Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 APRIL–30 JUNE 2011

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

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

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 APRIL–30 JUNE 2011

Print version ISBN: 978-1-74241-553-6

Online version ISBN: 978-1-74241-554-3

Publications Number D0536

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.a

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.

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 April to 30 June 2011.

During this period 34 physical containment facilities were certified, while 73 certifications and 16 licences were varied.

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

The Gene Technology Amendment Regulations 2011 were made by the Commonwealth Administrator on 2 June 2011 and I issued new *Guidelines for the Transport, Storage and Disposal of GMOs*, also on 2 June 2011. Both instruments commenced on 1 September 2011.

Yours sincerely

Dr Joe Smith
Gene Technology Regulator
30 September 2011

CONTENTS

LETTER OF TRANSMITTAL III

ABOUT THIS REPORT 1

Gene technology regulatory system 1
Regulation of genetically modified organisms 1
Statutory committee operations 1
Other activities of the Gene Technology Regulator 1

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM 4

Key achievements during this quarter 4
Licences and other instruments 4
Monitoring and Compliance 4
Working collaboratively with States and Territories 4
Gene Technology Ministerial Council 4
State and Territory consultation 4
Australian Government Agency liaison 5
Public participation 5

REGULATION OF GENETICALLY MODIFIED ORGANISMS 8

Types of Applications 8
GMO Register 9
New licences and other instruments 9
Processing of applications for Dealings involving Intentional Release licences 9
Applications received for Dealings involving Intentional Release licences 10
Consultation on applications for Dealings involving Intentional Release licences 10
Withdrawn applications and surrendered licences for Dealings involving Intentional Release licences 11
Clock stopped on Dealings involving Intentional Release licence applications 11
Decisions on applications for Dealings involving Intentional Release licences 11
Decisions on applications for Dealings Not involving Intentional Release licences 11
Changes to existing licences and other instruments 12
Emergency Dealing Determinations 12
Confidential Commercial Information 13

Monitoring and Compliance 13
Monitoring and Compliance Strategy 14
Overview of monitoring and compliance for the reporting period 14
Monitoring of Dealings involving Intentional Releases 15
Monitoring of Dealings Not involving Intentional Releases 16
Monitoring of Physical Containment Facilities 16
Monitoring Findings 17
Dealings involving Intentional Release 17
Findings for Dealings involving Intentional Release 17
Findings for Dealings Not involving Intentional Release 18
Findings for Physical Containment Facilities 20
Practice Reviews 20
Audits 21
Investigations 21

STATUTORY COMMITTEE OPERATIONS 24

Gene Technology Technical Advisory Committee 24
Gene Technology Ethics and Community Consultative Committee 24

OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR 26

Making of the Gene Technology Amendment Regulations 2011 26
International collaboration and coordination 26
Advice on gene technology regulation 27
Accredited organisations and Institutional Biosafety Committee training 27
OGTR website usage and statistics 27
Internet contacts and freecall number 29
OGTR email address and freecall number 29
Monitoring and compliance email inbox 29
Statutory Committee email inbox 29
Application and Licence Management email inbox 29
Contained Dealings Evaluation Section email inbox 29

APPENDIX 1 32

Gene Technology Technical Advisory Committee
COMMUNIQUÉ 32

APPENDIX 2 35

Gene Technology Ethics and Community Consultative Committee
COMMUNIQUÉ 35

GLOSSARY 37

ABOUT THIS REPORT

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

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

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

This report has four key sections.

Gene technology regulatory system

Provides advice on the activities and outcomes achieved in relation to the implementation and management of the national regulatory system during the quarter.

Regulation of genetically modified organisms

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

Statutory committee operations

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

Other activities of the Gene Technology Regulator

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

SECTION 1

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 April to 30 June 2011 quarter were:

Licences and other instruments

- 2 organisations issued with accreditation.
- 34 physical containment facilities certified
- 34 instruments surrendered
- Variation of 73 certifications, one DIR licence and 15 DNIR licences.

