for accreditation. These applications have a statutory timeframe of 90 working days for processing.

- **Certifications of contained facilities**

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

- **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 July to 30 September 2005

Application type	Number received	Number approved[1]
DIR licence	2	1
DNIR licence	7	4
Accreditations	1	0
Certifications	58	59
GMO Register	1	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 30 September 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 060/2005 DIR 061/2005	DIR 046/2003[2] DIR 059/2005 DIR 060/2005	DIR 058/2005	DIR 045/2003	DIR 056/2004

1. Includes posting of 'Early Bird' Notifications and summaries of applications on the OGTR website and to people on the OGTR mailing list.

2. The clock stopped on this application because further information was sought from the applicant

Applications received for DIR licences

The OGTR received two applications for DIR licences in the July to September 2005 quarter.

- DIR 060/2005 - Propagation and trial of imported genetically modified rose varieties – Florigene Limited
- DIR 061/2005 - Field testing of genetically modified salt tolerant wheat on saline land – Grain Biotech Australia Pty Ltd

Consultation on applications for DIR licences

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

- DIR 059/2005 - Commercial release of genetically modified herbicide tolerant/ insect resistant (Roundup Ready Flex® MON 88913/ Bollgard II®) cotton – Monsanto Australia Limited
- DIR 060/2005 - Propagation and trial of imported genetically modified rose varieties – Florigene Limited

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

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

- DIR 056/2004 - Field trial of herbicide tolerant (LLCotton25) and herbicide tolerant/insect resistant (LLCotton25/Bollgard II®) cottons - Bayer CropScience Pty Ltd
- DIR 058/2005 - Small scale field trial of genetically modified insect resistant (VIP) Cotton – Deltapine Australia Pty Ltd.

Withdrawn application for DIR licence

One DIR licence application was withdrawn in this quarter.

- DIR 045/2003 Vaccine Trial - Development of Porcine Adenovirus (PAV) Vaccine Vectors- Imugene Limited

Surrendered application for DIR licence

No DIR licence was surrendered during this quarter

Clock stopped on DIR licence application

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

This clock stop applied for some or all days in this quarter for the following DIR licence application:

- DIR 046/2003 - Development of Fowl Adenovirus (FAV) Vaccine Vectors-Imugene Limited

The clock was restarted on this application on 7 September 2005.

Decisions on application for DIR licence

During the quarter, the Regulator issued one DIR licence:

- DIR 056/2004 - Field trial of herbicide tolerant (LLCotton25) and herbicide tolerant/insect resistant (LLCotton25/Bollgard II®) cottons - Bayer CropScience Pty Ltd

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

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 application 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 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

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 88 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 July to September 2005 quarter.

Applications received and decisions made: existing licences and other instruments 1 July to 30 September 2005

Type	Number received	Number processed[1]
Surrender of certification	41	25
Surrender of DIR licence	1	0
Surrender of DNIR licence	8	8
Surrender of accreditation	0	0
Variation of certification[2]	57	58
Variation of accreditation	2	2
Variation of DIR licence[3]	28	16
Variation of DNIR licence[3]	21	22
Transfer of DNIR	0	0

1. Numbers reported in this quarter often relate to applications received in previous quarters. For the purposes of this table, 'processed' means the action on the licence or instrument was completed.
2. The increased volume of certification variation requests received in this quarter is due to the Guidelines being revised resulting in current holders of certifications progressively varying these to meet the new requirements.

3. The majority of variations are made at the request of the licence holder. Variations involve changes to licences where the Regulator is satisfied that the variation does not pose any additional risks to human health and safety and the environment that cannot be managed.

Confidential commercial information (CCI)

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

During the quarter, the Regulator received no CCI applications relating to DIR applications.

The Regulator received two CCI applications relating to DNIR licence applications that are currently being dealt with.

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 (PC) 4, PC3 and PC2 large-scale facilities per year; and
- selected PC2 and PC1 facilities.

