OPERATIONS OF THE GENE TECHNOLOGY REGULATOR
QUARTERLY REPORT
1 January to 31 March 2007

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 Number P3 -1683

Senator the Hon Brett Mason
Parliamentary Secretary to the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

Dear Parliamentary Secretary

In accordance with section 136A of the *Gene Technology Act 2000* (the Act), I am pleased to present to you the Quarterly Report of the Operations of the Gene Technology Regulator, covering the period 1 January to 31 March 2007.

During this quarter, key achievements included the issuing of two licences for dealings involving the intentional release of genetically modified organisms (GMOs), three licences for dealings not involving intentional release of GMOs, and the certification of 22 physical containment facilities.

In addition, the first entry was made on the GMO Register.

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

New and revised guidelines relating to the certification of physical containment facilities for the low risk and exempt dealings were issued as part of an ongoing review of the guidelines, and pursuant to the Gene Technology Amendment Regulations 2007 coming into effect on 31 March 2007.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator

May 2007

TABLE OF CONTENTS (PAGE NUMBERS TO BE ADDED AT THE GRAPHIC DESIGNER STAGE)

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 time does not run for purposes of the statutory time limit for making a decision – 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.

Its 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 1 January to 31 March 2007 quarter.

Regulation of genetically modified organisms

Provides details on 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.

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.

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 January to 31 March 2007 quarter were:

Licences and other instruments

- 2 licences issued for dealings involving the intentional release of GMOs into the environment (DIR licences);
- 3 licences issued for dealings not involving intentional release of GMOs into the environment (DNIR licences);
- 89 Notifiable Low Risk Dealing (NLRD) notifications received;
- 22 containment facilities certified;
- 81 surrenders of certifications processed; and
- 210 variations processed.

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

Monitoring and Compliance

Approximately 36 percent of current field trial sites and 12 percent of post harvest field trial sites were subjected to routine monitoring during the quarter. This exceeds the target minimum rate of five 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:

- 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; 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 Water Resources;
- 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 two applications for DIR licences and one RARMP.

Further information is contained in Section 2 of this report.

Public participation

During the quarter, the Regulator issued one invitation to the public to comment on the RARMP prepared in response to an application. The invitation was issued via email or post to people who have registered on the OGTR mailing list and via advertisements in:

- The Australian Government Gazette;
- The Australian;
- The Age;
- The Advertiser;
- The Sydney Morning Herald;
- relevant regional or rural press including; *The Land*, *The Weekly Times* and the *Stock Journal;* and
- OGTR website www.ogtr.gov.au

Further information is contained in Section 2 of this report.

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of the report outlines the regulatory activity undertaken during the 1 January to 31 March 2007 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 January to 31 March 2007

Application type	Number received	Number approved*
DIR licence	3	2
DNIR licence	6	3
Accreditations	1	0
Certifications	27	22
GMO Register	0	1

** 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 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 Risk Assessment and Risk Management Plan (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 DIR licences subject to evaluation during the

1 January to 31 March 2007 quarter

Application received	First round of consultation*	Second round of consultation	Withdrawn applications	Licence Issued
DIR 072/2006	DIR 071/2006	DIR 069/2006	DIR 061/2006	DIR 069/2006
DIR 073/2007	DIR 073/2007			DIR 070/2006
DIR 074/2006				

** 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 three applications for DIR licences in the 1 January to 31 March 2007 quarter:

- DIR 072/2006 - Commercial release of GloFish™ expressing red, green and yellow fluorescent proteins into the Australian ornamental fish industry - Yorktown Technologies LP;

- DIR 073/2007 - Limited and controlled release of GM insect resistant and insect resistant/herbicide tolerant cotton - Deltapine Australia Pty Ltd; and

- DIR 074/2007 - Unrestricted release covering Bollgard II® (MON 15985) and Roundup Ready Flex® (MON 88913) in Extra Long Staple Cotton (*Gossypium barbadense*) in Australia - Monsanto Australia Limited

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

- DIR 073/2007 - Limited and controlled release of GM insect resistant and insect resistant/herbicide tolerant cotton - Deltapine Australia Pty Ltd.

