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 2009

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

**'to protect the health and safety of people, and protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms'**

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

# QUARTERLY REPORT

## 1 JANUARY–31 MARCH 2009

ISBN: 1-74186-905-6

Online ISBN: 1-74186-906-4

Publications Number P3-5335

**Paper-based publications**



**Internet sites**



Office of the Gene Technology Regulator
MDP 54 GPO Box 9848
CANBERRA ACT 2601

Email: ogtr@health.gov.au

Website: <www.ogtr.gov.au>

Telephone: 1800 181 030

Fax: (02) 6271 4202

Quarterly Report web page:

<www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1>

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.

Senator the Hon Jan McLucas
Parliamentary Secretary to the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

Dear Parliamentary Secretary

In accordance with section 136A of the *Gene Technology Act 2000* (the Act), I am pleased to present to you the Quarterly Report of the Operations of the Gene Technology Regulator, covering the period 1 January to 31 March 2009.

During this period one licence for dealings involving intentional release of GMOs and four licences for dealings not involving intentional release of GMOs were issued, and 51 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. An extensive review of GMO storage practices found no non-compliances across all nineteen locations included in the review.

The office continued its active program of international collaboration, including participation in the 22nd meeting of the OECD Working Group for the Harmonisation of Regulatory Oversight in Biotechnology.

This is my first report since taking up the role of Gene Technology Regulatory on 23 March 2009. In presenting it, I would like to acknowledge the outstanding work of my predecessor, Dr Sue Meek, and extend my appreciation for the acting Regulator Ms Elizabeth Flynn.

Yours sincerely

Dr Joe Smith
Gene Technology Regulator

26 May 2009

# CONTENTS

# ABOUT THIS REPORT

Sub-section 136A(1) of the *Gene Technology Act 2000* (the Act) requires the Gene Technology Regulator (the Regulator) to prepare and give to the Minister after each quarter a report on the operations of the Regulator during that quarter. Sub-section 136A(2) of the Act requires that the report include information on:

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

Its purpose is to inform the community of our roles and responsibilities and to provide a summary of our achievements over the past quarter.

This report has four key sections and appendices.

**Gene technology regulatory system**

Provides advice on the activities and outcomes achieved in relation to the implementation and management of the national regulatory system during the 1 January to 31 March 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.

**Appendices**

The appendices contain information on the number of Dealings Not involving Intentional Release (DNIR) licences issued and communiqués for the statutory advisory committees.

SECTION 1

# NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

# NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

## Key achievements during this quarter

The key achievements of the 1 January to 31 March 2009 quarter were:

**Licences and other instruments**

- 1 licence issued for Dealings involving the Intentional Release (DIR) of GMOs into the environment
- 4 licences issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- 51 physical containment facilities certified
- surrender of 13 certifications, 2 DNIR licences and 1 accreditation
- variation of 49 certifications, 5 DIR licences and 13 DNIR licences.

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

**Monitoring and Compliance**

Approximately 16 percent of current field trial sites and seven 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 three 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. Three 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 January to 31 March 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 | Nil | 1 |
| DNIR licence | 4 | 4 |
| Accreditations | 1 | Nil |
| Certifications | 40 | 51 |

* *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 |
|---|---|---|---|
| Nil | 094 | 090 | 089 |
| | 095 | 092 | |
| | | 093 | |

* *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 organistations on the OGTR mailing list*

**Applications received for Dealings involving Intentional Release licences**

The Regulator did not receive any applications for a DIR licence in the quarter:

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

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

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

- DIR 090—Commercial release of rose genetically modified for altered flower colour—Florigene Pty Ltd
- DIR 092—Limited and controlled release of wheat genetically modified for altered grain composition—CSIRO
- DIR 093—Limited and controlled release of wheat and barley genetically modified for altered grain starch composition—CSIRO

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 or surrendered during the quarter.

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

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

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

One DIR licence was issued during this quarter.

- DIR 089—Limited and controlled release of white clover genetically modified to resist infection by Alfalfa mosaic virus—Victorian Department of Primary Industries.

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

## Decisions on applications for Dealings Not involving Intentional Release licences

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

During the quarter the Regulator issued four DNIR licences. More information about these licences is contained in Appendix 1 of this report.

A full listing of DNIR licence applications and their current status is available from the OGTR website.

## Changes to existing licences and other instruments

The Regulator can, directly or upon application, vary an issued licence or other instrument. Variations involve changes to conditions applied to an instrument or a licence. For example, the Regulator can vary a licence to better manage risks if new information or data comes to light. The Regulator must not vary the licence unless 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 processed[1] |
|---|---|---|
| Surrender of certification | 22 | 13 |
| Surrender of DIR licence | Nil | Nil |
| Surrender of DNIR licence | 1 | 2 |
| Variation of certification | 63 | 49 |
| Variation of DIR licence | 10 | 5 |
| Variation of DNIR licence | 17 | 13 |

[1] *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 two CCI applications in relation to DIR licence applications. The Regulator also made three CCI declarations in relation to DIR applications.

