



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT
1 OCTOBER–31 DECEMBER 2010

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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ISBN: 978-1-74241-418-8

Online ISBN: 978-1-74241-419-5

Publications Number D0260

Paper-based publications

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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.

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 October to 31 December 2010.

During this period one licence for a dealing involving intentional release of GMOs and six licences for dealings not involving intentional release of GMOs were issued, while 49 physical containment facilities were certified.

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

Yours sincerely



Dr Joe Smith
Gene Technology Regulator

23 February 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 1 October to 31 December 2010 quarter.

Regulation of genetically modified organisms

Provides details on the regulatory activity undertaken, including information about applications for, and action taken with respect to, GMO licences and other instruments under the Act. It also includes details of monitoring, auditing and compliance activities by the Regulator during this quarter.

Statutory committee operations

Reports on the activities of the two advisory committees established under the Act to assist the Regulator and the Gene Technology Ministerial Council.

Other activities of the Gene Technology Regulator

Describes other activities relating to the statutory functions of the Regulator that support the operations of the gene technology regulatory system.



SECTION 1

**NATIONAL GENE TECHNOLOGY
REGULATORY SYSTEM**



NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 October to 31 December 2010 quarter were:

Licences and other instruments

- Two organisations issued with accreditation
- One licence issued for a Dealing involving the Intentional Release (DIR) of GMOs into the environment
- Six licences issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- 49 physical containment facilities certified
- 45 instruments surrendered
- Variation of 59 certifications and 15 DNIR licences.

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

Monitoring and Compliance

Approximately 10 percent of current field trial sites and five 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 sought advice in respect of two DIR RARMPs.

Further information on the processing of DIR applications is contained in Section 2 of this report.

Public participation

The Act requires the Regulator to consult the public on the RARMPs for all DIR licence applications. Two invitations to the public to comment on a RARMP were issued during the quarter.

Further information on the processing of DIR applications is contained in Section 2 of this report.



SECTION 2

**REGULATION OF GENETICALLY
MODIFIED ORGANISMS**

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of this report outlines the regulatory activity undertaken during the 1 October to 31 December 2010 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	1	6
Certifications	67	49

* Approvals reported in the current quarter often relate to applications received in previous quarters.

Processing of applications for Dealings involving Intentional Release licences

The key steps the Regulator takes when considering an application for a DIR licence are:

- initial screening of the application for completeness
- determining whether or not the application is a limited and controlled release
- considering the applicant's suitability to hold a licence, having regard to relevant convictions, revocations and suspensions of related licences and permits, and ability to meet conditions of the licence
- seeking comments from prescribed experts, agencies and authorities on issues to consider in the RARMP for all DIR applications except limited and controlled releases
- preparing a consultation RARMP, including proposed licence conditions to manage risks to human health and safety and the environment, and determining whether the proposed dealings may pose a significant risk

- seeking comments on the RARMP from prescribed experts, agencies and authorities and the public
- considering all comments relating to the protection of human health and safety and the environment in finalising the RARMP
- confirming the applicant's suitability, including their capacity to meet licence conditions, and considering policy principles and any relevant policy guidelines.

Once these actions are completed, the Regulator can make a decision on whether or not to grant a licence and the conditions which are to be included in the licence if issued.

The statutory timeframes for making decisions on DIR licences effectively extend over approximately twelve months, and eight or nine months for limited and controlled releases, as they exclude weekends and public holidays observed in the Australian Capital Territory.

These timeframes 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 109	DIR 106	DIR 105 DIR 107	DIR 105

* 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 109—Limited and controlled release of banana genetically modified for enhanced nutrition—Queensland University of Technology

Consultation on applications for Dealings involving Intentional Release licences

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

- DIR 106—Limited and controlled release of sugarcane genetically modified for production of biopolymers and biopolymer precursors—University of Queensland

There were two invitations to comment on RARMPs issued during the quarter:

- DIR 105—Limited and controlled release of canola genetically modified for herbicide tolerance—Monsanto Australia Limited
- DIR 107—Limited and controlled release of banana genetically modified for disease resistance—Queensland University of Technology.

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.

Two DIR licences were surrendered during the quarter.

- DIR 034/2003—Field trial of genetically modified cotton (*Gossypium hirsutum*) expressing an insecticidal gene (*vip3A*)—Syngenta Seeds Pty Ltd
- DIR 083/2007—Limited and controlled release of cotton genetically modified for enhanced waterlogging tolerance—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 108—Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system (InVigor® × Roundup Ready® canola)—Bayer CropScience Pty Ltd

Decisions on applications for Dealings involving Intentional Release licences

One DIR licence was issued during the quarter:

- DIR 105—Limited and controlled release of canola genetically modified for herbicide tolerance—Monsanto Australia Limited

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.

