

Quarterly report of
the Gene Technology Regulator
for the period
1 January to 31 March 2003

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ISBN

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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 January to 31 March 2003.

The key achievements for the quarter covered in the report include the issuing of 38 licences for dealings not involving intentional release of genetically modified organisms into the environment, the accreditation of 31 organisations and the certification of 315 contained facilities. Routine monitoring activities remained well above the OGTR's minimum target rate.

In addition, I met with New Zealand Ministers and officials to discuss the GMO regulatory environment in both jurisdictions. Officials agreed to support further liaison with Australia to promote high quality decision making regarding GMOs.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator

27 June 2003

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Glossary

Accredited organisation	An organisation that is accredited under section 92 of the Act
Act	<i>Gene Technology Act 2000</i>
APVMA	Australian Pesticides and Veterinary Medicines Authority (formerly NRA)
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 e.g. 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 e.g. 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
GTEC	Gene Technology Ethics Committee
GTTAC	Gene Technology Technical Advisory Committee
HREOC	Human Rights and Equal Opportunity Commission
IBC	Institutional Biosafety Committee
NLRD	Notifiable low risk dealing (e.g. plant or tissue culture work undertaken in contained facilities)
NHMRC	National Health and Medical Research Council
Non-compliance	A failure to comply with legislative requirements including licence, accreditation or certification conditions
NRA	National Registration Authority for Agricultural and Veterinary Chemicals (renamed APVMA)
OGTR	Office of the Gene Technology Regulator
PC1, PC2, PC3, PC4	Physical containment levels of facilities as certified by the Regulator in accordance with the Regulator's <i>Guidelines for Certification of Facilities/Physical Containment Requirements</i>
RARMP	Risk assessment and risk management plan
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 January–March 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 the 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 January–March 2003 quarter were:

Licences and other instruments

In this quarter the Regulator:

- considered 17 dealings involving the intentional release of GMOs into the environment (DIR licences)
- issued 38 licences for dealings not involving intentional release of GMOs into the environment (DNIR licences)
- received 200 Notifiable Low Risk Dealing (NLRD) notifications
- accredited 31 organisations
- certified 315 contained facilities.

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

Monitoring and Compliance

In this quarter the Monitoring and Compliance Section exceeded minimum targets of monitoring for both current field trial sites and post-harvest field trial sites.

More information on monitoring and compliance is contained in Part 2 of this report.

International collaboration and coordination

The Regulator met New Zealand Ministers and officials to discuss the GMO regulatory environment in both jurisdictions. Officials agreed to support further liaison with Australia to promote high quality decision making regarding GMOs.

More information on international collaboration and coordination is contained in Part 4 of this report.

Working collaboratively with States and Territories

State and Territory consultation

The Regulator must consult with State and Territory Governments and relevant local councils twice during the evaluation process 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.

Further information is set out in Part 2.

Gene Technology Ministerial Council

The Gene Technology Ministerial Council consists of one Minister from each State and Territory and one Minister from the Commonwealth. Currently, the Council comprises Ministers from a range of portfolios including health, agriculture and environment.

The Gene Technology Ministerial Council did not meet this quarter.

Gene Technology Standing Committee

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

The Standing Committee held two teleconferences this quarter and progress was made on development of the draft Gene Technology (Recognition of Designated Areas) Policy Principle.

Commonwealth agency liaison

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

Under the *Gene Technology Act 2000*, the Regulator must seek advice from prescribed Commonwealth authorities and agencies and the Commonwealth Environment Minister. Advice is sought on matters relevant to preparation of the RARMP for each application made to the Regulator for a DIR licence.¹

¹ Consultation is also required with State and Territory Governments, GTTAC, relevant local councils and the public.

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

- Food Standards Australia New Zealand
- the Australian Quarantine and Inspection Service
- the National Health and Medical Research Council
- the National Industrial Chemicals Notification and Assessment Scheme
- the Australian Pesticides and Veterinary Medicines Authority²
- the Therapeutic Goods Administration.

Once a RARMP is prepared, the Regulator again seeks comment on the RARMP from the same prescribed Commonwealth authorities and agencies.³

In addition, comment is sought on each application and RARMP from a range of other Commonwealth agencies which, while not prescribed in the legislation, have maintained a strong interest in its implementation including:

- the Department of Agriculture, Fisheries and Forestry – Australia
- the Department of Foreign Affairs and Trade
- the Department of Industry, Tourism and Resources
- Environment Australia.

During the quarter, the Regulator sought advice and comment from Commonwealth agencies in respect of three applications for DIR licences. Further information is set out in Part 2.

Public participation

During the quarter, the Regulator issued an invitation to the public to comment on three 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 *Commonwealth Government Notices Gazette*
- *The Australian* newspaper

² Previously known as the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), renamed in March 2003.

³ Consultation is also required with State and Territory Governments, GTTAC, relevant local councils and the public.

- relevant regional press and rural press, such as *Courier Mail*, *Northern Territory News*, *Queensland Country Life*, *The Land*, *The West Australian* 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 January–March 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 licences have a statutory timeframe of 170 days for processing.

- **DNIR licences**

DNIR licences authorise contained dealings carried out in laboratories and other facilities designed to prevent release of the GMO into the environment. These licences 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. Before certification is granted, lower level facilities are inspected by the organisation's IBC or an appropriately qualified person nominated by the IBC, and high level facilities are inspected by the organisation's IBC and the OGTR.

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 January – 31 March 2003

Application type	Number received	Number approved¹
DIR licence	6	0
DNIR licence	52	42
Accreditations	24	31
Certifications	298	315

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 a RARMP
- preparing a draft RARMP including proposed licence conditions
- consulting with prescribed expert groups and key stakeholders (including the public) on the draft RARMP
- considering all comments received and 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. For example, for an application received on 1 January 2003 the Regulator is required to make a final decision by 4 September 2003. This time limit is 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.

During the processing of each application for a DIR licence, the Regulator is required to undertake two mandatory consultation periods with prescribed expert groups and key stakeholders. The second period, which includes public consultation, must be at least 30 days but usually more time is allowed to facilitate 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 as at 31 March 2003 of applications for DIR licences that underwent evaluation during the quarter.

Status as at 31 March 2003 of applications for a DIR licence subject to evaluation during the quarter

Application received	First round of consultation¹	Second round of consultation
DIR034/2003	DIR020/2002	DIR022/2002
DIR035/2003	DIR021/2002	DIR025/2002
DIR036/2003	DIR023/2002	DIR030/2002
DIR037/2003	DIR026/2002	
DIR038/2003	DIR027/2002	
DIR039/2003	DIR028/2002	
	DIR031/2002	
	DIR033/2002	

¹ Includes posting of 'early bird' notifications and summaries of applications on the OGTR website and to people on the OGTR mailing list.

New applications for DIR licence

The OGTR received six applications for DIR licences in the January–March 2003 quarter as follows

- DIR034/2003 ‘Field Trial – The evaluation of transgenic cotton plants expressing the VIP gene’ (Syngenta)
- DIR035/2003 ‘Field trials of herbicide tolerant (Roundup Ready[®]) cotton MON 88913) and herbicide tolerant/insect resistant (Roundup Ready[®] MON 88913/BollgardII[®]) cotton’ (Monsanto)
- DIR036/2003 ‘Field Trial – Breeding and pre-commercial evaluation of transgenic cotton expressing a vegetative insecticidal protein (VIP) gene and a herbicide tolerance gene’ (CSIRO)
- DIR037/2003 ‘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)
- DIR038/2003 ‘Field Trial – Breeding and pre-commercial evaluation of transgenic cotton expressing tolerance to the herbicide glufosinate ammonium’ (CSIRO)
- DIR 039/2003 ‘Field Trial – Field Evaluation of high-oleic (HO) cotton’ (CSIRO).

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

In-progress applications for DIR licence

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

- DIR 025/2002 ‘Seed increase and efficacy studies in northern Australia of transgenic cotton expressing a new insecticidal protein gene (VIP3A)’ (CSIRO)
- DIR 026/2002 ‘Field trial for evaluation of GM papaya to delay fruit ripening and to test the expression of the introduced gene’ (University of Queensland)
- DIR 027/2002 ‘Field test of pineapple plants modified to control flowering’ (University of Queensland)

- DIR 028/2002 'Field trial of pineapple plants modified for blackheart reduction and to delay flowering' (Qld Department of Primary Industries)
- DIR 030/2002 'On going commercial release of colour modified carnation (Extension of deemed licence GR-2)' (Florigene)
- DIR 031/2002 'Field trial of GM grapevines – Evaluation of berry colour, sugar composition, flower and fruit development and gene flow study' (CSIRO)
- DIR 033/2002 'Commercial release – Recombinant live oral cholera vaccine (Orochol Vaccine)' (CSL).

The Regulator invited comment from expert groups and key stakeholders, including the public, on RARMPs for the following applications:

- DIR 022/2002 'Commercial release of insecticidal (INGARD®) cotton' (Monsanto)
- DIR 025/2002 'Seed increase and efficacy studies in northern Australia of transgenic cotton expressing a new insecticidal protein gene (VIP3A)' (CSIRO)
- DIR 030/2002 'On going commercial release of colour modified carnation (Extension of deemed licence GR-2)' (Florigene).

Withdrawn applications for DIR licence

In this quarter, the following two applications were withdrawn:

- DIR024/2002 'Agronomic assessment and seed increase in northern Australia of transgenic cotton expressing Cry1Ac or Cry1Ac and Cry2Ab' (CSIRO)
- DIR029/2002 'Defining sustainable production systems for transgenic cotton in the Kimberley, Western Australia' (Department of Agriculture (WA)).

Clock stopped on applications for commercial release of GM canola (DIR020/2002 and DIR021/2002)

The counting of the statutory timeframe of 170 days for assessing an application for a DIR licence can be stopped for several reasons. For example, the Regulator can 'stop the clock' on an application while awaiting further information requested from the applicant.

During the quarter, the Regulator continued to stop the clock on the assessment of application DIR020/2002 'General release of Roundup Ready® canola (*Brassica napus*) in Australia' (Monsanto) which was put on hold during the previous quarter.

The clock was restarted on application DIR021/2002 'Commercial release of InVigor® canola (*Brassica napus*) for use in the Australian cropping system' (Bayer CropScience). The clock was stopped on application DIR021/2002 during the previous quarter.

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 38 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 notifications from organisations undertaking notifiable low risk dealings (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. Notifications are checked by the OGTR for compliance with legislative requirements.

The Regulator received 200 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 January–March 2003 quarter.

Applications received and decisions made; existing licences and other instruments, 1 January – 31 March 2003

Type	Number received	Number processed ¹
Surrender of certification	50	43
Variation of certification	10	11
Transfer of licence	3	1
Surrender of DIR licence	3	0
Variation of DIR licence ²	9	3
Surrender of DNIR licence	1	5
Variation of DNIR licence	10	9

- 1 Numbers reported in this quarter often relate to applications received in previous quarter. 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 minor 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 enable 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 DIRs, DNIRs, NLRDs and transitional arrangements for accreditation of organisations and certification of contained facilities are recognised under the Act until 21 June 2003.

To minimise any disruption to industry and researchers, the OGTR has initiated a phased program of review, in consultation with instrument holders, to ensure that new applications to replace previous approvals can be considered before the expiry date set down in the legislation.

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 has been declared CCI by the Regulator, 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 Commonwealth 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 five CCI applications in relation to applications for DIR licences, three CCI applications in relation to applications for DNIR licences and one CCI application in relation to an NLRD.

The Regulator made two CCI declarations in relation to applications for a DIR licence (DIR025/2002 and DIR035/2003) and one CCI declaration in relation to an application for a DNIR licence (DNIR169/2003).

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, on an annual basis. A minimum of five per cent of current trial sites and five per cent of trial sites subject to post-harvest monitoring are monitored each quarter. The purpose of routine monitoring of field trials is to ensure compliance with licence conditions.

