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 2009

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

'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 genetically modified organisms'

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The Hon Mark Butler MP
Parliamentary Secretary for Health
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 2009.

During this period two licences for dealings involving intentional release of GMOs and seven licences for dealings not involving intentional release of GMOs were issued, and 64 physical containment facilities were certified.

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

Yours sincerely

Dr Joe Smith
Gene Technology Regulator

16 February 2010

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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.

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 2009 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.

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 2009 quarter were:

Licences and other instruments

- two licences issued for Dealings involving the Intentional Release (DIR) of GMOs into the environment
- seven licences issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- 64 physical containment facilities certified
- surrender of one accreditation, 21 certifications, one DIR licence and three DNIR licences
- approval of applications for variation of three accreditations, 70 certifications, 10 DIR licences and 16 DNIR licences.

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

Monitoring and Compliance

Approximately nine percent of current field trial sites and 13 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.

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 one DIR RARMP.

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. One invitation to the public to comment on a RARMP was 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 2009 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 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	2
DNIR licence	7	7
Accreditations	4	3
Certifications	47	64

* *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	Consultation on application	Consultation on RARMP	Licences issued
DIR 099	DIR 098	DIR 097	DIR 091
DIR 100			DIR 096
DIR 101			
DID 102			

Applications received for Dealings involving Intentional Release licences

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

- DIR 099—Limited and controlled release of wheat and barley genetically modified for altered grain composition or nutrient utilisation efficiency—CSIRO
- DIR 100—Limited and controlled release of wheat genetically modified for enhanced carbon assimilation in drought and heat prone environments—CSIRO
- DIR 101—Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance—Monsanto Australia Limited
- DIR 102—Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance—The University of Adelaide.

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 RARMP for the following application:

- DIR 098—Commercial release of a genetically modified live viral vaccine to protect against Japanese encephalitis (IMOJEV™)—Sanofi Pasteur Pty Ltd.

One invitation to comment on a RARMP was issued during the quarter:

- DIR 097—Limited and controlled release of a genetically modified vaccine for prevention of selected childhood respiratory diseases—PPD Australia Pty Ltd.

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 applications were withdrawn during the quarter.

One DIR licence was surrendered during the quarter:

- DIR 065/2006—Limited and Controlled Release of Insect Resistant Genetically Modified Cotton—Monsanto Australia 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.

Two requests for further information were initiated in this quarter:

- DIR 091—Commercial release of cotton genetically modified for insect resistance (Widestrike Insect Protection cotton)—Dow AgroSciences Australia Pty Ltd
- DIR 101—Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance—Monsanto Australia Limited.

Decisions on applications for Dealings involving Intentional Release licences

Two DIR licences were issued during this quarter.

- DIR 091—Commercial release of cotton genetically modified for insect resistance (WideStrike™ Insect Protection Cotton)—Dow AgroSciences Australia Pty Ltd
- DIR 096—Limited and controlled release of sugarcane genetically modified for herbicide tolerance—BSES Limited.

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

Decisions on applications for Dealings Not involving Intentional Release licences

These dealings must be conducted in appropriate containment facilities and the dealings must not involve intentional release of a GMO into the environment.

Seven DNIR licences were issued during the quarter.

- DNIR 467—The role of LIMK1 and its interacting proteins in cancer metastasis—St Vincent's Institute of Medical Research, Victoria
- DNIR 468—Investigation of malaria parasite proteins—Queensland Institute of Medical Research, Queensland
- DNIR 469—Complementation of Mycobacterium spp and Streptomyces spp with genes required for the synthesis of mycolactones—The University of Melbourne, Victoria
- DNIR 470—Pathogenesis in Staphylococcus aureus—The University of Melbourne, Victoria
- DNIR 471—Adeno-associated virus expression of immunosuppressive genes in rodent livers—The University of Sydney, New South Wales
- DNIR 472—Vector competence studies on selected flavivirus mutants—The University of Queensland, Queensland
- DNIR 473—Cardiovascular reactivity to stress: role of redox signaling in the hypothalamus and brainstem—The University of Melbourne, Victoria.