Six DNIR licences were issued during the quarter:

- DNIR 490—Identification of determinants of virulence and vector competence factors in Ephemeroviruses—CSIRO, Victoria
- DNIR 491—Cloning and over-expression of a metalloprotease implicated in the virulence of a coral pathogen *Vibrio corallilyticus*—Australian Institute of Marine Science, Queensland
- DNIR 492—Construction of a Taura syndrome virus infectious clone—CSIRO, Victoria
- DNIR 493—Molecular analysis of *Streptococcus pyogenes*—The University of Queensland, Queensland
- DNIR 494—Regulation of tumour suppression—Peter MacCallum Cancer Centre, Victoria
- DNIR 495—Generation of recombinant Rabbit Caliciviruses—CSIRO, Australian Capital Territory.

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 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 ^a
Surrender of certification	1	2
Surrender of certification	51	38
Surrender of DIR licence	1	2
Surrender of DNIR licence	2	3
Variation of accreditation	0	0
Variation of certification	32	59
Variation of DIR licence ^b	3	0
Variation of DNIR licence	26	15

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 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 did not receive any CCI applications in relation to DIR applications. 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 OGTR monitoring and compliance activities 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 restricted
- the persistence of a GMO in the environment is restricted
- 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.

Routine monitoring visits of a minimum of 20 percent of field trial sites each year are conducted. 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 restrict the spread and persistence of the GMOs is more likely to occur (for example, flowering and harvest of GM crops).

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

These inspections focus on the integrity of the physical structure of the facility and on the general laboratory practices followed in that facility, including those practices followed for DNIRs and Notifiable Low Risk Dealings (NLRD).

Overview of monitoring and compliance for the reporting period

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

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

- **Current field trial sites:** Of the 20 sites current in the quarter, two were monitored. This represents a monitoring rate of ten percent of all current sites for the quarter.
- **Post-harvest field trial sites:** Of the 40 sites subject to post-harvest monitoring in the quarter, two were monitored. This represents a monitoring rate of five percent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection with contained dealings covered 10 organisations and 19 PC facilities. Monitoring of PC facilities encompassed nine PC2 laboratories, three PC2 animal containment facilities, one PC2 plant containment facility, two PC2 large scale facilities and, four PC3 laboratories.

Monitoring of contained dealings: During the quarter, the monitoring of the 19 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.

Twelve 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	Licence Number	No. sites visited	Site status	Crop type
The University of Queensland, Queensland	DIR 026/2002	1	Current	Papaya
Queensland Government Department of Primary Industries and Fisheries, Queensland	DIR 028/2002	1	*PHM	Pineapple
The University of Adelaide, South Australia	DIR 077/2007	1	*PHM	Wheat
	DIR 102	1	Current	
Total	4	4	Current = 2 *PHM = 2	

* PHM = post-harvest monitoring.

Monitoring of Dealings Not involving Intentional Release

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

Licensed Organisation Name	Licence Number
The University of Queensland, Queensland	DNIR 472
The University of Western Australia, Western Australia	DNIR 210
Murdoch University, Western Australia	DNIR 76 and 281
Telethon Institute for Child Health Research, Western Australia	DNIR 482
Royal Perth Hospital, Western Australia	DNIR 260
Australian Army Malaria Institute, Queensland	DNIR 71
Flinders University, South Australia	DNIR 435
Ludwig Institute for Cancer Research, South Australia	DNIR 26
CSL Limited, Victoria	DNIR 119 and 374
Sanofi-Aventis Australia Pty Ltd, Western Australia	DNIR 386
Total	12

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
The University of Queensland, Queensland	PC3 laboratory	2
The University of Western Australia, Western Australia	PC2 laboratory	2
Telethon Institute for Child Health Research, Western Australia	PC2 laboratory	1
	PC2 animal facility	1
Murdoch University, Western Australia	PC2 laboratory	1
	PC2 plant facility	1
Royal Perth Hospital, Western Australia	PC2 laboratory	2
Australian Army Malaria Institute, Queensland	PC2 laboratory	1
Flinders University, South Australia	PC2 laboratory	1
	PC2 animal facility	1
Queensland Institute of Medical Research, Queensland	PC3 laboratory	2
Ludwig Institute for Cancer Research, South Australia	PC2 laboratory	1
	PC2 animal facility	1
CSL Limited, Victoria	PC2 large scale	2
Total	5 facility types	19

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

Three non-compliance issues were observed for DNIRs in the quarter.

