Quarterly Report of the Gene Technology Regulator for the period 1 October to 31 December 2003

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

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

The Hon Trish Worth 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*, I am pleased to present to you the Quarterly Report of the Gene Technology Regulator, covering the period 1 October to 31 December 2003.

During this quarter, key achievements included hosting a workshop in Narrabri involving major Australian cotton researchers and industry groups to identify and address genetically modified cotton research priorities.

The key achievements in this quarter include the issuing of 7 licences for dealings involving intentional release of genetically modified organisms, including a licence for the general commercial–scale release of Roundup Ready® canola. In addition, 18 licences were issued for dealings not involving intentional release of genetically modified organisms, 4 organisations were accredited and 51 contained facilities were certified.

Routine monitoring activities for this quarter have again been well above the minimum target rate.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator
16 March 2004

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Glossary

Accredited organisation	An organisation that is accredited under section 92 of the Act
Act	*Gene Technology Act 2000*
APVMA	Australian Pesticides and Veterinary Medicines Authority
Breach	*see* 'Non-compliance'
CCI	Confidential commercial information
Certified 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 an application evaluation is suspended – usually whilst awaiting further information from the applicants
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DIR	A dealing with a GMO 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 a GMO into the environment (for example, experiments in 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 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 contained facilities)
Non-compliance	A failure to comply with legislative requirements including licence, accreditation or certification conditions
OGTR	Office of the Gene Technology Regulator
PC1, PC2, PC3, PC4	Physical containment levels of facilities as certified by the Regulator
RARMP	Risk assessment and risk management plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator
Spot checks	Unannounced visits by the OGTR Monitoring and Compliance Section
Volunteer	Regrowth of plants from seed that has remained on a site after a trial has been completed

Introduction

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

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

Structure of this report

This report is divided into four parts:

Part 1 outlines activities and outcomes achieved in relation to the implementation and management of the national regulatory system during the October–December 2003 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–December 2003 quarter were:

Licences and other instruments

- 7 applications considered and 7 licences issued for dealings involving intentional release of a GMO into the environment (DIR licence) including a licence for commercial-scale release of genetically modified (GM), herbicide tolerant canola
- 18 licences issued for dealings not involving intentional release of GMOs into the environment (DNIR licences)
- 86 notifiable low risk dealing (NLRD) notifications received
- 4 organisations accredited
- 51 contained facilities certified
- 21 Surrender of certifications processed
- 42 variations processed.

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

Monitoring and compliance

Approximately 48 per cent of current field trial sites and 16 per cent of post harvest field trial sites were subjected to routine monitoring during the quarter. This exceeds the target minimum rate of 5 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 GTMC consists of one Minister from each State and Territory and one Minister from the Australian Government. Currently, the Council comprises Ministers from a range of portfolios including health, agriculture, environment and innovation.

The Ministerial Council did not meet in this quarter.

Gene Technology Standing Committee

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

The Standing Committee held a face to face meeting in Melbourne on 9 October 2003.

Australian Government agency liaison

The close relationship between the OGTR and 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.[1]

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.

[1] Consultation is also required with state and territory governments, GTTAC, relevant local councils and, if the proposed dealing(s) may pose significant risk(s) to the health and safety of the environment, the public.

Once a RARMP is prepared, the Regulator again seeks comment on the RARMP from the same prescribed Australian Government authorities and agencies.[2]

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

During the quarter, the Regulator sought advice and comment in respect of 5 applications for DIR licences.

During October 2003, the OGTR and the Australian Pesticides and Veterinary Medicines Authority (APVMA) met to exchange information on GMO regulatory issues. The OGTR and the APVMA hold regular meetings to exchange information under the memorandum of understanding between the two agencies.

Further information is set out in Part 2.

Public participation

During the quarter, the Regulator issued 1 invitation to the public to comment on a RARMP prepared for an application for a DIR licence. The invitations are issued via email or post to people who have registered on the OGTR mailing list and via advertisements in:

- the *Australian Government Notices Gazette*
- *The Australian* newspaper
- relevant regional press, such as the *Courier Mail*, *Northern Territory News*, *The West Australian* and rural press such as *Queensland Country Life, The Land* and *The Weekly Times*
- OGTR website www.ogtr.gov.au.

Further information is set out in Part 2.

[2] Consultation is also required with state and territory governments, GTTAC, relevant local councils and the public.

PART 2 Regulation of genetically modified organisms

Part 2 of the report outlines the regulatory activity undertaken during the October–December 2003 quarter. This includes information about applications for, and action taken with respect to, GMO licences and other instruments under the Act. It also includes details of monitoring activities and any breaches of conditions of a GMO licence that have come to the Regulator's attention. Summary reports on investigations completed during the quarter are supplied. Information on confidential commercial information (CCI) applications has also been provided.

Applications received and decisions made

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

- **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 days for processing.

- **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 days for processing.

- **Accreditations of organisations**

  Licences require organisations which conduct work with GMOs to be accredited. To achieve accreditation, the Regulator must 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.

- **Certifications of contained facilities**

  The purpose of certification is 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 physical containment.

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–31 December 2003

Application type	Number received	Number approved[1]
DIR licence	5	7
DNIR licence	10	18
Accreditations	4	4
Certifications	46	51

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

Processing of applications for 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
- 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.

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 9 months as it excludes weekends and public holidays in the Australian Capital Territory (ACT). This time limit may be extended, that is, the clock is stopped, if the decision-making process is unable

to continue, for example, because of an unresolved application for declaration of CCI or because additional information is sought from the applicant.

The Act and the *Gene Technology Regulations 2001* (the Regulations) mandate minimum timeframes for the two rounds of consultation that the Regulator must undertake with prescribed expert groups and key stakeholders during the processing of each DIR application. However, longer periods are usually allowed to facilitate the provision of information and promote, particularly community, involvement in the decision-making process. 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 that underwent evaluation during the quarter.

Status, as at 31 December 2003, 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 044/2003	DIR 032/2002[2]	DIR 020/2002	DIR 041/2003	DIR 020/2002
DIR 045/2003	DIR 043/2003[2]		DIR 042/2003	DIR 034/2003
DIR 046/2003	DIR 044/2003			DIR 035/2003
DIR 047/2003	DIR 045/2003			DIR 036/2003
DIR 048/2003	DIR 046/2003			DIR 038/2003
				DIR 039/2003
				DIR 040/2003

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 was stopped on these applications.

Applications received for DIR licences

The OGTR received 5 applications for DIR licences in the October–December 2003 quarter as follows:

- DIR 044/2003 'Field trial – Agronomic assessment and seed increase of transgenic cotton expressing insect tolerance genes from *Bacillus thuringiensis*' (Dow AgroSciences Australia Limited)
- DIR 045/2003 'Development of Porcine Adenovirus (PAV) vaccine vectors' (Imugene Limited)
- DIR 046/2003 'Development of Fowl Adenovirus (FAV) vaccine vectors' (Imugene Limited)

- DIR 047/2003 'Field trial – Evaluation of GM white clover resistant to infection by *Alfalfa Mosaic Virus'* (Department of Primary Industries, Victoria)
- DIR 048/2003 'Field Trial – Assessment of transgenic cotton expressing natural plant genes for insect control' (Hexima Limited)

All applications for DIR licences received in the October–December 2003 quarter were screened for completeness and the applicants notified of the receipt of their applications within the quarter.

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 issues related to human health and safety and the environment to be considered in the RARMP for the following applications:

- DIR 032/2003 'Field trial – Seed increase and field evaluation of herbicide tolerant canola' (Bayer CropScience Pty Ltd)
- DIR 043/2003 'Field trial – Preliminary agronomic assessment of high sulphur lupin' (The University of Western Australia)
- DIR 044/2003 ' Field trial – Agronomic assessment and seed increase of transgenic cotton expressing insect tolerance genes from *Bacillus thuringiensis*' (Dow AgroSciences Australia Limited)
- DIR 045/2003 'Development of Porcine Adenovirus (PAV) vaccine vectors' (Imugene Limited)
- DIR 046/2003 ' Development of Fowl Adenovirus (FAV) vaccine vectors' (Imugene Limited)

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

- DIR 020/2002 'General release of Roundup Ready® canola (*Brassica napus*) in Australia' (Monsanto Australia Limited)

Withdrawn applications for DIR licences

- DIR 041/2003 Post field trial monitoring for licences PR64, PR64X, PR64X(2) and PR67 concerning clover transformed to resist infection by *Alfalfa Mosaic Virus*' (Department of Primary Industries, Victoria)
- DIR 042/2003 'Field trial – Field evaluation of white clover transformed to resist infection by *Alfalfa Mosaic Virus* and *Clover Yellow Vein virus'* (CSIRO)

Clock stopped on two field trial applications.