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 the inspection and monitoring of:

- a minimum of 20 per cent of Physical Containment (PC) 4, PC3 and PC2 large-scale facilities per year
- PC2 and PC1 facilities on a random basis.

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 Requirements*, which were based on GMACs previous guidelines. A revised draft document was produced, a consultation process was initiated and submissions were sought from key stakeholders. Another version of the guidelines is now being prepared to incorporate suggested improvements with the assistance of independent expert advice. (see Part 4, Reviews).

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 *Gene Technology Act 2000*. 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 January–March 2003 quarter, 64 monitoring visits were carried out on 61 sites, which included 3 follow-up visits. Monitoring was carried out on 18 licences and covered 6 plant species.

Current field trial sites monitored. Of the 25 sites current in the quarter, 6 were monitored. This represents a monitoring rate of 24 per cent of all current sites for the quarter.

Post-harvest field trial sites monitored. Of the 546 sites that were subject to post-harvest monitoring in the quarter, 55 were monitored. This represents a monitoring rate of 10 per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of contained dealings. During the January–March 2003 quarter, 20 PC2 facilities were monitored as part of the routine monitoring program. This encompassed PC2 laboratories (15 visited), PC2 plant houses (3 visited) and PC2 animal house (2 visited) across 7 organisations.

Monitoring conducted

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

Licensed Organisation name	Licence number ¹	No. sites visited	Site status ²	Crop type
Bayer CropScience	DIR10	4	C	Canola
	PR 110	1	PHM	Canola
	PR 62X(4)	10	PHM	Canola
	PR 63X(3)	2	PHM	Canola
	PR 63X(4)	25	PHM	Canola
	PR 63X(5)	1	PHM	Canola
	PR 93X	1	PHM	Canola
Bureau Of Sugar Experiment Stations	PR 68X	1	C	Sugarcane
CSIRO	PR 73	2	PHM	Sugarcane
	PR 105X(2)	1	PHM	Field Pea
	PR 136	2	PHM	Sugarcane
GlaxoSmithKline	PR129	1	PHM	Oilseed Poppy
	PR129X	1	PHM	Oilseed Poppy
La Trobe University	PR 64X(2)	1	C	White Clover
Monsanto Australia Limited	PR 77X	3	PHM	Canola
	PR 77X(2)	3	PHM	Canola
	PR 77X(3)	1	PHM	Canola

Licensed Organisation name	Licence number ¹	No. sites visited	Site status ²	Crop type
Queensland Department of Primary Industries	PR 141	1	PHM	Cotton
Totals	18	61	C=6 PHM=55	6 species

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

2 C = current; PHM = post-harvest monitoring

Inspection of PC2 facilities

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

Organisation	Physical Containment (PC) facility	No. facilities visited
Australian Institute of Marine Science	PC2 Laboratory	1
Bureau of Sugar Experiment Stations	PC2 Plant House	2
CSIRO - Health Science & Nutrition	PC2 Laboratory	2
Institute of Medical & Veterinary Science	PC2 Laboratory	3
Institute of Medical & Veterinary Science	PC2 Animal House	1
Melbourne Health	PC2 Laboratory	3
University of Melbourne	PC2 Laboratory	3
University of Melbourne	PC2 Plant House	1
University of Melbourne	PC2 Animal House	1
Western Sydney Area Health Service	PC2 Laboratory	3
Totals	3 facility types	20

Monitoring findings

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

PR Number and Site Number	110, Site 1
Summary of Dealing	Licence relates to field trials of canola (<i>Brassica napus</i>) modified for resistance to glufosinate-ammonium conducted by Bayer CropScience.
Findings	The site was observed to be sown to lucerne which had recently been cut for hay. At the time of the inspection, Bayer had not submitted a request to vary the licence to allow lucerne to be planted on the site.
Risk assessment	The OGTR risk assessment concluded there was a negligible risk of dissemination or persistence of the GMO arising from this land use.
Risk management	The accredited organisation is to ensure variations are sought before the alteration of cropping regimes on post trial sites.

PR No and Site No	141, Site 1
Summary of Dealing	Licence relates to field trials of cotton (<i>Gossypium hirsutum</i>) expressing the CryIA [®] delta-endotoxin from <i>Bacillus thuringiensis</i> .
Findings	The site was observed with an estimated 1000 mature plants with approximately 50% flowering or bolls open and lint apparent.
Risk assessment	The OGTR risk assessment was that there was a negligible risk of persistence/dissemination of the GMO due to risk management arrangements.
Risk management	The accredited organisation is to eliminate cotton volunteers prior to flowering, encourage germination of any present seed bank, in order for it to be destroyed before flowering through appropriate management within specified timeframes.

OGTR's monitoring of PC2 facilities in the quarter found a number of minor non-compliances and issues with certification of instruments. Each of the observed non-compliances were assessed for risk 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 and were 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* are currently under review to remove ambiguity and provide more effective guidance for all parties working with the document.

Reviews

The Monitoring and Compliance Section carries out reviews of incidents or practices in dealing 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 the environment and may be suspected to be a non-compliance with the *Gene Technology Act 2000* and associated legislation; and
- **practice reviews**: are initiated to determine if licence conditions can be, and are being, effectively implemented and include identification of potentially adverse effects of a GMO and may be prompted by observations or a set of observations made during monitoring activities.

The primary focus of the review process is to determine whether the incident that has occurred, or practice being used, has a potential human health or environmental risk that requires management actions to be implemented. In certain instances where there has been a suspected non-compliance with the *Gene Technology Act 2000*, the issue may be referred for investigation.

Two incident reviews were completed in this quarter and are outlined in the tables below.

Issue	The Department of Primary Industries (Victoria)(previously the Department of Natural Resources and Environment) reported an incident where a NLRD involving the genetic modification of vegetables had been varied and not reported to the OGTR. In addition, part of this research was performed in a plant growth cabinet that was not in a certified facility as required under the Act. When the incident was identified by the Institutional Biosafety Committee, the research was immediately stopped and all plants and seed were destroyed by autoclaving.
Risk assessment	The OGTR risk assessment was that this incident posed negligible risk to public health and the environment.
Determination	Negligible risk non-compliance: It was determined that the plant material had been disposed of in accordance with the OGTR's requirements.
Risk management	The Department of Primary Industries is undertaking a comprehensive review of compliance procedures and detailing a revised management plan further reducing the risk of any similar incidents occurring in the future.
Action	Not referred for investigation.

Issue	Monsanto Australia Ltd reported the unintended presence of a very low number of volunteer GM Roundup Ready® canola plants on a site previously sown to conventional canola. The site has never been involved in approved GM canola trials.
Risk assessment	The OGTR assessment was that this incident posed negligible risk to public health and environmental safety. The risk was further reduced by the immediate remedial actions taken by Monsanto and the absence of appropriate mechanisms to disseminate the GMO, such as the movement of stock and farm equipment off site.
Determination	The review included several site visits, discussions with the landholder, Monsanto and the seed company that provided the conventional canola seed and laboratory tests of both the volunteer plants and seed from the same lot that was used to sow the site to conventional canola. The findings were inconclusive with respect to the source of the volunteer plants.
Risk management	The OGTR has established arrangements between Monsanto and the landholder to ensure the site is regularly monitored and volunteers controlled.
Action	The incident has not been referred for investigation.

Investigations

There were no investigations completed in the reporting period.

Audits

No audits were initiated or completed in the quarter.

PART 3 Committee operations

The Act established three advisory committees:

- The **Gene Technology Technical Advisory Committee** (GTTAC)
 - provides scientific and technical advice to the Regulator and Ministerial Council
- 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.

Gene Technology Technical Advisory Committee

During the quarter, the GTTAC held one teleconference meeting on 31 January 2003. At this meeting the Committee considered six applications for DNIR licences and the associated RARMPs.

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

- two applications for DNIR licences and associated RARMPs
- two DIR RARMPs.

The sixth GTTAC Communiqué, outlining discussions held at the September and October 2002 meetings, is attached to this report as Appendix B. The seventh GTTAC Communiqué, outlining the discussions held at the December 2002 and January 2003 meetings is attached to this report as Appendix C. The GTTAC is scheduled to meet again in April 2003.

Further information about the dealings considered by the GTTAC can be obtained from the communiqués that are published on the OGTR website at www.ogtr.gov.au.

Gene Technology Ethics Committee

The GTEC did not hold a meeting during the quarter, however, working groups previously established to work on a range of priority areas have been engaged in out-of-session activity between meetings. Members have been focusing on

revising draft papers and drafting new papers for consideration at their first meeting in 2003.

Further information about the issues under consideration by the GTEC can be obtained from the October 2002 meeting communiqué attached to the October–December 2002 Quarterly Report and is also available on the OGTR website at www.ogtr.gov.au. Previous communiqués can also be found on the OGTR website.

Gene Technology Community Consultative Committee

During the quarter, the GTCCC held its fourth meeting on 20 February 2003 in Mount Gambier, South Australia and undertook site visits on 19 February 2003 in the Mount Gambier region. The Committee had previously requested that the Regulator provide an opportunity for members to become more informed about the growing of GM canola in Australia. This was achieved by undertaking a site visit to a limited and controlled GM canola release site. The visit was supported by Monitoring and Compliance staff from the OGTR and meetings requested by the Committee were arranged with an agronomist, a local farmer, and a local council officer.

During the visit the Committee received informative presentations on a wide range of topics, including presentations from the Gene Technology Grains Committee⁴, the District Council of Grant, and a presentation on local government nationally from a GTCCC member. At the February meeting, the Committee considered a number of standing items of business and received progress reports from the current working groups established in July 2002 to provide specific advice to the Regulator. The working groups are due to report again at the Committee's next meeting in 2003.

In addition, the Committee determined that it wished to provide advice to the Regulator on a number of topics arising from both the meeting and the discussions of the previous day, including the commercial GM canola applications under consideration by the Regulator. The GTCCC expressed concern to the Regulator that a state of community unreadiness exists concerning the risks to the environment of the commercial release of GM canola, so significant that the applications should be declined at this time. Further details of the advice and additional advice from the Committee to the

⁴ The GTGC comprises representatives from across the grains industry including scientists, growers, bulk handlers, marketers and exporters, food processors, technology providers and the organics industry, as well as Commonwealth and State Government observers.

Regulator in relation to canola industry stewardship protocols and communication with local government can be found in the meeting communiqué attached to this report (Appendix D).

The GTCCC is scheduled to meet again in mid-2003.

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 GM cotton, 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 a review by the OGTR, draft revised guidelines were released for wide consultation ending 30 September 2002. A total of 57 submissions were received and evaluated. Another version of the guidelines is now being prepared to incorporate suggested improvements with the assistance of independent expert advice.

International collaboration and coordination

Under the Act, two of the functions of the Regulator are to monitor international practice in relation to regulation of GMOs, and to maintain links with international organisations that deal with regulation of gene technology as well as with agencies that regulate GMOs in countries outside Australia.

International collaboration and coordination activities undertaken during the quarter include:

- a delegation from Japan visited the OGTR to gather information on regulation of gene technology in Australia.
- the OGTR attended the United Nations Environment Program – Global Environment Project on Development of National Biosafety Frameworks in Kuala Lumpur, Malaysia
- the OGTR attended the Organisation for Economic Co-operation and Development working group meeting *Harmonisation of regulatory oversight in biotechnology* in Paris, France

- the Regulator met with the New Zealand Minister of Research, Science and Technology, the Hon Pete Hodgson and the New Zealand Minister for the Environment, Hon Marian Hobbs in Wellington, New Zealand
- the Regulator met with New Zealand Environmental Risk Management Authority in Wellington, New Zealand
- the Regulator met with visiting delegates from Canada to inform them of the gene technology regulation in Australia.