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 he 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. Applications for variation to licences 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/instrument to another person or consent to the surrender of a licence/instrument request by a licence/instrument holder.

The following table describes the number and type of applications for variation and surrender received in relation to existing licences and other instruments, as well as the number of variations and surrenders approved during the quarter.

Type	Number received	Number approved*
Surrender of accreditation	1	1
Surrender of certification	22	21
Surrender of DIR licence	1	1
Surrender of DNIR licence	2	3
Variation of accreditation	2	3
Variation of certification	65	70
Variation of DIR licence	5	10
Variation of DNIR licence	18	16

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

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 five CCI applications in relation to DIRs and one CCI application in relation to a DNIR. The Regulator made one CCI declaration during the quarter in relation to a DIR.

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 Notifiable Low Risk Dealings (NLRD).

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored: During the 1 October to 31 December 2009 quarter, seven GM plant field trial sites under DIR licences were subjected to monitoring visits.

- **Current field trial sites:** Of the 22 sites current in the quarter, two were monitored. This represents a monitoring rate of nine percent of all current sites for the quarter.
- **Post-harvest field trial sites:** Of the 40 sites subject to post-harvest monitoring in the quarter, five were monitored. This represents a monitoring rate of 13 percent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection to contained dealings covered four organisations and nine PC facilities. Monitoring of PC facilities encompassed four PC2 laboratories, one PC2 animal containment facility, three PC3 laboratories and one PC3 animal containment facility.

Monitoring of contained dealings: During the quarter, the monitoring of the nine 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.

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 October to 31 December 2009.

Licensed Organisation Name	Licence Number	No. sites visited	Site status*	Crop type
Monsanto Australia Limited, New South Wales	DIR 064/2006	2	PHM	Cotton
The University of Adelaide, South Australia	DIR 077/2007	1	Current	Wheat and Barley
Bayer CropScience Pty Ltd, Victoria	DIR 032/2002	1	PHM	Canola
	DIR 057/2004	1	PHM	Indian Mustard and Canola
	DIR 069/2006	2	1 Current/ 1 PHM	Indian Mustard and Canola
Totals		**7**	**C = 2 PHM = 5**	**5 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 2009.

Licensed Organisation Name	Licence Number
Children, Youth and Women's Health Service, South Australia	DNIR 431
Central Northern Adelaide Health Service, South Australia	DNIR 107/2002
The University of Queensland, Queensland	DNIR 180/2003
Xenome Ltd, Queensland	DNIR 165/2002
Total	**4 DNIR licences**

Monitoring of Physical Containment Facilities

The organisations and the facility types the OGTR visited during the 1 October to 31 December 2009 quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
Children, Youth and Women's Health Service, South Australia	PC2 animal containment	1
	PC2 laboratory	1
Central Northern Adelaide Health Service, South Australia	PC2 laboratory	1
	PC3 animal containment	1
	PC3 laboratory	1
Griffith University, Queensland	PC3 laboratory	1
Royal Children's Hospital and Health Service District, Queensland	PC3 laboratory	1
The University of Queensland, Queensland	PC2 laboratory	1
Xenome Ltd, Queensland	PC2 laboratory	1
Total	**4 facility types**	**9**

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 were two findings of non-compliance for DIRs for the 1 October to 31 December 2009 quarter.