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 a RARMP for the following application:

- DIR 069/2006 – Limited and controlled release of GM herbicide tolerant hybrid *Brassica napus and Brassica juncea* – Bayer CropScience Pty Ltd

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

One DIR licence application was withdrawn for the 1 January to 31 March 2007 quarter:

- DIR 061/2006 - Field testing of genetically modified salt tolerant wheat on saline land - Grain Biotech Australia Pty Ltd.

Surrendered applications for Dealings involving Intentional Release licences

Five DIR licences were surrendered during the 1 January to 31 March quarter:

- DIR 019/2002 - Agronomic assessment of transgenic sugarcane engineered with reporter genes - BSES Limited;
- DIR 040/2003 - Agronomic assessment and seed increase of transgenic cotton expressing insect tolerance genes from *Bacillus thuringiensis* - Dow AgroSciences Australia Pty Ltd;
- DIR 053/2004 - Field trial of genetically modified salt tolerant wheat on saline land - Grain Biotech Australia Pty Ltd;
- DIR 055/2004 - Field trial of herbicide tolerant (Roundup Ready® Flex MON 88913) and herbicide tolerant/insect resistant (Roundup Ready® Flex MON 88913/Bollgard II®) cottons - Monsanto Australia Limited; and
- DIR 058/2005 - Limited and controlled release of insect resistant (VIP) GM cotton - Deltapine Australia Pty Ltd.

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.

No requests for further information were initiated in this quarter.

Decisions on applications for Dealings involving Intentional Release licences

During the quarter, the Regulator issued two DIR licences:

- DIR 069/2006 - Limited and controlled release of GM herbicide tolerant hybrid *Brassica napus* and *Brassica juncea* - Bayer CropScience 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.

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 three DNIR licences. Further information about these licences is contained in Appendix 1 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 IBC and do not require approval by the Regulator. The OGTR checks notifications for compliance with legislative requirements.

The Regulator received 89 NLRD notifications in the quarter. A listing of NLRDs and their date of notification is available from the OGTR website.

Dealings placed on the GMO Register

Sections 78 and 79 of the *Gene Technology Act 2000* provides for the Regulator to place GMOs which have been previously licensed, pose minimal risks to people or the environment, and are safe to be used by anyone without the need for a licence on the GMO Register.

The Regulator has made a determination, in response to an application from Florigene Pty Ltd, to include dealings with four genetically modified (GM) carnation lines on the GMO Register. As a result of the genetic modification, the lines (Moonlite™, Moonshade™, Moonshadow™ and Moonvista™) produce violet/mauve/purple flowers.

The GM carnation lines have over 10 years of history of safe use starting with field trials under limited and controlled conditions dating back to 1992 and since their commercial release in 1995 (refer Licence No: DIR 030/2002). Prior to making the determination, the Regulator obtained additional data from the company, reviewed the latest scientific literature, and sought advice from the public, the Gene Technology Technical Advisory Committee, relevant Australian Government agencies, and State and Territory Governments on any risks to human health and safety or the environment that may be posed by the dealings. No risks to human health and safety or the environment were identified during this process

The determination is a disallowable Legislative Instrument and therefore must be registered on the Federal Register of Legislative Instruments (FRLI) and tabled in Parliament. The determination was registered on FRLI on the 28 November 2006 and tabled in the House of Representatives on the 29 November and the Senate on the 30 November 2006.

The 15 sitting day disallowance period elapsed in both houses without a notice of motion for disallowance and the determination came into effect on the 27 March 2007. This is the first entry on the GMO Register

Further information is available on the OGTR website:
www.ogtr.gov.au/reg//reg001.htm

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 1 January to 31 March 2007 quarter.

