



OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 APRIL–30 JUNE 2008

ISBN: 1-74186-689-8

Online ISBN: 1-74186-690-1

Publications Number P3-4243

Paper-based publications

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Senator the Hon Jan McLucas
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 April to 30 June 2008.

During this period, three licences for dealings involving intentional release of GMOs and six licences for dealings not involving intentional release of GMOs were issued and 71 physical containment facilities were certified.

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

The Gene Technology Regulator, Dr Sue Meek, resigned from office on 30 April 2008 to take the position of Chief Executive with the Australian Academy of Science.

Yours sincerely



Elizabeth Flynn
A/g Gene Technology Regulator

26 September 2008

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ABOUT THIS REPORT

Sub-section 136A(1) of 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. Sub-section 136A(2) of the Act requires that the report include information on:

- GMO licences issued during the quarter
- breaches of conditions of a GMO licence that have come to the Regulator's attention during the quarter
- emergency dealing determinations (EDDs) made by the Minister during the quarter
- any breaches of conditions of an EDD that have come to the Regulator's attention during the quarter
- auditing and monitoring of dealings with GMOs under the Act by the Regulator or an inspector during the quarter.

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 April to 30 June 2008 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 two 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 dealings not involving intentional release (DNIR) licences issued and communicated for the statutory advisory committees.



SECTION 1

**NATIONAL GENE TECHNOLOGY
REGULATORY SYSTEM**



NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 April to 30 June 2008 quarter were:

Licences and other instruments

- three licences issued for dealings involving the intentional release (DIR) of GMOs into the environment
- six licences issued for dealings not involving the intentional release (DNIR) of GMOs into the environment
- 71 physical containment facilities certified
- approved surrenders of 48 certifications and nine DNIR licences
- 453 variations approved.

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

Monitoring and compliance

Approximately five percent of current field trial sites and six percent of post-harvest field trial sites were subjected to routine monitoring during the quarter. This meets 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 all DIR licences, except limited and controlled releases.

For each application for a DIR licence other than a limited and controlled release, 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. For each application for a limited and controlled release, the Regulator is only required to seek comment on the RARMP.

Further 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, on matters relevant to preparing the RARMP for each application for a DIR licence, except those that meet the criteria to be considered as a limited and controlled release.

The prescribed Australian Government authorities and agencies comprise:

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

Once a RARMP is prepared for any DIR licence application, the Regulator is required to seek comment on the RARMP from the same prescribed Australian Government authorities and agencies.

In addition, comment is sought on each 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 the Environment, Water, Heritage and the Arts
- Department of Foreign Affairs and Trade.

During the quarter, the Regulator sought advice and comment in respect of five RARMPs.

Further information on the processing of DIR applications is contained in Section 2 of this report.

Public participation

The Act requires the Regulator to consult the public on the RARMPs for all DIR licence applications. Six invitations to the public to comment on a RARMP were issued during the quarter.

Further information on the processing of DIR applications is contained in Section 2 of this report.



SECTION 2

**REGULATION OF GENETICALLY
MODIFIED ORGANISMS**

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of this report outlines the regulatory activity undertaken during the 1 April to 30 June 2008 quarter. This includes information about applications for GMO licences and other instruments under the Act. This section also details any EDDs made pursuant to 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.

Types of applications

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

- **Dealings involving intentional release licences**

DIR licences authorise dealings ranging from limited and controlled releases (e.g. field trials) through to more extensive general or commercial releases of GMOs. DIR licence applications received after 1 July 2007 have a statutory timeframe of 255 working days for processing unless the Regulator determines the application is a limited and controlled release. The timeframe for making a decision on a limited and controlled release is 150 working days, or 170 working days if the Regulator determines that the proposed dealings represent a significant risk to human health and the environment.

- **Dealings not involving intentional release 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.

- **Accreditation of organisations**

DIR and DNIR licences require organisations that 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.

- **Certification 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.

Application type	Number received	Number approved*
DIR licence	4	3
DNIR licence	4	6
Accreditations	2	3
Certifications	80	71

* 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 application is a limited and controlled release
- considering the applicant's suitability against disclosure of relevant convictions and/or revocations and suspensions of related licences and permits
- seeking comments from prescribed experts, agencies and authorities on issues to consider in the RARMP for all DIR applications except limited and controlled releases
- preparing a consultation RARMP, including determining whether the proposed dealings may pose a significant risk and proposing licence conditions to manage risks to human health and safety and the environment
- seeking comments on the RARMP from prescribed experts, agencies and authorities and the public

- considering all comments relating to the protection of human health and safety and the environment in finalising the RARMP
- confirming the applicant's suitability, including capacity to meet licence conditions, and considering policy principles and any relevant policy guidelines.

Once these actions are completed, the Regulator can make a decision on whether or not to grant a licence and the conditions which are to be included in the licence if issued.

The statutory timeframes for making decisions on DIR licences effectively extend over approximately 12 months, and eight or nine months for limited and controlled releases, as they exclude 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 a minimum 30 day timeframe for the one or two rounds of consultation that the Regulator must undertake during the processing of each DIR application. However, consultation periods longer than the minimum timeframe are usually allowed to facilitate the provision of information and promote involvement in the decision-making process, particularly by the community. 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 received	Notification of applications*	Surrendered applications	Licence issued
DIR 086/2008	DIR 085/2008	DIR 088	DIR 076/2007
DIR 087	DIR 086/2008		DIR 077/2007
DIR 088			DIR 80/2007
DIR 089			

* Although not required under the Act, all new DIR applications are notified on the OGTR website under 'What's New' and notified to all individuals and organisations on the OGTR mailing list.