The statutory timeframe of 170 days for assessing an application for a DIR licence can be suspended for several reasons. For example, the Regulator can stop the clock on an application because of an unresolved application for CCI, or while awaiting further information from the applicant.

The Regulator stopped the clock, in October 2003, on the assessment of application DIR 032/2002 'Field Trial - Seed Increase and Field Evaluation of Herbicide Tolerant Hybrid Canola' (Bayer CropScience Pty Ltd). This is the second time the clock has been stopped on this application in response to requests for additional information.

The Regulator also stopped the clock, in December 2003, on the assessment of application DIR 043/2003 'Field Trial - Preliminary agronomic assessment of high sulphur lupin' (The University of Western Australia), pending provision of additional information.

Finalised applications for DIR licences

During the quarter, the Regulator issued 7 DIR licences:

- DIR 020/2002 'General release of Roundup Ready® canola (*Brassica napus*) in Australia' (Monsanto Australia)
- DIR 034/2003 'Field trial - The evaluation of transgenic cotton plants expressing the Vegetative Insecticidal Protein (VIP) gene' (Syngenta Seeds)
- DIR 035/2003 'Field trials of Roundup Ready cotton MON 88913' (Monsanto)
- DIR 036/2003 'Field trial - Breeding and pre-commercial evaluation of transgenic cotton expressing a VIP gene and a herbicide tolerance gene' (CSIRO)
- DIR 038/2003 'Field trial - Breeding and pre-commercial evaluation of transgenic cotton expressing tolerance to the herbicide glufosinate ammonium' (CSIRO)
- DIR 039/2003 'Field trial - Field evaluation of high-oleic (HO) cotton' (CSIRO)
- DIR 040/2003 'Field trial - Agronomic assessment and seed increase of transgenic cotton expressing insect tolerance genes from *Bacillus thuringiensis*' (Dow AgroSciences).

Summary information on applications and RARMPs as well as the finalised RARMPs are available from the OGTR website at www.ogtr.gov.au, or can be obtained by contacting the OGTR directly. The information on DIR 020/2002 also includes related media releases and a set of plain English answers to frequently asked questions.

Finalised applications for DNIR licences

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

During the quarter the Regulator issued 18 DNIR licences. Further information about these licences is contained in Appendix A of this report.

A full listing of DNIR licences and their current status is available from the OGTR website at www.ogtr.gov.au.

Notifications of notifiable low risk dealings received

The Act requires the Regulator to receive notification from organisations undertaking NLRDs.

This category of dealings with GMOs has been assessed as posing low risks based on previous national and international experience. The NLRDs must comply with certain risk management conditions and be contained in facilities deemed suitable by the Regulator.

NLRDs are assessed by IBCs and do not require approval by the Regulator. The OGTR checks notifications for compliance with legislative requirements.

The Regulator received 86 NLRD notifications in the quarter.

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

Existing licences and other instruments

The Regulator can, directly or upon application, suspend, cancel, or 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 from the licence holder to another person and 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–December 2003 quarter.

Applications received and decisions made; existing licences and other instruments, 1 October–31 December 2003

Type	Number received	Number processed[1]
Surrender of certification	19	21
Surrender of DNIR licence	1	0
Variation of certification	150	25
Variation of accreditation	5	4
Variation of DIR licence[2]	5	3
Variation of DNIR licence	9	10

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 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

Under the Act a person may apply for a declaration from the Regulator that specified information is CCI. If an application meets strict criteria, the Act protects information that the Regulator has declared CCI, as well as information pending a decision from the Regulator as to its CCI status. CCI is protected from disclosure to anyone other than certain Australian Government and state authorities and agencies and the Gene Technology Technical Advisory Committee (which must, in turn, protect the confidential information), or with the consent of the applicant, or by order of a court.

During the quarter, the Regulator received 3 CCI applications in relation to applications for DIR licences, and 1 CCI application in relation to an NLRD.

The Regulator made 3 CCI declarations in relation to applications for DIR licences, and 6 declarations in relation to applications for DNIR licences, and 1 declaration in relation to an NLRD.

Monitoring and compliance

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

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

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

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

Monitoring and compliance strategy

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

The OGTR conducts routine monitoring visits of a minimum of 20 per cent of the field trial sites involving GMOs, each year. A minimum of 5 per cent of current trial sites and 5 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 unannounced spot checks.

The OGTR field trial monitoring strategy utilises risk profiling, which incorporates the accumulated operational experience of the office to date. OGTR field trial monitoring activity is scheduled, as far as possible, to identify inherently higher risk periods in dealings with gene technology (for example, flowering and harvest) and to perform monitoring activities accordingly.

The monitoring program for dealings conducted in 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.

This monitoring approach is under review due to current overlap with certification renewal processes, in which all PC4, PC3 and PC2 large-scale facilities that previously held deemed certifications were recently inspected by the OGTR.

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored. During the October–December 2003 quarter, 40 field trial sites were subject to monitoring visits. Three of these monitoring visits were follow-up visits conducted to determine whether remedial action required from the previous quarter had been adequately implemented by

licence holders. Monitoring was carried out on 9 DIR licences and covered 4 plant species.

Current field trial sites monitored. Of the 23 sites current in the quarter, 11 were monitored. This represents a monitoring rate of 48 per cent of all current sites for the quarter.

Post-harvest field trial sites monitored. Of the 176 sites subject to post-harvest monitoring in the quarter, 29 were monitored. This represents a monitoring rate of 16 per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of contained dealings. During the October–December 2003 quarter, 4 organisations holding 6 DNIR licences and 33 PC facilities across 11 organisations were monitored. Monitoring of PC facilities encompassed PC2 laboratories (26 visited), PC2 plant containment facilities (2 visited), PC2 animal containment facilities (4 visited) and a PC2 insectary (1 visited) across 11 organisations.

Monitoring conducted

The total monitoring coverage for field trial sites during the October–December 2003 quarter is shown in the following table.

Licensed organisation name	Licence number[1]	No. sites visited	Site status[2]	GMO type
CSIRO	DIR 006/2001	5	PHM	Cotton
	DIR 015/2002	1	PHM	Cotton
	DIR 016/2002	1	PHM	Cotton
	DIR 017/2002	2	PHM	Cotton
	DIR 031/2002	1	C	Grapevine
Department of Agriculture, WA	DIR 008/2001	17	PHM	Cotton
Monsanto Australia Limited	DIR 011/2001	2	C	Canola
	DIR 012/2002	6	C	Cotton
		2	PHM	Cotton
Queensland Department of Primary Industries	DIR 028/2002	2	C	Pineapple
		1	PHM	Cotton
Totals	**9**	**40**	**C=11**	**4 Species**
			PHM=29	

1 DIR= Dealing Involving Intentional Release

2 C= current, PHM = post-harvest monitoring

The total monitoring coverage for DNIRs during the 1 October to 31 December 2003 quarter is shown in the following table.

Licenced organisation name	Licence number[1]
Royal Perth Hospital	DNIR 130/2002
CSL Limited	DNIR 122/2002 DNIR 070/2002
Peter McCallum Cancer Institute	DNIR 144/2002
The University of New England	DNIR 207/2002 DNIR 140/2002
Total	**6**

1 DNIR = Dealing Not Involving Intentional Release

Monitoring of physical containment facilities conducted

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

Organisation	Physical containment facility	No. facilities visited
University of the Sunshine Coast	PC2 Laboratory	1
Animal Resources Centre	PC2 Animal containment facility	1
	PC2 Laboratory	1
Royal Perth Hospital	PC2 Animal containment facility	1
	PC2 Laboratory	2
Princess Margaret Hospital	PC2 Laboratory	2
Telethon Institute for Child Health Research	PC2 Laboratory	2
CSL Limited	PC2 Laboratory	5
Peter McCallum Cancer Institute	PC2 Laboratory	4
	PC2 Insectary	1
Baker Medical Research Institute	PC2 Animal containment facility	2
	PC2 Laboratory	3
The University of New England	PC2 Laboratory	2
Southern Cross University	PC2 Laboratory	2

	PC2 Plant Containment Facility	1
CSIRO	PC2 Laboratory	2
	PC2 Plant Containment Facility	1
Totals	**4 facility types**	**33**

Monitoring findings

Dealings involving intentional release

During the quarter, 6 non-compliances with licence conditions were identified as requiring further attention. A summary of each follows:

Organisation	CSIRO
Licence number and site	DIR 006/2001, site 6
Summary of dealing	Licence relates to the agronomic assessment and seed increase of cotton *(Gossypium hirsutum)* modified for resistance to caterpillar pests through the Cry1Ac or Cry1Ac and Cry2Ab from *Bacillus thuringiensis*.
Findings	At the time of inspection OGTR monitoring staff observed that the trial site was planted to safflower (*Carthamus tinctorius*), during its phase of post-harvest monitoring, as a biological means to remedy soil compaction. Due to the spiny nature of the safflower plant, inspection of the site, apart from the perimeter, was effectively prevented. No cotton volunteers were observed on the perimeter of the site (at the edge of the safflower planting) or emerging through the safflower 'canopy'.
Risk assessment	Overall, the risk of persistence of the GMO at the location, both at the time of inspection and into the future, was assessed as negligible, given the level of control and management exercised at the location when the safflower was planted and during establishment.
Risk management	The safflower crop was to be harvested and destroyed, with harvested material being treated by milling to further reduce the negligible risk of any viable cotton seed remaining in the harvested safflower.

