Quarterly Report of
the Gene Technology Regulator
for the period
1 January to 31 March 2004

ISBN 0 642 82509 2

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

Produced by:

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

Email: ogtr@health.gov.au
Website: www.ogtr.gov.au
Telephone: 1800 181 030
Fax: 02 6271 4202

Inquiries about the content of this report may be directed to the Policy, Secretariat and Communications Section of the Office of the Gene Technology Regulator.

Australian Government Department of Health and Ageing

Publications Approval Number 3500

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

The Hon Trish Worth MP
Parliamentary Secretary to the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

Dear Parliamentary Secretary

In accordance with section 136A of the *Gene Technology Act 2000*, I am pleased to present to you the Quarterly Report of the Gene Technology Regulator, covering the period 1 January to 31 March 2004.

During this quarter, key achievements included the issuing of 1 licence for a dealing involving the intentional release of a genetically modified organism, 6 licences for dealings not involving intentional release of genetically modified organisms, 1 organisation was accredited and 23 contained facilities were certified.

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

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator
30 July 2004

Address: MDP 54 PO Box 100 Woden ACT 2606 Website: www.ogtr.gov.au
Telephone: 1800 181 030 Facsimile: 02 6271 4202

Contents

Glossary

Accredited organisation	An organisation that is accredited under section 92 of the Act
Act	*Gene Technology Act 2000*
APVMA	Australian Pesticides and Veterinary Medicines Authority
Breach	*see* 'Non-compliance'
CCI	Confidential commercial information
Certified facility	A building or place certified by the Regulator, to a specified containment level, under section 84 of the Act
Clock stop	The period during which an application evaluation is suspended – usually whilst awaiting further information from the applicants
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DIR	A dealing with a GMO involving intentional release of a GMO into the environment (for example, field trial or commercial release)
DIR licence	A licence for a dealing involving intentional release of a GMO into the environment
DNIR	A contained dealing with a GMO not involving intentional release of a GMO into the environment (for example, experiments in a certified facility such as a laboratory)
DNIR licence	A licence for a dealing not involving intentional release of a GMO into the environment
Expert advisers	Advisers appointed by the Minister to give advice to either GTTAC or GTEC to assist them in the performance of their functions (Expert advisers are not committee members)
FSANZ	Food Standards Australia New Zealand
GM	Genetically modified
GM product	A thing (other than a GMO) derived or produced from a GMO

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

Introduction

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

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

Structure of this report

This report is divided into four parts:

Part 1 outlines activities and outcomes achieved in relation to the implementation and management of the national regulatory system during the January–March 2004 quarter.

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

Part 3 reports on the activities of the three advisory committees established under the Act to assist the Regulator and the Gene Technology Ministerial Council (GTMC).

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

Further information

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

Office of the Gene Technology Regulator
MDP 54 PO Box 100
WODEN ACT 2606

Email: ogtr@health.gov.au
Website www.ogtr.gov.au
Telephone: 1800 181 030
Fax: (02) 6271 4202

PART 1 National regulatory system

Key achievements during this quarter

The key achievements of the January–March 2004 quarter were:

Licences and other instruments

- 1 licence issued for a dealing involving the intentional release of a GMO into the environment (DIR licence) and 8 applications were under consideration.
- 6 licences issued for dealings not involving intentional release of GMOs into the environment (DNIR licences)
- 68 notifiable low risk dealing (NLRD) notifications received
- 1 organisation accredited
- 23 contained facilities certified
- 18 surrender of certifications processed
- 96 variations processed.

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

Monitoring and compliance

Approximately 17 per cent of current field trial sites and 11 per cent of post harvest field trial sites were subjected to routine monitoring during the quarter. This exceeds the target minimum rate of 5 per cent per quarter.

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

Working collaboratively with states and territories

State and territory consultation

The Regulator must consult with State and Territory Governments and relevant local councils twice during the evaluation of applications for DIR licences. For each application for a DIR licence, the Regulator seeks advice on matters relevant to the preparation of the Risk Assessment and Risk Management Plan (RARMP) and comment on the RARMP itself once it is prepared.

In this quarter the Regulator sought advice on the preparation of 4 RARMPS and requested comment on one RARMPS

More information is contained in Part 2.

Gene Technology Ministerial Council

The GTMC consists of one Minister from each State and Territory and one Minister from the Australian Government. Currently, the Ministerial Council comprises Ministers from a range of portfolios including health, agriculture, environment and innovation.

The Ministerial Council did not meet this quarter.

Gene Technology Standing Committee

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

The Standing Committee held a teleconference on 4 March 2004.

Australian Government agency liaison

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

The *Gene Technology Act 2000* is designed to operate in a cooperative legislative framework with other regulatory authorities that have complementary responsibilities and specialist expertise. As well as enhancing coordinated decision making, this arrangement avoids duplication. The OGTR liaises closely with other regulators to ensure the identification, evaluation and management of risks that may be associated with development and use of gene technology.

Under the Act, the Regulator must seek advice from prescribed Australian Government authorities and agencies and the Australian Government Environment Minister. Advice is sought on matters relevant to preparing the RARMP for each application made to the Regulator for a DIR licence.[1]

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

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

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

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

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

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

During the quarter, the Regulator sought advice and comment in respect of 4 applications for DIR licences, and one RARMP.

Further information is set out in Part 2.

Public participation

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

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

Further information is set out in Part 2.

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

PART 2 Regulation of genetically modified organisms

Part 2 of the report outlines the regulatory activity undertaken during the January–March 2004 quarter. This includes information about applications for, and action taken with respect to, GMO licences and other instruments under the Act. It also includes details of monitoring activities and any breaches of conditions of a GMO licence that have come to the Regulator's attention. Summary reports on investigations completed during the quarter are supplied. Information on confidential commercial information (CCI) applications has also been provided.

Applications received and decisions made

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

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

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

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

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

- **Accreditations of organisations**

  Most licences require organisations which conduct work with GMOs to be accredited. To achieve accreditation, usually 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. These applications have a statutory timeframe of 90 working days for processing.

