



**Australian Government**

**Department of Health and Ageing**

Office of the Gene Technology Regulator

**OPERATIONS OF THE GENE TECHNOLOGY REGULATOR**

**QUARTERLY REPORT**

**1 JANUARY–31 MARCH 2011**

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 Catherine King MP  
Parliamentary Secretary for Health and Ageing  
Parliament House  
CANBERRA ACT 2600

Dear Parliamentary Secretary

In accordance with section 136A of the *Gene Technology Act 2000* (the Act), I am pleased to present to you the Quarterly Report of the Operations of the Gene Technology Regulator, covering the period 1 January to 31 March 2011.

During this period one licence for dealings involving intentional release of GMOs and three licences for dealings not involving intentional release of GMOs were issued, while 44 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.

The process for appointment of new members to the Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee was finalised during the quarter.

Yours sincerely



Dr Joe Smith  
Gene Technology Regulator

31 May 2011



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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 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 January to 31 March 2011 quarter were:

#### Licences and other instruments

- Two organisations issued with accreditation.
- One licence issued for Dealings involving the Intentional Release (DIR) of GMOs into the environment.
- Three licences issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- Forty four physical containment facilities certified
- Forty five instruments surrendered
- Variation of 36 certifications, five DIR licences and 28 DNIR licences.

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

#### Monitoring and Compliance

Approximately ten percent of current field trial sites and six percent of post-harvest field trial sites were subjected to routine monitoring during the quarter. This exceeded 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 Sustainability, Environment, Water, Population and Communities
- Department of Foreign Affairs and Trade.

During the quarter the Regulator did not seek any advice in respect of 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. No 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**

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## REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of the report outlines the regulatory activity undertaken during the 1 January to 31 March 2011 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*
Accreditation	2	2
DIR licence	1	1
DNIR licence	4	3
Certifications	29	44

\* 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 110	DIR 109	DIR 108	DIR 107
	DIR 110		

\* 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 110—Limited and controlled release of cotton genetically modified for fungal control—Hexima Limited.

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 preparing the RARMPs for the following application:

- DIR 108—Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system (GM InVigor® × Roundup Ready® canola)—Bayer CropScience Pty Ltd

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

- DIR 109—Limited and controlled release of banana genetically modified for enhanced nutrition—Queensland University of Technology
- DIR 110—Limited and controlled release of cotton genetically modified for fungal control—Hexima Limited

There was no invitation to comment on a RARMP issued during the quarter.

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 067/2006—Limited and Controlled Release of Waterlogging Tolerant (GM) Cotton—CSIRO

### **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.

One request for further information on a DIR application was initiated in this quarter:

- DIR 106—Limited and controlled release of sugarcane genetically modified for production of naturally occurring compounds for use in bioplastics—The University of Queensland

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

One DIR licence was issued during the quarter:

- DIR 107—Limited and controlled release of banana genetically modified for disease resistance—Queensland University of Technology

Summary information on DIR applications, finalised RARMPs, licences issued 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.

Three DNIR licences were issued during the quarter:

- DNIR 496—Characterisation of the molecular determinants of host range and pathogenicity for *Henipaviruses*—CSIRO, Victoria
- DNIR 497—Expression and characterization of novel genes from Australian snakes—The University of Queensland, Queensland
- DNIR 498—Isolation and characterisation of genes involved in antifungal drug metabolism including drug resistance in pathogenic yeasts—Western Sydney Local Health Network, New South Wales

A full listing of DNIR licences 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 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 on 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 <sup>b</sup>
Surrender of certification	1	2
Surrender of certification	40	40
Surrender of DIR licence	2	1
Surrender of DNIR licence	3	2
Variation of accreditation	0	0
Variation of certification	66	36
Variation of DIR licence <sup>a</sup>	3	5
Variation of DNIR licence	15	28

*a Also includes variations initiated by the Regulator*

*b 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 the 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 two CCI applications in relation to DIR applications and two in relation to DNIRs. The Regulator made one CCI declaration in relation to a DIR application 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 containment facilities certified by the Regulator to ensure:

- the dissemination of a GMO and its genetic material is restricted
- the persistence of a GMO in the environment is restricted
- *the containment of GMOs for dealings not involving intentional release*
- 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. In addition inspections are conducted on a minimum of 20 percent of PC2 large-scale, PC3 and PC4 facilities per year.