Advice on gene technology regulation

Presentations and meetings

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

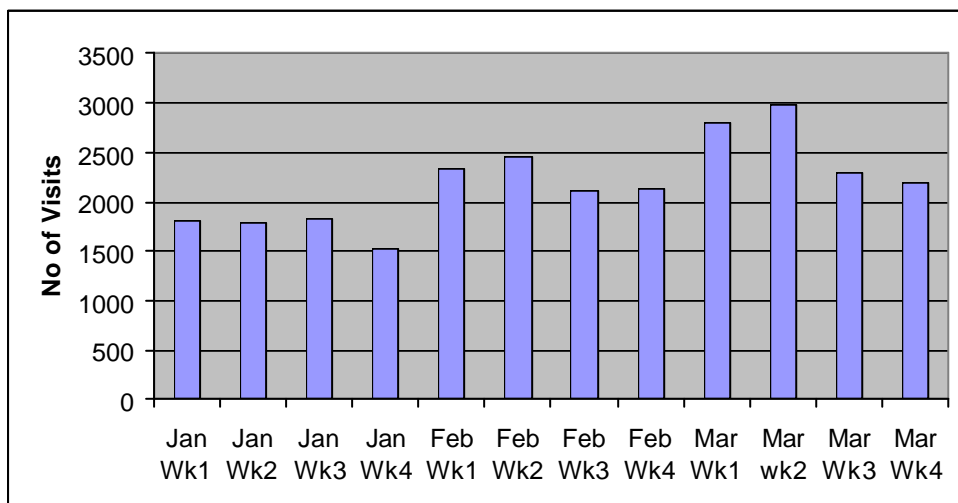
- presented *The regulation of gene technology in Australia* on 14 January 2003 at the National Youth Science Forum in Canberra, Australian Capital Territory
- established information exhibitions at the Cancer Conference on 13-16 February 2003 and the Genome Conference on 16-20 February 2003 at Lorne, Victoria
- presented *Process for gene regulation in Australia* on 25 February 2003 at the Women in Agriculture Forum *The good, the bad and the question marks – threats and opportunities in the GMO debate* in Perth, Western Australia
- presented *Australia's regulatory system for gene technology* on 3 March 2003 to the Victorian Department of Natural Resources and Environment's Gene Technology Standing Committee in Melbourne, Victoria
- presented *Gene technology regulation and Australian universities* on 7 March 2003 to the AVCC Deputy Vice Chancellors (Research)/Pro Vice Chancellors (Research) Committee meeting in Canberra, Australian Capital Territory
- participated in Biotechnology Australia's exhibit and the *Horsham Community Forum* during the Wimmeria Machinery Field Days on 4-6 March 2003 in Horsham, Victoria
- participated in the New South Wales Farmers Association Forum on genetically modified canola 27 March 2003 in Canowindra, New South Wales.

Institutional Biosafety Committees training sessions

OGTR regularly provides training sessions to organisations and institutional biosafety committees. During the January–March 2003 quarter, one session was conducted at the University of Western Australia.

OGTR website www.ogtr.gov.au

The OGTR website received 483,150 hits⁵ during the period 1 January to 31 March 2003, which represents an average of 5,368 hits per day.



The graph above illustrates the pattern of individual visits⁶ to the OGTR website, by week over the reporting period.

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 canola (Brassica napus)*
- *The biology and ecology of cotton (Gossypium hirsutum)*
- *Handbook on the regulation of gene technology in Australia.*

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

⁵ Hits = Total number of pages and images accessed on the website

⁶ Visits = Total number of visitors that entered the website

OGTR email address and freecall 1800 number

The 1800 number and the OGTR email address are points of contact for members of the public and other interested parties. Assistance for 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 230 calls and 70 emails in January 2003, 240 calls and 100 emails in February 2003, and 180 calls and 120 emails in March 2003.

Freedom of Information

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

The OGTR finalised and completed one FOI request from the Total Environment Centre (TEC) that commenced in the previous quarter. This request related to correspondence concerning the development of RARMPs as they relate to pesticide use on GM cotton and canola crops.

Consultants

During the reporting period, the OGTR managed 3 consultancy contracts worth a total of \$99,284. The table below lists the consultants, describes the purpose of the consultancy and the amount paid during the quarter.

Consultant	\$ Amount paid (GST exclusive)	Purpose
Dialog Information Technology	\$68,549	Develop Gene Technology Information Management System (GTIMS).
Agronico Pty Ltd	\$2,644	Brassica weed survey in the vicinity of two former GM canola sites.
Hassall & Associates	\$28,091	Review of guidelines for the certification of facilities.
Total Consultants for quarter	\$99,284	

Appendix A

DNIR licences issued 1 January – 31 March 2003

Application number	Application date	Organisation (State)	Project title	Project description	Licence issued
DNIR100/2002	27 Aug 02	South East Sydney Area Health Service (New South Wales)	Human and Ovine Adenovirus Vectors for Cancer Gene Therapy.	The aim of this dealing is to examine the efficacy of a treatment for prostate cancer that uses adenoviral vectors, in the mouse model.	4 Mar 2003
DNIR101/2002	27 Aug 02	Western Sydney Area Health Service (New South Wales)	The identification and investigation of virulence factors in <i>Legionella longbeachae</i> .	The aim of this dealing is to create a mutant strain of <i>Legionella longbeachae</i> (LL) lacking the pilD virulence gene and to study the role of this gene in the virulence of LL.	3 Jan 2003
DNIR102/2002	27 Aug 02	Western Sydney Area Health Service (New South Wales)	Genetic and biochemical characterisation of cryptococcal phospholipases in relation to fungal virulence.	The aim of this dealing is to first isolate the phospholipase gene from a particular cryptococcal strain and then study the role of this gene in the virulence of <i>Cryptococcus neoformans</i> by creating a mutant <i>C. neoformans</i> lacking the gene.	9 Jan 2003
DNIR103/2002	2 Sep 02	Department of Primary Industries (Queensland)	Cloning the complete genomes of alphaherpesviruses.	The aim of this dealing is to produce recombinant herpesvirus vaccines through the utilisation of infectious clone technology.	15 Jan 2003

Application number	Application date	Organisation (State)	Project title	Project description	Licence issued
DNIR104/2002	3 Sep 02	Melbourne Health (Victoria)	The antigenicity and replication of hepatitis B virus vaccine escape and lamivudine resistant mutants and humoral plus cellular immune responses to hepatitis C virus.	The aim of this dealing is to study the antigenicity (ability of a substance to cause an immune response) and replication of hepatitis B virus mutants and to analyse the humoral (antibody) and cellular (T-cell) immune responses to hepatitis C virus.	16 Jan 2003
DNIR105/2002	3 Sep 02	Melbourne Health (Victoria)	Studies of the replication of hepatitis C virus and hepatitis B virus in mammalian cells.	To study the replication of hepatitis B and C virus by using liver cells infected with baculovirus containing hepatitis B and C viral DNA.	16 Jan 2003
DNIR106/2002	9 Sep 02	Monash University (Victoria)	Genetics and pathogenesis of the clostridia.	To study genes putatively identified as having a role in the pathogenesis, antibiotic resistance or gene transfer in <i>Clostridia</i> spp.	22 Jan 2003
DNIR107/2002	11 Sep 02	Institute of Medical and Veterinary Science (South Australia)	Virus replication and viral pathogenesis.	To investigate the function of different viral genes and their role in regulating viral replication and viral pathogenesis.	24 Jan 2003

Application number	Application date	Organisation (State)	Project title	Project description	Licence issued
DNIR108/2002	11 Sep 02	Institute of Medical and Veterinary Science (South Australia)	Targeted gene delivery for vascular and neoplastic disease.	To use targeted gene delivery to investigate pulmonary vascular disease, tumour vasculature and cancer.	24 Jan 2003
DNIR109/2002	13 Sep 02	Peter MacCallum Cancer Institute (Victoria)	Signal transduction pathways in human cancers.	The aim of this dealing is to understand the genetic and biochemical changes involved in the development of cancer using human and mouse cells models.	29 Jan 2003
DNIR110/2002	13 Sep 02	Peter MacCallum Cancer Institute (Victoria)	Novel approaches for activation and expansion of genetically engineered T cells in vivo.	The aim of this dealing is to study the anti-tumour activity, expansion and survival of mouse and human primary lymphocytes (T cells) in vivo, that have been genetically modified to express single chain antibody receptors.	17 Jan 2003
DNIR111/2002	13 Sep 02	Peter MacCallum Cancer Institute (Victoria)	Analysis of the molecular functions of perforin: a critical role in tumour immunosurveillance.	The aim of this dealing is to express wildtype and mutant perforin cDNAs in perforin-deficient cell lines (rat mast cell line, RBL) and primary mouse T-lymphocytes to understand the structure/function relationship of the perforin molecule.	29 Jan 2003

Application number	Application date	Organisation (State)	Project title	Project description	Licence issued
DNIR112/2002	13 Sep 02	Deakin University (Victoria)	Overexpression of diabetes/obesity related genes in cultured cells and animals using recombinant adenovirus.	The aim of this dealing is to study the roles of newly identified genes in the development of diabetes and obesity.	28 Jan 2003
DNIR113/2002	13 Sep 02	Monash University (Victoria)	Infectious RNA of human caliciviruses.	Infection of cultured cells by calicivirus particles has not been demonstrated and the researchers hypothesise this is due to defective virus particle attachment and entry. The aim of this dealing is to bypass this block by using viral nucleic acid.	29 Jan 2003
DNIR115/2002	8 Oct 02	The Walter and Eliza Hall Institute of Medical Research (Victoria)	Transfection and gene knockout/down of <i>Plasmodium sp</i> and mammalian cell lines.	The researchers propose to use short sequences of dsRNA produced by stable expression vectors to silence the expression of genes in either mammalian cell lines or malaria. They also propose to study the pathogenesis of <i>P. berghei</i> malaria in various murine gene knockout models.	14 Feb 2003

Application number	Application date	Organisation (State)	Project title	Project description	Licence issued
DNIR116/2002	8 Oct 02	The Walter and Eliza Hall Institute of Medical Research (Victoria)	Functional analysis of malaria parasite proteins using transfection of <i>Plasmodium sp</i> of human and rodent origin.	The aim of this dealing is to study the role of particular malaria proteins in various aspects of the parasite's lifecycle by transfecting the parasite with Plasmodium genes.	7 Feb 2003
DNIR117/2002	9 Oct 02	AMRAD Operations Pty Ltd (Victoria)	Creation of a recombinant baculovirus harbouring a greater than genome length copy of the Hepatitis B virus (HBV) genome capable of transducing hepatoma cell lines.	The aim of this dealing is to create a recombinant baculovirus that harbours a greater than full length copy of the HBV genome and to use this virus to transfect cell lines. The transfected cells will be used to screen for antiviral compounds.	7 Feb 2003
DNIR118/2002	9 Oct 02	AMRAD Operations Pty Ltd (Victoria)	Construction of recombinant HIV clones and viruses.	The aim of this dealing is to construct and grow molecular clones of HIV in <i>E. coli</i> and to produce and grow HIV and recombinant HIV in mammalian cell lines. The viruses produced will be used in assays for the development of antiviral compounds.	12 Feb 2003

