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

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 OCTOBER–31 DECEMBER 2006

The object of the *Gene Technology Act 2000* is:

'to protect the health and safety of people, and 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 genetically modified organisms'

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Commonwealth Department of Health and Ageing

Publications Approval Number 3626

The Hon Christopher Pyne MP
Assistant Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

Dear Assistant Minister

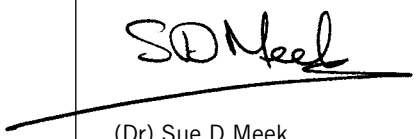
In accordance with section 136A of the *Gene Technology Act 2000* (the Act), I am pleased to present to you the Quarterly Report of the Operations of the Gene Technology Regulator, covering the period 1 October to 31 December 2006

During this quarter, key achievements included the issuing of five licences for dealings involving the intentional release of genetically modified organisms (GMOs), six licences for dealings not involving intentional release of GMOs, and the certification of 32 physical containment facilities.

Routine monitoring activities for this quarter have met the minimum target rate and no significant risks to either human health or the environment were identified.

The second National Institutional Biosafety Committee Forum, which was opened by you, took place in Canberra on 15–16 November 2006. A total of 131 delegates representing 19 accredited organisations from all States and Territories participated.

Yours sincerely



(Dr) Sue D Meek

Gene Technology Regulator

1 March 2007

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GLOSSARY, ACRONYMS AND ABBREVIATIONS

This section contains a brief description of terms relevant to an understanding of this quarterly report. They do not substitute for definitions of terms relevant to the operation of the gene technology regulatory system that are contained in section 10 of the *Gene Technology Act 2000.*

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 of a licence condition	A breach of a licence condition which has been proven either in court or by way of admission following investigation
CCI	Confidential commercial information
Certified contained 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 the statutory time limit for making a decision on an application is suspended — usually because evaluation cannot proceed until additional information requested from the applicant is received
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DIR	A dealing 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 the 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 expert 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 (work with transgenic plants, animals or microorganisms undertaken in certified contained facilities)
Non-compliance	An inconsistency between an event or state of affairs and the requirements imposed by licence accreditation or certification conditions, or any of the requirements of the Act or Regulations
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

ABOUT THIS REPORT

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; and
- auditing and monitoring of dealings with GMOs under the Act by the Regulator or an inspector during the quarter.

It's purpose is to inform the community of our roles and responsibilities and to provide a summary of our achievements over the past quarter.

This report has four key sections and appendices.

Gene Technology Regulatory System

Provides advice on the activities and outcomes achieved in relation to the implementation and management of the national regulatory system during the October to December 2006 quarter.

Regulation of genetically modified organisms

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

Statutory Committee Operations

Reports on the activities of the three advisory committees established under the Act to assist the Regulator and the Gene Technology Ministerial Council .

Other activities of the Gene Technology Regulator

Describes other activities relating to the statutory functions of the Regulator that support the operations of the gene technology regulatory system.

Appendices

The appendices contain information on the number of DNIR licences issued and communiqués for the statutory committees.

SECTION 1

NATIONAL REGULATORY SYSTEM

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the October to December 2006 quarter were:

Licences and other instruments

- 5 licences issued for dealings involving the intentional release of GMOs into the environment (DIR licences);
- 6 licences issued for dealings not involving intentional release of GMOs into the environment (DNIR licences);
- 78 Notifiable Low Risk Dealing (NLRD) notifications received;
- 32 contained facilities certified;
- 23 surrenders of certifications processed; and
- 114 variations processed.

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

Monitoring and Compliance

Approximately 8 percent of current field trial sites and 5 percent of post harvest field trial sites were subjected to routine monitoring during the quarter. This meets the target minimum rate of 5 percent per quarter.

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

Working collaboratively with States and Territories

Gene Technology Ministerial Council

The Gene Technology Ministerial Council (GTMC) oversees the implementation of the regulatory system and comprises one Minister from the Commonwealth and one Minister from each of the States and Territories. Currently, the GTMC includes Ministers from a range of portfolios including health, agriculture and environment.

State and Territory consultation

The Regulator must consult with State and Territory Governments and relevant local councils twice during the evaluation of applications for DIR licences.

For each application for a DIR licence, the Regulator seeks advice on matters relevant to the preparation of the Risk Assessment and Risk Management Plan (RARMP) and comment on the RARMP itself once it is prepared.

More information is contained in Section 2 of this report.

Australian Government Agency liaison

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

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

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

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

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

In addition, comment is sought on each DIR licence application and DIR 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; and
- Department of Industry, Tourism and Resources.

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

Further information is contained in Section 2 of this report.

Public participation

During the quarter, the Regulator issued two invitations to the public to comment on the RARMPs prepared in response to two applications. 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 Australian newspaper;

- relevant regional press such as; *Queensland Country Life*, the *Courier Mail,* the *Melbourne Times Northern Edition* and the *Preston Leader*; and
- OGTR website www.ogtr.gov.au

Further information is contained in Section 2 of this report.

SECTION 2

REGULATION OF GENETICALLY MODIFIED ORGANISMS

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of the report outlines the regulatory activity undertaken during the October to December 2006 quarter. This includes information about applications for genetically modified organisms (GMO) licences and other instruments under the Act. It also includes details of monitoring activities and of alleged, admitted or self-reported non-compliances with the Act, or with the conditions imposed by the Regulator on GMO licences or other instruments issued pursuant to the Act. 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:

- **Dealings 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.

- **Dealings Not involving Intentional Release (DNIR) licences**

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

- **Accreditations of organisations**

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

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

GMO Register

The GMO Register is a list of dealings with GMOs that the Regulator is satisfied pose minimal risks to human health and safety and the environment and can therefore be undertaken by anyone, subject to any specified conditions, without the oversight of a licence holder. Under

section 78 of the Act the Regulator may determine that dealings with a GMO previously authorised by a licence are to be included on the GMO Register. Such determinations are disallowable instruments.

New licences and other instruments

The following table describes the number and type of applications received for new licences and other instruments, as well as the approvals made by the Regulator in the quarter.

Applications received and decisions made, new licences and other instruments 1 October to 31 December 2006

Application type	Number received	Number approved*
DIR licence	1	5
DNIR licence	8	6
Accreditations	0	9
Certifications	34	32
GMO Register	0	0

* *Approvals reported in the current quarter often relate to applications received in previous quarters.*

Processing of applications for Dealings involving Intentional Release licences

The key steps the Regulator takes when considering an application for a Dealings involving Intentional Release (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 to manage risks to human health and safety and the environment;
- considering all comments relating to the protection of human health and safety and the environment in finalising the RARMP; and
- consideration of the 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 nine months as it excludes weekends and public holidays in the Australian Capital Territory.

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 of consultation 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 progress of applications for DIR licences undergoing evaluation during the quarter.

Applications for Dealings involving Intentional Release licences subject to evaluation during the quarter

Application received	First round of consultation*	Second round of consultation	Withdrawn applications	Licence issued
DIR 071/2006	DIR 069/2006	DIR 068/2006		DIR 064/2006
	DIR 071/2006	DIR 070/2006		DIR 065/2006
				DIR 066/2006
				DIR 067/2006
				DIR 068/2006

* *Includes posting of 'Early Bird' Notification and summary of application on the OGTR website and to people on the OGTR mailing list.*

Applications received for Dealings involving Intentional Release licences

The OGTR received one application for a DIR licence in the October to December 2006 quarter.

