



**Australian Government**

**Department of Health and Ageing**

Office of the Gene Technology Regulator

**OPERATIONS OF THE GENE TECHNOLOGY REGULATOR**

**QUARTERLY REPORT**

**1 JULY–30 SEPTEMBER 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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Inquiries about the content of this report may be directed to the Business Management and Communications Section, Regulatory Practice and Compliance Branch of the Office of the Gene Technology Regulator.

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 July to 30 September 2009.

During this period two licences for dealings involving intentional release of GMOs and two licences for dealings not involving intentional release of GMOs were issued, and 49 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

25 November 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.

### **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 July to 30 September 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.

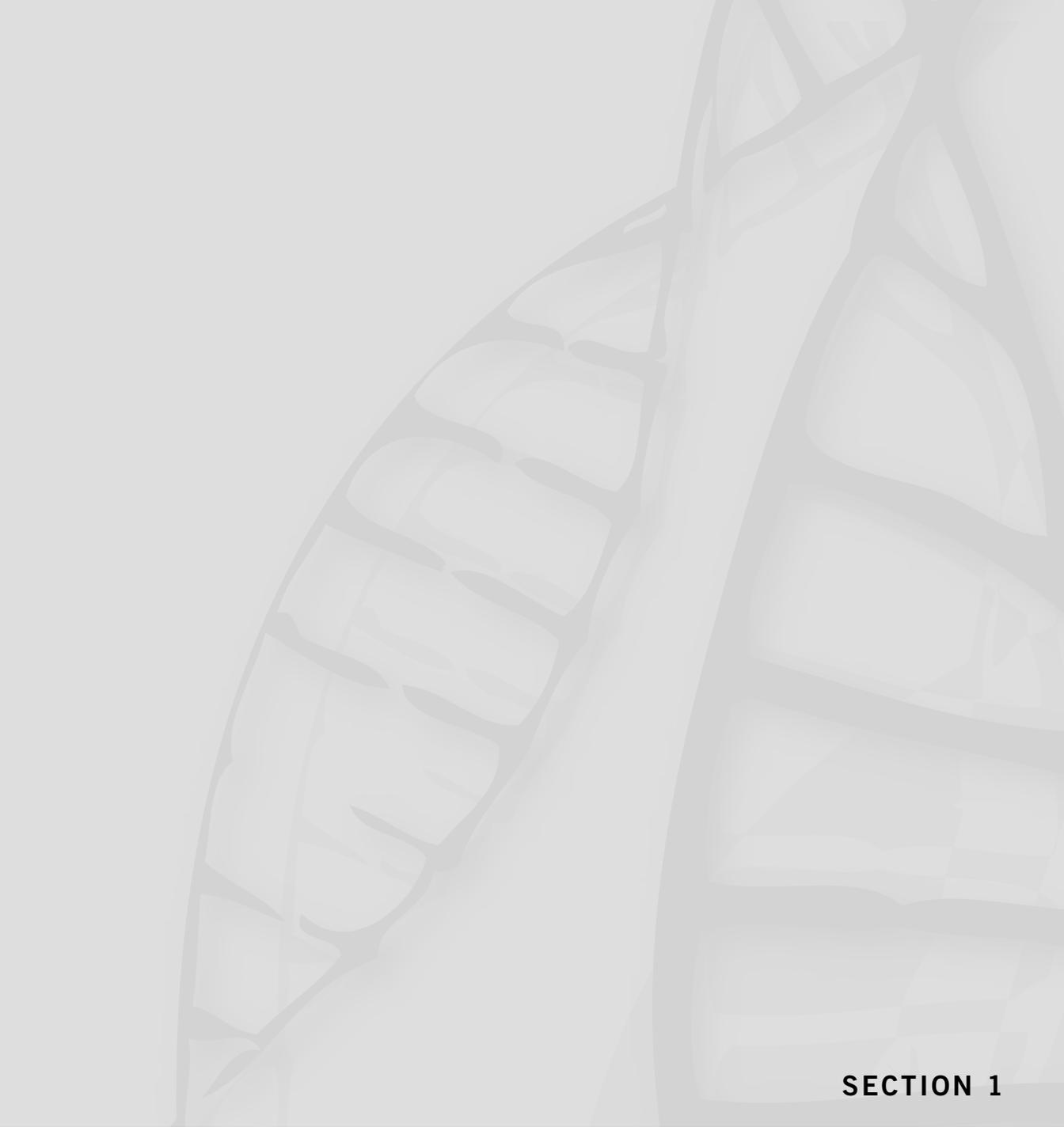
### **Statutory committee operations**

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 July to 30 September 2009 quarter were:

#### Licences and other instruments

- two licences issued for Dealings involving the Intentional Release (DIR) of GMOs into the environment
- two licences issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- 49 physical containment facilities certified
- surrender of 34 certifications, three DIR licences and one DNIR licence
- variation of two accreditations, 67 certifications, six DIR licences and 19 DNIR licences.