Organisation	Department of Agriculture (Western Australia)
Licence number and site	DIR 008/2001, (PR-144) site 14
Summary of dealing	Licence relates to the field trial of cotton *(Gossypium hirsutum)* modified for resistance to caterpillar pests through the *Cry1Ac* gene from the bacterium *Bacillus thuringiensis* (Bt).

Findings	OGTR monitoring staff observed two mature cotton plants 10-20m off the eastern side of the location. The two volunteer plants had bolls with lint and seed present. A significant proportion of lint had dropped from the plants and was lying adjacent to the base of the two plants.
Risk assessment	The risk of the GMO persisting at the location and not being contained to the location was assessed as being negligible, due to the immediate action that was taken to remove the plants and lint and the relatively benign nature of cotton as a weed.
Risk management	Immediate action was taken at the time of inspection with the volunteer plants and lint being removed from the site and destroyed. No further action was necessary.

Organisation	Monsanto Australia Limited
Licence number and site	DIR 011/2001, site 7
Summary of dealing	Licence relates to the field trial of canola *(Brassica napus)* modified for resistance to glyphosate.
Findings	OGTR monitoring staff observed that a portion of the southern end of the pollen trap had a very low density of flowering canola plants. OGTR staff were informed this was a result of a residual herbicide being inadvertently applied on the affected area. This took place during spraying of an adjacent wheat crop prior to the canola being sown. The licence holder had re-sown early maturing triazine tolerant (TT) canola as a pollen trap aiming to rectify the situation, however, the growth stage of the TT canola was considerably behind that of the GM trial. The closest conventional canola crop (435m in a north-west direction) was also in flower at the time of the inspection.
Risk assessment	Any potential risk of genetic material disseminating through pollen flow was considered negligible due to: • the relatively small area of the affected pollen trap; • the likelihood that the re-planted TT canola will produce some flowers during flowering of the GM trial; and • the distance to closest conventional crop being 435 m.
Risk management	The licence is to advise the OGTR immediately should similar instances occur in the future.

Organisation	Monsanto Australia Limited
Licence number and site	DIR 011/2001, site 9
Summary of dealing	Licence relates to the field trial of canola *(Brassica napus)* modified for resistance to glyphosate.
Findings	OGTR monitoring staff observed 20-25 flowering wild radish (*Raphanus raphanistrum)* plants within 50m of the trial site. 6 flowering wild radish plants were observed in the pollen trap and in the area planted to the GMO. Approximately 1% of the canola plants on the trial site were flowering at the time of inspection. None of the wild radish plants had set seed.
Risk assessment	Due to the low numbers of flowering wild radish and the low frequency of gene introgression between wild radish and canola, the risk of dissemination of genetic material through pollen flow and gene transfer was assessed as negligible.
Risk management	Immediate action was taken at the time of inspection to remove and destroy the wild radish. The licence holder was requested to conduct monitoring at an increased frequency for the remaining period the genetically modified canola was in flower.

Organisation	Queensland Department of Primary Industries
Licence number and site	DIR 028/2002 (PR-141) site 1
Summary of dealing	Licence relates to the field trial of cotton *(Gossypium hirsutum)* (formerly covered under PR –141) expressing the Cry1AC delta-endotoxin from *Bacillus thuringiensis*.
Findings	At the time of inspection mature cotton volunteers were observed at the location. Many of these mature volunteers had reached flowering or fruiting stages and some had bolls with lint and seed present. However, it was noted that the number of volunteers had significantly reduced by management practices introduced in the previous quarter.
Risk assessment	There are limited risks associated with dissemination of the GMOs, as the location has been constructed, and management actions applied, to ensure all GM material stays on site. The OGTR determined that there was a negligible risk to the environment and human health, provided action is taken to minimise persistence of the GMO at the location.
Risk management	Due to the continuing persistence of GM cotton plants, the accredited organisation was advised to complete the deep cultivation activities, that had commenced, at the location. The licence holder is to provide monthly reports of the state of the site.

Organisation	CSIRO
Licence number and site	DIR 031/2002, site 1
Summary of dealing	Licence relates to the field trial of grapevine *(Vitis vinifera)* modified for colour expression, sugar composition, flowering and fruit development.
Findings	At the time of inspection, OGTR staff observed 10-20 flowering bodies on the vines, unbagged. The flowering bodies were tendrils with a small number of flowers at the terminal end and are relatively rare and distinct from normal flowering bunches, which contain considerably more flowers. All normal flowering bunches were bagged at the time of inspection.
Risk assessment	The rate of out-crossing in *Vitis vinifera* has not been quantified, therefore the Licence requires that all flowers be bagged as a means of reducing the risk of gene transfer. While the presence of unbagged flowers represents a potential risk of gene transfer, anecdotal evidence and the characteristics of grapevine pollen suggest that outcrossing is highly unlikely to occur. Based on this and the small number of unbagged flowers observed, the risk was assessed as negligible.
Risk management	The flowering bodies observed were removed at the time of inspection. An increased amount of monitoring by the organisation was implemented during the flowering phase to increase the ability of the licence holder to remove or bag all flowers as they appear.

Physical containment facilities

OGTR's monitoring of PC2 facilities in the quarter found a number of minor non-compliances and issues with certification instruments. Each observed non-compliance was assessed for risks posed to human health and safety and the environment. All issues observed posed negligible or no additional risk to human health and safety and the environment. However, where necessary, risk management strategies were implemented commensurate with the level of risk identified.

In most instances, issues observed arose from the imprecision of Version 1 of the *Guidelines for Certification of Facilities/Physical Containment Requirements* and did not jeopardise the secure containment of GMOs. The *Guidelines for Certification of Facilities/Physical Containment Requirements* for PC2 Laboratories, PC2 Animal containment facilities and PC2 Plant containment facilities have been reviewed and Version 2 of the Guidelines was issued on 7 August 2003 and all such facilities that wish to continue operation into the future will be required to submit applications to have their certification instruments varied and will be required to meet Version 2 of the Guidelines by 30 June 2004. Guidelines for remaining facilities (PC1, PC2 aquatic and insectary, PC3 and PC4 facilities) continue to be reviewed. As drafts are consolidated the OGTR will be consulting with relevant facility holders.

Monitoring and compliance reviews

The Monitoring and Compliance Section carries out reviews of incidents or practices in dealings with GMOs that come to the notice of the section through monitoring activities or reports by accredited organisations. There are two types of reviews:

- ***incident reviews*** are initiated when an organisation reports a particular incident that may present a potential risk to human health and/or the environment and may be suspected to be a non-compliance with the Act and associated regulations
- ***practice reviews*** are initiated to determine if licence conditions can be, and are being, effectively implemented and include identification of potentially adverse affects of a GMO and may be prompted by observations or a set of observations made during monitoring activities.

The primary focus of the review process is to determine whether the incident that has occurred, or practice being used, has a potential human health or environmental risk that requires management actions to be implemented. In certain instances where there has been a suspected non-compliance with the Act, the issue may be referred for investigation.

Two incident reviews were completed in this quarter and are outlined below:

Organisation	CSIRO
Issue	On 18 September 2003, CSIRO Entomology reported that a water heater had exploded in a certified PC2 Plant Containment Facility. The explosion had caused a small crack in the wall separating the anteroom and plant growth room. There was no damage to any external walls of the facility. The facility contained an NLRD involving feeding studies by wild type *Heliothis* larvae on vegetative Bollgard II® cotton plants.
Risk assessment	The OGTR risk assessment for this incident concluded that this incident posed negligible risk to human health and the environment. The GM Bollgard II® cotton plants were at the vegetative growth stage (ie had not reached the stage of flowering) and could not have dispersed genetic material. As no damage occurred to any external walls of the facility, containment was not breached.
Determination	The CSIRO facility had been appropriately certified and maintained in accordance with legislative and guideline requirements. The dealing was being conducted in accordance with legislative requirements governing NLRDs.

