Quarterly Report of the Gene Technology Regulator for the period 1 April to 30 June 2003

ISBN

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

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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 April to 30 June 2003.

The key achievements for the quarter covered in the report include the issuing of 67 licences for dealings not involving intentional release of genetically modified organisms into the environment, the accreditation of 44 organisations and the certification of 315 contained facilities. Routine monitoring activities remained well above the OGTR's minimum target rate.

In addition, I signed bilateral memoranda of understanding with the Australian Pesticides and Veterinary Medicines Authority and the Department of Environment and Heritage, outlining the nature of the close working relationship between the OGTR and these agencies.

This quarter also marked the end of the two-year transition period from the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee to the new legislation.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator
2 September 2003

Contents

Glossary

Accredited organisation	An organisation that is accredited under section 92 of the Act
Act	*Gene Technology Act 2000*
APVMA	Australian Pesticides and Veterinary Medicines Authority
Breach	*see* 'Non-compliance'
CCI	Confidential commercial information
Certified facility	A building or place certified by the Regulator, to a specified containment level, under section 84 of the Act
Clock stop	The period during which an application evaluation is suspended – usually whilst awaiting further information from the applicants
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DIR	A dealing with a GMO involving intentional release of a GMO into the environment (for example, field trial or commercial release)
DIR licence	A licence for a dealing involving intentional release of a GMO into the environment
DNIR	A contained dealing with a GMO not involving intentional release of a GMO into the environment (for example, experiments in a laboratory)
DNIR licence	A licence for a dealing not involving intentional release of a GMO into the environment
Expert advisers	Advisers appointed by the Minister to give advice to either GTTAC or GTEC to assist them in the performance of their functions. (Expert advisers are not committee members.)
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
GTMC	Gene Technology Ministerial Council
GTEC	Gene Technology Ethics 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 *Guidelines for Certification of Facilities/Physical Containment Requirements*
RARMP	Risk assessment and risk management plan
Regulations	*Gene Technology Regulations 2001*
Regulator	Gene Technology Regulator
Spot checks	Unannounced visits by the OGTR Monitoring and Compliance Section
Volunteer	Regrowth of plants from seed that has remained on a site after a trial has been completed

Introduction

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

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

Structure of this report

This report is divided into four parts:

Part 1 details activities and outcomes achieved in relation to the implementation and management of the national regulatory system.

Part 2 outlines the regulatory activity undertaken during the April–June 2003 quarter. This includes information about applications for, and action taken with respect to, GMO licences and other instruments under the Act. It also includes details of monitoring, auditing and compliance activities by the Regulator during this quarter.

Part 3 reports on the activities of the three key advisory committees established under the Act to assist the Regulator.

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

Further information

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

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PART 1 National regulatory system

Key achievements during this quarter

The key achievements of the April–June 2003 quarter were:

Licences and other instruments

In this quarter the Regulator:

- considered 14 applications and issued 9 licences for dealings involving intentional release of GMOs into the environment (DIR licences)
- issued 67 licences for dealings not involving intentional release of GMOs into the environment (DNIR licences)
- received 254 notifiable low risk dealing (NLRD) notifications
- accredited 44 organisations
- certified 505 contained facilities.

This quarter marks the end of the two-year transition period from the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee to the new legislation.

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

Monitoring and compliance

Approximately 35 per cent of current field trial sites and 6 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 bilateral memoranda of understanding with the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Department of Environment and Heritage.

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.

In addition, during the quarter the Regulator met with:

- the Tasmanian Minister for Primary Industries, Water and the Environment, the Hon. Bryan Green MHA in Hobart, Tasmania
- Victorian Government officials from the Department of Primary Industries and the Department of Innovation, Industry and Regional Development in Melbourne, Victoria.

More information is contained in Part 2.

Gene Technology Ministerial Council

The Gene Technology Ministerial Council (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 did not meet this quarter.

Gene Technology Standing Committee

The Gene Technology Standing Committee supports the work of the GTMC. The Standing Committee consists of senior government officials from all jurisdictions with responsibility for gene technology issues.

The Standing Committee held one teleconference this quarter and a national consultation process was undertaken on the draft *Gene Technology (Recognition of Designated Areas) Policy Principle 2003*.

Australian Government agency liaison

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

Under the Act, the Regulator must seek advice from prescribed Australian Government authorities and agencies and the Australian Government

Environment Minister. Advice is sought on matters relevant to preparing the RARMP for each application made to the Regulator for a DIR licence.[1]

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

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

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 from Australian Government agencies in respect of 11 applications for DIR licences.

Further information is set out in Part 2.

In addition, the Regulator signed bilateral memoranda of understanding with the APVMA and the Department of Environment and Heritage. Memoranda of understanding outline the operation and the nature of the close working relationship between the OGTR and the other agency. This helps each agency meet their legislative requirements, exchange information and implement administrative procedures in efficient and cooperative ways.

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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.

Public participation

During the quarter, the Regulator issued an invitation to the public to comment on 9 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 April–June 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 April–30 June 2003

Application type	Number received	Number approved[1]
DIR licence	2	9
DNIR licence	38	69
Accreditations	30	44
Certifications	285	505

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 June 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 040/2003	DIR 034/2003	DIR 035/2003	DIR 021/2002	DIR 022/2002
DIR 041/2003	DIR 036/2003	DIR 039/2003		DIR 023/2002
	DIR 037/2003			DIR 025/2002
	DIR 038/2003			DIR 026/2002
				DIR 027/2002
				DIR 028/2002
				DIR 030/2002
				DIR 031/2002
				DIR 033/2002

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 two applications for DIR licences in the April–June 2003 quarter as follows:

- DIR 040/2003 'Field trial – Agronomic assessment and seed increase of transgenic cotton expressing insect tolerance genes (modified *Cry1Ac* and *Cry 1Fa*) from *Bacillus thuringiensis'* (Dow Agrosciences)
- DIR 041/2003 'Post-field trial monitoring for licences PR64/67, PR 64X and PR 64X(2) concerning white clover transformed to resist infection by *Alfalfa Mosaic Virus*' (Department of Primary Industries, Victoria).

All applications for DIR licences received in the April–June 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, applications for the following licences underwent the initial stages of evaluation but have not yet progressed to the consultation phase.

- DIR 034/2003 'Field Trial – The evaluation of transgenic cotton plants expressing the *vip* gene, for agronomic characteristics and their effect on target and non-target insects' (Syngenta Seeds)
- DIR 036/2003 'Field Trial – Breeding and pre-commercial evaluation of transgenic cotton expressing a vegetative insecticidal protein *(vip)* gene and a herbicide tolerance gene' (Commonwealth Scientific & Industrial Research Organisation - CSIRO)
- DIR 037/2003 'Field Trial – Preliminary field efficacy and seed increase of cotton expressing both an insect tolerance gene from *Bacillus thuringiensis* and tolerance to the herbicide glufosinate ammonium' (CSIRO)
- DIR 038/2003 'Field Trial – Breeding and pre-commercial evaluation of transgenic cotton expressing tolerance to the herbicide glufosinate ammonium' (CSIRO).

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 035/2003 'Field trials of herbicide tolerant (Roundup Ready® MON 88913) and herbicide tolerant/insect resistant (Roundup Ready® MON 88913/Bollgard II®) cotton' (Monsanto)
- DIR 039/2003 'Field evaluation of genetically modified high oleic (HO) cotton' (CSIRO)

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 application:

- DIR 021/2003 'Commercial release of genetically modified canola (*Brassica napus*) for use in the Australian cropping system (Bayer CropScience)

Clock stopped on applications for commercial release of GM canola (DIR 020/2002 and DIR 021/2002)

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.

During the quarter, the Regulator stopped the clock on assessment of the Bayer CropScience application DIR 021/2002 'Commercial release of InVigor® canola (*Brassica napus*) for use in the Australian cropping system' after the second round of consultation. This was to enable thorough examination of all relevant procedural issues, including a decision to be made on the declaration of some confidential commercial information.

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 nine DIR licences:

- DIR 022/2002 'Commercial release of insecticidal (INGARD®) cotton' (Monsanto). The licence authorises continued commercial release in the cotton growing regions of New South Wales and Queensland.
- DIR 023/2002 'Commercial release of herbicide tolerant (Roundup Ready®) and herbicide tolerant/insect resistant (Roundup Ready®/INGARD®) cotton' (Monsanto). The licence authorises continued commercial release in the cotton growing regions of New South Wales and Queensland.
- DIR 025/2002 'Seed increase and efficacy studies in Northern Australia of transgenic cotton expressing a new insecticidal protein gene (*vip3A)'* (CSIRO). The licence authorises a limited and controlled release of GM insect resistant cotton in the Shire of Wyndham–East Kimberley in northern Western Australia. The trial is over a maximum of three hectares.
- DIR 026/2002 'Field trial for evaluation of GM papaya to delay fruit ripening and to test the expression of the introduced genes' (University of Queensland). The licence authorises a continued limited and controlled release of GM papaya in the Shire of Redlands, in Queensland. The trial is over a maximum of one hectare.
- DIR 027/2002 'Field trial of pineapple plants modified to control flowering' (University of Queensland). The licence authorises a continued limited and

controlled release of GM pineapple in the shire of Redlands, in Queensland. The trial is over a maximum of 0.1 hectares.

- DIR 028/2002 'Field trial of pineapple plants modified for blackheart reduction and to delay flowering' (Queensland Department of Primary Industries). The licence authorises a continued limited and controlled release of GM pineapple in the shires of Redlands and Maroochy in Queensland. The trial is over a maximum of 0.22 hectares, over two sites.
- DIR 030/2002 'Ongoing commercial release of colour modified carnations (Extension of deemed licence GR-2)' (Florigene). The licence authorises the continued commercial release of GM carnation Australia-wide.
- DIR 031/2002 'Field trial of GM grapevines – Evaluation of berry colour, sugar composition, flower and fruit development and pollen flow study' (CSIRO). The licence authorises a continued limited and controlled release of GM grapevines in the Mildura Rural City Council in Victoria. The trial is over a maximum of 0.38 hectares.
- DIR 033/2002 'Commercial Release – Recombinant live oral cholera vaccine (Orochol® vaccine)' (CSL). The licence authorises the continued commercial release of a GM oral cholera vaccine Australia-wide.

