Australian Government

Department of Health

Office of the Gene Technology Regulator

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 JULY TO 30 SEPTEMBER 2015

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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Operations of the Gene Technology Regulator Quarterly Report 1 July to 30 September 2015

ISSN: 2205-4510 (Online)

ISSN: 1446-4950 (Print)

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

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LETTER OF TRANSMITTAL

Senator the Hon Fiona Nash
Minister for Rural 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 2015.

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 20 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.

The Gene Technology Amendment Bill 2015 received Royal Assent on 10 September 2015. The amendments will commence by 11 March 2015. The six month delay to commencement is to allow States and Territories time to update their own gene technology legislation, to maintain the national consistency of the scheme.

Yours sincerely

Robyn Cleland
Acting Gene Technology Regulator

23 November 2015

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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 the 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 2015 quarter were:

Licences and other instruments

- 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
- 20 physical containment facilities certified
- 24 instruments surrendered
- 96 certifications, 2 DIR licences and 10 DNIR licences varied.

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

Monitoring and Compliance

Approximately 10 per cent of current field trial sites and 10 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, primary industries, and science and innovation.

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 sought advice from State and Territory governments on matters relevant to preparing one RARMP, as well as comment on two RARMPs.

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 are:

- 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, Agricultural Policy Division
- Department of Foreign Affairs and Trade.

During the quarter the Regulator sought advice from Australian government agencies on matters relevant to preparing one RARMP, as well as comment on two 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. Summaries of public submissions are provided in the final RARMP.

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

SECTION 2

REGULATION OF GENETICALLY MODIFIED ORGANISMS

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of the report outlines the regulatory activity undertaken during the 1 July to 30 September 2015 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 investigations 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 is also provided.

Types of Applications

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

Licences for GMO Dealings involving Intentional Release

DIR licences authorise GMO 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.

Licences for GMO Dealings Not involving Intentional Release

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*

Application type	Number received	Number approved*
Accreditation	2	2
DIR licence	3	3
DNIR licence	2	2
Certifications	52	20

**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, relevant local councils 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 Regulator must not issue a licence unless satisfied that risks to human health and safety and the environment can be managed.

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 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 140	-	DIR 139	DIR 134	DIR 132
DIR 141			DIR 137	DIR 135
DIR 142				DIR 136

**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

The Regulator received three applications for DIR licences in the quarter:

- DIR-140 - GM Vaccinia virus (Clinical Network Services Pty Ltd) Clinical trial of a genetically modified virus for treatment of liver cancer

- DIR-141 - GM Tobacco (CSIRO) Limited and controlled release of tobacco genetically modified for accumulation of industrial oils within leaves
- DIR-142 - GM Wheat (Department of Economic Development, Jobs, Transport and Resources) Limited and controlled release of wheat genetically modified for enhanced nitrogen use efficiency and water use efficiency.

Consultation on applications and consultation on RARMPs for Dealings involving Intentional Release

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

- DIR 139 GM Canola (Pioneer Hi-Bred Australia Pty Ltd) Commercial release of canola genetically modified for herbicide tolerance.

Consultation on this application with expert groups and key stakeholders took place as part of the process to identify risks to human health and safety or the environment to be considered in preparing the RARMP.

Invitations to comment on two RARMPs were issued during the quarter:

- DIR-134 - GM Carnation (International Flower Developments Pty Ltd) Commercial import and distribution of genetically modified carnations with altered flower colour
- DIR 137 - GM Influenza (AstraZeneca Pty Ltd) Commercial supply of attenuated GM influenza vaccines.

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

No DIR licences were surrendered and no applications were withdrawn during the quarter.

Clock stopped on licence applications for Dealings involving Intentional Release

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.

The clock was stopped on two DIR applications in this quarter:

- DIR-140 - GM Vaccinia virus (Clinical Network Services Pty Ltd) Clinical trial of a genetically modified virus for treatment of liver cancer
- DIR-141 – GM Tobacco (CSIRO) Limited and controlled release of tobacco genetically modified for accumulation of industrial oils within leaves.

Decisions on applications for Dealings involving Intentional Release

Three DIR licences were issued during the quarter:

- DIR-132 - GM Herpes simplex virus (Amgen Australia Pty Ltd) Commercial supply of a tumour-selective genetically modified virus for cancer therapy
- DIR-135 - GM Sugarcane (The University of Queensland) Limited and controlled release of sugarcane genetically modified for enhanced sugar content
- DIR-136 - GM Cotton (CSIRO) Limited and controlled release of cotton genetically modified for enhanced fibre quality.

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

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-557 - An investigation of a single intranasal administration of the interferon alpha compound "DEF201" in longtail macaques (Monash University)
- DNIR-558 – Generation of protein for structural studies of membrane-bound pore forming toxins (St Vincent's Institute of Medical Research).

