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

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 JANUARY–31 MARCH 2012

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 JANUARY–31 MARCH 2012

Print version ISBN: 978-1-74241-756-1

Online version ISBN: 978-1-74241-757-8

Publications Number D0825

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*, I am pleased to present to you the Quarterly Report of the Operations of the Gene Technology Regulator, covering the period 1 January to 31 March 2012.

During this period two licences for dealings involving intentional release of GMOs were issued, while 55 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
5 June 2012

CONTENTS

ABOUT THIS REPORT

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

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

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

This report has four key sections.

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 Legislative and Governance Forum on Gene Technology (formerly Gene Technology Ministerial Council).

Other activities of the Gene Technology Regulator

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

SECTION 1

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 January to 31 March 2012 quarter were:

Licences and other instruments

- two organisations issued with accreditation
- two licence issued for Dealings involving the Intentional Release (DIR) of GMOs into the environment
- no licences issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- 55 physical containment facilities certified
- 92 instruments surrendered
- Variation of 124 certifications, two DIR licences and 16 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 nine 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

Legislative and Governance Forum on Gene Technology

The Legislative and Governance Forum on Gene Technology (LGFGT) (formerly the Gene Technology Ministerial Council) 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 LGFGT 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
- Department of Agriculture, Fisheries and Forestry (DAFF) Biosecurity (formerly 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 RARMPs were issued during the quarter.

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

SECTION 2

REGULATION OF GENETICALLY MODIFIED ORGANISMS

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of the report outlines the regulatory activity undertaken during the 1 January to 31 March 2012 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	2
DNIR licence	1	0
Certifications	35	55

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

Processing of applications for Dealings involving Intentional Release licences

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

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

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

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

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

This time limit may be extended, that is, the clock may be stopped, if the decision-making process is unable to continue, for example, because of an unresolved application for declaration of CCI or because additional information is sought from the applicant.

The Act and the Gene Technology Regulations 2001 (the Regulations) mandate a minimum 30 day timeframe for each of the one or two rounds of consultation that the Regulator must undertake during the processing of each DIR application. However, consultation periods longer than minimum timeframes are usually allowed to facilitate the provision of information and promote involvement in the decision-making process, particularly by the community. An application for a DIR licence cannot normally be received and decided upon within the same three month reporting period.

The following table shows the progress of applications for DIR licences undergoing evaluation during the quarter.

Applications received	Notification of applications*	Consultation on application	Licences issued
DIR 116	DIR 115	DIR 113	DIR 111
		DIR 114	DIR 112

* *Although not required under the Act, all new limited and controlled release 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 116—Limited and controlled release of genetically modified live viral vaccines against prostate cancer—PPD Australia Pty Ltd.

Consultation on applications for Dealings involving Intentional Release licences

Although not required by the Act, the Regulator issued a 'Notification of Licence Application' for one other 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 indicate when the RARMP is expected to be released for public comment:

- DIR 115—Limited and controlled release of cotton genetically modified for enhanced fibre yield—CSIRO.

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

- DIR 113—Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance—Bayer CropScience Pty Ltd
- DIR 114—Limited and controlled release of canola genetically modified for herbicide tolerance—Pioneer Hi-Bred Australia Pty Ltd.

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.

No DIR licences were surrendered during the quarter.

Clock stopped on Dealings involving Intentional Release licence applications

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

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

Decisions on applications for Dealings involving Intentional Release licences

Two DIR licence were issued during the quarter:

- DIR 111—Limited and controlled release of wheat and barley genetically modified for altered grain composition, nutrient utilisation efficiency, disease resistance or stress tolerance—CSIRO
- DIR 112—Limited and controlled release of wheat and barley genetically modified for altered grain composition and nutrient utilisation efficiency—CSIRO.