## Monitoring and Compliance

The aim of OGTR monitoring and compliance activities is to ensure that dealings with GMOs comply with legislative obligations and are consistent with the object of the Act:

> *'to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs'.*

In particular, the Monitoring and Compliance Sections focus on management of dealings at field trial sites and within contained facilities certified by the Regulator to ensure:

- the dissemination of a GMO and its genetic material is minimised
- the persistence of a GMO in the environment is managed
- effective management of the GMO is maintained.

OGTR monitoring activities comprise the functions of routine monitoring including spot checks, assessment of monitoring findings and, where necessary, recommending corrective action and follow-up activities.

OGTR compliance activities comprise reviews of potential compliance risks, investigations, audits and related enforcement activities.

The Monitoring Section conducts routine monitoring visits of a minimum of 20 percent of field trial sites each year. To achieve this goal a minimum of five percent of current trial sites and five percent of trial sites subject to post-harvest monitoring are monitored each quarter.

**Monitoring and Compliance Strategy**

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

The OGTR strategy for conducting field trial monitoring draws on accumulated operational experience of risk profiling in relation to compliance.

For example, OGTR field trial monitoring coincides, where possible, with periods or circumstances when non-compliance with licence conditions designed to limit the spread and persistence of the GMOs is more likely to occur (for example, flowering and harvest of GM crops).

The monitoring program for contained dealings involves inspecting DNIRs and the facilities that those dealings are conducted in, as well as monitoring a minimum of 20 percent of PC2 large-scale, PC3 and PC4 facilities per year.

These inspections focus on the integrity of the physical structure of the facility and on the general laboratory practices followed in that facility, including those practices followed for DNIRs and NLRDs.

**Overview of monitoring and compliance for the reporting period**

**Total field trial sites monitored:** During the 1 January to 31 March 2009 quarter, eight GM plant field trial sites under DIR licences were subjected to monitoring visits.

- **Current field trial sites:** Of the 31 sites current in the quarter, five were monitored. This represents a monitoring rate of 16 percent of all current sites for the quarter.
- **Post-harvest field trial sites:** Of the 42 sites subject to post-harvest monitoring in the quarter, three were monitored. This represents a monitoring rate of seven percent of all sites subject to post-harvest monitoring in this quarter.

**Monitoring of certified facilities:** Monitoring in connection to contained dealings covered ten organisations and 32 PC facilities. Monitoring of PC facilities encompassed 16 PC2 laboratories, one PC2 constant temperature room, three PC2 animal containment facilities, five PC2 plant containment facilities, 1 PC2 large scale laboratory, 3 PC3 laboratories and 3 PC3 animal containment facilities.

**Monitoring of contained dealings:** During the quarter, the monitoring of the 32 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.

Eleven 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 January to 31 March 2009.

| Licensed Organisation Name | Licence Number | No. sites visited | Site status* | Crop type |
|---|---|---|---|---|
| Monsanto Australia Limited, New South Wales | DIR 064/2006 | 2 | Current | Cotton |
| Bayer CropScience Pty Ltd, South Australia | DIR 069/2006 | 3 | 1 Current 2 PHM | Canola and Indian Mustard |
| Bayer CropScience Pty Ltd, Victoria | DIR 069/2006 | 2 | Current | Canola and Indian Mustard |
| Victorian Department of Primary Industries, Victoria | DIR082/2007 | 1 | PHM | Perennial Ryegrass and Tall Fescue |
| **Totals** | | **8** | **C = 5 PHM = 3** | **5 crop types** |

** C = current PHM = post-harvest monitoring.*

**Monitoring of Dealings Not involving Intentional Release**

The following table summarises monitoring activities for DNIRs for the period between 1 January to 31 March 2009.

| Licensed Organisation Name | Licence Number |
|---|---|
| The University of Adelaide, South Australia | DNIR 249/2003 |
| | DNIR 250/2003 |
| | DNIR 173/2003 |
| University of Wollongong, New South Wales | DNIR 081/2002 |
| | DNIR 082/2002 |
| The University of Newcastle, New South Wales | DNIR 394/2006 |
| The University of Western Australia, Western Australia | DNIR 090/2002 |
| | DNIR 392/2006 |
| | DNIR 208/2003 |
| Royal Perth Hospital, Western Australia | DNIR 260/2003 |
| The University of Queensland | DNIR 452 |
| **Total** | **11 DNIR licences** |

