

**Quarterly Report of
the Gene Technology Regulator
for the period
1 July to 30 September 2003**

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ISBN

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

Produced by:

Office of the Gene Technology Regulator
MDP54 PO Box 100
WODEN ACT 2606

Email: ogtr@health.gov.au

Website: www.ogtr.gov.au

Telephone: 1800 181 030

Fax: 02 6271 4202

Inquiries about the content of this report may be directed to the Committee Secretariat Section of the Office of the Gene Technology Regulator.



Office of the Gene Technology Regulator

THERAPEUTIC GOODS ADMINISTRATION

PO Box 100 Woden ACT 2606 Tel **1800 181 030** Fax 02 6271 4202

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* (the Act), I am pleased to present to you the Quarterly Report of the Gene Technology Regulator, covering the period 1 July to 30 September 2003.

The commencement of this quarter marks a milestone in the implementation of the Act. Over 3000 deemed instruments that were brought into the new system from the previous voluntary scheme overseen by the Genetic Manipulation Advisory Committee have either been replaced with approvals issued in accordance with the requirements of the Act or allowed to expire.

Another milestone was the issuing of the first licence for the commercial release of a genetically modified canola, following comprehensive scientific assessment and extensive expert and community consultation. Other key achievements covered in the report include the issuing of 32 licences for dealings not involving intentional release of genetically modified organisms, the accreditation of 7 organisations and the certification of 125 contained facilities.

In addition, I signed a bilateral memorandum of understanding with Food Standards Australia New Zealand, outlining the nature of the cooperative working relationship between the OGTR and this agency, in fulfilling our respective regulatory responsibilities.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator
15 December 2003

Contents

Glossary	vi
Introduction	viii
Structure of this report	viii
Further information	ix
PART 1 National regulatory system	1
Key achievements during this quarter	1
Licences and other instruments	1
Monitoring and compliance	1
Australian Government agency liaison	1
Working collaboratively with states and territories	1
State and territory consultation	1
Gene Technology Ministerial Council	2
Gene Technology Standing Committee	2
Australian Government agency liaison	2
Public participation	4
PART 2 Regulation of genetically modified organisms	5
Applications received and decisions made	5
New licences and other instruments	6
Processing of applications for DIR licences	6
Applications received for DIR licences	7
In-progress applications for DIR licences	8
Consultation on applications for DIR licences	8
Clock stopped on applications for commercial release of GM canola (DIR 20/2002)	9
Finalised applications for DIR licences	9
Finalised applications for DNIR licences	9
Notifications of notifiable low risk dealings received	9
Existing licences and other instruments	10
Renewal of transitional instruments	10
Confidential commercial information	11

Monitoring and compliance	12
Monitoring and compliance strategy	12
Monitoring and compliance protocols	13
Overview of monitoring and compliance for the reporting period	13
Monitoring conducted	14
Inspection of contained facilities	15
Monitoring findings	16
Monitoring and compliance reviews	17
Audits	19
Deemed authorisations post - 21 June 2003	19
PART 3 Committee operations	20
Gene Technology Community Consultative Committee	20
Gene Technology Ethics Committee	20
Gene Technology Technical Advisory Committee	21
PART 4 Other activities	22
Reviews	22
International collaboration and coordination	22
Advice on gene technology regulation	23
Presentations and meetings	23
Institutional Biosafety Committees training sessions	23
OGTR website	23
OGTR email address and freecall number	24
Freedom of information	24
Consultants	24
Appendix A	25
Appendix B	27
Appendix C	39

Glossary

Accredited organisation	An organisation that is accredited under section 92 of the Act
Act	<i>Gene Technology Act 2000</i>
APVMA	Australian Pesticides and Veterinary Medicines Authority
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 in accordance with the Regulator's <i>Guidelines for Certification of Facilities/Physical Containment Requirements</i>
RARMP	Risk assessment and risk management plan
Regulations	<i>Gene Technology Regulations 2001</i>
Regulator	Gene Technology Regulator
Spot checks	Unannounced visits by the OGTR Monitoring and Compliance Section
Volunteer	Regrowth of plants from seed that has remained on a site after a trial has been completed

Introduction

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

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

Structure of this report

This report is divided into four parts:

Part 1 outlines activities and outcomes achieved in relation to the implementation and management of the national regulatory system during the July–September 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:

Office of the Gene Technology Regulator

MDP 54 PO Box 100

WODEN ACT 2606

Email: ogtr@health.gov.au

Website: www.ogtr.gov.au

Telephone: 1800 181 030

Fax: (02) 6271 4202

PART 1 National regulatory system

Key achievements during this quarter

The key achievements of the July–September 2003 quarter were:

Licences and other instruments

- considered 10 applications and issued one licence for a dealing involving intentional release of a GMO into the environment (DIR licence)
- issued 32 licences for dealings not involving intentional release of GMOs into the environment (DNIR licences)
- received 112 notifiable low risk dealing (NLRD) notifications
- accredited 7 organisations
- certified 125 contained facilities.

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

Monitoring and compliance

Approximately 26 per cent of current field trial sites and 10 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.

Australian Government agency liaison

The Regulator signed a bilateral memorandum of understanding with Food Standards Australia New Zealand (FSANZ).

OGTR's liaison with Australian Government agencies is discussed below – see 'Australian Government agency liaison'.

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 GTMC met on the 31 July 2003 and agreed to issue the Gene Technology (Recognition of Designated Areas) Principle 2003. Subsequently the Policy Principle was gazetted in the *Commonwealth Government Special Gazette No. S340* on 5 September 2003 and tabled in both houses of the Australian parliament on 9 September 2003. It was issued for the purpose of recognising areas (if any) designated under a state law for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes.

The Chair for this meeting was the Australian Government Parliamentary Secretary to the Minister for Health and Ageing. At the conclusion of the meeting the Queensland Minister for Innovation and Information Economy was appointed as the new Chair for a 12 month period.

Further information about this meeting can be obtained from the joint communique attached to this report (Appendix A). Previous communiqués can also be found on the GTMC secretariat webpage at www.health.gov.au/tga/gene/communiq.htm

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 GTSC held a teleconference on 25 July 2003 to finalise the agenda and papers for the 31 July 2003 GTMC meeting.

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.

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 8 applications for DIR licences.

Further information is set out in Part 2.

In addition, the Regulator signed a bilateral memorandum of understanding with FSANZ. Memoranda of understanding outline the operation and the nature of the close working relationship between the OGTR and an agency or authority prescribed for consultation under the Act. This helps each agency meet their

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.

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

respective legislative requirements, exchange information and implement administrative procedures in efficient and cooperative ways.

Public participation

During the quarter, the Regulator issued invitations to the public to comment on 6 RARMPs prepared for applications for DIR licences. The invitation was issued via email or post to people who have registered on the OGTR mailing list and via advertisements in:

- the *Australian Government Notices Gazette*
- *The 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.

PART 2 Regulation of genetically modified organisms

Part 2 of the report outlines the regulatory activity undertaken during the July–September 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 any breaches of conditions of a GMO licence that have come to the Regulator’s attention. Information on the auditing and monitoring of dealings with GMOs and information on confidential commercial information (CCI) applications has also been included.

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 July–30 September 2003

Application type	Number received	Number approved ¹
DIR licence	2	1
DNIR licence	14	32
Accreditations	2	7
Certifications	44	125

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 30 September 2003, of applications for a DIR licence subject to evaluation during the quarter

Application received	In progress	First round of consultation ¹	Second round of consultation	Licence issued
DIR 042/2003	DIR 041/2003	DIR 032/2002	DIR 034/2003	DIR 021/2002
DIR 043/2003		DIR 043/2003	DIR 035/2003 DIR 036/2003 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.