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 67 DNIR licences. Further information about these licences is contained in Appendix A of this report.

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

Notifications of notifiable low risk dealings received

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

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

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

The Regulator received 254 NLRD notifications in the quarter.

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, with respect to licences, 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 April–June 2003 quarter.

Applications received and decisions made; existing licences and other instruments, 1 April–30 June 2003

Type	Number received	Number processed[1]
Surrender of certification	18	44
Variation of certification	15	11
Transfer of licence	1	3
Variation of DIR licence[2]	16	3
Surrender of DNIR licence	1	2
Variation of DNIR licence	7	12
Varied accreditation	1	1

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, safety or 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.

'Advices to proceed' issued by GMAC for the equivalent of the current DIRs, DNIRs, NLRDs and 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. Applications were handled in parallel with new workloads and have appeared in all quarterly reports issued to date, including the current document. The current status of former deemed instruments is, in summary:

- 49 deemed licences for DIRs of GMOs into the environment. Consultation with stakeholders indicated that 11 of these deemed licences required renewal. All applications for replacement licences for these dealings were received, assessed and licences issued prior to 21 June 2003;
- 504 deemed licences for DNIRs of GMOs into the environment. Consultation with stakeholders indicated that 200 were no longer required and were allowed to expire on 21 June 2003. Applications for renewal of 250 of these licences were received, assessed and licences issued by 21 June 2003. Some licence applications cover a number of previously approved dealings;
- deemed instruments for 1057 NLRDs with GMOs, of which approximately 400 have been received and renewed (some notifications cover a number of previously approved dealings). Consultation with stakeholders indicated that 300 were no longer required and were allowed to expire on 21 June 2003;
- deemed certifications for 1550 laboratory facilities, applications for approximately 1150 have been received and renewed. Consultation with stakeholders indicated that 250 were no longer required and were allowed to expire on 21 June 2003; and
- deemed accreditations for 119 organisations, of which approximately 100 were received and renewed prior to 21 June 2003.

Lists were compiled of 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.

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 (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 two CCI applications in relation to applications for DIR licences, one CCI application in relation to an application for a DNIR licence and three CCI applications in relation to NLRDs.

The Regulator made one CCI declaration in relation to an application for a DIR licence (DIR028/2002).

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, annually. 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.

On the basis of experience, the OGTR field trial monitoring strategy emphasises risk profiling and includes unannounced spot checks. OGTR field trial monitoring activity is scheduled, as far as possible, to identify inherently higher risk periods in dealings with gene technology (for example, flowering and harvest) and to perform monitoring activities accordingly.

The monitoring program for dealings conducted in contained facilities involves inspecting and monitoring:

- a minimum of 20 per cent of physical containment (PC) 4, PC3 and PC2 large-scale facilities per year; and

- selected PC2 and PC1 facilities.

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

As reported previously, a major review was undertaken of the *Guidelines for Certification of Facilities/Physical Containment Requirement,* which were based on GMAC's previous guidelines. *Guidelines for Certification of PC2 Facilities/ Physical Containment 2 Requirements* has been released and provided to all accredited organisations. These new guidelines come 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 April–June 2003 quarter, 42 monitoring visits were carried out on 42 sites. No follow-up visits were identified as being required this quarter. Monitoring was carried out on 12 licences and covered 5 plant species.

Current field trial sites monitored. Of the 26 sites current in the quarter, 9 were monitored. This represents a monitoring rate of 35 per cent of all current sites for the quarter.

Post-harvest field trial sites monitored. Of the 520 sites subject to post-harvest monitoring in the quarter, 33 were monitored. This represents a monitoring rate of 6 per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of contained dealings. During the April–June 2003 quarter, 23 PC2 facilities were monitored as part of the routine monitoring program. This encompassed PC3 laboratories (1 visited), PC2 laboratories (18 visited), PC2 plant houses (2 visited) and PC2 animal houses (2 visited) across 9 organisations.

Monitoring conducted

The total coverage for field trial sites during the April–June 2003 quarter is shown in the following table.

Licensed organisation name	Licence number[1]	No. sites visited	Site status[2]	GMO type
Australian National University	PR 126	1	PHM	*Psuedomonas*
Bayer CropScience	PR 62X(4)	5	PHM	Canola
	PR 62X(4)	12	PHM	Canola
CSIRO Plant Industry	PR 131X(2)	3	PHM	Cotton
	PR 102X	1	PHM	Wheat
Department of Agriculture (Western Australia)	PR 144	5	PHM	Cotton
	PR 87X	1	PHM	Cotton
Monsanto Australia Limited	PR 77X	1	PHM	Canola
	PR 77X(2)	2	PHM	Canola
	DIR 006/2001	1	PHM	Cotton
	DIR 012/2002	9	C	Cotton
Queensland Department of Primary Industries	PR 117	1	PHM	Lettuce
Totals	**12**	**42**	**C=9 PHM=33**	**5 species**

1 DIR = Dealing Involving Intentional Release, PR = Planned Release (involving release of GMO into the environment)

2 C= current, PHM = post-harvest monitoring

Inspection of PC2 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
Children's Medical Research Institute	PC3 Laboratory	1
CSIRO	PC2 Plant House	1
Macquarie University	PC2 Laboratory	1
Macquarie University	PC2 Plant House	1
Northern Territory University	PC2 Laboratory	2
St Vincent's Hospital Melbourne	PC2 Laboratory	4

South Eastern Sydney Area Health service	PC2 Laboratory	3
Children's Hospital at Westmead	PC2 Laboratory	2
University of New South Wales	PC2 Laboratory	1
University of New South Wales	PC2 Animal containment facility	1
Walter and Eliza Hall Institute of Medical Research	PC2 Laboratory	5
Walter and Eliza Hall Institute of Medical Research	PC2 Animal containment facility	1
Totals	**4 facility types**	**23**

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.

PR number site number	144, 22
Summary of dealing	Licence relates to field trials of cotton *(Gossypium hirsutum)* expressing the *Cry1Ac* delta-endotoxin from *Bacillus thuringiensis*.
Findings	Seven volunteers were found on the 20 hectare site at the time of the inspection. Plants were a result of regrowth from the roots of plants not previously destroyed by cultivation. One plant was fruiting having a fully formed boll. Lint containing cotton seed, was spread across the site and is likely to have originated from the GM cotton crop grown in 2001.
Risk assessment	The licence holder was advised by the OGTR to remove the volunteers. Due to removal of these plants, the OGTR risk assessment finds there is negligible risk of dissemination and/or persistence of the GMO.
Risk management	The licence holder is to irrigate the site to encourage germination of any viable cotton seed in the lint and control any subsequent volunteers before flowering.

PR number site number	DIR 006, 6
Summary of dealing	Licence relates to field trials of cotton *(Gossypium hirsutum*) expressing the *Cry1Ac* or *Cry 1Ac* and *Cry2Ab* delta endotoxins from *Bacillus thuringiensis*.
Findings	Monitoring findings have not been provided to the OGTR as per licence requirements. At the time of inspection a number of volunteers and regrowth from the roots of plants not destroyed by cultivation (estimated 100 to 1000 INGARD® plants) were observed in the northern part of the paddock. 10 to 50 of these plants were mature with bolls set and lint dropping. The trial (DIR 006/2002) was conducted in 2002. In 2003 part of the site has been used for a Bollgard II® trial under licence DIR 012/2002.
Risk assessment	The licence holder was advised by the OGTR to remove the volunteers. Due to the herbicide treatment of these plants, the OGTR risk assessment finds there is negligible risk of dissemination and/or persistence of the GMO.
Risk management	The licence holder is to: - provide accurate monitoring reports to the OGTR as per licence condition 6 - provide training to the Research Station staff in relation to post-harvest requirements of the licence - destroy all volunteers immediately, preferably through a combination of cultivation and herbicide treatment - submit an application to allow cotton to be sown on the site post-harvest (in relation to licence condition 7).

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 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 current *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.

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 legislation
- ***practice reviews*** are initiated to determine if licence conditions can be, and are being, effectively implemented and include identification of potentially adverse affects of a GMO and may be prompted by observations or a set of observations made during monitoring activities.

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

One incident review was completed in this quarter and is outlined below.

Issue	License transfer for DNIR 021/2002 from the University of Queensland, Sir Albert Sakzewski Virus Research Centre to the Queensland Institute of Medical Research. An incident review was conducted to confirm compliance with the Act and associated regulations. The OGTR review clarified Queensland Institute of Medical Research processes and procedures with regard to the transferred dealing, transportation and containment.
Risk assessment	The OGTR risk assessment determined that appropriate procedures had been followed. Therefore, this dealing posed negligible risk to public health and the environment.
Determination	The incident review established that the Queensland Institute of Medical Research complied with the Act and associated regulations in relation to the GMO dealing transfer and containment.
Risk management	The OGTR licence conditions for this dealing are based upon an appropriate RARMP.
Action	No further action.

Investigations

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

The OGTR provides summarised accounts of investigations, once completed, in the relevant quarterly report. However, the OGTR does not release information about ongoing investigations because the information may:

- jeopardise current or future investigations
- be protected by legislation (for example, the *Privacy Act 1988)*
- contain confidential commercial information
- unfairly damage the reputation of third parties who have not themselves breached legislative requirements.

However, if there was an imminent risk to the health and safety of people and the environment, the Regulator would consider whether release of information may be appropriate.