**Monitoring of Physical Containment Facilities**

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

| Organisation | Physical Containment (PC) facility | No. facilities visited |
|---|---|---|
| The University of Adelaide, South Australia | PC2 laboratory<br>PC2 constant temperature room<br>PC2 plant containment | 3<br>1<br>1 |
| Central Northern Adelaide Health Service, South Australia | PC2 animal containment | 1 |
| University of Wollongong, New South Wales | PC2 laboratory | 4 |
| Curtin University of Technology, Western Australia | PC3 laboratory | 1 |
| The University of Newcastle, New South Wales | PC2 laboratory<br>PC2 plant containment | 2<br>2 |
| The University of Western Australia, Western Australia | PC2 laboratory<br>PC2 animal containment<br>PC2 plant containment | 4<br>2<br>1 |
| Royal Perth Hospital, Western Australia | PC2 laboratory | 2 |
| Department of Agriculture & Food Western Australia, Western Australia | PC2 plant containment | 1 |
| The University of Queensland | PC2 laboratory<br>PC3 animal containment | 1<br>1 |
| Queensland Institute of Medical Research | PC2 large-scale<br>PC3 animal containment<br>PC3 laboratory | 1<br>2<br>2 |
| **Total** | **7 facility types** | **32** |

## 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 three finding of non-compliance for DIRs for the 1 January to 31 March 2009 quarter.

| Organisation | Bayer CropScience Pty Ltd |
|---|---|
| Licence number and site | DIR 069/2006 |
| Summary of dealing | Field trials of genetically modified canola and indian mustard, for herbicide tolerance and a hybrid breeding system. |
| Findings | During follow up activities after the inspection, it was identified that Bayer CropScience had not properly informed some persons (some contractors and casual staff) covered by the Licence of all the conditions of the licence that applied to them and had not properly obtained signed statements indicating they had understood licence conditions and agreed to be bound by them. |
| Assessment | Whilst contractors and casual staff had been notified of most of the conditions of the licence conditions that applied to them, these conditions had not been properly identified as licence conditions and they did not technically meet all the legal requirements of the Licence condition. Bayer CropScience was of the mistaken belief that these documents met the licence requirements. The issue is an administrative one and risks to human health, safety and environment were assessed as negligible. Bayer CropScience has updated their documents to rectify the issue. |
| Compliance management | Bayer CropScience is required to ensure that all persons covered are properly informed of the Licence conditions that apply to them and have signed a statement that clearly states that the Licence Holder has informed them of the licence conditions that apply to them, and that they have understood these conditions and agree to be bound by them. |

| Organisation | CSIRO |
|---|---|
| Licence number and site | DIR 086/2008 Site 1 |
| Summary of dealing | Limited and controlled release of maize genetically modified to investigate gene function. |
| Findings | During a routine monitoring inspection OGTR inspectors noted several small holes and gaps, larger than two centimetres, in the wire mesh of the birdcage.<br><br>During preparation for the inspection, it was also identified that the Licence Holder had not provided the inspection reports within 14 days of inspection taking place for this site to the Regulator for a three week period in December 2008. |
| Assessment | Prompt action was taken by the CSIRO to repair the holes in the Birdcage, which returned the Site to compliance with DIR 086/2008.<br><br>CSIRO had conducted monitoring inspection as required, but had not sent the reports to the Regulator within the required timeframe. CSIRO have since taken action to ensure the reports are provided to the Regulator within the required timeframes.<br><br>Risks to human health and safety and the environment as a result of these non-compliances were assessed to be negligible. |
| Compliance management | CSIRO is to repair any damage to the Birdcage as soon as practically possible to the reasonable satisfaction of the Regulator.<br><br>CSIRO is to monitor the site and provide inspection findings to the Regulator according to the monitoring requirements as outlined in the Licence. |

| Organisation | Monsanto Australia Limited |
|---|---|
| Licence number and site | DIR 065/2006, Site 1<br><br>DIR065/2006 was originally issued to Deltapine Australia Pty Ltd, but was transferred to Monsanto Australia Limited on 21 November 2008, following the purchase of Deltapine by Monsanto. |
| Summary of dealing | Field trials of genetically modified cotton for insect resistance. |
| Findings | Monsanto Australia self-reported a number of non-compliances that occurred in 2007 and 2008, relating to reporting requirements under DIR 065/2006. Specifically, a number of post-harvest monitoring reports were not provided within the timeframes specified by the licence, and the annual report for the 2006–07 reporting period was not provided, as required by the licence. Also reported was the use of a non-certified facility for experimentation on plant material obtained from the GMO's. |
| Assessment | The non-compliances outlined above occurred while Licence DIR 065/2006 was controlled by the previous Licence Holder. Although unable to address Deltapine Australia Pty Ltd's late provision of monitoring reports, Monsanto Australia Limited has supplied an annual report for DIR 065/2006 covering the 2006–2007 reporting period.<br>Monsanto Australia Limited has explained that the experimentation with GMO plant material in a non-certified facility resulted because Deltapine Australia Pty Ltd was of the mistaken belief that the experimentation conducted in their facility was permitted under this licence, as the plant material extracted was deemed non viable. Risks to human health and safety and the environment as a result of these non-compliances were determined to be negligible. |
| Compliance management | Monsanto Australia Limited was reminded of its obligations under the licence, and has provided refresher training for persons covered under the licence, to ensure that all persons are aware of their obligations in relation to the licence. |