Risk management	CSIRO undertook immediate repairs to the damaged facility and during these repairs access to the facility, including the plant growth rooms, was restricted. CSIRO replaced the water heater and has taken steps to ensure there are no similar models in any other certified facilities or sites.
Action	No further action required.

Organisation	The University of Newcastle
Issue	On 30 September 2003, the University of Newcastle reported a lapse in administrative process surrounding two dealings that commenced under the auspices of the voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC). The dealings proceeded under deemed DNIR licences during the two-year transition period when the regulatory system commenced. However, re-approval through the licensing system was not sought before the transition period ended on 20 June 2003. The University's Institutional Biosafety Committee (IBC) conducted a review of their GMAC dealings and identified that approval to continue these two contained dealings had not been sought. When this came to light, the University of Newcastle ceased research an application for a new licence could be processed. The dealings involved use of retroviral expression libraries to characterise mechanisms of drug resistance in leukaemia and c-Kit signalling and cellular responses in haemopoietic cells.
Risk assessment	The OGTR concluded that this incident posed a negligible risk to human health and the environment as the dealings were conducted in certified PC2 facility in accordance with relevant guideline requirements.
Determination	An OGTR Incident Review determined that the University of Newcastle was accredited to conduct GMO research in accordance with the Act and associated regulations. The lapses, once identified, were reported to the OGTR and the dealings were suspended until licences were issued by the OGTR.
Risk management	The University of Newcastle has implemented administrative changes to enhance its oversight of OGTR compliance requirements.
Action	No further action required.

Audits

An audit entails, depending on its scope:

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

Conducting these activities is done to:

- verify that an accredited organisation has relevant and effective management procedures and practices to meet requirements under the Act, including the accreditation requirements, guidelines and any licence requirements applicable to a dealing under the Act; and
- assess whether the procedures and practices provide mechanisms to identify and resolve emerging risks, by improving procedures and practices, (including seeking variations from the OGTR for specified licence conditions).

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.

Audit Type	Systems Audit on Licence DIR 012/2002
Name	DIR 012/2002 – Commercial release of Bollgard II cotton
Organisation	Monsanto Australia Ltd
Audit Coverage	The audit covered risk management of field trials of GM cotton being conducted in northern Australia under DIR 012/2002 and related transport operations.
Aim	To cooperatively: • visit facilities/sites to observe operations, management arrangements, documents and procedures; and • identify any barriers to effective management practices and any potential prevention strategies.

Methodology	The audit systematically canvassed and sought examples of Monsanto's: • related Standard Operational Procedures (SOPs); • risk management activities and control documents; • reporting mechanisms and records; and review and revision mechanisms.
Findings	At the completion of the audit visit it was evident that Monsanto: • has a well-developed risk and compliance management system applicable to field trials being conducted under DIR 012/2002, which has the capacity to be adaptive and cautious in preventing and managing risk; and • was able to provide quality examples of documentation to validate its procedures, practices in response to the audit queries. • A small number of suggestions were made regarding minor improvements to Monsanto's procedures and practices.
Completed Implementation actions	Monsanto provided revised procedures and practices to address the opportunities for improvement identified during the audit.

Unannounced visits

During the October–December 2003 quarter, the OGTR conducted unannounced visits to a number of accredited organisations to follow up on 'deemed' authorisations under the Act which expired on 21 June 2003. Details on visits finalised in this quarter are outlined in the table below.

Type	Unannounced Spot Check - Expiry of deemed instruments on 20 June 2003
Organisation	University of Western Australia (UWA)
Issues	All 'deemed' authorisations issued under the Act expired at the end of the two year transitional period on 20 June 2003. The OGTR conducted an unannounced spot check at UWA in order to ensure compliance with the legislation.
Determination	The unannounced inspections validated and confirmed that the UWA was compliant with the Act in relation to all lapsed, deemed instruments.
Action	No further action required.

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

At its sixth meeting, held in Melbourne on 1 December 2003, the current GTCCC working groups reported on their activities since the previous meeting. The Committee endorsed the report prepared by one working group on the new format for Risk Assessment and Risk Management Plans and this was provided to the Regulator for consideration. The Committee discussed the progress made to date by other working groups which are due to report again at their next meeting.

At the December meeting members received an update on applications for commercial release of GM canola.

The GTCCC also provided comments on the Transkingdom Gene Transfer paper referred to GTCCC from GTEC.

The GTCCC is scheduled to meet again in April 2004. Further information about the Committee's activities can be obtained from the December 2003 meeting communique attached to this report (Appendix B). Previous communiques can also be found on the OGTR website at www.ogtr.gov.au.

Gene Technology Ethics Committee

During the quarter GTEC held its fifth meeting on 10 and 11 November 2003 in Melbourne. At the Regulator's request GTEC is continuing work on a range of

agreed priority areas. The five working groups reported to the Committee on their progress since the last GTEC meeting and are due to report again at the sixth meeting to be held in March 2004.

At the November meeting Associate Professor Dunlop, from the Victorian Biotechnology Ethics Advisory Committee, and Professor Jenkin, from the Animal Welfare Committee, attended part of the meeting as invited observers. Professor Dunlop and Professor Jenkins informed GTEC members about their working backgrounds and current issues that these committees are working on.

Further information about the issues under GTEC consideration can be obtained from the November 2003 meeting communique attached to this report (Appendix C) and is also available on the OGTR website at www.ogtr.gov.au.

Gene Technology Technical Advisory Committee

During the quarter GTTAC held two teleconferences on 28 October 2003 and 18 December 2003 and a face-to-face meeting in Canberra on 19 and 20 November 2003. At these meetings the Committee considered:

- 4 applications for DIR licences
- 3 RARMPs for DIR licences
- 12 applications for DNIR licences and associated RARMPs

At the November meeting the Committee held a preliminary discussion regarding the review of the Regulations.

GTTAC also provided comments on the Transkingdom Gene Transfer paper referred to GTTAC from GTEC.

The tenth GTTAC communique, outlining discussions held at the October 2003 meeting, are attached to this report at (Appendix D). GTTAC is scheduled to meet again in March 2004.

Further information about the activities of GTTAC can be obtained from the communiques published on the OGTR website at www.ogtr.gov.au.

PART 4 Other activities

Reviews

The following reviews continued during this quarter:

- A review to develop a strategy to identify data required to assess future applications for DIRs, particularly large-scale limited and controlled releases. This review is ongoing.
- A review of *Guidelines for the Certification of Facilities/Physical Containment Requirements* to address practical difficulties that have been encountered in their implementation. In this quarter a desktop study of requirements for PC2 level containment of aquatic organisms was undertaken and drafting of revisions for higher level (PC3, 4) containment facilities guidelines continued.

International collaboration and coordination

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

International collaboration and coordination activities undertaken during the quarter include:

- Attendance at the Organisation for Economic Cooperation and Development's (OECD) Technical Meeting on Implementation of the Biosafety Clearing House in Industrialized Countries - Experiences and Future Development in Geneva, Switzerland (29 September – 1 October 2003)
- Attendance at the OECDs Workshop on Consensus Documents that was held in Washington D.C., USA (21 – 23 October 2003);
- The Executive Officer and the Senior Policy Advisor from the NZ Bioethics Council met with senior OGTR staff on 20 November 2003;
- Attendance at the OECDs 14th Meeting of the Working Group on Harmonization of Regulatory Oversight in Biotechnology convened in Paris, France (24 – 26 November 2003);
- The Regulator provided a presentation for the New Zealand Ministry of

Research, Science and Technology in Wellington, New Zealand (NZ) on 2 December 2003, the presentation was titled "Decision Making in Gene Technology Regulation"; and

- Attendance at the International Society for Risk Analysis Annual Conference in Baltimore, United States of America (USA) (8 – 11 December 2003).

Advice on gene technology regulation

Presentations and meetings

The OGTR endeavours to participate in presentations and meetings on gene technology wherever possible to inform the community and users about the regulatory system. During the quarter the OGTR:

- presented "Regulation of Gene Technology in Australia" to the University of Newcastle on 7 October 2003;
- gave a presentation to the Australian Academy of Technological Sciences and Engineering – South Australia (SA) Division in Adelaide, SA on 9 October 2003; the presentation was titled "The Role of Regulation in Developing Australia's Biotechnology Industries";
- provided an overview of gene technology regulation in Australia to the Canberra Institute of Technology, Reid, ACT on 29 October 2003;
- organised a workshop in Narrabri involving representatives from the cotton industry and the cotton research community to discuss research needs in relation to GM cotton (12 – 13 November 2003);
- attended and gave a presentation entitled "Gene Technology Regulation in Australia. A precautionary approach as part of the regulatory framework" at a conference on "The precautionary principle in environmental legislation, 10 years since Leatch" held at the Australian National University in Canberra, ACT on 20 – 21 November 2003;
- provided an overview of the regulatory system for gene technology to the Wide Bay Burnett Council Meeting, in Maroochydore, QLD (21 November 2003); and
- discussed the National Health and Medical Research Council's role as a prescribed consultation agency at its meeting in Adelaide, SA on 26 November 2003.