Two investigations were completed in the April–June 2003 quarter. Details are outlined in the tables below.

Type	**Transportation**
Name	An investigation into the spillage of Bollgard II® cotton seed whilst being transported from Narrabri NSW to Kununurra WA, for planting by CSIRO and Department of Agriculture (Western Australia) under the licensed dealing DIR 012/2002.
Current status	Closed – investigation finalised
Allegation	The investigation was instigated as a result of a report by the seed recipient advising that approximately 15 kgs of Bollgard II® cotton seed had been spilt from a 400 kg consignment containing genetically modified and conventional seed.
Summary of investigation	OGTR Compliance and Investigations staff conducted a thorough investigation and established the circumstances of the spill and location of the missing seed.

Findings	The investigation determined the spillage was contained within a secure trailer and found on arrival at a Darwin transport site, where the consignment was being held before on-shipment to Kununurra. An employee of the transport company, unaware that the seed was genetically modified, removed and cleaned the transport vehicle and placed the seeds in an on-site rubbish bin. The bin and contents were disposed of at a landfill which met Australian Quarantine Inspection Service standards.
Risk assessment and risk management	A risk assessment determined that the risk to human health and the environment was negligible. The licence holder, Monsanto Australia Ltd has also investigated the incident, and worked with all parties involved to strengthen transport procedures. An OGTR audit will be undertaken regarding management and practices relating to DIR 012/2002.

Type	**Licensing**
Name	An investigation into the commencement of a DNIR before approval of the licence application – DNIR 178/2003 Children's Hospital Westmead.
Current status	Closed – investigation finalised
Allegation	The investigation was instigated as a result of the OGTR Contained Dealings Evaluation Section validating project information and receiving advice that the dealing had commenced. The dealing involved use of a vector containing E6E7 region of the *Papilloma virus 16 retrovirus*.
Summary of investigation	OGTR Compliance and Investigations staff conducted an investigation and established the circumstances of the dealing commencing before the licence application was approved.
Findings	The investigation determined that the dealing commenced prior to the application approval as a result of the principal investigator believing all submitted GMO dealing applications were approved by the Children's Medical Research Institute/Children's Hospital Westmead – IBC. The principal investigator received four IBC letters at the same time, with three letters indicating approval for an exempt dealing and two NLRDs to commence. The fourth letter, advising that a DNIR licence was required and to await approval before proceeding, was inadvertently misread and the dealing commenced.
Risk assessment and risk management	The investigation determined that all appropriate safety precautions and containment were met in the conduct of the DNIR dealing. Hence there was negligible risk to human health and safety. The Children's Medical Research Institute /Children's Hospital Westmead IBC is conducting a review to strengthen procedural processes.

Audits

No audits were initiated or completed in the quarter.

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 Ministerial Council
- The **Gene Technology Ethics Committee** (GTEC)
  - provides advice on ethical issues relating to gene technology to the Regulator and Ministerial Council
- The **Gene Technology Technical Advisory Committee** (GTTAC)
  - provides scientific and technical advice to the Regulator and Ministerial Council.

Gene Technology Community Consultative Committee

At its fifth meeting, held in Melbourne on 5 June 2003, the current GTCCC working groups reported on their activities since the previous meeting and agreed on a new work strategy for each group. In addition to the existing work plan priorities, the Committee considered a request from the GTMC to comment on the draft policy principle for GM and non-GM designated areas and a new working group was established to review the revised format of the RARMPs developed by the OGTR.

Members also received a presentation from Dr John Keniry (GTCCC member and former chair of the National Registration Authority) and Dr Alison Turner (Chief Executive Officer of the APVMA) on the role of the APVMA.

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

Gene Technology Ethics Committee

During this quarter, GTEC held its fourth meeting on 9 and 10 April 2003. At the Regulator's request, GTEC is continuing its work on a range of agreed priority areas. The working groups reported to GTEC on their progress between meetings and are due to report again at the fifth meeting to be held later in 2003.

At the April meeting GTEC resolved to develop a set of specific ethical guidelines in relation to work with GMOs. Development of practical ethical values and principles specifically relevant to gene technology will be based on preliminary work undertaken by one of the working groups and the contributions of a number of individual members. The Regulator has also requested GTEC to provide advice on the proposed implementation of the new guidelines.

Also during this quarter, GTEC received a request from the GTMC to comment on the draft policy principle for GM and non-GM designated areas. GTEC considered this matter out-of-session and provided its advice to the GTMC in early June 2003.

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

Gene Technology Technical Advisory Committee

During the quarter, GTTAC held two face-to-face meetings in Canberra on 8 and 9 April and 22 May 2003. At these meetings the Committee considered:

- 5 applications for DIR licences
- 8 RARMPs for DIR licences
- 12 applications for DNIR licences and the associated RARMPs
- post-harvest monitoring conditions for deemed licences
- laboratory storage guidelines
- the draft policy principle for GM and non-GM designated areas.

At these meetings the Committee discussed presentations and papers on topics including gene flow, gene containment, viral vectors and plant viral transgenes.

In addition, the Committee considered the following applications and RARMPs out of session:

- 2 applications for DIR licences
- 2 applications for DNIR licences and the associated RARMPs.

The eighth GTTAC communique, outlining discussions held at the April 2003 meeting, is attached to this report at Appendix D. GTTAC is scheduled to meet again in July 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 for future risk assessments and risk management plans for dealings involving intentional release of GMOs, particularly large-scale 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. 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. The remainder of the revised guidelines will be finalised and released over the next two quarters.

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:

- Phillippine delegates, Chi Laigo-Vallido of the Philippine NGO Council on Population, Health, and Welfare, Inc., and Ma Perpetita Socorro Mercader of the Institute of Primary Health Care – Davao Medical School Foundation, to discuss human health and safety and the environment in relation to GMOs. The meeting was held in Canberra, ACT
- New Zealand Select Committee on Education and Science delegates, the Hon. Brian Donelly MP, Ms Jill Pettis MP, Ms Donna Awatere-Huata MP, Dr Ashraf Choudhary MP, Ms Helen Duncan MP, Dr Paul Hutchison MP, Mr Bernie Ogilvy MP, Ms Metiria Turei MP, Ms Angela Van Dam, Mr Paul O'Connell, the Hon. Neil Andrew MP and Senator the Hon. Paul Calvert, to discuss implementation of gene technology legislation. The meeting was held in Canberra, ACT

In addition, the OGTR briefed the Department of Environment and Heritage in preparation for the Organisation for Economic Co-operation and Development's *35th Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology* held in Paris, France during the quarter.

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:

- met with the Australian Honeybee Industry Council in Canberra, ACT
- met with Professor Hearne of the Australian National University in Canberra, ACT
- met with the Australian Academy of Science in Canberra, ACT
- met with the Tasmanian Farmers and Graziers Association in Hobart, Tasmania
- presented *Regulation of gene technology in Australia* at the *Biotechnology Innovation Festival* in Wagga Wagga, New South Wales
- presented *Australia's regulatory system for gene technology* at Ausbiotech's *AusIndustry innovation in biotechnology and agribusiness – information seminar* in Nowra, New South Wales
- presented *Australia's gene technology regulatory system and Bayer CropScience GM canola application* to the Department of Agriculture, Fisheries and Forestry – Australia's *GM Canola Forum* in Canberra, ACT
- presented *Australia's gene technology regulatory system* at the *Community Forum on GM Agriculture, FARMFEST,* in Toowoomba, Queensland
- attended the Office of Chemical Safety's *Science forum for best practice approaches to health risk assessment of chemicals* in Canberra, ACT

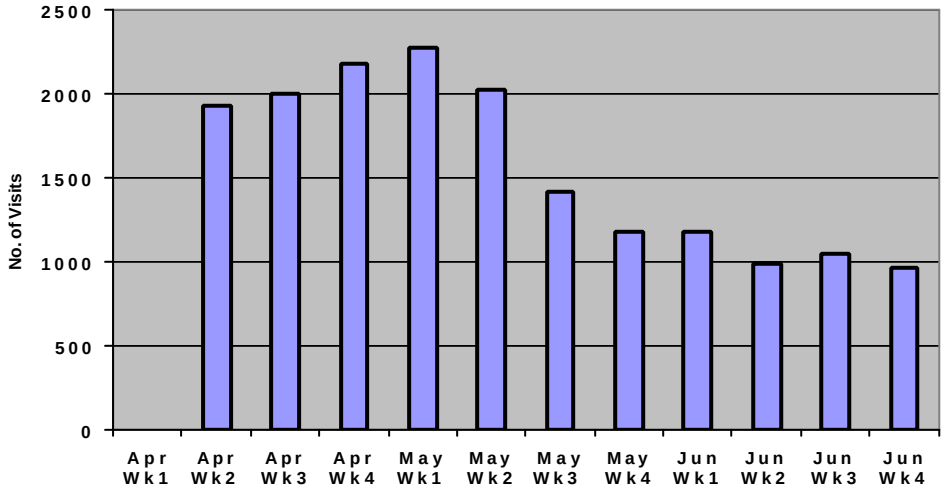
Institutional Biosafety Committees training sessions

OGTR regularly provides training sessions to organisations and IBCs. During the April–June 2003 quarter, one session was conducted at Monash University.

OGTR website

The OGTR website received 625 194 hits[3] during the period April to June 2003, which represents an average of 6 870 hits per day.

The graph below illustrates the pattern of individual visits[4] to the OGTR website, by week over the reporting period. Individual visits for the first week in April were not recorded.



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

- What's New
- Maps of current field trial locations
- Media Releases.

The most popular downloaded documents were:

- *The Biology and Ecology of Cotton*
- *The Biology and Ecology of Canola*
- *Handbook on the regulation of gene technology in Australia.*

[3] Hits = total number of pages and images accessed on the website.

[4] Visits = total number of visitors that entered the website.