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

Monitoring and Compliance

Approximately 27 percent of current field trial sites and 15 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 one DIR RARMP.

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

Public participation

The Act requires the Regulator to consult the public on the RARMPs for all DIR licence applications. One invitation to the public to comment on a RARMP was issued during the quarter.

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

SECTION 2

REGULATION OF GENETICALLY MODIFIED ORGANISMS

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of the report outlines the regulatory activity undertaken during the 1 April to 30 June 2011 quarter. This includes information about applications for GMO licences and other instruments under the Act. This section details any EDDs made pursuant to the Act. It also includes details of monitoring activities and of alleged, admitted or self-reported non-compliances with the Act, or with the conditions imposed by the Regulator on GMO licences or other instruments issued pursuant to the Act. Summary reports on investigations completed during the quarter are supplied. Information on Confidential Commercial Information (CCI) applications has also been provided.

Types of Applications

Under the Act the Regulator is required to make decisions in relation to applications for the following instruments:

- **Dealings involving Intentional Release licences**

DIR licences authorise dealings ranging from limited and controlled releases (e.g. field trials) through to more extensive general or commercial releases of GMOs. DIR licence applications have a statutory timeframe of 255 working days for processing unless the Regulator determines the application is a limited and controlled release application. Then the timeframe for making a decision is 150 working days, or 170 working days if the Regulator determines that the proposed dealings represent a significant risk to human health and the environment.

- **Dealings Not involving Intentional Release licences**

DNIR licences authorise contained dealings with GMOs carried out in laboratories and other containment facilities that are designed to prevent release of the GMO(s) into the environment. These licence applications have a statutory timeframe of 90 working days for making a decision.

- **Accreditations of organisations**

DIR and DNIR licences require organisations which conduct work with GMOs to be accredited. To achieve accreditation, the Regulator must be satisfied that the organisation has, or has access to, a properly constituted and resourced Institutional Biosafety Committee (IBC) and complies with the requirements of the Regulator's guidelines for accreditation. These applications have a statutory timeframe of 90 working days for making a decision.

- **Certifications of containment facilities**

Certification is required to satisfy the Regulator that a facility which is proposed to be used to conduct dealings with a GMO meets the guideline requirements for the particular level of physical containment specified. These applications have a statutory timeframe of 90 working days for making a decision.

GMO Register

The GMO Register is a list of dealings with GMOs that the Regulator is satisfied pose minimal risks to human health and safety and the environment and can therefore be undertaken by anyone, subject to any specified conditions, without the oversight of a licence holder. Under section 78 of the Act the Regulator may determine that dealings with a GMO previously authorised by a licence are to be included on the GMO Register. Such determinations are disallowable instruments.

New licences and other instruments

The following table describes the number and type of applications received for new licences and other instruments, as well as the approvals made by the Regulator in the quarter.

Application type	Number received	Number approved*
Accreditation	1	2
DIR licence	0	0
DNIR licence	3	0
Certifications	46	34

* *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.

Applications received for Dealings involving Intentional Release licences

The Regulator did not receive any applications for DIR licences in the quarter.

Consultation on applications for Dealings involving Intentional Release licences

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. There were no new limited and controlled DIR applications notified in the quarter.

There was one invitation to comment on a RARMP issued during the quarter.

- DIR 109—Limited and controlled release of banana genetically modified for enhanced nutrition—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

One DIR licence application was withdrawn during the quarter:

- DIR 110—Limited and controlled release of cotton genetically modified for fungal control—Hexima Limited

Four DIR licences were surrendered during the quarter:

- DIR 048/2003—Field trial to assess transgenic cotton expressing natural plant genes for insect control—Hexima Limited
- DIR 050/2004—Vaccination of cattle with recombinant bovine herpesvirus vaccines—Queensland Department of Primary Industries and Fisheries (now Queensland Department of Employment, Economic Development and Innovation)
- DIR 073/2007—Limited and controlled release of GM insect resistant and insect resistant/herbicide tolerant cotton—Monsanto Australia Limited
- DIR 081/2007—Limited and controlled release of cotton genetically modified for enhanced water use efficiency—Monsanto Australia Limited

Clock stopped on Dealings involving Intentional Release licence applications

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

No requests for further information on DIR applications were initiated in this quarter.