Applications received and decisions made: existing licences and other instruments 1 January to 31 March 2007.

Type	Number received	Number processed*
Surrender of certification	45	81
Surrender of DIR licence	5	5
Surrender of DNIR licence	4	3
Surrender of accreditation	2	0
Variation of certification	173	193
Variation of accreditation	4	3
Variation of DIR licence	6	3
Variation of DNIR licence	15	11

** 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 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 did not receive any new CCI applications and made three CCI declarations in relation to existing DIR applications.

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; and
- effective management of the GMO is maintained.

OGTR monitoring activities comprise the functions of routine monitoring including spot checks, assessment of monitoring findings and, where necessary, recommending corrective action and follow-up activities.

OGTR compliance activities comprise reviews of potential compliance risks, investigations, audits and related enforcement activities.

The Monitoring Section conducts routine monitoring visits of a minimum of 20 percent of field trial sites each year. To achieve this goal a minimum of five percent of current trial sites and five percent of trial sites subject to post-harvest monitoring are monitored each quarter.

Monitoring and Compliance Strategy

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 contained dealings involves inspecting Dealings Not involving Intentional Release (DNIRs) and the facilities that those dealings are conducted in, as well as monitoring a minimum of 20 percent of physical containment (PC) PC4, PC3 and PC2 large-scale facilities per year.

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 1 January to 31 March 2007 quarter, 13 field trial sites with GM plants were subjected to monitoring visits.

- *Current field trial sites:* Of the 22 current in the quarter, eight were monitored. This represents a monitoring rate of 36 percent of all current sites for the quarter.
- *Post-harvest field trial sites:* Of the 42 sites subject to post-harvest monitoring in the quarter, five were monitored. This represents a monitoring rate of 12 percent of all sites subject to post-harvest monitoring in this quarter.

Other limited and controlled releases monitored: The one trial current in the quarter was monitored.

Monitoring of certified facilities: Monitoring in connection to contained dealings covered eight organisations and 15 PC facilities. Monitoring of PC facilities encompassed PC3 laboratories (4 visited), PC2 laboratories (11 visited), and PC2 animal containment facilities (4 visited).

Monitoring of contained dealings: During the January to March 2007 quarter, the monitoring of the 15 PC facilities mentioned above also included monitoring for compliance with the general practices that must be followed when undertaking dealings (eg DNIRs) that are required to be conducted within contained facilities.

Eight DNIRs were monitored during the 1 January to 31 March 2007 quarter.

Monitoring of Dealings involving Intentional Releases

The following table summarises monitoring activities for field trials with GM crop plants for the period between 1 January and 31 March 2007.

Licensed Organisation Name	Licence Number	No. sites visited	Site status *	Crop type
Bayer CropScience	DIR 056/2004	1	C	Cotton
	DIR 057/2004	1	C	Indian mustard
CSIRO	DIR 031/2002	1	C	Grapevine
	DIR 067/2006	1	PHM	Cotton
Dow AgroSciences	DIR 044/2003	3	PHM	Cotton
University of Queensland	DIR 026/2002	1	C	Papaya
Hexima Ltd	DIR 048/2003	2	C	Cotton
	DIR 063/2005	2	C	Cotton
Grain Biotech Australia	DIR 053/2004	1	PHM	Wheat
Totals	9 DIR licences	13	C= 8 PHM= 5	5 types

* C = current PHM = post-harvest monitoring

In addition to the field trials with GM plants monitored during the Quarter, DIR050/2004 a current bovine herpes virus vaccine trial being conducted by the Department of Primary Industries and Fisheries (Queensland) was monitored and found to be compliant with licence requirements.

Monitoring of Dealings Not involving Intentional Release

The following table summarises monitoring activities for DNIRs for the period between 1 January and 31 March 2007.