- **Certifications of contained facilities**

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

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 2004

Application type	Number received	Number approved[1]
DIR licence	2	1
DNIR licence	6	6
Accreditations	2	1
Certifications	37	23

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

Processing of applications for DIR licences

The key steps the Regulator takes when considering an application for a DIR licence are:

- initial screening of the application for completeness
- determining whether the proposed dealings may pose a significant risk to human health and safety and the environment
- seeking comments from prescribed expert groups and key stakeholders (including the public if a significant risk is identified) on issues to consider in the RARMP
- preparing a consultation RARMP, including proposed licence conditions
- seeking comments from prescribed expert groups and key stakeholders (including the public) on the RARMP
- considering all comments relating to the protection of human health and safety and the environment in finalising the RARMP
- consideration of applicant's suitability, policy principles and any relevant policy guidelines.

Once these actions are completed, the Regulator can make a decision on whether to grant a licence, and the conditions which are to be included in any licence.

The Regulator must make a decision on an application for a DIR licence within 170 working days of receiving the application. This timeframe effectively extends over approximately 9 months as it excludes weekends and public holidays in the Australian Capital Territory (ACT).

This time limit may be extended, that is, the clock is stopped, if the decision-making process is unable to continue, for example, because of an unresolved application for declaration of CCI or because additional information is sought from the applicant.
The Act and the *Gene Technology Regulations 2001* (the Regulations) mandate minimum timeframes for the two rounds of consultation that the Regulator must undertake with prescribed expert groups and key stakeholders during the processing of each DIR application. However, longer periods are usually allowed to facilitate the provision of information and promote involvement in the decision-making process particularly by the community. Therefore an application for a DIR licence cannot normally be received and decided upon within the same three-month reporting period.

The following table shows the status of applications for DIR licences that underwent evaluation during the quarter.

Status, as at 31 March 2004, of applications for a DIR licence subject to evaluation during the quarter

Application received	First round of consultation[1]	Second round of consultation	Withdrawn applications	Licence Issued
DIR 049/2004	DIR 045/2003[2]	DIR 044/2003	DIR 043/2003	DIR 032/2002[2]
DIR 050/2004	DIR 046/2003[2]			
	DIR 047/2003			
	DIR 048/2003			

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

2 The clock was stopped on these applications. Clock also stopped on DIR 32/2002 from 15/10/03 to 15/1/04.

Applications received for DIR licences

The OGTR received 2 applications for DIR licences in the January–March 2004 quarter as follows:

- DIR 049/2004 'Field trial – Evaluation under field conditions of the cotton small subunit driving a reporter gene' (CSIRO)
- DIR 050/2004 'Vaccination of cattle with recombinant bovine herpesvirus vaccines' (Queensland Government Department of Primary Industries and Fisheries)

All applications for DIR licences received in the January–March 2004 quarter were screened for completeness and the applicants notified of the receipt of their applications within the quarter.

Consultation on applications for DIR licences

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

- DIR 045/2003 'Development of Porcine Adenovirus (PAV) vaccine vectors' (Imugene Limited)
- DIR 046/2003 'Development of Fowl Adenovirus (FAV) vaccine vectors' (Imugene Limited)
- DIR 047/2003 'Field trial – Evaluation of GM white clover resistant to infection by *Alfalfa Mosaic Virus'* (Department of Primary Industries, Victoria)
- DIR 048/2003 'Field Trial – Assessment of transgenic cotton expressing natural plant genes for insect control' (Hexima Limited)

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

- DIR 044/2003 'Field trial – Agronomic assessment and seed increase of transgenic cotton expressing insect tolerance genes from *Bacillus thuringiensis*' (Dow AgroSciences Australia Limited)

Withdrawn applications for DIR licences

- DIR 043/2003 'Field trial – Preliminary agronomic assessment of high sulphur lupin' (The University of Western Australia)

Clock stopped on two applications for DIR licences

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

The clock stopped in February 2004 on the assessment of applications DIR 045/2003 'Development of Porcine Adenovirus (PAV) vaccine vectors' and DIR 046/2003 ' Development of Fowl Adenovirus (FAV) vaccine vectors' (both from Imugene Limited), pending provision of additional information. The clock also stopped for application DIR 032/2003, Field trial - Seed increase and field evaluation of herbicide tolerant genetically modified canola incorporating a hybrid breeding system, until mid January 2004 pending provision of additional information.

Finalised applications for DIR licences

During the quarter, the Regulator issued 1 DIR licence:

- DIR 032/2003 'Field trial – Seed increase and field evaluation of herbicide tolerant canola' (Bayer CropScience Pty Ltd)

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

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 6 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 organisations to notify the Regulator when conducting NLRDs.

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

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

The Regulator received 67 NLRD notifications in the quarter.

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

Existing licences and other instruments

The Regulator can, directly or upon application vary an issued licence or other instrument. For example, the Regulator can vary a licence to better manage risks if new information or data comes to light. Additionally, the Regulator can make a decision in relation to an application to transfer a licence 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 2004 quarter.

Applications received and decisions made; existing licences and other instruments, 1 January–31 March 2004

Type	Number received	Number processed[1]
Surrender of certification	23	18
Surrender of DIR licence	1	0
Surrender of DNIR licence	0	1
Variation of certification	214	72
Variation of accreditation	1	2
Variation of DIR licence[2]	9	6
Variation of DNIR licence	21	16

1 Numbers reported in this quarter often relate to applications received in previous quarters. For the purposes of this table, 'processed' means the action on the licence or instrument was completed.

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

Confidential commercial information (CCI)

Under the Act a person may apply for a declaration from the Regulator that specified information is CCI. If the Regulator declares information to be CCI the information is protected from disclosure. More information on the protection of CCI can be found in Chapter 15 of the Handbook on the regulation of gene technology which is available on the OGTR website

During the quarter, the Regulator received 1 CCI application in relation to an application for a DIR licence, and 1 CCI application in relation to an NLRD.

The Regulator made 4 CCI declarations in relation to applications for DIR licences, 4 declarations in relation to applications for DNIR licences, and 5 declarations in relation to NLRDs.

