OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 July to 30 September 2013

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’

Print ISBN: 978-1-74186-086-3

Online ISBN: 978-1-74186-087-0

Publications approval number: 10593

Office of the Gene Technology Regulator

MDP 54 GPO Box 9848

CANBERRA ACT 2601

Email: ogtr@health.gov.au

Website:www.ogtr.gov.au

Telephone: 1800 181 030

Fax: (02) 6271 4202

Quarterly Report web page:

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

Inquiries about the content of this report may be directed to the Business Management and Communications Section, Regulatory Practice and Compliance Branch of the Office of the Gene Technology Regulator.

LETTER OF TRANSMITTAL

Senator the Hon Fiona Nash

Assistant Minister for Health

Parliament House

CANBERRA ACT 2600

Dear Minister

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 July to 30 September 2013.

During this period three licences were issued for dealings involving intentional release of GMOs, two licences were issued for dealings not involving intentional release of GMOs, and 45 physical containment facilities were certified.

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

Yours sincerely

Dr Joe Smith

Gene Technology Regulator

23 December 2013

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.

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 July to 30 September 2013 quarter were:

Licences and other instruments

- 2 organisations issued with accreditation
- 3 licences issued for Dealings involving the Intentional Release (DIR) of GMOs into the environment
- 2 licences issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- 45 physical containment facilities certified
- 47 instruments surrendered
- 87 certifications, 13 DIR licences and 22 DNIR licences varied.

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

Monitoring and Compliance

Approximately 13 per cent of current field trial sites and 6 per cent of post-harvest field trial sites were subjected to routine monitoring during the quarter. This exceeds the target minimum rate of five per cent 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, Biosecurity
- 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
- Department of Environment
- Department of Foreign Affairs and Trade.

During the quarter the Regulator sought advice in respect of two DIR RARMPs.

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

Public participation

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

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

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of the report outlines the regulatory activity undertaken during the 1 July to 30 September 2013 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	3	3
DNIR licence	5	3**
Certifications	49	45

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

** *This includes two applications that were integrated into a single licence.*

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 timeframe for public consultation on the RARMP of 30 days, or 50 days if the Regulator identifies a significant risk to people or the environment from the proposed dealings. 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. The following table shows the progress of applications for DIR licences undergoing evaluation during the quarter. There were three DIR applications received in this quarter.

Applications received	**Consultation on RARMP**	**Licences issued**
DIR 124	DIR 122	DIR 118
DIR 125	DIR 123	DIR 120
DIR 126		DIR 121

**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 three applications for a DIR licence in the quarter.

- DIR 124 – GM Cotton (Monsanto Australia Limited) Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard® III and Bollgard® III x Roundup Ready Flex®).
- DIR 125 – GM Escherichia coli vaccine (Zoetis Australia Research & Manufacturing Pty Ltd) Commercial release of a genetically modified vaccine to protect chickens against pathogenic Escherichia coli.
- DIR 126 – GM Cholera vaccine (PaxVax Aus Pty Ltd) Clinical trial of a genetically modified vaccine against Cholera.

Consultation on applications and RARMPs for Dealings involving Intentional Release licences.

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

- DIR 122 – GM Wheat (Victorian Government Department of Environment and Primary Industries) Limited and controlled release of wheat genetically modified for enhanced yield stability.
- DIR 123 – GM Canola (NuSeed Pty Ltd) Limited and controlled release of canola genetically modified for altered oil content.

Full copies of DIR applications can be obtained by contacting the OGTR. Summary information on DIR applications and full RARMPs, including proposed licence conditions, are available via the OGTR website or directly from the OGTR.

Withdrawn applications and surrendered licences for Dealings involving Intentional Release licences

No DIR licence applications were withdrawn during the quarter.

One DIR licence was surrendered during the quarter:

- DIR 046 – GM *fowl adenovirus* (Imugene Limited) Limited and controlled release of GM *fowl adenovirus* (FAV).

Clock stopped on Dealings involving Intentional Release licence applications

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

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

- DIR 125 – GM *Escherichia coli* vaccine (Zoetis Australia Research & Manufacturing Pty Ltd) Commercial release of a genetically modified vaccine to protect chickens against pathogenic *Escherichia coli*.

Decisions on applications for Dealings involving Intentional Release licences

Three DIR licences were issued during the quarter:

- DIR 118 – GM Cotton (Monsanto Australia Limited) Commercial release of herbicide tolerant (Roundup Ready Flex®MON88913) pima cotton in Australia.
- DIR 120 – GM Cotton (Monsanto Australia Limited) Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance.
- DIR 121 – GM Safflower (CSIRO) Limited and controlled release of safflower genetically modified for increased levels of oleic acid.

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.

Two DNIR licences were issued during the quarter.