- DIR 071/2006 — Limited and controlled release of GM drought tolerant wheat — Department of Primary Industries (Victoria).

Consultation on applications for Dealings involving Intentional Release 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 RARMPs for the following applications:

- DIR 069/2006 — Limited and controlled release of GM herbicide tolerant hybrid *Brassica napus* and *Brassica juncea* — Bayer CropScience Pty Ltd.
- DIR 071/2006 — Limited and controlled release of GM drought tolerant wheat — Department of Primary Industries (Victoria).

Although not required by the Act, the Regulator also issued an 'Early Bird' Notification to people and organisations on the OGTR's mailing list to advise receipt of these applications and when the RARMPs are expected to be released for public comment.

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

- DIR 068/2006 — Limited and controlled Release of genetically modified (GM) Torenia with altered flower colour — Florigene Pty Ltd; and
- DIR 070/2006 — Limited and controlled release of GM sugarcane with altered plant architecture, enhanced water or improved nitrogen use efficiency — BSES Limited.

Full copies of DIR applications can be obtained by contacting the OGTR. Summary information on DIR applications and consultation RAMPS, including proposed licence conditions, are available via the OGTR website or directly from the OGTR.

Withdrawn applications for Dealings involving Intentional Release licences

No DIR licence applications were withdrawn this quarter.

Surrendered applications for Dealings involving Intentional Release licences

Two DIR licences were surrendered during this quarter:

- DIR 008/2001 — Integrated pest management systems for INGARD® cotton — Department of Agriculture (Western Australia); and
- DIR 009/2001 — Preliminary field evaluation of Bollgard II® cotton in the Kimberley region of WA — Department of Agriculture (Western Australia).

Clock stopped on Dealings involving Intentional Release licence applications

The Regulations determine that a day on which the Regulator is unable to proceed with the decision-making process, or a related function, because information requested from the applicant has not been received, is not counted as part of the prescribed 170 day time-limit for a decision to be made on an application.

One clock stop period continued to apply to a DIR licence application during the quarter:

- DIR 061/2005 — Limited and controlled release of GM salt tolerant wheat — Grain Biotech Australia Pty Ltd.

Decisions on applications for Dealings involving Intentional Release licences

During the quarter, the Regulator issued five DIR licences:

- DIR 064/2006 — Limited and controlled release of water-efficient GM cotton — Monsanto Australia Limited;
- DIR 065/2006 — Limited and controlled release of GM insect resistant (VIP3A and/or modified Cry1Ab) cotton — Deltapine Australia Pty Ltd;
- DIR 066/2006 — Commercial release of GM herbicide tolerant and/or insect resistant cotton lines north of latitude 22° South — Monsanto Australia Limited;
- DIR 067/2006 — Limited and controlled release of waterlogging tolerant (GM) Cotton — CSIRO; and
- DIR 068/2006 — Limited and Controlled Release of genetically modified (GM) Torenia with altered flower colour — Florigene Pty Ltd.

Summary information on DIR applications, finalised RARMPs and copies of licences are available from the OGTR website or can be obtained by contacting the OGTR directly.

Decisions on applications for Dealings Not involving Intentional Release 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 six Dealings Not involving Intentional Release (DNIR) licences. Further information about these licences is contained in Appendix A of this report.

A full listing of DNIR licence applications and their current status is available from the OGTR website.

Notifications of Notifiable Low Risk Dealings received

The Act requires organisations to notify the Regulator when conducting Notifiable Low Risk Dealings (NLRDs).

This category of dealings with GMOs is defined in the Gene Technology Regulations 2001 and 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 PC2 facilities or those deemed suitable by the Regulator.

NLRDs are assessed by the submitting organisation's Institutional Biosafety Committee (IBC) and do not require approval by the Regulator. The OGTR checks notifications for compliance with legislative requirements.

The Regulator received 78 NLRD notifications in the quarter. A listing of NLRDs and their date of notification is available from the OGTR website.

Existing licences and other instruments

The Regulator can, directly or upon application, vary an issued licence or other instrument. Variations involve changes to conditions applied to an instrument or a licence. For example, the Regulator can vary a licence to better manage risks if new information or data comes to light. Most variations are made at the request of the instrument/licence holder. However, the Regulator must not vary the licence unless the Regulator is satisfied that any risks posed by the dealings proposed to be authorised by the licence as varied are able to be managed in such a way as to protect the health and safety of people and the environment.

Additionally, the Regulator can make a decision in relation to an application to transfer a licence to another person or consent to the surrender of a licence by a licence holder.

The following table describes the number and type of the applications received to surrender or vary existing licences and other instruments, as well as the number of applications processed during the October to December 2006 quarter.

Applications received and decisions made: existing licences and other instruments 1 October to 31 December 2006.

Type	Number received	Number processed*
Surrender of certification	65	23
Surrender of DIR licence	4	2
Surrender of DNIR licence	4	2
Surrender of accreditation	1	3
Variation of certification	77	78
Variation of accreditation	2	2
Variation of DIR licence	5	9
Variation of DNIR licence	32	25

* *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.*

Confidential Commercial Information

Under section184 of the Act a person may apply to the Regulator in accordance with section185 for specified information to be declared Confidential Commercial Information (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 four CCI applications relating to DIR applications and one CCI application relating to an NLRD notification.

The Regulator made three CCI declarations in relation to DIR applications, one declaration in relation to a DNIR application and one declaration in relation to an NLRD.

Monitoring and Compliance

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

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

In particular, the Monitoring and Compliance Sections focus on management of dealings at field trial sites and within contained facilities certified by the Regulator to ensure:

- the dissemination of a GMO and its genetic material is minimised;
- the persistence of a GMO in the environment is managed;
- effective management of the GMO is maintained; and
- OGTR monitoring and compliance activities comprise the functions of routine monitoring, reviews of risks, investigations and audits.

OGTR monitoring and compliance activities comprise the functions of routine monitoring, review of risks, investigations and audits and may result in remedial actions.

Monitoring and Compliance Strategy

The OGTR conducts routine monitoring visits of a minimum of 20 percent of field trial sites each year.

A minimum of five percent of current trial sites and five percent 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 spot checks.

The OGTR strategy for conducting field trial monitoring draws on accumulated operational experience of risk profiling in relation to compliance.

For example, OGTR field trial monitoring coincides, where possible, with periods or circumstances when non-compliance with licence conditions designed to limit the spread and persistence of the GMOs is more likely to occur (for example, flowering and harvest of GM crops).

The monitoring program for certified contained facilities involves inspecting and monitoring:

- a minimum of 20 percent of physical containment (PC) PC4, PC3 and PC2 large-scale facilities per year; and
- selected PC2 and PC1 facilities.

These inspections focus on the integrity of the physical structure of the facility and on the general laboratory practices followed in that facility, including those practices followed for DNIRs and NLRDs.

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored: During the October to December 2006 quarter, three field trial sites were subjected to monitoring visits.

Current field trial sites monitored: Of the 12 sites current in the quarter, one was monitored. This represents a monitoring rate of eight percent of all current sites for the quarter.