Licensed Organisation Name	Licence Number
Johnson and Johnson Research	DNIR 189/2003
University of Technology Sydney	DNIR 252/2003

Centenary Institute of Cancer Medicine and Cell Biology	DNIR 219/2003
St Vincent's Hospital Melbourne	DNIR 083/2002
Sydney West Area Health Service	DNIR 052/2002
Monash University	DNIR 106/2002
	DNIR 251/2003
	DNIR 287/2004
Total	8 DNIR licences

Monitoring of Physical Containment Facilities

The organisations and the facility types the OGTR visited during the 1 January to 31 March quarter are detailed in the following table.

Organisation	**Physical Containment (PC) facility**	**No. facilities visited**
Centenary Institute of Cancer Medicine and Cell Biology	PC2 Laboratory	2
	PC2 Animal Containment	1
University of Queensland	PC3 Laboratory	4
Johnson and Johnson Research	PC2 Laboratory	1
Sydney West Area Health Service	PC2 Laboratory	1
	PC2 Animal Containment	1
University of Technology Sydney	PC2 Laboratory	1
	PC2 Animal Containment	1
Australian Army Malaria Institute	PC2 Laboratory	1
	PC2 Animal Containment	1
Griffith University	PC2 Laboratory	2
Monash University	PC2 Laboratory	2
St Vincent's Hospital Melbourne	PC2 Laboratory	1
Totals	2 facility types	15

Monitoring Findings

Dealings involving Intentional Release

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	Grain Biotech Australia Pty Ltd (Grain Biotech)
Licence number and site	DIR053/2004 Site 1
Summary of dealing	The licence relates to the limited and controlled release of genetically modified salt tolerant wheat (*Triticum aestivum* L.) on saline land.
Findings	A post harvest monitoring inspection was not carried out by Grain Biotech during January 2007. The DIR 053/2004 licence requires inspection for volunteers and related species every 30 days during the post harvest monitoring period. Grain Biotech Australia resumed inspections in February 2007 and continued their inspection obligations under this licence. OGTR inspectors observed that there were no volunteers or related species present during inspection of the site in March 2007.
Assessment	Grain Biotech acknowledged the omission in their monitoring routine. The company's overall monitoring and compliance history is good. No volunteers have been observed at this site since February 2006 and no related species have been observed since October 2006. The risks to human health and safety and the environment as a result of this non-compliance were assessed to be negligible.
Compliance management	Grain Biotech was reminded of the need to comply with all licence conditions.

Organisation	University of Queensland
Licence number	DIR026/2002 Site 1
Summary of dealing	The licence relates to the limited and controlled release of genetically modified papaya (*Carica papaya L.*)
Findings	OGTR inspectors noted a small hole in the roof of the insect proof cage. As per the licence conditions, any damage to the cage must be repaired immediately.
Assessment	University of Queensland acknowledged the existence of the hole and agreed to undertake all required repairs immediately. The organisation's compliance history is good and the risks to human health and safety and the environment as a result of this non-compliance were assessed to be negligible.
Compliance management	University of Queensland was reminded of the need to inspect the insect proof cage thoroughly and to repair

	any damage immediately.

Organisation	Dow AgroSciences Australia Pty Ltd (Dow AgroSciences)
Licence number and site	DIR 044/2003, Site 22
Summary of dealing	The licence relates to the limited and controlled release of cotton (*Gossypium hirsutum*) genetically modified by introduction of genes to confer tolerance to herbicide and/or resistance to pests.
Findings	On 29 March 2007 OGTR inspectors observed four mature cotton volunteers growing on the site. The site was in PHM and had been planted with pigeon peas. The volunteer plants varied in height from approximately 60-90cm and all had open bolls. The cotton volunteers were destroyed by Dow AgroSciences at the time of the inspection.
Assessment	The row spacing of the pigeon pea crop growing on the site made it difficult to identify volunteers. The crop is due to be destroyed prior to the next post harvest inspection in end May 2007 and this will facilitate the identification of cotton volunteers during post harvest inspection as the volunteers will not be obscured by the crop. It was concluded that Dow AgroSciences had conducted monitoring inspections as required but that the density of the pigeon pea crop compromised their ability to detect cotton volunteers. Risks to human health and safety and the environment as a result of this non-compliance were assessed to be negligible.
Compliance management	Dow AgroSciences was reminded that it must ensure cotton volunteers are destroyed prior to reaching maturity. No further action is required. Since the planting of this pigeon pea crop occurred the OGTR has issued guidelines stipulating planting densities for pigeon pea to enhance volunteer identification.