Decisions on applications for Dealings involving Intentional Release licences

No DIR licences were issued during the quarter.

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.

No DNIR licences were issued during the quarter.

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

Changes to existing licences and other instruments

The Regulator can, directly or upon application, vary an issued licence or other instrument. Variations involve changes to conditions applied to an instrument or a licence. For example, the Regulator can vary a licence to manage risks if new information or data comes to light. The Regulator must not vary the licence unless he is satisfied that any risks posed by the dealings, proposed to be authorised by the licence as varied, are able to be managed in such a way as to protect the health and safety of people and the environment.

Most variations are made at the request of the instrument/licence holder. Applications for variation to licences have a statutory timeframe of 90 days for making a decision. Additionally, the Regulator can make a decision in relation to an application to transfer a licence/instrument to another person or consent to the surrender of a licence/instrument on request by a licence/instrument holder.

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

Type	Number received	Number approved[b]
Surrender of accreditations	0	0
Surrender of certification	42	29
Surrender of DIR licence	0	4
Surrender of DNIR licence	5	1
Variation of accreditation	0	0
Variation of certification	54	73
Variation of DIR licence	4	1
Variation of DNIR licence[a]	22	15

[a] Includes one variation to a DNIR 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 received one CCI application in relation to a DNIR application. The Regulator made one CCI declaration in relation to a DIR application during the quarter.

Monitoring and Compliance

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

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

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

- the dissemination of a GMO and its genetic material is restricted
- the persistence of a GMO in the environment is restricted
- the containment of GMOs for dealings not involving intentional release
- effective management of the GMO is maintained.

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

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

The Monitoring Section conducts routine monitoring visits of a minimum of 20 percent of field trial sites each year. To achieve this goal a minimum of five percent of current trial sites and five percent of trial sites subject to post-harvest monitoring are monitored each quarter. In addition inspections are conducted on a minimum of 20 percent of PC2 large-scale, PC3 and PC4 facilities per year.

Monitoring and Compliance Strategy

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

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

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

The monitoring program for contained dealings involves inspecting DNIRs and the facilities that those dealings are conducted in. These inspections focus on the integrity of the physical structure of the facility and on the general laboratory practices followed in that facility, including those practices followed for DNIRs and Notifiable Low Risk Dealings (NLRDs).

Overview of monitoring and compliance for the reporting period

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

Total field trial sites monitored: During the quarter, 12 GM plant field trial sites under DIR licences were subjected to monitoring visits.

- **Current field trial sites:** Of the 26 sites current in the quarter, seven were monitored. This represents a monitoring rate of 27 percent of all current sites for the quarter.
- **Post-harvest field trial sites:** Of the 33 sites subject to post-harvest monitoring in the quarter, five were monitored. This represents a monitoring rate of 15 percent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection with contained dealings covered four organisations and six PC facilities. Monitoring of PC facilities encompassed two PC2 laboratories, two PC2 animal containment facilities and two PC3 laboratories.

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

Seven DNIRs were monitored during the quarter.

Monitoring of Dealings involving Intentional Releases

The following table summarises monitoring activities for field trials with GM crop plants for the quarter.

