Australian Government

Department of Health

Office of the Gene Technology Regulator

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 JULY–30 SEPTEMBER 2014

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

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

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ISBN: 978-1-76007-010-6

Online ISBN: 978-1-76007-011-3

Publications approval number: 10988

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LETTER OF TRANSMITTAL

Senator the Hon Fiona Nash
Assistant Minister for Health
Parliament House
CANBERRA ACT 2600

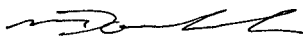
Dear Minister

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 2014.

During this period one licence was issued for dealings involving intentional release of GMOs, three licences were issued for dealings not involving intentional release of GMOs, and 35 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 Michael Dornbusch
Acting Gene Technology Regulator

21 November 2014

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ABOUT THIS REPORT

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

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

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

This report has four key sections.

Gene technology regulatory system

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

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 July to 30 September 2014 quarter were:

Licences and other instruments

- 2 organisations accredited
- 1 licence issued for Dealings involving the Intentional Release (DIR) of GMOs into the environment
- 3 licences issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- 35 physical containment facilities certified
- 48 instruments surrendered
- 70 certifications, 3 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 15 per cent of current field trial sites and 7 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 of all field trial sites 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) 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.

During the quarter the Regulator did not seek advice on matters relevant to preparing DIR RARMPs. Further information on the processing of DIR applications is contained in Section 2 of this report.

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 Government agencies that are not prescribed in legislation but have maintained a strong interest in gene technology regulation, including:

- Department of Agriculture
- Department of Environment
- Department of Foreign Affairs and Trade.

During the quarter the Regulator did not seek advice on matters relevant to preparing 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. Four invitations to the public to comment on a RARMP were issued during the quarter. Summaries of public submissions are provided in the final RARMP.

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 July 2014 to 30 September 2014 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 investigation 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. DIR licence applications have a statutory timeframe of 255 working days for making a decision 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 licence conditions 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 meets 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	4	1
DNIR licence	4	3
Certifications	24	35

* *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 issued by the LGFGT.

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 12 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.

Applications received	Notifications of applications*	Consultation on application	Consultation on RARMP	Licences issued
DIR 130	DIR 130		DIR 125	DIR 128
DIR 131	DIR 131		DIR 127	
DIR 132			DIR 128	
DIR 133			DIR 129	

* *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 four applications for a DIR licence in the quarter:

- DIR-130 - GM Wheat (Murdoch University) Limited and controlled release of wheat genetically modified for improved grain quality
- DIR-131 - GM Safflower (CSIRO) Limited and controlled release of Safflower modified for high oleic acid composition

- DIR-132 - GM Herpes simplex virus (Amgen Australia Pty Ltd) Commercial release of a tumour-selective genetically modified virus for cancer therapy
- DIR-133 - GM Cotton (Bayer CropScience Pty Ltd) Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance.

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

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

- DIR-131 - GM Safflower (CSIRO) Limited and controlled release of safflower modified for high oleic acid composition
- DIR-130 - GM Wheat (Murdoch University) Limited and controlled release of wheat genetically modified for improved grain quality.

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

- DIR-125 - GM *E. coli* (Zoetis Australia Research & Manufacturing Pty Ltd) Commercial release of a genetically modified vaccine to protect chickens against pathogenic *Escherichia coli*
- DIR-127 - GM Canola (Monsanto Australia Limited) Commercial release of canola genetically modified for herbicide tolerance
- DIR-128 - GM Wheat and Barley (The University of Adelaide) Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance or micronutrient uptake
- DIR-129 - GM Sugarcane (Sugar Research Australia Ltd) Limited and controlled release of sugarcane genetically modified for herbicide tolerance.

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

Two DIR licence applications were surrendered during the quarter:

- DIR 074 - GM Cotton (Monsanto Australia Limited) Limited and controlled release of GM insect resistant and/or herbicide tolerant Gossypium barbadense cotton
- DIR 101 - GM Cotton (Monsanto Australia Limited) Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance.

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-130 - GM Wheat (Murdoch University) Limited and controlled release of wheat genetically modified for improved grain quality.

Decisions on applications for Dealings involving Intentional Release licences

One DIR licence was issued during the quarter:

- DIR-128 - GM Wheat and Barley (The University of Adelaide) Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance or micronutrient uptake.

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.