Post-harvest field trial sites monitored: Of the 39 sites subject to post-harvest monitoring in the quarter, two were monitored. This represents a monitoring rate of five percent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection to contained dealings covered 19 organisations and 56 PC facilities. Monitoring of PC facilities encompassed PC3 laboratories (five visited) PC2 laboratories (35 visited), PC2 constant temperature rooms (one visited) and PC2 aquatic organism containment (one visited).

Monitoring of contained dealings: During the October to December 2006 quarter, monitoring of the 56 PC facilities mentioned above also included monitoring for compliance with the general practices that must be followed when undertaking dealings that are required to be conducted in containment.

Two DNIRs were monitored during the quarter.

Monitoring of Dealings involving Intentional Releases

The following table shows the total monitoring coverage for field trial sites for the reporting period:

Licensed organisation name	Licence number	No. sites visited	Site status*	Crop type
Department of Primary Industries (Victoria)	DIR 047/2003	1	PHM	White Clover
Florigene Pty Ltd	DIR 060/2005	1	C	Rose
Dow AgroSciences Pty Ltd	DIR 044/2003	1	PHM	Cotton
Totals	3 DIR licences	3	C=1 PHM=2	3 types

**. C = current, PHM = post-harvest monitoring*

Monitoring of Dealings Not involving Intentional Releases

The following table shows the total monitoring coverage for DNIRs for the reporting period:

Licensed organisation name	Licence Number
University of Adelaide	DNIR 230/2003
	DNIR 231/2003
Totals	2 DNIR licences

Monitoring of Physical Containment Facilities

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

Organisation	Physical Containment (PC) facility	No. facilities visited
Charles Sturt University	PC2 Laboratory	2
Department of Primary Industries Victoria	PC2 Laboratory	1
	PC2 Plant Containment	1
Therapeutic Goods Administration Laboratories	PC2 Laboratory	2
Department of Agriculture Western Australia	PC2 Plant Containment	1

Organisation	Physical Containment (PC) facility	No. facilities visited
Royal Perth Hospital	PC2 Laboratory	1
Animal Resources Centre	PC2 Laboratory	1
	PC2 Animal Containment	1
Telethon Institute for Child Health Research	PC2 Laboratory	2
Edith Cowan University	PC2 Laboratory	1
	PC2 Animal Containment	2
	PC2 Aquatic Organism Containment	1
Cytopia Pty Ltd	PC2 Laboratory	1
Macfarlane Burnet Institute for Medical Research and Public Health	PC2 Laboratory	2
Howard Florey Institute	PC2 Laboratory	3
	PC2 Animal Containment	1
Australian Genome Research Centre	PC2 Laboratory	1
	PC2 Plant Containment	1
The Australian Water Quality Centre	PC2 Laboratory	1
South Australian Research and Development Institute	PC2 Laboratory	2
The Queen Elizabeth Hospital and Health Services	PC2 Laboratory	5
University of Adelaide	PC2 Laboratory	7
	PC2 Animal Containment	3
	PC2 Plant Containment	3
Austin Research Institute	PC2 Laboratory	3
	PC2 Constant Temperature Room	1
	PC2 Animal Containment	1
Royal Brisbane and Women's Hospital *	PC3 Laboratory	1

Organisation	Physical Containment (PC) facility	No. facilities visited
University of Queensland *	PC3 Laboratory	4
Totals	**6 facility types**	**56**

* *Inspections performed jointly with Contained Dealings Evaluation Section*

Monitoring findings

The monitoring findings listed below are designed to indicate both the monitoring activities of the OGTR with respect to dealings with GMOs under this Act, in accordance with paragraph 136A(2)(c) of the Act, and the Regulator's response to those findings.

Findings by inspectors of inconsistencies between an event or state of affairs and the requirements imposed by licence or certification conditions are called non-compliances in this report. However, non-compliances are not regarded as breaches of licence conditions unless proven to be so after investigation. Non-compliances with licence conditions are assessed against a number of considerations before determining the OGTR response. The following aspects of the findings are taken into account as relevant:

- the extent of risk to the health and safety of people and the environment;
- the severity of the issue or event involved in the finding;
- the culpability of the licence holder or other relevant persons in bringing about the issue or event e.g. whether there was a bona fide mistake involved;
- the types of mechanisms available to address the issue or event;
- the compliance history of the licence holder or other relevant persons;
- mitigating factors such as self-reporting or steps taken voluntarily by the licence holder to address the issue or event; and
- the need for deterrence.

After having regard to those matters, the OGTR has a range of options including additional investigation to determine if further action is warranted e.g. a recommendation of prosecution for an alleged breach of a licence condition or that a licence be suspended or cancelled. A proven breach of a licence condition will be reported in accordance with paragraph 136A(2)(b) of the Act.

In the case of all matters reported below it was decided that the findings of non-compliances with licence conditions were minor in nature, involved negligible or nil culpability, and could be resolved by reminders, education and/or cooperative compliance.

Findings for Dealings involving Intentional Release

Organisation	Department of Primary Industries (DPI) Victoria
Licence number and site	DIR 047 / 2003, Site 2
Summary of dealing	The licence relates to field evaluation of GM white clover resistant to infection by alfalfa mosaic virus (post trial monitoring of Howlong, NSW site)
Findings	At the time of the inspection the site was fallow and no white clover plants were present. During the inspection OGTR staff ascertained that the site was not cultivated each spring and each autumn as required under the licence conditions. The site was last cultivated in 2004. Other post harvest procedures had been implemented and involved reducing the seed bank by repeated herbicide applications to remove any germinating seedlings in the test plots.
Assessment	DPI Victoria's compliance history is good, their monitoring inspections were regular, no white clover was present and the site had regularly been sprayed with herbicide to remove germinating clover seedlings. The risks to human health and safety and the environment as a result of this non-compliance were negligible. DPI Victoria stated that it would undertake all required cultivations in the future which will reduce the potential for a seed bank remaining at the site. DPI Victoria also stated that it would conduct core sampling of the soil at the site to determine the level of seed bank remaining.
Compliance Management	DPI Victoria was reminded of the need to cultivate the site as required by the licence conditions.

Findings for Dealings Not involving Intentional Release

No findings from monitoring conducted in the quarter.

Findings for Physical Containment Facilities

OGTR's monitoring of certified physical containment (PC) facilities in the quarter found a number of acts or omissions which the Regulator regarded as minor non-compliances with certification conditions which are summarised in the table below. All were found to pose negligible risks to human health and safety and the environment.

	Non-Compliance Issue					
Number of PC Facilities inspected	Structure	PPE*	Equipment	Waste disposal	Work practices	Transport
56	29	6	0	1	0	10

* *PPE = Personal Protective Equipment*

Practice Reviews

The OGTR may initiate Practice Reviews in response to observations made during monitoring activities, or to follow up incident reports that may relate to non-compliance with licence conditions by accredited organisations. Their objective is to determine if licence conditions can be, and are being, effectively implemented.

An accredited organisation may request a Practice Review to assess the effectiveness of systems used by its IBC(s) to ensure that dealings are being conducted in accordance with the Act.