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

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored: During the July to September 2005 quarter, 16 field trial sites were subjected to monitoring visits.

Current field trial sites monitored: Of the 40 sites current in the quarter, five were monitored. This represents a monitoring rate of 13 per cent of all current sites for the quarter.

Post-harvest field trial sites monitored: Of the 80 sites subject to post-harvest monitoring in the quarter, 11 were monitored. This represents a monitoring rate of 14 per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection to contained dealings covered three organisations and 12 PC facilities. Monitoring of PC facilities encompassed PC2 laboratories (four visited), PC2 animal containment facilities (three visited), PC2 plant containment facilities (one visited), PC2 large scale containment facilities (two visited), PC3 laboratory (one visited), PC3 laboratory re-certifications (one visited).

Monitoring of contained dealings: During the July to September 2005 quarter, monitoring of the 12 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.

In addition to these general practices, compliance with specific licence conditions for one DNIR were monitored.

Monitoring of dealings involving intentional releases

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

Licensed Organisation Name	Licence Number	No. sites visited	Site status[1]	Crop type
CSIRO	DIR 036/2003	2	PHM	Cotton
	DIR 038/2003	3	PHM	Cotton
	DIR 039/2003	1	PHM	Cotton
	DIR 049/2004	1	PHM	Cotton
Dow AgroSciences Australia Pty Ltd	DIR 044/2003	1	C	Cotton
		1	PHM	Cotton
	DIR 040/2003	2	PHM	Cotton
Monsanto Australia Limited	DIR 012/2002	4	C	Cotton
	DIR 012/2002	1	PHM	Cotton
Total	8	16	C=5 PHM=11	1 type

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

Monitoring of dealings not involving intentional release (DNIR)

The following table shows the total monitoring coverage for DNIRs
1 July to 30 September 2005

Licensed Organisation Name	Licence Number
Flinders University	DNIR 289/2004
GroPep Limited	DNIR 024/2002
Institute of Medical and Veterinary Science	DNIR 092/2002 DNIR 093/2002 DNIR 108/2002
Total	5

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
Institute of Medical and Veterinary Science	PC2 Animal	1
	PC3 Laboratory	1
	PC3 Animal	1
	PC2 Laboratory	1
Flinders University	PC2 Plant	1
	PC2 Animal	2
	PC2 Laboratory	1
GroPep Limited	PC2 Large scale	2
	PC2 Laboratory	2
Totals	9	12

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.

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	CSIRO
Licence number and site	DIR 038/2003, Sites 10, 11, 12, 13, 14 and 16
Summary of dealing	Licence relates to field trial of cotton (*Gossypium hirsutum*) genetically modified by introduction of a bacterial herbicide tolerance gene that confers tolerance to and detoxifies the herbicide glufosinate ammonium. These sites are in the post harvest monitoring phase.
Findings	These sites were planted to GM cotton under DIR 038/2003 in October and November 2004 and harvested and cleaned in April and May 2005. The OGTR was notified by CSIRO of the post-harvest cleaning dates of these sites in July 2005. CSIRO did not provide notice of the dates within 14 days as required by the licence conditions for DIR 038/2003.

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	CSIRO were reminded of the licence condition to provide written notice to the OGTR of post-harvest cleaning dates within 14 days of cleaning.

Organisation	CSIRO
Licence number and site	DIR 039/2003, Site 1
Summary of dealing	Licence relates to field trial of cotton (*Gossypium hirsutum*) genetically modified by introduction of an altered cotton gene that changes fatty acid ratios in cottonseed and a bacterial antibiotic resistance gene used as a selectable marker. This site is in the post harvest monitoring phase.
Findings	CSIRO had not provided an annual report to the OGTR for DIR 039/2003 as required by 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	CSIRO was requested to provide an annual report. The required report has now been provided.