Three 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 request, 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 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	22	43
Surrender of DIR licence	5	2
Surrender of DNIR licence	1	2
Variation of accreditation	0	0
Variation of certification	86	70
Variation of DIR licence	3	3
Variation of DNIR licence	31	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 for specified information to be declared confidential commercial information (CCI) in accordance with section 185 of the Act. 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 three CCI applications. The Regulator made no 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 unannounced 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). Post-harvest monitoring continues until the site is free of volunteers.

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, nine GM plant field trial sites under DIR licences were subjected to monitoring visits.

- **Current field trial sites:** Of the 33 sites current in the quarter, five were monitored. This represents a monitoring rate of 15 per cent of all current sites for the quarter

- **Post-harvest field trial sites:** Of the 57 sites subject to post-harvest monitoring in the quarter, four were monitored. This represents a monitoring rate of seven 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 four PC2 laboratories, three PC2 plant facilities, three PC3 laboratories and one PC4 laboratory.

Monitoring of contained dealings: During the quarter, the monitoring of the 11 certified facilities mentioned above included monitoring of DNIRs for compliance with licence conditions that must be followed when undertaking dealings that are required to be conducted within contained facilities.

Five DNIRs were monitored during the quarter.

Monitoring of GMO Dealings involving Intentional Release

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
Nuseed Pty Ltd, Victoria	DIR 123	1	Current	Canola
Monsanto Australia Limited, Victoria	DIR 105	2	PHM	Canola
Bayer CropScience Pty Ltd, Victoria	DIR 069	2	PHM	Canola
CSIRO, Western Australia	DIR 121	1	Current	Safflower
Bayer CropScience Pty Ltd, Western Australia	DIR 113	1	Current	Cotton
Queensland University of Technology, Northern Territory	DIR 107	2	Current	Banana
Total		**9**	**Current = 5 PHM* = 4**	

* *PHM = post harvest monitoring*

Monitoring of Dealing Not involving Intentional Release

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

Licensed Organisation Name	Licence Number
Queensland University of Technology, Queensland	DNIR 539
Griffith University, Queensland	DNIR 255
	DNIR 389
	DNIR463
	DNIR 509
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	2
	PC2 Plant Facility	3
	PC3 Laboratory	1
Griffith University, Queensland	PC2 Laboratory	2
	PC3 Laboratory	1
Department of Agriculture, Fisheries and Forestry Queensland, Queensland	PC3 Laboratory	1
Queensland Health Forensic and Scientific Services, Queensland	PC4 Laboratory	1
Total		**11**

Monitoring Findings

Dealings involving Intentional Release

The monitoring findings listed below indicate the monitoring activities of the OGTR with respect to dealings with GMOs , 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 GMO Dealings Not involving Intentional Release

There was one non-compliance issue observed for DNIRs in the quarter.

Organisation	Queensland University of Technology
Licence number and site	DNIR 539
Summary of dealing	The aim of the dealings is to use genetically modified banana streak virus-based vectors to introduce genetic material related to *Fusarium* disease development or resistance into banana plants in order to identify key genes in banana - *Fusarium* interactions.
Findings	The licence holder did not inform all persons covered by the licence of conditions that applied to them or obtain signed statements from all persons, prior to their commencing dealings, indicating that they understood and agreed to be bound by licence conditions.
Assessment	Only staff members who autoclave waste had not been informed of licence conditions and these staff were otherwise appropriately trained in their duties. The risks to human health and safety and the environment have been assessed as negligible.
Compliance management	Queensland University of Technology is reminded that prior to permitting persons to commence work on the dealing they must 1. inform all persons covered by a licence of the conditions that apply to them and; 2. obtain a signed statement from each person covered by the licence acknowledging that the licence holder has informed the person of the conditions of the licence, or variations to those conditions, that apply to that person.

Findings for Physical Containment Facilities

The OGTR's monitoring of certified PC facilities in the quarter found four non-compliances with certification conditions.

All were found to pose negligible risks to human health and safety and the environment.

	Non-Compliance Issue					
Number of PC Facilities inspected	Structure	PPE[1]	Equipment	Waste disposal	Work practices[2]	Transport
11	1	-	-	-	2	1

[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 implementation of any management actions. 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	Griffith University
Aim	This audit is part of the OGTR ongoing audit program and was conducted to: • trace, assess and reinforce Griffith University's compliance management arrangements for meeting compliance obligations under the national regulatory system for gene technology; • promote an internal audit framework for risk assessment and management of compliance risks to Griffith University's Institutional Biosafety Committee (IBC) and compliance risk management personnel and decision makers; and • include Griffith University as a party to ongoing Practice Reviews.
Determination	The audit found that; • there were no Griffith University non-compliances or breaches evident; and • Griffith University 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 Griffith University development of their compliance arrangements. 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.