**Findings for Dealings Not involving Intentional Release**

There were five findings of non-compliance for DNIRs for the 1 January to 31 March 2009 quarter.

| Organisation | The University of Western Australia |
|---|---|
| Licence number | DNIR 392/2006 and DNIR 208/2003 |
| Summary of dealing | Plasmids in Neisseria sp<br>and<br>Recombinant Murine Cytomegalovirus Encoding Hepatitis Virus C Proteins |
| Findings | At the time of the inspection OGTR staff noted that staff that had carried out work under Licence DNIR 392/2006 and DNIR 208/2003 had not signed a statement indicating that the licence holder had informed them of the conditions of the licence that apply to that person. |
| Assessment | Staff had been trained in the obligations imposed on them by the conditions of the licence and the University of Western Australia has a good compliance history. The risks to human health and safety and the environment have been assessed as negligible. |
| Compliance management | The University of Western Australia was reminded of the requirement to have signed statements from each person covered by the licence acknowledging that the licence holder has informed the person of the conditions of the licence that apply to that person. |

| Organisation | The University of Adelaide |
|---|---|
| Licence number | DNIR 249/2003 and 250/2003 |
| Summary of dealing | Studies of avian hepatitis B viruses—<br>virulence, replication and pathogenesis<br>and<br>Cellular interactions between HBV and HCV. |
| Findings | At the time of the inspection OGTR staff noted that staff that had carried out work under Licence DNIR 249/2003 and 250/2003 had not signed a statement indicating that the licence holder had informed them of the conditions of the licence that apply to that person. |
| Assessment | Staff had been trained in the obligations imposed on them by the conditions of the licence and the University of Adelaide had provided acknowledgement forms to assist staff in obtaining signed statements; however staff had not signed these. At the time of inspection the only dealings being conducted under DNIR 249/2003 and 250/2003 were storage of the GMOs and furthermore the University of Adelaide has a good compliance history. The risks to human health and safety and the environment have been assessed as negligible. |
| Compliance management | The University of Adelaide was reminded of the requirement to have signed statements from each person covered by the licence acknowledging that the licence holder has informed the person of the conditions of the licence that apply to that person. |

| Organisation | University of Adelaide |
|---|---|
| Licence number | DNIR 173/2003 |
| Summary of dealing | Molecular Breeding of Grapevines for Resistance to Major Root Pests |
| Findings | At the time of the inspection OGTR staff noted that staff that had carried out work under Licence DNIR 173/2003 had not signed a statement indicating that the licence holder had informed them of the conditions of the licence that apply to that person. |
| Assessment | Staff had been trained in the obligations imposed on them by the conditions of the licence and the University of Adelaide had provided acknowledgement forms to assist staff in obtaining signed statements; however staff had not signed these. At the time of inspection the only dealings being conducted under DNIR 173/2003 were storage of the GMOs and furthermore the University of Adelaide has a good compliance history. The risks to human health and safety and the environment have been assessed as negligible. |
| Compliance management | The University of Adelaide was reminded of the requirement to have signed statements from each person covered by the licence acknowledging that the licence holder has informed the person of the conditions of the licence that apply to that person. |

**Findings for Physical Containment Facilities**

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

| | Non-Compliance Issue | | | | | |
|---|---|---|---|---|---|---|
| Number of PC Facilities inspected | Structure | PPE[1] | Equipment | Waste disposal | Work practices[2] | Transport |
| 32 | 3 | 0 | 2 | 1 | 0 | 3 |

*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 was one practice review completed in the 1 January to 31 March 2009 quarter.

| Practice Review | GMO Storage Practice Review |
|---|---|
| Issues | This practice review was conducted to:<br>• contribute to ongoing consideration by the OGTR on the development of specifications of transport and storage of GMOs and the Regulations;<br>• confirm that participating organisations/IBCs have effective policies/ governance–arrangements/practices in place to meet regulatory requirements for GMO storage;<br>• verify that on the request of the Regulator or an inspector, stored DIR/ DNIR/NLRD GMOs can be: retrieved and presented for inspection and/or for other regulatory actions; or confirmed as being in use in the designated facility; or confirmed as destroyed; or confirmed as transferred to another organisation;<br>• collect and transfer information on compliance performance storage risks arising from ongoing change (to staff, facilities, requirements, business objectives, resource levels and new operational/business structures and relationships);<br>• raise awareness of new provisions related to storage of NLRDs; and<br>• identify and raise awareness of effective compliance management approaches.<br><br>The organisations included in the review were:<br>• Royal Perth Hospital<br>• CSIRO Perth (CSIRO Audit site included in Practice Review)<br>• Sydney University<br>• IDT Australia Ltd (Clinical, Medical and Analytical Excellence—CMAX) Laboratories at Royal Adelaide Hospital<br>• Flinders University (Royal Adelaide Hospital)<br>• Central Northern Adelaide Health Service<br>• Adelaide University<br>• Children, Youth and Women's Health Service<br>• Canberra University<br>• CSIRO Australian Animal Health Laboratories<br>• CSIRO Floriet Park<br>• CSIRO Entomology—Black Mountain, ACT<br>• CSIRO Plant Industry—Black Mountain/Hall ACT<br>• CSIRO, Bioscience Precinct, St Lucia, Queensland<br>• CSIRO Marine Research Station Cleveland Qld<br>• Australian Army Malaria Institute<br>• Griffith University (Gold Coast campus)<br>• Queensland University of Technology<br>• Royal Children's Hospital and Health Service District |