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

#### Monitoring and Compliance

Approximately 33 percent of current field trial sites and 11 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 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 July to 30 September 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	1	2
DNIR licence	7	2
Accreditations	0	0
Certifications	53	49

\* 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 RARMP	Licences issued
DIR 098	DIR 097	DIR 091	DIR 094
		DIR 096	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 one application for a DIR licence in the quarter:

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

### Consultation on applications for Dealings involving Intentional Release licences

Although not required by the Act, the Regulator issued a 'Notification of Licence Application' for one DIR licence application. This notification was posted on the OGTR website and sent to people and organisations on the OGTR mailing list to advise receipt of the application and when the RARMP is expected to be released for public comment.

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

Two invitations to comment on a RARMP were issued during the 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.

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.

Three DIR licences were surrendered during the quarter:

- DIR 039—Field Evaluation of Genetically Modified High Oleic (HO) Cotton—CSIRO
- DIR 052—Field trial of genetically modified rice (*Oryza sativa* L.) functional characterisation of the rice genome—CSIRO
- DIR 068—Limited and Controlled Release of Genetically Modified (GM) Torenia with altered flower colour—Florigene Pty Ltd.

### Clock stopped on Dealings involving Intentional Release licence applications

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

A request for further information was initiated in this quarter:

- DIR 091—Commercial release of cotton genetically modified for insect resistance (Widestrike Insect Protection cotton)—Dow AgroSciences Australia Pty Ltd

### **Decisions on applications for Dealings involving Intentional Release licences**

Two DIR licences were issued during this quarter.

- DIR 094—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 altered plant growth, enhanced drought tolerance, enhanced nitrogen use efficiency, altered sucrose accumulation, and improved cellulosic ethanol production from sugarcane biomass—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.

Two DNIR licences were issued during the quarter.

- DNIR 463—Engineering anaerobic bacteria for multimodal cancer therapy—Griffith University, Queensland
- DNIR 465—Investigation of polymerase (PB1) fidelity from different influenza strains—South Eastern Sydney and Illawarra Area Health Service New South Wales.

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 certification	21	34
Surrender of DIR licence	3	3
Surrender of DNIR licence	2	1
Variation of accreditation	3	2
Variation of certification	60	67
Variation of DIR licence	9	6
Variation of DNIR licence	23	19

\* 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 one CCI application in relation to a Notifiable Low Risk Dealing. The Regulator made no CCI declarations during the quarter.

## 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 July to 30 September 2009 quarter, 11 GM plant field trial sites under DIR licences were subjected to monitoring visits.

- **Current field trial sites:** Of the 18 sites current in the quarter, six were monitored. This represents a monitoring rate of 33 percent of all current sites for the quarter.
- **Post-harvest field trial sites:** Of the 46 sites subject to post-harvest monitoring in the quarter, five were monitored. This represents a monitoring rate of 11 percent of all sites subject to post-harvest monitoring in this quarter.

**Monitoring of certified facilities:** Monitoring in connection to contained dealings covered five organisations and 13 PC facilities. Monitoring of PC facilities encompassed five PC2 laboratories, two PC2 animal containment facilities, three PC4 facilities, one PC3 laboratory, one PC3 animal containment facility and one PC2 large scale laboratory.

**Monitoring of contained dealings:** During the quarter, the monitoring of the 13 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.

Five 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 July to 30 September 2009.

Licensed Organisation Name	Licence Number	No. sites visited	Site status*	Crop type
The University of Queensland, Queensland	DIR 078/2007	2	C	Sugarcane
BSES Limited, Queensland	DIR 070/2006	3	C	Sugarcane
Department of Primary Industries, Victoria	DIR 071/2006	1	PHM	Wheat
	DIR 080/2007	1	C	Wheat
Hexima Ltd, Queensland	DIR 063/2005	4	PHM	Cotton
<b>Totals</b>		<b>11</b>	<b>C = 6 PHM = 5</b>	<b>3 crop types</b>

\* 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 July to 30 September 2009.