Applications received for DIR licences

The OGTR received 2 applications for DIR licences in the July–September 2003 quarter as follows:

- DIR 042/2003 'Field trial - Field evaluation of white clover transformed to resist infection by Alfalfa Mosaic Virus and Clover Yellow Vein Virus' (Commonwealth Scientific & Industrial Research Organisation - CSIRO)
- DIR 043/2003 'Field trial - Preliminary agronomic assessment of high sulphur lupin' (University of Western Australia).

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

In-progress applications for DIR licences

In this quarter, an application for the following licence underwent the initial stages of evaluation but has not yet progressed to the consultation phase.

- DIR 041/2003 'Post-field trial monitoring for licences PR64, PR64X, PR64X(2) and PR67 concerning white clover transformed to resist infection by Alpha Mosaic Virus' (Department of Primary Industries, Victoria).

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 hybrid canola' (Bayer CropScience)
- DIR 43/2003 'Field trial - Preliminary agronomic assessment of high sulphur lupin' (University of Western Australia).

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

- 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).

Clock stopped on applications for commercial release of GM canola (DIR 20/2002)

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 continued the clock stop on the assessment of application DIR 020/2002 'General release of Roundup Ready[®] canola (*Brassica napus*) in Australia' (Monsanto) which was put on hold in November 2002 pending provision of information by the applicant.

Finalised applications for DIR licences

During the quarter, the Regulator issued 1 DIR licence:

- DIR 021/2002 'Commercial release of Invigor[®] canola for use in the Australian cropping system' (Bayer CropScience).

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 32 DNIR licences. Further information about these licences is contained in Appendix B 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 112 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 July–September 2003 quarter.

Applications received and decisions made; existing licences and other instruments, 1 July–30 September 2003

Type	Number received	Number processed ¹
Surrender of certification	12	54
Variation of certification	31	17
Variation of DIR licence ²	10	4
Variation of DNIR licence	17	11
Varied accreditation	2	3

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.

Renewal of transitional instruments

The transitional provisions in the Act enabled dealings with GMOs that were authorised by the Genetic Manipulation Advisory Committee (GMAC) under the previous voluntary system to be transferred into the new regulatory system.

Over 3000 'Advices to proceed' issued by GMAC for the equivalent of the current DIRs, DNIRs, NLRDs, transitional arrangements for accreditations of organisations, and certifications of contained facilities were recognised under the Act until 21 June 2003.

During the two-year transitional period, since commencement of the Act on 21 June 2001, the OGTR undertook a phased program of renewal of these deemed instruments, details of which were reported in previous quarterly reports.

At the end of the transitional period lists were compiled of licences and instruments that were not accounted for and letters were sent to the organisations involved. The letters asked the organisations to cease work on any dealings not covered by a licence or not notified to the Regulator, and to remove GMOs from facilities no longer certified. As reported in the Monitoring and Compliance Section, spot checks were made on a number of these organisations to validate information held and to ensure compliance with requirements for lapsed GMO dealings.

This process has represented a very significant component of the overall workload of the office since its establishment. The outcomes are summarised below:

Approved	Original Number	Replaced	Comment
DIRs	109	11	60 trials completed and post harvest monitoring signed off prior to 20 June 2003. 38 required post harvest monitoring past 20 June 2003.
DNIRs	506	227	87 reclassified as NLRDs, 192 no longer required and allowed to expire. Some combine several previous approvals and others extend initial scope of work.
NLRDs	1266	396	870 no longer required and allowed to expire. Some combine previous approvals.
Certifications	1673	1143	524 no longer required and surrendered, 6 renewal applications have had the 'clock stopped'.
Accreditations	119	101	18 no longer required and surrendered.

Confidential commercial information

Under the Act a person may apply for a declaration from the Regulator that specified information is CCI. The Act protects confidential information that the Regulator has declared CCI, as well as confidential 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 4 CCI applications in relation to applications for DIR licences and 1 CCI application in relation to an application for a DNIR licence.

The Regulator made 8 CCI declarations in relation to applications for DIR licences, and 1 declaration in relation to an application for a DNIR licence.

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 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 target is under review due to overlap with certification renewal processes, in which all PC4, PC3 and PC2 large-scale facilities that previously held deemed certifications were inspected by the OGTR in 2002.

As reported previously, a major review was undertaken of the *Guidelines for Certification of Facilities/Physical Containment Requirements*, which were based on GMAC's previous guidelines. *Guidelines for Certification of PC2 Facilities/ Physical Containment 2 Requirements* have been released and provided to all accredited organisations. These new guidelines came into force in August 2003. Work is continuing on revising guidelines for PC2 large-scale, PC3 and PC4 facilities.

Monitoring and compliance protocols

The Monitoring and Compliance Section has developed a range of documents to provide organisations and interested parties with guidance on monitoring and compliance activities under the Act. Monitoring and compliance activities are subject to continual improvement and these protocols are recorded in working documents that are updated to reflect improvements made to the system. Links to the protocols are provided on the OGTR website at www.ogtr.gov.au.

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored. During the July–September 2003 quarter, 54 monitoring visits were carried out on 54 sites. No follow-up visits were identified as being required this quarter. Monitoring was carried out on 8 licences and covered 7 plant species.

Current field trial sites monitored. Of the 31 sites current in the quarter, 8 were monitored. This represents a monitoring rate of 26 per cent of all current sites for the quarter.

Post-harvest field trial sites monitored. Of the 450 sites subject to post-harvest monitoring in the quarter, 46 were monitored. This represents a monitoring rate of 10 per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of contained dealings. During the July–September 2003 quarter, 5 organisations holding 7 DNIR licences were monitored. Also as part of the monitoring program 25 facilities were monitored which encompassed PC3 laboratories (1 visited), PC2 laboratories (16 visited), PC2 plant houses (4 visited) and PC2 animal houses (3 visited) across 12 organisations.

Monitoring conducted

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

Licensed organisation name	Licence number ¹	No. sites visited	Site status ²	GMO type
Bayer CropScience Pty Ltd	DIR 010/2001	1	C	Canola
		12	PHM	Canola
		8	PHM	Indian Mustard
Bureau of Sugar Experiment Stations	DIR 019/2002	1	C	Sugarcane
		1	PHM	Sugarcane
CSIRO	DIR 017/2002	2	PHM	Sugarcane
Department of Agriculture (Western Australia)	DIR 009/2001	5	PHM	Lupins
Monsanto Australia Limited	DIR 011/2001	2	C	Canola
		16	PHM	Canola
Queensland Department of Primary Industries	DIR 028/200	2	C	Pineapple
		1	PHM	Cotton
The University of Queensland	DIR 026/2002	1	C	Papaya
	DIR 027/2002	1	C	Pineapple
		1	PHM	Pineapple
Totals	8	54	C=8 PHM=46	7 Species

1 DIR= Dealing Involving Intentional Release

2 C= current, PHM = post-harvest monitoring

The total monitoring coverage for DNIRs during the 1 July to 30 September 2003 quarter is shown in the following table.

Licenced organisation name	Licence number ¹
Australian Army Malaria Institute	DNIR 071/2002
Queensland University of Technology	DNIR 162/2002 DNIR 163/2002 DNIR 129/2002
The University of Adelaide	DNIR 165/2002
The University of Southern Queensland	DNIR 028/2002
Xenome Limited	DNIR 165/2002
Total	7

1 DNIR = Dealing Not Involving Intentional Release

Inspection of contained facilities

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
Australian Army Malaria Institute	PC2 Laboratory	2
	PC2 Insectary	1
Australian Red Cross Blood Service Endeavour	PC2 Laboratory	2
Bureau of Sugar Experiment Stations	PC2 Plant House	1
Griffith University	PC2 Animal House	1
	PC3 Laboratory	1
Queensland University of Technology	PC2 Laboratory	2
	PC2 Plant House	2
Royal North Shore Hospital	PC2 Laboratory	2
The Australian Museum	PC2 Laboratory	1
The Queen Elizabeth Hospital and Health Service	PC2 Laboratory	1
The University of Adelaide	PC2 Laboratory	2

The University of Southern Queensland	PC2 Laboratory	1
	PC2 Animal House	1
The University of Technology, Sydney	PC2 Laboratory	2
	PC2 Plant House	1
	PC2 Animal House	1
Xenome Limited	PC2 Laboratory	1
Totals	5 facility types	25

Monitoring findings

This section reports on the final outcomes of routine monitoring activities.