Organisation	CSIRO
Licence number and site	DIR 049/2004, Site 1
Summary of dealing	Licence relates to field trial of cotton (*Gossypium hirsutum*) genetically modified to express a reporter gene and bacterial antibiotic resistance selectable marker genes This site is in the post harvest monitoring phase.
Findings	On 27 July 2005 during routine monitoring OGTR staff were informed that the site was harvested (hand picked) on 19 May 2005. This was the first notification of cleaning of the site therefore a written notification was not provided within 14 days of the date on which cleaning occurred as required by the licence. CSIRO also had not provided a written contingency plan, compliance management plan and a testing methodology to the OGTR for DIR049/2004.
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	CSIRO was requested to provide a written contingency plan, compliance management plan and a testing methodology and reminded to provide a notice in writing of when the Location was cleaned. The required documents have now been provided.

Organisation	Monsanto Australia Ltd
Licence number and site	DIR 012/2002, Site 29
Summary of dealing	Licence relates to field trials of cotton (*Gossypium hirsutum*) genetically modified by introduction of two insecticidal genes or insecticidal genes in combination with a gene that confers tolerance to the herbicide glyphosate, the active ingredient of Roundup®. The site is in the post harvest monitoring phase.
Findings	On 6 July 2005 during routine monitoring OGTR staff observed that mature (flowering) chickpea crop was present on site 29. The site was planted to chickpea on 7 June 2005. The licence conditions of DIR 012/2002 were varied on 21 June 2005 to allow the planting of chickpea as a post harvest crop. The variation incorporated additional monitoring requirements to ensure the detection and destruction of GM cotton volunteers at the site prior to flowering as required under the licence. No GM cotton volunteers were detected during the monitoring. The chickpea crop had been planted prior to approval from the Regulator as required by the licence to plant chickpea as a post harvest crop at the 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	Monsanto was reminded that post harvest crops not specifically authorised in the licence must not be planted without prior approval from the Regulator. Monsanto was also reminded of the additional monitoring activities required while the chickpea crop is growing at the site.

Organisation	Monsanto Australia Ltd
Licence number and site	DIR 012/2002, Site 32
Summary of dealing	Licence relates to field trials of cotton (*Gossypium hirsutum*) genetically modified by introduction of two insecticidal genes insecticidal genes in combination with a gene that confers tolerance to the herbicide glyphosate, the active ingredient of Roundup®. The site is now in the post harvest monitoring phase.
Findings	On 6 July 2005 during routine monitoring of sites notified to the OGTR under licence DIR 012/2002, OGTR staff were advised of and observed a site of GM cotton that had not been notified to the OGTR. The site, now designated as site 32 was planted on 16 April 2005 with GM Cotton authorised by DIR 012/2002 and it was being managed in accordance with licence conditions of DIR 012/2002. The GM cotton at site 32 had been planted without notification to the OGTR prior to planting as required by 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	Monsanto was reminded of the importance of complying with licence conditions requiring the prior notification to OGTR of locations at which GMOs are released. If release locations are not notified to the OGTR, monitoring for compliance with licence conditions is not possible. Monsanto have co-operatively complied with this requirement of DIR 012/2002 by destroying the GM crop on site 32. The site will be subject to post harvest monitoring in accordance with the conditions of DIR 012/2002.

Dealings not Involving Intentional Release

During the quarter no non-compliances with the conditions of a licence were identified as a result of monitoring DNIR Licences.

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.

	Non-Compliance Issue					
Number of PC Facilities inspected	**Structure**	**PPE**	**Equipment**	**Waste disposal**	**Work practices**	**Transport**
12	26	1	5	1	1	1

PPE: Personal Protective Equipment

In addition monitoring staff were also involved in joint inspections (re-certification and pre-certification) of six PC3 facilities and one PC1 large scale facility with officers from the Contained Dealings Evaluation Section of the OGTR.

Practice Reviews

The Monitoring and Compliance Section may initiate Practice Reviews in response to observations made during monitoring activities, or to follow up of 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 IBCs to ensure that dealings are being conducted in accordance with the Act.