Application number	Application date	Organisation (State)	Project title	Project description	Licence issued
DNIR119/2002	11 Oct 02	CSL Limited (Victoria)	Expression of human papillomavirus antigens.	The aim of this dealing is to express human papillomavirus protein antigens in <i>E. coli</i> and to purify these proteins in order to formulate a vaccine.	12 Feb 2003
DNIR122/2002	17 Oct 02	CSL Limited (Victoria)	Pilot scale fermentation and processing of antibody fragments expressed in GMOs.	The aim of this dealing is to produce antibody fragments using GMOs and to evaluate them for the treatment of a variety of animal and human disease conditions.	28 Feb 2003
DNIR123/2002	17 Oct 02	Melbourne Health (Victoria)	Studies on the replication of hepatitis C virus (HCV).	The aim of this dealing is to produce a DNA copy of HCV that contains only the regions of the virus necessary for the virus to replicate. The researchers intend to study HCV replication and design and test antiviral compounds that stop this process.	10 Feb 2003
DNIR124/2002	17 Oct 02	Melbourne Health (Victoria)	Replication of hepatitis B virus (HBV), duck hepatitis B virus (DHBV) and woodchuck hepatitis virus (WHV) and the testing of antiviral agents.	The aim of this dealing is to study the replication of HBV, DHBV and WHV and to investigate the growth of these viruses in the presence of antiviral agents. Variants of HBV associated with resistance to antiviral agents will also be studied.	21 Feb 2003

Application number	Application date	Organisation (State)	Project title	Project description	Licence issued
DNIR125/2002	17 Oct 02	Melbourne Health (Victoria)	Studies of the replication of hepatitis B virus (HBV) using recombinant HBV/adenovirus as a delivery system for mammalian cells and studies of HBV and HCV co-infection using HBV/adenovirus and HCV clones.	The aim of this dealing is to study the replication of HBV by infecting liver cells with HBV using a modified adenovirus containing HBV DNA. HCV genetic material will also be introduced to HBV infected cells to investigate HBV and HCV co-infection.	28 Feb 2003
DNIR126/2002	18 Oct 02	University of New South Wales (New South Wales)	Molecular regulation of cell lifespan and malignant transformation.	The aim of this dealing is to investigate the molecular regulation of cell lifespan and malignant transformation by genetically modifying mammalian cells with genes of interest.	14 Feb 2003
DNIR127/2002	21 Oct 02	Department of Primary Industries (Queensland)	Development of a gene transfer vector for banana.	The aim of this dealing is to develop a gene transfer vector for the banana plant and other plant species.	19 Feb 2003

Application number	Application date	Organisation (State)	Project title	Project description	Licence issued
DNIR128/2002	22 Oct 02	Western Australia Institute for Medical Research (Western Australia)	Expressing haemopoietic regulators in cells using amphotropic retroviruses.	The aim of this dealing is to transfer genes associated with haemopoietic regulation into cells using a replication defective retrovirus, and to study the effects of this altered gene expression on haematopoiesis.	6 Mar 2003
DNIR129/2002	25 Oct 02	Queensland University of Technology (Queensland)	Cloning of genes from potentially toxigenic risk group 2 bacteria.	The aim of this dealing is to analyse genes from a variety of risk group 2 bacteria for commonalities.	7 Mar 2003
DNIR130/2002	28 Oct 02	Royal Perth Hospital (Western Australia)	Use of retroviral and lentiviral gene delivery systems for the expression of hepatitis C virus (HCV) proteins in cell culture.	The aim of this dealing is to use retroviruses and lentiviruses to express various HCV proteins. These viruses will be used to study the replication of HCV in cell culture.	7 Mar 2003
DNIR132/2002	30 Oct 02	University of Southern Queensland (Queensland)	Whooping Cough Vaccine VI.	The aim of this dealing is to develop a genetically modified non-toxic whooping cough vaccine.	13 Mar 2003
DNIR133/2002	30 Oct 02	University of Southern Queensland (Queensland)	<i>Pasteurella multocida</i> Type A genes and gene products – 1.	The aim of this dealing is to study the role of various genes and gene products in the pathogenesis of <i>P. multocida</i> .	13 Mar 2003

Application number	Application date	Organisation (State)	Project title	Project description	Licence issued
DNIR134/2002	30 Oct 02	University of Southern Queensland (Queensland)	Mechanisms of immunity in salmonellosis.	The aim of this dealing is to characterise the immunoregulating factors produced by mice vaccinated with two attenuated strains of <i>Salmonella typhimurium</i> .	13 Mar 2003
DNIR136/2002	1 Nov 02	Orica Australia Pty Ltd (Victoria)	Production of pesticide-degrading enzymes using recombinant <i>E. coli</i> .	The aim of this dealing is to produce commercial quantities of pesticide-degrading enzymes using recombinant <i>E. coli</i> .	6 Mar 2003
DNIR137/2002	6 Nov 02	Progen Industries (Queensland)	GeneSwitch.	The aim of this dealing is to produce large amounts of plasmid that will be purified and formulated into a drug product (erythropoetin) for clinical investigation in humans.	24 Mar 2003
DNIR138/2002	8 Nov 02	BresaGen Ltd (South Australia)	Large scale production of recombinant peptides or proteins.	The aim of this dealing is to produce a sufficient quantity of specific recombinant peptides or proteins to supply product for clinical trials and/or commercialisation.	26 Mar 2003
DNIR139/2002	13 Nov 02	CSIRO – Sustainable Ecosystems (Australian Capital Territory)	Recombinant canine herpesvirus as a vaccine vector.	The aim of this dealing is to construct a recombinant canine herpesvirus to be used as a vaccine vector.	31 Mar 2003

Application number	Application date	Organisation (State)	Project title	Project description	Licence issued
DNIR168/2002	24 Dec 02	Hunter Grain Pty Ltd (New South Wales)	Yellow corn import.	To import grain from the USA for processing as stockfeed. Since there are commercial crops of GM corn in the USA, the shipment may contain GM corn.	2 Jan 2003
DNIR169/2002	24 Dec 02	Hunter Grain Pty Ltd (New South Wales)	Importation of soybeans for processing into soy oil and stockfeed.	To import soybeans from the USA for processing and solvent extraction to produce soybean meal for use in stockfeed and soybean oil for use in margarines and cooking oils (approved by FSANZ in 2000). Since there are commercial crops of GM soybeans in the USA, the shipment may contain GM soybeans (approved in the USA).	3 Jan 2003
DNIR215/2003 -replaces DNIR002/2001	12 Dec 03	University of Queensland (Queensland)	Gene therapy of hypertension – long term regulated atrial natriuretic peptide gene transfer in spontaneously hypersensitive rats using new lentivectors.	The aim is to develop a new model for gene therapy by treating rats with hypertension (high blood pressure) with a gene which produces atrial natriuretic peptide.	19 Mar 2003

Appendix B

GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE

COMMUNIQUE No. 6

This is the sixth communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the ninth and tenth meetings of GTTAC held on 19 September and 24 October 2002 respectively.

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.

RARMPs for the following DNIRs were assessed:

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 063 Retroviral mediated gene transfer into murine haematopoietic cells</p>	<p>The researchers propose to transfer and study genes thought to be involved in cell growth, proliferation, apoptosis (programmed cell death) and differentiation in cell cultures.</p>	<p>GTTAC agreed that the risk assessment identified all the risks associated with the proposed dealings and that the measures proposed in the risk management plan are adequate to deal with the identified risks. GTTAC advised that laboratory guidelines must be followed and in particular, 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.</p>
<p>DNIR 065 Immunotherapy of cancer using recombinant viruses</p>	<p>This project aims to assess the anti-tumour potential of a melanocyte protein vaccine.</p>	<p>As for DNIR 063. GTTAC also recommended that the development of autoimmune responses be considered. In addition researchers should be vaccinated against <i>vaccinia</i>.</p>
<p>DNIR 067 Development of vaccines to protect against members of the <i>Pasteurellaceae</i></p>	<p>This project aims to develop vaccines against <i>Pasteurellaceae</i> associated diseases in production animal species.</p>	<p>As for DNIR 063.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 068 Fowl adenovirus recombinants</p>	<p>The proponents intend to construct and test different genetically modified fowl adenoviruses as potential vaccines against diseases in chickens and dogs.</p>	<p>As for DNIR 063.</p>
<p>DNIR 071 JE Chimerivax</p>	<p>The aim is to test the safety and efficacy of a yellow fever vaccine genetically modified to vaccinate against Japanese encephalitis in human volunteers.</p>	<p>As for DNIR 063.</p>
<p>DNIR 072 Construction of recombinant ranaviruses</p>	<p>Ranaviruses are viruses of fish, frogs and reptiles and this project aims to develop technology to genetically modify these viruses.</p>	<p>As for DNIR 063.</p>
<p>DNIR 076 Generation of infectious <i>cucumber mosaic virus</i> clones</p>	<p>Cucumber mosaic virus is a disease of lupins and many other plants. The researchers intend to study the interactions between the virus and lupins.</p>	<p>As for DNIR 063.</p>
<p>DNIR 077 Bioassay evaluation of bacteria expressing insecticidal genes</p>	<p>The aim of DNIR 077 is to identify proteins toxic to the rice bloodworm <i>Chironomus tepperi</i> from bacteria.</p>	<p>As for DNIR 063.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 078 Toxicity of modified rice callus to <i>Chironomus</i> larvae</p>	<p>The aim of DNIR 078 is to insert and test proteins toxic to the rice bloodworm <i>Chironomus tepperi</i> in tissue cultures of rice.</p>	<p>As for DNIR 063.</p>
<p>DNIR 079 Development of new vaccines against tuberculosis</p>	<p>The aim is to develop and test vaccines to protect against the human bacterial disease tuberculosis.</p>	<p>As for DNIR 063.</p>
<p>DNIR 080 Packaging of hepatitis delta virus (HDV) with modified envelope protein</p>	<p>The researchers propose to genetically modify hepatitis delta virus (HDV) so that it can infect cells other than liver cells, such as cancer cells, as a potential treatment.</p>	<p>As for DNIR 063.</p>
<p>DNIR 081 Molecular analysis of <i>Streptococcus pyogenes</i></p>	<p>The aim is to understand the role of specific gene products of the bacteria <i>Streptococcus pyogenes</i> in the onset of disease and to develop vaccines to protect against the disease.</p>	<p>As for DNIR 063. In addition, GTTAC advised that the vaccination of operators is not recommended.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 082 Molecular analysis of <i>Mycoplasma hyopneumoniae</i> and vaccine development</p>	<p>The aim is to understand the role of specific gene products of the bacterium <i>Mycoplasma hyopneumoniae</i> in the onset of disease and to develop vaccines to protect against the disease.</p>	<p>As for DNIR 063.</p>
<p>DNIR 084 The role of SDF-1 in normal and leukemic pre-B cell interactions with bone marrow stroma</p>	<p>SDF-1 is thought to be a key regulator of the behaviour of cells involved in acute lymphoblastic leukemia and this project aims to study how it works.</p>	<p>As for DNIR 063.</p>
<p>DNIR 085 Analysis of the effects of CD44 variant exon expression on adhesion and migration of human leukemia cells</p>	<p>CD44 is thought to affect cells involved in myeloid leukemia and this project aims to study how variations of CD44 act.</p>	<p>As for DNIR 063.</p>
<p>DNIR 091 Recombinant vaccinia virus encoding CMV or HCV genes</p>	<p>The aim is to examine the host response to cytomegalovirus and hepatitis C virus proteins to test for protective immune responses.</p>	<p>As for DNIR 063. In addition GTTAC advised that there was no evidence to suggest that viruses from different families could complement each other to produce replication competent chimeric viruses.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 092 Molecular mechanisms of bone and tissue remodelling</p>	<p>The aim is to introduce genes of interest into primary human and rodent cell lines of bone origin to study the effects of their forced expression on the formation of bone and other connective tissue.</p>	<p>As for DNIR 063.</p>
<p>DNIR 093 Novel retroviral expression cloning strategies to isolate genes with roles in haemopoiesis and stromal biology</p>	<p>The aim is to isolate novel cDNAs that encode for proteins that regulate haemopoietic and stromal cell differentiation. This will be achieved using retroviral expression cloning techniques.</p>	<p>As for DNIR 063.</p>
<p>DNIR 094 Clinical protocol HVDDT NO1 AI-05395 – fowlpox virus</p>	<p>The aim of these dealings is to determine the safety and immunogenicity of an HIV vaccine regimen.</p>	<p>As for DNIR 063.</p>
<p>DNIR 095 Clinical protocol HVDDT NO1 AI-05395 – DNA vaccine</p>	<p>The aim of these dealings is to determine the safety and immunogenicity of an HIV vaccine regimen.</p>	<p>As for DNIR 063.</p>

DNIR licence for the importation of stock feed

- **Importation of soy beans for use as stockfeed**

Due to the current drought, an application is anticipated requesting approval to import soy beans as stockfeed from the U.S.A, a proportion of which may be genetically modified. GTTAC advised that the RARMP prepared with respect to this application should address all risks associated with the importation of GM soy beans. GTTAC suggested that the risk management plan should also identify measures to recover any seed spilled at the processing plant. In addition, GTTAC questioned the licence condition requiring the processing plant to be within 20km of the wharf. This condition is required by AQIS and all plants are AQIS approved.