Licensed Organisation Name / Location of trial site	Licence Number	No. sites visited	Site status	Crop type
Bayer CropScience Pty Ltd, Victoria	DIR 069/2006	4	Current	Canola and Indian Mustard
CSIRO, Western Australia	DIR 099	1	Current	Wheat and Barley
CSIRO, Australian Capital Territory	DIR 092	2	1 Current 1 PHM*	Wheat
	DIR 093	3	1 Current 2 PHM*	Wheat and Barley
	DIR094	2	PHM*	Wheat and Barley
Total	**5**	**12**	**Current = 7 PHM* = 5**	

** PHM = post-harvest monitoring.*

Monitoring of Dealings Not involving Intentional Releases

Licensed Organisation Name	Licence Number
St Vincent's Hospital Sydney Limited, New South Wales	DNIR 253
The University of Melbourne, Victoria	DNIR 469 and 470
Macfarlane Burnet Institute for Medical Research & Public Health, Victoria	DNIR 307
University of Technology Sydney, New South Wales	DNIR 252 and 336
The University of Sydney, New South Wales	DNIR 471
Total	**7**

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
St Vincent's Hospital Sydney Limited, New South Wales	PC3 laboratory	1
The University of Melbourne, Victoria	PC2 laboratory PC2 animal containment	1 1
Macfarlane Burnet Institute for Medical Research & Public Health, Victoria	PC2 laboratory PC3 laboratory	1 1
The University of Sydney, New South Wales	PC2 animal containment	1
Total	**3 facility types**	**6**

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 inspected in the quarter.

Findings for Dealings Not involving Intentional Release

There were four non-compliance issues observed for DNIRs that were finalised in the quarter.

Organisation	**Bioproperties Pty Ltd**
Licence number and site	DNIR 391
Summary of dealing	The aim of this dealing is to produce large scale volumes of four types of recombinant pili antigens to be used in the manufacture of a vaccine against neonatal scours in pigs.
Findings	At the time of inspection, the licence holder had obtained signed statements from staff undertaking dealings which did not satisfactorily indicate that staff had been informed of, and trained in, licence conditions that applied to them.
Assessment	Staff members have received PC2 laboratory training consistent with elements of the licence specific training mandated under DNIR 391. The risks to human health and safety and the environment from this non-compliance issue have been assessed as negligible.
Compliance management	Bioproperties was reminded of the requirement to provide training to all persons covered under the licence and to create a record of this training. Bioproperties must obtain signed statements from the persons covered by the licence indicating that they have been informed of, and trained in licence conditions that applied to them.
Organisation	**The University of Sydney**
Licence number(s)	DNIR 376
Summary of dealing	This study aims to identify human and mouse genes that are responsible for maintaining a normal differentiation program in keratinocytes.
Findings	The licence holder did not obtain signed statements or provide licence specific training for staff members conducting dealings under DNIR 376.
Assessment	Staff members have received PC2 laboratory training consistent with elements of the licence specific training mandated under DNIR 376. The risks to human health and safety and the environment have been assessed as negligible.
Compliance management	The licence holder was reminded of the requirements to provide training to all persons covered under the licence so that they understand the licence conditions that apply to them, and conduct all dealings with GMOs in accordance with licence conditions.

Organisation	**Macfarlane Burnet Institute for Medical Research and Public Health**
Licence number(s)	DNIR 307
Summary of dealing	The proponents intend to study the fusion and entry of *Human immunodeficiency virus* and *Hepatitis C virus* into human cell lines in vitro in order to develop antivirals and vaccines targeting this process.
Findings	At the time of inspection the Macfarlane Burnet Institute for Medical Research and Public Health had not complied with licence conditions requiring that a copy of the licence be available in certified facilities.
Assessment	The Macfarlane Burnet Institute for Medical Research and Public Health has ensured that all staff are aware of applicable licence conditions. The risks to human health and safety and the environment have been assessed as negligible.
Compliance management	The Macfarlane Burnet Institute for Medical Research and Public Health is required to ensure that a paper or electronic copy of the licence is available in each facility listed in the licence.
Organisation	**The University of Melbourne**
Licence number(s)	DNIR 470
Summary of dealing	The purpose of this dealing is to understand: 1. how *S. aureus* strains develop low-level resistance to the antibiotic vancomycin; and 2. the role of *S. aureus* protein toxins in disease.
Findings	Not all persons disposing of GM waste were fully trained in licence conditions, as required by the licence.
Assessment	Persons conducting dealings with the GMO (i.e. waste disposal) who are not fully trained in licence conditions are at risk if exposed to the GM *S. aureus*. There is no evidence, however, to suggest this issue has resulted in any harm to human health and safety.
Compliance management	The University of Melbourne is required to ensure that only authorised persons fully trained in DNIR 470 licence conditions dispose of waste containing GMOs.