SECTION 3

STATUTORY COMMITTEE OPERATIONS

STATUTORY COMMITTEE OPERATIONS

The Act establishes two committees to provide advice to the Regulator and the Legislative and Governance Forum on Gene Technology (LGFGT):

- Gene Technology Technical Advisory Committee (GTTAC)
- Gene Technology Ethics and Community Consultative Committee (GTECCC).

Committee appointments 2014-17

Membership of GTECCC expired on 31 January 2014. The process for appointment of new members to GTECCC for the 2014–17 triennium is ongoing.

Gene Technology Technical Advisory Committee

The function of the GTTAC under the Act is to provide scientific and technical advice, on the request of the Regulator or 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 face-to-face on 24 September 2014

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.

There were no GTECCC meetings in this 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 included:

- Visit by Chair of the National Biosafety Committee, Ghana, August 2014
  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:

- Regulatory Science Network meeting, Canberra, September 2014
- Lecture to Biosecurity students at Australian National University, Canberra, September 2014
- Regulator's forum meeting, Canberra, August 2014

OGTR officers also participated in the following meetings/conferences:

- ComBio 2014, Canberra, September 2014
- Australian & New Zealand Animal Association conference 2014, Canberra, September 2014
- Risk Communication and Outrage Management workshop by Professor Peter Sandman, Canberra, September 2014
- Crawford Fund Conference - Ethics, Efficiency & Food Security, Canberra, August 2014
- Australian Seed Federation Conference, Albury, August 2014
- International Association of Plant Biotechnology Congress 2014, Melbourne, August 2014

OGTR website usage and statistics

The OGTR website is a comprehensive source of information on activities of the office. The table below provides 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	364258	47668
August	346769	41995
September	298832	40593

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:

- Guidelines and forms for Certification of Physical Containment Facilities
- Maps of Trial Sites
- List of applications and licences for Dealings involving Intentional Release (DIR) of GMOs into the environment
- About the OGTR
- List of Genetically Modified Product approvals
- What's New
- Record of GMOs and GM Product Dealings
- Fact Sheets
- Guidelines
- DIR 127 – Commercial release of canola genetically modified for herbicide tolerance – Monsanto Australia Limited

The most popular downloaded documents were:

- *Risk Analysis Framework*
- The Biology and Ecology of Rice (*Oryza sativa* L.) in Australia
- The Biology of *Saccharum spp* (Sugarcane)
- PC2 Laboratory guidelines
- The Biology of *Gossypium hirsutum* L. and *Gossypium barbadeuse* L. (Cotton)
- The Biology of *Ananas comosus* var. *comosus* (Pineapple)

- The Biology of *Zea mays* L. *ssp mays* (maize or corn)
- The Biology of *Musa* L. (banana)
- Application for the Certification of a Physical Containment facility
- Food produced using gene technology and approved for sale under the *Food Standards Australia New Zealand Act 1991.*

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	64	78
August	66	65
September	89	75

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 225 emails during the quarter.

Application Entry Point 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 Entry Point. The inbox received 798 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 111 emails during the quarter.

APPENDIX

APPENDIX 1:

Gene Technology Technical Advisory Committee Communiqué 46th Meeting, 24 September 2014 Canberra

This Communiqué covers matters considered at the 46th meeting of the Gene Technology Technical Advisory Committee (GTTAC)

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 hold office on a part-time basis.

The Regulator seeks advice from GTTAC when assessing 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 Risk Assessment and Risk Management Plans (RARMPs) and, in accordance with Regulation 29 of the Gene Technology Regulations 2001, any Committee resolutions provided to the Regulator. The Communiqué also provides an overview of other major issues discussed by GTTAC.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED ORGANISMS

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

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

The RARMP for every DIR licence application is also released for public consultation. 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 RARMP – LIMITED AND CONTROLLED RELEASE

GTTAC considered the following RARMP for a limited and controlled release application:

1.1 DIR 129 RARMP – Limited and controlled release of sugarcane genetically modified for herbicide tolerance

Sugar Research Australia Ltd (SRA, formerly BSES Limited) has applied for a licence for a limited and controlled release of sugarcane that has been genetically modified (GM) for herbicide tolerance. The trial is proposed to take place in Queensland between November 2015 and November 2021 on a combined maximum area of 30 hectares per year. The trial would continue the work done over the last five years by SRA under licence DIR 096, and aims to evaluate the field performance of the GM sugarcane.

