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

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 OCTOBER–31 DECEMBER 2008

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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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 October to 31 December 2008.

During this period I issued three licences for dealings involving intentional release of GMOs, three licences for dealings not involving intentional release of GMOs, and certified 87 physical containment facilities.

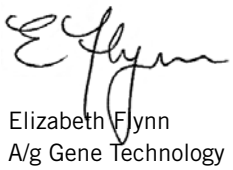
Routine monitoring activities for this quarter exceeded the target rate and no significant risks to either human health or the environment were identified.

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

- ASEAN Regional Workshop on Risk Assessment and Risk Management of LMOs/GMOs—20–22 November 2008, Dalat, Vietnam
- Conceptual Models to Predict the Probability of Introgression, Invasion and Impacts of GM and Non-Native Plants workshop—14–15 November 2008, Christchurch, New Zealand
- Global Commercial Pipeline of New GM Crops workshop—12–13 November 2008, Seville, Spain.

In November 2008 the 10th International Symposium on the Biosafety of Genetically Modified Organisms, in which OGTR was a co-sponsor, was held in Wellington, New Zealand. A number of OGTR staff attended and gave presentations. The feedback from these events indicates that the Australian gene technology regulatory system is highly regarded with many countries in our region looking to the OGTR for capacity building in the area of risk assessments for GMOs

Yours sincerely



Elizabeth Flynn
A/g Gene Technology Regulator

6 March 2009

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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 October to 31 December 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 communiqués 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 October to 31 December 2008 quarter were:

Licences and other instruments

- three licences issued for dealings involving the intentional release (DIR) of GMOs into the environment
- three licences issued for dealings not involving the intentional release (DNIR) of GMOs into the environment
- 87 physical containment facilities certified
- surrender of certifications of four certified facilities, one DIR, nine DNIR licences and three accredited organisations processed
- 80 variations processed.

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

Monitoring and Compliance

Approximately 17 percent of current field trial sites and eight 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 appropriate local councils during the evaluation of applications for all DIR licences.

For each application for a DIR licence other than a limited and controlled release, the Regulator is required to seek advice on matters relevant to the preparation of the Risk Assessment and

Risk Management Plan (RARMP), and must also seek comment on the RARMP itself once it is prepared. For each application for a limited and controlled release, the Regulator is 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 the Australian Government Environment Minister, and prescribed Australian Government authorities and agencies, 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.

During the quarter the Regulator sought advice in respect of 2 DIR applications.

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 in respect of two DIR 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. Two 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 the report outlines the regulatory activity undertaken during the 1 October to 31 December 2008 quarter. This includes information about applications for GMO licences and other instruments under the Act. This section 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 application. Then the timeframe for making a decision 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 making a decision.

- **Accreditations of organisations**

DIR and DNIR licences require organisations which conduct work with GMOs to be accredited. To achieve accreditation, the Regulator must be satisfied that the organisation has, or has access to, a properly constituted and resourced Institutional Biosafety Committee (IBC) and complies with the requirements of the Regulator's guidelines for accreditation. These applications have a statutory timeframe of 90 working days for making a decision.

- **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 making a decision.

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	6	3
Accreditations	3	3
Certifications	66	87

* *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 or not the application is a limited and controlled release
- considering the applicant's suitability to hold a licence, having regard to relevant convictions, revocations and suspensions of related licences and permits, and ability to meet conditions of the licence
- 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 proposed licence conditions to manage risks to human health and safety and the environment, and determining whether the proposed dealings may pose a significant risk
- 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 their 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 twelve months, and eight or nine months for limited and controlled releases, as they exclude weekends and public holidays observed in the Australian Capital Territory.