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

No practice reviews were completed in the July to September 2005 quarter.

Audits

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

- documentary evidence; and/or
- observations; and
- assessments of procedures and practices.

These activities are conducted to:

- verify that an accredited organisation has relevant and effective management procedures and practices to meet requirements under the Act, including accreditation requirements, guidelines and any licence conditions applicable to a dealing under the Act;
- assess whether procedures and practices provide mechanisms to identify and resolve emerging risks; and
- where appropriate suggest improvements to procedure and practices.

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

No audits were completed in the July to September 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.

No investigations were completed in the July to September 2005 quarter.

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PART 3 Committee operations

The Act established three advisory committees:

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

Gene Technology Community Consultative Committee

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

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

Gene Technology Ethics Committee

The Gene Technology Ethics Committee (GTEC) did not meet this quarter. However, GTEC issued a call for comment on the 16 September on its consultation draft paper entitled "*National Framework for the Development of Ethical Principles in Gene Technology*".

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) met on 1 August 2005. At this meeting GTTAC considered:

- 2 DIR applications
- 1 DIR RARMP
- 2 DNIR applications and the associated RARMPs
- 1 application to the GMO Register

GTTAC also received presentations on the monitoring and compliance work of the OGTR, the new DIR RARMP structure which fully incorporates the processes and terminology described in the *Risk Analysis Framework 2005,* and feedback on the OGTR's National Institutional Biosafety Committee Forum which was held in April 2005.

The 15th communiqué summarising discussions held at this meeting is attached to this Quarterly Report (Appendix B).Further information about the work of the GTTAC and the new membership is available from the OGTR website www.ogtr.gov.au.

GTTAC also considered the following items out-of-session during the quarter:

- 1 DNIR variation and the associated RARMP
- 1 DIR RARMP

PART 4 Other activities

Reviews

The following reviews continued during this quarter:

- Review of the *Gene Technology Regulations 2001*.
- Review of the *Guidelines for the Certification of Facilities/Physical Containment Requirements* - consultation drafts of revised guidelines for PC3 Laboratory facilities and PC1 and PC2 Large Scale facilities were circulated to accredited organisations and their Institutional Biosafety Committees for an eight week comment period on 25 July 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 wherever possible to inform stakeholders, the Australian community and users about the regulatory system. During the quarter two presentations were given:

- Australia-New Zealand Laboratory Animal Sciences Conference 'Dealing with OGTR Regulations in PC2 Animal Containment Facilities'. 27-29 September, Perth, Western Australia.

National Strategy for Unintended Presence of Unapproved GMOs

An interdepartmental working group established by the Biotechnology Ministerial Council and chaired by Biotechnology Australia to develop risk based strategy for the unintended presence of unapproved GMOs identified imported seeds for sowing as the most likely source. In this quarter the OGTR concluded the compilation of information relevant for the rapid preparation of risk management responses for the eight most commonly imported seeds for sowing for which GM traits are known to have received approval for commercial release in countries other than Australia.

Consultants

During the reporting period, the OGTR managed two consultancy contracts worth a total of $ 28,056. The table below lists the consultants, describes the purpose of the consultancy and the amount paid during the quarter. The amount paid is net of GST.

Consultant	Amount paid (GST exclusive)	Purpose
Dialog Information Technology	$13,336	Ongoing work on the Gene Technology Information System (GTIMS)
PB&B Consulting	$14,720	Prepare report, risk assessment & incident response for GM soybean (Glycine max L.)
Total Consultants for quarter	$ 28,056	

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	58

OGTR website

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

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

The most popular downloaded documents were:

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

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

OGTR email address and freecall number

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

The OGTR 1800 number and website received over 160 calls and 60 emails in July 2005, 90 calls and 150 emails in August 2005, and 140 calls and 90 emails in September 2005.