Findings for Physical Containment Facilities

The OGTR's monitoring of certified PC facilities in the quarter found two minor non-compliances with certification conditions in relation to structure and work practices within facilities. 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
6	1	0	0	0	1	0

[1] PPE = Personal Protective Equipment.

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

Practice Reviews

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

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

The primary focus of the review process is to determine whether or not practices being used pose potential human health or environmental risks that require management actions to be implemented. In certain instances, where a suspected non-compliance with the Act is identified, the issue may be referred for investigation.

There were no practice reviews completed in the 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 on 3 February 2011 for the 2011–2014 triennium by the Hon Catherine King, Parliamentary Secretary for Health and Ageing.

Gene Technology Technical Advisory Committee

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

GTTAC met on 11 and 12 May during the quarter. The Communiqué is at Appendix 1.

Further information about GTTAC, including the membership for 2011–2014, 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 on 14 and 15 April during the quarter. The Communiqué is at Appendix 2.

Further information about GTECCC, including the membership for 2011–2014, is available from the OGTR website at 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

Making of the Gene Technology Amendment Regulations 2011

The Gene Technology Amendment Regulations 2011 (Amendment Regulations 2011) were made by the Administrator of the Commonwealth of Australia on 2 June 2011. The Amendment Regulations 2011 are a disallowable instrument and were tabled in the House of Representatives on 14 June 2011 and the Senate on 15 June 2011.

The Amendment Regulations 2011 represents the culmination of a technical review of the Gene Technology Regulations 2001 (the Regulations) initiated by the Regulator in 2008–2009. Consultation with a wide range of stakeholders was undertaken and feedback in submissions was taken into consideration in finalising the Amendment Regulations 2011. The amendments include changes to: classification of some GMO dealings as exempt dealings or NLRDs; classification of some GMO dealings involving viral vectors; and the oversight and timeframes of NLRDs.

The Amendment Regulations are due to commence on 1 September 2011.

International collaboration and coordination

Under the Act the Regulator's functions include:

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

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

- International Life Sciences Institute (ILSI) Conference on Environmental Risk Assessment of Genetically Modified Crops, Hanoi, Vietnam, June 2011
- ILSI Conference on Risk Assessment of Genetically Modified Crops, New Delhi, India, May 2011
- ILSI Biotechnology Workshop 2011, Paris, France, May 2011
- Organisation for Economic Co-operation and Development (OECD) working group on Harmonisation of Regulatory Oversight in Biotechnology (WGHROB) 25th meeting, Paris, France, May 2011
- World Health Organization (WHO) informal consultation on guidelines for environmental risk assessment of GM Dengue vaccines, Geneva, Switzerland, April 2011.

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.

OGTR officers also participated in the following meetings/conferences:

- 39th GTTAC meeting, Canberra, May 2011
- 7th Meeting of the Australasian Gene Therapy Society, Melbourne, May 2011
- 33rd Conference of Australian Society of Sugarcane Technologists, Mackay, May 2011
- Exploring the impact of social technologies on science communication, Brisbane, April 2011
- 5th GTECCC meeting, Canberra, April 2011

Accredited organisations and Institutional Biosafety Committee training

The fourth National Institutional Biosafety Committee Forum was held in Canberra on 7 and 8 June 2011 at the National Gallery of Australia. Representatives from all States and Territories except the Northern Territory attended; 137 delegates represented 64 accredited organisations.

The forum was opened with an address from Professor Peter Rathjen, Vice-Chancellor, University of Tasmania and the Regulator followed with an update of the achievements of the OGTR over the past 10 years. A number of guest speakers from other Australian Government agencies and the IBCs, as well as officers from several sections of the OGTR, also gave presentations.