This time limit may be extended, that is, the clock may be 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 each of the one or two rounds of consultation that the Regulator must undertake during the processing of each DIR application. However, consultation periods longer than minimum timeframes 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*	Consultation on application	Consultation on RARMP	Licences issued
DIR 092	DIR 092	DIR 090	DIR 087	DIR 085/2008
DIR 093	DIR 093	DIR 091	DIR 089	DIR 086/2008
DIR 094				DIR 087
DIR 095				

* *Although not required under the Act, all new limited and controlled 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 092—Limited and controlled release of wheat genetically modified for altered grain composition—CSIRO
- DIR093—Limited and controlled release of wheat and barley genetically modified for altered grain starch composition—CSIRO
- DIR094—Limited and controlled release of wheat and barley genetically modified for enhanced nutrient utilisation efficiency—CSIRO
- DIR 095—Limited and controlled release of sugarcane genetically modified for improved drought tolerance, nitrogen use efficiency and sucrose and fermentable sugars accumulation and altered plant growth—BSES 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 the 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 090—Commercial release of roses genetically modified for altered flower colour—Florigene Limited
- DIR 091—Commercial release of cotton genetically modified for insect resistance (Widestrike Insect Protection cotton)—Dow AgroSciences Australia Pty Ltd

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.

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

- DIR 087—Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance—Bayer CropScience 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

Full copies of DIR applications can be obtained by contacting the OGTR. Summary information on DIR applications and full 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 licences

No DIR licence application was withdrawn during the quarter. One DIR licence was surrendered during the quarter:

- DIR 060/2005—Limited and controlled release of GM rose lines—Florigene Limited

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 timeframe for making a decision on an application.

No requests for further information were initiated in this quarter.

Decisions on applications for Dealings involving Intentional Release licences

Three DIR licences were issued during this quarter.

- DIR 085/2008—Limited and controlled release of cotton genetically modified for altered fatty acid composition of the cottonseed oil—CSIRO
- 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

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. 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 making a decision. 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 for variation received in relation to existing licences and other instruments, as well as the number of variations processed during the quarter.

Type	Number received	Number processed[1]
Surrender of certification	9	4
Surrender of DIR licence	1	1
Surrender of DNIR licence	6	9
Variation of certification	47	57
Variation of DIR licence	5	4
Variation of DNIR licence	13	19
Applications for CCI	6	4

[1] *Numbers reported in this quarter often relate to applications received in previous quarters. For the purposes of this table, 'processed' means that action on the authorisation was completed.*

Emergency Dealing Determinations

During this quarter the Regulator did not receive any requests for advice in relation to the making of any Emergency Dealing Determinations (EDD) and no EDDs were in effect.

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 confidential commercial 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 is available on the OGTR website.

During the quarter, the Regulator received six CCI applications in relation to DIR licence applications. The Regulator also made three CCI declarations in relation to DIR applications.

Monitoring and Compliance

The aim of OGTR monitoring and compliance activities is to ensure that 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 that those dealings are conducted in, as well as monitoring a minimum of 20 percent of PC2 large-scale, PC3 and PC4 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 October to 31 December 2008 quarter, six GM plant field trial sites under DIR licences were subject to monitoring visits.

- **Current field trial sites:** Of the 17 sites current in the quarter, three were monitored. This represents a monitoring rate of 17 percent of all current sites for the quarter
- **Post-harvest field trial sites:** Of the 39 sites subject to post-harvest monitoring in the quarter, three were monitored. This represents a monitoring rate of eight percent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection to contained dealings covered three organisations and four PC facilities. Monitoring of PC facilities encompassed two PC2 laboratories, one PC2 animal containment facility and one PC2 large-scale facility.

Monitoring of contained dealings: During the quarter, the monitoring of the four PC 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.

Two 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 October to 31 December 2008.

Licensed Organisation Name	Licence Number	No. sites visited	Site status*	Crop type
CSIRO, Australian Capital Territory	DIR 054/2004	1	PHM	Wheat
Department of Primary Industries—Victoria, Victoria	DIR 080/2007	2	C	Wheat
The University of Adelaide	DIR 077/2007	1	PHM	Wheat
Bayer CropScience Pty Ltd	DIR069/2006	2	PHM,C	Canola
Totals		**6**	**C = 3 PHM = 3**	**2 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 October to 31 December 2008.

Licensed Organisation Name	Licence Number
EnGeneIC Pty Ltd, New South Wales	DNIR 261/2003
University of Canberra, Australian Capital Territory	DNIR 389/2006
Total	**2 DNIR licences**

Monitoring of Physical Containment Facilities

The organisations and the facility types the OGTR visited during the 1 October to 31 December 2008 quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
Menzies School of Health Research, Northern Territory	PC3 laboratory	1
Department of Primary Industries Fisheries and Mines, Northern Territory	PC3 laboratory PC3 arthropod	1 1
Charles Darwin University, Northern Territory	PC2 laboratory	3
Progen Industries Limited, Queensland	PC2 large-scale	1
EnGeneIC Pty Ltd, New South Wales	PC2 laboratory	1
University of Canberra, Australian Capital Territory	PC2 laboratory PC2 animal containment	1 1
Total	**5 facility types**	**10**

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 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
- 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 was one finding of non-compliance for DIRs for the 1 October to 31 December 2008 quarter.