Monitoring and compliance

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

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

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

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

Monitoring and compliance strategy

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

The OGTR conducts routine monitoring visits of a minimum of 20 per cent of the field trial sites involving GMOs, each year. A minimum of 5 per cent of current trial sites and 5 per cent of trial sites subject to post-harvest monitoring are monitored each quarter. The purpose of routine monitoring of field trials is to ensure compliance with licence conditions, and includes unannounced spot checks.

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

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

- a minimum of 20 per cent of physical containment (PC) 4, PC3 and PC2 large-scale facilities per year; and
- selected PC2 and PC1 facilities.

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored. During the January–March 2004 quarter, 16 field trial sites were subject to monitoring visits. Monitoring was carried out on 5 DIR licences and covered 5 plant species.

Current field trial sites monitored. Of the 29 sites current in the quarter, 5 were monitored. This represents a monitoring rate of 17 per cent of all current sites for the quarter.

Post-harvest field trial sites monitored. Of the 103 sites subject to post-harvest monitoring in the quarter, 11 were monitored. This represents a monitoring rate of 11 per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of contained dealings. During the January–March 2004 quarter, monitoring in connection to contained dealings covered 9 organisations, 2 DNIR licences and 26 PC facilities. Monitoring of PC facilities encompassed PC2 laboratories (19 visited), PC2 plant containment facilities (2 visited) and PC2 animal containment facilities (5 visited).

Monitoring of dealings involving intentional releases conducted

The total monitoring coverage for field trial sites during the January–March 2004 quarter is shown in the following table.

Licensed organisation name	Licence number	No. sites visited	Site status[1]	GMO type
Bayer CropScience Pty Ltd	DIR 010/2001	8	PHM	Canola
		1	PHM	Indian Mustard
CSIRO	DIR 038/2003	2	C	Cotton
Queensland Department of Primary Industries	DIR 028/2002	1	C	Pineapple
		1	PHM	Cotton
The University of Queensland	DIR 026/2002	1	C	Papaya
	DIR 027/2002	1	C	Pineapple
		1	PHM	Pineapple
Totals	5	16	C=5	5 Species
			PHM=11	

1 C= current, PHM = post-harvest monitoring

Monitoring of containment dealings conducted

The total monitoring coverage for DNIRs during the January - March 2004 quarter is shown in the following table.

Licensed organisation name	Licence number
Australian Water Quality Centre	DNIR 010/2001
Mater Medical Research Institute	DNIR 166/2002
Total	2

Monitoring of physical containment facilities conducted

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

Organisation	Physical containment facility	No. facilities visited
Australian National University	PC2 Laboratory	1
Australian Water Quality Centre	PC2 Laboratory	1
CSIRO	PC2 Laboratory	3
	PC2 Plant Containment Facility	2
Garvan Institute of Medical Research	PC2 Laboratory	3
	PC2 Animal Containment Facility	2
Mater Medical Research Institute	PC2 Laboratory	1
	PC2 Animal Containment Facility	1
NSW Agriculture	PC2 Laboratory	5
Royal Prince Alfred Hospital	PC2 Laboratory	3
	PC2 Animal Containment Facility	1
The Canberra Hospital	PC2 Laboratory	1
	PC2 Animal Containment Facility	1
The University of South Australia	PC2 Laboratory	1
Totals	3 facility types	26

Monitoring findings

Dealings involving intentional release

During the quarter, 4 non-compliances with licence conditions were identified as requiring further attention. A summary of each follows:

Organisation	Bayer CropScience Pty Ltd
Licence number and site	DIR 010/2001, PR-85X(2) Site 3
Summary of dealing	Licence relates to a field trial of canola (*Brassica rapa*) genetically modified to confer tolerance to the herbicide glufosinate ammonium. The trial is in the post harvest phase.
Findings	At the time of inspection OGTR observed that the trial site was planted to lupini beans (*Lupinus albus*). The lupini planting was 'windrowed' (ie. cut and stacked to dry) approximately 2 weeks prior to inspection and seed was due to be harvested approximately one week after inspection. No *B. rapa* volunteers were observed on the trial site. While the licence holder had submitted an application to vary the licence conditions to allow planting of lupini on the trial site during its post harvest phase, no variation of the licence was approved by the OGTR to allow the planting.
Risk assessment	No B. *rapa* volunteer plants were observed on the trial site at the time of inspection. As there was negligible likelihood of dissemination of the GMO or its genetic material, the risk posed to human health and the environment by the non-compliance was assessed as negligible.
Risk management	Based on the risk assessment, no additional measures were imposed. However, Bayer CropScience was advised to ensure it meet its obligations under DIR010/2001 with regard to the use of the trial site during the post harvest phase, and was advised that crops which require a licence variation are not to be planted without receiving written approval from the Regulator.

Organisation	Bayer CropScience Pty Ltd
Licence number and site	DIR 010/2001, PR-85X(3) Site 1
Summary of dealing	Licence relates to a field trial of canola (*Brassica rapa*) genetically modified to confer tolerance to the herbicide glufosinate ammonium. The trial is in the post harvest phase.
Findings	At the time of the inspection, OGTR observed that the trial site was planted with a mixed lucerne and chicory pasture. No *B. rapa* volunteers were observed on the trial site. The licence holder had not applied for a variation of the licence to permit the planting of chicory on the trial site.
Risk assessment	No B. *rapa* volunteer plants were observed on the trial site at the time of inspection. As there was negligible liklihood of dissemination of the GMO or its genetic material, the risk posed to human health and the environment by the non-compliance was assessed as negligible.
Risk management	Based on the risk assessment, no immediate additional measures were placed on the licence holder. However, Bayer CropScience was advised to submit an application for a licence variation to the OGTR, to allow the crop to remain on the site.