Dealings Involving the Intentional Release of Genetically Modified Organisms

Dealings Involving the Intentional Release (DIRs) of GMOs are dealings that are undertaken outside of a contained facility. DIRs may range from the limited and controlled release (field trial) of a GMO to 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

GTTAC considered the RARMPs prepared in response to four applications concerning the release of transgenic cotton in Australia, and provided advice on issues to be considered in preparing RARMPs for four others.

Advice on Cotton RARMPs

- **Agronomic Assessment and Seed Increase of Transgenic Cotton Expressing the *Cry1Ac* and *Cry2Ab* Genes from *Bacillus thuringiensis* (DIR 014)**

The Commonwealth Scientific and Industrial Research Organisation (CSIRO) has applied for a licence for the limited and controlled release (field trial) of two types of genetically modified (GM) cotton, Bollgard II[®] and Bollgard II[®]/Roundup Ready[®] cotton, into the environment.

Bollgard II[®] cotton is resistant to the major caterpillar pests that attack cotton. It contains two insecticidal genes that produce proteins toxic to specific insects and was derived from INGARD[®] cotton which contains one of the insecticidal genes. Bollgard II[®]/Roundup Ready[®] cotton was produced by conventional breeding of Bollgard II[®] cotton with Roundup Ready[®] cotton that contains a gene for tolerance to glyphosate, the active ingredient in the herbicide Roundup[®]. Bollgard II[®]/Roundup Ready[®] cotton therefore contains the two insecticidal genes from Bollgard II[®] cotton as well as the glyphosate tolerance gene from Roundup Ready[®] cotton.

CSIRO proposes to carry out a release on a total of 20 sites in NSW and Qld, covering a total area of 42 hectares. The purpose of this release is to continue evaluation of the agronomic performance of a number of different GM cotton lines, and to produce seed for possible future releases (which would be subject to separate application and assessment processes). In addition, the efficacy of the insecticidal proteins in controlling insect pests will be evaluated.

GTTAC advised the Regulator that the RARMP prepared for DIR 014 covered all relevant issues. The Committee agreed with the main conclusions from the risk assessment, including that:

- the Bollgard II[®] and Bollgard II[®]/Roundup Ready[®] cotton is not likely to prove more toxic or allergenic to humans or other organisms (other than targeted lepidopteran insects) than conventional cotton;
- the risk of the Bollgard II[®] and Bollgard II[®]/Roundup Ready[®] cotton establishing as a weed as a result of the proposed release is low and not likely to be greater than that of conventional cotton;
- the risk of development of herbicide-resistant weeds is negligible due to the small scale of the release;
- the likelihood of some gene transfer from the Bollgard II[®] and the Bollgard II[®]/Roundup Ready[®] cotton to cultivated cotton is high, but the overall frequency of out-crossing would be very low. This would not pose any risks additional to those posed by the Bollgard II[®] and Bollgard II[®]/Roundup Ready[®] cotton itself;
- the potential for transfer of the introduced genes to wild or native cotton is functionally zero because of the geographical isolation and genetic incompatibility with the native species;
- the likelihood of transfer of the introduced genes to organisms other than cotton is negligible, but even if such transfer occurred would be unlikely to pose any hazard to human health and safety or the environment; and

- the risk of development of target insects resistant to the insecticidal proteins is negligible due to the small scale of the release.
- **Agronomic Assessment and Seed Increase of Transgenic Cotton Expressing Tolerance to the Herbicide Glufosinate Ammonium (DIR 015)**

The CSIRO has applied for a licence for the limited and controlled release (field trial) of a GM herbicide-tolerant cotton, known as Liberty[®] cotton, into the environment.

Liberty[®] cotton contains the *bar* gene from a common soil bacterium that encodes the enzyme phosphinothricin acetyl transferase (PAT) that confers tolerance to the herbicide glufosinate ammonium, the active constituent of Basta[®], Liberty[®] and a number of other herbicides. The *bar* gene was also used as a marker during the genetic modification process to enable selection in the laboratory of plants containing the desired modification.

CSIRO is proposing to carry out a limited release on one site, in the shire of Narrabri (NSW), over a total area of up to 2 hectares. None of the cotton plants from the proposed release, or their by-products, would be used for human food or animal feed. However, the applicant proposes to sell lint from the release. Lint does not contain genetic material or protein.

GTTAC considered the RARMP for this application. The Regulator was advised that the Committee agreed with the conclusions of the risk assessment and endorsed the proposed risk management plan, which included the following licence conditions:

- an isolation zone of 50 metres in all directions from the outer edge of the pollen trap;
- the outer edge of the pollen trap should not be within 50 metres of natural waterways;
- any viable material not required for subsequent releases should be destroyed; and
- the release should be monitored for a period of twelve months after the release and the volunteers removed.

- **Evaluation under Field Conditions of Sub-clover Stunt Virus Promoters Driving an Insect Tolerance Gene (*Cry1Ab*) from *Bacillus thuringiensis* (DIR 016)**

CSIRO has applied for a licence for the limited and controlled release (field trial) of GM insecticidal/herbicide-tolerant cotton into the environment. The main aim of the proposed release is to assess the relative activity of different promoters by measuring the insecticidal activity of the cotton. A promoter is a piece of DNA that determines whether or not a gene is expressed, and to what extent. The applicant states that this GM cotton is not intended for commercial release.

The GM cotton contains an insecticidal protein that makes the cotton resistant to lepidopteran caterpillar pests. Expression of the *Cry1Ab* gene encoding the insecticidal protein is driven by promoters derived from plant viruses.

The GM cotton also contains the *bar* gene from a common soil bacterium, which encodes a protein that confers tolerance to glufosinate ammonium, the active constituent in Basta[®], Liberty[®] and a number of other herbicides. This herbicide tolerance gene was used as a marker during the genetic modification process, to enable selection in the laboratory of plants containing the desired modification.

CSIRO is proposing to carry out a limited release of approximately 60 different cotton lines, representing different transformation events. The release would be carried out on a total area of 1.5 hectares on two sites in the shire of Narrabri (NSW). None of the cotton plants from the proposed release, or their by-products, would be used for human food or animal feed. However, the applicant proposes to sell lint from the release. Lint does not contain genetic material or protein.

GTTAC considered the RARMP for this application and agreed that the risk assessment adequately identified the risks associated with this proposal, however the Committee suggested that further information on the activity of the stunt7 and stunt4 virus promoters could be included.

GTTAC endorsed the risk management plan, and advised the Regulator that similar licence conditions to those proposed for DIR 015 would be appropriate for this application.

- **Agronomic Assessments and Efficacy Studies of Transgenic Cotton Expressing a New Insecticidal Tolerance Gene (DIR 017)**

CSIRO has applied for a licence for the limited and controlled release (field trial) of GM insecticidal cotton into the environment. The main aim of the proposed release is to assess the agronomic performance and the insecticidal activity of the GM cotton. CSIRO also proposes to produce seed from selected lines for possible future releases, which would be subject to separate applications and assessment processes.

Details of the gene construct, including the identity of the insecticidal gene, the antibiotic resistance gene and the identity/origin of the regulatory sequences, as well as the specific cultivars proposed for release, have been declared as Confidential Commercial Information (CCI) under Section 185 of the *Gene Technology Act 2000*. However, this information was made available to GTTAC and the other prescribed expert authorities that were consulted on the RARMP.

The GM cotton contains a gene that produces an insecticidal protein derived from *Bacillus thuringiensis*, a common soil bacterium, which makes the cotton resistant to lepidopteran caterpillar pests. The protein is different from insecticidal proteins derived from genes of the same bacterium that are present in other types of GM cotton available commercially or currently being trialed in Australia. The new gene may provide additional options to manage the risk of development of insect resistance to the other insecticidal proteins.

Some of the GM cotton also contains an antibiotic resistance gene, from the bacterium *Escherichia coli*. The antibiotic resistance gene was used as a marker during the genetic modification process, to enable selection in the laboratory of plants containing the desired modification.

CSIRO is proposing to carry out a limited release on three sites in the shires of Narrabri and Moree Plains (NSW), over a total area of 3 hectares. None of the cotton plants from the proposed release, or their by-products, would be used for human food or animal feed. However, the applicant proposes to sell lint from the release. Lint does not contain genetic material or protein.

GTTAC considered the RARMP for this application. The Committee endorsed the risk management plan and advised the Regulator that similar licence conditions to those proposed for DIR 015 would be appropriate for this application.

Advice on Cotton Applications

- **Commercial Release of INGARD® Cotton Event 531 in Australia (DIR 022)**

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 22° South. Approval would enable the continued commercial release of the GM cotton. Monsanto also proposes the phasing-out of INGARD® cotton over the next three 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 22° South, and no limitations on transportation or storage are proposed (see below for further explanation). However, the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) will remain responsible for determining the total planting area of INGARD® cotton each season. The NRA currently only allows up to 30% of the cotton crop to be planted to this GM cotton to guard against the emergence of resistant insects.

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

- monitoring dairies and their immediate surrounds for the presence and destruction of volunteers in northern Australia (above latitude 22° S);
- double bagging, or covering of GM cotton seed and seed material by tarpaulins while being transported in areas above latitude 22° South;

- approaching the Cotton Research and Development Corporation to conduct research into gene flow and environmental impacts of GM cotton; and
- conformance with any conditions set by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA).

GTTAC further advised the Regulator that the licence conditions proposed for a previous cotton application (DIR 012/2002) could also apply to this proposal.

- **Commercial Release of Roundup Ready[®] Cotton Event 1445 (DIR 023)**

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

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

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

The applicant seeks approval for commercial release of the GM cotton in all Australian cotton growing regions south of latitude 22° South, without limitations on transportation and storage in northern Australia.

GTTAC discussed this application and advised the Regulator that the issues to be considered in the preparation of the RARMP were the same as for the previous application (DIR 022).

- **Seed Increase and Efficacy Studies in Northern Australia of Transgenic Cotton Expressing *Cry1Ac* or *Cry 1Ac* and *Cry 2Ab* (DIR 024)**

CSIRO has applied for a licence for the limited and controlled release (field trial) into the environment of transgenic cotton expressing insecticidal and/or herbicide tolerance genes.

The proposed release aims to evaluate agronomic performance and seed increase of GM cottons in northern Australia. The agronomic studies would involve growing INGARD[®], Bollgard II[®] and Bollgard II[®]/Roundup Ready[®] cotton. In addition, the release will collect information on the environmental impacts of the GM cotton. Effects of the GM cotton on the type and abundance on pest and beneficial insects, the potential development of insects resistant to the insecticidal activity of the GM cotton and the potential weediness of GM cotton in the northern environment will be studied.

INGARD[®] and Bollgard II[®] cotton are resistant to the lepidopteran caterpillar pests that attack cotton. They contain one or two insecticidal genes, respectively, that produce proteins that are toxic to specific insects. Bollgard II[®]/Roundup Ready[®] cotton also contains a gene for tolerance to the herbicide, glyphosate (Roundup[®]).