Licensed Organisation Name	Licence Number
The Walter and Eliza Hall Institute of Medical Research, Victoria	DNIR 116
Monash University, Victoria	DNIR 106
CSIRO, New South Wales	DNIR 214/2003
University of New South Wales, New South Wales	DNIR 454/2009 DNIR 306/2004
<b>Total</b>	<b>5 DNIR licences</b>

### Monitoring of Physical Containment Facilities

The organisations and the facility types the OGTR visited during the 1 July to 30 September 2009 quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
The Walter and Eliza Hall Institute of Medical Research, Victoria	PC2 animal containment	1
	PC2 laboratory	1
Monash University, Victoria	PC2 laboratory	2
CSIRO, Victoria	PC3 animal containment	1
	PC3 laboratory	1
	PC4 Facility	3
Hospira Adelaide Pty Ltd, South Australia	PC2 large scale	1
CSIRO, New South Wales	PC2 laboratory	1
	PC2 animal containment	1
University of New South Wales, New South Wales	PC2 laboratory	1
<b>Total</b>	<b>6 facility types</b>	<b>13</b>

## 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 no findings of non-compliance for DIRs for the 1 July to 30 September 2009 quarter.

### Findings for Dealings Not Involving Intentional Release

There was one finding of non-compliance for DNIRs for the 1 July to 30 September 2009 quarter.

Organisation	Monash University
Licence number	DNIR 106
Summary of dealing	The aim of this dealing is to study genes identified as potentially having a role in the pathogenesis, antibiotic resistance or gene transfer of <i>Clostridium perfringens</i> , <i>C. septicum</i> and <i>C. difficile</i> .
Findings	Dealings under licence DNIR 106 were being conducted in facilities not listed on the licence.
Assessment	Monash University moved into new facilities in early 2009 and continued work under DNIR 106. Whilst the new facilities were OGTR Certified PC2 facilities Monash University had not sought to have the new facilities listed on Attachment C of the licence. Monash University identified this non-compliance during preparation for this OGTR inspection. The risks to human health and safety and the environment have been assessed as negligible.
Compliance management	Monash University applied for a variation to DNIR 106 to correctly reflect the facilities to be used and this request was granted subsequently. Monash University was reminded that they must only deal with the GMOs in the facilities listed in Attachment C of the licence.

### 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.

Number of PC Facilities inspected	Non-Compliance Issue					
	Structure	PPE <sup>1</sup>	Equipment	Waste disposal	Work practices <sup>2</sup>	Transport
13	1	0	2	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 July to 30 September 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.