Organisation	The University of Queensland
Licence number and site	DIR 026/2002, Site 1
Summary of dealing	Licence relates to a field trial of papaya (*Carica papaya* L.) genetically modified to delay fruit ripening, reporter gene expression and antibiotic resistance.
Findings	OGTR observed a small hole (5-10cm long and 2-3 cm wide) in the fabric of the cage containing the GMO planting.
Risk assessment	The risk assessment conducted by the inspection team concluded: • the risk of gene flow was negligible due to the papaya plants being at the fruiting stage • the risk of movement of the GMO through animal interference or consumption was deemed negligible due to the small size of the hole • the risk of the movement of the GMO through human interference was also deemed negligible due to the security of the trial location. At the time of the inspection, there was no evidence of any tampering or removal of papaya plants or fruit.
Risk management	The University of Queensland was advised to immediately repair the hole in the cage and reminded of its obligation to comply with the licence condition to regularly inspect for holes in the caging material.

Organisation	The University of Queensland
Licence number and site	DIR 027/2002, Site 1
Summary of dealing	Licence relates to a field trial of pineapple (*Ananas comosus* (L.) Merrill, cv. "Smooth Cayenne") genetically modified to delay flowering, for herbicide resistance and for reporter gene expression.
Findings	OGTR observed that the trial site did not display signage required in the licence conditions indicating the GM status of the pineapples or warning against unauthorised removal of any GMO material from the trial site.
Risk assessment	There is a hazard that staff on the research station where the trial is situated or other people may not be aware of the GM status of the plant material. Furthermore, staff on the station or other people may not be informed that unauthorised removal of GMO material from the trial site is prohibited. However, OGTR assessed the risk posed by the occurrence as negligible due to the restricted nature of access to the trial area and the procedures in place for personnel working at the research station.
Risk management	The University of Queensland was instructed to: • comply with the licence condition to erect a durable sign that indicated the pineapples are GM and that no GM material is to be removed from the site; and • until signage is erected, inform any station staff of the GM status of the pineapples and that no GM material is to be removed from the site.

Monitoring and compliance reviews

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

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

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

No incident or practice reviews were completed in this quarter.

Audits

An audit entails, depending on its scope:

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

These activities are conducted to:

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

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

No audits were completed in this quarter.

Unannounced visits

During the January–March 2004 quarter, the OGTR finalised the outcomes of unannounced visits conducted on a number of accredited organisations to follow up on the replacement or resolution of 'deemed' authorisations under the Act which expired on 21 June 2003. Details on visits finalised in this quarter are outlined in the table below.

Type	Unannounced spot check – Expiry of Deemed Authorisations on 21 June 2003
Organisations	Curtin University of Technology Macfarlane Burnet Institute for Medical Research and Public Health The University of Melbourne
Issues	All authorisations issued as 'deemed' instruments under the Act during the two-year transitional period ended on 21 June 2003. The OGTR Monitoring and Compliance Section conducted unannounced spot checks in order to validate information and to ensure all GMO dealings were authorised.
Determination	The unannounced inspections confirmed that the organisations were compliant with the Act.
Action	No further action required.

Investigations

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

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

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

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

One investigation was completed in the quarter January-March 2004. Details are outlined in the tables below.

Type	Certification / Licencing
Name	Australian National University (ANU) - Research School of Biological Sciences (RSBS).
Current Status	Closed – Investigation Finalised.
Allegation	The investigation was instigated as a result of a third party report to the OGTR that a water spill, possibly involving genetically modified organisms (GMOs), occurred at a PC2 facility at the RSBS.
Summary of Investigation	OGTR compliance and investigations staff conducted an investigation and established that although a water spill had occurred, no GMOs were involved.
Findings	The water spillage was due to an overflow of water caused by a blocked drain from the water-jacket of a water-cooled incubator. RSBS have implemented actions to avoid future blockages and improve staff awareness. The investigation also noted that the RSBS maintains strong Quality Management System (QMS) and Standard Operation Procedures (SOPs) and is committed to ongoing training of users of the facility. The investigation concluded that no offences were committed against the *Gene Technology Act 2000* or the *Gene Technology Regulations 2001*.
Risk Assessment and Management	No GMOs were involved in the spillage and therefore no risk to human health and safety or the environment is found in the context of the *Gene Technology Act 2000*.

Physical containment facilities

OGTR's monitoring of PC2 facilities in the quarter found a number of minor non-compliances and issues with certification instruments. Each observed non-compliance was assessed for risks posed to human health and safety and the environment. All issues observed posed negligible or no additional risk to human health and safety and the environment.

In most instances, issues observed arose from the imprecise wording of Version 1 of the *Guidelines for Certification of Facilities/Physical Containment Requirements* (the Guidelines) and did not jeopardise the secure containment of GMOs. The Guidelines are currently being revised and Version 2 of the requirements for PC2 laboratories and animal and plant containment facilities were issued on 7 August 2003. The certifications for these facilities are being progressively varied as holders confirm that they meet the new requirements.

Guidelines for the remaining facility types (PC1, PC2, aquatic, arthropod and large scale, PC3 and PC4) continue to be reviewed.

PART 3 Committee operations

The Act established three advisory committees:

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

Gene Technology Community Consultative Committee

The GTCCC did not hold a meeting during the quarter. However, working groups previously established to work on a range of priority areas that were agreed with the Regulator have been engaged in out-of-session activity between meetings. Two of the working groups held meetings in this quarter focusing on revising draft papers for consideration at the next meeting of the committee (April 2004).

Further information about the issues under consideration by GTCCC can be obtained from the December 2003 meeting communique included in the October – December 2003 Quarterly Report. Previous communiques can also be found on the OGTR website at <www.ogtr.gov.au>.

Gene Technology Ethics Committee

During the quarter GTEC held its Sixth meeting on 25 and 26 March 2004 in Canberra. GTEC is continuing work on a range of priority areas that were agreed with the Regulator. The five working groups reported to the Committee on their progress since the last GTEC meeting. The committee resolved to concentrate their efforts on three priority areas including progress of ethical guidelines for dealings involving GMOs, and finalisation of two discussion papers. In addition the committee discussed their second submission to the National Health and Medical Research Council (NHMRC) on the *Draft Guidelines on Xenotransplantation Research*.