### **Monitoring and Compliance Strategy**

The purpose of routine inspections is to ensure compliance with licence conditions and includes spot checks.

The OGTR strategy for conducting 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 restrict the spread and persistence of the GMOs is more likely to occur (for example, during flowering and harvest of GM crops).

The monitoring program for contained dealings involves inspecting DNIRs and the facilities that those dealings are conducted in. 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**

In addition to routine monitoring visits, compliance with key administrative requirements in licences have been examined.

**Total field trial sites monitored:** During the quarter, five GM plant field trial sites under DIR licences were subjected to monitoring visits.

- **Current field trial sites:** Of the 29 sites current in the quarter, three were monitored. This represents a monitoring rate of ten percent of all current sites for the quarter.
- **Post-harvest field trial sites:** Of the 32 sites subject to post-harvest monitoring in the quarter, two were monitored. This represents a monitoring rate of six percent of all sites subject to post-harvest monitoring in this quarter.

In addition to the routine monitoring of field trial sites, inspections were conducted of a number of field trial sites in Queensland and Victoria that were located in areas that were affected by floods and/or Cyclone Yasi. A total of 19 sites comprising 12 current sites and 7 sites subject to post harvest monitoring were inspected. All the sites were compliant with licence conditions at the time of inspection and there was no evidence that any loss of containment of GMOs had occurred at any of the sites.

**Monitoring of certified facilities:** Monitoring in connection with contained dealings covered two organisations and four PC facilities. Monitoring of PC facilities encompassed four PC2 laboratories.

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

Three 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 quarter.

Licensed Organisation Name / Location of trial site	Licence Number	No. sites visited	Site status	Crop type
CSIRO, New South Wales	DIR 099	1	PHM*	Wheat and Barley
Monsanto Australia Limited, New South Wales	DIR 074/2007	2	1 Current 1 PHM*	Cotton
	DIR 101	2	Current	
<b>Total</b>	<b>3</b>	<b>5</b>	<b>Current = 3 PHM* = 2</b>	

\* PHM = post-harvest monitoring.

### Monitoring Post Cyclone/Flood

Licensed Organisation Name / Location of trial site	Licence Number	No. sites visited	Site status	Crop type
Hexima Ltd, Queensland	DIR 063/2005**	3	1 PHM* 2 Current	Cotton
Queensland University of Technology, Queensland	DIR 76/2007^	1	Current	Banana
The University of Queensland, Queensland	DIR 078/2007^	2	Current	Sugarcane
BSES Limited, Queensland	DIR 095^	3	Current	Sugarcane
	DIR 096^	4	Current	
Department of Primary Industries, Victoria	DIR 080**	1	PHM*	Wheat
	DIR 047**	1	PHM*	White clover
	DIR 082**	1	PHM*	Perennial Ryegrass and Tall Fescue
Bayer CropScience Pty Ltd, Victoria	DIR 069**	3	PHM*	Canola, Indian Mustard
<b>Total</b>	<b>9</b>	<b>19</b>	<b>Current = 12 PHM* = 7</b>	

\*\*Post Floods Inspection

^ Post Cyclone Inspection

### Monitoring of Dealings Not involving Intentional Release

The following table summarises monitoring activities for DNIRs for the quarter.

Licensed Organisation Name	Licence Number
Health Reform Transitional Organisation Western, New South Wales	DNIR 303 and 401
Peter MacCallum Cancer Centre, Victoria	DNIR 460
<b>Total</b>	<b>3</b>

## Monitoring of Physical Containment Facilities

The organisations and the facility types the OGTR visited during the quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
Health Reform Transitional Organisation Western, New South Wales	PC2 laboratory	3
Peter MacCallum Cancer Centre, Victoria	PC2 laboratory	1
<b>Total</b>	<b>1 facility type</b>	<b>4</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 non-compliance issues observed for DIRs that were inspected in the quarter.

### Findings for Dealings Not involving Intentional Release

There was one non-compliance issue observed for a DNIR that was finalised in the quarter.