The primary focus of the review process is to determine whether practices being used pose potential human health or environmental risks that require management actions to be implemented. In certain instances, where a suspected non-compliance with the Act is identified, the issue may be referred for investigation.

There were no practice reviews completed in the October to December 2006 quarter.

Audits

Audits can be initiated by the OGTR or an accredited organisation, an audit can entail:

- documentary evidence;
- 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 procedures 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.

There were no audits completed in the October to December 2006 quarter.

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.

There were no investigations completed in the October to December 2006 quarter.

Directions Issued by the Regulator under a Section 146 Notice

In circumstances where the Regulator has reasonable grounds to believe that a licence holder or a person covered by a licence is not complying with the Act or the Regulations, the Regulator may, in order to protect the health and safety of people or to protect the environment, issue directions to a licence holder or a person covered by a licence, to take such steps as are necessary in order to comply with the Act or the Regulations.

A section 146 notice was issued by the Regulator to Imugene Ltd on the basis that she had reasonable belief that Imugene, as a person covered by the licence, was non-compliant with licence conditions for DNIR 068/2002.

The notice directed Imugene Ltd to stop all dealings and to either destroy the GMOs, or to store them, subject to conditions, pending the outcome of a licence application to conduct the dealings as a licence holder in its own right.

Two new DNIR licence applications were subsequently received from Imugene Ltd and are currently being assessed.

An investigation is underway into the circumstances which led the Regulator to reasonably believe a non-compliance had occurred. The outcomes will be reported when the investigation has been finalised. OGTR inspectors are also appropriately monitoring compliance with the section 146 notice.

SECTION 3

STATUTORY COMMITTEE OPERATIONS

STATUTORY COMMITTEE OPERATIONS

The Act establishes three committees to provide advice to the Regulator and the Gene Technology Ministerial Council:

- Gene Technology Technical Advisory Committee;
- Gene Technology Community Consultative Committee; and
- Gene Technology Ethics Committee.

Gene Technology Technical Advisory Committee

As set out in section 101 of the Act, the functions of the Gene Technology Technical Advisory Committee (GTTAC) are to provide scientific and technical advice, on the request of the Regulator or the Ministerial Council, on gene technology, GMOs, GM products, applications made under the Act, the biosafety aspects of gene technology and the need for policy principles, policy guidelines, codes of practice, technical and procedural guidelines in relation to GMOs and GM products and the content of such principles and codes.

The GTTAC held its 29th meeting on 7 December 2006 in Canberra. The Committee considered one DIR application, two DIR RARMPS and two DNIR RARMPS. The Committee also received a presentation on the genetic modification of fatty acids in oilseed and cereals to improve the nutritional value and functionality of food oils and starches, and to develop plants as renewable sources of novel, high-value fatty acids for industrial use.

The communiqués for the 28th and 29th meetings of GTTAC are provided in Appendix 2 as Communiqué numbers 18 and 19 respectively. Communiqué 18 also contains information on advice provided in two out of session meetings.

Further information about the work of GTTAC, including its communiqués, is available from the OGTR website www.ogtr.gov.au/committee/gttac

Gene Technology Community Consultative Committee

As set out in section 107 of the Act, the functions of the Gene Technology Community Consultative Committee (GTCCC) are to provide advice on the request of the Regulator or the Ministerial Council, on matters of general concern identified by the Regulator in relation to applications made under this Act, matters of general concern in relation to GMOs and the need for policy principles, policy guidelines, codes of practice, technical and procedural guidelines in relation to GMOs and GM products and the content of such principles and codes.

The GTCCC did not meet during this quarter

Further information about the work of GTCCC , including its communiqués is available from the OGTR website www.ogtr.gov.au/committee/gtccc

Gene Technology Ethics Committee

As set out in section 112 of the Act, the functions of the Gene Technology Ethics Committee (GTEC) are to provide advice on the request of the Regulator or the Ministerial Council, ethical issues relating to gene technology, the need for, and content of codes of practice in relation to ethics in respect of contained dealings with GMOs and the need for and content of policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons.

The GTEC held a face-to-face meeting in Canberra on 15 November 2006. The meeting was held in conjunction with the OGTR's 2nd National Institutional Biosafety Committee Forum, at which the *National Framework for the Development of Ethical Principles in Gene Technology* was officially launched by the then Parliamentary Secretary to the Minister for Health and Ageing, the Hon Christopher Pyne MP.

The communiqué regarding the November GTEC meeting is provided in Appendix 3.

Further information about the work of GTEC, including its communiqués, is available from the OGTR website www.ogtr.gov.au/committee/gtec

SECTION 4

OTHER ACTIVITIES

OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

Reviews

Review of the *Guidelines for the Certification of Facilities/Physical Containment Requirements* — during this quarter the OGTR continued work on revising the certification guidelines for the following facility types: Physical Containment (PC)1 Laboratory; PC1 Animal (new guideline); PC1 Plant; PC1 Large Grazing Animal; PC2 Laboratory; PC2 Animal; and PC2 Plant.

Work also commenced on drafting revisions to the certification guidelines for PC4 facilities. This included a meeting of stakeholders with expertise in higher level containment, held in conjunction with the 2nd National Institutional Biosafety Committee Forum in Canberra in November 2006.

Review of the *Guidelines for the Guidelines for the Transport of GMOs* — during this quarter the OGTR continued work on drafting revisions to the transport guidelines.

International collaboration and coordination

Under the Act the Regulator's functions include:

- monitoring international practice in relation to regulation of GMOs;
- maintaining links with international organisations that regulate GMOs in countries outside Australia; and
- promoting the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies.

International collaboration and coordination activities undertaken during the quarter involved participation in a presentation to:

- Organisation for Economic Cooperation and Development Working Group on the Harmonisation of Regulatory Oversight in Biotechnology — Steering Group for the Parameters for Environmental Risk/Safety Assessment of Transgenic Plants, 7–8 December 2006, Ottawa, Canada.

Advice on Gene Technology Regulation

The Regulator and the OGTR endeavour to participate in events that inform stakeholders, the Australian community and/or users about the regulatory system.

During the quarter the OGTR provided the following presentation:

- Public Health Laboratory Network Meeting, Regulation of Physical Containment Facilities and Development of Facility Guidelines, 26 October 2006, Sydney, New South Wales

Institutional Biosafety Committee training

The 2nd National Institutional Biosafety Committee Forum (IBC Forum) was held in Canberra on 15–16 November 2006 at the National Museum of Australia. A total of 131 delegates representing 91 accredited organisations across all States and Territories attended.

The purpose of the IBC Forum was to facilitate exchange of information between IBCs and the OGTR and to discuss prospective changes to the legislation relating to regulation of GMOs in light of recent reviews of the Act and the Regulations. The two day meeting also provided an opportunity for organisations to discuss their own specific regulatory issues with OGTR staff.

The IBC Forum was officially opened by the then Parliamentary Secretary for Health and Ageing, the Honourable Christopher Pyne MP, who also launched the *National Framework for the Development of Ethical Principles in Gene Technology* that was developed by the Gene Technology Ethics Committee. The program began with a comprehensive 5 year overview of the work of the OGTR by the Regulator and included a number of guest speakers from other Australian government agencies and IBCs, as well as officers from several sections of the OGTR.