At the March meeting GTEC received a presentation from the General Manager Biotechnology Australia on the activities of the Biotechnology Liaison Committee (BLC). He provided an overview of the draft *National Ethical Guidelines for Biotechnology* currently being developed by the BLC. It was concluded that the two Committees may be able to assist each other. GTEC also undertook to provide a copy of their draft ethical guidelines to the BLC later in the year.

Members also received a presentation from the OGTR providing an update on the progress of the review of the Office's *Risk Analysis Framework*.

Also in this quarter, GTEC provided a submission to the NHMRC on the *Draft Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (7th Edition)*.

The GTEC communique, outlining discussions held at the March 2004 meeting is included in this report (Appendix C). GTEC is scheduled to meet again on the 19 and 20 July 2004.

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

Gene Technology Technical Advisory Committee

During the quarter GTTAC considered a number of items out-of-session including:

- 2 applications for DIR licences
- 1 application and RARMP for a DNIR licence

The eleventh GTTAC communique, outlining discussions held at the November and December 2003 meetings is included in this report (Appendix B). GTTAC is scheduled to meet again in April and July 2004.

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

Reviews

The following reviews continued during this quarter:

- A review to develop a strategy to identify common data requirements for future applications for DIRs, particularly large-scale limited and controlled releases. This review is ongoing.
- A review of the OGTR's *Risk Analysis Framework*.
- A review of *Guidelines for the Certification of Facilities/Physical Containment Requirements* to address practical difficulties that have been encountered in the implementation. In this quarter:
    - draft revised guidelines for PC2 aquatic facilities were circulated to selected stakeholders for comment;
    - work commenced on the revision of PC2 insectary guidelines, to be renamed as arthropod containment facilities; and
    - drafting of revisions to PC3 laboratory facilities guidelines continued.

International collaboration and coordination

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

International collaboration and coordination activities undertaken during the quarter include:

- Participation in the Food Standards Australia New Zealand Capacity Building training in the Safety Assessment of Genetically Modified Foods that was held in Bangkok, Thailand (23 – 27 February)
- Representation on the Australian Delegation to the First Meeting of the Conference of the Parties to the Convention on Biological Diversity (serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety) that was held in Kuala Lumpur, Malaysia (23 – 27 February).

Advice on gene technology regulation

Presentations and meetings

The Gene Technology Regulator and her office endeavour 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 Regulator:

- Gave a presentation entitled “Regulation of Gene Technology in Australia” at the National Youth Science Forum held in Canberra, ACT on 16 January 2004
- Gave a presentation to the Australian Academy of Technological Sciences and Engineering, Crawford Fund University of New England - Master Class in Research Management held in Sydney, NSW on 11 February 2004; the presentation was titled “Decision Making in Gene Technology Regulation”
- Attended and gave an address at the Curtin University Graduation Ceremony on 23 February 2004
- Attended and gave an address at the Edith Cowan University Graduation Ceremony in Perth, WA on 11 March 2004.

Institutional Biosafety Committee training sessions

The OGTR regularly provides training sessions to accredited organisations and their IBCs. During the January–March 2004 quarter, sessions were conducted in:

- WA: Edith Cowan University, The University of Western Australia, Department of Agriculture Western Australia;
- VIC: Howard Florey Institute, Royal Melbourne Institute of Technology, Florigene Pty Ltd, Platform Sciences Laboratory, Prince Henry’s Institute for Medical Research;
- NSW: EnGeneIC Pty Ltd, Johnson and Johnson Research Pty Ltd; Royal North Shore Hospital, Royal Prince Alfred Hospital, The Australian Museum;
- QLD: Bureau of Sugar Experimental Stations, Prince Charles Hospital, Royal Children’s Hospital and Health Service District, Xenome Ltd.

Gene Technology Information Management System

During the January-March 2004 quarter, the OGTR provided a series of presentation sessions to assist organisations to use the Gene Technology Information Management system (GTIMS). Sessions were held at 24 different locations across QLD, NSW, VIC and ACT.

The GTIMS rollout to date as follows

State	Number of Organisations	Completed
ACT	6	6
TAS	2	2
NT	3	3
SA	7	7
WA	5	5
NSW	18	8
VIC	13	9
QLD	21	11
Total	75	51

OGTR website

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

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

The most popular downloaded documents were:

- The biology and ecology of pineapple *(Ananas comosus var. comosus) in Australia*
- Handbook on the regulation of gene technology in Australia
- The biology and ecology of cotton (*Gossypium hirsutum*) in Australia
- The biology and ecology of papaya, (paw paw, *Carica papaya L)* in Australia
- The biology and ecology of canola (*Brassica napus*) in Australia

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

OGTR email address and freecall number

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

OGTR received approximately 113 calls and 431 emails in January 2004, 133 calls and 559 emails in February 2004, and 211 calls and 707 emails in March 2004.

Freedom of information

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

Appendix A

DNIR Licences issued 1 January–31 March 2004

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 274/2003	29 January 2004	Australian Army Malaria Institute, Queensland	Experimental infection of *Culex annulirostris*, *Ochlerotatus vigilax* and *Culex gelidus* with *Japanese encephalitis virus* vaccine candidate Chimerivax(TM)-JE	Assessing the potential of the ChimeriVax™-JE vaccine to infect and replicate in Australian mosquitoes.
DNIR 275/2003	22 January 2004	Biotron Limited, Australian Capital Territory	Viral protein gene function in whole virus for screening anti-viral compounds	To screen for novel compounds which disrupt viral replication using whole recombinant viruses.
DNIR 280/2003	10 March 2004	University of New South Wales, New South Wales	Production of recombinant protiens in Chinese Hamster Ovary (CHO) cells.	To produce large amounts of recombinant protiens of commercial value in Chinese Hamster Ovary (CHO) cells.
DNIR 281/2003	27 February 2004	Murdoch University, Western Australia	Development of a *Subterranean clover mottle virus* as a gene-silencing vector	To use *Subterranean clover mottle virus* as a vector for silencing plant genes in culture and in live plants.
DNIR 283/2003	2 February 2004	Queensland University of Technology, Queensland	Generation of an infectious clone of *Taro bacilliform virus* (TaBV)	Determining if taro plant disease can be caused by infection with TaBV alone.
DNIR 284/2003	10 March 2004	Griffith University	Cloning and characterisation of *Campylobacter* species pathogenicity genes in *E.coli* and construction of a vector dedicated to cloning and expression of *Campylobacter* DNA functional in *E.coli* and *Campylobacter* species	Develop a system to express genes from the bacterial species *Campylobacter* in both *Campylobacter* and *E. coli* and use this system to characterise genes from the bacteria *Campylobacter jejuni* that affect pathogenicity.