Findings for Dealings Not involving Intentional Release

Organisation	Monash University
Licence number	DNIR106/2002
Summary of dealing	The licensed dealings include studying genes that

	potentially have a role in pathogenesis, antibiotic resistance or gene transfer in *Clostridia.*
Findings	OGTR inspectors observed that a container used for transporting GMO waste from the facility was not appropriately labelled to state it contained GMOs and did not have any contact numbers as required by the licence conditions.
Assessment	The compliance history of Monash University is good and agreement was obtained to use appropriately labelled containers in the future. The risks to human health and safety and the environment were assessed to be negligible.
Compliance management	Monash University was reminded of the requirement to comply with OGTR's transport guidelines.

Organisation	Monash University
Licence number	DNIR287/2004
Summary of dealing	The licenced dealings include studying the localisation of a *Dengue virus* protein during infection of cultured mammalian and insect cells.
Findings	OGTR inspectors observed that a container used for transporting GM material from the facility was not appropriately labelled with a contact phone number as required by the licence conditions.
Assessment	The compliance history of Monash University is good An agreement was obtained to use appropriately labelled containers in the future. The risks to human health and safety and the environment was assessed to be negligible.
Compliance management	Monash University was reminded of the requirement to comply with OGTR's transport guidelines.

Organisation	St Vincent's Hospital Melbourne
Licence number and site	DNIR083/2002
Summary of dealing	The licenced dealings include inoculating breast cancer cells into mice to assess how tumours develop.
Findings	OGTR inspectors observed that the secondary container used for transporting GMOs from the facility was not unbreakable or appropriately labelled to state it contained GMOs as required by the licence conditions.

Assessment	The compliance history of St Vincent's Hospital is good and agreement was obtained to use appropriate, labelled containers in the future. The risks to human health and safety and the environment were assessed to be negligible.
Compliance management	St Vincent's Hospital was reminded of the requirement to comply with OGTR's transport guidelines.

Findings for Physical Containment Facilities

The 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**
19	11	0	0	3	6	3

**. 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.

A Practice Review was conducted by the OGTR in this quarter which is summarised in the table below:

Issue	A Practice Review was conducted during January 2007 to examine compliance with the following standard conditions: • The licence holder must inform each person covered by this licence of the obligations imposed on them by the conditions of the licence; • The licence holder must provide the Regulator, on the Regulator's written request, with a signed statement from each person covered by this licence that the licence holder has informed the person of the conditions of this licence that apply to that person. The Compliance Section conducted unannounced inspections in all States and Territories except Tasmania (where there are currently no active licences other than a DIR PHM site) to educate licence holders on the requirement for signed statements from persons involved in licensed GMO dealings in order to demonstrate they have been informed of licence conditions. The OGTR foreshadowed this proactive approach to ensuring persons covered by a licence were informed of the licence conditions at the National Institutional Biosafety Committee (IBC) Forum held on the 16th November 2006.
Determination	The review found that the majority of organisations were able to provide appropriate signed statements by persons covered by the licence. A small number of organisations were assisted with enhancing their arrangements to meet these licence requirements or in conducting a review of key documents to ensure they were current. All organisations that were visited responded cooperatively and positively to the review. In many cases, the visit also provided an opportunity to discuss other minor problems which were resolved at the time through discussion.
Action	Ongoing obligations for the licence holders to observe these conditions.