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 calendar 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	3	3
Surrender of certification	34	20
Surrender of DIR licence	0	0
Surrender of DNIR licence	1	1
Variation of accreditation	0	0
Variation of certification	105	96
Variation of DIR licence	5	2
Variation of DNIR licence	17	10

[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 five CCI applications. The Regulator made three 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 and 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 relating to 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 OGTR inspectors monitored 10 GM plant field trial sites under DIR licences:

- **Current field trial sites:** Of the 39 sites current in the quarter, 4 were monitored. This represents a monitoring rate of 10 per cent of all current sites for the quarter
- **Post-harvest field trial sites:** Of the 61 sites subject to post-harvest monitoring in the quarter, 6 were monitored. This represents a monitoring rate of 10 per cent of all sites subject to post-harvest monitoring in this 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	GM Crop type
University of Adelaide, Western Australia	DIR 128	2	Current	Wheat and Barley
	DIR 102	4	PHM	Wheat and barley
Pioneer Hi-Bred Australia Pty Ltd, Western Australia	DIR 114	4	2 PHM 2 Current	Canola

**PHM = post-harvest monitoring*

Monitoring of certified facilities:

Monitoring in connection with contained dealings covered five organisations and 17 certified facilities. Monitoring of certified facilities encompassed six PC2 laboratories, seven PC2 animal facilities, one PC2 aquatic facility, one PC3 laboratory, one PC2 plant facility and one PC3 animal facility.

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
Macquarie University, New South Wales	PC2 Laboratory	2
	PC2 Aquatic Facility	1
	PC2 Animal Facility	1
University of Southern Queensland, Queensland	PC2 Laboratory	1
	PC2 Plant Facility	1
Murdoch Children's Research Institute, Victoria	PC2 Animal Facility	1
	PC2 Laboratory	1
University of Queensland, Queensland	PC2 Animal Facility	3
	PC3 Laboratory	1
	PC3 Animal Facility	1
Children's Medical Research Institute, New South Wales	PC2 Laboratory	2
	PC2 Animal Facility	2
Total		**17**

Monitoring of contained dealings: During the quarter, the monitoring of the 17 certified facilities mentioned above included monitoring one DNIR for compliance with licence conditions.

Monitoring of Dealings Not involving Intentional Release

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

Licensed Organisation Name	Licence Number
Macquarie University, New South Wales	DNIR 546
Total	1

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 Regulator 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

The OGTR's monitoring of DIRs in the quarter identified no non-compliances.

Findings for GMO Dealings Not involving Intentional Release

The OGTR's monitoring of DNIRs in the quarter identified no non-compliance issues with licence conditions.

Findings for Physical Containment Facilities

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

Non-Compliance Issue						
Number of PC Facilities inspected	Structure	PPE[1]	Equipment	Waste disposal	Work practices[2]	Transport
17	-	-	-	-	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. The objective of Practice Reviews 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 at the request of an accredited organisation. An audit can entail:

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

These activities are conducted to:

- verify that an accredited organisation has relevant and effective management procedures and practices to meet requirements under the Act, including accreditation requirements, guidelines and any licence conditions applicable to a dealing under the Act

- assess whether or not procedures and practices provide mechanisms to identify and resolve emerging risks
- where appropriate suggest improvements to procedures and practices.

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

There were 2 audits completed in the quarter.

Audit	Queensland University of Technology (QUT)
Aim	This audit is part of the OGTR ongoing audit program and was conducted to: • trace, assess and reinforce QUT's compliance management arrangements for meeting compliance obligations under the national regulatory system for gene technology; and • examine the potential for emerging compliance risks to arise from new operations on agricultural research stations.
Determination	The audit found that; • there were no non-compliances or breaches evident; and • QUT 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 development of QUT's 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.

Audit	RMIT
Aim	This audit is part of the OGTR ongoing audit program and was conducted to: • trace, assess and reinforce RMIT's compliance management arrangements for meeting compliance obligations under the national regulatory system for gene technology; and • examine the potential for emerging compliance risks to arise from new operations on agricultural research stations.
Determination	The audit found that; • there were no non-compliances or breaches evident; and • RMIT 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 RMIT's ongoing 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).

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 once during the quarter on 4 August 2015. The Communiqué for this meeting is at Appendix 1.

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

Gene Technology Ethics and Community Consultative Committee

The function of 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.

As at 30 September 2015, the appointment process for a new membership of GTECCC was ongoing. There were no meetings of GTECCC during this period.