Freedom of information

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

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Appendix A

DNIR Licences issued July–September 2005

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 330/2004	22 July 2005	The University of Melbourne, Victoria	Novel approaches to vaccination against bacterial diseases	The aims of this dealing are to study the immunobiology of *Salmonella* infection and to investigate attenuated *Salmonella* as potential vaccines.
DNIR 356/2005	16 August 2005	Queensland Institute of Medical Research	Expression and characterisation of novel genes from Australian snakes	The aims of this research are to clone and express venom proteins from Australian elapid snakes in relation to the treatment of envenomation victims or as therapeutic agents.
DNIR 357/2005	22 August 2005	The University of Queensland	Investigations into the role of genes in neural development and repair	The aims of this research are to use replication defective lentiviral vectors as a tool to investigate the function of genes that are involved in neural development and repair.
DNIR 366/2005	26 September 2005	PPD Pty Ltd, Victoria	Phase III clinical trials of ChimeriVax™-JE	The aims of this dealing are to conduct two phase III clinical trials of ChimeriVax-JE™ a live, attenuated, genetically modified vaccine against Japanese encephalitis (JE).

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Appendix B

Gene Technology Technical Advisory Committee

COMMUNIQUE
No. 15

This is the fifteenth communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the twenty-fifth meeting of GTTAC, held on 1 August 2005 and matters considered out of session in May 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 Involving the Intentional Release of Genetically Modified Organisms

Dealings Involving the Intentional Release of GMOs (DIRs) are dealings that are undertaken outside of a certified physical containment facility. DIRs involve the limited and controlled release (field trial) of a GMO or a commercial (general) release of a GMO.

A Risk Assessment and Risk Management Plan (RARMP) is prepared in respect of every licence application for a DIR licence and released for public comment as part of the consultation process for these applications. Information on how to obtain copies of applications and RARMPs for DIRs is provided at the end of this document.

Advice on RARMPs

Advice on GM cotton

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

DIR 056/2004 - Field trial - herbicide tolerant (LLCotton25) and herbicide tolerant/insect resistant (LLCotton25/Bollgard II®) cottons

The OGTR has received an application from Bayer CropScience for the limited and controlled release of herbicide tolerant (LLCotton25) and herbicide tolerant/insect resistant (LLCotton25/Bollgard II®) cottons into the environment. The aims of the trial are to transfer the introduced traits (insect resistance and herbicide tolerance) into elite Australian cotton varieties; to test the agronomic performance of the GM cottons; to conduct demonstration trials for farmers, to produce seed for future releases (which would require separate applications and approval processes); and to conduct tests with material from the GM cottons in the laboratory.

A maximum total area of 500 hectares would be planted in each of the 2005/06 and 2006/07 summer growing seasons in the cotton growing regions of New South Wales (NSW) and southern and central Queensland (Qld).

LLCotton25 cotton contains a single copy of a gene (bar), derived from a common soil bacterium. The protein encoded by the bar gene is an enzyme[2] (PAT) that confers tolerance to glufosinate ammonium (the active constituent in herbicides such as Basta® and Liberty®).

[2] Enzymes are proteins which catalyse specific biochemical reactions.

The PAT enzyme converts glufosinate ammonium into an inactive form and thus allows the application of glufosinate ammonium-containing herbicide for the control of weeds that emerge in the crop, without damaging the crop itself.

LLCotton25/Bollgard II® cotton was produced by crossing of LLCotton25 with GM Bollgard II® cotton via conventional breeding. This process introduces two genes derived from another soil bacterium that produce insecticidal proteins which are highly specific and toxic to the major caterpillar pests of cotton.

Limited and controlled releases of LLCotton25 were previously approved under licences DIR 015/20002 and DIR 038/2003 (both issued to CSIRO). These field trials are being conducted from 2002 to 2005 in NSW and Qld. The other parent GMO, Bollgard® II cotton, was approved for commercial release south of latitude 22° South in Australia in 2002 (DIR 012/2002).