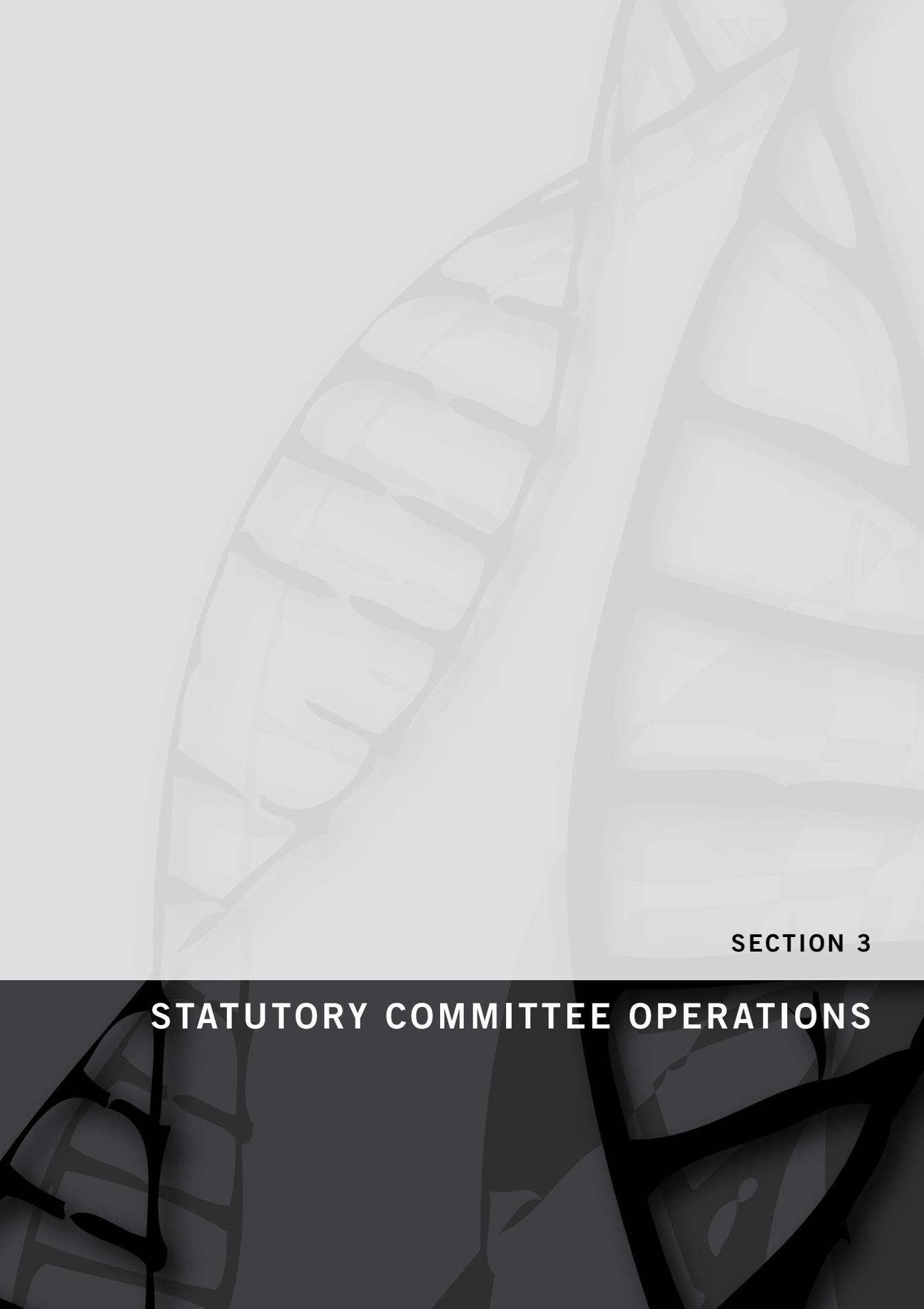
Audits are an opportunity for accredited organisations and the OGTR to share information to improve the risk management of dealings with GMOs under the Act. Audits may focus on a single dealing, a range of dealings (e.g. dealings with a common host organism or dealings within a common climatic zone), 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 July to 30 September 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 were no investigations completed in the 1 July to 30 September 2009 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 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 considered the following items out-of-session:

- Consultation RARMP for licence application DIR 094 (Limited and controlled release of wheat and barley genetically modified for enhanced nutrient utilisation efficiency)
- Consultation RARMP for licence application DIR 095 (Limited and controlled release of sugarcane genetically modified for improved drought tolerance and nitrogen use efficiency, enhanced sucrose and fermentable sugars accumulation, and altered plant growth)
- Review of the Gene Technology Regulations 2001: Classification of Exempt Dealings and Notifiable Low Risk Dealings.

GTTAC did not meet during the quarter.