- DNIR 532 – HCV founder virus: evolution and vaccine targets (University of New South Wales, NSW) *
  DNIR 535 – Investigation of malaria parasite proteins (Griffith University, Queensland).

* This licence also includes dealings that were included in Licence application DNIR 533 from the University of New South Wales

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

Changes to existing licences and other instruments

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

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

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

Type	**Number received**	**Number approved**[a]
Surrender of accreditations	2	2
Surrender of certification	24	39
Surrender of DIR licence	0	1
Surrender of DNIR licence	7	5
Variation of accreditation	0	0
Variation of certification	65	87

Variation of DIR licence	4	13
Variation of DNIR licence	11	22

[a] *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 five CCI applications. The Regulator made nine CCI declarations 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.

Monitoring and Compliance Strategy

The Monitoring Section conducts routine inspections of field trials and contained dealings to ensure compliance with licence conditions. These inspections include announced inspections and 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).

A minimum of 20 per cent of field trial sites are inspected each year. To achieve this goal a minimum of five per cent of current trial sites and five per cent of trial sites subject to post-harvest monitoring are monitored each quarter.

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). Inspections are conducted on a minimum of 20 per cent of PC2 large-scale, PC3 and PC4 facilities per year.

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 23 sites current in the quarter, three were monitored. This represents a monitoring rate of 13 per cent of all current sites for the quarter.
- **Post-harvest field trial sites:** Of the 69 sites subject to post-harvest monitoring in the quarter, four were monitored. This represents a monitoring rate of six per cent 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 11 certified facilities. Monitoring of certified facilities encompassed five PC2 laboratories, two PC2 plant facilities, one PC2 arthropod facility, one PC3 animal facility, and two PC3 laboratories.

Monitoring of contained dealings: During the quarter, the monitoring of the 11 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.

Five 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
Queensland University of Technology, Queensland	DIR 076 DIR 109	1 2	Current 1 Current 1 PHM	Banana Banana
Bayer CropScience Pty Ltd, Victoria	DIR 069 DIR 104	1 1	PHM PHM	Canola Canola
Pioneer Hi-Bred Australia Pty Ltd, Victoria	DIR 114	2	1 Current 1 PHM	Canola
Total			Current = 3 PHM* = 4	

Monitoring of Dealing Not involving Intentional Releases

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

Licensed Organisation Name	Licence Number
The University of Queensland, Queensland	DNIR 160, 414 and 440
South Eastern Sydney Local Health District, New South Wales	DNIR 291 and 465
Total	5

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

Queensland University of Technology, Queensland	PC2 laboratory	1
	PC3 laboratory	2
The University of Queensland, Queensland	PC2 arthropod facility	1
	PC2 laboratory	2
	PC3 animal facility	1
South Eastern Sydney Local Health District, New South Wales	PC2 laboratory	1
The University of Sydney, New South Wales	PC2 plant facility	2
	PC2 laboratory	1
Total		11

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 were no non-compliance issues observed for DNIRs in the quarter.

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 equipment. 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
11	0	0	2	0	0	0

[1] *PPE = Personal Protective Equipment.*

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

Practice Reviews

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

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

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

There were no practice reviews completed in the quarter.

Audits

Audits can be initiated by the OGTR or an accredited organisation. An audit can entail:

- documentary evidence
- observations
- assessments of procedures and practices.

These activities are conducted to:

- verify that an accredited organisation has relevant and effective management procedures and practices to meet requirements under the Act, including accreditation requirements, guidelines and any licence conditions applicable to a dealing under the Act
- assess whether or not procedures and practices provide mechanisms to identify and resolve emerging risks
- where appropriate suggest improvements to procedures and practices.

Audits are an opportunity for accredited organisations and the OGTR to share information to improve the risk management of dealings with GMOs under the Act. Audits may focus on a single dealing, a range of dealings (e.g. dealings with a common host organism or dealings within a common climatic zone), the activity of an organisation across a range of dealings, or an activity common to a range of organisations.

There was one audit completed in the quarter.

Audit	Australian National University (ANU)
Aim	This audit is part of the OGTR ongoing audit program and was conducted to: • trace, assess and reinforce ANU compliance management arrangements for meeting compliance obligations under the national regulatory system for gene technology; • promote an internal audit framework for assessing and managing compliance risks; • provide compliance risk education and communication to ANU Institutional Biosafety Committee (IBC) and compliance / risk management personnel and decision makers; • recognise and take best practice principles from current ANU compliance risk management arrangements; and

	• include ANU as a party to ongoing Practice Reviews.
Determination	The audit found that; • there were no non-compliances or breaches evident; and • ANU has effective arrangements to meet national gene technology regulatory requirements.
Action	The audit team proposed a number of compliance risk management techniques to be considered as part of ongoing ANU improvement and in internal auditing of compliance. The audit promoted: • the benefits of internal risk management and auditing in compliance and containment arrangements; and • organisational arrangements to link risk management and internal auditing expertise with scientific and biosafety expertise.