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 1 January to 31 March 2007 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 was one investigation completed in the 1 January to 31 March 2007 quarter which is summarised in the table below:.

Organisation	PPD Australia Pty Ltd
Licence number	DNIR 366/2005
Issue	PPD Australia Pty Ltd reported a deviation from trial protocol in relation to a randomised, double blind, multicentre, placebo controlled phase III study (Protocol H-040-010) of the safety and tolerability of a live,

	attenuated vaccine against Japanese Encephalitis (ChimeriVax^{TM}-JE) . The non-compliance was identified by PPD Australia Ltd and its IBC. A trial participant was found to have donated blood, contrary to trial procedures which require participants to refrain from donating blood for 30 days after vaccination. The blood was subsequently transfused into two patients.
Findings	PPD Australia Pty Ltd and its IBC undertook actions to promptly report, remedy and assist the OGTR Compliance staff with the subsequent investigation**.** The investigation established that:- • The trial participant was a regular blood donor; • That the trial participant had inadvertently donated blood as a result of confusion arising from the trial procedures for a similar vaccine (JE-VAX®) which permitted blood donation; • The two blood recipients were not adversely affected by the vaccine as a result of the donation; • Licence conditions and clinical trial protocols were followed by PPD Australia Ltd: and • PPD Australia Ltd had implemented three consent level checks within the protocols including initial pre-screening, interviews and a subject diary card which was signed by participants at day 14 of the trial to reduce the risk of unintentional release.
Risk assessment	It was concluded that risks to human health and safety and the environment as a result of this non-compliance were negligible.
Determination	The non-compliance was due to an unfortunate, incomplete understanding of the trial procedures by a trial participant. There were no consequential adverse effects to human health and safety or the environment. Changes to the trial procedures have been introduced for all countries involved in the study to raise participants' awareness that they must not donate blood or organs for 30 days after vaccination.

Action	No further action required.

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 did not meet during the 1 January to 31 March quarter. However, comment was sought out-of-session on the consultation RARMP for licence application DIR 69/2006 during the quarter.

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 held a face-to-face meeting in Canberra on 15 March 2007. The Committee discussed procedures for consultation with local government authorities and received a presentation form the OGTR on GM Cotton in Australia.

GTCCC also participated in a joint meeting with the Gene Technology Ethics Committee (GTEC). The Committees discussed the *State, Territory and Australian Governments' Response to the Recommendations of the Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement*

2001 and the GTCCC working group project on the current community consultation practices of the OGTR.

The 10th communiqué regarding the March 2007 meeting is available at Appendix 3.
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.

GTEC held a face-to-face meeting in Canberra on 14 March 2007, prior to participating in the joint meeting with GTCCC on 15 March 2007. GTEC discussed further promotion of the *National Framework for the Development of Ethical Principles in Gene Technology* and developments in the use of plants to produce biologically active materials, sometimes described as 'biopharming'

The 14th GTEC communiqué regarding the March 2007 meeting is available in Appendix 2.

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

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 consulted with stakeholders on draft revisions to the guidelines for the following facility types: PC1 Laboratory; PC1 Animal (new guideline); PC1 Plant; PC1 Large Grazing Animal; PC2 Laboratory; PC2 Animal; and PC2 Plant.

Following consultation it was decided to amalgamate the PC1 Laboratory, PC1 Animal and PC1 Plant guidelines into a single, 'PC1 Facility' guideline and the *Guidelines for Certification of a Physical Containment Level 1 Facility* were issued on 30 March 2007. The Regulator also issued revised *Guidelines for Certification of a Physical Containment Level 1 Large Grazing Animal Facility*.

Review of the *Guidelines for the Guidelines for the Transport of GMOs* – during this quarter the OGTR consulted with stakeholders on draft revisions to the transport guidelines.