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

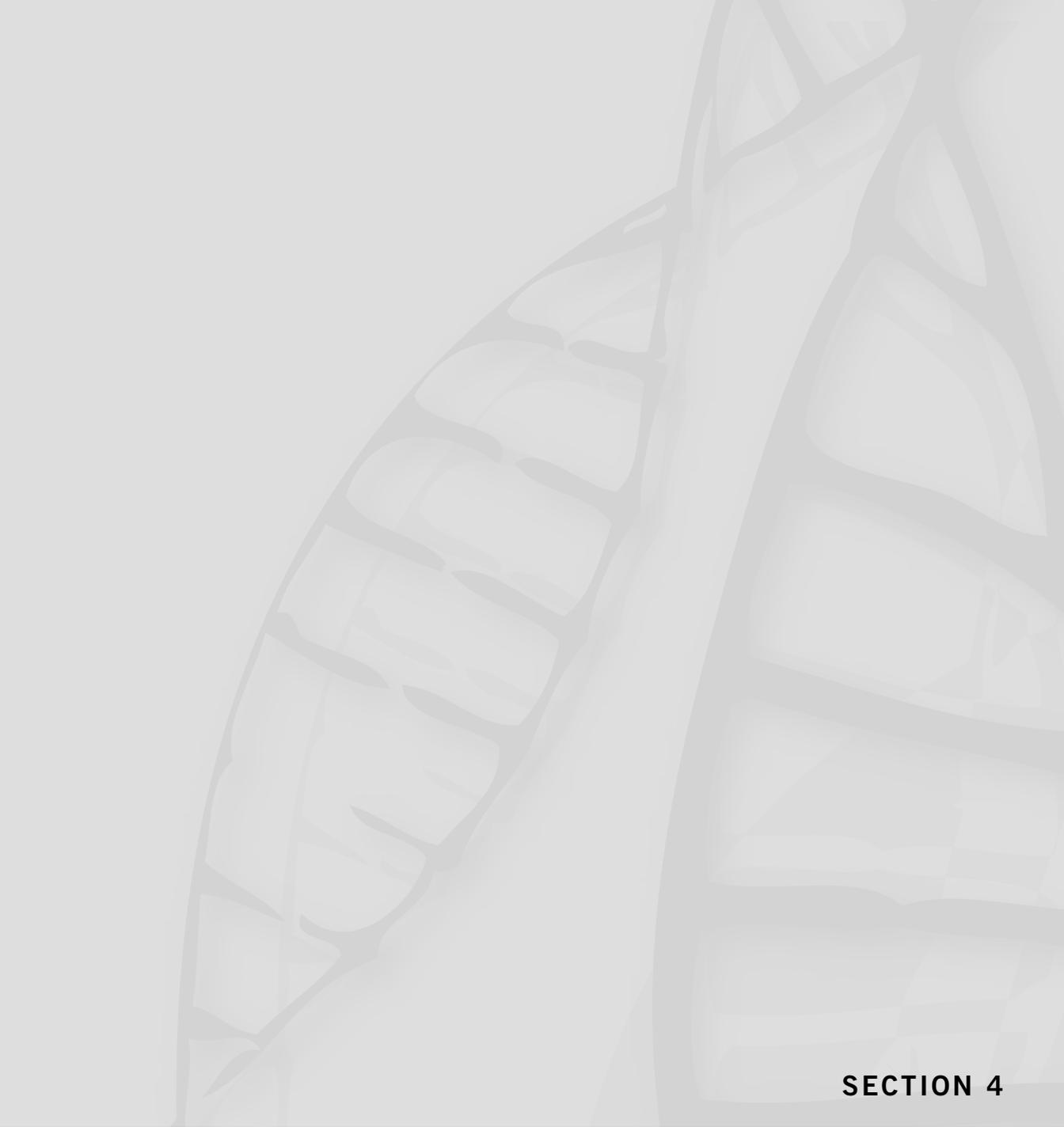
## Gene Technology Ethics and Community Consultative Committee

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](http://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:

- Measures of Hope and Promises Delivered: An International Conference on Socioeconomic and Environmental Impact Assessment of Biotech Crops, Bangkok, Thailand, 29–30 September 2009
- meeting with senior staff of the German Federal Office for Consumer Affairs (BVL), responsible for the regulation of GMOs, Berlin, Germany, 17–18 September 2009
- European Food Safety Authority conference on Risk Assessment of GMOs for Human Health and the Environment, Brussels, Belgium, 14–15 September 2009
- meetings with United Kingdom Advisory Committee on Releases to the Environment and senior staff of the Department of Environment, Food and Rural Affairs responsible for the regulation of GMOs, London, England, 10–11 September 2009
- presentation at the Workshop for Malaysian Institutional Biosafety Committees, Kuala Lumpur, Malaysia, 29 June–2 July 2009.

## 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 Brisbane and the ACT.

During the quarter the OGTR provided presentations to the following:

- Industry Link Gene Technology for Decision Makers Course—CSIRO, Canberra, 8 September 2009
- 14th Australian Plant Breeding and 11th Society for Advancement in Breeding Research in Asia and Oceania Conference, Cairns, Queensland, 10–14 August 2009

OGTR officers also attended the following meetings/conferences:

- Australasian Environmental Law Enforcement and Regulators Network Conference. Hobart, 16–17 September 2009
- Australian Seeds Federation Conference, Canberra, 24–27 August 2009
- ASM 2009 Australian Society of Microbiology Conference, 6–10 July 2009.