| | |
|---|---|
| Determination | The review found no non-compliances in the assessed storage arrangements of participants. All testing of GMO containment/control/retrieval was successful. Some OGTR Compliance and Investigation Section education activities covered:<br>• new regulatory provisions for the storage of GMOs; and<br>• suggestions for improvements to storage management practices to make them more durable over time. |
| Action | Reviews and audits of practices and systems for the storage of GMOs will continue to be undertaken periodically by the Compliance and Investigations Section. Some awareness raising activity about recent regulatory provisions for the storage of GMOs will be addressed at IBC Forums and through routine Compliance and Investigations Section activities. |

## 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 January to 31 March 2009 quarter.

## Investigations

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

There was one investigation completed in the 1 January to 31 March 2009 quarter.

| Organisation | Flinders University |
|---|---|
| Licence numbers | Not Applicable. |
| Issue | Flinders University made a self-reported allegation of a possible non-compliance in relation to Notifiable Low Risk Dealings with genetically modified (GM) mice being undertaken by a Flinders researcher. The allegation of non-compliance related specifically to cross breeding two strains of GM mice. |
| Findings | The matter was investigated by the OGTR Compliance and Investigations Section. The Institutional Biosafety Committee (IBC) and the researcher were interviewed with a view to establishing whether the matter warranted the application of criminal or administrative sanctions in accordance with the *Gene Technology Act 2000*.<br><br>The investigation concluded that:<br>• there was no risk to the health and safety of people and the environment and the GM mice were maintained in the appropriate level of physical containment at all times.<br>• there are insufficient legal, factual or policy grounds to pursue the matter further with a view to establishing an offence or pursuing a prosecution under the Act.<br>• dealings with the GM mice, including cross breeding, are correctly classified as NLRDs. Dealings with the individual strains of GM mice had been assessed and appropriately notified as NLRDs. Cross breeding of the particular strains of GM mice was not prohibited once the assessment and notification of the proposed dealings with the individual GM mice strains as NLRDs had taken place. |
| Determination | That no further action is required in relation to the alleged non-compliance. However other general actions have been suggested to Flinders University which may assist the IBC and researchers in understanding the requirements of the legislation. |
| Action | That the compliance section undertakes a future audit of Flinders University to assist and provide guidance to the IBC with their organisations processes and procedures. |

SECTION 3

# STATUTORY COMMITTEE OPERATIONS

## STATUTORY COMMITTEE OPERATIONS

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

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

Appointments to the two gene technology advisory committees were made by the Parliamentary Secretary to the Minister for Health and Ageing, Senator the Hon Jan McLucas, in January 2008. Senator McLucas appointed Professor Brian Priestly as a member of GTTAC in November 2008.

### Gene Technology Technical Advisory Committee

As set out in section 101 of the Act, the functions of the Gene Technology Technical Advisory Committee (GTTAC) are to provide scientific and technical advice, on the request of the Regulator or the Ministerial Council, on gene technology, GMOs, GM products, applications made under the Act, the biosafety aspects of gene technology and the need for policy principles, policy guidelines, codes of practice, technical and procedural guidelines in relation to GMOs and GM products and the content of such principles and codes.

GTTAC 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>

### 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 met once during the quarter, on 18 February 2009. The communiqué is at Appendix 2.

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

SECTION 4

# OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

# OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

## International collaboration and coordination

Under the Act the Regulator's functions include:

- monitoring international practice in relation to regulation of GMOs
- maintaining links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia
- promoting the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies.

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

- 22nd meeting of the OECD Working Group for the Harmonisation of Regulatory Oversight in Biotechnology—9–11 February 2009, Paris, France.
- Asia region Regional Real-time Online Conference on Risk Assessment and Risk Management (of living modified organisms) under the UN Cartagena Protocol on Biosafety—17 February 2009
- CFIA Science Symposium hosted by the Canadian Food Inspection Agency: 'Challenge for Plant Risk Assessment: Climate, Comparators and Confined Field Trials'—4–6 March 2009, Ottawa, Canada.

## Advice on gene technology regulation

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

During the quarter the OGTR provided presentations to the following:

- ACTEWAGL—Water Risk Workshop—24 February 2009, Canberra, ACT.