Applications received for dealings involving intentional release licences

The Regulator received four applications for a DIR licence in the quarter:

- DIR 086/2008—Limited and controlled release of maize genetically modified to investigate gene function—CSIRO
- DIR 087—Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance—Bayer CropScience Pty Ltd
- DIR 088—ProteqFlu® Suspension for Horses—Merial Australia Pty Ltd
- DIR 089—Limited and controlled release of white clover genetically modified to resist infection by Alfalfa mosaic virus—Victorian Department of Primary Industries.

(DIR 088 did not progress through the evaluation process because the application was incomplete).

Consultation on applications for dealings involving intentional release licences

No consultations commenced on any DIR licence applications during this quarter as all those under consideration were deemed by the Regulator to qualify as limited and controlled releases.

Although not required by the Act, the Regulator issued a 'Notification of Licence Application' for two DIR licence applications. These notifications were posted on the OGTR website and sent to people and organisations on the OGTR mailing list to advise receipt of these applications and when the RARMPs are expected to be released for public comment.

Six invitations to comment on a RARMP were issued during the quarter:

- DIR 077/2007—Limited and controlled release of wheat and barley genetically modified for enhanced tolerance to abiotic stresses or increased beta glucan—The University of Adelaide
- DIR 078/2007—Limited and controlled release of sugarcane genetically modified for altered sugar production—The University of Queensland
- DIR 079/2007—Limited and controlled release of banana genetically modified for disease resistance—Queensland University of Technology
- DIR 080/2007—Limited and controlled release of wheat genetically modified for drought tolerance—Victorian Department of Primary Industries
- DIR 082/2007—Limited and controlled release of perennial ryegrass and tall fescue genetically modified for improved forage qualities—Victorian Department of Primary Industries
- DIR 083/2007—Limited and controlled release of cotton genetically modified for enhanced waterlogging tolerance—CSIRO.

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

Withdrawn applications and surrendered licences for dealings involving intentional release

No DIR licences were surrendered or withdrawn during the quarter

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.

A request for further information was initiated in this quarter:

- DIR 081/2007—Limited and controlled release of cotton genetically modified for enhanced water use efficiency—Monsanto Australia Ltd.

Decisions on applications for dealings involving intentional release licences

Three DIR licences were issued during this quarter:

- DIR 076/2007—Limited and controlled release of banana genetically modified for enhanced nutrition—Queensland University of Technology
- DIR 077/2007—Limited and controlled release of wheat and barley genetically modified for enhanced tolerance to abiotic stresses or increased beta glucan—The University of Adelaide
- DIR 080/2007—Limited and controlled release of wheat genetically modified for drought tolerance—Victorian Department of Primary Industries.

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 DNIR licences. More 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.

Changes to 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. The Regulator must not vary the licence unless she 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.

Most variations are made at the request of the instrument/licence holder and those applications have a statutory timeframe of 90 days for processing. 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 applications received to change existing licences and other instruments, as well as the number of applications processed during the quarter.

Type	Number received	Number approved ¹
Surrender of certification	48	48
Surrender of DNIR licence	12	9
Variation of certification ²	282	417
Variation of DIR licence	2	1
Variation of DNIR licence	26	35
Applications for CCI	3	2

1 Numbers reported in this quarter often relate to applications received in previous quarters.

2 Large number of applications to vary certifications of contained facilities in response to recent revisions to guidelines and often coincides with pending expiry of existing instruments.

Confidential commercial information

Under section 184 of the Act a person may apply to the Regulator in accordance with section 185 for specified information to be declared commercial confidential information (CCI). Specified information awaiting a decision on an application for CCI is treated as if it were CCI until a decision is made. 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 <www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/cci>

During the quarter, the Regulator received three CCI applications in relation to DIR licence applications. The Regulator made one CCI declaration in relation to a DIR licence application and one CCI declaration in relation to a DNIR licence application.

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.

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 DNIRs and the facilities in which those dealings are conducted, as well as monitoring a minimum of 20 percent of physical containment level 4 (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 notifiable low risk dealings (NLRDs).

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored: During the 1 April to 30 June 2008 quarter, three field trial sites with GM plants were subjected to monitoring visits.

- **Current field trial sites:** Of the 21 sites current in the quarter, one was monitored. This represents a monitoring rate of five percent of all current sites for the quarter, and
- **Post-harvest field trial sites:** Of the 35 sites subject to post-harvest monitoring in the quarter, two were monitored. This represents a monitoring rate of six percent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection to contained dealings covered seven organisations and 12 physical containment facilities. Monitoring of physical containment facilities encompassed four PC2 laboratories, five PC3 laboratories, one PC4 laboratory, one PC2 animal containment facility and one PC3 arthropod facility.

Monitoring of contained dealings: During the quarter, the monitoring of the 12 physical containment facilities mentioned above included monitoring for compliance with the general practices that must be followed when undertaking dealings (e.g. DNIRs) that are required to be conducted within contained facilities.

Four DNIRs were monitored during the 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 April and 30 June 2008.

Licensed Organisation Name	Licence Number	No. sites visited	Site status*	Crop type
Department of Primary Industries, Victoria. New South Wales	DIR 047/2003	1	PHM	White clover
Dow AgroSciences Australia Pty Ltd, New South Wales	DIR 044/2003	1	PHM	Cotton
The University of Queensland, Queensland	DIR 026/2002	1	C	Papaya
Total		3	C = 1 PHM = 2	3 crop types

* C = current PHM = post-harvest monitoring.