Feedback from attendees regarding the IBC Forum was strongly positive. There was unanimous support for the format of the program and topics covered were considered highly useful in assisting IBCs to fulfil their important role in the national regulatory system.

OGTR website usage and statistics

The OGTR's website is a comprehensive and increasingly popular source of information on activities of the office. The table below describes the successful hits on the OGTR web site, the number of visitor sessions and their activity level during the week, as well as most requested information sheets and web site pages during the October to December 2006 quarter.

Month	Hits	Visitors
October	1,321,127	29,580
November	1,291,985	29,588
December	1,220,721	33,273

Day of the week pattern for the quarter	Hits*	Visitors
Sunday	519,798	12,740
Monday	592,605	13,922
Tuesday	561,170	13,641
Wednesday	566,995	13,615
Thursday	563,628	13,477
Friday	568,099	13,314
Saturday	461,538	11,732

** Hits are the number of times the file started to download, or didn't fully download, and visitors are actual downloads.*

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

- Home page;
- What's new;
- Handbook on the Regulation of Gene Technology in Australia;
- GMO Record;
- About the OGTR; and
- Intentional Release and Evaluation Processes.

The most popular downloaded documents were:

- *Risk Analysis Framework;*
- Handbook on the Regulation of Gene Technology in Australia;
- Media releases;
- The Biology and Ecology of Pineapple (*Ananas comosus var. comosus*) in Australia;
- The Biology and Ecology of Wheat (*Triticum aestivum L.*) in Australia; and
- The Biology and Ecology of Clover (*Trifolium repens L.*) in Australia.

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

Internet contacts and 1800 number

OGTR email address and 1800 number

The OGTR's 1800 number and email address are points of contact for members of the public and other interested parties to obtain information about the regulation of GMOs. Assistance with specific questions and additional mechanisms for public feedback are among some of the services provided by the 1800 line and email facilities. The table below describes the activity of these facilities throughout the quarter.

Month	Emails	1800 number
October 2006	179	154
November 2006	125	177
December 2006	170	Not available*

* *Due to maintenance on the PABX system, the number of calls to the 1800 number for December is not available.*

Monitoring and Compliance email inbox

The OGTR maintains an email inbox to provide a central point for accredited organisations to contact the OGTR regarding queries, legislative notifications and self reporting of non-compliances. The email inbox ensures that all communications are answered efficiently whilst monitoring staff are away from the office. The inbox received 30 emails during the October to December quarter.

Statutory Committee email inbox

The Policy and Secretariat Section maintain an email inbox to facilitate efficient communication between committee members and secretariat staff.

The inbox ensures that all communications are answered in a timely manner by secretariat staff. The inbox received 146 emails during the October to December quarter.

Freedom of Information requests

No freedom of information request was received by the OGTR during the reporting period.

APPENDIX 1

APPENDIX 1

Dealings Not involving Intentional Release (DNIR) Licences issued October to December 2006

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 398/2006	9 Nov 2006	Queensland Institute of Medical Research, Queensland	Large scale production of a human/ chimeric IgG4 antibody for clinical trials	The purpose of this dealing is to produce large scale quantities of a chimeric IgG4 antibody via cell culture for clinical use.
DNIR 397/2006	28 Nov 2006	CSL Limited, Victoria	Development of improved attenuated H5 influenza virus for production of killed influenza vaccine	The aim of the proposed dealings is to use reverse genetics to produce an improved, attenuated H5 influenza vaccine strain with increased levels of surface haemagglutinin (HA) through modification of the HA gene.
DNIR 396/2006	21 Nov 2006	The University of Queensland, Queensland	Analysis of invertebrate virus genomes	This dealing aims to analyse the function of various invertebrate viral genomes by mutagenesis and subsequent analysis of virus function *in vitro* and *in vivo.*
DNIR 394/2006	10 Nov 2006	The University of Newcastle, New South Wales	Generation of low-pathogenic enteroviral full length infectious clones	The purpose of this dealing is to generate full-length infectious clones of several low-pathogenic enteroviruses of the picornaviridae for characterisation of the virus genome(s) by *in vitro* studies.

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 392/2006	2 Nov 2006	The University of Western Australia, Western Australia	Plasmids in *Neisseria sp*	The aims of this dealing are to identify and study the expression and function of genes involved in pathogenicity/virulence of *Neisseria meningitidis* and *N. gonorrhoeae*.
DNIR 391/2006	31 Oct 2006	Bioproperties Pty Ltd, New South Wales	Production of Neovac antigens	The aim of this dealing is to produce four types of recombinant pili antigens to be used in the manufacture of a vaccine against neonatal scours in pigs.

APPENDIX 2

Gene Technology Technical Advisory Committee

COMMUNIQUE No. 18

This is the eighteenth communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the twenty-eighth meeting of GTTAC, held on 19 September 2006 and out-of-Session items considered in July and August 2006.

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 Plans (RARMPs) that are prepared for these applications and form the basis of the Regulator's decision whether to issue a licence.

The purpose of this Communiqué 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 Communiqué also provides an overview of any other major issues discussed by GTTAC.

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 certified physical containment facility. DIRs involve the limited and controlled release (field trial) of a GMO or a commercial (general) release of a GMO.

A Risk Assessment and Risk Management Plan (RARMP) is prepared in respect of every licence application for a DIR licence and released for public comment as part of the consultation process for these applications. Information on how to obtain copies of applications and RARMPs for DIRs is provided at the end of this document.

Advice on Applications

GTTAC considered the following applications and provided advice on matters that should be taken into account in preparing the RARMP.

DIR069/2006 — Field trial of GM herbicide tolerant GM hybrid *Brassica napus* and hybrid *Brassica juncea* lines

The OGTR has received an application from BayerCropScience Pty Ltd for the intentional release of GM herbicide tolerant, hybrid *Brassica napus* (canola) and *Brassica juncea* (Indian mustard) lines into the environment on a limited scale and under controlled conditions. The proposed release would take place at up to 42 sites over four years (2007–2010), with a maximum area of less than 300 hectares in New South Wales, Victoria and South Australia.

The aim of the proposed trial is to produce seed and to evaluate agronomic traits such as herbicide tolerance, germination and flowering dates of the GM canola and Indian mustard lines under Australian cropping systems.

The Committee suggested that additional information should be provided on the trial protocols and literature review.

GTTAC indicated that any movement of introduced genetic material was only likely to occur at very low levels and that herbicide tolerance was unlikely to increase the weediness of either the GM canola or Indian mustard.

DIR 067/2006 — Limited and Controlled Release of GM cotton lines with tolerance to waterlogging stress

GTTAC was asked to provide out-of-session advice in August 2006 on an application from CSIRO seeking approval for a limited and controlled release of up to 30 cotton lines that have been genetically modified to provide tolerance to waterlogging stress. The release is proposed to take place at one site in the shire of Narrabri, NSW on a maximum total area of 0.1 ha during each of the three summer growing seasons between September 2006 and May 2009.

The purpose of the release is early stage research to measure the levels of expression of the waterlogging tolerance gene and to assess the effectiveness of the protein it produces under simulated waterlogged conditions. In addition, the agronomic performance of the GM cotton lines will be compared to that of non-GM cotton and some seed will be collected for testing or possible future trials (subject to additional applications and assessments).