The OGTR also received visitors and presentations from:

- Dr Lim, Director of the Quarantine and Planning Division of the Korean National Plant Quarantine Service, during a two week placement which constituted one leg of a year long visit to Australia sponsored by the Department of Agriculture Fisheries and Forestry, Canberra, 24 August–4 September 2009
- Professor Richard Mack, School of Biological Sciences, Washington State University, 3 August 2009.

## 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 July to 30 September 2009 quarter.

MONTH	HITS <sup>1</sup>	VISITS <sup>2</sup>
July	194,433	25,822
August	191,850	32,869
September	195,675	34,346

DAY OF THE WEEK PATTERN FOR THE QUARTER	HITS <sup>1</sup>	VISITS <sup>2</sup>
Sunday	48,203	11,100
Monday	90,047	13,362
Tuesday	90,754	13,096
Wednesday	94,182	14,260
Thursday	100,694	12,985
Friday	110,042	12,860
Saturday	48,203	11,100

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
- Intentional Release and Evaluation Process
- Publication and Forms—Certification of Physical Containment Facilities
- About the OGTR
- Guidelines
- GMO Record
- Home Page
- IBC & Accredited Organisations Information

- GMO Products
- Classess of dealings.

The most popular downloaded documents were:

- 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 Pineapple (*Ananas comosus var. comosus*) in Australia
- Risk Analysis Framework
- PC2—Guidelines for Certifications of Physical Containment Facilities
- The Biology of the Sugarcane (*Saccharum spp.*) in Australia
- The Biology of *Lolium multiflorum* Lam. (Italian ryegrass), *Lolium perenne* L. (perennial ryegrass) and *Lolium arundinaceum* (Schreb.) Darbysh (tall fescue)
- The Biology and Ecology of Carnation (*Dianthus caryophyllus L.*) in Australia
- DIR 090 Risk Assessment and Risk Management Plan for commercial release of rose genetically modified for altered flower colour.

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
July	105	105
August	76	102
September	99	131

**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 115 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 166 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 534 emails during the quarter.