Monitoring of dealings not involving intentional release

The following table summarises monitoring activities for DNIRs for the period between 1 April and 30 June 2008.

Licensed Organisation Name	Licence Number
The University of New England, New South Wales	DNIR 140/2002
	DNIR 207/2003
Imugene Limited, New South Wales	DNIR 407/2006
University of New South Wales, New South Wales	DNIR 306/2004
Total	4 DNIR licences

Monitoring of physical containment facilities

The organisations and the facility types the OGTR visited during the 1 April to 30 June 2008 quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
University of New South Wales, New South Wales	PC2 laboratory	2
The University of New England, New South Wales	PC2 laboratory	2
Imugene Limited, New South Wales	PC2 animal containment	1
Johnson & Johnson Research Pty Ltd, New South Wales	PC3 laboratory	1
Griffith University, Queensland	PC3 laboratory	1
The University of Queensland, Queensland	PC3 laboratory	1
Queensland Health Forensic and Scientific Services, Queensland	PC3 laboratory	2
	PC3 arthropod containment	1
	PC4 laboratory	1
Total	5 facility types	12

Monitoring findings

Dealings involving intentional release

The monitoring findings listed below indicate both the monitoring activities of the OGTR with respect to dealings with GMOs under the Act, in accordance with paragraph 136A(2)(c), 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
- 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

There were no findings from monitoring of DIRs for the 1 April to 30 June 2008 quarter.

Findings for dealings not involving intentional release

There were no findings from monitoring of DNIRs for the 1 April to 30 June 2008 quarter.

Findings for physical containment facilities

The OGTR's monitoring of certified physical containment facilities in the quarter found a small number of minor structural non-compliances with certification conditions. All were found to pose negligible risks to human health and safety and the environment.

Number of PC Facilities inspected	Non-Compliance Issue					
	Structure	PPE ¹	Equipment	Waste disposal	Work practices ²	Transport
12	5	0	0	0	0	0

1 PPE = Personal Protective Equipment.

2 Work practices include personnel training, record keeping, or other actions affecting compliance with certification instruments.

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 was one Practice Review completed in the 1 April to 30 June 2008 quarter.

Practice Review	DIR Post-Harvest Management (PHM) Site Control Practice Review
Issues	<p>A practice review was conducted in January and February 2008 by Compliance and Investigations to:</p> <ul style="list-style-type: none"> • assess the site control arrangements of licencees • evaluate their DIR post-harvest practices • identify any compliance risks in practices • identify and raise awareness of effective compliance approaches.
Determination	<p>The review included the conduct of a number of interviews and included the collection and assessment of:</p> <ul style="list-style-type: none"> • monitoring records • site control documentation • training methods and records • administrative information • contracts for personnel and land use • operational protocols. <p>The licencees were selected because they hold current active post-harvest sites, and/or records showed that they had sites for which obligations under the licence has been extended, and/or to reflect major host crop types. The review included Dow AgroSciences Australia Limited, CSIRO, Deltapine, Queensland Department of Primary Industries, Queensland University, Bureau of Sugar Experiment Stations, Bayer Cropscience Pty Ltd, and Monsanto Australia Ltd.</p> <p>No non-compliances of participants were found during the practice review. All observed site control and monitoring practices and participants' procedures were assessed as capable of supporting effective compliance and GMO containment.</p> <p>Post-harvest trial sites are subject to licence conditions for long periods until the GMOs are destroyed or the site is shown to be free of volunteers after the trial period. Regular OGTR and licencee monitoring remains fundamental to effective site containment and ensuring the validity of site sign-off acquittal.</p>
Action	<p>Post-harvest site control will continue to be the subject of ongoing strategic monitoring, practice reviews and auditing by the OGTR. Best practice approaches and collated site control techniques will be shared at IBC Fora.</p>

Audits

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

- documentary evidence
- observations
- 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
- suggest improvements to procedures and practices, where appropriate.

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 (e.g. dealings with GMOs derived from a common host organism or dealings with GMOs 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 was one audit completed in the 1 April to 30 June 2008 quarter.

Audit	Bayer CropScience Pty Ltd
Issues	<p>This audit is part of the OGTR ongoing audit program and was conducted to:</p> <ul style="list-style-type: none"> • assess the company's compliance procedures and operational arrangements • identify barriers to compliance or compliance management concerns • identify any compliance performance risks • identify and raise awareness of effective compliance approaches.

Determination

The audit found that Bayer CropScience Pty Ltd compliance management arrangements (under the Act) appear to:

- be well developed, adaptive, and comprehensive
- comprise a number of compliance management mechanisms which could be drawn upon by the OGTR in developing effective compliance performance principles for future IBC Forums and other OGTR awareness activities
- have the capacity to underpin Bayer CropScience compliance with regulatory provisions/licence conditions.

Feedback on OGTR specification of regulatory requirements or OGTR regulatory practices did not suggest the need for any particular revision at this stage.

No barriers to effective licensee compliance performance under the Act were identified by Bayer CropScience Pty Ltd or the OGTR during the audit. The audit noted that Bayer CropScience was able to manage compliance requirements for OGTR together with other regulatory arrangements.

Action

A number of this licensee's compliance management mechanisms can be drawn upon by the OGTR in developing effective compliance performance principles for ongoing education and information of stakeholders and other OGTR awareness activities.