The office also attended the following meetings/conferences:

- Australian Library Information Association 14th Exhibition & Conference—Information Online—20–22 January 2009,Sydney, New South Wales
- Sugar Biotech CRC—2–3 March 2009, Canberra, ACT.

The OGTR also received visitors and presentations from:

- Malaysian Delegation—APEC High Level Policy Dialogue Project—23 February 2009.

## National Strategy for Unintended Presence of Unapproved GMOs

The Australian Government Biotechnology Ministerial Council has endorsed a risk-based national strategy to manage the unintended presence of unapproved GMOs in imported seeds for sowing (the UP strategy). The strategy was developed by an interdepartmental working group chaired by Biotechnology Australia and comprised of the then Department of Agriculture, Fisheries and Forestry; the Department of the Environment and Heritage; Department of Foreign Affairs and Trade; Department of Education, Science and Training; Department of Industry, Tourism and Resources; Department of Health and Ageing; FSANZ; and the OGTR.

The OGTR is responsible for implementing the UP strategy and has liaised closely with the Australian Seed Federation (ASF) to develop a voluntary auditing and testing program of existing industry quality assurance measures. During the quarter the OGTR and the ASF continued development of the next stage which is to expand the program to involve additional companies and to broaden the reach of the program across additional segments of the industry.

## Reviews

During this quarter, new activity in the programme of review of Guidelines for Certification of Physical Containment Facilities commenced, with drafting of revised PC3 Animal and PC3 Arthropod guidelines.

## 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 January to 31 March 2009 quarter.

| MONTH | HITS[1] | VISITORS[2] |
|---|---|---|
| January | 194,327 | 14,285 |
| February | 195,632 | 16,153 |
| March | 213,065 | 18,517 |

| DAY OF THE WEEK PATTERN FOR THE QUARTER | HITS [1] | VISITORS[2] |
|---|---|---|
| Sunday | 52,202 | 4,967 |
| Monday | 97,056 | 6,951 |
| Tuesday | 98,622 | 7,791 |
| Wednesday | 92,967 | 6,990 |
| Thursday | 91,322 | 7,176 |
| Friday | 102,559 | 7,097 |
| Saturday | 68,296 | 5,479 |

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

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

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

- What's New
- Intentional Release and Evaluation Process
- About the OGTR
- Publication and Forms—Certification of Physical Containment Facilities
- Guidelines
- GMO Record
- Home Page
- IBC & Accredited Organisations Information
- *Risk Analysis Framework*
- GMO Products.

The most popular downloaded documents were:

- *Risk Analysis Framework*
- The Biology of Carica papaya L. (*papaya, papaw, paw paw*) in Australia
- The Biology and Ecology of Rice (*Oryza sativa* L.) in Australia
- The Biology and Ecology of Cotton (*Gossypium hirsutum* L.) in Australia
- The Biology and Ecology of Pineapple (*Ananas comosus var. comosus*) in Australia

- The Biology and Ecology of Banana (*Musa spp.*) in Australia
- The Biology of the Sugarcane (*Saccharum spp.*) in Australia
- The Biology and Ecology of Carnation (*Dianthus caryophyllus* L.) in Australia
- PC3 Guidelines
- The Biology and Ecology of Ryegrass (*Lolium multiflorum, Lolium perenne, Lolium arundinaceum*) in Australia.

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

## 2008 Client Service Survey

The OGTR is committed to providing quality services as part of implementing the regulatory scheme. To ensure that we meet the needs of our clients we undertake customer surveys against the standards of service outlined in our Service Charter. A link to our service charter is provided at the bottom of every OGTR webpage. Feedback on these surveys is reported and used for continuous improvement in the delivery of the regulatory scheme. An OGTR client satisfaction survey was conducted in late 2008. The survey indicates that a majority of survey respondents have a positive view of, or have no dissatisfaction with, OGTR client services. For example, 47 percent of accredited organistions that responded to the survey reported they were very satisfied with their dealings with the OGTR and 52 percent indicated they were satisfied. Although the report generally indicates that OGTR client services are performing well, some respondents also provided advice on possible improvements to services. In response to survey findings and issues raised in responses the OGTR has undertaken some improvements to services. The key areas where the OGTR has focused attention to make improvements in response to the survey are:

- website functionality
- the levels and location of information on the website
- staff interactions with clients
- ongoing review and improvement of guidance and regulatory instruments.

Further information about the survey is available on the OGTR service charter webpage (under *Our Service Delivery*).

## Internet contacts and freecall number

### OGTR email address and freecall number

The OGTR's 1800 number and email address are points of contact for members of the public and other interested parties to obtain information about the regulation of GMOs. Assistance with specific questions and additional mechanisms for public feedback are among some of the services provided by the 1800 line and email facilities. The table below describes the activity of these facilities throughout the quarter.

| MONTH | EMAILS | OGTR 1800 NUMBER |
|---|---|---|
| October | 123 | 87 |
| November | 118 | 84 |
| December | 142 | 121 |

### 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 123 emails during the quarter.

### Statutory Committee email inbox

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

The inbox ensures that all communications are answered in a timely manner by secretariat staff. The inbox received 184 emails during the quarter.