The forum facilitated exchange of information between IBCs and the OGTR and provided an arena in which to discuss the impending changes to Gene Technology Regulations 2001. The two day meeting also provided an opportunity for organisations to discuss specific issues with OGTR staff.

Feedback was strongly positive. Attendees found the Forum interesting and informative, and valued the opportunity to meet OGTR staff in person and to exchange ideas with IBC members from other organisations.

OGTR website usage and statistics

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

MONTH	HITS[1]	VISITS[2]
April	190,842	24,028
May	214,302	24,770
June	218,873	24,770

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
- About the OGTR
- List of applications and licences for Dealings involving Intentional Release (DIR) of GMOs into the environment
- Guidelines and forms for Certification of Physical Containment Facilities
- Forms and Guidelines
- List of Intentional Release of Licence Application under Evaluation
- Publications
- Record of GMOs and GM Product Dealings
- IBC & Accredited Organisations Information

The most popular downloaded documents were:

- Risk Analysis Framework
- The Biology of *Ananas comosus var. comosus* (Pineapple)
- The Biology of *Carica papaya* L. (Papaya, pawpaw, paw paw)
- The Biology and Ecology of Rice (Oryza sativa) in Australia
- The Biology of *Gossypium hirsutum* L. and *Gossypium barbadeuse* L. (Cotton)
- PC2 Laboratory guidelines
- The Biology of *Saccharum* spp (Sugarcane)
- The Biology of Hybrid Tea Rose (*Rosa x hybrida*)
- Operation of the Gene Technology Regulator Annual Report 2009–2010
- The Biology of *Triticum aestivum* L. em Thell. (Bread Wheat).

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

Internet contacts and freecall number

OGTR email address and freecall number

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

MONTH	EMAILS	OGTR 1800 NUMBER
April	100	78
May	175	107
June	84	94

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 129 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 343 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 407 emails during the quarter.

Contained Dealings Evaluation Section email inbox

This email inbox provides a central common point for efficient coordination of responses to queries relating to classification of GMO dealings, certification requirements for higher level containment facilities and GMO licences accessed by the contained dealings evaluation section. The inbox received 213 emails during the quarter.

APPENDICES

APPENDIX 1

Gene Technology Technical Advisory Committee

COMMUNIQUÉ

This is the 29th communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 39th meeting of GTTAC, held on 11 & 12 May 2011.

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).

GTTAC members were appointed by the Hon Catherine King, Parliamentary Secretary for Health and Ageing on 3 February 2011 for a three year term, following consultation with the Regulator, State/Territory Ministers and relevant scientific, consumer, health, environmental and industry organisations. The term for the previous committee expired on 31 January 2011.

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 108—Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system (InVigor® x Roundup Ready® canola).

GTTAC noted that application from Bayer Crop Science Pty Ltd was for the commercial release of GM canola, produced by crossing currently approved GM lines; InVigor® canola and Roundup Ready® canola. InVigor® x Roundup Ready® canola was produced by conventional breeding between InVigor® canola and Roundup Ready® canola, which were individually approved by the Regulator in 2003 for commercial release under licences DIR 021/2002 and DIR 020/2002, respectively.

The InVigor® x Roundup Ready® canola proposed for commercial release will contain genes conferring tolerance to the herbicides glufosinate-ammonium and glyphosate, and genes conferring a hybrid breeding system. Bayer is also seeking approval from the Regulator to release GM canola derived from conventional breeding between GM Roundup Ready® elite line GT73 and all GM canola lines authorised for release under licence DIR 021/2002.

The applicant proposes the release to occur in all commercial canola growing areas of Australia. GM canola and GM canola-derived products from GM InVigor® x Roundup Ready® canola would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand (FSANZ) has approved the use of food derived from GM InVigor® canola and GM Roundup Ready® canola for human consumption. These approvals also cover GM InVigor® x Roundup Ready® canola.