GTTAC advised that the Regulator should consider toxicity, allergenicity, increased weediness and proposed containment measures.

DIR 068/2006 — Limited and controlled release of GM *torenia* with altered flower colour

GTTAC was asked to provide out-of-session advice in August 2006 on an application from Florigene Pty Ltd seeking approval for a limited and controlled release of nine torenia lines that have been genetically modified to produce a range of flower colours. A field trial with up to 200 plants is proposed at one site of approximately 100m^2 during the summer of 2007/08. The GM plants will be grown in hanging baskets suspended above a concrete or gravel surface.

The purpose of the release is to evaluate the performance of the GM torenia lines by measuring the expression of the introduced genes, horticultural characteristics such as plant size, number and longevity of flowers, flower colour stability and susceptibility to pests and diseases.

GTTAC advised that the Regulator should consider toxicity, allergenicity, increased weediness and proposed containment measures.

DIR 070/2006 — Limited and controlled release of GM sugarcane for altered shoot architecture, drought tolerance and nitrogen efficiency

GTTAC was asked to provide out-of-session advice in August 2006 on an application from Bureau of Sugar Experiment Stations Limited seeking approval for a limited and controlled release of twenty two sugarcane lines. The GM sugar cane lines have been genetically modified to produce altered shoot architecture, increased drought tolerance and increased nitrogen use efficiency. A field trial with up to 2500 lines derived from 22 gene constructs is proposed at three sites of approximately 2 hectares each from March 2007 to November 2010.

The purpose of the release is to evaluate the performance of the GM sugarcane lines by measuring the horticultural characteristics including sugar yields, plant size, number and length of tillers, drought tolerance, and nitrogen use efficiency.

GTTAC advised that the Regulator should consider toxicity, allergenicity, increased weediness and proposed containment measures.

Advice on RARMPs

GTTAC considered the consultation RARMPs prepared by the OGTR in response to the following applications:

Advice on GM Cotton

DIR 064/2006 — Limited and controlled release of GM water-efficient cotton

GTTAC considered the RARMP for licence application DIR064/2006 received from Monsanto Australia Ltd to carry out a small scale field trial of GM cotton lines on up to 10 sites per season in New South Wales and/or Queensland covering an area of up to 20 hectares each season for two summer growing seasons in 2006/07 and 2007/08. Each site would be no more than 2 hectares in size.

The purpose of the proposed trial is to conduct 'proof of concept' research to assess the agronomic characteristics of the GM cotton lines in the field including water use efficiency, yield and fibre quality under different irrigation treatments. Seed would be collected for further studies and possible future releases of lines selected for further development (subject to additional applications and approvals).

Each GM cotton line contains 1 of 24 introduced genes encoding proteins believed to enhance the water use efficiency of cotton. Twenty-three of the genes are derived from the plants *Arabidopsis thaliana* (thale cress), *Zea mays* (maize), *Glycine max* (soybean), *Oryza sativa* (rice) and *Gossypium hirsutum L.* (cotton). One gene is derived from the bacterium *Escherichia coli.*

There have been no previous releases of these GM cotton lines in Australia.

In addition to providing comments on the adequacy of the hazard identification, risk assessment and licence conditions, GTTAC was asked to consider any risks which may or may not arise from potential asynchronous or altered flowering patterns arising from the genetic modification.

GTTAC advised that information on possible altered flowering patterns might be collected during that trial. GTTAC also suggested that information be sought on the proximity of the proposed trial site to commercial seed production sites.

GTTAC agreed with the risk assessment and that the proposed licence conditions were adequate to contain the release to the locations, size and duration of the trial.

DIR 065/2006 — Limited and controlled release of GM insect resistant (VIP3A and/or Cry1Ab) cotton

GTTAC considered the RARMP for licence application DIR065/2006 from Deltapine Australia Pty Ltd seeking approval to conduct a small scale field trial of up to 11 lines of insect resistant cotton at one site of 1.5 hectares in the shire of Narrabri in NSW, over one season (summer 2006/07). The purpose of the trial is to conduct early stage research to produce seed from the GM cotton lines for use in further studies in future trials (subject to further applications and approvals). The applicant also proposed selling lint from the release.

The Committee considered the proximity of bee hives to trial sites and accepted that isolation zones were similar to those applied in previous licences.

GTTAC advised the Regulator that the Committee agreed with the risk assessment and that the proposed licence conditions are adequate to contain the release to the proposed location, size and duration requested by the applicant.

DIR 066/2006 — Commercial release of GM herbicide tolerant and/or insect resistant cotton lines north of latitude 22° South

GTTAC considered a RARMP for licence application DIR066/2006 from Monsanto Australia Ltd seeking approval to release GM cotton, without specific containment measures, north of latitude 22° South.

The five types of GM cottons have all been previously approved for commercial release in southern Australia. They comprise:

- insect resistant Bollgard II® cotton (also known as MON15985);

- herbicide tolerant Roundup Ready® cotton (also known as MON1445);
- herbicide tolerant Roundup Ready Flex® cotton (also known as MON88913);
- herbicide tolerant/insect resistant Roundup Ready®/Bollgard II® cotton (also known as MON1445/MON15985); and
- herbicide tolerant/insect resistant Roundup Ready Flex®/Bollgard II® cotton (also known as MON88913/MON15985).

The committee indicated its agreement with the conclusion of the RARMP. GTTAC noted its satisfaction with research data which enabled the risk of increased weediness in northern Australia as a result of insect resistance to be assessed as negligible,

DIR 067/2006 — Limited and controlled release of waterlogging tolerant GM cotton

GTTAC considered a RARMP for licence application DIR067/2006 from CSIRO Plant Industry to conduct a small scale field trial of up to 30 lines of waterlogging tolerant GM cotton on a 0.1 ha at one site in the shire of Narrabri, NSW, during three summer growing seasons (2006/07, 2007/08, 2008/09). The purpose of the proposed release is to conduct 'proof of concept' research to measure the expression levels of the *AHb1* gene; to evaluate the tolerance of the GM cotton plants to waterlogging stress under simulated conditions; and to assess their agronomic performance in the field.

Cotton seed will also be collected for further studies and possible future releases (subject to additional applications and approvals). No products from the release would be used for human food, animal feed or for the production of fabrics and/or other cotton products.

The Committee discussed the RARMP and members agreed that the risk assessment identifies all risks associated with the release. The Committee also believed that the proposed licence conditions, which are based on previous licences, for the release of this GM cotton are adequate to contain the release to the location, size and duration of the trial.

DIR 062/2005 — Commercial Release of Herbicide Tolerant Liberty Link® Cotton for use in the Australian Cropping System

Advice was sought from GTTAC out-of-session in July 2006 on a RARMP for licence application DIR062/2005 from Bayer CropScience seeking approval to commercially release herbicide tolerant Liberty Link® Cotton without specific containment measures. The applicant indicated that, if approval was received, growing of GM cotton would occur initially in the existing cotton growing regions of New South Wales and Queensland, followed by uptake in other areas where environmental conditions are suitable for cotton cultivation.