During the quarter, two issues were identified as requiring further attention. A summary of each follows.

Licence number and site	DIR 028/2002 Maroochy Research Station Redlands Research Station
Summary of dealing	Licence relates to field trials of pineapple (<i>Ananas comosus</i>) modified for blackheart reduction and to delay flowering.
Findings	At the time of inspection, OGTR observed that at the Maroochy Research Station, GM pineapple plants were being held at a secure location on the station to 'sun harden' prior to planting, but were not in an OGTR certified PC2 Plant House and not at the location specified in DIR 028/2002. The OGTR also observed that no appropriate signage was evident to indicate the trial site locations at either Maroochy or Redlands Research Stations.
Risk assessment	The OGTR risk assessment concluded these issues posed negligible risk of dissemination of the GMO due to the plants not flowering and being located in the security of a research station.
Risk management	The accredited organisation is to ensure that: <ul style="list-style-type: none"> all GM pineapple plants are re-located and retained in a certified PC2 Plant House or planted at the location stated in the licence, and; appropriate signage be displayed at the trial site locations at Maroochy and Redlands Research Stations.

Licence number and site	DIR 028/2002, Site 1
Summary of dealing	Licence relates to a field trial of cotton (<i>Gossypium hirsutum</i>) (formerly covered under PR 141) expressing the Cry1AC delta-endotoxin from <i>Bacillus thuringiensis</i> . The trial is in the post-harvest monitoring phase.
Findings	At the time of inspection, over a thousand cotton plants were observed on the trial site. Several hundred of these cotton plants were mature with many already having set seed.
Risk assessment	The OGTR risk assessment was that there was a negligible risk to the environment or human health due to the containment procedures in place on the trial site.
Risk management	Due to the continuing persistence of GM cotton plants, the accredited organisation was advised to undertake deep cultivation of the site to destroy any plants and bury any viable root stock. The accredited organisation was asked to provide evidence to the OGTR that this management had taken place within 30 days of receiving the request.

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 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 facilities have been reviewed and the remainder are in progress to remove ambiguity and provide more effective guidance for all parties working with the document.

Further information on the review of the guidelines is contained in Part 4 of this report.

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 effects 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:

Issue	The CSIRO Plant Industry, Black Mountain Canberra, reported an incident where a break-in and theft of experimental GM poppy plants and poppy seeds occurred. The dealing was a NLRD and the subsequent inquiry and review conducted by both the OGTR and CSIRO into the circumstances of the break-in and theft established that the seeds were not mature on the small quantity of stolen plants. They were not considered viable nor likely to propagate. The matter was also referred to the police.
Risk assessment	Due to the unviable nature and maturity of the plants, the OGTR risk assessment concluded that this incident posed negligible risk to human health and the environment.
Determination	The CSIRO facility had been appropriately certified and maintained. The perpetrators are unknown.
Risk management	CSIRO has tightened security at the facility to minimise the likelihood of any similar incident occurring.
Action	No further action. If additional information is obtained from the police the OGTR will conduct further inquiries.
Issue	The Department of Primary Industries (Victoria), reported an incident where small quantities of GM canola seed had been inadvertently sown in small scale variety trials at two sites in Victoria as part of a collaborative canola breeding program with Cargill Pty Ltd (Canada). When Cargill identified their inadvertent inclusion of two lines of GM seed in the trial material, the Department of Primary Industries removed the GM canola plants, including the two adjacent non-GM plots sown immediately after the GM canola plots. All plants were removed prior to flowering and destroyed by autoclaving.

Risk assessment	The OGTR risk assessment was that this incident posed negligible risk to human health and safety and the environment. The risk was mitigated by early advice from the company, the expedient actions taken by the Department of Primary Industries to destroy the plants and the absence of mechanisms for the GMO to disseminate off site (such as movement of stock or farm equipment).
Determination	It was determined that the plant material had been disposed of in accordance with the OGTR's regulatory requirements.
Risk management	The OGTR has established arrangements with the Department of Primary Industries to ensure the site is regularly monitored and any late germinating GM canola plants are controlled. The Department of Primary Industries and Cargill Pty Ltd are undertaking a comprehensive review of their procedures for importing and receiving canola seed into Australia and have provided the OGTR with evidence to show they have revised their systems to ensure that similar incidents do not occur in the future.
Action	No further action.

Audits

No audits were completed in the quarter

Deemed authorisations post - 21 June 2003

During the July–September 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 Authorisations on 21 June 2003
Name	The University of Queensland Queensland Institute of Medical Research
Issues	The expiry of authorisations 'deemed' under the Act during the two-year transitional period ended on 21 June 2003. The OGTR Monitoring and Compliance Section conducted unannounced spot checks in order to validate information and to ensure compliance with lapsed GMO dealings.
Determination	The unannounced inspections validated and confirmed that both the organisations were compliant with the Act.
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

The GTCCC did not hold a meeting during the quarter, however, working groups previously established to work on a range of priority areas engaged in out-of-session activity between meetings. Two of the working groups held meetings in this quarter focusing on revising draft papers and drafting new papers for consideration at the next meeting of the Committee which will be held in December 2003.

Further information about these issues under consideration by the GTCCC can be obtained from the June 2003 meeting communique attached to the April–June 2003 Quarterly Report and are also available on the OGTR website at www.ogtr.gov.au. Previous communiqués can also be found on the OGTR website.

Gene Technology Ethics Committee

The GTEC did not hold a meeting during the quarter, however, working groups previously established to work on a range of priority areas have been engaged in out-of-session activity between meetings. Members have been focusing on revising draft papers and drafting new papers for consideration at their next meeting scheduled for November 2003.

Further information about the issues under GTEC consideration can be obtained from the April 2003 meeting communique attached to the April–June 2003 Quarterly Report and is also available on the OGTR website

at www.ogtr.gov.au. Previous communiques can also be found on the OGTR website.

Gene Technology Technical Advisory Committee

During the quarter GTTAC held a teleconference on 24 July 2003 and a face-to-face meeting in Canberra on 18 September 2003. At these meetings the Committee considered:

- 1 application for a DIR licence
- 5 RARMPs for DIR licences
- 11 applications for DNIR licences and associated RARMPs
- new certification guidelines for contained facilities.

At these meetings the Committee discussed presentations and papers on topics including antibiotic resistance genes in GMOs in Australia, the precautionary principle and evolved glyphosate resistance worldwide.

In addition, the Committee considered 7 applications for DNIR licences and the associated RARMPs out-of-session.

The ninth GTTAC communique, outlining discussions held at the May 2003 and July 2003 meetings, is attached to this report at Appendix C. GTTAC is scheduled to meet again by teleconference in October 2003.

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 dealings involving intentional release of GMOs, 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. Following an OGTR review, draft revised guidelines were released for wide consultation ending on 30 September 2002. A total of 57 submissions were received and evaluated.

As reported in the last quarterly report, on 30 June 2003, revised guidelines were released for PC2 laboratories, plant containment facilities and animal containment facilities, to take effect on 1 August 2003. Minor revisions were made to these three guidelines, to resolve inconsistencies identified in early feedback from IBCs. These revisions, along with a guideline for PC2 constant temperature rooms, were released to take effect on 7 August 2003. Work is continuing on the revision of the remainder of the guidelines.

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:

- A meeting between the Regulator and Dr Gabrielle Persley, in her capacity as a Kenyan Government consultant regarding a Canadian government funded aid project for capacity building in gene technology.
- The OGTR attended the Biological and Toxic Weapons Convention – Experts Meeting during the period 21 – 29 August 2003 in Geneva, Switzerland.