Organisation	The University of Adelaide
Licence number	Dir 077/2007, Site 1
Summary of dealing	Limited and controlled release of wheat and barley genetically modified for enhanced tolerance to abiotic stresses or increased beta glucan
Findings	During a routine monitoring inspection OGTR inspectors were notified by The University of Adelaide that they had transported leaf disc samples of GM plant material from the trial location to a facility, for analysis work. This facility was later identified as one that is neither a PC 2 certified facility nor a facility approved in writing by the Regulator, a requirement under DIR 077/2007 licence conditions.
Assessment	The University of Adelaide transported the GM leaf disc samples to an uncertified facility under the mistaken belief that non-viable plant material could be analysed in a facility of their choice. These samples were however transported in accordance with the OGTR *Guidelines for the Transport of GMOs* as current at the time of transportation. OGTR informed The University of Adelaide that regardless of the samples being viable or not, they still constitute Plant Material and in either case analytical work on these samples must be conducted in a PC2 certified facility or any facility approved in writing by the Regulator. Risks to human health, safety and environment were assessed as negligible.
Compliance management	The University of Adelaide were reminded of their obligation to ensure that all analytical work on Plant Material collected from the trial location (whether GM or non-GM and viable or non-viable) must be conducted only in a PC2 certified facility or a facility approved in writing by the Regulator. Given the corrective action already agreed to and initiated by The University of Adelaide in addressing this non-compliance, no further action is required.

Organisation	BSES Limited
Licence number	DIR 070/2006: All Sites
Summary of dealing	Limited and controlled release of GM sugarcane with altered plant architecture, enhanced water or improved nitrogen use efficiency.
Findings	During routine administrative management of this licence by OGTR, it was found BSES Ltd have not been appropriately destroying GM plant material obtained from harvest and GM plant material had not been destroyed as soon as practicable as required in the licence. Transport of GM plant material was not conducted in accordance with the OGTR Guidelines for the Transport of GMOs as current at the time of transportation. It was also noted by OGTR that the Licence Holder had not provided sufficient prior notification of harvest for Site 3.
Assessment	BSES stated that, in order to destroy harvested sugarcane, the material was cut into small "sett" pieces then deposited these in a waste dump area for subsequent burning. The intended burning was delayed significantly due to environmental constraints imposed on BSES by fire regulations and high water content in the cane material. BSES records indicate that there were only 10 germinations from a deposit of approximately 40,000 setts in the waste dump area. The volunteers that had germinated were destroyed with herbicide spray immediately. Although transport was not conducted in accordance with OGTR Guidelines for the Transport of GMOs, BSES claimed that accountability of GM plant material was maintained during transport by way of bar code scanning at origin and destination. In addition, the transport route was inspected by BSES personnel to ensure that no material was lost during transportation. Whilst appropriate harvest notification had originally been provided, the harvest date was advanced to avoid damage to the GM crop from an expected rainfall event on the initially planned harvest date. Risks to human health, safety and environment were assessed as negligible for all issues.
Compliance management	BSES Ltd was reminded of their obligation to ensure that all harvested plant material must be destroyed such that it is rendered non-viable. Similarly, BSES was reminded to transport GM plant material in accordance with licence conditions. BSES was also reminded to provide to OGTR notifications as required by the licence. Given the corrective action taken by BSES in addressing these non-compliances, no further action is required.

Findings for Dealings Not involving Intentional Release

There was one finding of non-compliance for DNIRs for the 1 October to 31 December 2009 quarter.

Organisation	Xenome Ltd
Licence number	DNIR 165/2002
Summary of dealing	Isolation and Characterisation of Venom Peptide Genes
Findings	At the time of the inspection OGTR staff noted that Xenome Ltd staff that had carried out work under Licence DNIR 165/2002 had not signed a statement indicating that the licence holder had informed them of the conditions of the licence that apply to that person.
Assessment	Staff had been trained in the obligations imposed on them by the conditions of the licence and Xenome Ltd has a good compliance history. The risks to human health and safety and the environment have been assessed as negligible.
Compliance management	Xenome Ltd was reminded of the requirement to have signed statements from each person covered by the licence acknowledging that the licence holder has informed the person of the conditions of the licence that apply to that person.