The OGTR monitors ongoing developments in other regulatory systems and, where appropriate, provides advice to avoid any emerging conflicting policies or provisions. Audits, practice reviews, IBC Forums, OGTR awareness activities and inspections provide opportunities for licensees to convey observations about such developments to the OGTR.

The OGTR audit program will continue to assess licensee compliance management arrangements and operational practices. Audit data will continue to be compiled, together with other compliance performance information, and used in future compliance assessments. Such information also contributes to the continual improvement of OGTR compliance management processes.

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 April to 30 June 2008 quarter.

Organisation	Cargill Australia Pty Ltd
Licence numbers	DNIR 400/2006, DNIR 277/2003
Issue	Cargill Australia Pty Ltd (Cargill) failed to disclose relevant convictions in applications made with respect to two licences for dealings not involving intentional release. The company further failed to report a number of relevant convictions as required by its licence conditions.
Findings	<p>The matter was thoroughly investigated by the OGTR Compliance and Investigations Section. Relevant Cargill employees were interviewed with a view to establishing whether the matter warranted the application of criminal or administrative sanctions in accordance with the Act.</p> <p>Investigations concluded that while the non-disclosures were unintentional, Cargill's capacity to gather and report information on relevant convictions across the full extent of its operations for the purposes of meeting its statutory and licence obligations was compromised by inadequate corporate arrangements.</p> <p>The failure to report relevant company convictions for the purposes of acquiring a licence is regarded as a serious matter. In cases where such non-disclosures are intentional or otherwise criminally culpable, the Regulator would be justified in proceeding with a view to criminal and/or significant administrative sanctions.</p> <p>The investigation established that the majority of the convictions were not directly associated with the commercial operations of the Grains and Oil Seeds business that made applications to the OGTR, but rather those of the Beef (abattoir) side of the company. The investigation established that the nature of the non-compliances would not have caused the Regulator to come to a different decision with respect to the issuing of licences or which would have required any action on existing licences.</p>

Determination	<p>In determining a course of action, the Regulator had regard to the OGTR's non-compliance protocols. The non-disclosures were unintentional and in that respect culpability was confined to negligence and oversight. The non-disclosures did not pose a risk to the health and safety of people and the environment. Cargill's compliance history is satisfactory and the company was cooperative and candid during the investigation. Cargill also satisfied the inspectors that it had now put in place appropriate measures to ensure that all required corporate disclosures would be identified and communicated to the Regulator in the future.</p>
Action	<p>Cargill has been given an official warning regarding future compliance with reporting all relevant convictions in accordance with the Act.</p> <p>Changes have also been made to OGTR application forms to provide additional explanatory information on identifying and reporting relevant convictions.</p>



SECTION 3

STATUTORY COMMITTEE OPERATIONS

STATUTORY COMMITTEE OPERATIONS

The Act establishes two committees to provide advice to the Regulator and the Gene Technology Ministerial Council (GTMC):

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

Appointments to the two gene technology advisory committees were made by the Parliamentary Secretary to the Minister for Health and Ageing, Senator the Hon Jan McLucas, in January 2008.

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 GTMC, 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 term of the second GTTAC triennium expired on 8 December 2007 and appointment of members for the third GTTAC triennium was finalised in January 2008.

GTTAC met twice during this quarter: 9–10 April and 11 June 2008.

Further information about the work of GTTAC, including its communiqués, is available from the OGTR website <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gttac-2>>

Gene Technology Ethics and Community Consultative Committee

The Gene Technology Ethics and Community Consultative Committee (GTECCC) is a new Committee that replaces the former Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC). The terms of GTEC and GTCCC expired on 8 December 2007 and 30 June 2007 respectively.

GTECCC was established through changes to the Act introduced by the *Gene Technology Amendment Act 2007* (the Amendment Act). The Amendment Act gave effect to the response agreed by Commonwealth and state and territory governments to the recommendations made by the *Statutory Review of the Gene Technology Act 2000* and the *Gene Technology Agreement 2001*. Most of the provisions of the Amendment Act commenced on 1 July 2007, however the date for the commencement of GTECCC was 1 January 2008.

As set out in section 107 of the Act, the function of GTECCC is to provide advice on the request of the Regulator or the GTMC, on a number of matters, including ethical issues relating to gene technology, the need for and content of policy principles, policy guidelines, codes of practice, community consultation in respect of the process for applications for licences covering dealings involving the intentional release of a GMO into the environment, and risk communication matters in relation to those dealings. The appointment process for this new Committee was finalised in January 2008.

GTECCC held its inaugural meeting during this quarter, on 27–28 May 2008.

Further information about GTECCC is available from the OGTR website at www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gteccc-2

Information about the work of the former GTEC and GTCCC, including their communiqués, is also available from the OGTR website at www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gtecgccc-1



SECTION 4

**OTHER ACTIVITIES OF THE
GENE TECHNOLOGY REGULATOR**



OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

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
- 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 presentations to and/or participation in:

- The 21st session of the OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology, 25–27 June 2008, Paris, France.
- The Australian delegation to the UN Cartagena Protocol on Biosafety, 4th Meeting of the Parties, 12–16 May 2008, Bonn, Germany.
- The Australia–India Transgenic Crop Workshop, 21–23 April 2008, New Delhi, India.
- The Australian delegation to the Australia Group Plenary, 14–18 April 2008, Paris, France.
- Meetings with the Scientific Advisory Committee on Genetic Modification (Contained Use) and with technical officials from the Health and Safety Executive, 21 April 2008, London, United Kingdom.
- A meeting with technical experts of the Health Protection Agency (high level containment), 22 April 2008, Salisbury, United Kingdom.