GTTAC noted that aspects of the field trial would also be subject to regulation by the Australian Pesticides and Veterinary Medicines Authority (APVMA), which has regulatory responsibility for the use of herbicides in Australia. GM sugarcane from this trial would not be used in human food or animal feed.

GTTAC noted the key points in the consultation RARMP, including the conclusion that this release poses negligible risks to human health and safety and the environment. GTTAC discussed the draft licence conditions, which are similar to those used for previous GM sugarcane licences including DIR 096.

RESOLUTION:

GTTAC advised the Regulator that:

- GTTAC agrees with the overall conclusions of the RARMP;
- GTTAC agrees that all plausible risk scenarios have been identified;
- GTTAC generally agrees with the limits and controls proposed in the RARMP but recommends that the Regulator:
  a. further consider in the RARMP the adequacy of, and clarify the requirements for, temporal and physical separation of flowering GM and non-GM sugarcane in proposed crossing facilities at the Meringa location;
  b. clarify in the RARMP the requirements and rationale for separation between GM and commercial non-GM sugarcane in the field trial locations in order to avoid confusion;
  c. clarify and ensure consistency in the RARMP of descriptions of hot water treatments;
  d. clarify in the RARMP the proposed number and locations of sites at which crossing would be performed;
  e. clarify in the RARMP the post-harvest requirements that will apply for trial sites.

2. ADVICE ON CONSULTATION RARMP – COMMERCIAL RELEASE

GTTAC considered the following RARMPs for commercial release applications:

2.1 DIR 125 – Commercial release of genetically modified vaccine to protect chickens against pathogenic *Escherichia coli*

DIR 125 is an application from Zoetis Australia Research & Manufacturing Pty Ltd for the commercial release of a GM *E. coli* poultry vaccine. In December 2013, GTTAC provided advice on the preparation of the RARMP for DIR 125, and members noted they were now being asked for advice on the RARMP that Regulator has prepared.

The GM vaccine is intended for use on commercial poultry farms in Australia to protect chickens from disease caused by *E. coli* infection. GTTAC noted that Zoetis is seeking approval from the Regulator for the commercial release of the GMO for the purposes of import, transport, storage and disposal. Before the GM vaccine could be used in Australia, approval would also be required from the APVMA. GTTAC noted that, if approval is granted by the APVMA, the vaccine is likely to be classified as a prescription animal remedy and would require supervision by a registered veterinarian to be used in commercial poultry farms.

GTTAC discussed the RARMP prepared for DIR 125 and noted that the risk assessment concludes that this release poses negligible risks to the health and safety of people and to the environment.

RESOLUTION:

GTTAC advised the Regulator that:

- GTTAC agrees with the overall conclusions of the RARMP; that the proposed GMO dealings pose negligible risk to the health and safety of people and the environment and that the RARMP identifies all plausible risk scenarios.
- However, GTTAC recommends that the RARMP includes further detail to clarify the characterisation of the risk scenarios and the assessment of likelihood and consequences:
  a. clarify the characterisation of *E. coli* 078 as "not a human pathogen" in the context of current scientific evidence and understanding of the zoonotic potential of APEC strains, including the potential for subclinical infection and/or cause clinical disease in mammals, and inclusion of any additional relevant published evidence;
  b. clarify the wording and argumentation regarding potential for the *E. coli* 078 vaccine strain to result in zoonotic infections or infection of wild birds;
  c. clarify and/or include further consideration of the current management practices for use of chicken manure as fertiliser, in the context of potential persistence and dispersal of the vaccine strain; and
  d. consider whether there is any additional information regarding the potential for the vaccine strain to grow or persist in eggs, including in the context of the timing of vaccination and chicken production timeline.
- GTTAC recommends that the Regulator convey issues raised by GTTAC to the APVMA, in particular regarding the potential exposure to people or other organisms other than vaccinated chickens.
- GTTAC noted:
  a. the role of the APVMA in the assessment and potential commercial registration of this vaccine for administration as a veterinary medicine;
  b. that administration would be overseen by trained veterinarians; and
  c. that APVMA's assessment would consider incidental exposure, including potential occupational health and safety issues.