- A visit to OGTR by Professor Diran Makinde, from the University of Venda for Science and Technology, South Africa and AfricaBio during the week of 25 August 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:

- Conducted a briefing on gene technology for Australian Pesticides and Veterinary Medicines Authority staff on 4 July 2003 at their Canberra, ACT offices
- Participated in the Crop Pollination Annual Conference on 15 August 2003 in Young, South Australia (SA)
- Presented “*Gene Technology Regulation and Agricultural Biotechnology*” on 17 August 2003 at the Aus Biotech 2003 forum in Adelaide, SA
- Attended the New South Wales (NSW) Agricultural Advisory Council on Gene Technology on 20 August 2003 in Sydney, NSW
- Presented “*Australia’s Policy and Regulatory Framework for Gene Technology*” at the Australian Quarantine and Market Access Forum on 24 September 2003 in Canberra, ACT.

Institutional Biosafety Committees training sessions

OGTR regularly provides training sessions to organisations and IBCs. During the July–September 2003 quarter, sessions were conducted at Monash University, Ballarat University, Dow Agrosiences, Therapeutic Goods Administration, La Trobe University and at the Health and Safety Conference at Queensland University.

OGTR website

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

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

The most popular downloaded documents were:

- Handbook on the regulation of gene technology in Australia
- The biology and ecology of pineapple (*Ananas comosus* var. *comosus*)
- Fact sheet on the GMO regulatory system
- Guidelines for the certification of PC2 facilities/Physical containment level 2 requirements
- IBC Facility Checklist – PC4 Plant House

The OGTR welcomes any 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 203 calls and 508 emails in July 2003, 178 calls and 438 emails in August 2003, and 119 calls and 463 emails in September 2003.

Freedom of information

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

Consultants

During the reporting period, the OGTR managed one consultancy contract worth a total of \$24,808. The table below lists the consultants, describes the purpose of the consultancy and the amount paid during the quarter. The amount paid is net of GST.

Consultant	Amount paid (GST exclusive)	Purpose
Dialog Information Technology	\$24,808	Develop Gene Technology Information Management System (GTIMS)
Total Consultants for quarter	\$24,808	

Appendix A

GENE TECHNOLOGY MINISTERIAL COUNCIL

JOINT COMMUNIQUE

July 31st 2003

The Gene Technology Ministerial Council at its second annual meeting, held today in Perth, agreed to the issuing of a policy principle that would bring greater legislative certainty to States and Territories who wished to designate specific areas for either genetically modified (GM) or non-GM crops, based on marketing considerations. The Northern Territory Government abstained.

The Gene Technology Ministerial Council oversees the national regulatory framework for gene technology in Australia. This is a nationally cooperative scheme involving all States and Territories. The scheme began on 21 June 2001 with the commencement of the *Gene Technology Act 2000* and has been characterised by a continuously high level of collaboration throughout its development and implementation.

A key part of the scheme is the provision for policy principles that may be issued by the Ministerial Council to establish parameters for the national regulatory system. They also govern the work of the Gene Technology Regulator.

Ministers agreed today to issue its first Policy Principle which has undergone extensive consultation and assessment.

“This principle will mean that the Gene Technology Regulator will recognise States’ rights to designate under State law special areas that are for either GM or non-GM crops for market purposes,” the chair of today’s meeting, Commonwealth Parliamentary Secretary for Health, Ms Trish Worth, said.

The Ministerial Council on Gene Technology comprises Commonwealth and State and Territory Ministers from a range of portfolios including health, agriculture and the environment.

On the second anniversary of the national gene technology regulatory scheme, Ministers restated their support for the regulatory framework and the Office of the Gene Technology Regulator.

Ministers agreed that, while the gene technology regulatory scheme is scheduled for review in a further two years, the strong regulatory system implemented through nationally consistent legislation was working well, ensuring the protection of public health and safety and the environment.

Media contact: Kay McNiece, Gene Technology Ministerial Council, 0412 132 585

Appendix B

DNIR Licences issued 1 July–30 September 2003

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 207/2003	18 Feb 2003	1 Jul 2003	University of New England, NSW	Molecular aspects of plant-pathogen interactions - <i>Thielaviopsis</i>	The aim of this dealing is to identify genes in <i>T. basicola</i> (a pathogen causing black root disease in plants) which may be involved in virulence.
DNIR 213/2003	4 Mar 2003	15 Aug 2003	Alpharma Animal Health Pty Ltd, VIC	Porcine growth hormone	The aim of this dealing is to continue the commercial production of porcine somatotropin which is sold into Australian and international markets under the tradename Reporcin®.
DNIR 216/2003	21 Mar 2003	28 Jul 2003	The University of Melbourne, VIC	Development of <i>Trichoderma harzianum</i> for biocontrol of plant pathogens	The aim of this dealing is to improve the biocontrol efficacy of <i>T. harzianum</i> by inserting the chitinase gene into its genome.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 217/2003	24 Mar 2003	1 Aug 2003	The University of Western Australia, WA	Structure/activity studies of novel toxins from native venomous organisms (Jellyfish)	The aim of this dealing is to produce milligram quantities of toxic jellyfish venom proteins by expressing them in a bacterial host and assess their activity.
DNIR 218/2003	25 Mar 2003	4 Aug 2003	CSIRO – Sustainable Ecosystems, ACT	Generation of recombinant canine herpesviruses (CHVs)	The aim of this dealing is to develop recombinant CHVs that express heterologous antigens derived from genomic, viral or bacterial genes and use the viruses to immunise foxes, dogs and ferrets against infectious diseases and/or to reduce their fertility.
DNIR 219/2003	25 Mar 2003	4 Aug 2003	Centenary Institute, NSW	Recombinant mycobacteria as new anti-tuberculosis vaccines	The aim of this dealing is to express <i>Mycobacterium tuberculosis</i> antigens in the vaccine strain <i>M. bovis</i> BCG to develop a potential tuberculosis vaccine.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 220/2003	27 Mar 2003	6 Aug 2003	Menzies School of Health Research, NT	Cloning of streptococcal DNA to and from streptococcal species	The aim of this dealing is to understand how streptococcal gene products contribute to the pathogenesis of streptococcal infections by inserting the genes of interest into strains of streptococci that do not normally harbour these genes.
DNIR 221/2003	27 Mar 2003	6 Aug 2003	Queensland Institute of Medical Research, QLD	Cloning of DNA between group A streptococcal strains	The aim of this dealing is to understand how group A streptococcal (GAS) gene products contribute to the pathogenesis of streptococcal infections by inserting the genes of interest into GAS strains that do not normally harbour these genes.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 222/2003	27 Mar 2003	6 Aug 2003	Queensland Institute of Medical Research, QLD	Expression of virus encoded antigens using vaccinia expression systems	The aim of this dealing is to study cell lines infected with vaccinia viruses containing genes encoding <i>Epstein-Barr virus</i> (EBV) and <i>Cytomegalovirus</i> antigens.
DNIR 223/2003	31 Mar 2003	8 Jul 2003	Institute of Medical and Veterinary Science, SA	Identification of novel molecular targets in angiogenesis	The aim of this dealing is to identify genes involved in endothelial cell function by overexpressing genes of interest in human endothelial cells and mice using viral vectors.
DNIR 224/2003	2 Apr 2003	14 Jul 2003	Macfarlane Burnet Institute for Medical Research, VIC	Molecular virology of <i>Hepatitis A, B and E</i> viruses	The aim of this dealing is to investigate the role of various hepatitis genes and gene products in the gene expression, replication, virus particle assembly and pathogenesis of <i>Hepatitis A, B and E</i> .