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:

- Malaysian Genetic Modification Advisory Committee, Kuala Lumpur, Malaysia, August 2015
- International Centre for Genetic Engineering and Biotechnology (ICGEB) Symposium, Embassy of Italy (Canberra), September 2015
- OECD Steering Group on Environmental Considerations for the Risk/Safety Assessment of Transgenic Crop Plants, Washington DC, USA, September 2015
- Workshop on Genome Editing in Agricultural Area, Tokyo, Japan, September 2015
- Participation in discussions about regulation of gene stacking with Chinese colleagues, September, Canberra, Australia.

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 attended the following meetings and events:

- Risk Governance Symposium – a Regulatory Science Network event, Canberra, July 2015
- Crawford Fund Food Security Conference, Canberra, August 2015
- Regulatory Science Network meetings, Canberra, August and September 2015
- Workshop on a Framework for Assessing the Social and Ethical, Environmental and Economic Impacts of Emerging Technologies, Melbourne, September 2015
- 17th Australian Agronomy Conference, Hobart, September 2015
- ComBio2015, Melbourne, September/October 2015.

The OGTR also provided a presentation to the following:

- Australian Society for Microbiology conference, Canberra, July 2015
- International Life Sciences Institute (ILSI) Symposium on Sustainability, Genetics, and New Technologies, Melbourne, July 2015
- Australian Seed Federation Convention, Brisbane, August 2015
- Australia Africa Conference , Canberra, August 2015
- Agricultural Bioscience International Conference, Melbourne, September 2015
- Australian and New Zealand Laboratory Animal Association, Adelaide, September 2015.

During the quarter the Regulator was invited to make a submission to the House of Representatives Standing Committee on Agriculture and Industry (the Committee) inquiry into Agricultural Innovation. The Regulator's submission concluded that the national gene technology regulatory scheme provides an efficient and effective system for the application of gene technology in Australia that allows work with the technology while ensuring any risks to people and the environment are appropriately managed.

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	SESSIONS[1]	USERS[2]
July	4425	2953
August	5063	3529
September	5845	3942

[1] Session is a number of times the OGTR website has been visited

[2] Users is the number of people visited the OGTR website

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

List of Genetically Modified Product approvals

Table of applications and authorisations for Dealings involving Intentional Release (DIR) into the environment

Record of GMOs and GM products

Application to certify facilities

Legislation

Applications forms to work with GMOs

Guidelines for Certification of Physical Containment 2 Facilities

About Regulator

Maps of Trial Sites

The most popular downloaded documents were:

Risk Analysis Framework

The Biology of *Saccharum spp* (Sugarcane)

The Biology of Z*ea mays* L. *ssp mays* (maize or corn)

The Biology of *Ananas comosus* var. *comosus* (Pineapple)

The Biology and Ecology of Rice *(Oryza sativa* L.) in Australia

Guidelines for Certification of a Physical Containment Level 2 Laboratory

The Biology of *Musa* L. (banana)

The Biology of *Carica papaya* L. (papaya, papaw, paw paw)

DIR 020/2002 – Risk Assessment and Risk Management Plan

The Biology of *Gossypium hirsutum* L. and *Gossypium barbadeuse* L. (Cotton)

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	44	75
August	52	63
September	66	73

Monitoring and compliance email inbox

The OGTR maintains an email inbox to provide a central point for accredited organisations to contact the OGTR regarding monitoring and compliance matters, such as queries, notifications required under licences, and self reporting of non-compliances. The email inbox ensures that all communications are answered efficiently while monitoring staff are away from the office. The inbox received 200 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 404 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 124 emails during the quarter.

Total emails received by OGTR during the quarter, 953.

APPENDIX

APPENDIX 1

Gene Technology Technical Advisory Committee 48th Meeting 4 August 2015, Canberra Communiqué

This Communiqué covers matters considered at the 48th meeting of the Gene Technology Technical Advisory Committee (4 August 2015)

The Gene Technology Technical Advisory Committee (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.

The Regulator seeks advice from GTTAC on licence applications to work with genetically modified organisms (GMOs) and on Risk Assessment and Risk Management Plans (RARMPs) prepared for applications. The purpose of this Communiqué is to provide a brief overview of GTTAC's consideration of applications and RARMPs and, in accordance with the Gene Technology Regulations 2001 (the Regulations), to publish Committee resolutions given to the Regulator. The Communiqué also provides an overview of any other major issues discussed by GTTAC.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF A GMO (DIR)

Dealings involving the Intentional Release (DIR) of a GMO can involve the limited and controlled release (clinical trial or field trial) or a 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 DIR applications which do not qualify as limited and controlled under Section 50A of the Act.

The RARMP for every DIR licence application is issued for public consultation. Information on how to obtain copies of DIR applications and RARMPs is provided at the end of this document.