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 200 calls and 250 emails in April 2003, 300 calls and 630 emails in May 2003, and 130 calls and 500 emails in June 2003.

The large number of emails received in May 2003 were in response to the call for comment on the Bayer CropScience application (DIR021/2002) proposing commercial release of genetically modified canola.

Freedom of information

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

Consultants

During the reporting period, the OGTR managed two consultancy contracts worth a total of $36 816. The table below lists the consultants, describes the purpose of the consultancy and the amount paid during the quarter. The amount paid is nett of GST.

Consultant	Amount paid (GST exclusive)	Purpose
Dialog Information Technology	$33 566	Develop Gene Technology Information Management System
Australian Protective Service	$3 250	Provide a Security Risk Management Review
Total Consultants for quarter	**$36 816**	

Appendix A

DNIR Licences issued 1 April–30 June 2003

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 135/2002	1 Nov 2002	29 April 2003	Institute of Medical and Veterinary Science, SA	Conditionally replicative adenoviruses for neoplastic disease	The aim of this dealing is to generate adenoviruses that will only replicate in the presence of specific tumour cell proteins. The adenoviruses will be tested for their impact on cell function.
DNIR 140/2002	15 Nov 2002	2 Apr 2003	University of New England, NSW	Characterisation of a DNA region associated with virulence of *Dichelobacter nodosus*	The aim of this dealing is to identify genes which control virulence of *D. nodosus*, and to use this information to assist in the diagnosis, treatment or prevention of footrot.
DNIR 142/2002	19 Nov 2002	4 Apr 2003	Agen Biomedical, Qld	Thromboview cell culture	The aim of this dealing is to produce enough material from cell culture to support later Phase Trials and to develop large-scale manufacturing procedures.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 143/2002	21 Nov 2002	4 Apr 2003	Peter MacCallum Cancer Institute, Vic.	The role of sialomucins in regulation of haemopoiesis	The aim of this dealing is to study the role of sialomucin cell surface adhesion molecules in the regulation of haemopoiesis, by expressing them in a range of mouse and human cell types.
DNIR 144/2002	21 Nov 2002	4 Apr 2003	Peter MacCallum Cancer Institute, Vic.	The role of hyaluronic acid in normal and aberrant stem cell biology	The aim of this dealing is to analyse the role of hyaluronic acid in leukaemiagenesis by over expressing or inhibiting hyaluronic acid synthase genes in primary human leukaemic cells.
DNIR 145/2002	22 Nov 2002	8 Apr 2003	CSIRO – Sustainable Ecosystems, ACT	Expression and vaccine systems using viruses expressing zona pellucida (ZP) genes	The aim of this dealing is to produce recombinant *Myxoma* and *Vaccinia viruses* that express ZP proteins for use in rabbit immunocontraceptive trials and assays respectively.
DNIR 148/2002	25 Nov 2002	10 Apr 2003	CSIRO – Sustainable Ecosystems, ACT	A viral vectored mouse immunocontraceptive	The aim of this dealing is to infect mice with a GM virus that will induce an autoimmune response which targets the developing oocyte within the ovary and renders female mice infertile.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 149/2002	29 Nov 2002	15 Apr 2003	AMRAD Corporation Limited, Vic.	Generation of recombinant wild-type and mutant Hepatitis B virus (HBV) capsid and polymerase proteins for use in *in vitro* assays	The aim of this dealing is to generate HBV mutant and wild type capsid and polymerase proteins that can be used in *in vitro* assays to measure the sensitivity of mutant and wild type HBV polymerases to potential inhibitors of HBV replication.
DNIR 150/2002	29 Nov 2002	16 Apr 2003	University of Queensland, Qld	Lentiviral delivery of genes and/or DNA to cells	The aim of this dealing is to use various replication defective lentiviruses to introduce genetic information into cells.
DNIR 151/2002	2 Dec 2002	16 Apr 2003	Institute of Medical and Veterinary Science, SA	Construction and *in vitro* and *in vivo* testing of recombinant Fowlpox virus (rFPV) vectors that express human or rat prostatic acid phosphatase with or without coexpression of human interleukin-2	The aim of this dealing is to investigate the immune response to recombinant Fowlpox virus vectors in laboratory strains of mice and rats and in primary human peripheral blood mononuclear cell cultures.
DNIR 152/2002	2 Dec 2002	16 Apr 2003	Institute of Medical and Veterinary Science, SA	Induction of autoimmune prostatitis in rats and mice using recombinant Vaccinia virus vectors that encode human or rat prostatic acid phosphatase	The aim of this dealing is to induce experimental prostatitis in laboratory strains of rats by infecting them with recombinant Vaccinia virus vectors containing the gene for human prostatic acid phosphatase.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 153/2002	4 Dec 2002	23 Apr 2003	CSIRO – Entomology, ACT	Isolation and expression of genes from endogenous soil micro-organisms	The aim of this dealing is to clone various genes from soil micro-organisms. The gene products will be investigated for use in the degradation of pesticide residues/ toxins or for their insecticidal properties.
DNIR 154/2002	5 Dec 2002	24 Apr 2003	Monash University, Vic.	Novel virulence determinants of *Enterohaemorrhagic Escherichia coli* (EHEC)	The aim of this dealing is to identify and characterise bacterial genes in EHEC that may be required for colonisation of the host.
DNIR 155/2002	9 Dec 2002	28 Apr 2003	Progen Industries, Qld	MPT64	The aim of this dealing is to generate recombinant protein (MPT64) that will be purified and formulated into a topical drug for clinical investigation in humans.
DNIR 156/2002	10 Dec 2002	30 Apr 2003	University of Western Australia, WA	Gene mediated cell death in ovarian cancer	The aim of this dealing is to study gene mediated cell death in ovarian cancer by infecting human cancer cells with viral particles containing the Y81 gene. The Y81 protein is hypothesised to slow the growth of the infected cells.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 157/2002	3 Dec 2002	22 Apr 2003	Department of Primary Industries, Qld	Molecular analysis of Cucumber mosaic virus (CMV) host range factors	The aim of this dealing is to study CMV replication, symptom development and host range by inoculating plants with CMV and recombinant CMV RNA.
DNIR 158/2002	19 Dec 2002	1 May 2003	Western Sydney Area Health Service, NSW	Focal modification of cardiac conduction by gene transfer	The aim of this dealing is to introduce specific genes into human and animal cells in order to induce electrical conduction between these cells in a network.
DNIR 159/2002	11 Dec 2002	1 May 2003	Australian National University, ACT	Flavivirus host/pathogen interactions	The aim of this dealing is to study flaviviral host/pathogen interactions in mice and mammalian and mosquito cell lines.
DNIR 160/2002	17 Dec 2002	6 May 2003	University of Queensland, Qld	Metabolic engineering of hyaluronic acid (HA) production	HA forms the capsule of some Group A and C S*treptococci*. The aim of this dealing is to identify and study genes involved in the regulation of HA production.
DNIR 161/2002	18 Dec 2002	7 May 2003	Queensland University of Technology, Qld	Expression of adhesins from bacterial pathogens in non-pathogenic lactic acid bacteria	The aim of this dealing is to genetically modify non-pathogenic lactic acid bacteria to express adhesin molecules from pathogenic organisms.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 162/2002	18 Dec 2002	8 May 2003	Queensland University of Technology, Qld	Investigation of host range determinants in *Papaya ringspot virus* (PRSV)	There are two types of PRSV (P & W) that differ in host range – ie. one infects papaya and another does not. The aim of this dealing is to determine the gene sequence/s that allow PRSV to infect papaya.
DNIR 163/2002	18 Dec 2002	8 May 2003	Queensland University of Technology, Qld	The development of *Glycine mosaic comovirus* (GMV) as a vector for heterologous gene expression in plants	The aim of this dealing is to test GMV-based vectors for high level expression of genes in plants.
DNIR 164/2002	19 Dec 2002	9 May 2003	CSIRO Entomology, ACT	Small RNA viruses of insects	The aim of this dealing is to study the potential use of small RNA viruses of insects for pest control and biotechnological purposes.
DNIR 165/2002	20 Dec 2002	12 May 2003	Xenome Limited, Qld	Isolation and characterisation of venom peptide genes	The aim of this dealing is to investigate venom peptides for therapeutic potential.
DNIR 166/2002	20 Dec 2002	6 May 2003	Mater Medical Research Institute, Qld	Retroviral expression cloning to discover new molecules expressed by leukocytes	The aim of this dealing is to isolate novel gene sequences from leukocytes (white blood cells) to better understand immune function.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 167/2002	20 Dec 2002	6 May 2003	CSIRO Sustainable Ecosystems, ACT	Production of recombinant proteins by *Vaccinia virus* for *in vitro* use	The aim of this dealing is to express proteins in *Vaccinia virus* that will be used in serological assays.
DNIR 170/2002	23 Dec 2002	13 May 2003	Johnson & Johnson Research Pty Ltd, NSW	A clinical trial to evaluate the safety and efficacy of genetically modified CD34+ cells in patients with *Human immunodeficiency virus -1* (HIV-1) infection	The aim of this trial is to evaluate the safety and efficacy of CD34+ blood progenitor cells modified with a delivery gene construct (OZ1 -which comprises an anti-HIV-1 ribozyme and the retroviral vector LNL6) in HIV patients receiving their first or second regimen of potent, combination antiretroviral therapy (ART).
DNIR 171/2003	3 Jan 2003	2 May 2003	Macquarie University, NSW	Comparative genomics of *Equine herpesvirus* (EHV)	The aim of this dealing is to analyse gene functions of EHV-1 and EHV-4 which are genetically closely related but have different cell culture host ranges and disease outcomes.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 172/2003	7 Jan 2003	14 May 2003	CSIRO – Sustainable Ecosystems, ACT	Myxoma virus/Kunjin replicon vaccine system	The aim of this dealing is to produce a recombinant *Myxoma virus* that expresses genes coding for contraceptive proteins via a *Kunjin* replicon. This will be tested as an immunocontraceptive for rabbits.
DNIR 173/2003	8 Jan 2003	15 May 2003	University of Adelaide, SA	Molecular breeding of grapevines for resistance to major root pests	Root-knot nematode and *Phylloxera* are pests that can cause significant reductions in grapevine yield or even vine death. The aim of this dealing is to genetically modify grapevine to resist these pests.
DNIR 174/2003	10 Jan 2003	23 May 2003	University of Sydney, NSW	Cloning of *Duck hepatitis B virus* (DHBV)	The aim of this dealing is to clone naturally occurring variants of DHBV and to assess the infectivity of these variants in cell cultures and ducklings.
DNIR 175/2003	28 Jan 2003	10 Jun 2003	Virax Holdings Limited, Vic.	Clinical trial of Fowlpox virus vaccines expressing *Human immunodeficiency virus -1* (HIV-1) antigens and human interferon-gamma	The aim of this dealing is to express HIV antigens and interferon-gamma in *Fowlpox virus* and to use this virus to elicit an immune response to these antigens in HIV infected individuals.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 176/2003	28 Jan 2003	10 Jun 2003	University of Western Australia, WA	Characterisation of haemolysin produced by *Vibrio alginolyticus*	*V. alginolyticus* is a marine bacterium capable of infecting humans, fish and prawns. Haemolysins are proteins which are virulence factors in other bacterial pathogens. The aim of this dealing is to characterise the haemolysin produced by *V. alginolyticus* and determine its relationship to others previously reported.