CSIRO proposes to carry out a limited release at five sites, Katherine and Douglas Daly in the Northern Territory and at Kununurra in Western Australia, over a total area of 136.5 hectares. None of the cotton plants from any of the trials, or their by-products, will be used for human food. The applicant proposes to transport the INGARD[®] cottonseed from the release for use as cattle feed in the eastern states. All transport and storage would be in accordance with requirements of the OGTR. The applicant proposes to sell lint from the release. Lint does not contain genetic material or protein.

GTTAC advised the Regulator that the issues to consider in the preparation of the RARMP are similar to previous GM cotton applications such as DIR 013 and DIR 014.

In addition, GTTAC recommended that an isolation distance be implemented where the cotton is to be planted in close proximity to other cotton crops.

- **Seed Increase and Efficacy Studies in Northern Australia of Transgenic Cotton Expressing a New Insecticidal Protein Gene (DIR 025)**

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

CSIRO has sought approval for details of the gene construct, and the regulatory sequences (promoters), including the plasmid map, to be declared Confidential Commercial Information (CCI). This aspect of the application is still under consideration, 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 that is toxic to lepidopteran caterpillar pests. The lines also contain an antibiotic resistance marker gene. 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 noted the limited scale of the release and agreed that the issues associated with this application were similar to the previous application (DIR 024). GTTAC advised the Regulator that the issues to consider in the preparation of the RARMP were similar to previous GM cotton applications.

Advice on Poppy

GTTAC considered one RARMP for the release of transgenic poppies in Australia.

Advice on Poppy RARMP

- **Field Assessment of Alkaloids in Modified Poppy (DIR 018)**

CSIRO has applied for a licence for a limited and controlled release (field trial) of GM oilseed poppies (*Papaver somniferum* subsp. *somniferum*) into the environment. Some details of the gene construct, including the identity of the alkaloid pathway genes, and the identity and origins of the regulatory

sequences have been declared as Confidential Commercial Information (CCI) under section 185 of the Act.

A total of eight types of GM oilseed poppy are proposed to be trialed in order to examine the effect of the modifications on alkaloid production under field conditions.

The modifications intend to vary alkaloid production by altering the expression of one of five plant genes that produce proteins that function at different steps in the alkaloid synthesis pathway.

Four of the five modified alkaloid synthesis genes are derived from oilseed poppy, while the fifth is from the related Californian poppy (*Eschscholzia californica*). The expression of each of the introduced genes is under the control of one of two viral promoters and a termination sequence that acts as a 'stop signal' for the expression of the introduced genes.

All of the modified poppies also contain the selectable marker gene *nptII* from the bacterium *Escherichia coli*. The *nptII* gene encodes the enzyme neomycin phosphotransferase II (NPTII) which confers resistance to the antibiotics neomycin, kanamycin, and gentamicin. The *nptII* gene also contains an intron derived from the catalase-1 gene of the castor bean, *Ricinus communis*. The expression of the *nptII* gene is under the control of the cauliflower mosaic virus (CaMV) 35S promoter and termination sequence.

CSIRO is proposing to carry out a limited and controlled field release at one site in the Meander Valley shire, Tasmania. The GM oilseed poppy plantings would comprise an area of 0.064 ha. The GM poppies would be surrounded by a 10 metre pollen trap of non-GM poppies, making up a total trial site area of 0.21ha. None of the oilseed poppy plants from the release or their by-products will be used for human or animal feed, or therapeutics, or for any other commercial use.

GTTAC considered the RARMP for this application and advised the Regulator that the risk assessment adequately addressed the issues associated with this proposal. In consideration of the risk management plan GTTAC suggested that the small size of the release would hamper the applicant's ability to effectively conduct research into gene flow and recommended that this requirement be removed from the licence conditions. GTTAC also advised that, due to lack of evidence of increased alkaloid production by the GM poppies, it may be too early to conduct research into the environmental impact of this trait, as proposed in the application.

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 on 1800 181 030. The RARMPs are also available electronically from our website at <http://www.ogtr.gov.au/publications/riskassessments.htm>

Appendix C

GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE

COMMUNIQUE No. 7

This is the seventh communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the eleventh and twelfth meetings of GTTAC held on 5 December 2002 and 31 January 2003 respectively.

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

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

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

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

Dealings Not Involving the Intentional Release of Genetically Modified Organisms

Dealings Not Involving the Intentional Release of GMOs (DNIRs) are dealings that are usually undertaken within a certified facility (so that the organism is physically contained) and where the personnel involved in the dealing have

been assessed as having adequate training and experience for the task. These are typically laboratory-based projects.

Applications and RARMPs for the following DNIRs were assessed:

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 002/2001 Gene therapy of hypertension and tumour sensitisation to radiotherapy.</p>	<p>The aim is to develop a new model for gene therapy by treating rats with hypertension (high blood pressure).</p>	<p>GTTAC discussed the early stage vector proposed to be used in this project and suggested that further data should be collected by the applicant on the inability of the viral vector to replicate in human cells. In addition, GTTAC suggested that further information on the gene mutations of interest be requested. GTTAC agreed with the conclusions of the risk assessment and advised that the measures proposed in the risk management plan were adequate to deal with the identified risks.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 090/2002 Immunocontraception and antigen delivery by recombinant cytomegalovirus.</p>	<p>The aim of this dealing is to genetically modify various cytomegaloviruses (CMVs) to contain reproductive proteins and other proteins. The GMOs will then be tested as immunocontraceptives and as vaccines in a number of animal species.</p>	<p>GTTAC agreed that the risk assessment identified all the risks associated with the proposed dealings and that the measures proposed in the risk management plan are adequate to deal with the identified risks. GTTAC advised that laboratory guidelines must be followed and in particular, 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.</p>
<p>DNIR 107/2002 Virus replication and pathogenesis.</p>	<p>This project aims to investigate the function of different viral genes and their role in regulating viral replication and viral pathogenesis.</p>	<p>As for DNIR 090/2002.</p>
<p>DNIR 108/2002 Targeted gene delivery for vascular and neoplastic disease.</p>	<p>The aim of this dealing is to use targeted gene delivery to investigate pulmonary vascular disease, tumour vasculature and cancer.</p>	<p>As for DNIR 090/2002. In addition, GTTAC advised that there is a very small chance of replication competent virus being produced, however, during recombination the transgene would be lost. Therefore any competent virus produced would be wild type adenovirus which humans are exposed to on a regular basis.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 109/2002 Signal transduction pathways in human cancers.</p>	<p>The aim of this dealing is to understand the genetic and biochemical changes involved in the development of cancer using human and mouse cells as model systems for human disease.</p>	<p>As for DNIR 090/2002.</p>
<p>DNIR 110/2002 Novel approaches for activation and expansion of genetically engineered T-cells.</p>	<p>The aim of this dealing is to study the anti-tumour activity, expansion and survival of mouse and human genetically modified (GM) primary lymphocytes (T cells) <i>in vivo</i>. The GM lymphocytes will be modified to express single chain antibody receptors.</p>	<p>As for DNIR 090/2002.</p>
<p>DNIR 112/2002 Overexpression of diabetes/obesity related genes in cultured cells and animals using recombinant adenovirus.</p>	<p>The aim of this dealing is to study the roles of newly identified genes in the development of diabetes and obesity.</p>	<p>As for DNIR 090/2002.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 115/2002</p> <p>Transfection and gene knockout/down of <i>Plasmodium</i> and mammalian cell lines.</p>	<p>The researchers propose to use short sequences of dsRNA produced by stable expression vectors to silence the expression of genes in either mammalian cell lines or malaria. They also propose to study the pathogenesis of <i>Plasmodium berghei</i> malaria in various mouse knockout models.</p>	<p>As for DNIR 090/2002. In addition, GTTAC agreed that the risks posed by the GMO were less than that of the wild type parasite.</p>
<p>DNIR 123/2002</p> <p>Studies on the replication of hepatitis C virus.</p>	<p>The aim of this dealing is to produce a DNA copy of hepatitis C virus (HCV) that contains only the regions of the virus necessary for the virus to replicate. The researchers intend to study HCV replication, as well as design and test antiviral compounds that stop this process.</p>	<p>As for DNIR 090/2002. In addition, GTTAC advised that the risks associated with this proposal were no greater than working with the wild type virus.</p>
<p>DNIR 125/2002</p> <p>Studies of the replication of hepatitis B virus using recombinant HBV/adenovirus as a delivery system for mammalian cells and studies of HBV and HCV co-infection using HBV/adenovirus and HCV clones.</p>	<p>The aim of this dealing is to study the replication of hepatitis B virus (HBV) by infecting liver cells with HBV using a modified adenovirus containing HBV DNA. HCV genetic material will also be introduced to HBV infected cells to investigate HBV and HCV co-infection.</p>	<p>As for DNIR 090/2002. GTTAC also discussed the possibility of replication competent virus with a broad host range being produced. GTTAC advised that the risk of producing competent virus was low and that this virus would be unable to replicate outside liver cells.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 126/2002 Molecular regulation of cell lifespan and malignant transformation.</p>	<p>The aim of this dealing is to investigate the molecular regulation of cell lifespan and malignant transformation by genetically modifying mammalian cells with genes of interest.</p>	<p>As for DNIR 090/2002.</p>
<p>DNIR 127/2002 Development of a gene transfer vector for banana.</p>	<p>The aim of this dealing is to develop a gene transfer vector for the banana plant and other plant species.</p>	<p>As for DNIR 090/2002.</p>
<p>DNIR 129/2002 Cloning of genes from potentially toxigenic risk group 2 bacteria.</p>	<p>The aim of this dealing is to analyse genes from a variety of risk group 2 bacteria for commonalities.</p>	<p>As for DNIR 090/2002.</p>
<p>DNIR 130/2002 Use of retroviral and lentiviral gene delivery systems for the expression of HCV proteins in cell culture.</p>	<p>The aim of this dealing is to use retroviruses and lentiviruses to express various HCV proteins. These viruses will be used to study the replication of HCV in cell culture.</p>	<p>As for DNIR 090/2002.</p>

Application Number and Title	Project Description	GTTAC Comments
<p>DNIR 132/2002 Whooping cough vaccine VI.</p>	<p>The aim of this dealing is to develop a genetically engineered non-toxic whooping cough vaccine.</p>	<p>As for DNIR 090/2002. In addition, GTTAC advised that it was not necessary for the applicant to check for reversions of the two point mutations used to create the vaccine strain, as either of the mutations is capable of eliminating pathogenic activity in the GMO on its own.</p>
<p>DNIR 133/2002 <i>Pasteurella multocida</i> Type A genes and gene products.</p>	<p>The aim of this dealing is to study the role of various genes and gene products in the pathogenesis of <i>Pasteurella multocida</i>.</p>	<p>As for DNIR 090/2002.</p>
<p>DNIR 134/2002 Mechanisms of immunity to salmonellosis.</p>	<p>The aim of this dealing is to characterise the immunoregulating factors produced by mice vaccinated with two attenuated strains of <i>Salmonella typhimurium</i>.</p>	<p>As for DNIR 090/2002.</p>
<p>DNIR 139/2002 Recombinant canine herpesvirus as vaccine vector.</p>	<p>The aim of this dealing is to construct a recombinant canine herpesvirus to be used as a vaccine vector.</p>	<p>As for DNIR 090/2002. In addition, GTTAC agreed that the virus is very species specific and that the genetic modifications are likely to attenuate the virus. GTTAC discussed the potential effect of an unintentional release of the GMO and agreed that the likelihood of the virus spreading among foxes in the wild was very low.</p>

Advice on containment levels for genetically modified pathogenic viruses

GTTAC was asked for advice on the containment level required for work with particular GM viruses. The GMOs included vaccinia virus recombinants carrying HCV antigens, as well as viral hybrids containing segments of Flaviviruses including HCV, Murray Valley encephalitis virus, Bovine viral diarrhoea virus and GBV-C virus.