Appendix B

GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE

COMMUNIQUE
No. 11

This is the eleventh communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the eighteenth and nineteenth meetings of GTTAC, held on 19–20 November 2003 and 18 December 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
DNIR 266/2003 Construction of influenza viruses by reverse genetics for diagnostic and research purposes.	The aim of this project is to employ a technique known as reverse genetics to produce influenza viruses synthetically in order to derive potential influenza virus vaccine candidates in a more rapid and reproducible manner.	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. Additionally, the Committee recommmended that details of the laboratory staff to be involved in this dealing be provided.
DNIR 271/2003 Investigations on parasite virulence using cross complementation.	The aim of this dealing is to study virulence proteins from parasites.	GTTAC agreed that the risk assessment identified all the risks associated with the proposed dealings and that the measures proposed in the risk management plan are adequate to deal with the identified risks. However, the Committee recommended the applicant provide more detail regarding the housing arrangements for the animals involved in the dealing. The Committee also recommended the licence conditions contain a requirement for the applicant to ensure lab staff are aware of the potential risk associated with this dealing for pregnant women and women likely to become pregnant, and to advise these women not to be involved in the dealing.

Application Number and Title	Project Description	GTTAC Comments
DNIR 272/2003 Delivery of replication defective lentiviruses into mice.	The aim of this dealing is to produce defective lentiviral vectors to be introduced into mammalian cell lines and mice.	GTTAC agreed that the risk assessment identified all the risks associated with the proposed dealings. The Committee recommended that screening for replication competent virus generation and minimising the use of sharps will manage the potential risks associated with this dealing in addition to the measures proposed in the risk management plan.
DNIR 273/2003 Repression of hepatic drug metabolism by solid tumours.	The aim of this dealing is to characterise the pathway of down-regulation of CYP3A4 in transgenic mice.	The Committee agreed that the potential risks associated with this dealing can be managed by implementing standard Physical Containment (PC) 2 procedures and minimising the use of sharps while working with recombinant adenoviruses. GTTAC also recommended the applicant clarify the experience of the staff involved in the dealing.
DNIR 274/2003 Experimental infection of *Cules annulirostris, Olerotatus vigilax* and *Culex gelidus* with Japanese encephalitis virus vaccine candidate ChimeraVax™-JE.	The aim of this dealing is to determine if the ChimeriVax™-JE vaccine can infect and replicate in the mosquitoes *C. annulirostris*, *O. vigilax* and *C. gelidus* after oral or intrathoracic infection.	GTTAC agreed that the risk assessment identified all the risks associated with the proposed dealings and that the measures proposed in the risk management plan are adequate to deal with the identified risks.

Application Number and Title	Project Description	GTTAC Comments
DNIR 275/2003 Viral protein gene function in whole virus for screening anti-viral compounds.	The aim of this dealing is identify proteins from human viral pathogens that play a role in viral replication.	As for DNIR 274/2003
DNIR 281/2003 Development of *Subterranean clover mottle virus* (SCMoV) as a gene-silencing vector.	This study aims to use *subterranean clover mottle virus* (SCMoV) as a vector for silencing plant genes *in vivo* and *in vitro* experiments.	As for DNIR 274/2003
DNIR 283/2003 Generation of an infectious clone of *Taro bacilliform virus* (TaBV).	The aim of this dealing is to determine whether a single infection with *Taro bacilliform virus* (TaBV) causes alomae disease.	As for DNIR 274/2003.

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 Applications

Advice on Cotton

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

- **Agronomic assessment and seed increase of transgenic cottons expression insecticidal genes from *Bacillus thuriengiensis* (DIR 044/2003)**

  The OGTR has received an application from Dow AgroSciences Australia Limited for the limited and controlled release of GM cotton containing insecticidal genes (chimeric *cry1Ac* and *cry1Fa*) toxic to lepidopteran

caterpillar pests of cotton, and a herbicide tolerance marker gene (*pat*). The small scale trial is proposed to occur over a total of 10 hectares over two summer and two winter cotton growing seasons (May 2004 – May 2006) in cotton growing regions of Queensland (Qld), New South Wales (NSW) and in the Northern Territory.

The aims of the proposed release are to test the efficacy of the two-gene insecticidal cotton line (Widestrike™) against lepidopteran caterpillar pests of cotton as compared to its two parental lines, one introducing the chimeric *cry1Fa* gene or the other introducing the chimeric *cry1Ac* gene, and to evaluate their respective agronomic performance in a range of Australian cotton growing regions. All three lines contain a herbicide tolerance marker gene that confers tolerance to the herbicide glufosinate ammonium.

The applicant also aims to collect data to develop insect resistance management plans. In addition, the applicant intends to measure the expression levels of the insecticidal proteins in cotton leaves and roots and residues of these proteins in soil, as well as to test the effect of GM cotton lines on non-target organisms. Seed would also be retained for potential future releases. None of the cotton plants from the release, or their by-products, would be used for animal feed or human food.

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

- The risks posed by DIR 044/2003 are similar to those posed by previous cotton applications;
- Advice provided in relation to previously assessed GM cottons should be considered in the preparation of the RARMP for DIR 044/2003;
- The applicant should be requested to provide data on levels of expression under Australian field conditions at the completion of the four seasons of field trials; and
- The applicant should be asked to provide details of the CRY protein expression levels and the lethal dose delivered by the GM plants.