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 225/2003	3 Apr 2003	13 Aug 2003	Ludwig Institute for Cancer Research, VIC	Mouse models of colorectal cancer using a TVA based retroviral gene transfer system	The aim of this dealing is to investigate the role of various genes in colorectal cancer by transferring candidate oncogenes and a tumour suppressor gene directly into the intestinal epithelium of mice using an avian retrovirus.
DNIR 227/2003	14 Apr 2003	1 Aug 2003	University of Western Australia, WA	Structure/activity studies of novel toxins from native venomous organisms (Brown snake)	The aim of this dealing is to introduce genes encoding brown snake venom proteins into bacterial and/or eukaryotic hosts to produce milligram quantities of these proteins for biophysical and functional studies.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 232/2003	22 Apr 2003	7 Jul 2003	University of Newcastle, NSW	HIV vaccine design and development teams	The aim of this dealing is to develop a safe and effective vaccine against HIV using a mouse model using DNA vaccines and recombinant fowlpoxvirus vaccines to induce both mucosal and systemic HIV-specific immune responses.
DNIR 233/2003	22 Apr 2003	28 Aug 2003	Murdoch University, WA	Mutation of an infectious clone of BIV R29	The aim of this dealing is to investigate the role of accessory genes in <i>Bovine immunodeficiency virus</i> (BIV) by creating point mutations in these genes which result in either a deletion or truncation of the proteins they encode.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 234/2003	22 Apr 2003	28 Aug 2003	Murdoch University, WA	Transcomplementation of <i>vif</i> deleted BIV with <i>Bovine lentivirus</i>	The aim of this dealing is to determine whether there is functional homology between the Vif and Tmx proteins from <i>Bovine immunodeficiency virus</i> (BIV) and the related <i>Jembrana disease virus</i> .
DNIR 235/2003	22 Apr 2003	28 Aug 2003	Murdoch University, WA	Use of an infectious clone of BIV R29	The purpose of this dealing is to use an infectious clone of <i>Bovine immunodeficiency virus</i> (BIV) as a standard in molecular biological tests.
DNIR 236/2003	23 Apr 2003	9 Jul 2003	Women's and Children's Hospital, SA	Functional analysis of genes involved in haemopoiesis by retroviral expression in human cells and cell lines	This project aims to investigate the function of various genes involved in normal and abnormal growth of human blood cells.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 238/2003, 239/2003, 240/2003, 241/2003	12 May 2003	16 Sep 2003	Murdoch University, WA	Mutational analysis and production of infectious clones of the Australian strains of <i>Porcine circovirus type 1</i> and type 2 (PCV-1 and PCV-2)	The aim of these dealings is to investigate the importance of particular coding regions, conserved motifs and domains in the genomes of both PCV-1 and PCV-2 by creating mutations in these genes and to clone full-length genomes of PCV-1 and PCV-2 to be used in further studies and as standards in diagnostic techniques.
DNIR 242/2003	15 May 2003	7 Jul 2003	University of Queensland, QLD	Investigating the molecular pathways controlling cell survival in acute and chronic renal failure	The aim of this dealing is to modify renal disease processes by using replication defective lentiviruses to overexpress various genes associated with apoptosis (programmed cell death) in the rats and mice.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 243/2003	15 May 2003	12 Aug 2003	University of Melbourne, VIC	Investigating the biological requirements for prion formation	The aim of this dealing is to transform bacterial, fungal and mammalian cells with the gene encoding the prion protein (PrP) and use these cells to study PrP function and metabolism.
DNIR 247/2003	26 May 2003	30 Sep 2003	Virax Holdings Limited, VIC	GMP manufacturing of recombinant <i>Fowlpox virus</i> vectored vaccines	The researchers intend to undertake large-scale production of recombinant <i>Fowlpox virus</i> vector-based vaccines from tissue cultured avian cells.
DNIR 248/2003	26 May 2003	30 Sep 2003	CSL Limited, VIC	Production of Neovac antigens	The aim of this dealing is to produce four types of recombinant pili antigens to be used in the manufacture of a vaccine against neonatal scours in pigs.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 249/2003	28 May 2003	1 Jul 2003	University of Adelaide, SA	Studies of <i>avian Hepatitis B viruses</i> (HBV) – virulence, replication and pathogenesis	The aim of this dealing is to study the growth characteristics, replication and pathogenesis of different <i>avian Hepatitis B virus</i> (avian HBV) strains by transfecting cultured cells or ducklings with plasmids containing clones of full-length wild type and mutated viral genomes.
DNIR 252/2003	10 Jun 2003	9 Jul 2003	University of Technology, Sydney, NSW	Paralysis tick vaccine development	The aim of this dealing is to produce recombinant forms of Australian paralysis tick (<i>Ixodes holocyclus</i>) salivary proteins for the development of a veterinary vaccine.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 255/2003	25 Jun 2003	8 Aug 2003	Griffith University, QLD	Studies on the virulence and physiology of <i>Burkholderia pseudomallei</i>	The aim of this dealing is to identify and characterise virulence genes in the pathogen <i>B. pseudomallei</i> , including those involved in adherence to epithelial cells, and to develop diagnostic and preventative strategies.
DNIR 258/2003	20 Jun 2003	5 Aug 2003	Australian Red Cross Blood Service, NSW	Cell mediated immune responses against blood-borne viral pathogens	This study aims to express genes from human pathogenic viruses in mammalian cell cultures for use as targets in cytotoxic T lymphocyte (CTL) activity assays or antigen presenting cells to stimulate virus-specific CTLs in vitro.
DNIR 263/2003	21 Jul 2003	9 Sep 2003	University of Technology Sydney, NSW	Development of recombinant immunotoxins	The aim of this dealing is to develop a recombinant cytotoxic agent from an ant venom peptide that can be used as a therapeutic agent for selected cancers.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 264/2003	23 Jul 2003	19 Sep 2003	Western Sydney Area Health Service, NSW	Liver cell biology and liver injury, metabolic liver disease and mitochondrial dysfunction in drug- induced liver disease	The aim of this dealing is to use mice and rats with experimentally induced liver injury to identify cellular proteins that mediate important liver injury resulting from medical conditions or after exposure to alcohol and drug toxins.