Organisation	CSIRO
Licence number and site	DIR054/2004 Site 1
Summary of dealing	Field trial of genetically modified wheat with altered grain starch and antibiotic resistance.
Findings	During inspection activities it was identified that the Licence Holder had not provided the post-harvest monitoring reports for this site to the Regulator for the previous three months prior to inspection i.e. for the period of July–September 2008.
Assessment	CSIRO had conducted post-harvest monitoring as required and had kept records of that monitoring. CSIRO have since taken action to ensure the reports are provided to the Regulator. Risks to human health, safety and environment were assessed as negligible.
Compliance management	CSIRO is to monitor the site and provide inspection findings to the Regulator every month according to post harvest monitoring requirements as outlined in the Licence.

Findings for Dealings Not involving Intentional Release

There were no findings of non-compliance for DNIRs for the 1 October to 31 December 2008 quarter.

Findings for Physical Containment Facilities

The OGTR's monitoring of certified PC 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.

	Non-Compliance Issue					
Number of PC Facilities inspected	Structure	PPE[1]	Equipment	Waste disposal	Work practices[2]	Transport
10	2	0	0	0	1	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 or not practices being used pose potential human health or environmental risks that require management actions to be implemented. In certain instances, where a suspected non-compliance with the Act is identified, the issue may be referred for investigation.

There were no practice reviews completed in the 1 October to 31 December 2008 quarter.

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 or not procedures and practices provide mechanisms to identify and resolve emerging risks
- 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 (e.g. 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 October to 31 December 2008 quarter.

Investigations

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

There were no investigations completed in the 1 October to 31 December 2008 quarter.

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:

- 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. Senator McLucas appointed Professor Brian Priestly as a member of GTTAC in November 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 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.

GTTAC met once during this quarter, on 15 October 2008. The communiqué is at Appendix 2.

During this quarter GTTAC members were also invited to comment on the draft revised OGTR Risk Analysis Framework out-of-session.

Further information about the work of GTTAC is available from the OGTR website <www.ogtr.gov.au/committee/gttac>

Gene Technology Ethics and Community Consultative Committee

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 did not meet during this quarter.

Further information about GTECCC is available from the OGTR website <www.ogtr.gov.au/committee/gteccc>

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 deal with the regulation of gene technology and with agencies 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 participation in and presentation to:

- ASEAN Regional Workshop on Risk Assessment and Risk Management of LMOs/GMOs—20–22 November 2008, Dalat, Vietnam
- Conceptual Models to Predict the Probability of Introgression, Invasion and Impacts of GM and Non-Native Plants workshop—14–15 November 2008, Christchurch, New Zealand
- Global Commercial Pipeline of New GM Crops workshop—12–13 November 2008, Seville, Spain.

In November 2008 the 10th International Symposium on the Biosafety of Genetically Modified Organisms, in which OGTR was a co-sponsor, was held in Wellington, New Zealand. A number of OGTR staff attended and gave presentations.

Advice on gene technology regulation

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

During the quarter the OGTR provided presentations to the following:

- Society for Risk Analysis Conference—29 September–1 October 2008, Canberra, ACT
- Australian Institute of Agricultural Science and Technology/NSW Weed Society meeting, 12 November, Sydney, NSW
- Weed Risk Management Workshop—16–17 December 2008, Melbourne, Victoria.

The office also attended the following meetings/conferences:

- Agriculture in Climate Change—3 September 2008, Canberra, ACT
- ComBio—22–25 September 2008, Canberra, ACT
- BSES & CSIRO Sugarcane Projects—23 October 2008, Canberra, ACT
- Technical subcommittee meeting to review Australian Standards, Safety in Laboratories—Microbiology—19–20 November 2008, Melbourne, Victoria.