Organisation	Flinders University
Licence number	DNIR 435
Summary of dealing	To investigate the potential for lentiviral mediated gene therapy to improve the survival of corneal grafts in animal models.
Findings	Flinders University informed inspectors that, when transporting GMOs from collaborators, the containers were not labelled with contact details or biohazard labels. The Regulator's Guidelines for Transport of GMOs require that the outermost container must be labelled with contact details and biohazard labels during transport.
Assessment	Transport of GMOs is conducted by authorised persons and are double contained. Risks to human health, safety and environment were assessed as negligible.
Compliance management	Flinders University was required to ensure that the outermost containers used for the transport of GMOs, or material containing GMOs, be labelled according to the Regulator's Guidelines for Transport of GMOs.
Organisation	Murdoch University
Licence number	DNIR 281
Summary of dealing	Development of Subterranean clover mottle virus as a gene-silencing vector.
Findings	At the time of inspection the licence holder notified OGTR inspectors that two boxes of GMOs related to DNIR 281 were inadvertently being stored securely in a certified PC2 laboratory. DNIR 281 expired on 31 October 2008 and the licence conditions stipulated that all GMOs be disposed of prior to this date.
Assessment	This issue was the result of an oversight, and the GMOs were being stored in a certified PC2 laboratory in a manner consistent with the laboratory's conditions of certification. As such the risks posed to human health and safety and the environment are negligible.
Compliance management	The licence holder must either dispose of the GMOs in a manner approved by the Regulator or contact OGTR to discuss obtaining an alternate storage authorisation.

Organisation	Ludwig Institute for Cancer Research Melbourne— Austin Branch
Licence number	DNIR 026
Summary of dealing	The mechanisms of establishing and maintaining immunological memory
Findings	<p>Prior to the monitoring inspection, OGTR staff were informed by the Ludwig Institute that dealings authorised by DNIR 026 were no longer conducted in facilities listed on the licence, and were now being conducted in a new PC2 Laboratory and a PC2 Animal Facility.</p> <p>At the time of inspection, OGTR staff observed that the outermost containers used to transport the GMOs and material containing GMOs outside of certified facilities were not labelled with contact details of person responsible for the dealings or affixed with biohazard labels.</p>
Assessment	<p>The persons authorised under DNIR 026 working in the new facilities under DNIR 026 were appropriately trained and the facilities were certified by the Regulator and appropriate for the conduct of the dealings with the GMOs. However, Ludwig Institute for Cancer Research Melbourne-Austin Branch failed to notify the Regulator of this change. This issue was an oversight on part of the organisation, the risk to the environment and human health and safety was assessed as negligible.</p> <p>Authorised persons ensured that transport containers were always carried, the risk of losing or misplacing the container(s) over a short distance is considered negligible.</p>
Compliance management	<p>The licence holder must seek a variation to DNIR 026 to add the currently used facilities and remove certified facilities no longer in use.</p> <p>The Project Supervisor provided assurance that, effective immediately, all transport containers will be labelled with contact details and that a biohazard symbol will be affixed.</p>

Findings for Physical Containment Facilities

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

Number of PC Facilities inspected	Non-Compliance Issue					
	Structure	PPE ¹	Equipment	Waste disposal	Work practices ²	Transport
19	2	0	4	0	4	2

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

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 in 2007 by the then Parliamentary Secretary to the Minister for Health and Ageing, Senator the Hon Jan McLucas. The process for appointment of new members for the 20011-2014 triennium progressed during the quarter.

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 met once during the quarter on 23 November 2010. The Communiqué is at Appendix 1.

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

Gene Technology Ethics and Community Consultative Committee

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 met once during the quarter on 9 December 2010. The Communiqué is being finalised. Once finalised, it will be available on the OGTR website.

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



SECTION 4

**OTHER ACTIVITIES OF THE
GENE TECHNOLOGY REGULATOR**



OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

International collaboration and coordination

Under the Act the Regulator's functions include:

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

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

- Meeting with Croplife Biotechnology committee, 7 December 2010, Sydney, Australia
- Participated in, including Plenary presentation to, the 11th International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO), 15–19 November 2010, Buenos Aires, Argentina
- Meeting with Namibian regulatory officials, 15 November 2010, Canberra
- Hosted Malaysian Ministry of National Resources and Environment Biosafety Core Team study visit to OGTR, 8–12 November 2010, Canberra, Australia
- Presented at Risk Analysis Discussion with Brazilian regulators, 10–12 November 2010, Recife, Brazil
- Conducted Risk Assessment Workshop for Cambodian government agencies, Sihanoukville, Cambodia, 1–5 November 2010
- Participated in Australian delegation to the Fifth Meeting of the Parties to the UN Cartagena Protocol on Biosafety, 11–15 October 2010, Nagoya, Japan
- Keynote presentation to Organisation for Economic Cooperation and Development (OECD) Cooperative Research Programme symposium: 'Decision Making and Science: the balancing of risk based decision that influence the sustainability of agricultural production', 6–8 October 2010, Berlin, Germany
- Meetings with officials of the European Food Safety Authority (EFSA), the Netherlands Institute of Food Safety, (RIKILT), the GMO Office of the Netherlands National Institute for Public Health and Environment (RIVM), 4–5 October 2010, Bilthoven, Netherlands.