Institutional Biosafety Committee training sessions

OGTR regularly provides training sessions to organisations and IBCs. During the October–December 2003 quarter, sessions were conducted at the University of Newcastle, the University of New South Wales, the Edith Cowan University, Murdoch University, the University of Western Australia, the Womens and Childrens Hospital, Adelaide, Flinders University and the University of Adelaide.

Gene Technology Information Management System

The electronic lodgement component of Gene Technology Information Management System (GTIMS) commenced a staged on-line release in late October 2003.

This component provides a facility for OGTR's external clients to submit their applications and view progression of their applications on-line in a secure environment.

In order to promote awareness of the new facility and to educate current and potential applicants about its use, the OGTR conducted a series of training sessions for Accredited organisations and their IBCs.

A total of 20 presentations were made across Australia between 3 November and 12 December 2003.

During that period the OGTR visited:

State	Organisation
ACT	Biotron Limited
	CAMBIA (Centre for the Application of Molecular Biology to International Agriculture)
	The Canberra Hospital
	Phenomix Australia Pty Ltd
	Therapeutic Goods Administration Laboratories
TAS	Tasmanian Alkaloids Pty Ltd - Launceston
	The University of Tasmania - Launceston
	The University of Tasmania - Hobart

WA	Animal Resources Centre
	Department of Agriculture WA
	Grain Biotech Australia
	Ozgene Pty Ltd
	Western Australian Institute for Medical Research
NT	Menzies School of Health Research
	Charles Darwin University
SA	Australian Water Quality Centre
	Bionomics Limited
	BresaGen Limited
	TGR Biosciences Pty Ltd
	The Queen Elizabeth Hospital
	The University of South Australia

Presentations will continue in 2004 until all accredited organisations and IBCs have received training.

OGTR website

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

- Maps of current field trial locations
- What's New
- Intentional Release and Evaluation Process
- About the OGTR
- Media Releases.

The most popular downloaded documents were:

- The biology and ecology of pineapple *(Ananas comosus var. comosus)*
- Handbook on the regulation of gene technology in Australia
- Accredited Annual Report to the Gene Technology Regulator
- Application for a licence for dealings with a GMO involving intentional release of the GMO into the environment

- The biology and ecology of papaya (paw paw), *Carica papaya L.,* 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 benefits provided by the 1800 line and email facilities.

OGTR received approximately 128 calls and 248 emails in October 2003, 111 calls and 448 emails in November 2003, and 77 calls and 491 emails in December 2003.

Freedom of information

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

Consultants

During the reporting period, the OGTR managed 1 consultancy contract worth a total of $10,673. The table below lists the consultant, 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	$10,673	Develop Gene Technology Information Management System
Total Consultants for quarter	**$10,673**	

Appendix A

DNIR Licences issued 1 October–31 December 2003

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 250/2003	28-May-2003	02-Oct-2003	The University of Adelaide, South Australia	Cellular interactions between *Hepatitis B virus* (HBV) and *Hepatitis C virus* (HCV)	The aim of this dealing is to investigate the effect that HBV replication has on HCV replication, cell growth, cell viability and cellular gene expression.
DNIR 253/2003	16-Jun-2003	21-Oct-2003	St Vincent's Hospital Sydney Limited	HIV Biology	The aim is to understand the biology of the H*uman immune deficiency virus* (HIV) as the basis for better drug and vaccine development.
DNIR 254/2003	17-Jun-2003	03-Oct-2003	The University of Western Australia	Evaluation on the effects of apoptosis and necrosis on tumour antigen presentation and anti-tumour response	The aim of this dealing is to determine whether induction of different types of cell death mechanisms in tumours can increase the immune response to these tumours.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 256/2003	19-Jun-2003	06-Nov-2003	CSIRO (Livestock Industries Geelong), Victoria	Genetics of *Clostridium perfringens* pathogenesis	The aim of this dealing is to investigate the role of specific, defined toxin proteins in the pathogenesis of *C. perfringens*.
DNIR 259/2003	23-Jun-2003	30-Oct-2003	Queensland Department of Primary Industries	Study of plant virus interactions using fluorescence tagged viruses	The aim of this dealing is to study the function of viral genes in virus movement and host interaction in resistant and susceptible plants.
DNIR 260/2003	23-Jun-2003	30-Oct-2003	Royal Perth Hospital, Western Australia	Use of *Adenovirus* and *Adeno associated virus* gene delivery systems for the expression of *Hepatitis C virus* (HCV) proteins	Recombinant *Adenovirus* and *Adeno-associated virus* carrying HCV genes will be used to produce HCV proteins in cell cultures and mice to study the structure and function of the proteins and act as a source of HCV protein for immune studies.
DNIR 261/2003	26-Jun-2003	30-Oct-2003	EnGeneIC Pty Ltd, New South Wales	Novel Gene Delivery Vector	The aim of this dealing is to develop a novel drug delivery vector that combines drug biosynthesis and targeted delivery.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 266/2003	31-Jul-2003	27-Nov-2003	CSL Limited, Victoria	Construction of *Influenza viruses* by reverse genetics for diagnostic and research purposes.	The aim of this project is to employ a technique known as reverse genetics to produce rapidly and reproducibly *Influenza viruses* for testing as vaccines.
DNIR 267/2003	11-Aug-2003	18-Nov-2003	Queensland University of Technology	Chimeric Dengue vaccines	The aim of this dealing is to test different vaccine strategies against multiple Dengue virus serotypes in mice.
DNIR 268/2003	13-Aug-2003	27-Nov-2003	Queensland University of Technology	The development of a novel resistance strategy against single stranded DNA (ssDNA) plant viruses	The aim of this dealing is to develop resistance to ssDNA viruses in several plant species by introducing a gene to the plants that will trigger the death of cells infected with the virus.
DNIR 269/2003	28-Aug-2003	12-Dec-2003	Murdoch Childrens Research Institute	Characterisation of genes involved in haematopoietic stem cell growth and regulation	This project will examine the role of known and novel genes in human blood cell growth with the aim of learning more about normal blood cell development and what goes wrong in this process to cause leukaemia.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 270/2003	2-Sep-2003	18-Dec-2003	The Walter and Eliza Hall Institute of Medical Research	Retroviral and adenoviral mediated gene transfer into murine mammary cells and breast cancer cell lines	The aim of this dealing is to study the role of specific genes in cell growth, mammary gland development and oncogenesis.
DNIR 271/2003	3-Sep-2003	10-Dec-2003	University of Technology, Sydney, New South Wales	Investigations on parasite virulence using cross complementation	This project involves studying factors affecting the effect of the parasites *Toxoplasma gondii* and *Neospora caninum* on their hosts.
DNIR 272/2003	4-Sep-2003	10-Dec-2003	The University of Queensland	Delivery of replication defective lentiviruses into mice	The aim of this dealing is to develop novel anticancer treatments against both skin cancers and cancers caused by viruses, using a mouse model.
DNIR 273/2003	11-Sep-2003	09-Dec-2003	Western Sydney Area Health Service	Repression of hepatic drug metabolism by solid tumours	The aim of this dealing is to investigate how the inflammatory factors released by tumours into the blood reduce hepatic levels of enzymes involved in drug metabolism.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 276/2003	2-Oct-2003	18-Dec-2003	Queensland Institute of Medical Research	Functional analysis of DNA damage responsive genes by retroviral transfections	The aim of this dealing is to determine the function and importance of specific genes in keeping the genome intact and in preventing cancer.
DNIR 277/2003	23-Oct-2003	19-Dec-2003	Cargill Australia Limited	Importation and Processing Soybeans	The applicant intends to import soybeans from the USA for processing as oil and stockfeed. Since there are commercial crops of GM soybeans in the USA, the shipment may contain GM soybeans.
DNIR 278/2003	23-Oct-2003	23-Dec-2003	The University of Newcastle	Analysis of oncogenes and their protein products, and investigation of drug resistance mechanisms.	The purpose of this dealing is to investigate specific genes involved in the onset of cancers and characterise various mechanisms of cancer cell drug resistance to conventional and new cancer therapies.