The OGTR also received visitors and presentations from:

- New Zealand Environmental Risk Management Authority—2–3 October
- Embrapa, Brazil Agricultural Research Corporation—25 November

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 comprised of the then Department of Agriculture, Fisheries and Forestry; the Department of the Environment and Heritage; Department of Foreign Affairs and Trade; Department of Education, Science and Training; Department of Industry, Tourism and Resources; Department of Health and Ageing; FSANZ; 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 continued development of the next stage which is to expand the program to involve additional companies and to broaden the reach of the program across additional segments of the industry.

OGTR website usage and statistics

The OGTR 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 October to 31 December 2008 quarter.

MONTH	HITS[1]	VISITORS[2]
October	201,156	20,019
November	184,453	17,474
December	179.223	13,004

DAY OF THE WEEK PATTERN FOR THE QUARTER	HITS [1]	VISITORS[2]
Sunday	45,081	5,286
Monday	86,917	7,060
Tuesday	93,208	7,434
Wednesday	90,934	7,756
Thursday	89,091	7,364
Friday	92,603	7,280
Saturday	67,008	5,725

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 times the OGTR website has been visited

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

- About the OGTR
- GMO Record
- What's New
- Intentional Release and Evaluation Process
- Publication and Forms—Certification of Physical Containment Facilities
- Guidelines
- Home Page

- Legislation
- Classes of dealings involving Genetically Modified Organisms
- IBC & Accredited Organisations Information

The most popular downloaded documents were:

- Risk Analysis Framework
- The Biology and Ecology of Pineapple (*Ananas comosus var. comosus*) in Australia
- The Biology and Ecology of Cotton (*Gossypium hirsutum* L.) in Australia
- The Biology of Carica papaya L. (*papaya, papaw, paw paw*) in Australia
- The Biology and Ecology of Rice (*Oryza sativa* L.) in Australia
- Mapping Protocol July 2007
- The Biology and Ecology of Carnation (*Dianthus caryophyllus* L.) in Australia
- The Biology and Ecology of Rose (*Rosa x hybrida*) in Australia
- The Biology of the Sugarcane (*Saccharum spp.*) 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
October	123	89
November	108	111
December	130	79

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 128 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 178 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 1033 emails during the quarter.

APPENDICES

APPENDIX 1

DNIR licences issued 1 October to 31 December 2008

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR-449	6 November 2008	Peter MacCallum Cancer Centre, VIC	Phase I study of autologous T lymphocytes with an anti LeY chimeric receptor gene for patients with Multiple Myeloma, AML or high-risk MDS	Analysis of the safety and efficacy of autologous administration of genetically modified T-lymphocytes expressing an anti-Lewis Y antibody for the treatment of cancer in patients enrolled in a Phase I clinical trial
DNIR-451	10 December 2008	Children, Youth and Women's Health Service, SA	Expression of lysosomal enzymes and shRNA from a lentiviral vector and gene therapy for MPS	Development of gene therapies for the treatment of lysosomal storage diseases using lentiviral vectors
DNIR-452	22 December 2008	The University of Queensland, QLD	Genome wide knockdown of mRNA transcripts at the level of the cell	Use of replication defective lentiviral vectors encoding gene silencing constructs to study gene expression in mammalian cells *in vitro*

APPENDIX 2

Gene Technology Technical Advisory Committee
15 October 2008, Canberra
COMMUNIQUÉ

This is the 24th communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 34th meeting of GTTAC, held on 15 October 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 Applications

GTTAC considered the following commercial release applications:

DIR 090—Commercial release of rose genetically modified for altered flower colour

The application, from Florigene Pty Ltd, involves the commercial release of a Hybrid Tea Rose genetically modified to alter flower colour from pink to purple/blue. GTTAC noted that Florigene propose to licence only one grower to supply cut flowers through the normal commercial distribution chain, but that it would be possible for home gardeners to propagate the GM rose from cut flower stems and that it may be grown in gardens throughout Australia.

GTTAC advised the Regulator that the risk assessment should be done on the assumption that, if released commercially, the GM rose would be widely grown in home gardens. The committee also advised that, although there is potential for exposure of humans and animals to products derived from the GM flowers, but that no issues were identified which might give rise to adverse outcomes.

DIR 091—Commercial release of Widestrike™ Insect Protection cotton.