Findings for Physical Containment Facilities

The OGTR's monitoring of certified PC facilities in the quarter found a small number of minor 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
9	1	0	2	1	1	1

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 2009 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 2009 quarter.

Investigations

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

consequence of monitoring by the OGTR, self-reporting by an accredited organisation or by third party reporting.

There was one investigation completed in the 1 October to 31 December 2009 quarter.

Organisation	Queensland Insitute of Medical Resarch (QIMR)
Issue	QIMR IBC made a self-report concerning a possible non-compliance occurring in relation to an unauthorized notifiable low risk dealing (NLRD) being undertaken by QIMR researchers. The incident was reported to the OGTR following an IBC review of a needle stick injury.
Findings	The matter was investigated by the OGTR Compliance and Investigations Section. The investigation concluded that: • there was no risk to the health and safety of people and the environment • the laboratory head responsible for ensuring the administration of the research failed to ensure that the dealing was current and that the dealing had appropriate QIMR IBC assessment as required under Regulations • the researcher involved in the needle stick injury did not ensure that the dealing undertaken held approval as a current NLRD • there was no deliberate intent to avoid compliance on the part of the QIMR researchers involved, rather an administrative deficiency on the lapsing of approved NLRDs and the need for the supervisor to follow correct QIMR procedural requirements and provide forms to the IBC for assessment.
Determination	• Both the researchers involved have been interviewed and have both been cautioned to adhere to the requirements under the Act and Regulations. • QIMR has also been requested by the Regulator to undertake a number of actions to rectify compliance management arrangements to ensure that a similar event does not occur in future. • The general operating systems used by QIMR were sufficient and adequate in the operational requirements of the *Gene Technology Act 2000* and the Gene Technology Regulations 2001.
Action	The researchers have submitted an updated NLRD to the QIMR IBC and have undertaken to ensure future compliance with the requirements of the Act and Regulations. The OGTR Compliance and Investigation Section will undertake a future audit of QIMR to verify outcomes of the Regulator's requirements and to assist and provide guidance on making such improvements.

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 (GTTAC)
- Gene Technology Ethics and Community Consultative Committee (GTECCC).

Appointments to the two gene technology advisory committees were made by the then 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 the quarter, on 14 October 2009. The communiqué is at Appendix 1.

Further information about the work of GTTAC is available from the OGTR website www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gttac-2

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 the quarter.

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

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 or presentation to:

- The International Conference on Knowledge Management in Agricultural Biotechnology: The Asian Experience, 1–2 October 2009, Bangkok, Thailand
- The Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management under the UN Cartagena Protocol on Biosafety (Biosafety Protocol), 10–14 October 2009, The Hague, Netherlands
- The 23rd Session of the Organisation for Economic Cooperation and Development (OECD) Working Group on Harmonisation of Regulatory Oversight in Biotechnology (WGHROB), 19–21 October 2009, Paris, France
- GMO Risk Assessment Workshop for Malaysian Genetic Manipulation Advisory Committee, 4–6 November 2009, Kuala Lumpur, Malaysia
- Risk Assessment Workshop on Transgenic Trees, 7–9 December 2009, Kuala Lumpur, Malaysia

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.

As part of an ongoing program, the Regulator met with stakeholders in Hobart and Western Australia. On 12 October the Regulator also presented at the Western Australia Department of Agriculture and Food Forum on GMOs in Western Australia.

During the quarter the OGTR provided a presentation at the following:

- International Society for Cellular Therapy Workshop, 16–18 October 2009, Adelaide

OGTR officers also attended the following meetings/conferences:

- Systems Applications and Products Business Intelligence Conference, 19–20 October 2009
- Genetically Modified Crops Coexistence Conference, 9–12 November 2009
- Food, Biotechnology and the New Consumer 2009 Forum, 12 November 2009
- The Genomics of Salinity Conference, 16–18 November 2009
- Biosecurity and the New Bioeconomy, 19–21 November 2009
- National Weed Risk Management Forum, 21–22 November 2009
- Australian College of Toxicology and Risk Assessment Annual Meeting, 4 December 2009
- Combio 2009, 6–10 December 2009.