2.2 DIR 127 – Commercial release of canola genetically modified for herbicide tolerance

DIR 127 is an application from Monsanto Australia Ltd (Monsanto) for the commercial release of one new variety of GM canola (MON 88302 or TrueFlexTM Roundup Ready® canola), which has been modified for herbicide tolerance. Members noted that they had provided advice on the preparation of the RARMP at the 45th GTTAC meeting in February 2014, and that they were now being asked for advice on the consultation RARMP that has been prepared by the Regulator.

MON 88302 canola contains one copy of the *cp4 epsps* gene from a soil bacterium, which confers tolerance to the herbicide glyphosate. Compared to Roundup Ready® canola, which is currently approved for commercial release in Australia, MON 88302 canola can tolerate higher rates of glyphosate herbicides and has a wider window for herbicide application.

GTTAC noted that this GM canola has been field trialled in Australia under licence DIR 105. If approved, the GM canola and its products would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand (FSANZ) has assessed and approved food made from this GM canola.

GTTAC noted that the label instructions and conditions of registration imposed by the APVMA for the herbicide, together with the relevant Crop Management Plan developed by Monsanto, would address herbicide resistance management.

RESOLUTION:

GTTAC advised the Regulator that:

1. GTTAC agrees with the overall conclusions of the RARMP;
2. GTTAC agrees that all plausible risk scenarios relating to human health and safety and the environment have been identified and that characterisation of the risk scenarios is adequate;
3. GTTAC notes that herbicide resistance management issues are addressed primarily through herbicide registration requirements of the Australian Pesticides and Veterinary Medicines Authority.

3. ADVICE ON APPLICATION – COMMERCIAL RELEASE

GTTAC considered the following commercial release application:

3.1 DIR 132 – Commercial release of a tumour-selective genetically modified virus for cancer therapy

Application DIR 132 from Amgen Australia Pty Ltd (Amgen) is for the commercial release of a GM *Human simplex virus 1*, referred to as Talimogene laherparepvec (T-VEC), for cancer treatment. T VEC has been used in clinical trials in several countries, including in Australia under licence DNIR-461 issued by the Regulator.

GTTAC was provided an agenda paper that outlined key issues for consideration in the RARMP, and was asked for advice on any other issues that should be considered.

GTTAC noted that the GMO is intended for use as a prescription only treatment for patients with skin cancer and other suitable solid tumours and would be injected directly into the tumour. As a result of the genetic modifications, T-VEC cannot replicate efficiently in non-dividing cells and so selectively replicates in tumours, which are made up of dividing cells. The modifications also enable T-VEC to trigger an enhanced immune response in and around the injected tumour.

Amgen will also require registration of the GMO with the Therapeutic Goods Administration (TGA) and import authorisation from the Department of Agriculture. GTTAC noted that the TGA has primary responsibility for assessing patient safety and the efficacy of the GMO, and that the Regulator's assessment would be limited to risks posed by authorising the import, transport, storage and disposal of the GMO.

RESOLUTION:

GTTAC advised the Regulator that:

1. GTTAC agrees with the issues identified in the agenda paper;
2. GTTAC advises that, in preparing the RARMP, the Regulator should:
   a. consider the evidence for potential routes of accidental exposure and potential risks, including in relation to clinical waste; and
   b. consider the potential for recombination with other viruses.
3. GTTAC notes the role of the TGA in the assessment and potential commercial approval of T-VEC as a therapeutic, including interactions with other immune treatments, and the provisions for reciprocal advice in the respective assessment processes.

INFORMATION ITEMS AND REPORTS

GTTAC presentations from an APVMA officer about the roles and responsibilities of the APVMA, and from an OGTR officer on 'New technologies – implications for the gene technology regulatory scheme'. The committee discussed the scope of the Australian gene technology regulatory scheme as determined by the definitions in the Act, and some of the issues around regulation keeping pace with new technologies, domestically and internationally.

GTTAC also received a report from the acting Gene Technology Regulator that provided updates on activities undertaken by the Regulator and the OGTR since the previous face-to-face GTTAC meeting (20 February 2014).

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
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
Current	In relation to a field trial location (planted under a DIR Licence) refers to a location that has been planted with a GMO and has not yet been harvested.
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
PHM	In relation to a field trial location (planted under a DIR Licence) refers to a location that has been harvested but is still subject to regular monitoring by the licence holder
RARMP	Risk assessment and risk management plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator
Spot checks	Unannounced visits by the OGTR Monitoring or Compliance Sections
Volunteer	Regrowth of plants or other plant parts e.g. sugarcane that has remained on a site after a trial has been completed

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All information in this publication is correct as at 4.12.14