Dow AgroSciences have applied to release GM cotton into the Australian environment without specific containment measures south of latitude 22° South. The GM cotton contains two genes that have been shown to provide resistance to lepidopteran pests of cotton plants.

GTTAC noted that the GM cotton also contained a gene which may confer tolerance to specific herbicides and suggested that more information should be sought about the level of tolerance expressed under field conditions. GTTAC advised the Regulator that the following items should be considered in the development of the RARMP:

- The specificity of the combination of the two Cry proteins in the GM cotton and potential toxicity to non-target organisms under Australian conditions;
- The tolerance to glufosinate ammonium, conferred by the presence of two full length copies of the *pat* gene and risks that may be associated with this trait;
- The potential for unintended presence of the GM cotton in areas north of latitude 22° South and the possible impacts of any unintended presence north of this latitude; and
- The impact of this GM cotton if crossed with other previously commercially approved GM cotton lines which have insect resistance and herbicide tolerance traits (DIRs 062/2005 and 066/2006).

Advice on Consultation RARMPs

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

DIR 079/2007—Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance.

GTTAC considered the consultation RARMP prepared in response to an application from Bayer CropScience Pty Ltd for a limited and controlled release of cotton to take place at one site in the Narrabri area of New South Wales.

GTTAC advised the Regulator that the consultation RARMP adequately identifies and addresses risks to human health and safety and risks to the environment from the proposed release.

DIR 085—Limited and controlled release of cotton genetically modified for altered fatty acid composition of the cottonseed oil

GTTAC considered the consultation RARMP prepared in response to an application from CSIRO for a limited and controlled release of one line of cotton genetically modified for altered fatty acid composition of the cottonseed oil. The proposed site is in the Narrabri area of New South Wales.

GTTAC discussed the possibility that the altered fatty acid profile of the cottonseed may lead to changes in the dormancy or germination potential of the GM cotton, and concluded that the proposed licence conditions are adequate. GTTAC advised the Regulator that the consultation RARMP adequately identifies and addresses risks to human health and safety and risks to the environment.

DIR 086—Limited and controlled release of maize genetically modified to investigate gene function

GTTAC considered the consultation RARMP prepared in response to an application for a limited and controlled release of 11 GM maize lines at a CSIRO research facility in the Australian Capital Territory.

GTTAC advised the Regulator that the consultation RARMP adequately identifies and addresses risks to human health and safety and risks to the environment.

DIR 089—Limited and controlled release of white clover genetically modified to resist infection by Alfalfa mosaic virus

GTTAC considered the consultation RARMP prepared in response to an application from the Victorian Department of Primary Industries for a limited and controlled release of one line of white clover genetically modified to resist infection by Alfalfa mosaic virus (AMV). The trial is proposed to take place in the Corowa area of New South Wales.

GTTAC advised that more information is needed about the extent to which AMV limits growth of white clover in non-agricultural environments.

Out of Session Advice

GTTAC noted that Out of Session advice had been provided on the following consultation RARMPs:

- DIR 078—Limited and controlled release of sugarcane genetically modified for altered sugar production; and
- DIR 081—Limited and controlled release of cotton genetically modified for enhanced water use efficiency.

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 449—Phase 1 study of autologous T lymphocytes with an anti LeY chimeric receptor gene for patients with Multiple Myeloma, Acute Myeloblastic Leukaemia or high-risk Myelodysplastic Syndrome

GTTAC considered the RARMP prepared in response to an application to conduct a Phase 1 clinical trial involving six patients. The trial would test the safety and efficacy of GM T-lymphocytes for the treatment of tumours in patients with Multiple Myeloma, Acute Myeloblastic Leukaemia or high-risk Myelodysplastic Syndrome.

GTTAC advised the Regulator:

- to seek clarification of the exclusion criteria for the trial, particularly with reference to female patients of childbearing age;
- that the GM cells should be screened to exclude replication competent virus before administration to patients.

GTTAC noted that 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 clinical trial participants form part of the ethical and scientific review conducted by Human Research Ethics Committees. 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/CTX process.