The office continued to liaise with New Zealand officials on arrangements for the 10th International Symposium on the Biosafety of Genetically Modified Organisms. This conference, co-sponsored by the OGTR, will be held in Wellington, New Zealand in November 2008.

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 April to 30 June 2008 quarter the OGTR provided the following presentations:

- Australia/India Transgenic Crops Workshop/Australia's Regulatory System for Gene Technology, 22 April 2008, Delhi, India

- Australian Compliance Institute Conference, 1 May 2008, Sydney, Australia
- 21st Session of the OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology, 25–27 May 2008, Paris, France
- Australian post border Weed Risk Management forum, 12 June 2008, Adelaide, Australia

Other conferences/seminars/meetings:

- Visiting Chinese GMO Biosafety Delegation/Regulation of Gene Technology in Australia, 3 April 2008, Canberra, Australia
- The office also participated in technical subcommittee meetings to review Australian/New Zealand Standard 4232, Safety in Laboratories—Microbiology, Melbourne, Australia

The office held training sessions for Institutional Biosafety Committees in Melbourne and Sydney.

National Strategy for Unintended Presence of Unapproved GMOs

The Australian Government Biotechnology Ministerial Council has endorsed a risk-based national strategy to manage the unintended presence of unapproved GMOs in imported seeds for sowing (the UP Strategy). The strategy was developed by an interdepartmental working group chaired by Biotechnology Australia and comprising the Department of Agriculture, Fisheries and Forestry; the then Department of the Environment and Heritage (now Environment, Water, Heritage and the Arts); Department of Foreign Affairs and Trade; Department of Education, Science and Training (now Education, Employment and Workplace Relations); Department of Industry, Tourism and Resources (now Innovation, Industry, Science and Research); Department of Health and Ageing; Food Standards Australia New Zealand; and the OGTR.

The OGTR is responsible for implementing the UP strategy and has liaised closely with the Australian Seed Federation (ASF) to develop a voluntary auditing and testing program of existing industry quality assurance measures. During the quarter, no reviews were conducted as the OGTR and the ASF assessed the effectiveness of the first stage of reviews. The OGTR is continuing work with the ASF to expand the quality assurance review program on a needs basis.

OGTR 2008 Service Delivery Survey

The OGTR recently conducted a service delivery survey, which provided an opportunity for stakeholders to provide feedback to the OGTR on the quality and suitability of our services in meeting organisations' needs, and our performance as set out in the OGTR Client Service Charter. This is available at <www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/about-charter-1>.

ORIMA Research Pty Ltd (ORIMA Research) was commissioned to undertake the survey on behalf of the OGTR. The survey was conducted over June/July 2008. It was voluntary, and the information obtained from it will be used to assist the OGTR to improve its services.

The survey was open to:

- accredited organisations regulated under the Act and related arrangements
- relevant Commonwealth and state and territory government agencies
- any individuals or organisations who are registered via the online OGTR Client Register
- any interested members of the general public.

The results of this survey are currently being evaluated by ORIMA Research, with a report to be provided to the OGTR in the near future. The outcomes of the survey will be provided on the OGTR website 'What's new' page and discussed at the next Institutional Biosafety Committee (IBC) forum. Further information will be provided in the next quarterly report for 2008.

OGTR website usage and statistics

The OGTR's website is a comprehensive source of information on activities of the office. The tables below provide information on the number of hits on the OGTR website and the number of visitor sessions by month, and day of week pattern during the 1 April to 30 June 2008 quarter.

MONTH	HITS ¹	VISITORS ²
April	1,156,185	44,851
May	1,337,704	46,039
June	1,321,538	36,938

DAY OF THE WEEK PATTERN FOR THE QUARTER	HITS ¹	VISITORS ²
Sunday	495,947	16,202
Monday	499,611	19,100
Tuesday	574,964	19,940
Wednesday	568,114	21,411
Thursday	582,517	19,227
Friday	540,642	17,215
Saturday	453,629	14,733

1 'A hit' is a request made to the server. Each file that is requested is counted as a hit

2 'Visitors' is the number of how many times the OGTR website has been visited.

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

- Home Page
- What's New
- Publication and Forms—Certification of Physical Containment Facilities
- Handbook on the Regulation of Gene Technology in Australia
- Intentional Release and Evaluation Process
- About the OGTR
- GMO Record

The most popular downloaded documents were:

- Risk Analysis Framework
- The Biology and Ecology of Banana (*Musa* spp.) in Australia
- The Biology and Ecology of Papaya (*Carica papaya*) in Australia
- The Biology and Ecology of Pineapple (*Ananas comosus* var. *comosus*) in Australia
- The Biology and Ecology of Wheat (*Triticum aestivum* L) in Australia
- The Biology and Ecology of Cotton (*Gossypium hirsutum* L.) in Australia
- DIR 069/2007 Risk Assessment and Risk Management Plan
- The Biology and Ecology of Canola (*Brassica napus*) in Australia

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

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 table below describes the activity of these facilities throughout the quarter.

MONTH	EMAILS	OGTR 1800 NUMBER
April	96	133
May	144	110
June	137	153

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 while monitoring staff are away from the office. The inbox received 51 emails during the quarter.