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.

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.

Call for nominations 2014-17

Current memberships of the Gene Technology Technical Advisory Committee (GTTAC) and GTECCC will expire on 31 January 2014. A public call for nominations for members to GTTAC and GTECCC for the 2014 – 17 triennium was sent to over 520 relevant organisations, posted on the OGTR website and advertised in all major metropolitan newspapers. Nominations opened on 22 February and closed on 28 March 2013. The selection and appointment process is ongoing.

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 Legislative and Governance Forum on Gene Technology (LGFGT) on gene technology, GMOs, GM products, applications made under the Act, the biosafety aspects of gene technology and the need for policy principles, policy guidelines, codes of practice, technical and procedural guidelines in relation to GMOs and GM products and the content of such principles and codes.

GTTAC met once by video conference during the quarter on 17 September 2013.

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

Gene Technology Ethics and Community Consultative Committee

The function of GTECCC under the Act is to provide advice, on the request of the Regulator or the LGFGT on: ethical issues relating to gene technology; the need for and content of policy principles, policy guidelines, codes of practice; community consultation processes and risk communication for environmental release of GMOs; and matters of general concern in relation to GMOs.

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

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 included:

- Visit by Decio Ripandelli, Director, International Centre for Genetic Engineering and Biotechnology
- Presentation at Symposium on Biotechnology Commercialisation and Trade in APEC Economies – Biosafety Regulatory Perspective, September 2013, Kuala Lumpur, Malaysia
- Presentation at International Life Sciences Institute South Asia Biosafety Conference and Workshop, September 2013, Delhi, India.

The Regulator has signed a Memorandum of Understanding with the International Centre for Genetic Engineering and Biotechnology to collaborate on providing capacity building for risk assessment and regulation of GMOs to people from African biosafety regulatory agencies.

National collaboration and coordination

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

The OGTR provided a presentation to the following:

- Australian Seed Federation 2013 Convention, September 2013, Gold Coast
- Society for Risk Analysis – Australia and New Zealand Conference, September 2013, Canberra
- Biosecurity course at the Australian National University, September 2013, Canberra.

OGTR officers also participated in the following meetings/conferences:

- Australian Society for Microbiology Annual Meeting 2013, July 2013, Adelaide
- InterDrought IV Conference, September 2013, Perth.
- Regulators Forum meeting, July 2013, Canberra

- Food Standards Australia New Zealand workshop on new plant breeding techniques, August 2013
- Meeting of South Australian Institutional Biosafety Committees, September 2013.

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 during the quarter.

MONTH	HITS[1]	VISITS[2]
July	273,687	32,138
August	293,963	32,470
September	279,727	35,968

[1] *A hit is a request made to the server. Each file that is requested is counted as a hit*
[2] *Visits" is the number of times the OGTR website has been visited.*

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

What's New
Maps of Trial Sites
List of applications and licences for Dealings involving Intentional Release (DIR) of GMOs into the environment
Guidelines and forms for Certification of Physical Containment Facilities
About the OGTR
Record of GMOs and GM Product Dealings
List of Genetically Modified Product approvals
Guidelines
Fact sheets
Documents relating to the Risk Assessment process

The most popular downloaded documents were:

Risk Analysis Framework
The Biology of *Saccharum spp* (Sugarcane)
The Biology of *Gossypium hirsutum* L. and *Gossypium barbadeuse* L. (Cotton)
The Biology of *Carica papaya* L. (Papaya, pawpaw, paw paw)
PC2 Laboratory guidelines
The Biology and Ecology of Rice (*Oryza sativa* L.) in Australia
The Biology of *Ananas comosus* var. *comosus* (Pineapple)
The Biology of *Zea mays* L. ssp *mays* (maize or corn)
The Biology of Hybrid Tea Rose (*Rosa x hybrida*)
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
July	106	72
August	70	35
September	82	89

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 173 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 348 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 658 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 59 emails during the quarter.

APPENDIX 1:

Gene Technology Technical Advisory Committee Communiqué

17 September 2013 Videoconference, Canberra

Communiqué

This Communiqué covers matters considered at the 4th videoconference of the Gene Technology Technical Advisory Committee (GTTAC) (*17 September 2013*)

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 ministerial Legislative and Governance Forum on Gene Technology. All Committee members and expert advisers on GTTAC are appointed by the Commonwealth Minister responsible for gene technology. The Committee is comprised of scientific and technical experts with skills and experience prescribed in the Act.