DNIR 177/2003	28 Jan 2003	10 Jun 2003	Children's Medical Research Institute, NSW	Immortalisation of human cells	The aim of this dealing is to use human cells transformed with genes that may alter their growth properties to study how normal cells become cancer cells.
DNIR 178/2003	28 Jan 2003	6 Jun 2003	Children's Hospital Westmead, NSW	Functional and molecular analysis of defects of the mitochondrial electron transport chain	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.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 179/2003	28 Jan 2003	10 Jun 2003	Children's Hospital Westmead, NSW	Ex-vivo transduction of CD34 selected haemopoietic stem cells for clinical gene therapy trials	The aim of this dealing is to introduce genes into CD34 haemopoietic stem cells to treat patients with X-linked Severe Combined Immunodeficiency (X-SCID) and to provide resistance to alkylating drugs used in cancer therapy.
DNIR 180/2003	3 Feb 2003	11 Jun 2003	University of Queensland, Qld	Functional analysis of cloned avirulence/pathogenesis genes from plant pathogenic microbes	The aim of this dealing is to determine the function of cloned genes encoding putative avirulence and pathogenesis determinants in pathogenic fungi and oomycetes.
DNIR 181/2003	3 Feb 2003	11 Jun 2003	Bureau of Sugar Experiment Stations, Qld	Transposon and marker exchange mutagenesis of *Leifsonia xyli subspecies* (Lxx) to study pathogenesis on sugarcane	Lxx is an important pathogen of sugarcane and the causal agent of ratoon stunting disease. The aim of this dealing is to identify Lxx genes encoding proteins essential for the interaction between Lxx and sugarcane that could be targeted by antimicrobial compounds or antibodies.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 182/2003	3 Feb 2003	11 Jun 2003	Bureau of Sugar Experiment Stations, Qld	Development of a virus-based assay system to elucidate gene function in sugarcane	The aim of this dealing is to produce a virus-based vector containing sugarcane virus gene sequences that will be used in further studies to elucidate the function of sugarcane genes.
DNIR 183/2003	4 Feb 2003	5 Jun 2003	La Trobe University, Vic.	Nucleotide sequences of the coat protein of *Johnson grass mosaic virus* (JGMV) determining host specificity	JGMV is a pathogen of sorghums. Prior to 1980 the JGMV-Jg strain could not infect Krish sorghums. The aim of this dealing is to identify the critical changes in the amino acids of the JGMV coat protein that allowed the evolution of a Krish-infecting strain of JGMV.
DNIR 184/2003	4 Feb 2003	13 Jun 2003	Ludwig Institute for Cancer Research, Vic.	Induction of tumour formation and tumour regression by adenoviral mediated gene transfer	The aim of this dealing is to introduce genes that are involved in tumour formation and suppression into cultured cells and organs in living mice in order to mimic and/or reverse the sporadic genetic alterations that occur in adults with colorectal cancer.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 185/2003	4 Feb 2003	16 Jun 2003	CSIRO – Plant Industry, ACT	The use of virus vectors for gene silencing in plants (virus induced gene silencing)	The aim of this dealing is to infect plants of interest with viruses containing RNA sequences that will silence specific genes in the plants. This technique can be used to identify agronomically important genes.
DNIR 186/2003	4 Feb 2003	13 Jun 2003	MacFarlane Burnet Institute for Medical Research and Public Health, Vic.	Molecular Virology of *Human immunodeficiency virus -1* (HIV-1) and Simian immunodeficiency virus (SIV)	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.
DNIR 187/2003	4 Feb 2003	16 Jun 2003	MacFarlane Burnet Institute for Medical Research and Public Health, Vic.	Viral assembly of *Moloney murine leukemia virus* (MoMLV), *Mason-Pfizer monkey virus* (M-PMV), *Human foamy virus* (HFV) and *Avian sarcoma / leukosis virus* (ASLV)	The aim of this dealing is to understand the role of various *Moloney murine leukaemia virus, Mason-Pfizer monkey virus, human foamy virus* or *avian sarcoma / leukosis virus genes* by transfecting mammalian cells with mutated or wild type clones of these retroviruses.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 188/2003	4 Feb 2003	16 Jun 2003	MacFarlane Burnet Institute for Medical Research and Public Health, Vic.	Pathogenesis of macrophage-tropic *Human immunodeficiency virus –1 (HIV-1)*	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.
DNIR 189/2003	4 Feb 2003	17 Jun 2003	Johnson & Johnson Research Pty Ltd, NSW	*In vitro* murine and human cell transformation or mouse reconstitution for a gene therapy approach to acute myeloid leukemia	The aim of this dealing is to provide a model for leukemia development by oncogene (cancer causing gene) activation and to assess the effects of tumour suppressor genes in arresting leukemia development.
DNIR 190/2003	6 Feb 2003	16 Jun 2003	South East Sydney Area Health Service, NSW	Cellular immunity to *Human immunodeficiency virus* (HIV) and *Hepatitis C virus* (HCV)	The aim of this dealing is to examine cellular immunity to HIV and HCV by expressing part of the HIV or HCV genome in *Vaccinia virus* and infecting human cells with this virus.
DNIR 192/2003	6 Feb 2003	18 Jun 2003	Australian National University, ACT	Immunoregulatory gene studies and vaccine vector library development	The aim of this dealing is to develop an ongoing library of vaccine vectors (viruses containing genes of interest) for use in vaccine development and the study of immunoregulatory molecules.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 193/2003	6 Feb 2003	16 Jun 2003	University of Queensland, Qld	Studies on the immune response to recombinant *Vaccinia virus*	The aim of this dealing is to use *Vaccinia viruses* containing Papillomavirus genes to study the processes governing immune activation or tolerance to DNA tumour viruses and to improve the quality of immune responses against human Papillomavirus proteins.
DNIR 194/2003	7 Feb 2003	5 Jun 2003	Western Sydney Area Health Service, NSW	Evaluation of cellular immunological function with recombinant virus	The aim of this dealing is to evaluate if a treatment can augment or sustain 'Hhuman immunodeficiency virus (HIV) positive patients' cellular immune response to HIV and help further define the mechanisms involved.
DNIR 197/2003	7 Feb 2003	20 Jun 2003	CSIRO Entomology, ACT	DNA viruses of invertebrates	The aim of this dealing is to produce recombinant insect DNA viruses to improve understanding of their properties and characteristics and to assess their suitability as biological control agents for insect pests.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 198/2003	5 Feb 2003	18 Jun 2003	Austin Research Institute, Vic.	The expression of leukocyte antigens	The aim of this dealing is to use retroviruses to express cloned genes of interest in mouse and human cell lines. The function of the proteins encoded by these genes will then be assessed.
DNIR 200/2003	11 Feb 2003	20 Jun 2003	University of Canberra, ACT	Mutagenesis of vaccine antigen genes and related proteins in bacterial respiratory pathogens	The aim of this dealing is to disrupt genes encoding candidate vaccine antigens and related proteins in bacterial respiratory pathogens to gain a better understanding of their function.
DNIR 201/2003	14 Feb 2003	20 Jun 2003	University of Melbourne, Vic.	The mechanisms of tolerance and immunity in systemic rheumatic diseases	The aim of this study is to examine immunological tolerance to self antigens when they are encountered during an infection by infecting mice with *Vaccinia viruses* containing genes encoding self (La) or foreign (ovalbumin) antigens. The outcome will determine the efficiency of self-tolerance under the stress of infection and provide clues to the causes of autoimmune disease in humans.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 202/2003	14 Feb 2003	20 Jun 2003	University of Melbourne, Vic.	Gene regulation of osteoclastogenesis	The aim of this project is to examine the action of candidate genes on the process of osteoclast generation from precursor cells by infecting these cells with *Adenoviruses* / *Retroviruses* containing the candidate genes.
DNIR 203/2003	14 Feb 2003	19 Jun 2003	University of Melbourne, Vic.	Construction and use of Herpes simplex virus (HSV) mutants	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.
DNIR 204/2003	14 Feb 2003	20 Jun 2003	University of Melbourne, Vic.	Molecular biology of retroviral replication, pathogenesis and productive infection	The aim of this dealing is to study the RNA elements that modulate the expression of *Human immunodeficiency virus* (HIV) proteins and to develop drugs that target these elements.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 205/2003	14 Feb 2003	20 Jun 2003	University of Melbourne, Vic.	Nucleic acid (DNA and RNA) and viral vectored vaccines for *Human immunodeficiency virus* (HIV)	The aim of this dealing is to develop a safe and effective vaccine against HIV by injecting animals with DNA plasmids, a recombinant *Fowlpox virus* or a recombinant *Sindbis virus* containing HIV or Simian immunodeficiency virus (SIV) genes. Some animals will then be exposed to HIV and SIV to test if the immune responses generated by these vaccines can protect against AIDS.
DNIR 208/2003	19 Feb 2003	20 Jun 2003	University of Western Australia, WA	Recombinant *Murine cytomegalovirus* (MCMV) encoding Hepatitis C virus (HCV) proteins	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.
DNIR 210/2003	26 Feb 2003	20 Jun 2003	University of Western Australia, WA	Use of *Vaccinia virus* as a vector for antigens and cytokines in murine tumour models	The aim of this dealing is to use a recombinant *Vaccinia virus* containing genes coding for various tumour antigens and cytokines to elicit an anti-tumour immune response in mice.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 211/2003	27 Feb 2003	18 Jun 2003	Telethon Institute for Child Health Research, WA	Construction and manipulation of an infectious cDNA clone of *Enterovirus 71* and *Coxsackievirus A16*	The aim of this dealing is to investigate the molecular basis of *Human enterovirus 71* virulence by inserting genome regions from related viruses of low virulence into its genetic background. The virulence of these chimeras will be studied in the mouse model.
DNIR 212/2003	3 Mar 2003	20 Jun 2003	University of Adelaide, SA	Pathogenicity and virulence genes of the barley pathogen *Rhynchosporium secalis*	The aim of this dealing is to identify and isolate pathogenicity determinant genes from the barley pathogen *R. secalis*
DNIR 214/2003	10 Mar 2003	20 Jun 2003	CSIRO Molecular Sciences, NSW	*Adenoviruses* as gene delivery vectors	The aim of this dealing is to transiently express a foreign gene in a variety of cells and animal models using recombinant *Adenoviruses* containing this gene.
DNIR 226/2003	14 April 2003	15 May 2003	Department of Primary Industries, Vic.	Molecular breeding of grapevines for resistance to major root pests	The aim of the proposed dealings is to challenge transgenic grapevines that may be resistant to root pests with those pests and monitor the response.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 230/2003	22 Apr 2003	26 Jun 2003	University of Adelaide, SA	Pathogenesis, prevention and treatment of *Shiga toxigenic Escherichia coli* (STEC) infections	The aim of this dealing is to clone and characterise STEC genes involved in the pathogenesis of disease. The researchers hope to identify novel drug targets and develop vaccines against STEC infection.
DNIR 231/2003	22 Apr 2003	26 Jun 2003	University of Adelaide, SA	Pathogenesis and prevention of pneumococcal disease	The aim of this dealing is to clone and characterise *Streptococcus pneumoniae* genes involved in the pathogenesis of pneumococcal disease. The researchers hope to identify novel drug targets and develop vaccines against pneumococcal disease.