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[a]
Surrender of accreditations	1	1
Surrender of certification	54	88
Surrender of DIR licence	0	0
Surrender of DNIR licence	1	3
Variation of accreditation	0	0
Variation of certification	132	124
Variation of DIR licence[b]	3	2
Variation of DNIR licence	16	16

[a] *Numbers reported in this quarter often relate to applications received in previous quarters.*

[b] *Includes variations initiated by the Regulator.*

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 DIR 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 (NLRD).

Overview of monitoring and compliance for the reporting period

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

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

- **Current field trial sites:** Of the 31 sites current in the quarter, three were monitored. This represents a monitoring rate of 10 percent of all current sites for the quarter.
- **Post-harvest field trial sites:** Of the 45 sites subject to post-harvest monitoring in the quarter, four were monitored. This represents a monitoring rate of nine 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 five certified facilities. Monitoring of certified facilities encompassed one PC2 laboratory, three PC2 large scale facilities and one PC3 laboratory.

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

Three DNIRs were monitored during the quarter.

Monitoring of Dealings involving Intentional Releases

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

Licensed Organisation Name / Location of trial site	Licence Number	No. sites visited	Site status	Crop type
BSES, Queensland	DIR 070	3	PHM	Sugarcane
Monsanto, NSW	DIR 105	1	PHM	Canola
CSIRO, ACT	DIR 092	1	C	Wheat
CSIRO, ACT	DIR 093	1	C	Wheat and Barley
CSIRO, ACT	DIR 094	1	C	Wheat and Barley
Total			**Current = 3 PHM* = 4**	

** PHM = post-harvest monitoring.*

Monitoring of Dealings Not involving Intentional Releases

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

Licensed Organisation Name	Licence Number
Sanofi-Aventis Australia Pty Ltd	DNIR 386
South Eastern Sydney Local Health District	DNIR 291 and DNIR 465
Total	3

Monitoring of Physical Containment Facilities

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

Organisation	Physical Containment (PC) facility	No. facilities visited
CSL	PC2 Large Scale	3
Western Sydney Local Health District	PC3 Laboratory	1
South Eastern Sydney Local Health District	PC2 Laboratory	1
Total		**5**

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 in the quarter.

Findings for Dealings Not involving Intentional Release

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

Organisation	South Eastern Sydney Local Health District
Licence number(s)	DNIR 291 and DNIR 465
Summary of dealing	(DNIR 291) The aim of this dealing is to determine the role of different gene regions of CMV in infection and growth of the virus and inhibition of growth by antiviral drugs, focusing on the DNA polymerase and protein kinase mutations. (DNIR 465) The purpose of the dealing is to construct re-assorted influenza viruses by reverse genetics for research purposes.
Findings	At the time of inspection, the licence holder had not obtained signed statements from all persons undertaking dealings indicating that they understand and agreed to follow licence conditions.
Assessment	Although signed statements were not obtained from all persons undertaking dealings, all persons had received appropriate training. The risks to human health and safety and the environment have been assessed as negligible.
Compliance management	South Eastern Sydney Local Health District was reminded of the requirement to have signed statements from each person covered by the licence acknowledging that the licence holder has informed the person of the conditions of the licence that apply to that person before that person commences work on the dealing.

Findings for Physical Containment Facilities

The OGTR's monitoring of certified PC facilities in the quarter found no non-compliances with certification conditions.

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 (now the Legislative and Governance Forum on Gene Technology (LGFGT)):

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

Gene Technology Technical Advisory Committee

Under the Act, the Gene Technology Technical Advisory Committee (GTTAC) provides scientific and technical advice, on the request of the Regulator or the LGFGT. GTTAC may provide advice on gene technology, GMOs or GM products; applications made under the Act and biosafety aspects of gene technology; and the need for policy principles, policy guidelines, codes of practice or 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 6 March 2012. 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

Under the Act, the Gene Technology Ethics and Community Consultative Committee (GTECCC) provides advice, on the request of the Regulator or the LGFGT. GTECCC may provide advice 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 assessment process for applications for licences covering dealings involving the intentional release of a GMO into the environment; and risk communication in relation to those dealings.