GTTAC discussed this application from Bayer CropScience and 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 Mustard

DIR 57/2004 Field trial - Gene Technology Modified Herbicide Tolerant Hybrid Indian Mustard

The OGTR prepared a RARMP for a licence application proposing the intentional release of GM Brassica juncea (Indian mustard) into the environment on a limited scale and under controlled conditions. The GM mustard lines proposed for release have been genetically modified by the introduction of genes for herbicide tolerance and a hybrid breeding system. The trial is proposed to take place on up to a total of 96 hectares over three years during the winter and summer growing seasons of 2005-08. Sites will be chosen from 17 shires in Victoria, South Australia and New South Wales.

The main aims of the proposed trial are to evaluate the effectiveness of the herbicide tolerance trait in the field, to observe the agronomic performance of the GM mustard lines and to increase seed.

GTTAC considered the draft RARMP for this application and advised the Regulator that:

- although not necessary to manage risks associated with this release, information on agronomic performance should be recorded during the release;
- the risk assessment identifies all the risks associated with the proposed dealings;

and

- the measures proposed in the risk management plan are adequate to deal with the identified risks.

Advice on Applications

Advice on Cotton

Commercial release of Roundup Ready Flex cotton MON88913 (DIR 059/2005)

The OGTR has received an application from Monsanto Australia Ltd for a commercial release of genetically modified (GM) Roundup Ready Flex® cotton in the cotton growing areas south of latitude 22° South in Australia and for small scale plantings in other areas south of latitude 22° South for evaluation trial and demonstration, education and research purposes.

Roundup Ready Flex® cotton differs from the previous commercially released Roundup Ready® cotton in that tolerance to Roundup Ready® herbicide is prolonged. Currently, if Roundup Ready® herbicide is applied to Roundup Ready® cotton after the four leaf growth stage, the cotton plants would be susceptible to the herbicide. Cottons containing the Roundup Ready Flex® trait are able to tolerate application of Roundup Ready® herbicide at later stages of plant growth without yield loss, allowing a wider window to apply herbicide during growth of the cotton crop. This is intended to give growers increased flexibility in timing of herbicide use for weed management. An application has also been submitted by Monsanto to Australian Pesticides and Veterinary Medicines Authority to allow the use of Roundup on GM cotton beyond the 4-leaf stage.

GTTAC discussed this application and advised the Regulator that the risks associated with toxicity, allergenicity, weediness and gene flow in relation to commercial scale release of Roundup Ready Flex® should be considered in the RARMP.

Advice on Rose

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

The OGTR has received a licence application from Florigene Ltd (Florigene) for the limited and controlled release of genetically modified (GM) coloured rose. The three GM rose lines proposed for release have been genetically modified by insertion of genes which will affect the colour of the rose flowers. The GM rose lines are of hybrid tea and floribunda varieties.

The aims of the proposed release are to: enable evaluation of the imported GM rose lines in a semi-contained Australian facility; conduct limited propagation; and provide data to support a future application for commercial release. The GM rose lines would be grown in pots in a greenhouse. About 100 plants of each GM rose line are proposed for release, along with about 100 each of the two non-GM plants parental rose varieties.

The trial is proposed to be conducted within a free standing greenhouse of framed heavy duty plastic, with a soil floor. The GM roses will be grown in pots using a hydroponic system above soil level.

There has been no previous release of these GM rose lines in Australia. However, under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee (GMAC) two field trials by Calgene Pacific Pty Ltd (now Florigene) of GM roses with modified flower colour were approved (PR 30 and PR 35).

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

- proposed methods of disposal should be more clearly defined by the applicant;
- mulching and composting the GM material as a method of disposal would be sufficient and the compost should be monitored after six months to check for regrowth;
- further information should be sought from the applicant regarding the security of the greenhouses. GTTAC recommended that the greenhouses should be locked;
- further information should be sought from the applicant regarding whether the GM roses would be grown on rootstock, and if so what type of rootstock would be used; and
- details of the AQIS import permit held by Florigene for the import of the GM roses should be clarified.