Appendix B

Gene Technology Community Consultative Committee Meeting

Melbourne, Victoria

1 December 2003

COMMUNIQUE

The Gene Technology Community Consultative Committee (GTCCC) held its sixth meeting in Melbourne, Victoria on 1 December 2003.

The GTCCC 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 hold office on a part-time basis.

At its sixth meeting the current GTCCC working groups reported on their activities since the previous meeting. In addition to the existing work plan priorities, the Committee provided comment on a transkingdom gene transfer paper produced by the Gene Technology Ethics Committee (GTEC) and received reports of the recent work of GTEC, the Gene Technology Technical Advisory Committee (GTTAC), and from the Gene Technology Regulator.

In addition, members received a presentation by Mr O'Connor Cox from the Office of the Gene Technology Regulator (OGTR) about applications proposing the commercial release of genetically modified canola and an update by Mr Benyei, also from the OGTR, regarding the proposed process for reviewing the Risk Analysis Framework.

GTCCC's Work Plan

GTCCC's first communique from its meetings of April and July 2002, detailed a number of priority areas that would form the basis of the Committee's future work plan and result in the provision of advice to the Regulator. Since that time

the working groups have been developing and refining their ideas out-of-session and at each subsequent meeting of the Committee. Details of the current working groups are provided below.

Review of processes by which the OGTR can improve community consultation and participation including review of the effectiveness of information and communication provided to the community in general and to the regions involved in limited and controlled releases and the processes used to assess the fitness of applicants to be issued a licence

The working group provided the Committee with the draft document for their consideration. Amendments proposed by the Committee will be used in redrafting the document. The working group will hold a face-to-face meeting to finalise the revised draft document and will provide it to the Committee at its next meeting for final consideration.

Consider issues associated with public understanding of science, risk, and public perceptions of gene technology

The second working group sought comment from the Committee regarding a framework covering issues of concern relating to gene technology: precaution; trust in the regulatory system; health and safety; environment; economic issues; and risk. The working group will reconvene in the new year to develop the document in line with the comments provided by the Committee. The draft paper will be considered at the next GTCCC meeting.

Review of the new format of the Risk Assessment and Risk Management Plans (RARMPs) for dealings involving an intentional release of GMOs into the environment.

This working group determined the improvements made by the OGTR to the RARMPs were very positive. The working group proposed a number of additional changes which may further improve the RARMPs. The Committee formally endorsed the report of the working group and provided the report to the Gene Technology Regulator for her consideration.

Review of the Risk Analysis Framework

Mr Benyei provided the Committee with an update on the proposed process for reviewing the Risk Analysis Framework. He informed the Committee that they would be formally asked to provide input at their first meeting in 2004.

GTEC paper on transkingdom gene transfer

The Committee was provided with a discussion paper on transkingdom gene transfer by the Gene Technology Ethics Committee (GTEC). Members

expressed their appreciation for the opportunity to comment on the GTEC's paper. The Committee's comments will be conveyed to the GTEC.

For all inquiries, please contact the Office of the Gene Technology Regulator on

1800 181 030 (free-call)

Appendix C

Gene Technology Ethics Committee Meeting

10-11 November 2003, Canberra

COMMUNIQUE

The Gene Technology Ethics Committee (GTEC) held its fifth meeting in Canberra on the 10th and 11th of November 2003.

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

At its November 2003 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 were informed of relevant work from other national committees via cross-member reports, as well as a Chair's activity report and a report from the Regulator on activities undertaken by the Office of the Gene Technology Regulator (OGTR) since the fourth meeting held in April 2003. Key outcomes from the meeting are reported below.

GTEC's Work Plan

GTEC's first communique from its inaugural meeting in December 2001 detailed a number of priority areas that would form the basis of the Committee's future work plan and result in the provision of advice to the Regulator. Since that time the working groups have been developing and refining their ideas out-of-session and at each subsequent meeting of the Committee. Details of the status of a number of the current working groups are provided below for information.

Ethical Guidelines in Relation to Genetically Modified Organisms

The working group presented an initial report on the development of ethical guidelines in relation to genetically modified organisms.

The Committee suggested a number of amendments to further develop the values and principles to be addressed in the guidelines. The working group will continue developing the guidelines in parallel with other documents currently being produced by the Committee.

Ethical Issues Associated with Transkingdom Gene Transfer [2]

The working group established to consider the ethical issues associated with transkingdom gene transfer provided a revised report to members which incorporated comments from the previous GTEC meeting.

Members agreed the report was close to finalisation and proposed some minor amendments. The Committee noted that the paper was to be provided to the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Community Consultative Committee (GTCCC), and feedback from these Committees would be incorporated as part of the final stages of the report's preparation.

When the paper has been finalised by the GTEC it will be published on the Committee's page on the OGTR website.

Release of Information and Notification under the Gene Technology Act 2000

The GTCCC cross-member brought to the Committee's attention that this paper is similar to a paper currently being developed by the GTCCC (*Review of processes by which the OGTR can improve community consultation and participation).* The Committee acknowledged the overlap and agreed to coordinate activities between the Committees through the cross-member.

The working group will continue to develop the report and incorporate the comments provided by the Committee. A revised report will be prepared for members' consideration at the next meeting in March 2004.

[2] Transkingdom gene transfer involves the transfer of DNA into the cells of an organism from a different 'kingdom'. Organisms are grouped on the basis of fundamental similarities and common ancestry into a taxonomic system. One widely accepted taxonomic system designates five such kingdoms: animals; plants; fungi; prokaryotes (bacteria); and protista (algae and molds).

Managing Risk Ethically

The working group provided the draft report which has developed into two parts, for the Committee's consideration. The Committee's comments will be incorporated into a revised draft report and be provided to members at the next meeting in March 2004.

Extent of Ethical Consideration in Applications (formally Qualitative Survey of Institutional Biosafety Committees)

The GTEC has been examining the need for an ethical review for all types of applications for genetic modification work in relation to plants and animals. At the November 2003 meeting, members formally welcomed a representative from Victorian Biotechnology Ethics Advisory Committee (VBEAC) who had accepted an invitation to join a working group to address this issue.

This working group is undertaking a broad fact-finding exercise relating to the work of Institutional Biosafety Committees, in place of the originally proposed quantitative survey. The working group provided the Committee with a paper outlining the revised approach.

The Committee considered this paper and suggested a number of different avenues that could be pursued to further progress the fact-finding exercise.

GTEC and Relationships with Other Committees

The Committee welcomed a member from the Animal Welfare Committee (AWC) to the meeting. It was agreed that the AWC member would liase with the Committee during the finalisation of a GTEC submission on the Draft Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (7th Edition) prepared by the National Health and Medical Research Council. As reported in the previous communique, GTEC made a submission on the previous draft of the code in June 2003.

As a standing item at every GTEC meeting, the Committee receives verbal reports on activities from the cross-members with the GTTAC, the GTCCC and the OGTR. On behalf of the GTTAC cross-member, the Secretariat reviewed key outcomes from the recent GTTAC meetings. The GTCCC cross-member reported on GTCCC working group developments discussed at the GTCCC meeting in June 2003. Communiques covering meetings for all gene technology advisory committees are publicly available from the OGTR website.

The Regulator reported on the operations of the OGTR which are publicly available in quarterly reports on the OGTR website and from the OGTR on request.

The Committee was also informed of the current activities of the Australian Health Ethics Committee (AHEC) and that a review of the *National Statement on Ethical Conduct in Research Involving Humans* is planned for 2004.

Next Meeting

The next GTEC meeting will be held in March 2004.

For all inquiries, please contact the Office of the Gene Technology Regulator on

1800 181 030 (free-call)

Appendix D

GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE

COMMUNIQUE
No. 10

This is the tenth communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the sixteenth and seventeenth meeting of GTTAC, held on 18 September 2003 and 28 October 2003 respectively, as well as matters considered by GTTAC out-of-session in the period from 25 July to 28 October 2003.

GTTAC is a statutory advisory committee to the Gene Technology Regulator (the Regulator) and the Gene Technology Ministerial Council. All Committee members and expert advisers hold office on a part-time basis.

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

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

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

Dealings Not Involving the Intentional Release of Genetically Modified Organisms

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

Applications and RARMPs for the following DNIRs were assessed:

Application Number and Title	Project Description	GTTAC Comments
DNIR 233/2003 Mutation of an infectious clone of BIV R29. DNIR 234/2003 Transcomplementation of vif deleted BIV with bovine lentivirus. DNIR 235/2003 Use of an infectious clone of BIV R29.	The aim of these dealings is to investigate the role of accessory genes in Bovine immunodeficiency virus (BIV) by creating point mutations in these genes which result in either a deletion or truncation of the proteins they encode. In addition the applicant aims to determine whether there is functional homology between certain proteins from BIV and the related Jembrana disease virus, and to use an infectious clone of BIV as a standard in molecular biological tests.	These applications were considered together. GTTAC agreed that the risk assessment identified all the risks associated with the proposed dealings and that the measures proposed in the risk management plan are adequate to deal with the identified risks. However, the Committee suggested that the risk of the formation of novel recombinant viruses be considered in more detail.