Application number	Application date	Licence issued	Organisation and State	Project title	Project description
DNIR 251/2003	5 Jun 2003	23 Jun 2003	Monash University, Vic.	Function of *Dichelobacter nodosus* genes	The aim of this dealing is to determine the role of potential disease causing genes in *D. nodosus* by inactivating them and adding the wild-type genes back onto the *D. nodosus* chromosome. The ability of these genes to complement equivalent inactivated genes in *Pseudomonas aeruginosa* will also be studied.

Appendix B

Gene Technology Community Consultative Committee Meeting

Melbourne, Victoria

5 June 2003

COMMUNIQUE

The Gene Technology Community Consultative Committee (GTCCC) held its fifth meeting in Melbourne, Victoria on 5 June 2003.

The GTCCC was established by the *Gene Technology Act 2000* (the Act) as a statutory advisory committee to the Gene Technology Regulator (the Regulator) and the Gene Technology Ministerial Council. All Committee members hold office on a part-time basis.

At its fifth meeting the current GTCCC working groups reported on their activities since the previous meeting and agreed on a new work strategy for each of the groups. In addition to the existing work plan priorities, the Committee considered a request from the Gene Technology Ministerial Council to comment on the draft policy principle and a new working group was established to review the revised format of the Risk Assessment and Risk Management Plans developed by the Office of the Gene Technology Regulator (OGTR). The outcomes of these discussions are summarised below.

Members also received a presentation from the Australian Pesticides and Veterinary Medicines Authority (the APVMA – formerly the National Registration Authority), a report on recent OGTR activities from the Gene Technology Regulator (the Regulator) as well as reports from the cross-members with the Gene Technology Ethics Committee and the Gene Technology Technical Advisory Committee.

GTCCC's Work Plan

GTCCC's first communique from its meetings of April and July 2002, detailed a number of priority areas that would form the basis of the Committee's future

work plan and result in the provision of advice to the Regulator. Since that time the working groups have been developing and refining their ideas out-of-session and at each subsequent meeting of the Committee. Details of the status of a number of the current working groups are provided below for information.

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

The working group provided the Committee with further advice and agreed to hold a face-to-face meeting to finalise their draft document. The draft document will be provided to the Committee at their next meeting.

Preparation of an overview of the public understanding of science literature
The second working group provided the meeting with a discussion paper. After discussion the Committee agreed to refocus the work being undertaken by this group. The working group will also meet out-of-session to finalise a draft paper on *the consideration of issues associated with public understanding of science, risk, and public perceptions of gene technology* which will be provided to the Committee at its next meeting .

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

The GTCCC was asked by the Regulator to provide advice on the new format of the RARMP, in particular the extent to which the restructured documentation improved public communication and enhanced transparency of the regulatory process. The Committee decided to establish a new working group which will meet out-of-session and prepare advice which will be provided to the Committee for consideration at its next meeting.

Policy Principle on GM Designated Areas

On 12 May 2003 a package was sent to all members concerning the draft policy principle which was referred to the Committee by the Gene Technology Ministerial Council. The Committee discussed the policy principle and the following amendments:

Amendment 1

The following amendment to the Regulatory Impact Statement was proposed to the Committee:

Page 1, 2nd paragraph, line 9

Current wording

….., the Regulator will not allow the proposed dealing to proceed.

Amended wording

….., the Regulator will not issue a licence for the proposed dealing to proceed.

The Committee recommends this change because it will increase consistency with the language used elsewhere in the document, for example:

- Page 2, paragraph 4
- Page 4, last paragraph

The motion was carried unanimously by the Committee.

Amendment 2: amendment to the policy principle

The following amendment to the policy principle was proposed to Committee.

> *An area is recognised as an area that is designated for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes, if the area is so designated under a State law.*
>
> *The designated area may only be recognised by the Regulator where one or more states have produced peer reviewed scientific data, after taking into consideration proposed licence conditions, buffer zones, demonstrating that the GM event will move by sexual or asexual means to a level beyond the acceptable threshold for adventitious presence into GM or non-GM crops for that area's major market.*
>
> *The Regulator may only recognise the designated area where the GM event (DNA) is present in the commercial product used in human food manufacture.*
>
> *Licence conditions that flow from the recognition of this policy principle shall be reviewed annually taking into consideration new scientific data and market threshold requirements.*

Seven members voted against and four in favour.

No request was made for the reasons for dissent to be recorded.

Information Presentation

GTCCC members expressed their appreciation for the presentation by Dr John Keniry (former Chairman of the National Registration Authority, NRA) and Dr Alison Turner, the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority (the APVMA – formerly the National Registration Authority), provided the Committee with an overview of the role and processes of the APVMA and an explanation of its interaction with the OGTR in relation to the national regulatory system for gene technology.

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

1800 181 030 (free-call)

Appendix C

Gene Technology Ethics Committee Meeting

9–10 April 2003, Canberra

COMMUNIQUE

The Gene Technology Ethics Committee (GTEC) held its fourth meeting in Canberra on the 9th and 10th of April 2003. GTEC was established by the *Gene Technology Act 2000* (the Act) as a statutory advisory committee to the Gene Technology Regulator (the Regulator) and the Gene Technology Ministerial Council. All committee members and expert advisers hold office on a part-time basis. (A reference to 'members' in the communique includes 'expert advisers').

At its fourth meeting the current GTEC working groups reported on their activities since the previous meeting and agreed on new work for a number of the groups. In addition to the existing work plan priorities, a new working group was established at the April meeting to build upon foundation research undertaken in the previous eighteen months by the Committee. Members were kept informed of relevant work from other national committees via cross-member reports and the Committee received a Chair's activity report and a report from the Regulator on activities undertaken by the Office of the Gene Technology Regulator (OGTR) since the third meeting held in October 2002. Key outcomes from the meeting are reported below.

GTEC's Work plan

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

Ethical Guidelines in Relation to Genetically Modified Organisms

At the April meeting the Committee resolved to develop a set of specific ethical guidelines in relation to genetically modified organisms. The development of practical ethical values and principles specifically relevant to gene technology

will be based upon preliminary work undertaken by one of the working groups and the contributions of a number of individual members. The Regulator has also requested that the Committee provide advice on the proposed implementation of the new guidelines.

A new working group has been established to draft an initial paper for the Committee's consideration later in 2003. The new guidelines are to be completed before the end of the inaugural GTEC term of appointment in October 2004.

Qualitative Survey of Institutional Biosafety Committees

The Committee has been examining the need for an ethical review process for all types of applications for genetic modification work in relation to plants and animals. Earlier this year the GTEC and the Victorian Biotechnology Ethics Advisory Committee (VBEAC) have discussed the possibility of a joint survey of Institutional Biosafety Committees (IBCs) in Victoria. The VBEAC is an advisory committee that has been established to provide independent advice to the Victorian Government on the social and ethical issues of biotechnology.