**GENE TECHNOLOGY TECHNICAL ADVISORY
COMMITTEE**

**COMMUNIQUE
No. 9**

This is the ninth communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the fourteenth and fifteenth meetings of GTTAC held on 22 May 2003 and 24 July 2003 respectively, as well as matters considered by GTTAC out-of-session in the period from 10 April 2003 to 24 July 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
<p>DNIR 163/2003</p> <p>The development of glycine mosaic comovirus (GMV) as a vector for heterologous gene expression in plants.</p>	<p>The aim of this dealing is to develop GMV based vectors to express genes in plants.</p>	<p>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.</p>
<p>DNIR 178/2003</p> <p>Functional and molecular analysis of defects of the mitochondrial electron transport chain.</p>	<p>The aim of this dealing is to study human cells that have a metabolic defect of the mitochondrial energy production pathways to determine on which chromosome the disease causing gene is located. These cells will be transformed with a gene to immortalise them prior to study.</p>	<p>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.</p> <p>GTTAC advised that laboratory guidelines must be followed and that the use of sharp instruments should be avoided where possible.</p> <p>GTTAC requested that the applicant should be asked why they have chosen this method of immortalising cells.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 186/2003</p> <p>Molecular virology of HIV-1 and SIV.</p>	<p>The aim of this dealing is to analyse the structure/function relationship between wild type and mutant viral genes and elements in HIV-1 and SIV to understand their role in viral gene expression, replication, particle assembly and pathogenesis.</p>	<p>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.</p> <p>GTTAC advised that laboratory guidelines must be followed and that the use of sharp instruments should be avoided where possible.</p> <p>GTTAC also advised that laboratory workers should be warned of an increased risk to people who are immunosuppressed.</p>
<p>DNIR 187/2003</p> <p>Viral Assembly of Moloney murine leukaemia virus (MoMLV), Mason-Pfizer monkey virus (M-PMV), human foamy virus (HFV) and avian sarcoma / eukosis virus (ASLV).</p>	<p>The aim of this dealing is to understand the role of various MoMLV, M-PMV, HFV or ASLV genes by transfecting mammalian cells with mutated or wild type clones of these retroviruses.</p>	<p>As for DNIR 186/2003.</p>
<p>DNIR 188/2003</p> <p>Pathogenesis of macrophage-tropic HIV-1.</p>	<p>The aim of this dealing is to examine the ability of HIV-1 strains to induce cell killing by transfecting mammalian cell lines with HIV-1 DNA.</p>	<p>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.</p> <p>GTTAC advised that laboratory guidelines must be followed and that the use of sharp instruments should be avoided where possible.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 194/2003</p> <p>Evaluation of cellular immunological function with recombinant virus.</p>	<p>The aim of this dealing is to evaluate if a treatment can augment or sustain HIV positive patients' cellular immune response to HIV and help further define the mechanisms involved.</p>	<p>As for DNIR 188/2003.</p>
<p>DNIR 203/2003</p> <p>Construction and use of herpes simplex virus mutants</p>	<p>The aim of this dealing is to determine how minor changes to the HSV viral protein gB will alter the response of cytotoxic T lymphocytes (immune cells) by infecting mice with HSV-1 gB mutants.</p>	<p>As for DNIR 188/2003.</p> <p>GTTAC suggested that the applicants consider using a cannula to deliver GMOs to mice.</p>
<p>DNIR 207/2003</p> <p>Molecular aspects of plant-pathogen interactions - Thielaviopsis</p>	<p>The aim of this dealing is to identify genes in <i>T. basicola</i> (a pathogen causing black root disease in plants) which may be involved in virulence.</p>	<p>As for DNIR 163/2003.</p> <p>GTTAC advised that extra care should be taken to ensure that waste and equipment potentially contaminated with fungal spores is successfully decontaminated.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 208/2003</p> <p>Recombinant murine cytomegalovirus (MCMV) encoding hepatitis C virus (HCV) proteins.</p>	<p>The aim of this dealing is to insert genes encoding HCV proteins into MCMV. The recombinant MCMV will be used as a delivery system to express HCV proteins in murine liver.</p>	<p>As for DNIR 188/2003.</p>
<p>DNIR 216/2003</p> <p>Development of <i>Trichoderma harzianum</i> for biocontrol of plant pathogens</p>	<p>The aim of this dealing is to improve the biocontrol efficacy of <i>Trichoderma harzianum</i> by inserting the chitinase gene into its genome.</p>	<p>As for DNIR 163/2003.</p>
<p>DNIR 217/2003</p> <p>Structure/activity studies of novel toxins from native venomous organisms (jellyfish)</p>	<p>The aim of this dealing is to produce milligram quantities of toxic jellyfish venom proteins by expressing them in a bacterial host. The structure and activity of these proteins will be assessed.</p>	<p>As for DNIR 163/2003.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 218/2003</p> <p>Generation of recombinant canine herpesviruses (CHV)</p>	<p>The aim of this dealing is to develop recombinant CHVs that express heterologous antigens derived from genomic, viral or bacterial genes. These viruses will be used as experimental vaccines to immunise foxes, dogs and ferrets against infectious diseases and/or to reduce their fertility.</p>	<p>As for DNIR 163/2003.</p>
<p>DNIR 219/2003</p> <p>Recombinant mycobacteria as new anti-tuberculosis vaccines</p>	<p>The aim of this dealing is to express mycobacterium tuberculosis antigens in the vaccine strain <i>mycobacterium bovis</i> bacillus Calmette-Geurin. The recombinant bacteria will be tested as a vaccine against tuberculosis.</p>	<p>As for DNIR 163/2003.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 222/2003</p> <p>Expression of virus encoded antigens using vaccinia expression systems</p>	<p>The aim of this dealing is to construct recombinant vaccinia viruses containing genes encoding Epstein-Barr virus (EBV) and cytomegalovirus (CMV) antigens. The viruses will be used to infect cell lines, which will be used as targets in T cell assays.</p>	<p>As for DNIR 186/2003.</p> <p>GTTAC advised that there is also a risk to people undertaking the dealing from exposure to aerosols and splashes containing GM vaccinia viruses. GTTAC recommended that these people be vaccinated against vaccinia virus.</p>
<p>DNIR 225/2003</p> <p>Mouse models of colorectal cancer using a TVA based retroviral gene transfer system</p>	<p>The aim of this dealing is to investigate the role of various genes in colorectal cancer by transferring candidate oncogenes and a tumour suppressor gene directly into the intestinal epithelium of mice using an avian retrovirus.</p>	<p>As for DNIR 188/2003.</p>
<p>DNIR 227/2003</p> <p>Structure/activity studies of novel toxins from native venomous organisms (brown snake)</p>	<p>The aim of this dealing is to introduce genes encoding brown snake venom proteins into bacterial and/or eukaryotic hosts to produce milligram quantities of these proteins for biophysical and functional studies.</p>	<p>As for DNIR 163/2003.</p>

Dealings Involving the Intentional Release of Genetically Modified Organisms

Dealings Involving the Intentional Release of GMOs (DIRs) are dealings that result in the introduction of a GMO into the environment. DIRs may involve a limited and controlled release (field trial) where measures are imposed in the licence conditions to control the movement of the GMO or its genetic material, or a general (commercial) release of a GMO where minimal oversight conditions have been required, to date.

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 Applications

GTTAC considered the following applications concerning the release of transgenic cotton in Australia and provided advice on issues to be considered in the preparation of the associated RARMPs.

- **Field trial of genetically modified cotton (*Gossypium hirsutum*) expressing an insecticidal gene (*vip3A*) (DIR 034/2003)**

The OGTR has received a licence application from Syngenta Seeds Pty Ltd (Syngenta) for the limited and controlled release of genetically modified (GM) insecticidal cotton into the environment. Syngenta proposes to conduct trials on 30 sites covering a total area of 10 hectares, over three years, in the cotton growing regions of Queensland (QLD), New South Wales (NSW) and Western Australia (WA).

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.

The insecticidal VIP3A protein produced by this GM cotton is different from insecticidal (Cry) proteins that are present in most other types of GM cotton that are currently being trialed or grown commercially in Australia.

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

- The risks posed by DIR 034/2003 are similar to those posed by previous cotton applications;
 - The advice provided in relation to previously assessed GM cottons (DIR 017/2002 and DIR 025/2002) should be considered in the preparation of the RARMP for DIR 034/2003; and
 - At the completion of the three years of field trials, the applicant should be requested to provide data on the levels of expression of the introduced proteins under Australian field conditions.
- **Breeding and pre-commercial evaluation of transgenic cotton expressing an insecticidal protein gene and a herbicide tolerance gene (DIR 036/2003)**

The OGTR has received an application from the Commonwealth Scientific and Industrial Research Organisation (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 3 seasons.

Three insecticidal GM cottons are proposed for release which 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 trialed or grown commercially in Australia. The applicant expects the new GM cottons to provide alternative options to manage the risk of resistance development in insect populations. The COT102 cotton

line contains insecticidal and antibiotic resistance genes. COT102 was previously approved under the voluntary system as PR-151 and more recently under the current regulatory system in licences DIR 017/2002 and DIR 025/2002. The COT200 series cotton lines express only the insect resistance gene under a different promoter to that of COT102. The COT200 series lines do not contain the antibiotic resistance gene. The third type of insecticidal GM cotton proposed for release will be derived by conventional crosses between insecticidal cotton (COT102) and another GM cotton tolerant to the herbicide Liberty® (glufosinate ammonium), generated previously as part of a separate dealing (DIR 015/2002). It is expected that addition of the Liberty® cotton trait will allow more effective weed control in insect resistant cotton crops by allowing the crop to be sprayed with glufosinate-ammonium to kill problem weeds without damaging the crop itself.