Advice on vaccines

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

- **Development of Porcine adenovirus (PAV) vaccine vectors (DIR 045/2003)**

  The OGTR received a licence application from Imugene Ltd for a licence for the limited and controlled release of GM pig adenoviruses. The

application proposes the use of up to three sites of PC1 animal house facilities in Victoria (Vic) and the inoculation of up to 200 pigs.

The proposed trial involves four GMOs that have each been modified by introducing one of two pig genes under the control of one of two promoters. The pig genes produce different proteins, known as interferon gamma (IFN-γ) and interleukin 5 (IL-5), that play roles in regulating the immune system of pigs.

Pigs raised in commercial production facilities are exposed to a range of organisms that may cause low grade infections that adversely affect their general health and production. To counteract this, antibiotics is sometimes added to pig feed. If the research is successful, the inoculation of pigs with the modified virus may provide an alternative to the use of antibiotics in commercial pig meat production.

Pigs will be inoculated via intranasal or oral routes or by subcutaneous injection, with one or more of the GM viruses. None of the pigs from the trial, or their by-products, will be used for animal feed or human food. Following each trial, inoculated pigs will be euthanased and all animal material disposed of under strict conditions that would destroy the GMOs.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has regulatory responsibility for veterinary medicine use in Australia, including the registration of vaccines. Data from this proposed trial on the effectiveness of the treatment is necessary before the APVMA could evaluate an application for registration of the GM viruses as products for veterinary use. Further information about the APVMA can be obtained from www.apvma.gov.au.

The Committee advised the Regulator that the applicant should be asked to provide further information regarding:

- The potential for transmission of the GM viruses by insects and whether insects could be excluded from the PC1 animal house;
- Whether the porcine and avian adenoviruses use the same receptors as human adenoviruses;
- Whether expression of the cytokines may increase the pathogenicity or virulence of the GM viruses or a subsequent challenge pathogen; and
- The waste disposal procedures to be used.

GTTAC also advised the Regulator that the applicant should be asked to provide evidence that:

- The GM viruses cannot enter or replicate in human cells; and
- The cytokines are not functionally active in human cells.

- **Development of Fowl adenovirus (FAV) vaccine vectors (DIR 046/2003)**

  The OGTR received a licence application from Imugene Ltd for the limited and controlled release of GM fowl adenoviruses (vaccine) which have been modified by the addition of a chicken interferon gamma gene (*ChIFN-γ),* that encodes an immuno-regulatory protein. Imugene proposes to carry out multiple limited and controlled releases, within PC1 animal containment facilities in Victoria, from the time of issuing the licence until December 2006.

  Inoculation with the GM fowl adenoviruses is expected to stimulate the chickens' immune systems, with a view to replacing the use of antibiotics in chicken feed. Data on the efficacy of the treatment would be necessary for registration of the GM fowl adenoviruses by the APVMA. APVMA approval would be required for these GMOs to be used for inoculation of chickens on a larger scale or outside of contained research facilities. Further information about the APVMA can be obtained from www.apvma.gov.au.

  Up to 5000 chickens will be inoculated with the GM viruses. None of the chickens or their by-products, would be used for animal feed or human food. Following each trial, inoculated chickens will be euthanased and all animal material disposed of under strict conditions that would destroy the GMOs.

  GTTAC advised the Regulator that the applicant should be asked to provide further information regarding:

  - The potential for transmission of the GM viruses to wild birds and the steps that will be taken to prevent this;
  - The effects of the transgenes on the immune system of wild birds;
  - The methods to be used for waste disposal, particularly of bird litter;
  - The possible effects of maternal antibody on trial results;
  - Whether expression of cytokines may increase the pathogenicity or virulence of the GM viruses or a subsequent challenge pathogen;
  - The potential for increased pathogenicity in the GM viruses from the genetic modification;
  - Whether the porcine and avian adenoviruses use the same receptors as human adenoviruses;
  - The waste disposal procedures to be used; and
  - The relationship between the GM fowl adenoviruses in the trial and commercially available non-GM vaccine strains, and the conventions of the latter's use in industry.

The Committee also advised the Regulator that the applicant should be asked to provide evidence that:

- The GM viruses cannot enter or replicate in human cells; and
- The cytokine is not functionally active in human cells.

Advice on RARMPs

Advice on Canola

GTTAC considered the RARMPs prepared in response to the following applications concerning the release of GM canola in Australia:

- **General release of Roundup Ready (*Brassica napus)* in Australia (DIR 020/2002)**

  The OGTR received an application from Monsanto Australia Ltd (Monsanto) for a licence for the intentional release of GM Canola that has been modified to tolerate glyphosate, the active ingredient in the herbicide Roundup®. The use of Roundup Ready® canola will allow the application of glyphosate for the control of weeds which emerge following crop planting. A parallel application for registration for the use of Roundup® on Roundup Ready® canola was made to the Australian Pest and Veterinary Medicines Authority (APVMA). The APVMA is responsible for the registration of agricultural chemicals for use in Australia.

  Monsanto proposes the commercial cultivation of Roundup Ready® canola in all current and future canola growing regions of Australia, which potentially includes NSW, Vic, Qld, South Australia (SA), Western Australia, Tasmania and the Australian Capital Territory. Release of Roundup Ready® canola requires State or Territory government approval where various moratoria regarding GM crops have been imposed.

  The canola plants and their by-products, would be used in the same manner as conventional canola, including for human food and animal feed. The use of oil derived from Roundup Ready® canola was approved by Food Standards Australia New Zealand in November 2000.

  GTTAC discussed the RARMP and supporting information at length and agreed that this GMO is as safe to human health and safety and the environment as conventional canola. However, during the comprehensive discussion members raised concerns relating to the practical use of Roundup Ready® canola and Roundup® herbicide. These concerns included the potential impact the introduction and management of Roundup Ready® canola may have on herbicide usage and the development of herbicide resistance. The Committee discussed the use of non-glyphosate herbicides on GM volunteers in non GM canola crops, and management of roadside volunteers resulting from seed spillage. The Committee

recognised that these concerns were being considered by the APVMA as the responsible regulatory authority

The Committee resolved to write to the APVMA outlining their concerns regarding the potential for development of herbicide resistance as a result of inappropriate herbicide use following the introduction of Roundup Ready® canola.