The OGTR also received visitors and presentations from:

- Dr Harvey Glick, Monsanto, 27 October 2009
- Dr Wada, Japanese Institute for Future Technology, 24 November 2009
- All China Federation of Supply and Marketing Co-operatives, 25 November 2009.

Reviews

During the quarter the OGTR commenced work on revising the *Guidance Notes for the Containment of Exempt Dealings* and began a review of the *Requirements for Physical Containment Level 2 (PC2) Constant Temperature Rooms*, which were issued on 7 August 2003.

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 2009 quarter.

MONTH	HITS[1]	VISITS[2]
October	214,000	39,892
November	136,268	24,264
December	119,106	24,912

DAY OF THE WEEK PATTERN FOR THE QUARTER	HITS [1]	VISITS[2]
Sunday	41,123	11,301
Monday	67,778	12,639
Tuesday	75,052	13,167
Wednesday	71,130	12,729
Thursday	77,036	14,091
Friday	84,405	12,494
Saturday	52,850	11,218

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

2 'Visits' is the number of times the OGTR website has been visited

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

- What's New
- List of applications and licences for Dealings involving Intentional Release (DIR) of GMOs into the environment
- Record of GMOs and GM Product Dealings
- About the OGTR
- Guidelines and Forms for Certification of Physical Containment Facilities
- Licence Application and Assessment Process

- IBC & Accredited Organisations Information
- Annual and Quarterly Reports
- Classes of dealings involving Genetically Modified Organisms (GMOs)
- Fact Sheets

The most popular downloaded documents were:

- *Risk Analysis Framework*
- The Biology and Ecology of Cotton *(Gossypium hirsutum L.)* in Australia
- The Biology and Ecology of Rice *(Oryza sativa)* in Australia
- The Biology and Ecology of Papaya *(Carica papaya)* in Australia
- The Biology and Ecology of Pineapple *(Ananas comosus var. comosus)* in Australia
- PC2 Laboratory guidelines
- The Biology and Ecology of Sugarcane *(Saccharum spp.)* in Australia
- The Biology and Ecology of Rose *(Rosa x hybrida)* in Australia
- The Biology of Carnation *(Dianthus caryophyllus)* in Australia
- The Biology and Ecology of Italian Ryegrass *(Lolium multiflorum)* 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	125	136
November	92	146
December	60	99

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 117 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 142 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 406 emails during the quarter.

APPENDIX

APPENDIX 1:

Gene Technology Technical Advisory Committee COMMUNIQUÉ No. 26

This is the 26th communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 36th meeting of GTTAC, held on 14 October 2009.

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 in respect of applications 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 RARMPs prepared in respect of all DIR applications.

The Regulator must also seek GTTAC advice during the preparation of the RARMP for all DIR applications which are **not** assessed as 'limited and controlled' under Section 50A of the Act.

1. Advice on Consultation RARMP—Commercial Release

GTTAC considered the consultation RARMP prepared in response to the following commercial release application:

DIR 091—Widestrike™ Insect Protection Cotton

The application, from Dow AgroSciences, involves the commercial release of genetically modified Widestrike™ cotton into the Australian environment south of latitude 22ºS without specific containment measures. GTTAC noted that they had previously provided advice to the Regulator on this application prior to the development of the RARMP, as required for commercial releases.

RESOLUTION: *GTTAC advised the Regulator:*

– that the identified risks had been adequately characterised and assessed in the RARMP prepared for this application;

– that they supported the Post Release Review measures proposed in the RARMP; and

– that they did not identify any additional information that should be considered.