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 COT102 event have previously been declared as CCI. CSIRO has sought approval for details of the gene construct including the plasmid map and regulatory sequences of the COT200 series lines to be declared as CCI. 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 this application and advised the Regulator that the following issues should be considered in the preparation of the RARMP:

- The risks posed by DIR 036/2003 are similar to those posed by previous cotton applications such as DIR 015/2002, DIR 017/2002 and DIR 025/2002;
- Advice provided in relation to previously assessed GM cottons should be considered in the preparation of the RARMP for DIR 036/2003; and

- The applicant should be requested to provide data on the levels of expression of the introduced proteins under Australian field conditions at the completion of the three year field trial.
- **Field trial for breeding and pre-commercial evaluation of GM cotton expressing tolerance to the herbicide glufosinate ammonium (DIR 038/2003)**

The OGTR has received 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 from the conventional cotton plants in the surrounding buffer rows as well as from the GM cotton plants.

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

- The risks posed by DIR 038/2003 are similar to those posed by previous Liberty® cotton applications such as DIR 015/2002, PR-82, PR-82X, PR 124, PR 124-X and PR 124X(2);
- Advice provided in relation to previously assessed GM cottons (Liberty® cotton) should be considered in the preparation of the RARMP for DIR 038/2003;

- At the completion of the three years of field trials, the applicant should be requested to provide data on levels of expression of the introduced protein under Australian field conditions; and
 - Herbicide application practices for commercial release of the same GMO should incorporate rotation of herbicides.
- **Field evaluation of high-oleic (HO) cotton (DIR 039/2003)**

The OGTR has received 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 two 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 derived from conventional cottonseed is used in food applications around the world, following processing to remove gossypol and other toxic or anti-nutritional compounds such as cyclopropenoid fatty acids. The high levels of polyunsaturated fatty acids present in most non-GM cotton seed often necessitates additional processing through partial hydrogenation to obtain oil with higher stability and more resistant to oxidation (ie to avoid becoming rancid). However, hydrogenation results in fatty acid structural forms (trans, rather than the cis arrangement of hydrogen atoms more commonly found in nature) that may increase cholesterol levels upon consumption. HO cotton has an altered ratio of fatty acids in cottonseed oil, with increased oleic acid levels (monounsaturated fatty acid) and decreased levels of linoleic (polyunsaturated fatty acid with low stability) and palmitic acids (saturated fatty acid associated with blood cholesterol-raising properties). 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 this application and advised the Regulator that the following issues should be considered in the preparation of the RARMP:

- The risks posed by DIR 039/2003 are low and manageable;

- Advice provided in relation to previously assessed cottons should be considered in the preparation of the RARMP for DIR 039/2003;
- The applicant should be requested to provide complete fatty acid, gossypol and protein profiles of cottonseed at the completion of the field trial; and
- Post-harvest monitoring should be conducted for twelve months, although non-cotton crops could be planted six months post-harvest.
- **Agronomic assessment and seed increase of GM cotton expressing insecticidal genes from *Bacillus thuringiensis* (DIR 040/2003)**

The OGTR has received 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 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 this application and advised the Regulator that the following issues should be considered in the preparation of the RARMP:

- The risks posed by DIR 040/2003 are similar to those posed by previous GM cotton applications;
- The advice provided in relation to previously assessed DIRs 005/2001,

006/2001, 008/2001, 009/2001, 017/2002 and 023/2002 should be considered in the preparation of the RARMP for DIR 040/2003; and

- At the completion of the field trial, the applicant should be requested to provide data on the levels of expression of the introduced proteins under Australian field conditions.

Advice on RARMPs

Advice on cotton

GTTAC considered the RARMP prepared in response to the following application concerning the release of transgenic cotton in Australia.

- **Commercial release of herbicide tolerant (Roundup Ready®) and herbicide tolerant/insect resistant (Roundup Ready®/INGARD®) cotton (DIR 023/2002)**

The OGTR has received a licence application from Monsanto for the intentional release of Roundup Ready® and Roundup Ready®/INGARD® cotton into the environment in the cotton growing regions of NSW and QLD, south of latitude 22° South. Approval would enable the continued commercial release of the GM cotton. Monsanto also proposes the phasing-out of Roundup Ready®/INGARD® cotton over the next two years while Roundup Ready®/Bollgard II® cotton (which was approved for commercial release in September 2002; DIR 012/2002) is phased-in over the same period.

Roundup Ready® cotton contains a gene that provides tolerance to glyphosate, the active ingredient of the herbicide Roundup®. Conventional cotton is susceptible to glyphosate. The use of Roundup Ready® cotton allows the application of Roundup® for the control of weeds that emerge in the crop. Roundup Ready®/INGARD® cotton was produced by conventional breeding of Roundup Ready® cotton with INGARD® cotton. The Roundup Ready®/INGARD® cotton inherits an insecticidal gene from INGARD® cotton that produces a protein toxic to lepidopteran caterpillar pests.

It is intended that GM cotton plants and their by-products, including cottonseed, be used in the same manner as conventional cotton, including for human food and stockfeed. Cottonseed is processed for oil that is used in a variety of food products and for cotton linters (a type of fibre that does not contain any genetic material) that are used as a cellulose base for several consumer food products. FSANZ has approved the use of oil and

linters from Roundup Ready®, INGARD® and Bollgard II® cotton in human food.

GTTAC discussed the RARMP for this application and advised the Regulator as follows:

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

Advice on Papaya

GTTAC considered the RARMP prepared in response to the following application concerning the release of transgenic papaya in Australia.

- **Field trial for evaluation of genetically modified papaya to delay fruit ripening and to test the expression of the introduced genes (DIR 026/2002)**

An application has been received from the University of Queensland for a licence for the intentional release of GM papaya (*Carica papaya* L, cultivar 'Solo') plants into the environment. Approval would enable the continued limited and controlled release (field trial) of GM papaya approved under the former voluntary system (PR-128), as well as for several new lines of GM papaya. The applicant proposes to study up to 300 individual papaya plants at one site, over a total area of 1.7 hectares in QLD.

Papaya fruit has poor storage qualities. If fruit ripening is delayed over several days to weeks it may be possible to decrease spoilage due to over-ripening during transportation and storage. The release involves growing several lines of papaya plants that have been modified to delay fruit ripening by down-regulation of a plant hormone, ethylene, or by modifying the ethylene receptor molecule. Some plants have also been modified to express a reporter gene that can be used to identify the plants with genetic modifications.

The applicant aims to assess the rate of fruit ripening on the tree for a limited number of fruits but proposes to harvest most fruits before full ripening has occurred. Additionally, reporter gene expression will be evaluated to assess the effectiveness of the same promoter that drives expression of the fruit ripening genes. Other physiological, nutritional and quality attributes of the fruit will also be evaluated.

None of the fruits that are produced during the trial will be used for human or animal consumption.

GTTAC discussed the RARMP for this application and advised the Regulator as follows:

- The Committee agrees with the assessment made by the OGTR on the risk of toxicity, allergenicity, weediness and gene transfer;
- The condition requiring bagging of all flowers, including male, female and hermaphrodite flowers, could be removed;
- Reference to gene containment due to 'geographical isolation' should be removed from the RARMP;
- The integrity of the insect-proof cage should be ensured by appropriate construction and frequent monitoring; and
- The GMO's susceptibility to disease compared to that of wild-type papaya should be an area of future study.

Advice on Pineapple

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

- **Field test of pineapple plants modified to control flowering (DIR 027/2002)**

An application has been received from the University of Queensland for a licence to continue the limited and controlled release (field trial) of GM pineapple (*Ananas comosus*, now called *Ananas comosus* var. *comosus*) first planted in 1999 under the former voluntary system (PR-95). The University of Queensland is proposing to continue the trial on one site in QLD, over a total area of 0.1 hectares.

The aim of the proposed release is to test pineapple plants that have been modified to control flowering. Another aim of the release is to assess the activity of different regulatory sequences under field conditions.