GTTAC discussed the risks involved with this work and determined that, because the RNA polymerase gene had been removed from each of the GMOs, the GM viruses would be unable to replicate.

GTTAC advised the Regulator that further information regarding this application should be sent to three Committee members for further consideration.

DNIR licence for the importation of corn as stockfeed

Due to the current drought, an application has been received requesting approval to import corn as stockfeed from the U.S., a proportion of which may be GM. GTTAC advised the Regulator that the RARMP addressed all risks associated with the importation of GM corn.

Revision of the DNIR application form

GTTAC reviewed the draft revision of the DNIR application form prepared by the Office of the Gene Technology Regulator (OGTR). Members provided feedback on the new format and revised questions. The new application form is due for release early in 2003.

Dealings Involving the Intentional Release of Genetically Modified Organisms

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

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

Advice on Papaya

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

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

An application has been received from the University of Queensland for a licence for the intentional release of GM papaya (*Carica papaya* L, cultivar 'Solo') plants into the environment. Approval would enable the continued limited and controlled release (field trial) of GM papaya approved under the former voluntary system, as well as for several new lines of GM papaya.

The applicant proposes to study up to 300 individual papaya plants at one site, over a total area of 1.7 hectares in the Shire of Redlands (Qld).

The release involves growing several lines of papaya plants that have been modified to delay fruit ripening by down-regulation of a plant hormone, ethylene, or by modifying the ethylene receptor molecule. Some plants have also been modified to express a reporter gene that can be used to identify the plants with genetic modifications.

The GM papaya plants contain either:

- additional copies of *capacs 1* or *capacs 2* genes from papaya, which are associated with the biosynthesis of ethylene; or
- the *etr1-1* gene encoding the modified ethylene receptor protein from the plant *Arabidopsis thaliana*.

One type of GM papaya contains a reporter gene (GUS) to aid selection of the GMO in the laboratory.

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

- In order to minimise the risk of outcrossing, the male flowers of the GM plants should be removed and non-GM male plants grown to facilitate pollination.
- The netting enclosure proposed by the applicant would be adequate to prevent pollen dispersal, so long as the enclosure is 'sealed' to ground level.
- The enclosed area used for this trial should be monitored every 3 months for 12 months following harvest.
- Further information should be sought on whether seeds are shed by the GM plants.
- If the applicant proceeds with the viral work at a later date, further advice should be sought on the viral work proposed as the virus used could potentially affect cucurbits, possibly including those in the wild.
- Further information from the applicant on the polygalacturonase (PGA) promoter should be requested.
- The proposed dealing posed no significant risk to human health and safety, or the environment.

Advice on Pineapple

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

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

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

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

The GM pineapple plants have been modified by insertion of a truncated copy of the pineapple ACC (1-aminocyclopropane-1-carboxylate) synthase (*ACACS3*) gene to 'silence' the existing gene in the pineapple. ACC synthase is a key enzyme in the pathway that leads to formation of ethylene in plants and has a role in natural flowering.

Other GM pineapple plants have been modified by insertion of a reporter gene (*uidA*), which allows assessment of the activity of different regulatory sequences under field conditions.

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

Short regulatory sequences that control expression of the introduced genes are also present in the GM pineapples. Although some of these sequences are derived from plant pathogens like cauliflower mosaic virus and *Agrobacterium tumefaciens*, the regulatory sequences comprise only a small part of the pathogen's total genome and are not in themselves capable of causing disease.

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

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

- The application posed no risk to human health and safety or the environment.
- Army worm moths do not pose a risk and therefore guard rows are not required.
- A six to seven month monitoring period would be adequate.
- Either incineration or burial would be adequate for disposal of the GM plants.
- The applicant should be asked to fence the trial site.
- Only the release site needs to be monitored post-harvest.

- **Field trial of pineapple plants modified for blackheart reduction and to delay flowering (DIR 028/2002)**

An application has been received from the Queensland Department of Primary Industries for a licence to continue the limited and controlled release (field trial) of GM pineapple (*Ananas comosus*, now called *Ananas comosus* var. *comosus*) first planted in 2001 under the former voluntary system. The applicant is proposing to continue the trial on one site in the Shire of Redlands (Qld) and one site in the Shire of Maroochy, (Qld), over a total area of 0.12 hectares. [NB - *Following the meeting the applicant requested that the total trial area be increased to 0.22 hectares.*]

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

The GMOs covered by this proposal contain one of the following modifications:

- A truncated copy of the pineapple *PPO2* gene to reduce the expression of the PPO enzyme, believed to be responsible for tissue discolouration (blackheart) in pineapples.
- A truncated copy of the pineapple *ACACS2* which 'silences' the existing gene for natural flowering in the pineapple.
- A truncated copy of the pineapple *PPO2* and *ACACS2* gene to 'silence' the existing genes for blackheart and flowering in the pineapple.
- The *uidA* gene (a marker gene) used to assess the activity of different regulatory sequences under field conditions.

All GM pineapple plants contain a selectable marker gene (*nptII*) conferring antibiotic resistance used to select GMOs containing the modified DNA. The GM plants also contain the non-expressed bacterial genes *bla* (ampicillin resistance), *aad* (streptomycin and spectinomycin) and *LacZ* (β galactosidase).

Short regulatory sequences that control expression of the introduced genes are also present in the GM pineapples.

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

- The proposal poses no risk to human health and safety or to the environment.
- The use of the antibiotic resistance genes had been discussed by GTTAC previously and had been found to be of no risk to human health and safety and the environment.
- Advice given for DIR 027/2002 would also be applicable to DIR 028/2002.

Advice on Cotton

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.

- **Defining sustainable production systems for transgenic cotton (INGARD[®], Bollgard II[®] and Bollgard II[®]/Roundup Ready[®]) in the Kimberley region of Western Australia (DIR 029/2002)**

An application has been received from the Department of Agriculture, Western Australia for a licence for the intentional release of GM insecticidal (INGARD[®] and Bollgard II[®]) and insecticidal/herbicide tolerant (Bollgard II[®]/Roundup Ready[®]) cotton (*Gossypium hirsutum* L) into the environment. The applicant proposes to carry out a limited and controlled release (field trial) at 10 sites, over 82 hectares in Kununurra and Broome in Western Australia.

INGARD[®] and Bollgard II[®] cotton are resistant to the lepidopteran caterpillar pests that attack cotton. They contain one or two insecticidal genes, respectively, that produce proteins that are toxic to specific insects. Bollgard II[®]/Roundup Ready[®] cotton also contains a gene for tolerance to the herbicide glyphosate (Roundup[®]).

On 23 September 2002, Bollgard II[®] cotton and Bollgard II[®]/Roundup Ready[®] cotton were approved for commercial release (licence number DIR 012/2002). However, the release was restricted to south of latitude 22° South, because of continuing concerns about the potential weediness of the insecticidal cotton in tropical areas, as well as the potential for out-crossing to naturalised cotton in these areas. Therefore, field trials to gather additional data on these issues must be conducted under limited and controlled conditions.

The proposed release aims to assess the performance of the GM cotton varieties in the Kimberley environment and will compare the effectiveness of conventional insecticide and Bt resistance. Effects of the GMOs on the type and abundance of pest and beneficial insects, as well as the potential development of insects resistant to the insecticidal activity of the GM cotton will be studied. In addition, the applicant will measure the refuge value of alternative crops to Bt insecticidal resistance management in the northern tropical environment.

None of the cotton plants from this release, or their by-products, will be used for human food, however the applicant proposes to sell some of the GM cottonseed as stockfeed after it has been rendered non-viable. It is also proposed that lint from the release be sold commercially. Lint does not contain genetic material or protein.

GTTAC discussed this application and advised the Regulator that the following issues should be considered when preparing the RARMP:

- The application is similar, and poses risks similar to, DIR applications 005/2001, 006/2001, 008/2001, 009/2001 and 012/2001.
- The advice provided for DIR applications 005/2001, 006/2001, 008/2001, 009/2001 and 012/2001 would also apply to this application.

Advice on Carnation

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

- **Ongoing commercial release of colour modified carnations (extension of deemed licence GR-2) (DIR 030/2002)**

An application has been received from Florigene for a licence for the ongoing commercial release of GM carnations (*Dianthus caryophyllus*). The current application is an extension of a general release of colour modified carnations that was approved in 1995 under the former voluntary system.

The present application is for a licence to deal with any transgenic carnation line produced after transformation with either of two binary vectors, pCGP1470 or pCGP1991.

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. The GM carnations in this application contain the genes coding for the enzymes flavonoid 3', 5' hydroxylase (F3'5'H) and dihydroflavonol reductase (DFR) which allow production of delphinidins. The delphinidins are responsible for the blue spectrum of colours in flowers.

The GM carnations also contain a selectable marker conferring resistance to sulfonylurea herbicides, as well as regulatory sequences designed to enhance expression of the inserted genes.

GTTAC discussed this application and advised the Regulator that the proposed dealings posed no risks to human health and safety, or to the environment.

Advice on Grapevine

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

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

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

The aims of the proposal are to evaluate the field performance of GM grapevines containing additional copies of various grapevine genes which are modified to improve berry colour, sugar composition, flowering and fruit quality. The applicant also proposes to monitor pollen flow using GM grapevine containing green fluorescent protein (GFP).

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

- The *gus* reporter gene from *Escherichia coli* which enables the visual identification of plant tissues expressing the transgene.

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

Most of the above GMOs contain an antibiotic resistance gene, *nptII*, except for one group that contains *hph*. These genes are used as selectable markers in the initial laboratory stages to select grapevine plants containing the modified genes. All of the GMOs also contain short regulatory sequences that control expression of the inserted genes.

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

GTTAC discussed this application and advised the Regulator that the following issues should be considered when preparing the RARMP:

- The applicant should be asked to ensure all *Agrobacterium* are removed from the GM plants before release.
- The applicant should be asked to construct a fence around the enclosure to exclude small mammals from the trial site.
- The applicant should be asked to manage the site to control volunteers.
- A large isolation zone is not required, given that the fruit will be bagged.

- Any potential effect of the genetic modifications on other plant functions, which may have potentially adverse consequences to human health, should be considered.
- The applicant should be advised to notify Food Standards Australia New Zealand prior to conducting taste testing of sultanas and wine derived from GM fruit.

Advice on Canola

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

- **Field trial – seed increase and field evaluation of herbicide tolerant hybrid canola (DIR 032/2002)**

An application has been received from Bayer CropScience Pty Ltd (Bayer) for a licence for the limited and controlled release (field trial) of GM canola (*Brassica napus* L) into the environment. The aim of the proposed release is to allow seed increase of promising canola lines that are herbicide tolerant hybrids (to produce seeds for future trials) and for ongoing evaluation trials planned for Canada and Australia. The proposed release would occur at 4 sites in 4 different locations per year for 3 years. The total area of land to be used is 16 ha per year in Victoria, South Australia and New South Wales.

Bayer has developed a novel breeding system, based on GM male sterile (MS) and fertility restorer (RF) lines to emulate the natural phenomenon of hybrid vigour.

The MS *barnase* gene is derived from the bacterium *Bacillus amyloliquefaciens*. The enzyme encoded by this gene prevents pollen production, thus conferring male sterility. The RF *barstar* gene is also derived from *B. amyloliquefaciens* and encodes a protein that inhibits the Barnase enzyme produced in the MS line. Crosses of the MS line with the RF line ensure the production of fertile hybrids. It is this resultant hybrid seed that is employed in agricultural production.

The MS and RF lines have also been modified to confer tolerance to a herbicide. The herbicide tolerance trait may be used to control weeds in the canola crop. Bayer has sought to have the origin and identity of the herbicide tolerance gene and regulatory sequences declared as Confidential Commercial Information (CCI) under s185 of the *Gene Technology Act 2000*. However, this information was made available to GTTAC and other prescribed expert authorities that were consulted on the preparation of the RARMP.