RESOLUTION:

GTTAC advised the Regulator that in preparing the RARMP the Regulator should consider:

- the potential for commercial scale growing of the GM canola to affect weediness
- the potential for the GM canola to cross with existing non-GM herbicide tolerant canola and any possible associated risk to the environment
- the potential for gene flow to related species and possible risk of weediness.

1.2 DIR 109—Limited and controlled release of banana genetically modified for enhanced nutrition.

GTTAC noted that the application from the Queensland University of Technology involved the intentional release of up to 1241 lines of GM bananas on a limited scale and under controlled conditions. The modified traits are for enhanced pro-vitamin A and/or iron levels.

The trial is proposed to take place at one site in the Shire of Johnstone, Queensland on a maximum area of 2.0 ha between August 2011 and August 2013. The proposed trial is to assess various promoter-gene combinations that would enhance pro-vitamin A and/or iron levels without the associated negative effects on GM plant growth and development. The GM bananas will not be permitted to enter the commercial human or animal food supply chain.

RESOLUTION:

GTTAC advised the Regulator that:

- the Regulator should consider alternative containment measures for transport by courier.

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 did not consider any Consultation RARMPs prepared for dealings not involving intentional release at the meeting.

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.

.

APPENDIX 2

Gene Technology Ethics and Community Consultative Committee

COMMUNIQUÉ

The Gene Technology Ethics and Community Consultative Committee (GTECCC) held its first meeting of the 2011–2014 Triennium in Canberra on 14 & 15 April 2011.

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.

GTECCC members were appointed by the Hon Catherine King MP, Parliamentary Secretary for Health and Ageing on 3 February 2011 for a three year term, The term for the previous committee expired on 31 January 2011.

The purpose of this Communiqué is to provide a brief overview of the key matters considered by GTECCC at its meeting on 14 & 15 April 2011.

GTECCC's Work Plan

GTECCC reviewed the work done by the previous committee and agreed to continue work to finalise projects begun in the previous triennium. The committee also agreed on a work-plan for the 2011–2014 triennium.

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

The Chair briefed members on the background, the results of the independent survey conducted in April 2010 and progress of the National Framework Review. The Committee agreed that the draft National Framework should proceed as an aspirational document—which is intended to foster the consideration of ethical issues by those working in gene technology. The Committee agreed to present the framework at the 4th National Institutional Biosafety Committee (IBC) forum on 8 June 2011 and to consult IBCs and accredited organisations with a view to finalisation.

Environmental Ethics and Gene Technology

The Environmental Ethics Working Group reported on the finalisation of the environmental ethics paper entitled "Environmental ethics as it relates to gene technology in Australia" and informed members of its availability on the OGTR website. This paper is an outcome of GTECCC's deliberations and is independent from the OGTR.

Community Consultation

The GTECCC agreed to establish a working group to comment on the consultation processes undertaken by the Regulator and OGTR with a focus on dealings involving intentional release (DIR) applications. The objectives of the working group will be to prepare an analysis of current processes and suggestions for improvement for consideration of the full committee.

Risk Communication

GTECCC also agreed to establish a working group in relation to risk communication issues. The risk communication working group will work with the OGTR in its review of the OGTR's Risk Analysis Framework.

Issues for future consideration

The Committee agreed that the Secretariat liaise with the NHMRC regarding potential input into ongoing consideration of ethical issues in relation to xeno-transplantation, for collaboration with other committees (Animal Welfare Committee and Australian Health Ethics Committee) that consider issues intersecting with gene technology.

GTECCC discussed several other areas of potential work, including consideration of ethical issues in synthetic biology.

Reports

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

The new committee was welcomed by the Chair and the Gene Technology Regulator. The contributions of previous members were also acknowledged by the Chair and the Gene Technology Regulator.

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
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 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

www.ogtr.gov.au

All information in this publication is correct as of October 2011

D0536 Oct 2011