2. Advice on Licence Application—Commercial Release

GTTAC considered the following commercial release application:

DIR 098—GM live viral vaccine to protect against Japanese encephalitis (IMOJEV™)

Sanofi Pasteur Ltd have applied for a licence to release a live GM viral vaccine as a prescription medicine. GTTAC noted that an application had also been made to the Therapeutic Goods Administration (TGA) to include IMOJEV™ on the Australian Register of Therapeutic Goods (ARTG) as a prescription medicine, and that they would be assessing data on the quality, safety and efficacy of the GM vaccine for use in humans. The TGA had requested advice from the Regulator to inform its assessment of IMOJEV™. Members noted that this was the first application received by the OGTR for a live recombinant viral vaccine and that the TGA would play a key role in the assessment of any risks to human safety.

RESOLUTION: *GTTAC advised the Regulator that the following matters should be taken into account in the development of the RARMP for DIR 098:*

– *the potential for transmission of the GM vaccine to people, animals and insects;*

– *the potential for viral recombination with wild type flavivirus.*

GTTAC advised the Regulator that, in advising the TGA with regard to DIR 098, he should consider that:

- *There is very limited potential for transmission of the GM vaccine to people, animals and insects;*
- *Viral recombination with wild type flavivirus is highly unlikely to occur.*

3. Advice on Consultation RARMPs—Limited and Controlled Release

GTTAC considered the Consultation RARMPs prepared in response to the following applications for limited and controlled releases:

3.1 DIR 096—Limited and controlled release of sugarcane genetically modified for herbicide tolerance

GTTAC noted that the application from BSES involved the intentional release of up to 6,000 lines of sugarcane genetically modified for herbicide tolerance on a limited scale and under controlled conditions. The trial was proposed to take place at six locations in Queensland on a maximum of 26 hectares between November 2009 and November 2015.

RESOLUTION: *GTTAC agreed that the RARMP for DIR 096 adequately identifies and addresses risks to people and the environment.*

3.2 DIR 097—Limited and Controlled Release—Clinical Trial of a Candidate Vaccine against *Human respiratory syncytial virus* (RSV) and *Human parainfluenza virus type 3* (hPIV3)

GTTAC were informed that the purpose of the proposed clinical trial was to investigate the safety and tolerability of multiple doses of the GM vaccine in RSV and hPIV3 seronegative children aged from 6 to less than 24 months of age, and in unscreened infants 2 months of age. Secondary objectives of the study were to examine the immunogenicity, viral shedding and genotypic stability of the GM vaccine.

RESOLUTION: GTTAC advised the Regulator that the potential for increased shedding of the GM virus should be taken into account in finalising the RARMP for DIR 097:

- *GTTAC advised the Regulator that data on shedding of the GM virus, infection and disease in animals, and on the genetic stability of the GM virus, might be required in support of any future application for commercial release.*

4. Other Advice:

4.1 Review Of The Gene Technology Regulations 2001

The Committee received a summary of the advice given by GTTAC members Out-of-Session, together with an explanation of how that advice had been taken into account in finalizing the drafting instructions. GTTAC noted that draft amendments were currently being prepared by the Office of Legislative Drafting and Publishing in the Attorney General's Department, and that public consultation on the draft amendments would include consultation with States and Territory Governments, Institutional Biosafety Committees (IBCs) and GTTAC.

RESOLUTION: *GTTAC noted the progress made in the Review of the Gene Technology Regulations 2001 and thanked the OGTR for the comprehensive feedback on the committee's Out-of-Session advice.*

4.2 Review Of GTTAC Out-Of-Session Procedures

GTTAC agreed to implement some changes to the procedures for advice requested by the Regulator Out-of-Session. The changes will provide more clarity and will ensure that advice to the Regulator represents a consensus of the committee.