Application Number and Title	Project Description	GTTAC Comments
DNIR 238/2003 Mutational analysis of the Australian strain of Porcine circovirus type 1. DNIR 239/2003 Production of an infectious clone from the Australian strain of Porcine circovirus type 1. DNIR 240/2003 Mutational analysis of the Australian strain of Porcine circovirus type 2. DNIR 241/2003 Production of an infectious clone from the Australian strain of Porcine circovirus type 2.	The aim of these dealings is to investigate the importance of particular coding regions, conserved motifs and domains in the genomes of both Porcine circovirus type 1 (PCV-1) and PCV-2 by creating mutations in these genes. In addition the applicant aims to clone full-length genomes of PCV-1 and PCV-2 to be used in further studies and as standards in diagnostic techniques.	These applications were considered together. GTTAC agreed that the risk assessment identified the risks associated with the proposed dealings and that the measures proposed in the risk management plan are adequate to deal with the identified risks. However the Committee suggested that further information regarding the genes being used should be sought from the applicant and added to the RARMP. They also suggested that more detail be included in the RARMP about the possible risk to operators from the GM viruses.
DNIR 250/2003 Cellular interactions between HBV and HCV.	The aim of this dealing is to investigate the effect that Hepatitis B virus (HBV) replication has on Hepatitis C virus (HCV) replication, cell growth, cell viability and cellular gene expression by transfecting hepatocyte cells containing a HCV replicon (a truncated, non-infectious HCV genome) with plasmids containing the HBV genome.	GTTAC agreed that the risk assessment identified all the risks associated with the proposed dealings and that the measures proposed in the risk management plan are adequate to deal with the identified risks.

Application Number and Title	Project Description	GTTAC Comments
DNIR 254/2003 Evaluation of the effects of apoptosis and necrosis on tumour antigen presentation and anti-tumour response.	The aim of this dealing is to determine whether induction of different types of cell death mechanisms in tumours can increase the immune response to these tumours.	As for DNIR 250/2003.
DNIR 256/2003 Genetics of Clostridium perfringens pathogenesis.	The aim of this dealing is to investigate the role of specific, defined toxin proteins in the pathogenesis of C. perfringens.	As for DNIR 250/2003. In addition GTTAC recommended that masks and goggles be used by operators when handling infected animals and that a Class II biosafety cabinet be used for performing necroscopies.
DNIR 259/2003 Study of plant-virus interactions using fluorescence-tagged viruses.	The aim of this dealing is to study the function of viral genes in virus movement and host interaction in resistant and susceptible plants.	As for DNIR 250/2003.
DNIR 260/2003 Use of adenovirus and adeno-associated virus gene delivery systems for the expression of HCV proteins.	Recombinant adenovirus and adenovirus-associated viruses carrying Hepatitis C virus (HCV) genes will be used to produce HCV proteins in cell cultures and mice to study the structure and function of the proteins as well produce HCV protein for immune studies.	As for DNIR 250/2003.

Application Number and Title	Project Description	GTTAC Comments
DNIR 261/2003 Novel gene delivery vector.	The aim of this dealing is to develop a novel drug delivery vector that combines drug biosynthesis and targeted delivery.	As for DNIR 250/2003.
DNIR 269/2003 Characterisation of genes involved in hematopoietic stem cell growth and regulation.	The aim of this project is to examine the role of known and novel genes in human blood cell growth with the purpose of learning more about normal blood cell development and what goes wrong in this process to cause leukaemia.	As for DNIR 250/2003.
DNIR 270/2003 Retroviral and adenoviral mediated gene transfer into murine mammary cells and breast cancer cell lines.	The aim of this dealing is to elucidate the role of mammalian genes in mammary cell growth, proliferation, apoptosis, differentiation and oncogenesis.	As for DNIR 250/2003.

Dealings Involving the Intentional Release of Genetically Modified Organisms

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

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

Advice on Clover

GTTAC considered the following application concerning the release of transgenic clover in Australia and provided advice on issues to be considered in the preparation of the associated RARMP.

- **Field trial – Field evaluation of white clover transformed to resist infection by *Alfalfa Mosaic virus* and *Clover yellow vein virus* (DIR 042/2003)**

  The OGTR has prepared a RARMP for an application from the Commonwealth Scientific and Industrial Research Organisation (CSIRO) for the limited and controlled release of GM white clover that has been modified to resist infection by *Alfalfa mosaic virus* (AMV) and *Clover yellow vein virus* (CYVV). CSIRO proposes to conduct field trials on one site in New South Wales (NSW), over a total area of 2 hectares.

  The aim of the proposed release is the field evaluation of GM white clover to determine the maintenance of resistance to AMV and CYVV that was observed in the plants grown in the glasshouse. The GM white clover plants contain coat protein genes from AMV and/or CYVV, which reduces the susceptibility of the clover plants to AMV and CYVV, respectively. CSIRO proposes evaluation of four types of GM white clover.

  GTTAC discussed this application and advised the Regulator that the following issues should be considered in the preparation of the RARMP:

  - The experiments involving GM white clover expressing CYVV coat protein genes should not be allowed to proceed;
  - The risks posed by the AMV resistant GM white clover are similar to those posed by previous white clover applications PR-64, PR-64X, PR-64X2 and PR-67;
  - The applicant should be requested to provide data to clarify whether white clover is present in the area surrounding the trial site;
  - The applicant should also be requested to provide information on the risks related to the distance of the trial site from the Murray River; and
  - The applicant should be asked to remove the seeds produced at the trial site.

Advice on Cotton

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

- **The evaluation of transgenic cotton plants expressing the *vip* gene (DIR 034/2003)**

  The OGTR has prepared a RARMP for an application from Syngenta Seeds Pty Ltd (Syngenta) for the limited and controlled release of GM insecticidal cotton into the environment. Syngenta proposes to conduct trials on 30 sites covering a total area of 10 hectares, over two years, in the cotton growing regions of NSW and Queensland (Qld).

The main aim of the proposed release is to assess the agronomic performance and efficacy of the insecticidal activity of the new lines in all the major cotton growing areas of Australia.

The GM cotton proposed for release is a backcross of an insecticidal cotton, described by Syngenta as COT102, into three elite Australian cotton cultivars. Limited and controlled field trials of COT102 have been previously approved in Australia under PR-151, DIR 017/2002 and DIR 025/2002.

The GM cotton contains an insecticidal gene (*vip3A*), derived from a common soil bacterium, which encodes an insecticidal protein (VIP3A) that is toxic to lepidopteran caterpillar pests of cotton. It also contains a bacterial gene *hph*, conferring resistance to hygromycin, an antibiotic that was used as a selectable marker in the initial laboratory stages of developing the GM cotton.

None of the cotton plants from the proposed release, or their by-products, will be used for human food or animal feed. The applicant proposes to sell the lint for use in clothing and upholstery. Lint does not contain genetic material or protein.

Details of the plasmid map, including the gene construct containing the insecticidal *vip3A* gene, and the regulatory sequences (promoters), have been declared Confidential Commercial Information (CCI) under section 185 of the *Gene Technology Act* (the Act). However, this information has been made available to GTTAC and other prescribed expert authorities that are being consulted on the preparation of the RARMP.

GTTAC discussed the RARMP prepared for this application and advised the Regulator that:

- The Committee agrees with the assessment made by the OGTR on the risk of toxicity, allergenicity, weediness and gene transfer;
- The Committee agrees with the proposed licence conditions;
- The applicant should be requested to provide further data and information on the toxicity of the GMO to non-target organisms and the biochemical pathways involving VIP3A protein; and
- The Committee recommends that research should be commissioned to investigate potential risks of the GMO to Australian species of non-target insects.

- **Field trials of Roundup Ready cotton MON 88913 (DIR 035/2003)**

  The OGTR has prepared a RARMP for an application from Monsanto Australia Limited (Monsanto) for the limited and controlled release of GM herbicide tolerant cotton (Roundup Ready® MON 88913) and herbicide tolerant/insect resistant cotton (Roundup Ready® MON 88913 /Bollgard II®). Monsanto proposes to conduct trials on 50 sites covering a total of 954 hectares, over three years, in the cotton NSW, Qld, NT, and WA.