Guidelines for the Containment of Exempt Dealings – During this quarter the OGTR undertook consultation on draft *Guidelines for the Containment of Exempt Dealings.*

On 30 March 2007, the Regulator issued the *Guidelines for the Containment of Exempt Dealings* pursuant to the *Gene Technology Amendment Regulations 2006,* coming into effect on 31 March 2007.

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 a presentation to:

Environmental Risk Management Authority New Zealand - Australia's Gene Technology Regulatory System- 9 March 2007, Wellington, New Zealand.

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 1 January to 31 March quarter the OGTR provided the following presentations:

- Quarantine and Export Advisory Council - Australia's Regulatory System for Gene Technology - 7 February 2007, Canberra, ACT;

- National Industrial Chemicals Notification and Assessment Scheme - Gene Technology Regulation in Australia - 20 February 2007, Sydney, New South Wales; and

- Wattle Range Council - Introduction to Gene Technology in Australia – 13 March 2007, Millicent, South Australia.

National Strategy for Unintended Presence of Unapproved GMOs

An interdepartmental working group established by the Australian Government Biotechnology Ministerial Council and chaired by Biotechnology Australia has developed a risk based strategy for managing the unintended presence of unapproved GMOs. The OGTR has been asked to implement the strategy.

The OGTR has liaised closely with the Australian Seeds Federation to develop a voluntary auditing and testing program of existing industry quality assurance measures. The OGTR has commenced this program and expects to review a number of major seed breeding companies this year.

The first review was conducted in March of Bayer CropSciences. From the information provided the OGTR did not identify any obvious weakness in Bayer's quality assurance program.

OGTR Website Usage and Statistics

The OGTR's website is a comprehensive and increasingly popular source of information on activities of the office. The tables below provide information on the number of hits on the OGTR web site and the number of visitor sessions by month, and day of week pattern during the 1 January to 31 March 2007 quarter.

MONTH	**HITS** [1]	**VISITORS**[2]
January	1,267,854	35,913
February	1,226,655	34,759
March	1,400,564	42,481

DAY OF THE WEEK PATTERN FOR THE QUARTER	HITS [1]	VISITORS[2]
Sunday	461,792	14,053
Monday	613,468	16,639
Tuesday	588,331	17,287
Wednesday	591,990	18,532
Thursday	578,233	17,139
Friday	577,677	15,627
Saturday	483,582	13,876

1 'Hits' are the number of times the files started to download or did not fully download.
2 'Vvisitors' are actual downloads.

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

- Home page;
- What's new;
- About the OGTR;
- Handbook on the Regulation of Gene Technology in Australia;
- GMO Record; and
- Media Information.

The most popular downloaded documents were:

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

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

Internet Contacts and Freecall Number

OGTR Email Address and Freecall 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 tables below describes the activity of these facilities throughout the 1 January to 31 March quarter.

MONTH	EMAILS	OGTR 1800 NUMBER
January	133	79
February	134	144
March	171	102

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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 71 emails during the January to March 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 129 emails during the 1 January to 31 March quarter.

Freedom of Information Requests

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

Appendix 1

DNIR Licences issued 1 January to 31 March 2007

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 405/2006	5 March 2007	The University of Queensland, Queensland	Over-expression and mutant complementation in Cryptococcus	To investigate mating and growth regulators in *Cryptococcus* species.
DNIR 402/2006	16 January 2007	Clinical Network Services Pty Ltd, Queensland	Single armed, multi-centre, open label clinical study evaluating the safety and tolerability of NovaCaps in patients with inoperable pancreatic carcinoma	Phase I clinical trial of an encapsulated cell therapy product (NovaCaps) that activates the prodrug ifosfamide in patients with inoperable pancreatic carcinoma.
DNIR 401/2006	23 January 2007	Sydney-West Area Health Service, New South Wales	Transmissible genetic elements in bacteria	To characterise antibiotic resistance-associated genetic loci such as resistance genes and mobile genetic elements in bacteria.