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 Regulator participated in a Regulators' Forum involving the prescribed agency regulators who have complementary role in the regulation of gene technology in Australia.

OGTR officers also participated in the following meetings/conferences:

- Darwin Symposium 2010—Evolution in Science, Technology and Society, 6-7 December 2010, Victorian Department of Primary Industries & La Trobe University, Melbourne
- Attended Enabling Technologies, Government Communications Meeting, 23 November 2010, Canberra
- Plenary presentation to Australasian Environmental Law Enforcement and Regulators Network 2010 Conference—Diversity in Environmental Regulatory Responses, 3–5 November 2010, Canberra
- Attended/presented at OzBio 2010 Conference, 27 September–1 October 2010, Melbourne.

Research

One of the Regulator's functions under the Act is to commission research in relation to risk assessment and the biosafety of GMOs. Following a targeted request for quotation, during this quarter the Regulator executed a contract with Deakin University to conduct a study to determine the viability of seeds after consumption by birds, to inform risk assessment and risk management plans for GM plants. The research is to be conducted in the first half of 2011.

OGTR website usage and statistics

The OGTR website is a comprehensive source of information on activities of the office. The table below provide information on the number of hits on the OGTR website and the number of visitor sessions by month during the quarter.

MONTH	HITS ¹	VISITS ²
October	199,974	24,554
November	201,940	26,498
December	167,125	22,021

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
- About the OGTR
- Guidelines and forms for Certification of Physical Containment Facilities
- Record of GMOs and GM Product Dealings
- Forms and Guidelines
- Licence Application & Assessment Process
- Fact sheets and Information Bulletins
- Legislation

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 Sugarcane (*Saccharum spp.*) in Australia
- Operation of the Gene Technology Regulator Annual Report 2009–2010
- The Biology and Ecology of Cotton (*Gossypium hirsutum L.*) in Australia
- The Biology and Ecology of Pineapple (*Ananas comosus var. comosus*) in Australia
- PC2 Laboratory guidelines
- The Biology of *Triticum aestivum L. em Thell.* (Bread Wheat)
- The Biology and Ecology of *Dianthus caryophyllus L.* (Carnation)

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

Internet contacts and freecall number

OGTR email address and freecall number

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

MONTH	EMAILS	OGTR 1800 NUMBER
October	79	98
November	118	92
December	102	71

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 163 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 318 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.

Contained Dealings Evaluation Section email inbox

The Contained Dealings Evaluation Section has established an email inbox to provide a central point for efficient coordination of responses to queries relating to: classification of contained dealings with GMOs; certification requirements for higher level containment facilities; and DNIR licences. The inbox received 158 emails during the quarter.



APPENDIX



APPENDIX 1

Gene Technology Advisory Committee

COMMUNIQUÉ No. 28

This is the 28th communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 38th meeting of GTTAC, held on 23 November 2010.

GTTAC is a statutory advisory committee established under the *Gene Technology Act 2000* (the Act) to provide scientific and technical advice to the Gene Technology Regulator (the Regulator) and the Gene Technology Ministerial Council. All Committee members and expert advisers hold office on a part-time basis.

The Regulator receives advice from GTTAC on Risk Assessment and Risk Management Plans (RARMPs) prepared in respect of applications for licences to conduct dealings with genetically modified organisms (GMOs).

The purpose of this Communiqué is to provide a brief overview of the applications and RARMPs considered by GTTAC and, in accordance with Regulation 29 of the Gene Technology Regulations 2001, any resolutions the Committee has provided to the Regulator with regard to those applications and RARMPs.

The Communiqué also provides an overview of any other major issues discussed by GTTAC.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED ORGANISMS

Dealings Involving the Intentional Release of GMOs (DIRs) involve the limited and controlled release (field trial) of a GMO or a commercial (general) release of a GMO.

The RARMP for every DIR licence application is released for public comment as part of the consultation process. Information on how to obtain copies of applications and RARMPs for DIRs is provided at the end of this document.