At the April GTEC meeting it was resolved that a member of the VBEAC would formally join the GTEC survey working group to work collaboratively on a broad fact-finding exercise to be conducted with selected IBCs. GTEC is very aware of the current IBC workload nationally leading up to the 21 June 2003 expiration of deemed instruments[1]. Therefore, the proposed consultations with IBCs will proceed after June 2003 and the working group will report on its findings to the GTEC later in 2003.

Ethical Issues Associated with Transkingdom Gene Transfer[2]

A working group was established to consider the ethical issues associated with transkingdom gene transfer. The working group reported at the April meeting and presented a revised paper for consideration. GTEC resolved to seek the Regulator's support to refer the paper to the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Community Consultative Committee (GTCCC) for comment.

When the paper has been finalised by the GTEC it will be published on the Committee's page on the OGTR website later in 2003.

Managing Risk Ethically

One of the proposed outcomes for the paper being developed by the 'Managing Risk Ethically' working group is that it will inform a planned review of the *Risk*

Analysis Framework for Licence Applications to the OGTR in 2003. The working group will also seek the Regulator's assistance to refer the paper to the GTTAC and GTCCC for comment.

GTEC Attendance at Australian Health Ethics Conference

The GTEC/Australian Health Ethics Committee (AHEC) cross-member and a local GTEC member attended a recent AHEC conference, 'Ethics in Human Research Conference', held from 2-4 April 2003 in Canberra.

It was reported that the national conference was well attended as was an associated research ethics training day held prior to the conference. The two GTEC delegates reported on their attendance and expressed the view that the conference was informative and that their attendance had been valuable.

GTEC and Relationships with Other Committees

As a standing item at every GTEC meeting, the Committee receives verbal reports on activities from the cross-members with the GTTAC and the GTCCC. Communiques from meetings of these committees are also published on the OGTR website. At this meeting, the GTTAC cross-member report included advice regarding the Committee's workload and recent membership changes and the GTCCC cross-member report included updates on the progress of the working groups established by that Committee.

The verbal cross-member report from the AHEC contained advice in relation to a number of projects being completed by that committee including finalisation of draft ethical guidelines on the use of reproductive technology in clinical practice and research. GTEC resolved to make a submission to the AHEC in response to the recent public invitation to comment on the draft guidelines.

GTEC also considered advice from one of its members in relation to the National Health and Medical Research Council's (NHMRC) invitation for public consultation on a *Draft Australian Code of Practice for the Care and Use of Animals for Scientific Purposes.* GTEC resolved to prepare a submission by the due date of 4 June 2003.

The NHMRC has announced that it will hold a second round of public consultation on xenotransplantation in 2003. GTEC intends to prepare a second submission building on their first submission on this topic in 2002. A copy of the first GTEC xenotransplantation submission is available on the Committee's page on the OGTR website.

Next Meeting

The next GTEC meeting will be held in late 2003.

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

1800 181 030 (free-call)

[1] The *Gene Technology Act 2000* (the Act) and the Gene Technology Regulations 2001 contain transitional provisions related to approvals granted under the previous voluntary scheme. Section 190 of the Act sets out the arrangements that have the effect of 'deeming' certain dealings to be licensed if a Genetic Manipulation Advisory Committee Advice to Proceed covering that dealing was in force on 21 June 2001 when the Act came into effect.

All of these deemed instruments lapse in June 2003 and the Regulator has no powers to extend that date. The OGTR has been communicating with organisations that currently hold these instruments to try to ensure that they can continue their work uninterrupted. Most of these organisations have now submitted appropriate applications to ensure that this work can continue and these applications form part of the overall figures reported here.

Over 3000 deemed instruments were transferred from the former voluntary system into the new regulatory scheme including:

- 49 dealings involving the intentional release of a GMO into the environment;
- 504 dealings not involving the intentional release of a GMO into the environment; and
- 1057 notifiable low risk dealings (which must take place in contained facilities).

In addition, the transitional arrangements involved:

- deeming the certification of 1550 contained facilities at various levels of security; and
- the accreditation of 119 organisations.

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

Appendix D

GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE

COMMUNIQUE No. 8

This is the eighth communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the thirteenth meeting of GTTAC held on 8 and 9 April 2003, as well as matters considered by GTTAC out-of-session in the period from 1 February to 9 April 2003.

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

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

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

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

Dealings not involving the intentional release of genetically modified organisms

Dealings Not Involving the Intentional Release of GMOs (DNIRs) are dealings that are usually undertaken within a certified facility (so that the organism is

physically contained) and where the personnel involved in the dealing have been assessed as having adequate training and experience for the task. These are typically laboratory-based projects.

Applications and RARMPs for the following DNIRs were assessed:

Application number and title	Project description	GTTAC comments
DNIR 135/2002 Conditionally replicative adenoviruses for neoplastic disease.	The aim of this dealing is to generate adenoviruses that will only replicate in the presence of specific tumour cell proteins. The adenoviruses will be tested for their impact on cell function.	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. In addition, GTTAC advised that the specificity of the vectors should be tested by the applicant and suggested that a new application would be required if the applicant proposed to add non-viral genes into the constructs.
DNIR 144/2002 The role of hyaluronic acid in normal and aberrant stem cell biology.	The aim of this dealing is to analyse the role of hyaluronic acid in leukaemiagenesis by over expressing or inhibiting hyaluronic acid synthase genes in primary human leukaemic cells.	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. GTTAC advised that laboratory guidelines must be followed and that the use of sharp instruments should be avoided where the possibility of accidental inoculation existed. However, when sharps are required, extra care should be taken.
DNIR 156/2002 Gene mediated cell death in ovarian cancer.	The aim of this dealing is to study gene mediated cell death in ovarian cancer by infecting human cancer cells with viral particles containing the Y81 gene. The Y81 protein is hypothesised to slow the growth of the infected cells.	As for DNIR 144/2002.

Application number and title	Project description	GTTAC comments
DNIR 158/2002 Focal modification of cardiac conduction by gene transfer.	The aim of this dealing is to introduce specific genes into human and animal cells in order to induce electrical conduction between these cells in network.	As for DNIR 144/2002. In addition, GTTAC advised that sheep treated with lentiviral vectors should be kept in a PC2 facility for as long as there is a risk of the animals shedding viable virus. Following this period it would be safe to house the animals in a PC1 facility.
DNIR 160/2002 Metabolic engineering of hyaluronic acid production.	Hyaluronic acid (HA) forms the capsule of some Group A and C Streptococci. The aim of this dealing is to identify and study genes involved in the regulation of HA production in bacterial fermentation processes.	As for DNIR 144/2002. In addition, GTTAC advised that as the GMO included a marker gene that conferred resistance to one of the antibiotics used to treat infection with *Streptococcus*, the applicant should be required to identify alternative antibiotics in case of infection with the GMO.
DNIR 161/2002 Expression of adhesins from bacterial pathogens in non-pathogenic lactic acid bacteria.	The aim of this dealing is to genetically modify non-pathogenic lactic acid bacteria to express adhesin molecules from pathogenic bacteria of risk group 2 or less.	As for DNIR 144/2002. In addition, GTTAC advised that the adhesin molecules could be cloned in *Escherichia coli* in order to amplify the DNA, however they should not be expressed in *E. coli* as this may alter the attachment properties of *E. coli*.
DNIR 166/2002 Retroviral expression cloning to discover new molecules expressed by leukocytes.	The aim of this dealing is to isolate novel gene sequences from leukocytes (white blood cells) to better understand immune function.	As for DNIR 144/2002.
DNIR 172/2002 *Myxoma virus*/Kunjin replicon vaccine system.	The aim of this dealing is to test the feasibility of a recombinant *Myxoma virus*/Kunjin replicon hybrid as an immuno-contraceptive vaccine in rabbits.	GTTAC advised that the ability of the recombinant virus to infect human cells should be tested by the applicant. GTTAC agreed that, if the virus is rabbit-specific, the risk assessment identifies all the risks associated with the proposed dealings and the measures proposed in the risk management plan are adequate to deal with the identified risks. GTTAC advised that laboratory guidelines must be followed and the use of sharp instruments should be avoided where the possibility of accidental inoculation exists. However, when sharps are required, extra care should be taken.

Advice on containment levels for genetically modified (GM) pathogenic viruses

At the previous GTTAC meeting the Committee agreed to provide further advice on the containment level required for work with particular GM viruses. This involved viral hybrids containing segments of Flaviviruses including HCV, *Murray Valley encephalitis virus*, *Bovine viral diarrhoea virus* and *GBV-C virus*.

The Committee discussed the potential virulence and likely frequency of replication competent virus production of the GMOs.

GTTAC advised the Regulator that:

- With regard to the recombination work conducted in *Escherichia coli*, it is safe for the applicant to undertake this work in a PC2 facility;
- The applicant should provide further data regarding the GMO sequences and frequency of replication competent virus production; and
- The viral replication component of the work should be conducted in a PC3 facility until the requested information can be considered.

Dealings involving the intentional release of genetically modified organisms

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

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

Advice on cotton

Advice on cotton applications

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

- **Field trials for herbicide tolerant (Roundup Ready® MON 88913) and herbicide tolerant/insect resistant (Roundup Ready® MON 88913 / Bollgard II®) cotton (DIR 035/2002)**
  The OGTR has received a licence application from Monsanto Australia Limited (Monsanto) for the limited and controlled release of GM herbicide

tolerant cotton (Roundup Ready® MON 88913) and herbicide tolerant/insect resistant cotton (Roundup Ready® MON 88913 /Bollgard II®). Monsanto proposes to conduct trials on 50 sites covering a total of 954 hectares, over three years, in the cotton growing regions of NSW and Qld and in northern WA, northern Qld and the NT.