Appendix 2

Gene Technology Ethics Committee

14-15 March 2007, Canberra

COMMUNIQUE

The Gene Technology Ethics Committee (GTEC) held its fourteenth meeting in Canberra on 14-15 March 2007.

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 14-15 March meeting included a combined session with the Gene Technology Community Consultative Committee (GTCCC).

The main items discussed were the further promotion of the *National Framework for the Development of Ethical Principles in Gene Technology* and developments in the area of biopharming. During the combined session with GTCCC, the Committees discussed the *State, Territory and Australian Governments' Response to the Recommendations of the Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement 2001*, and the GTCCC working group project on the current community consultation practices of the OGTR. Members of both Committees also received reports from the Chair regarding relevant events he has attended since the last GTEC and GTCCC meetings, 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 fourteenth meeting are reported below.

GTEC's Work Plan

National Framework for the Development of Ethical Principles in Gene Technology

Members considered feedback on the Framework which has been received since the official public launch of the document on 15 November 2006. Members agreed to attend meetings within their States, which will be arranged later in the year, to discuss the Framework with IBCs and researchers.

Biopharming

GTEC was given an overview of the current state of the technology for using genetically modified plants to produce therapeutics, often referred to as 'biopharming'. The Committee discussed ethical issues that may be associated with the technology and technical aspects of the research, with reference to US research recently reported in the media.

The Committee agreed to consider the relevant literature and the development of a scoping paper on the topic.

Review of the *Gene Technology Act 2000* (the Act) – All of Governments' Response

GTEC and GTCCC were given a presentation outlining the Governments' response to the recommendations of the Review of the Act. In particular, the members noted the recommendation to combine the roles of the two Committees.

'Community Consultation and Participation'

GTEC and GTCCC discussed the working group paper on 'Community Consultation and Participation', which was initiated by the original membership of GTCCC and further developed by the new membership.

The Committees agreed that the OGTR already has good systems in place for community consultation and suggested methods for evaluating the existing systems and identifying possible areas for improvement.

GTEC and Relationships with Other Committees

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

GTEC noted that the Animal Welfare Committee (AWC) *Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes* would soon be published and would be co-badged by GTEC.

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

Appendix 3

Gene Technology Community Consultative Committee

15 March 2007, Canberra

COMMUNIQUE

The Gene Technology Community Consultative Committee (GTCCC) held its tenth meeting in Canberra on 15 March 2007.

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

The 15 March meeting included a combined session with the Gene Technology Ethics Committee (GTEC).

The main items discussed were the development of the working group project on communication with local government authorities and developments in the area of genetically modified cotton. During the combined session with GTEC, the Committees discussed the *State, Territory and Australian Governments' Response to the Recommendations of the Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement 2001*, and the GTCCC working group project on the current community consultation practices of the OGTR. Members of both Committees also received reports from the Chair regarding relevant events he has attended since the last GTEC and GTCCC meetings, 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.

GTCCC's Work Plan

Consultation with Local Government Authorities

The Committee discussed the working group project on developing a strategy for enhancing communication between the OGTR and Local Government Authorities (LGAs). GTCCC agreed that effective communication with LGAs is a complex issue, and made a number of suggestions on how the Regulator could improve existing communication pathways.

‘Community Consultation and Participation’

GTEC and GTCCC discussed the working group paper on ‘Community Consultation and Participation’, which was initiated by the original membership of GTCCC and further developed by the new membership.

The Committees agreed that the OGTR already has good systems in place for community consultation and suggested methods for evaluating the existing systems and identifying possible areas for improvement.

Review of the *Gene Technology Act 2000* (the Act) – All of Governments’ Response

GTEC and GTCCC were given a presentation outlining the Governments’ response to the recommendations of the Review of the Act. In particular, the members noted the recommendation to combine the roles of the two Committees.

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 Ethics Committee (GTEC).

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