<b>Organisation</b>	<b>Sanofi-Aventis Australia Pty Ltd</b>
<b>Licence number</b>	DNIR 386
<b>Summary of dealing</b>	Clinical trials of ChimeriVax™ Tetravalent Dengue Vaccine
<b>Findings</b>	<p>Sanofi-Aventis Australia Pty Ltd self reported that a staff member had disposed of a dose of GM vaccine into a sink contrary to specific disposal requirements. In addition, there was a time delay between the event and notification of the OGTR and the licence holder's IBC.</p> <p>During a follow up inspection OGTR staff identified a number of deficiencies in processes to meet general reporting requirements and also identified that a requirement regarding wearing of personal protective equipment (gloves) was not being followed.</p>
<b>Assessment</b>	<p>It was assessed that the disposal of GM vaccine would not cause harm to people or the environment and therefore the delay in reporting to OGTR also did not pose any additional risks.</p> <p>The risk assessment and risk management plan (RARMP) prepared by the OGTR for this licence identifies that inoculation and aerosol exposure are the main routes for causing harm to staff handling GM vaccine, therefore the risks associated with not wearing gloves was assessed as negligible.</p>

**Compliance management**

The licence holder has implemented a re-training program for all staff at all trial sites with regards to licence conditions, including disposal. The licence holder has also developed a new incident reporting plan that ensures reporting of incidents on a priority basis.

The licence holder was reminded that it must comply with all specific work practices and behaviours mandated by licence conditions.

**Findings for Physical Containment Facilities**

The OGTR's monitoring of certified PC facilities in the quarter found no non-compliances with certification conditions in relation to work practice (conditions relating to washing of hands/equipment for washing hands) within facilities.

Number of PC Facilities inspected	Non-Compliance Issue					
	Structure	PPE <sup>1</sup>	Equipment	Waste disposal	Work practices <sup>2</sup>	Transport
4	0	0	0	0	0	0

1 PPE = Personal Protective Equipment.

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

**Practice Reviews**

The OGTR may initiate Practice Reviews in response to observations made during monitoring activities, or to follow up incident reports that may relate to non-compliance with licence conditions by accredited organisations. Their objective is to determine if licence conditions can be, and are being, effectively implemented.

An accredited organisation may request a Practice Review to assess the effectiveness of systems used by its IBC(s) to ensure that dealings are being conducted in accordance with the Act.

The primary focus of the review process is to determine whether 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 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 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 quarter.



**SECTION 3**

**STATUTORY COMMITTEE OPERATIONS**

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## 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.

### **New committee appointments 2011–2014**

Appointments to the two gene technology advisory committees were made in February 2011 by the Hon Catherine King, Parliamentary Secretary to the Minister for Health and Ageing.

### **Gene Technology Technical Advisory Committee**

The function of the Gene Technology Technical Advisory Committee (GTTAC) under the Act is 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 did not meet during the quarter.

Further information about the work of GTTAC including the membership for 2011–2014, 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**

The function of the Gene Technology Ethics and Community Consultative Committee (GTECCC) under the Act 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.

GTECCC did not meet during the quarter. The Communiqué for the meeting held on 9 December 2010 is included in Appendix 1, and is available on the OGTR website <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gttacomm-1>

Further information about GTECCC, including the membership for 2011–2014, 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 a presentation to:

- The Canadian Food Inspection Agency (CFIA) International Science Symposium, Ottawa, Canada, February 2011.

During the quarter the OGTR also hosted meetings with delegations from the Japanese Research Institute and also the Korean Department of Agricultural Bio-resources.

### 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.

The OGTR provided presentations to the following:

OGTR officers also participated in the following meetings/conferences:

- GM Canola Forum, Perth, February 2011
- Regulators Forum meeting, Canberra, March 2011
- ABARES Outlook Conference 2011, Canberra, March 2011
- Clinical Waste Workshop, Melbourne, March 2011.