Statutory committee email inbox

The Regulatory Practice and Secretariat Section maintains 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 184 emails during the quarter.

Application and licence management email inbox

This electronic mail inbox provides a central, shared communication point to allow efficient coordination of responses for correspondence and queries about applications received by the Application and Licence Management Section. The inbox received 554 emails during the quarter.



APPENDICES

APPENDIX 1

DNIR licences issued 1 April to 30 June 2008

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 435/2007	2 April 2008	Flinders University, SA	Lentivirus-mediated gene transfer to prolong corneal graft survival	The aims of these dealings are to investigate the potential for lentiviral mediated gene therapy to improve the survival of corneal grafts in animal models
DNIR 437/2008	28 April 2008	Queensland Institute of Medical Research, QLD	Cleanroom manufacturing of a chemotherapeutic drug delivery technology for use in cancer therapy	The purpose of this dealing is to produce large-scale preparations of a drug delivery vehicle for use in cancer therapy
DNIR 438/2008	20 June 2008	Royal Prince Alfred Hospital, NSW	Phase 1 safety study in subjects with severe Hemophilia B (Factor IX Deficiency) using adeno-associated viral vector to deliver the gene for Human Factor IX into the liver coupled with transient immunomodulation.	The purpose of this dealing is to conduct a phase I clinical trial of a genetically modified, replication defective Adeno-associated viral vector in patients suffering Hemophilia B in combination with immunosuppressive therapy.

DNIR 439/2008	30 June 2008	The University of Queensland, QLD	Virus-mediated approaches to examine cardiovascular disease in vitro and in vivo	The aim of the proposed dealings is to investigate the regulation of cardiac function in vivo by the delivery of cardiac regulatory genes into rodents using replication-defective viral vectors.
DNIR 440/2008	30 June 2008	The University of Queensland, QLD	Mechanisms of growth hormone signalling II	This project will investigate how growth hormone signals via the growth hormone receptor and other genes to control growth and metabolism, and its role in the development of cancer.
DNIR 444/2008	4 April 2008	The University of Melbourne, VIC	Gene transfer of neurotrophins for survival and reconnection of regenerating auditory nerves	This study aims to utilise adenoviral and adeno-associated viral vector gene therapy to determine whether locally expressed neurotrophins can promote nerve survival and nerve regeneration in the inner ear of animals

APPENDIX 2

Gene Technology Technical Advisory Committee 9th & 10th April 2008, Canberra Communiqué for the 22nd meeting

This is the 22nd communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 32nd meeting of GTTAC, held on 9th and 10th April 2008.

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 Risk Assessment and Risk Management Plans (RARMPs) prepared for licences to conduct dealings with genetically modified organisms (GMOs).

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.

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

Advice on Consultation RARMPs

GTTAC considered the Consultation RARMP's prepared in response to the following applications:

- DIR 076/2007—Limited and controlled release of banana (*Musa* sp.) genetically modified for enhanced nutrition

The purpose of the proposed trial is to conduct proof of concept research involving experiments with GM banana lines to assess growth, fruit and yield characteristics and analyse nutrient content of fruit and vegetative parts. A number of promoters will also be tested in order to identify those that achieve best expression of the genes in the fruit. The GM bananas will not be used for human food or animal feed.

GTTAC discussed this application and RARMP and advised the Regulator that:

- the hazard characterisation and risk identification are adequate;
 - the proposed licence conditions are adequate to manage the release;
 - confirmation of the *Agrobacterium*-free status of GM plants prior to release should be considered; and
 - the RARMP should include a discussion of the fact that there is a habitat that is capable of supporting the presence of a native *Musa* species near the trial site, and address the possibility of gene flow.
- DIR 077/2007—Limited and controlled release of wheat and barley genetically modified for enhanced tolerance to abiotic stresses or increased beta glucan

The purpose of the proposed trial is to conduct proof of concept research involving experiments with GM wheat and barley lines to assess their agronomic performance under field conditions, and to obtain tissue samples for subsequent analysis of characteristics such as gene and protein expression levels, and metabolite profiles. Some seed will be saved for possible future trials which would be subject to further approval(s).

GTTAC considered the consultation RARMP for this application and advised the Regulator that: given the fact that the trial will be conducted at a Research Station where other cereal varieties may be grown, the likelihood and consequences from gene flow to proximate sexually compatible cereals should be assessed.

Advice on DNIR Application

- DNIR 438/2008—A Phase I safety study in subjects with severe Haemophilia B (Factor IX deficiency) using Adeno-Associated Viral vector to deliver the gene for human Factor IX into the liver combined with transient immunomodulation.

A previous related clinical trial in severe Haemophilia B patients in the USA used vectors based on Adeno-associated virus serotype 2 (AAV2) to deliver the Factor IX gene directly to the liver. AAV2 is a naturally replication-defective virus that is not associated with human disease and is ubiquitous in the environment.

The results of this trial demonstrated that AAV2-mediated Factor IX gene therapy can achieve clinically significant levels of the Factor IX clotting factor with no serious adverse events reported to date; however, expression of therapeutic levels was short-lived in these trials due to clearance by the patient's immune system.

The proposed study will be conducted in conjunction with the ongoing clinical trial in the USA and aims to determine the safety, optimal dose and efficacy of intrahepatic administration of the AAV2 vector expressing human Factor IX (AAV2-FIX) to patients with severe Haemophilia B.

In addition patients will receive transient administration of oral immunosuppressants to prevent immune clearance of the vector and extend the period of expression of therapeutic levels of Factor IX.