The GM pineapple plants have been modified by insertion of a truncated copy of the pineapple ACC (1-aminocyclopropane-1-carboxylate) synthase (ACACS3) gene to 'silence' the existing gene in the pineapple. ACC synthase is a key enzyme in the pathway that leads to formation of ethylene in plants and has a role in natural flowering. Other GM pineapple plants have been modified by insertion of a reporter gene (*uidA*), which allows assessment of the activity of different regulatory sequences under field

conditions. All of the GM pineapples also contain a selectable marker gene (*SuRB*) conferring resistance to ALS inhibitors, including sulfonylurea herbicide, which is used to select transgenic plants in the laboratory.

None of the pineapple plants from the trial, or their by-products, will be used for human food, animal feed or therapeutics.

GTTAC discussed the RARMP for this application and advised the Regulator as follows:

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

GTTAC provided the following general advice on DIR RARMPs:

- Future RARMPs should indicate where the applicant proposes containment measures that are incorporated into the licence conditions.
- **Field trial of pineapple plants modified for blackheart reduction and to delay flowering (DIR 028/2002)**

An application has been received from the Queensland Department of Primary Industries for a licence to continue the limited and controlled release (field trial) of GM pineapple (*Ananas comosus*, now called *Ananas comosus* var. *comosus*) first planted in 2000 under the former voluntary system (PR-137 and PR-152). The applicant is proposing to continue the trial on two sites in QLD covering a total area of 0.22 hectares.

The aims of the proposed release are to conduct a field evaluation of pineapple plants that have been modified for blackheart reduction and/or to control flowering, as well as to assess the activity of different regulatory sequences under field conditions.

The QDPI proposes the release of four types of genetically modified pineapples. One type of GM pineapple proposed for release contains an additional copy of the pineapple polyphenol oxidase (*PINPPO2*) gene that controls the occurrence of blackheart disorder and an additional copy of the pineapple ACC (1-aminocyclopropane-1-carboxylate) synthase (*AC-ACS2*) gene that controls natural flowering. Two other types of GM pineapple contain an additional copy of either the polyphenol oxidase gene or ACC synthase gene. The fourth type of pineapple has been genetically modified by introduction of β -glucuronidase (*uidA*) gene responsible for β -glucuronidase expression to test for activity of regulatory sequences under field conditions. All the GMOs also contain the neomycin phosphotransferase (*nptII*) gene, which confers antibiotic resistance and some associated regulatory sequences. In addition, some of the GMOs

also contain non-expressed bacterial genes, ie. β -galactosidase (*Lac Z*), ampicillin (*bla*) and streptomycin/spectinomycin (*aad*) genes. These genes are under the control of bacterial promoters and will not be expressed in the GM pineapple plants.

None of the pineapple plants from the trial, or their by-products, will be used for human food, animal feed or therapeutics.

Details of the gene constructs and the gene silencing strategy 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 RARMP.

GTTAC discussed the RARMP for this application and advised the Regulator as follows:

- 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.

GTTAC provided the following general advice to the Regulator:

- GTTAC recommends that a paper on the pleiotropic effects of polyphenol oxidase (PPO) should be commissioned to aid the Committee in assessing future applications involving silencing PPO genes.

Advice on Grapevine

GTTAC considered the RARMP prepared in response to the following application concerning the release of transgenic grapevine in Australia.

- **Field trial of genetically modified grapevines – evaluation of berry colour, sugar composition, flower and fruit development and gene flow study (DIR 031/2002)**

An application has been received from CSIRO for a licence for the intentional release of GM grapevines (*Vitis vinifera* L) into the environment. Approval would enable the continued limited and controlled release (field trial) of GM grapevines, approved under the former voluntary system, on one site in Victoria, over a total area of 0.38 hectares.

The aims of the proposal are to evaluate the field performance of GM grapevines containing additional copies of various grapevine genes which are modified to improve berry colour, sugar composition, flowering and fruit

quality. The applicant also proposes to monitor pollen flow using GM grapevine containing green fluorescent protein (GFP).

Several types of GM grapevines are proposed for release. The GMO's will contain one of the following modifications:

- Additional copies of the *ppo* gene, derived from grapevine, coding for the enzyme polyphenol oxidase. The modified *ppo* gene derived from grapevine has been introduced to test silencing of the natural copy of the *ppo* gene, thereby reducing browning in GM sultanas.
- Modified *sh4* gene from grapevine, designed to improve flower and fruit characters, which are beneficial to the grape industry.
- Additional copies of a *ufgt* gene encoding UDP glucose flavonoid 3-O-glucosyl transferase from grapevine which is involved in the anthocyanin pathway, designed to improve berry colour through enhanced expression of the *ufgt* gene.
- The modified *dfr* gene from grapevine which is designed to down-regulate the expression of the enzyme dihydroflavonol reductase, to alter the production of anthocyanin or tannin which are important for the stabilisation of colour during wine making and for wine mouthfeel.
- The modified *inv* gene designed to down-regulate the invertase enzyme, which breaks down sucrose into fructose and glucose. This is expected to maintain sucrose levels in the grape berries.
- The *gfp* reporter gene isolated from jellyfish (*Aequorea victoria*), encoding for GFP that enables the visual identification of plant tissues expressing the transgene.
- All of the GM grapevines contain antibiotic resistance marker genes, either *nptII* (confers resistance to kanamycin & neomycin) or *hph* (confers resistance to hygromycin).

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

GTTAC discussed the RARMP for this application and advised the Regulator as follows:

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

- The RARMP should be amended to clarify that taste testing would not be allowed until further information on toxicity and allergenicity of the GM fruit became available.

Advice on Cholera Vaccine

GTTAC considered the RARMP prepared in response to the following application concerning the release of genetically modified cholera vaccine in Australia.

- **Orochol® vaccine (DIR 033/2002)**

An application has been received from CSL Limited for a licence for the continued commercial release of live GM cholera vaccine (Orochol®). The proposal was previously approved under the former voluntary system.

Cholera is a disease with an extremely low incidence in Australia. In the last ten years, an average of four cases have been reported annually. The majority of these cases involved people who had entered or returned to Australia from other countries.

Orochol® is a self-administered prescription medicine to immunise people intending to travel against cholera. Following extensive evaluation of its safety, quality and efficacy, the vaccine was registered as a prescription medicine under the *Therapeutic Goods Act 1989* in April 2000. Since this time, over 60,000 doses have been distributed nationally.

Orochol® vaccine contains the live bacterium *Vibrio cholerae*. Native cholera bacteria produce a toxin containing 2 subunits, A and B. The GM vaccine strain has been produced by deleting most of the toxic A-subunit gene (*ctxA*) and inserting a mercury resistance operon (*mer*) into the haemolysin gene (*hlyA*). The non-active B-subunit of the cholera molecule is still synthesised but it does not cause disease.

GTTAC discussed the RARMP for this application and advised the Regulator as follows:

- The Committee endorsed the RARMP and the proposed licence conditions for DIR 033/2002; and
- The GMO should be considered for entry on the GMO Register.

New certification guidelines for contained facilities

OGTR representatives provided the Committee with a copy of the proposed revised *Guidelines for the Certification of Physical Containment Facilities* (the

Guidelines) that will be issued in August 2003. The Committee discussed the draft document, provided advice to the Regulator on waste disposal in plant containment facilities and endorsed these revised Guidelines.

Draft policy principle

OGTR representatives provided the Committee with an overview and copy of the draft Gene Technology (Recognition of Designated Areas) Policy Principle 2003. The Committee was asked to provide advice to the Gene Technology Ministerial Council (GTMC) on the content of the draft policy principle.

The Committee discussed the draft Gene Technology (Recognition of Designated Areas) Policy Principle 2003.

GTTAC advised the GTMC that:

- No amendments are required to the content of the draft policy principle and related documents; however
- The Committee seeks the GTMC's assurance that the policy principle could not be used to restrict contained dealings involving GMOs (ie DNIRs and NLRDs).

Presentations

At the May meeting of GTTAC the Committee received and discussed a presentation on *Gene Containment*.