GTECCC did not meet during the quarter.

Further information about the work of 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:

- Contributing to development of guidance documents by groups under the OECD and UN Cartagena Protocol on Biosafety.
- Key speaker at Conference on enviromental uses of Micro-organisms and participate in 26th session of OECD—WGHROB steering group meeting, Paris, France, March 2012
- Participated in the Organisation for Economic Co-operation and Development (OECD) Working Group for the Harmonisation of Regulatory Oversight in Biotechnology: 26th Session, Paris, France, March 2012
- Participated in the OECD Working Group for the Harmonisation of Regulatory Oversight in Biotechnology: Conference on the Environmental Uses of Micro-organisms, Paris, France, March 2012
- Presented at the World Health Organisation expert working group on guidelines for environmental risk assessment of genetically modified Japanese encephalitis (JE) vaccines, Bangkok, Thailand, February 2012
- Presented at the Ecology Regarding Genetically Modified Organisms (ERGO) congress, Amsterdam, Netherlands, February 2012.

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

The OGTR participated in or provided presentations to the following:

- Regulatory Science Network risk analysis workshop, Canberra, March 2012
- Regulators Forum Meeting, Sydney, March 2012
- Agrifood Awareness board meeting, Canberra, February 2012
- National Weed Risk Assessment Protocol review, Melbourne, February 2012.

National Strategy for Unintended Presence of Unapproved GMOs

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

The OGTR is responsible for implementing the UP strategy and continues to liaise closely with the Australian Seed Federation (ASF) to develop a voluntary auditing and testing program of existing industry quality assurance measures.

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]
January	164,235	26,990
February	214,400	29,332
March	239,118	30,011

[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
- Record of GMOs and GM Product Dealings
- 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
- About the OGTR
- Forms and Guidelines
- Publications
- What are Notifiable Low Risk Dealings (NLRD)?
- Annual and Quarterly Reports under the *Gene Technology Act 2000*

The most popular downloaded documents were:

- Risk Analysis Framework
- The Biology of *Saccharum spp* (Sugarcane)
- The Biology and Ecology of Rice (*Oryza sativa* L.) in Australia
- The Biology of *Carica papaya* L. (Papaya, pawpaw, paw paw)
- The Biology of *Ananas comosus var. comosus* (Pineapple)
- The Biology of *Gossypium hirsutum* L. and *Gossypium barbadense* L. (Cotton)
- PC2 Laboratory guidelines
- The Biology of Hybrid Tea Rose (*Rosa x hybrida*)
- The Biology of *Zea mays* L. ssp *mays* (maize or corn)
- The Biology of *Musa* L. (banana)

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

Internet contacts and freecall number

OGTR email address and freecall number

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

MONTH	EMAILS	OGTR 1800 NUMBER
January	65	49
February	115	89
March	74	73

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 122 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 371 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 452 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 114 emails during the quarter.

APPENDIX

APPENDIX 1:

Gene Technology Technical Advisory Committee Communiqué

Meeting 6 March 2012, Canberra

This communiqué covers matters considered at the 41st meeting of the Gene Technology Technical Advisory Committee (GTTAC) (6 March 2012)

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 Legislative and Governance Forum on Gene Technology (formerly the Gene Technology Ministerial Council). All Committee members and expert advisers hold office on a part-time basis[1].

The Regulator seeks 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 GTTAC's consideration of applications and RARMPs and, in accordance with Regulation 29 of the Gene Technology Regulations 2001, any Committee resolutions provided to the Regulator regarding those applications and RARMPs.

Dealings Involving the Intentional Release of Genetically Modified Organisms

Dealings involving the Intentional Release (DIRs) of GMO's 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. The Regulator must seek GTTAC advice on RARMPs prepared in relation to DIR applications.

1. Advice on Consultation RARMPS—Limited and Controlled Release

1.1 GTTAC considered the Consultation RARMP for the following CSIRO application:

- DIR 112—Limited and controlled release of wheat and barley genetically modified for altered grain composition and nutrient utilisation efficiency.