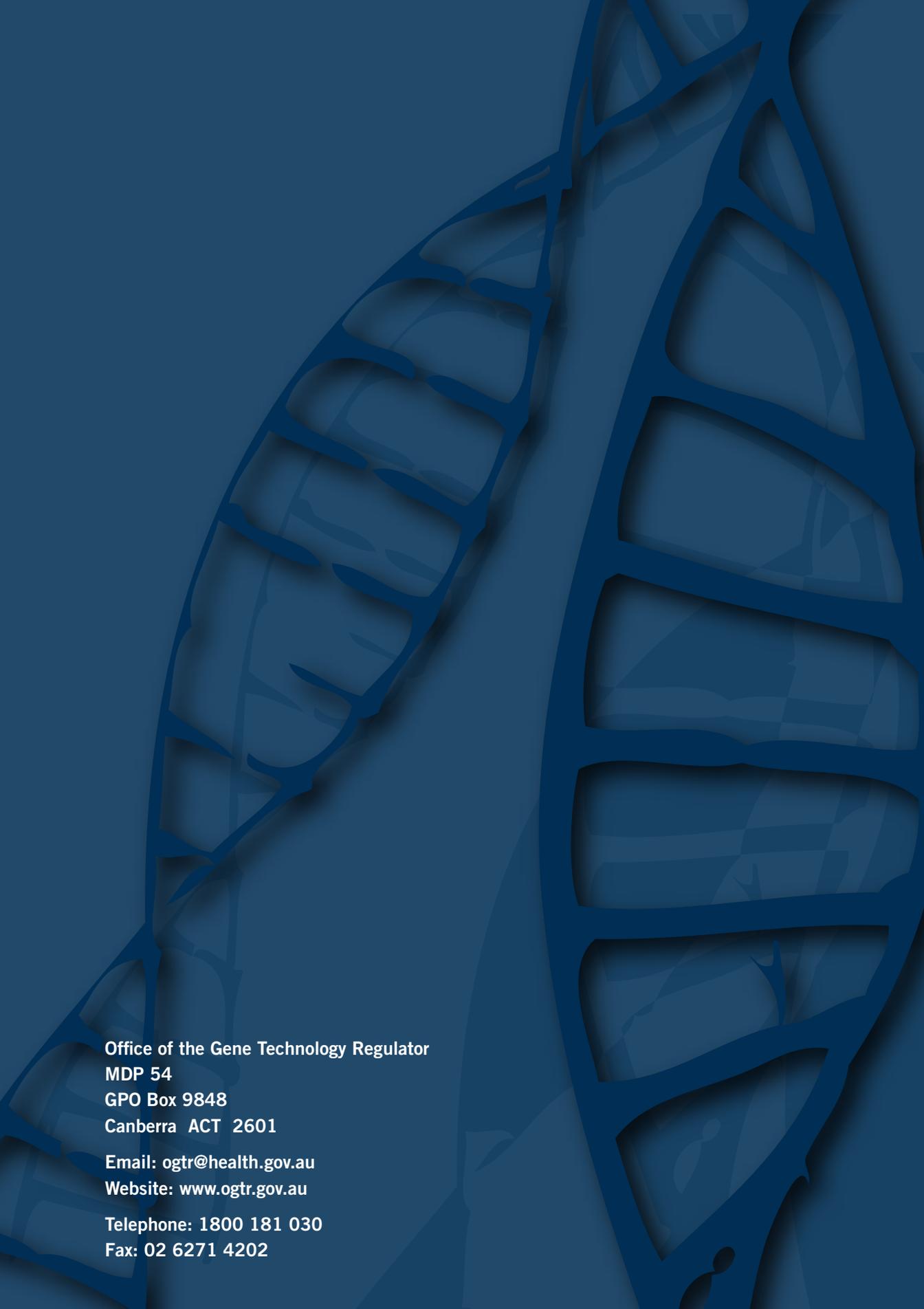
## GLOSSARY

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*.

<b>Accredited organisation</b>	An organisation that is accredited under section 92 of the Act
<b>Act</b>	<i>Gene Technology Act 2000</i>
<b>APVMA</b>	Australian Pesticides and Veterinary Medicines Authority
<b>Breach of a licence condition</b>	A breach of a licence condition which has been proven either in court or by way of admission following investigation
<b>CCI</b>	Confidential commercial information
<b>Certified containment facility</b>	A building or place certified by the Regulator to a specified containment level under section 84 of the Act
<b>Clock stop</b>	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
<b>CSIRO</b>	Commonwealth Scientific and Industrial Research Organisation
<b>DIR</b>	A dealing involving intentional release of a GMO into the environment (e.g. field trial or commercial release)
<b>DIR licence</b>	A licence for a dealing involving intentional release of a GMO into the environment
<b>DNIR</b>	A contained dealing with a GMO <u>not</u> involving intentional release of the GMO into the environment (e.g. experiments in a certified facility such as a laboratory)
<b>DNIR licence</b>	A licence for a dealing not involving intentional release of a GMO into the environment
<b>Expert advisers</b>	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)
<b>EDD</b>	Emergency dealing determination
<b>FSANZ</b>	Food Standards Australia New Zealand

<b>GM</b>	Genetically modified
<b>GM product</b>	A thing (other than a GMO) derived or produced from a GMO
<b>GMAC</b>	Genetic Manipulation Advisory Committee
<b>GMO</b>	Genetically modified organism
<b>GTECCC</b>	Gene Technology Ethics and Community Consultative Committee
<b>GTMC</b>	Gene Technology Ministerial Council
<b>GTSC</b>	Gene Technology Standing Committee
<b>GTTAC</b>	Gene Technology Technical Advisory Committee
<b>IBC</b>	Institutional Biosafety Committee
<b>Incident</b>	A self-reported event which may constitute a non-compliance with regulatory requirements and a public health or environment risk
<b>Limited and controlled release</b>	A type of DIR which meets certain criteria relating to limiting and controlling the dealings with the GMO (e.g. a field trial)
<b>NLRD</b>	Notifiable low risk dealing (work with transgenic plants, animals or microorganisms undertaken in certified contained facilities)
<b>Non-compliance</b>	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
<b>OGTR</b>	Office of the Gene Technology Regulator
<b>PC1, PC2, PC3, PC4</b>	Physical containment levels of facilities as certified by the Regulator
<b>RARMP</b>	Risk assessment and risk management plan
<b>Regulations</b>	Gene Technology Regulations 2001
<b>Regulator</b>	Gene Technology Regulator
<b>Spot checks</b>	Unannounced visits by the OGTR Monitoring and Compliance Section
<b>Volunteer</b>	Regrowth of plants from seed that has remained on a site after a trial has been completed





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