The GM canola also contains regulatory sequences that control the expression of the inserted genes.

None of the GM plants or their by-products will be used for human or animal consumption, or as therapeutics.

GTTAC discussed this application and advised the Regulator that the licence conditions imposed for previous canola trials should be considered in the preparation of the RARMP.

Advice on Sugarcane

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

- **Agronomic assessment of transgenic sugarcane engineered with reporter genes (DIR 019/2002)**

An application has been received from the Bureau of Sugar Experiment Stations (BSES) for a licence for the limited and controlled release (field trial) of GM sugarcane (*Saccharum* hybrid) on one site over a total area of 0.7 ha in the Cairns district of Queensland. The applicant proposes to conduct extensive evaluation and comparison of 60 GM sugarcane lines produced by either a new tissue culture process or by a standard tissue culture process.

The GM sugarcane would contain three new genes:

- The *gfp* gene, derived from jellyfish (*Aequorea victoria*), which encodes a reporter protein that acts as a marker to distinguish between GM and unmodified plants.
- The *nptII* gene, derived from the bacterial Tn5 transposon, which encodes resistance to the antibiotics kanamycin and neomycin and is therefore useful for selecting GM plants in the laboratory.

- The *bla* gene, derived from the bacterium *Escherichia coli*, which encodes ampicillin resistance. This gene is not expressed in the GM sugarcane and was used to select for bacteria containing the desired genes, in the laboratory, prior to the production of the GM plants.

Short regulatory sequences that are required to control the expression of the genes are also present in the GM sugarcane.

None of the GM sugarcane from the trial, or its by-products, would be used as human food or animal feed.

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

- The likelihood of adverse impacts on human or other species as a result of toxicity or allergenicity of the GM sugarcane is extremely low.
- Evidence from toxicological and allergenicity studies, together with the low level of expression of the introduced proteins, suggests that the GM sugarcane will not be more toxic or allergenic than conventional sugarcane.
- The risk of the GM sugarcane establishing and causing harm in the environment is low.
- Sugarcane itself is not a problematic weed and the introduced genes do not increase the weediness potential of the plants.
- The likelihood of dispersal of GM sugarcane, through vegetative material, from the release site is extremely low.
- Expression of NPT II is not likely to have any adverse effect on the rhizosphere.
- Transfer of genes to other sugarcane crops, naturalised sugarcane populations or weedy relatives will be managed by harvesting the sugarcane before flowering.
- The applicant should be asked to prevent public access to the trial site.

Advice on Cholera Vaccine

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

- **Orochol® vaccine (DIR 033/2002)**

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

Cholera is a disease with an extremely low incidence in Australia. In the last ten years, an average of four cases have been reported annually from across Australia, with the exception of Tasmania, where there has been no reported cases. The majority of these cases involved people who had entered or returned to Australia from other countries.

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

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

GTTAC discussed this application and advised the Regulator that this proposal posed no risks to human health and safety or to the environment.

Organisms that are not genetically modified organisms

GTTAC was asked for advice on the interpretation of Item 1 of Schedule 1 of the Gene Technology Regulations (the regulations) which reads:

'A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).'

The Committee was asked whether this Item was intended to include organisms created by the introduction of foreign DNA, followed by the subsequent deletion of the foreign DNA along with a gene of interest, resulting in the GM end product containing no foreign DNA.

An applicant had requested advice on whether an attenuated fowlpox vaccine created in the above manner should be classified as a GMO.

GTTAC discussed this issue and concluded that such organisms (missing a copy of a gene) occurred spontaneously in nature and therefore posed no greater risk than the wild type organism.

GTTAC advised the Regulator that:

- Attenuated fowlpox vaccine does not pose a risk to human health or the environment as a result of the genetic modification.
- Item 1 of Schedule 1 of the regulations could be modified as follows: 'A mutant organism which does not contain any foreign nucleic acid (that is, non-homologous DNA, usually from another species)'.

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>

Appendix D

**Gene Technology Community Consultative Committee Meeting
Mount Gambier, South Australia
20 February 2003**

COMMUNIQUE

The Gene Technology Community Consultative Committee (GTCCC) held its fourth meeting in Mount Gambier, South Australia on 20 February 2003.

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.

As well as holding a regular meeting on 20 February 2003 in Mount Gambier, the GTCCC undertook site visits on 19 February 2003 in the Mount Gambier region. Three committee members were not present at the site visits and the subsequent meeting of the Committee: Professor Marjory Martin; Dr John Keniry; and Mrs Margaret Cover. The Committee had previously requested that the Regulator provide an opportunity for members to become more informed about the growing of genetically modified (GM) canola in Australia. This was to be achieved by undertaking a site visit to a limited and controlled canola trial site. The visit was supported by Monitoring and Compliance staff from the OGTR and meetings requested by the Committee were arranged with an agronomist, a local farmer, and a local council officer.

A summary of the site visits and the outcomes from the meeting are provided below.

Acknowledgment

The Committee wishes to express its appreciation to everyone involved in facilitating the site visits and delivering presentations during the trip to Mount Gambier, and in particular to:

- the farmers whose land the Committee visited;
- the District Council of Grant;
- members of the Gene Technology Grains Committee¹;
- representatives from Bayer CropScience Australia; and
- officers from the South Australian Research and Development Institute (SARDI) and Rural Solutions SA (Department of Primary Industries and Resources South Australia).

Visit to Limited and Controlled Genetically Modified Canola Trial Sites

On 19 February 2003 the Committee assembled in Mount Gambier for a briefing from the OGTR Monitoring and Compliance Section on the licence conditions for the trial sites and the protocols to be observed during the visit. This occurred prior to embarking upon the visits, which were facilitated by the licence holder for the field trial, Bayer CropScience Pty Ltd (formerly Aventis CropScience Pty Ltd), and hosted by local farmers. Committee members were able to see first hand a 0.5 hectare area of GM canola growing; stubble left on a 7 hectare area after harvesting; the requirements for cleaning harvesters; and view a commercial non-GM canola crop being harvested following windrowing².

OGTR Monitoring and Compliance staff were present at both on-site farm locations and ensured that protocols for entering and leaving the sites were strictly observed.

Information Presentations

As previously requested by the Committee, presentations were received on the following topics:

¹ The GTGC comprises representatives from across the grains industry including scientists, growers, bulk handlers, marketers and exporters, food processors, technology providers and the organics industry, as well as Commonwealth and State Government observers.

² Windrowing involves cutting the crop and placing it in rows directly on the cut stubble. This hastens the drying rate of the crop, ensures even ripening and reduces the possibility of seed losses from wind and hail. After the crop dries to a uniform seed moisture it is then ready for harvesting.

1. *Gene Technology Grains Committee*: Mr Bob Watters, Eastern Chair of the GTGC, and Ms Rosemary Richards, GTGC Member, gave a brief presentation on the *Canola Industry Stewardship Protocols for Coexistence of Production Systems and Supply Chains*, December 2002, developed by the GTGC. The two members then took part in an informal question and answer session on the topic that continued during the site visits on 19 February 2003;
2. *District Council of Grant*: Mr Russell Peate, Chief Executive Officer, District Council of Grant, provided an overview of the Council including: its geographic location; size of the local government area; and the number of residents, councillors, and staff. The Council has a long-standing involvement with both the Interim OGTR and the OGTR and was an active participant in the development of the current gene technology legislation. There are a number of limited and controlled trial sites located within the Council's local government area and Mr Peate answered questions based on his Council's experience;
3. *Local Government in Australia*: Councillor Robartson, GTCCC member, gave an overview presentation during the meeting on local government in Australia. The presentation was designed to increase members' understanding and knowledge of the role and capacity of local government in Australia; and
4. *Fitness of Applicants to be Issued a Licence*: Mr Jonathan Benyei, Acting Director, Evaluation Branch, OGTR, made a presentation for members' information on the process undertaken by the OGTR to assess the fitness of applicants to be issued a licence, particularly in relation to commercial releases.

GTCCC Communication with the Other Gene Technology Advisory Committees

At each meeting the Committee receives verbal reports from the cross-members with GTTAC and the Gene Technology Ethics Committee on meetings held and activities undertaken by those committees since GTCCC last met. On this occasion, the reports were postponed to the next available GTCCC meeting. Communiqués from all of the gene technology advisory committee meetings are published on the OGTR website.

Key Meeting Outcomes

The GTCCC meeting agenda on 20 February 2003 was a full agenda incorporating a report tabled by the Regulator on the activities of the OGTR since the Committee last met in November 2002 and a detailed report on the status of two applications received by the OGTR for the commercial release of GM canola. The Committee received progress reports from the current working groups established in July 2002 to provide specific advice to the Regulator. These working groups will continue out-of-session and are due to report again at the next meeting in 2003.

The Committee determined that it wished to provide advice to the Regulator on a number of topics arising from both the meeting and the discussions of the previous day:

Commercial GM Canola Applications

Following considerable discussion of this item, it was moved by Dr Rosemary Robins and seconded by Professor Frank Vanclay that the Regulator be advised, in relation to these applications, that:

‘The GTCCC expresses concern that a state of community unreadiness exists concerning the risks to the environment of the commercial release of GM canola, so significant that the applications should be declined at this time.’

Seven members voted in favour of this resolution and two against.

The GTCCC having previously resolved that the extent and nature of any dissent from the majority opinion in a meeting be included in the meeting communique, Mr Donald Coles and Mr Bruce Lloyd requested that their dissenting votes be formally recorded. Mr Coles, in dissenting, outlined the following reasons for his dissent:

- the perception that there is a state of community unreadiness is not borne out by the response to date from the GTGC in releasing their consultation draft on canola industry stewardship protocols;
- the Plant Industries Committee of the Primary Industries Standing Committee³ also released consultation guidelines in 2002 for industry stewardship programs and crop management plans;

³ This Standing Committee is an intergovernmental forum of chief executive officers of the Commonwealth, State, and Territory government primary industry departments. Its role is to

- the GTCCC was not technically qualified to review the risks to the environment posed by or as a result of the commercial release of GM canola;
- it is not the role of the GTCCC to deny a potentially valuable tool for reducing herbicide resistant weeds to the Australian farming community; and
- it is not the role of the OGTR, as specified in the Act, to dictate supply chain matters.

Mr Lloyd, in dissenting, outlined the following reasons for his dissent:

- the GTCCC was not technically qualified to review the risks to the environment posed by or as a result of the commercial release of GM canola; and
- the matter should be referred by the Regulator to the Gene Technology Technical Advisory Committee for consideration of any risks.

The Regulator will take into account the Committee's advice as part of the applications assessment process. The assessment process includes extensive public consultation, which is yet to commence, on the risk assessment and risk management plans that are prepared in respect of each application.

Canola Industry Stewardship Protocols

Following consideration on the GTGC presentation on the draft *Canola Industry Stewardship Protocols* the Committee resolved to thank the GTGC representatives for their time in coming to Mount Gambier and for their preparedness to answer wide-ranging questions on the day.

The GTCCC will also write to the GTGC requesting that they further develop the coexistence protocol framework to enable the GTCCC to make a more informed judgement about the state of readiness for the commercial release of GM canola in Australia.

Communication with Local Government

Two presentations on local government resulted in the GTCCC resolving to ask the Regulator to consider a range of suggestions for future communication between the OGTR and councils in relation to dealings involving the intentional release (DIR) of a GM organism.

facilitate national consensus and coordinated action on primary industry matters, under the auspices of the Primary Industries Ministerial Council.

The advice suggests that, in those local government areas where a DIR trial is being conducted, OGTR inspection reports be promptly made available to the appropriate local government officer; a request that technical and financial support be provided to assist councils in fulfilling their responsibilities in relation to DIR dealings; and, that applicants be encouraged to improve their communication and cooperation with local government councils.

The Regulator will consider the advice and respond to the recommendations.

Next Meeting

GTCCC is scheduled to meet again in mid-2003.

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