### Application and Licence Management email inbox

This electronic mail inbox provides a central, shared communication point to allow efficient coordination of responses for correspondence and queries about applications received by the Application and Licence Management Section. The inbox received 439 emails during the quarter.

# APPENDICES

# APPENDIX 1:

## DNIR licences issued 1 January to 31 March 2009

| Application number | Licence issued | Organisation and State | Project title | Project description |
|---|---|---|---|---|
| DNIR-454 | 24 February 2009 | University of New South Wales, NSW | Development of a pseudo-typed NoV to investigate NoV replication in cell culture | The purpose of this dealing is to develop a pseudo-typed murine Norovirus to investigate Norovirus replication in cell culture. |
| DNIR-456 | 19 March 2009 | The University of Western Australia, WA | Development of a Prime-Boost anti-cancer vaccine | The purpose of this dealing is to test prime-boost anti-cancer vaccines using in vivo murine tumour models. |
| DNIR-457 | 20 March 2009 | The Walter and Eliza Hall Institute of Medical Research, VIC | Knockdown of gene expression in human and mouse cells using lentiviral libraries | The purpose of these dealings is to use replication defective lentiviral vectors encoding gene silencing constructs to study cellular behaviour in vitro. |
| DNIR-460 | 20 March 2009 | Peter MacCallum Cancer Centre, VIC | Use of a short hairpin microRNAi (shRNA-mir) lentiviral based library for small and large scale functional genomics screens | The purpose of these dealings is to use replication defective lentiviral vectors encoding gene silencing constructs to study cellular behaviour in vitro. |

# APPENDIX 2:

## Gene Technology Ethics and Community Consultative Committee COMMUNIQUÉ 18 February 2009, Canberra

**The Gene Technology Ethics and Community Consultative Committee (GTECCC) held its second meeting of the Triennium in Canberra on 18 February 2009.**

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 second meeting on 18 February 2009.

### GTECCC's Work Plan

GTECCC reviewed work undertaken to date and resolved to focus on several key areas, including finalisation of some unfinished projects. The following will remain as the main objectives for GTECCC in the short term:

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

GTECCC resolved to commence a review of the Framework, noting that it had been the former GTEC's intention to take stock of the document after three years.

GTECCC established a working group which will undertake consultation with stakeholders to obtain feedback on the usefulness and operationalisation of the Framework's nine principles.

**Environmental Ethics and Gene Technology**

GTECCC reviewed progress on finalisation of this paper and requested the working group to review the current draft and recirculate to members for any additional revisions. The paper will be referred to the working group established to review the National Framework for the Development of Ethical Principles in Gene Technology (the Framework) to inform their work.

GTECCC also noted and discussed a significant report recently produced by the European Ethics Group (EGE)—*Opinion No 24—Ethics of modern developments in agriculture technologies*. The document included a number of principles that the committee considered would provide a useful reference for future GTECCC activities.

**Community Consultation**

GTECCC considered a compilation of surveys undertaken in Australia since 1999 to gauge community attitudes to gene technology. The Committee re affirmed that its role was to provide advice to the Regulator on facilitating community engagement in OGTR processes.

**GTECCC and Relationships with Other Committees**

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

An invitation was extended to Dr David Adams from the National Health and Medical Research Council's (NHMRC's) Animal Welfare Committee as an observer. Dr Adams is invited to participate in future GTECCC meetings.

The GTECCC Committee agreed that consideration of the most effective approaches and tools for community consultation remains an important issue and will remain on the agenda at the next meeting. The background paper produced by the former GTCCC and documents from the Canadian Deliberative Democracy and the International Association for Public Participation will be incorporated in discussion.

GTECCC also considered whether there were other key committees that they might establish formal links with. None were identified however, GTECCC noted that interactions with other committees should be determined on a case by case needs basis if issues arose.