Bayer does not propose to use any containment measures and intends that the GM cotton plants and their products would be used in the same manner as conventional and other commercially approved GM cottons. The dealings would include use of oil and linters in human food,

conventional breeding with non-GM cotton varieties. The sale of seed and lint and exporting seed and could involve transportation and use of cotton seed as stockfeed anywhere in Australia.

GTTAC indicated agreement with the conclusions of the RARMP ie that the proposed commercial release of Liberty Link® Cotton poses negligible risks to the health and safety of people and the environment as a result of gene technology and that specific risk treatments measures are not required.

DIR 063/2005 — GM Cotton Field Trial — Assessment of transgenic cotton (*Gossypium Hirsutum*) expressing natural plant genes for fungal control

Advice was sought from GTTAC out-of-session in July 2006 on a RARMP for licence application DIR063/2005 from Hexima Limited seeking approval to carry out a small scale field of one GM cotton line on two sites in the Pittsworth Shire (Queensland), and one site in the Narrabri or Moree Plains Shires (New South Wales), covering an area of up to 1.0 hectare each season during each of three growing seasons between 2006 and 2009.

The GM cotton line contains a fungal resistance gene *(nad1)* encoding a plant defensin protein which is expected to enhance resistance against major fungal diseases of cotton, including Fusarium wilt, black root rot and Verticillium wilt.

The aim of the proposed trial is to evaluate the GM cotton line's resistance to fungal diseases as compared to non-GM cotton; to assess its agronomic performance under field conditions; to measure the expression levels of the defensin protein and to test for adverse impacts on selected beneficial soil micro-organisms (mycorrhiza). Seed would also be collected for further studies and possible future releases (subject to additional assessments and approvals).

GTTAC advised the Regulator that the Committee agreed with the risk assessment and that the proposed licence conditions were sufficient to contain the release to the locations, size and duration proposed by the applicant.

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.

DNIR 396/2006 — Clinical Trial of ChimeriVax™-DEN

Advice was sought from GTTAC out-of-session in July 2006 on an application from Institute of Drug Technology Australia Limited to conduct a Phase IIa clinical trial (CYD10) of ChimeriVax™-DEN, a tetravalent, live, attenuated, chimeric, genetically modified vaccine against Dengue virus (DV).

The protocol proposed in the dealing has been approved under the Therapeutic Goods Administration clinical trial exemption (CTX) scheme. The National Health and Medical Research Council's Gene and Related Therapies Research Advisory Panel (GTRAP) provided advice on the risks to the volunteers receiving the vaccine.

GTTAC considered the application for DNIR386/2006 and advised the Regulator that the RARMP identified and managed all risks to people and the environment associated with the Phase II clinical trial.

Presentations

The following presentations were made to GTTAC:

- legal issues relating to the release of information held by the OGTR;
- update on the review of the Gene Technology Regulations 2001; and
- an update on the revision of Certified Contained Facilities Guidelines.

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.

Gene Technology Technical Advisory Committee

COMMUNIQUE No. 19

This is the nineteenth communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the twenty-ninth meeting of GTTAC, held on 7 December 2006.

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 Plans (RARMPs) that are prepared for these applications and form the basis of the Regulator's decision whether to issue a licence.

The purpose of this Communiqué 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 Communiqué also provides an overview of any other major issues discussed by GTTAC.

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 certified physical containment facility. DIRs may involve the limited and controlled release (field trial) of a GMO or a commercial (general) release of a GMO.

A Risk Assessment and Risk Management Plan (RARMP) is prepared in respect of every licence application for a DIR licence and 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

DIR071/2006 — Limited and controlled release of drought tolerant wheat

The OGTR has received an application from Department of Primary Industries (DPI) Victoria to release up to 30 lines of GM bread wheat (*Triticum aestivum L.*) lines into the environment on a limited scale and under controlled conditions.

The proposed release would take place at 2 sites over an area of 1500m^2 in the Shire of Horsham and an area of 750m^2 in the Shire of Mildura, over one season (May 2007–March 2008).

The aim of the trial is to evaluate the agronomic performance, including yield analysis of the GM wheat lines under rain-fed, drought prone conditions. Seed will also be collected and retained for seed increase or further experimentation (subject to additional approval).

The Committee was informed that all containment measures proposed by the applicant would be assessed in the course of the evaluation and consistent measures would be applied commensurate with the assessed level of risk.

The Committee noted that it would comment further on the proposed conditions when the RARMP was provided to the Committee in 2007.

Advice on RARMPs

GTTAC considered the consultation RARMPs prepared by the OGTR in response to the following applications:

DIR 068/2006 — Limited and controlled release of genetically modified torenia with altered flower colour

GTTAC considered the RARMP for licence application DIR068/2006 received from Florigene Pty Ltd to carry out a trial of nine genetically modified (GM) torenia lines (*Torenia X hybrida)* with altered flower colour at a single site in Darebin, Victoria, from October 2007 to May 2008 under limited and controlled conditions.

The proposed field trial would involve growing up to 200 GM plants individually in hanging baskets suspended over gravel or concrete in an area not exceeding 100m^2. The aim of the proposed field trial was to assess outdoor performance. Horticultural characteristics such as plant size, number and longevity of flowers, flower colour stability and susceptibility to pests and diseases would be evaluated compared to the non-GM parent plant.

The Committee noted that there was potential for rooting if the plant was grown in moist soil with stems attached. However if the stem was broken off, propagation would require manual intervention and the correct environment to persist. Members noted that the applicant had provided information to indicate that detached stem pieces or cuttings cannot survive under natural conditions.

The Committee considered the possibility of dissemination of plant segments by birds that might give rise to vegetative reproduction of the GMO. The Committee concluded that this posed a negligible risk as torenia is a summer annual plant and will not survive the cold winter temperatures of Victoria.

GTTAC suggested that further information on the current distribution of non-GM varieties of torenia might be obtained.

GTTAC advised the Regulator that the Committee agreed with the risk assessment and that the proposed licence conditions are adequate to contain the release to the location, size and duration of the trial requested by the applicant.

DIR 070/2006 — Limited and controlled release of GM sugarcane with altered plant architecture, enhanced water or nitrogen use efficiency.

GTTAC considered the RARMP for licence application DIR070/2006 received from the BSES Ltd seeking approval for the limited and controlled release of up to 2500 GM sugarcane lines in to the environment under limited and controlled conditions. The sugar cane lines have been modified to alter shoot architecture (shoot number, stalk size and height), and enhance water or nitrogen use efficiency. The trial is proposed to take place at up to three sites per cropping cycle from March 2007 to November 2010 in the local government areas of Bundaberg, Caboolture and/or Cairns, Queensland.

Members advised that the cross pollination of non GM sugar cane was unlikely as sugar cane had very low fertilisation and the gene flow, if any, would pose negligible risk.

Members noted that this trial was an early stage project and further allergenicity data would be required if any commercial release was applied for in the future.

GTTAC advised the Regulator that the committee agreed with the risk assessment and that the proposed licence conditions are appropriate to contain the release to the location, size and duration of the trial requested by the applicant.

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.

DNIR 402/2006 — Single armed, multi-centre, open label clinical study evaluating the safety and tolerability of NovaCaps® in patients with inoperable pancreatic carcinoma

An application has been submitted to the OGTR to conduct a Phase I clinical study into the safety and tolerability of an encapsulated cell therapy product (NovaCaps®) in patients with inoperable pancreatic carcinoma who are receiving the chemotherapeutic drug ifosfamide.