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

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

Roundup Ready® MON 88913/Bollgard II® cotton was produced by conventional breeding of Roundup Ready® MON 88913 cotton with GM Bollgard II® cotton which is resistant to the major caterpillar pests of cotton.

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

Details of the gene construct, including the plasmid map, some of the regulatory sequences and preliminary protein expression data have been declared 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 035/2003 are similar to those posed by previous Roundup Ready® and Roundup Ready®/Bollgard II® cotton applications;
- The advice provided in relation to previously assessed GM cottons (Bollgard II® and Roundup Ready® cottons) should be considered in the preparation of the RARMP for DIR 035/2003; and

- The applicant should be asked to provide data on the expression levels of the introduced proteins under Australian field conditions, at the completion of the field trials.

Advice on cotton RARMPs

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

- **Commercial release of INGARD cotton event 531 in Australia (DIR 022/2002)**

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

  INGARD® cotton is resistant to lepidopteran caterpillar pests that attack cotton. It contains an insecticidal gene, *cry1Ac*, derived from the soil bacterium *Bacillus thuringiensis,* that produces a protein that is toxic to specific insects.

  It is intended that the 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. Food Standards Australia New Zealand, FSANZ, (formerly the Australia New Zealand Food Authority, ANZFA) has already approved the use of oil and linters from INGARD® cotton in human food.

  The applicant seeks approval for commercial release of the GM cotton in all Australian cotton growing regions south of latitude 22º South, and no limitations on transportation or storage are proposed (see below for further explanation). However, the Australian Pesticides and Veterinary Medicines Authority (APVMA), formerly known as the National Registration Authority, will remain responsible for determining the total planting area of GM cotton each season. The APVMA currently only allows up to 30% of the cotton crop to be planted to GM cotton to guard against the evolution and emergence of resistant insects.

GTTAC advised the Regulator that they endorsed the risk assessment and management plan for DIR 022/2002 but suggested clarification of the licence conditions relating to:

- The control of volunteer plants after feeding stock with cottonseed.
- The research on the distribution of feral cotton populations in Queensland.

- **Seed increase and efficacy studies in Northern Australia of transgenic cotton expressing a new insecticidal protein gene – extension of DIR 017/2002 (DIR 025/2002)**

  CSIRO has applied for a licence for the limited and controlled release (field trial) into the environment of GM cotton containing an insecticidal gene (*vip3A*).

  Details of the gene construct and the regulatory sequences (promoters), including the plasmid map, have been declared as Confidential Commercial Information (CCI). However this information was made available to GTTAC and the other prescribed expert authorities that were consulted on the preparation of the RARMP.

  The main aim of the proposed release is to evaluate the agronomic performance of cotton lines modified to express a new insecticidal protein (VIP3A) that is toxic to lepidopteran caterpillar pests. The lines also contain an antibiotic resistance marker gene (*hph*). The release would also be used to produce seed for future releases in an ongoing breeding program (which would be subject to further approvals).

  CSIRO proposes to carry out a limited and controlled release on three sites, in the shire of Wyndham-East Kimberley, over a total area of 3 hectares. None of the cotton plants from the release, or their by-products, would be used for animal and human food. However, the applicant proposes to sell lint from the release. Lint does not contain genetic material or protein.

  GTTAC advised the Regulator that they agreed with the conclusions of the risk assessment and noted that:

  - Gene flow to native cotton species does not need to be managed as there is very little potential for this to occur;
  - The licence conditions should specify a minimum width for pollen traps;
  - The licence conditions should be clarified to explain how the stability of proteins in the soil will be evaluated if these proteins are already in the soil from indigenous populations of *Bacillus thuringensis*; and
  - The level and frequency of reporting required should be reviewed.

Advice on canola

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

- **Commercial release of InVigor® canola (*Brassica napus*) for use in the Australian cropping system (DIR 021/2002)**

  The OGTR has received an application from Bayer CropScience Pty Ltd (Bayer) for the commercial release of GM canola into the environment.

  Bayer are seeking regulatory approval for seven similar GM 'lines' of canola which have all been trialed previously in Australia under limited and controlled conditions. Although Bayer only intends to commercialise two lines in Australia, the applicant is seeking approval for all seven GM canola lines to achieve consistency with existing overseas regulatory approvals.

  Oil derived from all seven canola lines has been approved for use in human food in Australia by Food Standards Australia New Zealand. The GM canola from the proposed release would be used as oil in human food, or in animal feed, in the same way as conventional (non-GM) canola.

  The hybrid canola seed, which Bayer seeks to commercialise in Australia as InVigor® canola, is produced with a novel hybrid generation system based on two genetically modified 'parent' lines of canola: a male sterile (MS) line that contains a male sterility gene (*barnase*), and a fertility restorer (RF) line containing a fertility restorer gene (*barstar*). The progeny are expected to have enhanced agronomic performance, otherwise known as 'hybrid vigour'.

  All seven GM canola lines include a gene that confers tolerance to the herbicide glufosinate ammonium. The herbicide tolerance serves as a dominant marker for the introduced traits during breeding and hybrid seed production. It may also be used for the control of weeds in the canola crop, although glufosinate ammonium is not currently registered for use in broad-acre cropping in Australia. Bayer is seeking registration of glufosinate ammonium for use on InVigor® canola under the trade name Liberty® through the APVMA.

  Four of the GM canola lines contain a gene that provides a 'marker' for antibiotic resistance in plants. This gene is used to identify and select modified plants during the development stage.

  In accordance with section 184 of the Act, Bayer has sought approval to enable detailed technical information on precise gene constructs and molecular characterisation data to be declared 'Confidential Commercial Information'. However, this information was made available to GTTAC and

other prescribed expert authorities that were consulted on the preparation of 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 risk of toxicity, allergenicity, weediness and gene transfer. There is no risk to human health and safety above those presented by conventional canola, and that while the probability of gene transfer to other canola plants was high, the overall rate of outcrossing would be very low and the impact of this would be negligible; and
- The Committee agrees with the proposed licence conditions, however advised that consideration should be given to:

  clarifying licence condition Part 2, Section 2.2.2 which requires the applicant to report adverse impacts to human health and safety and the environment.; and

  the means of collecting data on the area planted to each GMO, as required by licence condition Part 2, Section 2.2.3 as it would be preferable to collect this information independently rather than via the applicant.

Advice on carnations

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

- **Commercial release of colour modified carnation (continuation of deemed licence GR2) (DIR 030/2002)**

  An application has been received from Florigene for a licence for the ongoing commercial release of GM carnations (*Dianthus caryophyllus)*. The general release of colour modified carnations (GR-2) was authorised in 1995 under the former voluntary system. Under GR-2 Florigene has release four transgenic lines representing four transgenic events.

  The carnations have been modified to produce violet, mauve, or purple coloured flowers. Non-GM carnations lack the part of the anthocyanin biosynthetic pathway that is responsible for the production of delphinidins, which produce the blue spectrum of colours in flowers. The GM carnations in this application contain the genes coding for the two key enzymes in this pathway: flavonoid 3', 5' hydroxylase (F3'5'H) and dihydroflavonol reductase (DFR).

The GM carnations also contain a selectable marker conferring resistance to acetolactate synthase (ALS) inhibiting herbicides, as well as regulatory sequences designed to enhance expression of the inserted genes.

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

- The Committee agrees with the assessment made by the OGTR that, in regard to toxicity, allergenicity, weediness and gene transfer, the risks posed to human health and safety or to the environment are no greater than those posed by non-GM carnations;
- The Committee agrees with the proposed licence conditions; and
- GM carnations are suitable for the GM Register.

Advice on post-harvest monitoring conditions

In accordance with Section 190 of the *Gene Technology Act 2000* (the Act), 'deemed' licences were issued for limited and controlled releases (field trials) of GMOs under the previous voluntary system, prior to the commencement of the Act on 21 June 2001. Deemed licences are only in effect for the transition period and therefore, in the absence of a licence from the Regulator, these deemed licences will expire on 20 June 2003.

Where only post-harvest monitoring of trial sites will continue past 21 June 2003, applicants have not been asked to submit an application for a DIR licence under the new regulatory system. Instead, the conditions for post-harvest monitoring of the trial sites will be attached to other relevant DIR licences held by the same organisation.

GTTAC was asked for advice on the post-harvest monitoring conditions for fourteen deemed licences currently in the post-harvest phase.

GTTAC discussed the proposed post-harvest monitoring conditions and advised the Regulator as follows:

- Conditions relating to cultivation should be made more specific.
- If volunteer plants were seen at the end of a specified monitoring period then further post-harvest monitoring should be required;
- Bi-monthly monitoring would be appropriate for GM white clover, subclover, field peas, and lupins;
- GM *Brassica* species should be treated as in recent canola applications; and
- References to isolation distances and insect proof screens should be removed from the post-harvest monitoring conditions as these applied to the trial phase.

Review of Gene Technology Regulations

OGTR representatives explained the process required for the amendment of the *Gene Technology Regulations 2001* (the Regulations), which is scheduled to begin later in 2003. The Committee discussed the way in which they could most efficiently provide advice to the Regulator on any proposed amendments of a scientific nature.

GTTAC advised the Regulator that:

- Prior to GTTAC's review of the proposed amendments, the Institutional Biosafety Committees should be invited to submit proposed changes to the Regulations.
- A one or two-day face-to-face meeting should be organised to allow GTTAC to provide advice on the proposed changes.

Presentations

At the April meeting of GTTAC the Committee received and discussed presentations on the following topics:

- horizontal gene flow
- defective viral vectors
- plant viral trangenes

Enquiries and risk assessment and risk management plans

For all enquiries and to obtain copies of applications or RARMPs for dealings involving the intentional release of GMOs into the environment, please phone the OGTR Free-call hotline on 1800 181 030. The RARMPs are also available electronically from our website at
http://www.ogtr.gov.au/publications/riskassessments.htm