### Reviews

During the quarter the Regulator sought comments from the regulated community on the draft revision of the *Guidelines for the Transport, Storage and Disposal of GMOs*, Version 3.1. These guidelines are intended to replace both the *Guidelines for Transport of GMOs*, Version 2.1, which were issued on 1 July 2007, and the *Guidelines for Storage and Disposal of Notifiable Low Risk Dealings*, Version 1.0, which were issued on 18 April 2008

## 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 quarter.

MONTH	HITS <sup>1</sup>	VISITS <sup>2</sup>
January	177,675	24,043
February	198,663	24,480
March	212,248	27,507

*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
- Maps of Trial Sites
- 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
- Forms and Guidelines
- List of Intentional Release of Licence Application under Evaluation
- Licence Application & Assessment Process
- IBC & Accredited Organisations Information

The most popular downloaded documents were:

- *Risk Analysis Framework*
- The Biology and Ecology of Papaya (*Carica papaya*) in Australia
- The Biology and Ecology of Rice (*Oryza sativa*) in Australia
- The Biology and Ecology of Cotton (*Gossypium hirsutum L.*) in Australia
- Operations of the Gene Technology Regulator Annual Report 2009–2010
- 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 of Hybrid Tea Rose (*Rosa x hybrida*)
- The Biology of *Triticum aestivum L. em Thell.* (Bread Wheat)

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
January	77	49
February	79	85
March	97	91

### Monitoring and compliance email inbox

The OGTR maintains an email inbox to provide a central point for accredited organisations to contact the OGTR regarding monitoring and compliance matters, such as queries, notifications required under licences, 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 109 emails during the quarter.

### Statutory Committee email inbox

The Regulatory Practice and Secretariat Section maintain an email inbox to facilitate efficient communication between committee members and secretariat staff.

The inbox ensures that all communications are answered in a timely manner by secretariat staff. The inbox received 181 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 438 emails during the quarter.

**Contained Dealings Evaluation Section email inbox**

This email inbox provides a central common point for efficient coordination of responses to queries relating to classification of GMO dealings, certification requirements for higher level containment facilities and GMO licences accessed by the contained dealings evaluation section. The inbox received 84 emails during the quarter.





**APPENDIX**



## APPENDIX 1

### Gene Technology Ethics and Community Consultative Committee

Meeting 9th December 2010, Canberra

#### COMMUNIQUÉ

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**The Gene Technology Ethics and Community Consultative Committee (GTECCC) held its fourth meeting of the Triennium in Canberra on 9 December 2010.**

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GTECCC is a statutory advisory committee to the Gene Technology Regulator (the Regulator) and the Gene Technology Ministerial Council. All Committee members hold office on a part-time basis.

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

The purpose of this Communiqué is to provide a brief overview of the key matters considered by GTECCC at its fourth meeting on 9 December 2010.

#### **GTECCC's Work Plan**

GTECCC reviewed progress in the following key areas, which had been identified as priorities at the previous meeting:

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

The Chair gave a brief update on the progress by the National Framework Review Working Group. The Committee suggested various means of engaging the research community to increase awareness of the importance of ethics when conducting research. The Committee agreed that the National Framework overlapped with other national research ethics frameworks and could be cross-referenced.

The Committee agreed that the draft National Framework should proceed as an aspirational document—which is intended to foster good research.

#### **Environmental Ethics and Gene Technology**

The Environmental Ethics Working Group reported on their presentation of the Environmental Ethics paper at the Australasian Association of Bioethics and Health Law conference in July 2010.

GTECCC agreed for the working group to finalise the environmental ethics information paper and make it available on the OGTR website. This paper is an outcome of GTECCC's deliberations and is independent from the OGTR.

**Community attitudes to biotechnology**

An officer from the Department of Innovation, Industry, Science and Research (DIISR), presented the results of the 2010 IPSOS-Eureka Social Research Institute survey on community attitudes to biotechnology. A key finding was that the Australian public continued to strongly support biotechnologies that provide health or environmental benefits; however, support for genetically modified (GM) foods has dropped since 2007. The Chair noted the importance that community attitudes had in assisting GTECCC in it's task and thanked DIISR for it's ongoing work and support.

**Reports**

The Committee received a report from the Gene Technology Regulator regarding the activities of the Office of the Gene Technology Regulator. Reports were also received from the committee's cross-members with the Gene Technology Technical Advisory Committee (GTTAC) and the Australian Health Ethics Committee (AHEC).

The committee noted that this was the last meeting for the current membership of GTECCC.

For all enquiries, please contact the Office of the Gene Technology Regulator on 1800 181 030 (freecall).

## 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>BSG</b>	Biosecurity Services Group of the Department of Agriculture, Fisheries and Forestry
<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 not 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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