Advice on Carnation

Request to place GM carnations on the GMO Register (Reg 001/2004)

The OGTR has received an application from Florigene Ltd (Florigene) to place GM carnations on the GMO Register. This is the first application that the Regulator has received to include dealings with a GMO on the GMO Register.

Section 79 of the Gene Technology Act 2000 sets out matters the Regulator must take into account when considering whether dealings with a GMO may be included in the GMO Register:

- The Regulator must be satisfied that any risks posed by the dealings with the GMO are minimal. This matter has been addressed in the RARMP for licence application DIR 030/2002 from Florigene. All risks considered in this RARMP were assessed as negligible. If new information is identified that warrants updating the RARMP, then the RARMP for DIR 030/2002 will be updated to incorporate the new information and risks associated with the proposed dealings will be reassessed.

- The Regulator must also have regard to any available data on adverse effects posed by the dealings and any other information on risks associated with the dealings. The licence holder estimates that 150,000-200,000 GM carnations have been grown and sold within Australia up to September 2004 and approximately 5.5 million GM carnations have been produced in the USA, Japan, Eucador and Colombia. Annual reports provided by the licence holder state that no unintended or adverse effects have been reported and no additional risks associated with dealing with the GMOs have been identified.

- The Regulator must also consider whether there is a need for the dealings to be subject to conditions. Specific conditions in licence DIR 030/2002 included a condition that testing methods for identifying the GMOs be provided to the Regulator. These methods have since been supplied. In addition, the licence holders were required to report any adverse effects caused as a result of the GMOs and keep written records of contact details for all persons contracted to propagate and grow the GMOs, the locations at which GMOs were propagated and grown and the total number of GMOs propagated and grown. These records were included in the organisation's annual report to the Regulator.

Before a GMO can be considered for listing on the GMO Register it must have been licensed by the Regulator.

A determination by the Regulator that a dealing be placed on the GMO Register is a disallowable instrument and must be tabled in the Australian Parliament.

The dealings that Florigene propose for inclusion on the GMO Register are those dealings that have previously been authorised under DIR licence DIR030/2002. In brief the proposed dealings are for an ongoing, Australia-wide commercial release of carnations genetically modified for blue flower colour.

GTTAC considered the current RARMP that was prepared for the commercial release of GM carnations (DIR 030/2002) and advised the Regulator that:

- the RARMP identifies all of the risks posed by the proposal to list GM carnations on the GMO Register; and
- the risks are negligible and dealings with GM carnations are suitable for inclusion on the GMO Register.

Other Advice

DNIR 298/2004 - VARIATION: Phase I/IIA, Two centre, open-label, dose escalation study to assess the safety, tolerability and efficacy of FP253 in combination with fludarabine phosphate

GTTAC previously considered the DNIR licence application for this dealing which involves a human clinical trial. The applicant has subsequently submitted an application to vary the licence and the Regulator sought GTTAC advice on the proposed licence variation.

GTTAC considered the application and advised the Regulator on containment and safety issues.

DNIR 366/2005 - Phase III clinical trials of ChimeriVax™-JE

An application has been submitted to the OGTR to conduct phase III clinical trials of the ChimeriVax™-JE vaccine. ChimeriVax-JETM has previously been considered by the OGTR for phase II clinical trials (DNIR 319/2004, 320/2004).

GTTAC considered the application and advised the Regulator that the risk assessment prepared for phase II clinical trials identifies all risks associated with the phase III trial.

Presentations

The following presentations were made to GTTAC:

- Overview of the work conducted by the Monitoring and Compliance Section at OGTR;
- Introduction to the revised format to be used for the presentation of Risk Assessment and Risk Management Plans (RARMP) for DIR licence applications in line with the revised Risk Analysis Framework; and
- Feedback from the inaugural national Institutional Biosafety Committee Forum that was held in Canberra in April 2005.

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