Enquiries and Risk Assessment and Risk Management Plans

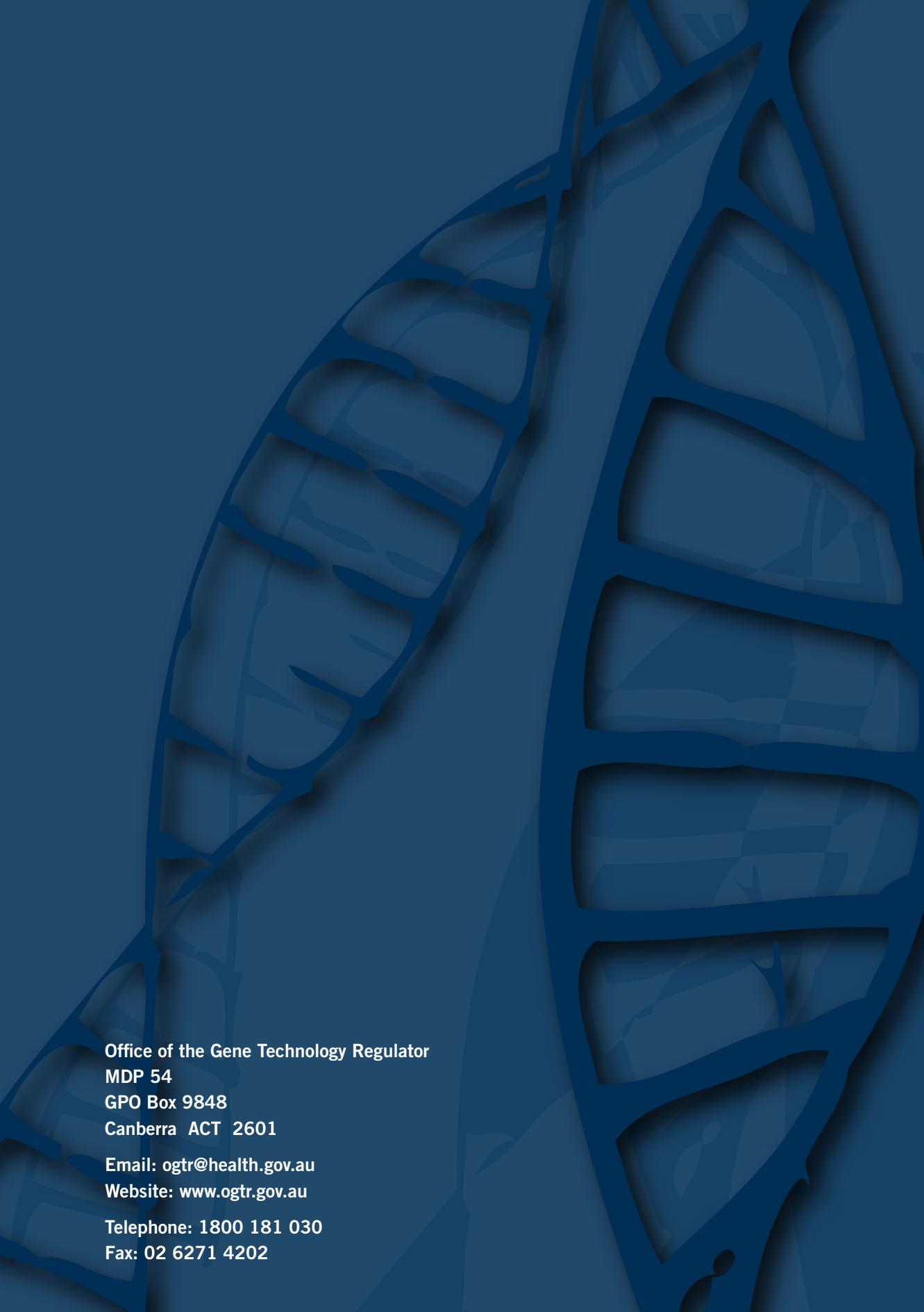
For all enquiries and to obtain copies of applications or RARMPs for dealings involving the intentional release of GMOs into the environment, please phone the OGTR on 1800 181 030. The RARMPs are also available electronically from our website at <www.ogtr.gov.au>

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	*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 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 (e.g. field trial or commercial release)
DIR licence	A licence for a dealing involving intentional release of a GMO into the environment
DNIR	A contained dealing with a GMO not involving intentional release of the GMO into the environment (e.g. 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
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 (e.g. 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



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