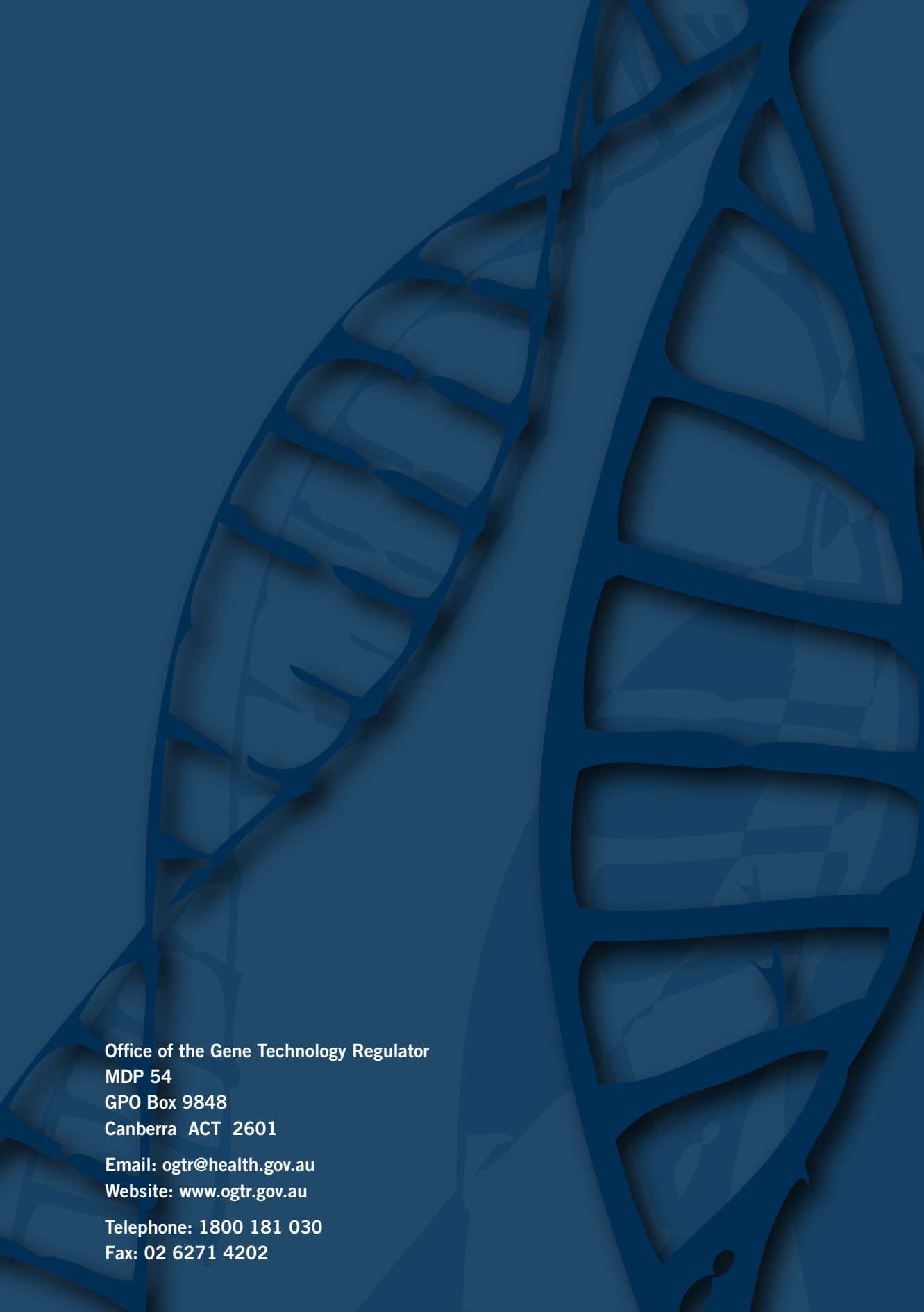
**For all inquiries, please contact the Office of the Gene Technology Regulator on 1800 181 030 (free-call)**

## GLOSSARY

This section contains a brief description of terms relevant to an understanding of this quarterly report. They do not substitute for definitions of terms relevant to the operation of the gene technology regulatory system that are contained in section 10 of the *Gene Technology Act 2000*.

| | |
|---|---|
| **Accredited organisation** | An organisation that is accredited under section 92 of the Act |
| **Act** | *Gene Technology Act 2000* |
| **APVMA** | Australian Pesticides and Veterinary Medicines Authority |
| **Breach of a licence condition** | A breach of a licence condition which has been proven either in court or by way of admission following investigation |
| **CCI** | Confidential commercial information |
| **Certified containment facility** | A building or place certified by the Regulator to a specified containment level under section 84 of the Act |
| **Clock stop** | The period during which time does not run for purposes of the statutory time limit for making a decision—usually because evaluation cannot proceed until additional information requested from the applicant is received |
| **CSIRO** | Commonwealth Scientific and Industrial Research Organisation |
| **DIR** | A dealing involving intentional release of a GMO into the environment (e.g. field trial or commercial release) |
| **DIR licence** | A licence for a dealing involving intentional release of a GMO into the environment |
| **DNIR** | A contained dealing with a GMO not involving intentional release of the GMO into the environment (e.g. experiments in a certified facility such as a laboratory) |
| **DNIR licence** | A licence for a dealing not involving intentional release of a GMO into the environment |
| **Expert advisers** | Advisers appointed by the Minister to give expert advice to either GTTAC or GTECCC to assist them in the performance of their functions (expert advisers are not committee members) |
| **EDD** | Emergency dealing determination |
| **FSANZ** | Food Standards Australia New Zealand |

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



Office of the Gene Technology Regulator
MDP 54
GPO Box 9848
Canberra ACT 2601

Email: ogtr@health.gov.au
Website: www.ogtr.gov.au

Telephone: 1800 181 030
Fax: 02 6271 4202