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

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED ORGANISMS

The Regulator must seek GTTAC advice on RARMPs prepared in respect of all Dealings Involving the Intentional Release of a GMO (DIR). The Regulator must also seek GTTAC advice during the preparation of the RARMP for all DIR applications involving the commercial release of a GMO.

A DIR may 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 issued for public comment as part of the consultation process. Information on how to obtain copies of applications and RARMPs for DIR applications is provided at the end of this document.

1. ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

GTTAC considered the consultation RARMPs prepared in response to the following limited and controlled release applications:

1.1 DIR 122 - Limited and controlled release of wheat genetically modified for enhanced yield stability

GTTAC noted that application DIR 122 from the Department of Environment and Primary Industries – Victoria (DEPI-Vic) is for a limited and controlled release of GM

wheat modified for enhanced yield stability. The trial size is 2 ha and it is proposed to take place at a DEPI-Vic research station, Horsham, Victoria, between November 2013 and March 2015.

The primary purpose of the trial is to assess biomass and seed yield, and to improve drought tolerance of the GM wheat under Australian field conditions and generate data for possible future commercial release applications. The GM wheat would not be permitted for use in human food or animal feed.

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. GTTAC also noted that the draft licence conditions are similar to those for previous GM wheat trials. The licence would impose stringent controls during the trial and extensive monitoring and management post-harvest to ensure the GMO does not persist after the trial. The licence would require the destruction of any GM plant material after the completion of the trial.

Key points discussed by the Committee:

- **Potential for dissemination by birds** – the Committee concluded that the likelihood of this occurring was low. However, GTTAC noted a proposal to grow the trial in the off-season and suggested that the RARMP could include further detail about potential for bird dispersal if GM wheat is grown in the off-season;
- **Potential for dissemination by rodents** – GTTAC noted the controls and measures in the RARMP to restrict dissemination of the GMO by rodents. GTTAC agreed that in the event of a rodent plague the GMO would be destroyed by the rodents, and the potential for dispersal of viable GM seed would be highly unlikely;
- **Potential for human health effects as a result of eating GM wheat products** - GTTAC noted that the applicant does not propose to use the GM wheat as food, but agreed that the RARMP should include consideration of risk involving fructose intolerance in people.
- **Potential for crossing between GM lines** - the Committee agreed that the RARMP should note that the probability of crossing between GM lines is low, and that the associated risks are negligible; and
- **References to similar trials overseas** - GTTAC suggested that more detail and referencing could be included in the RARMP to other trials with similar gene inserts approved overseas.

RESOLUTION:

GTTAC advised the Regulator that:

1. The Committee agrees with the overall conclusions of the RARMP; and
2. The Regulator should further consider potential for dispersal of GM wheat by birds if grown in the off-season.

1.2 DIR 123 RARMP - Limited and controlled release of canola genetically modified for altered oil content

GTTAC noted that application DIR 123 from Nuseed Pty Ltd is for a limited and controlled release of GM canola modified for altered oil content. The trial is proposed

to take place between March 2014 and March 2019. The GM canola trial would be planted at 4 sites (2 ha/site) in the first year, 6 sites (10 ha/site) in the second year and 10 sites (20 ha/site) in each subsequent year. All trial sites would be selected from 153 possible Local Government Areas in NSW, VIC and WA.

The primary purpose of the trial is to evaluate the agronomic characteristics, oil content and genetic stability of up to 200 lines of GM canola under field conditions and to generate data for possible future commercial release applications. The GM canola would not be permitted for use in human food or animal feed. The applicant proposes to use oil from crushed GM seed in a small-scale animal feeding study.

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. GTTAC also noted the draft licence conditions are similar to those used for past GM canola trials. The licence would impose stringent controls to restrict gene flow and extensive monitoring and management post-harvest to ensure the GMO does not persist after the trial. The licence would require the destruction of any GM plant material after the completion of the trial.

Key points discussed by the Committee:

- **Post-trial destruction requirements** - the Committee agreed that the OGTR should further consider the rationale for the destruction of GM plant material by burial;
- **Potential for pollen movement** - GTTAC agreed that information on pollen movement and outcrossing should be clarified and additional detail could be added to the RARMP in relation to bee mediated pollen movement;
- **Post-trial activities** - the Committee suggested that details about the use of non-viable seed for any animal feeding trials could be clarified, and that containment, transport and storage of GMOs would be conducted in accordance with guidelines issued by the Regulator; and
- **Isolation requirements** – the Committee noted that for trials where insect proof mesh would be used to restrict pollen movement, a smaller monitoring zone would be required.

RESOLUTION:

GTTAC advised the Regulator that:

1. The Committee agrees with the overall conclusions of the RARMP; and
2. The Regulator should further consider the basis for burial as means of disposal of GM canola.

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. 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
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
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
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