GTTAC discussed this application and advised the Regulator that:

- The risks to people conducting the dealings and to the environment were considered to be minimal

(NB: Safety issues related to participants in the trial are considered by Human Research Ethics Committees and/or the Therapeutic Good Administration and are outside of the terms of reference of the Regulator)

Presentations

As this was the first meeting of a newly appointed committee, the following presentations were made to GTTAC by OGTR staff:

- Overview of the *Gene Technology Act 2000* and the Gene Technology Regulations 2001
- Overview of the work of GTTAC, application processes and the mechanisms for providing advice to the Regulator
- Overview of the risk assessment methodology used by the Regulator.

Enquiries and Risk Assessment and Risk Management Plans

For all enquiries and to obtain copies of applications or RARMPs for dealings involving the intentional release of GMOs into the environment, please phone the OGTR on 1800 181 030. The RARMPs are also available electronically from our website at <www.ogtr.gov.au>

Gene Technology Technical Advisory Committee 11th June 2008, Canberra Communiqué for the 23rd meeting

This is the 23rd communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 33rd meeting of GTTAC, held on 11 June 2008.

GTTAC is a statutory advisory committee established under the *Gene Technology Act 2000* (the Act) to provide scientific and technical advice 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 advice from GTTAC on Risk Assessment and Risk Management Plans (RARMPs) prepared for licences to conduct dealings with genetically modified organisms (GMOs).

The purpose of this Communiqué is to provide a brief overview of the applications and RARMPs considered by GTTAC and, in accordance with Regulation 29 of the *Gene Technology Regulations 2001*, any resolutions 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) involve the limited and controlled release (field trial) of a GMO or a commercial (general) release of a GMO.

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

GTTAC Advice

The Regulator must seek GTTAC advice on the preparation of the RARMP for all applications, except for those that the Regulator has determined may be assessed as a 'limited and controlled' release (section 50A of the Act). The Regulator must seek GTTAC advice on RARMPs prepared in respect of all DIR applications

Advice on Consultation RARMP's

GTTAC considered the Consultation RARMPs prepared in response to the following applications:

DIR 079/2007—Limited and controlled release of banana genetically modified for disease resistance.

The purpose of the proposed trial is to conduct proof of concept research involving experiments with the GM banana lines to assess their development and disease response. The bananas would contain a nematode gene which is expected to confer disease resistance by preventing cells from undergoing apoptosis (programmed cell death) in response to infection by certain pathogenic micro-organisms. The GM bananas will not be used for human food or animal feed.

GTTAC discussed this proposed release and RARMP and advised the Regulator that:

- It is highly unlikely that the unintended release of viable *Agrobacterium* in the banana plants could lead to harm to the environment; and
- Consideration be given to the possibility that residual *Agrobacterium* may be present in the GM banana plants and whether any risk treatment measures (e.g. confirmation of absence of *Agrobacterium*) are warranted.

DIR 082/2007—Limited and controlled release of perennial ryegrass and tall fescue genetically modified for improved forage qualities.

The purpose of the proposed trial is to conduct proof of concept research involving experiments with GM perennial ryegrass and tall fescue lines to assess their agronomic performance and forage qualities under field conditions. Expression of the introduced genes is expected to improve forage qualities by altering fructan and lignin metabolism in these pasture grasses. GM plants will be transferred from the trial site to a PC2 glasshouse prior to flowering for controlled breeding experiments. Some seed will be saved for possible future trials which would be subject to further approval(s).

GTTAC considered the consultation RARMP for this application and advised the Regulator that:

- It agreed with the conclusions of the RARMP; and
- The proposed licence conditions are adequate to manage potential risks of the trial.

DIR 080/2007—Limited and controlled release of wheat genetically modified for drought resistance.

The purpose of the trial is to conduct proof of concept research, including continuing assessment of some wheat lines that were initially authorised for release under DIR 071/2006. The agronomic performance, including yield of the GM wheat lines will be evaluated under rain-fed, drought prone conditions. Seed and tissue samples will be collected and retained for analysis and possible future trials, subject to further approval(s). The GM wheat will not be used for human food or animal feed.

GTTAC considered the consultation RARMP for this application and advised the Regulator that consideration should be given to:

- Whether the use of a mechanical harvester is likely to lead to increased spread and persistence of the GMO compared with hand harvesting;
- Risks that might be posed by the dispersal of seed by wildlife or strong winds; and
- Risks that might be posed by gene flow from the GMOs to non-GM wheat breeding material.

DIR 083/2007—Limited and controlled release of cotton genetically modified for enhanced waterlogging tolerance.

The purpose of the proposed trial is to conduct proof of concept research involving experiments with the GM cotton lines to assess their agronomic performance and waterlogging tolerance under field conditions. Some seed will be saved for possible future trials which would be subject to further approval(s).

GTTAC considered the consultation RARMP for this application and advised the Regulator that:

- No additional events which could give rise to risks to the health and safety of people or the environment were identified; and
- The measures in the risk management plan are adequate to manage potential risks of the trial.

DIR 084/2008—Limited and controlled release of torenia genetically modified for enhanced phosphate uptake.

The principal purpose of the proposed release is to conduct proof of concept research involving experiments with three GM torenia lines to assess their capacity to absorb phosphate and slow or repress algal overgrowth in the surrounding water. The GM torenia plants will not be used for human food or animal feed.