GTTAC advised the Regulator that:

- The Committee agrees with the risk assessment made by the OGTR, including the conclusions of the RARMP;
- The section on Toxicity and Allergenicity should clearly indicate that there is no difference between the GM and non-GM plants, except for the expressed genes;
- The RARMP should adequately explain why the main areas of concern identified by GTTAC (potential development of herbicide resistance) do not fall under the Gene Technology Act; and
- The Committee agrees with the proposed licence conditions;
- The RARMP should include information on current industry standards for the proximity of seed crops to commercial crops.

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

  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 lines with the RF lines 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. The GM canola also contains regulatory sequences that control the expression of the inserted genes. Bayer has sought and received approval for detail of the origin and identity of the herbicide tolerance gene and regulatory sequences declared as CCI. However, this information was made available to GTTAC and other prescribed expert authorities that were consulted on the preparation of the RARMP.

The Committee advised the Regulator that:

- The Committee agrees with the risk assessment made by the OGTR and the conclusions of the RARMP; and
- The Committee agrees with the proposed licence conditions, with one minor correction required to clarify that deep tillage is not permissible.

Gene Technology Ethics Committee (GTEC) Paper

The Committee was asked to comment on a paper prepared by a GTEC working group on ethical issues associated with transkingdom gene transfer. The Committee discussed the paper and provided a number of suggestions for the final version of the document. Further information regarding the operations of the GTEC are available from the OGTR website.

Review of the Gene Technology Regulations 2001 (Regulations)

The Committee was provided with an overview of New Zealand's *Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003* which are similar to Australia's regulations for exempt and notifiable low risk dealings.

The Committee advised the Regulator that the approach adopted by New Zealand to regulate low risk dealings with GMOs warranted further consideration while reviewing Australia's Regulations.

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 C

Gene Technology Ethics Committee Meeting
25-26 March 2004, Canberra

COMMUNIQUE

The Gene Technology Ethics Committee (GTEC) held its sixth meeting in Canberra on the 25th and 26th of March 2004.

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

At its March 2004 meeting, the current GTEC working groups reported on their activities since the previous meeting and received feedback and suggestions to further develop their projects. In addition to two presentations by invited guests, members were informed of relevant work from other national committees via cross-member reports, as well as a Chair's activity report, and a report from the Regulator on activities undertaken by the Office of the Gene Technology Regulator (OGTR) since the fifth meeting held in November 2003. Key outcomes from the meeting are reported below.

GTEC's Work Plan

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

Ethical Guidelines in Relation to Genetically Modified Organisms

The working group presented a revised report on the development of ethical guidelines in relation to genetically modified organisms. The revised report incorporated comments provided to the working group at the previous GTEC meeting.

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

Ethical Issues Associated with Transkingdom Gene Transfer [2]

The working group, established to consider the ethical issues associated with transkingdom gene transfer, received feedback from the other gene technology advisory committees. The working group valued the comments from the GTTAC and GTEC and resolved to incorporate, where possible, these comments into a revised paper.
Once the paper has been finalised by the GTEC, it will be published on the Committee's page on the OGTR website.

Release of Information and Notification under the Gene Technology Act 2000

As noted in the communique for the November 2003 GTEC meeting, there is overlap between this paper and a similar one currently being produced by GTCCC. The Committee discussed the future direction of this paper and agreed it should be referred to the ethical guidelines working group to inform revision of the values and principles section.

Managing Risk Ethically

The working group presented GTEC with a revised paper that incorporated comments received at the November 2003 GTEC meeting. The paper will now be provided to GTTAC and GTCCC for their comment. On receipt of comments from the other Committees, the document will be made publicly available.

---

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

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

The GTEC has been examining the need for an ethical review for all types of applications for genetic modification work in relation to plants and animals. The Committee agreed not to progress the paper further at this time. GTEC thanked the working group for their progress and the development of working relations with the Victorian Biotechnology Ethics Advisory Committee.

GTEC and Relationships with Other Committees

The Committee welcomed a member from the Animal Welfare Committee (AWC) to the meeting who presented the Committee with a *draft Guidelines for the Creation, Breeding, Care and Use of Genetically Modified Animals for Scientific Purposes* for GTEC's comment. As reported in the previous communique, GTEC made a submission to the *Draft Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (7th Edition)* from which the above guidelines developed. GTEC will continue its involvement with the development of *Guidelines for the Creation, Breeding, Care and Use of Genetically Modified Animals for Scientific Purposes.*

The Committee also welcomed an invited guest from the Australian Health Ethics Committee (AHEC) who reported on the current activities of AHEC. GTEC decided prior to the March 2004 meeting that it would respond to the second call for submissions from the AHEC on the development *of Animal-to-human transplantation research: How should Australia proceed?* GTEC viewed a draft submission prepared by the GTEC working group and provided comments on the draft. The working group will incorporate these comments and finalise the submission to be provided to the AWC. GTEC's submission will be made available on the OGTR website.

GTEC welcomed an invited guest from Biotechnology Australia (BA) who presented an overview of the organisation and the work of the Biotechnology Liaison Committee (BLC), which comprises State, Territory and Australian Government biotechnology officials, regarding a national approach to ethics in biotechnology. The presentation formed the basis of the discussion regarding areas in which GTEC and BLC may collaborate. Once finalised, GTEC will present its ethical guidelines for use of GMOs to the BLC for their consideration. GTEC will also provide interim reports about the progress of the guidelines to the BLC.

As a standing item at every GTEC meeting, the Committee receives verbal reports on activities from the cross-members with the GTTAC and the GTCCC. Communiques covering meetings for all gene technology advisory committees are publicly available from the OGTR website.

The Regulator reported on the operations of the OGTR. This information is publicly available in Quarterly Reports of the Gene Technology Regulator, available on the OGTR website or on request by phoning the number below.

Next Meeting

The next GTEC meeting will be held in July 2004.

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