Enquiries and Risk Assessment and Risk Management Plans

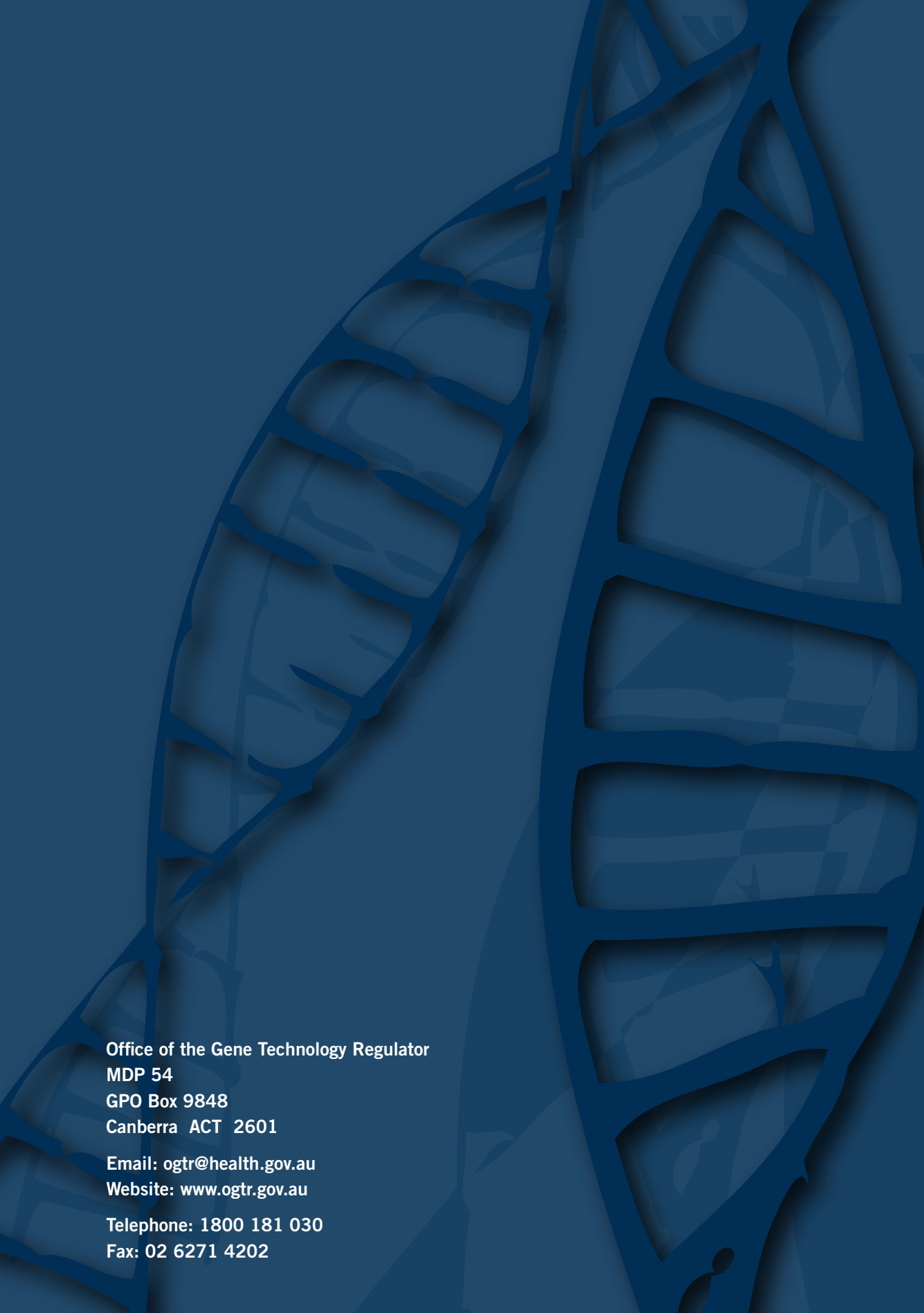
For all enquiries and to obtain copies of applications or RARMPs for dealings involving the intentional release of GMOs into the environment, please phone the OGTR on 1800 181 030. The RARMPs are also available electronically from our website at http://www.ogtr.gov.au

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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