GTTAC considered the consultation RARMP for this application and advised the Regulator that:

- Consideration should be given to whether additional risk treatment measures are necessary to prevent dissemination of plant material by birds or its dispersal from tanks into drains.

Other Advice:

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 facility where 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.

DNIR 438/2008—A Phase I safety study in subjects with severe Haemophilia B (Factor IX deficiency) using Adeno-Associated Viral vector to deliver the gene for human Factor IX into the liver combined with transient immunomodulation.

The application, which had been discussed at the previous GTTAC meeting, involves the use of a GM replication defective Adeno-associated viral vector in patients suffering from Hemophilia B, in combination with oral immunosuppressive therapy.

The proposed study will be conducted in conjunction with the ongoing clinical trial in the USA and aims to determine the safety, optimal dose and efficacy of intrahepatic administration of the AAV2 vector expressing human Factor IX (AAV2-hFIX16) to patients with severe Haemophilia B. In addition, patients will receive transient administration of oral immunosuppressants to prevent immune clearance of the vector and extend the period of expression of therapeutic levels of Factor IX. AAV2-hFIX16 will be produced in the USA and imported into Australia for this trial

GTTAC discussed this application and advised the Regulator that:

- No additional events which could give rise to risks to the health and safety of people or the environment had been identified; and
- The measures in the risk management plan are adequate to manage potential risks of the trial.

The applicant will conduct the trial as per the clinical trial CTN/CTX framework administered by the Therapeutic Goods Administration (TGA).

NB: Safety issues related to participants form part of the ethical and scientific review of clinical trials conducted by Human Research Ethics Committees prior to endorsement. In addition, the TGA may seek additional information and clarification about safety or other aspects of clinical trials that are notified as part of the CTN process.

Presentations

The following presentations were made to GTTAC:

- Example of a Contingency Plan for a DIR licence; and
- Regulatory interactions—an overview of the wider regulatory environment for clinical trials, and the role of the Gene Technology Regulator within that environment.

Enquiries and Risk Assessment and Risk Management Plans

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

APPENDIX 3

Gene Technology Ethics and Community Consultative Committee 27th & 28th May 2008, Canberra Communiqué for the 1st meeting

The Gene Technology Ethics and Community Consultative Committee (GTECCC) held its inaugural meeting in Canberra on 27th and 28th May 2008.

GTECCC is 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 independent *Statutory Review of the Gene Technology Act 2000* and the *Gene Technology Agreement* (the Review) conducted in 2005–06, recommended that the roles of the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC) be combined to form the GTECCC. The Review had also recommended that the functions of GTECCC include providing advice on community consultation in respect of the process for applications for licences covering dealings that involve the intentional release (DIR) of a genetically modified organism (GMO) into the environment, and risk communication matters in relation to those dealings.

The recommendations of the Review were given effect by the *Gene Technology Amendment Act 2007* which was passed in June 2007. The commencement date for the establishment of GTECCC was 1 January 2008. The terms for GTEC and GTCCC expired on 8 December 2007 and 30 June 2007 respectively.

The function of GTECCC is to provide advice to the Regulator (and the GTMC) on request, on issues of ethical or community concern relating to gene technology.

The purpose of this Communiqué is to provide a brief overview of the key matters considered by GTECCC at its inaugural meeting on 27th and 28th May 2008.

GTECCC's Work Plan

GTECCC reviewed the work done by its predecessors, GTEC and GTCCC, and agreed to continue work on the development of unfinished projects. The following were identified as the main objectives for GTECCC in the short term:

National Framework for the Development of Ethical Principles in Gene Technology (the Framework)

This document was produced by GTEC and is intended to provide guidance to Institutional Biosafety Committees and to stimulate debate and ethical reflection in the research community. GTECCC agreed that this remains an important project and that the review and further

development of the document should be a major focus for discussion at their next meeting.

The committee suggested that copies of the Framework be sent to coordinators of undergraduate biotechnology courses in Australia with a letter asking them to consider incorporating it into their course.

GTECCC noted that the OGTR was about to launch a Service Delivery Survey and asked that a question be added concerning awareness and use of the Framework.

Environmental Ethics and Gene Technology

A GTEC working group had prepared this discussion paper, which remained unfinished. GTECCC appointed a working group to develop the paper further.

Community Consultation

GTECCC reviewed the GTCCC discussion paper *Public Consultation: Community and Stakeholders* and agreed on some editorial changes to be made before the paper is published on the OGTR website. The committee noted that one of their functions is to provide advice to the Regulator on community consultation and risk communication matters and discussed the need to find out more about community attitudes to gene technology. The possibility of commissioning a survey will be explored further at the next meeting.

GTECCC and Relationships with Other Committees

The Committee received a report from the acting Gene Technology Regulator regarding the activities of the Office of the Gene Technology Regulator. Reports were also received from the committee's cross-members with the Gene Technology Technical Advisory Committee (GTTAC) and the Australian Health Ethics Committee (AHEC). It was agreed that the Animal Welfare Committee (AWC) should be invited to nominate an Observer to attend GTECCC meetings.

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

GLOSSARY

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	<i>Gene Technology Act 2000</i>
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 containment 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 <u>not</u> 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 GTECCC to assist them in the performance of their functions (expert advisers are not committee members)
EDD	Emergency dealing determination
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
GTECCC	Gene Technology Ethics and Community Consultative 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
Limited and controlled release	A type of DIR which meets certain criteria relating to limiting and controlling the dealings with the GMO (eg a field trial)
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