GTTAC noted that CSIRO has applied for a licence for dealings involving the intentional release of genetically modified (GM) wheat and barley on a limited scale and under controlled conditions. The GM wheat and barley lines have been modified for altered grain composition and nutrient utilisation efficiency. The trial is proposed to take place at one site in Western Australia.

[1] On 3 February 2011, GTTAC members were appointed for a three year term by the Hon Catherine King MP, Parliamentary Secretary for Health and Ageing.

The primary purpose of the trial is to assess whether the respective genetic modifications result in increased biomass and yield of the GM plants compared to the unmodified plants. The GM wheat and barley would not be permitted to enter the commercial human food or animal feed supply chains. GTTAC noted the key points in the consultation RARMP including that:

- the risk assessment concludes that this release poses negligible risks to the health and safety of people and to the environment; and
- these negligible risks do not require specific risk treatment measures.

GTTAC also noted the draft licence conditions, which are similar to those used for other recent wheat and barley licences.

RESOLUTION:

GTTAC advised the Regulator that:

1. the Committee agrees with the overall conclusions of the RARMP;
2. the Regulator should consider clarifying arrangements for buffer zones between the trials at the location; and
3. the Regulator should consider clarifying the wording in the RARMP relating to handling of GM and non-GM material grown at the location.

1.2 GTTAC considered the Consultation RARMP for the following Bayer CropScience application:

- DIR 113—Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance.

GTTAC noted that Bayer CropScience Pty Ltd has applied for a licence for dealings involving the intentional release of GM cotton into the environment on a limited scale and under controlled conditions. The GM cotton varieties have been genetically modified for insect resistance and herbicide tolerance. The field trial is proposed to take place at up to six sites per year in a number of local government areas (LGAs) in NSW, WA, and Qld.

The purpose of the proposed trial is to assess the agronomic performance of the GM cotton varieties, and to produce seed for use in further studies or releases (subject to additional approvals). The GM cotton varieties would not be permitted to enter the commercial human or animal food supply chains. GTTAC noted the key points in the consultation RARMP including that:

- the risk assessment concludes that this release poses negligible risks to the health and safety of people and to the environment; and
- these negligible risks do not require specific risk treatment measures.

GTTAC also noted that a number of the individual GM lines involved in this application have been approved for commercial release overseas and that all of the individual GM events have been approved for food use in Australia by Food Standards Australia New Zealand (FSANZ).

RESOLUTION:

GTTAC advised the Regulator that:

- The Committee agrees with the overall conclusions of the RARMP.

1.3 GTTAC considered the Consultation RARMP for the following Pioneer HiBred application:

- DIR 114—Limited and controlled release of canola genetically modified for herbicide tolerance.

Pioneer Hi-Bred Australia Pty Ltd (Pioneer) has applied for a licence for dealings involving the intentional release of one line of GM canola on a limited scale and under controlled conditions. The GM canola line has been genetically modified for herbicide tolerance. The trial is proposed to take place over four years with up to 8 sites planted in the first year and 20 sites in subsequent years.

GTTAC noted the conclusions of the draft RARMP including that:

- the risk assessment concludes that this release poses negligible risks to the health and safety of people and to the environment.
- these negligible risks do not require specific risk treatment measures.

RESOLUTION:

GTTAC advised the Regulator that:

- The Committee agrees with the overall conclusions of the RARMP.

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 Office of the Gene Technology Regulator (OGTR) on 1800 181 030. 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	*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 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 days are not counted 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
DAFF	Australian Government Department of Agriculture, Fisheries and Forestry
DIR	A dealing involving intentional release of a GMO into the environment (e.g., field trial or commercial release)
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)
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
GMO	Genetically modified organism
GTECCC	Gene Technology Ethics and Community Consultative Committee
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
LGFGT	Legislative and Governance Forum on Gene Technology
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 containment 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 June 2012

D0825 June 2012