GTTAC Advice

The Regulator must seek GTTAC advice on RARMPs prepared in respect of all DIR applications.

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

1. ADVICE ON CONSULTATION RARMPs—LIMITED AND CONTROLLED RELEASE

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

1.1 DIR 105—Limited and controlled release of canola genetically modified for herbicide tolerance

GTTAC noted that the GM canola from Monsanto had been modified to contain a gene derived from a common soil bacterium. Expression of the gene in the GM canola plants is expected to confer tolerance to herbicides containing glyphosate. The GM canola would not be used in human food or animal feed. The trial is proposed to take place over four years, from March 2011 to December 2014. Sites may be located in canola growing regions in 46 possible local government areas (LGAs) in New South Wales, 28 possible LGAs in Victoria and 53 possible LGAs in Western Australia.

RESOLUTION:

- GTTAC advised the Regulator that the potential for spread and persistence of the GM canola as a result of 'windrowing' should be considered.
- GTTAC advised the Regulator that the Brassica napus biology document should be reviewed to ensure it captures wind dispersal and growers' observations.
- GTTAC advised that the Regulator reconsider wording of conditions relating to isolation zones to improve clarity.

1.2 DIR 107—Limited and controlled release of banana genetically modified for disease resistance.

GTTAC noted that the application from the Queensland University of Technology involved the intentional release of GM banana into the environment on a limited scale and under controlled conditions. Cavendish and Lady Finger bananas would be genetically modified for disease resistance, primarily to Fusarium wilt (Panama disease) and Yellow sigatoka (leaf spot).

A trial is proposed to take place at one site in the local government area (LGA) of Litchfield Municipality, Northern Territory, on a maximum area of 1.5 ha between November 2010 and November 2014.

RESOLUTION:

- GTTAC advised the Regulator that means of clearly separating GM and non-GM banana plants should be considered.
- GTTAC advised the Regulator that the potential for unintended effects had been adequately considered in the RARMP.

DEALINGS NOT INVOLVING INTENTIONAL RELEASE

Dealings not involving the intentional release of GMOs (DNIRs) are dealings that are usually undertaken within a facility where the organism is physically contained.

2. ADVICE ON CONSULTATION RARMPs—DEALINGS NOT INVOLVING INTENTIONAL RELEASE

GTTAC considered the Consultation RARMPs prepared in response to the following application for dealings not involving intentional release:

2.1 DNIR 496-Characterisation of the molecular determinants of host range and pathogenicity for Henipaviruses

GTTAC discussed the RARMP prepared by the Regulator in response to an application from the CSIRO and noted that the application concerns:

- the generation of plasmids encoding the GM viral genomes;
- transfecting mammalian cells lines with the GM plasmids expressing mutant or chimeric Hendra virus (HeV) or Nipah virus (NiV) to produce replication competent genetically modified (GM) virus particles;
- infecting mammalian tissue culture cells with the GM virus particles to characterise viral infectivity using *in vitro* assays;
- inoculating ferrets, mice, fruit bats, pigs and horses with the GM virus particles; and
- histological and immunological characterization.

GTTAC noted that the dealings with plasmids will be conducted in PC3 facilities and dealings with the GM viruses will be conducted in PC4 facilities and noted that infection in the general population was unlikely. GTTAC discussed possible risks to health and safety of staff undertaking the dealings, including administering the GMO to animals. GTTAC also noted that all reasonable precautions have already been proposed.

RESOLUTION:

- GTTAC advised the Regulator to consider further references relating to the consequence assessment for Risk Scenario 2*
- GTTAC advised the Regulator to consider having formalised responses to unexpected circumstances such as infected or symptomatic staff member.

*Risk scenario 2: exposure to replication competent GM Henipavirus (or tissue culture cells that contain GM Henipavirus) that has the capacity to infect humans leading to disease or death

ENQUIRIES AND RISK ASSESSMENT AND RISK MANAGEMENT PLANS


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

GLOSSARY

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

Accredited organisation	An organisation that is accredited under section 92 of the Act
Act	<i>Gene Technology Act 2000</i>
APVMA	Australian Pesticides and Veterinary Medicines Authority
BSG	Biosecurity Services Group of the Department of Agriculture, Fisheries and Forestry
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 <u>not</u> involving intentional release of the GMO into the environment (e.g. experiments in a certified facility such as a laboratory)
DNIR licence	A licence for a dealing not involving intentional release of a GMO into the environment
Expert advisers	Advisers appointed by the Minister to give expert advice to either GTTAC or GTECCC to assist them in the performance of their functions (expert advisers are not committee members)
EDD	Emergency dealing determination

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



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