The National Health and Medical Research Council's Gene and Related Therapies Research Advisory Panel (GTRAP) provided advice on the protocol proposed in the dealing.

GTTAC considered that the risk to patients would be low. Also due to the nature of the GMO, no significant risks were identified to medical staff undertaking the dealing or to any other people or the environment in the event of an unintentional release is negligible.

GTTAC advised the Regulator that the RARMP adequately identified and managed the risks associated with the proposed clinical trial.

DNIR 401/2006 — Transmissible Genetic Elements in Bacteria

The OGTR has received an application seeking to further characterise transmissible genetic elements responsible for antibiotic resistance in medically significant bacterial isolates.

The aim of the proposed dealing is to characterise antibiotic resistance-associated genetic loci such as resistance genes and mobile genetic elements in bacteria.

The Committee advised the Regulator that PC2 containment and work practices were adequate for the stacking of multiple resistance genes into risk group 2 human eubacterial pathogens.

Presentations

The following presentations were made to GTTAC:

- Feedback from the 2nd National Institutional Biosafety Committee Forum held in Canberra on 15 and 16 November, 2006.

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

APPENDIX 3

Gene Technology Ethics Committee Meeting

15 November 2006, Canberra

COMMUNIQUE

The Gene Technology Ethics Committee (GTEC) held its thirteenth meeting in Canberra on 15 November 2006.

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 communiqué includes 'expert advisers').

The 15 November 2006 GTEC meeting was a half-day meeting held following the official public launch of the National Framework for the Development of Ethical Principles in Gene Technology (the Framework). The launch was held in conjunction with the Office of the Gene Technology Regulator's 2nd National Institutional Biosafety Committee Forum.

At the meeting, the main items discussed were the launch of the Framework and developments with the Committee's draft discussion paper on 'Environmental Ethics and Gene Technology'. Members received a report from the Chair regarding relevant conferences he has attended since the last GTEC meeting, and from the Regulator regarding the ongoing and completed work of the Office. Members were informed of relevant work from other national committees via cross-member reports.

Key outcomes from the thirteenth meeting are reported below.

GTEC's Work Plan

National Framework for the Development of Ethical Principles in Gene Technology

Members discussed the outcomes of the Framework launch and ideas for further promoting the document. The Committee thanked the Working Group and all the people who contributed to the development of the Framework. The Committee also thanked the Parliamentary Secretary to the Minister for Health and Ageing, the Hon Christopher Pyne MP, for launching the document.

Environmental Ethics and Gene Technology

The Committee held an extensive and detailed discussion about the latest draft of the discussion paper 'Environmental Ethics and Gene Technology'. The Working Group outlined the major changes which have been made to the paper since GTEC's last meeting in July 2006. GTEC considered the major themes of the paper and the ways in which they may be

expanded further.

The Committee identified a number of editorial and structural changes, to be completed before the first meeting in 2007.

GTEC and Relationships with Other Committees

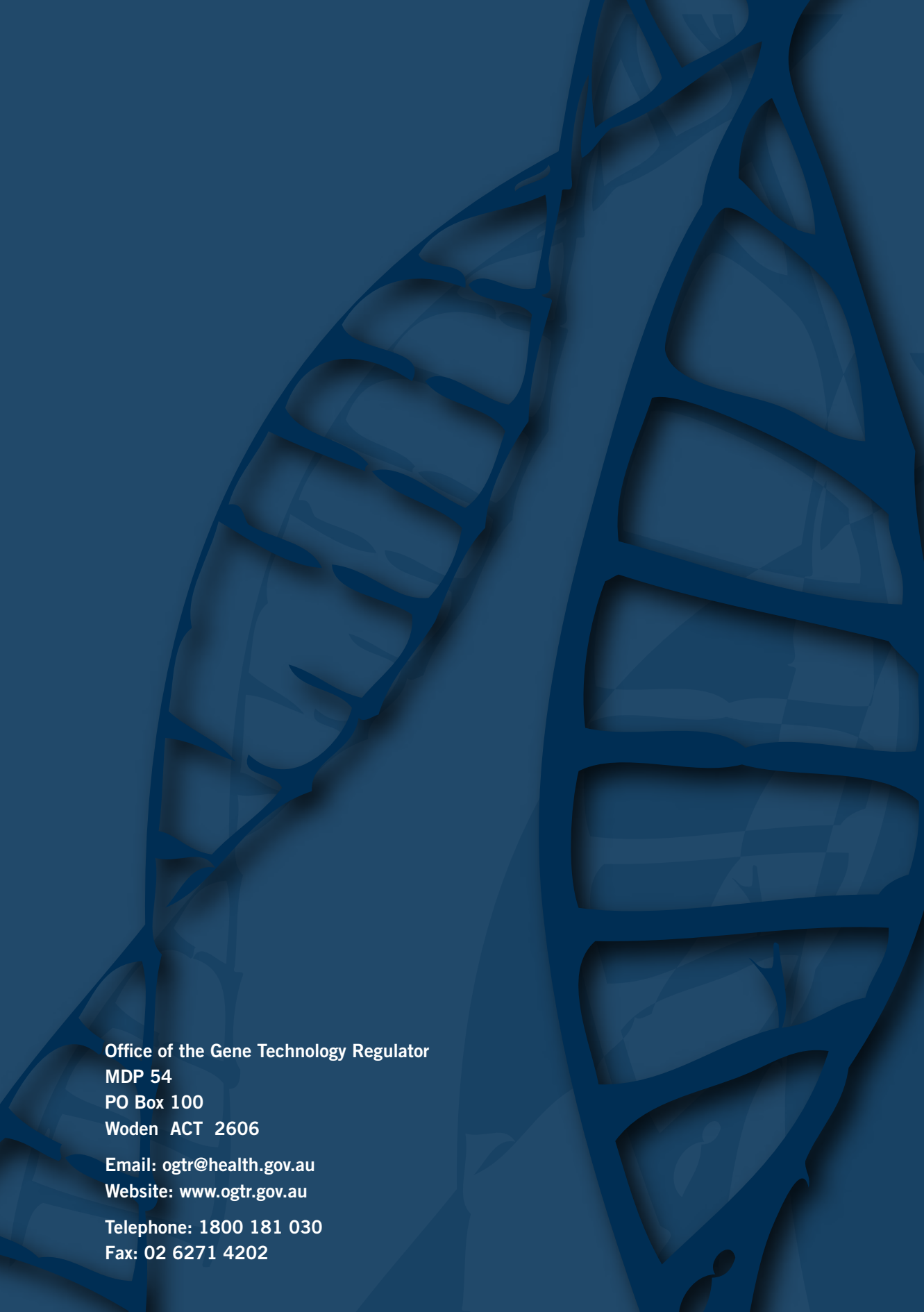
The Committee received reports from the Chair, the Gene Technology Regulator, the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Community Consultative Committee (GTCCC).

GTEC considered the final draft of the Animal Welfare Committee (AWC) Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes. The Committee resolved to make comments on the document and forward these to the AWC.

Next meeting

The next GTEC meeting will be held in March 2007.

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



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