  Roundup Ready® MON 88913 cotton differs from the previous commercially released Roundup Ready® cotton in that it contains two copies of the *cp4 epsps* gene that provides tolerance to glyphosate (the active ingredient in the herbicide Roundup®). The applicant anticipates that this will enable Roundup® to be applied to control weeds over a longer period of plant growth, giving growers increased flexibility in timing herbicide applications for integrated weed management.

  The proposed field trials aim to transfer and establish the MON 88913 trait into elite cotton varieties and to evaluate the GM cottons' agronomic performance in Australian agricultural conditions. Additional aims are to conduct evaluation and gather data on Roundup Ready® MON 88913 levels of CP4 EPSPS protein expression, tolerance to glyphosate, seed composition, weed control effectiveness and glyphosate residue levels for future large scale or commercial releases, which would require separate approvals.

  None of the cotton plants from the release, or their by-products, would be used for animal and human food. However, the applicant proposes to sell lint. Lint does not contain genetic material or protein. Transport of the GM material would be in accordance with the transport guidelines issued by the Regulator.

  Details of the gene construct, including the plasmid map, some of the regulatory sequences and preliminary protein expression data, have been declared CCI under section 185 of the Act. However, this information has been made available to GTTAC and other prescribed expert authorities that are being consulted on the preparation of the RARMP.

  GTTAC discussed the RARMP prepared for this application and advised the Regulator that:

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

- **Breeding and pre-commercial evaluation of transgenic cotton expressing a vegetative insecticidal protein (VIP) gene and a herbicide tolerance gene – continuation of DIR 017/2003 and DIR 025/2003 (DIR 036/2003)**

  The OGTR has prepared a RARMP for an application from the CSIRO for a licence for the limited and controlled release of GM cotton into the environment. CSIRO proposes to release the transgenic cotton on 16 sites within existing cotton growing regions in Qld and NSW, covering a total area of less than 45 hectares per growing season for three seasons.

  The three insecticidal GM cotton lines proposed for release, COT200, COT102, and COT102xLL25, express vegetative insecticidal protein (VIP) from the *vip* gene. This protein is different to the other insecticidal proteins present in the GM insecticidal cottons being trialled or grown commercially in Australia. In addition to the *vip* gene, COT102 contains an antibiotic resistance gene and COT102xLL25 contains an antibiotic resistance gene and a herbicide tolerance gene.

  The proposed trial is part of an ongoing breeding program to develop lines suitable for commercial development. The main aim of the proposed release is to evaluate the agronomic performance of cotton lines modified to express a new insecticidal protein that is toxic to lepidopteran caterpillar pests of cotton. The release would also allow the assessment of the efficacy of the insecticidal protein, the combining of the insecticidal and herbicide tolerance traits by crossing different GM lines (containing insecticidal and herbicide tolerant traits), and production of seed for future releases, subject to future approvals.

  None of the cotton plants from the release, or their by-products, would be used for animal feed or human food. However, the applicant proposes to sell lint from the release. Lint does not contain genetic material or protein.

  Details of the gene construct, including the plasmid map and regulatory sequences for the COT200, COT102 and LL25 events, have been declared as CCI. CSIRO has sought approval for details of the gene construct, including the plasmid map and regulatory sequences of the COT102xLL25 line, to be declared CCI. CCI information is made available to GTTAC and other prescribed expert authorities that are being consulted on the preparation of the RARMP.

  GTTAC discussed the RARMP for this application and advised the Regulator that:

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

- **Breeding and pre-commercial evaluation of transgenic cotton expressing tolerance to the herbicide glufosinate ammonium – continuation of DIR 015/2003 (DIR 038/2003)**

  The OGTR has prepared a RARMP for an application from CSIRO for a licence for the limited and controlled release of GM cotton into the environment. CSIRO is proposing to release this transgenic cotton on 16 sites, in NSW and Qld, over a total area of 45 hectares per year over three growing seasons.

  The aim of the proposed release is breeding and pre-commercial field evaluation of GM herbicide tolerant Liberty® cotton. The release would also be used for demonstration purposes.

  Liberty® cotton is tolerant to the herbicide glufosinate ammonium (also called phosphinothricin), the active constituent of herbicides Basta® and Liberty® (hence the name Liberty® cotton). It is expected that use of Liberty® cotton plants will allow more effective weed control in cotton crops by allowing the crop to be sprayed with glufosinate ammonium to kill problem weeds without damaging the crop itself.

  None of the cotton plants from the release, or their by-products, would be used for animal feed or human food. However, the applicant is proposing to sell lint, which does not contain any genetic material, from the GM cotton plants and the conventional cotton plants in the surrounding pollen trap.

  CSIRO has requested that details of the gene construct, including the plasmid map and regulatory sequences, be declared as CCI under section 185 of the Act. However, this information has been made available to GTTAC and other prescribed expert authorities that are being consulted on the preparation of the RARMP.

  GTTAC discussed the RARMP prepared for this application and advised the Regulator that:

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

- **Field evaluation of high-oleic (HO) cotton (DIR 039/2003)**

  The OGTR has prepared a RARMP for an application from CSIRO for a licence for the limited and controlled release of GM cotton into the environment. CSIRO is proposing to release two transgenic cotton lines on 2 hectares at one site at the Australian Cotton Research Centre Narrabri, NSW.

The main aims of the proposed release are to conduct agronomic evaluation of the GM cotton lines and to test for maintenance of the HO phenotype under field conditions.

Oil from GM HO cottonseed is expected to have a greater stability than other seed oils. This may enable direct use in frying or for margarine hard stock, without the need for hydrogenation that current oils require.

None of the cotton plants from the release, or their by-products, will be used for animal or human consumption. The applicant is proposing to sell lint from non-GM cotton used as pollen trap rows surrounding the release site, but not from the release. Lint does not contain genetic material or protein.

GTTAC discussed the RARMP prepared for this application and advised the Regulator that:

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

- **Agronomic assessment and seed increase of transgenic cotton expressing insect tolerance genes from *Bacillus thuringiensis* (DIR 040/2003)**

  The OGTR has prepared a RARMP for an application from Dow AgroSciences Australia Limited (Dow AgroSciences) for a licence for the intentional release of GM insect resistant / herbicide tolerant cotton into the environment, on a limited scale and under controlled conditions on two sites covering a total area of 0.04 hectares in NSW.

  There have been no previous releases of this particular variety of GM cotton in Australia. The main aim of the proposed release is to evaluate the agronomic performance and insecticidal efficacy of a cotton line modified to express two insecticidal proteins (Cry1Ac and Cry1Fa) that are toxic to lepidopteran caterpillar pests of cotton. This line also contains a marker gene (*pat*) which confers tolerance to the herbicide glufosinate ammonium. Seed would also be retained for potential future releases, which would require further licence applications and separate assessment processes.

  None of the cotton plants from the release, or their by-products, would be used for animal or human food.

  Some specific Dow AgroSciences documents, which contain some details of the gene construction, gene sequence information and molecular characterisation of the GMO, have been declared as CCI under section 185 of the Act. However, this information has been made available to GTTAC and other prescribed expert authorities that are being consulted on the preparation of the RARMP.

GTTAC discussed the RARMP prepared for this application and advised the Regulator that:

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

Advice on Lupins

GTTAC considered the following application concerning the release of transgenic lupins in Australia and provided advice on issues to be considered in the preparation of the associated RARMP.

- **Preliminary agronomic assessment of high sulphur lupin (DIR 043/2003)**

  The OGTR has received an application from the University of Western Australia proposing to conduct a single field trial at one site, over a single year, covering a total area of 0.5 hectares.

  The aim of the proposed release is to determine the agronomic performance of two high sulfur lupin lines and their F_1 progeny and to compare this with the non-transgenic cultivar Kalya, from which they were derived. The applicant also proposes to harvest and store seed from the trial for sulfur analysis.

  The high sulfur lupin contains the sunflower seed albumen (*ssa*) gene derived from the sunflower (*Helianthus annuus* L.) and associated regulatory sequences from pea (*Pisum sativum*). The effect of the modification is to increase methionine and cysteine content in the seed. These are nutritionally important amino acids especially in stockfeeds.

  GTTAC advised the Regulator that:

  - The risks posed by the genetically modified high sulphur lupins are similar to those posed by previous lupin applications PR-49, PR-49X, PR-49X(2) and PR-49X(3); and
  - The applicant should be requested to provide a protocol for cleaning the harvesting machinery.

Presentations

The Committee received and discussed presentations on the following topics:

- The Precautionary Principle
- Evolved Glyphosate Resistance
- Antibiotic Resistance Genes in GMOs in Australia

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/publications/riskassessments.htm