1. ADVICE ON APPLICATIONS – COMMERCIAL

1.1 DIR 137 – Commercial supply of attenuated GM influenza vaccines

AstraZeneca Pty Ltd has applied for a licence for the commercial supply of two types of genetically modified (GM) influenza vaccines: a seasonal flu vaccine to target currently circulating flu viruses; and one to target a pandemic flu strain, should one arise. GM vaccines based on the same attenuated strains as the GMOs are currently approved in United States of America (USA), Canada and the European Union. If

approved in Australia the GMOs would be imported from overseas and distributed to healthcare facilities where the vaccines would be administered as a nasal spray by qualified health professionals to consenting patients.

Import and therapeutic use of the GM vaccines will require import authorisation from the Department of Agriculture and registration with the Therapeutic Goods Administration, respectively.

The Regulator sought advice from GTTAC on the following matters that have been identified by the Regulator as key issues to be considered in the preparation of the RARMP:

Potential for accidental exposure of humans, animals or other organisms to the GM viruses, leading to harm; and

Potential for reassortment of the GMOs and a circulating influenza strain, resulting in a pathogenic phenotype.

GTTAC was also asked to provide advice on any other key issues that should be considered in the preparation of the RARMP.

GTTAC discussed that these dealings with the GMO posed negligible risk to human health and the environment, including during the handling of the GMOs during transportation and in healthcare facilities. The committee considered the likelihood of a spill during transportation, and the possible need for information labels on vials or containers to better manage accidental exposure. GTTAC discussed the proposal by the applicant for a licence that would allow the applicant to vary the GMO strains each year to reflect the World Health Organisation recommendations on seasonal influenza strains.

RESOLUTION

GTTAC advised the Regulator that:

1. GTTAC agrees that the RARMP should consider issues identified [by the Regulator] in the agenda paper; and
2. GTTAC recommends that the Regulator consider:
    a. Transport, storage, and disposal in the context of intended vaccine-delivery workforce and facilities
    b. The need for labelling of packaging
    c. The need for oversight of each new vaccine strain
    d. Risk associated with incidental exposure

1.2 DIR 138 – Commercial release of canola genetically modified for dual herbicide tolerance and a hybrid breeding system

Bayer CropScience Pty Ltd (Bayer) has applied for a licence for commercial cultivation of GM canola variety InVigor® x TruFlex™ Roundup Ready® canola Australia-wide. The variety contains genes for a hybrid breeding system and tolerance to the herbicides glufosinate-ammonium and glyphosate. The GMO is the result of conventional breeding between GM InVigor® canola and GM TruFlex™ Roundup Ready® canola which are individually authorised for commercial release under licences DIR 021/2002 and DIR 127, respectively.

If a licence is issued, the GM canola and GM canola-derived products would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand has assessed and approved food made from InVigor® canola and TruFlex™ Roundup Ready® canola. These approvals also cover InVigor® x TruFlex™ Roundup Ready® canola.

The Regulator requested advice from GTTAC on matters that have been identified by the Regulator as key issues to be considered in the preparation of the RARMP:

- the potential for the GM canola to be harmful to people through toxicity or allergenicity
- the potential for the GM canola to be harmful to other desirable organisms through toxicity
- whether the introduced hybrid breeding system and tolerance to two herbicides will increase the potential for InVigor® x TruFlex™ Roundup Ready® canola to spread and persist, leading to harm to the environment
- the potential for gene flow to other canola, including other commercially approved GM canola and non-GM herbicide tolerant canola, and whether this could lead to harm to the environment
- whether commercial release is likely to result in changes to agricultural practices that may have an adverse environmental impact
- any other key issues

GTTAC was also asked to provide advice on any other key issues that should be considered in the preparation of the RARMP.

GTTAC noted that GM InVigor® canola and GM TruFlex™ Roundup Ready® canola were individually authorised previously by the Regulator for commercial release. The committee discussed appropriate comparators for the GMO in the risk assessment.

RESOLUTION

GTTAC advised the Regulator that:

1. GTTAC agrees that the RARMP should consider issues identified [by the Regulator] in the agenda paper

1.3 DIR 139 - General Release of Canola Genetically Modified for Herbicide Tolerance

Pioneer Hi-Bred Australia Pty Ltd (Pioneer) is proposing commercial cultivation of the GM canola variety Optimum™ GLY Canola Australia-wide. The GM canola is modified for tolerance to the herbicide glyphosate. Field trials of Optimum™ GLY Canola have been conducted in Australia under licence DIR 114 since 2012.

If a licence is issued, the GM canola would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand has assessed and approved food made from Optimum™ GLY Canola.

Advice was sought from GTTAC on the following matters that have been identified by the Regulator as key issues to be considered in the preparation of the RARMP:

- the potential for the GM canola to be harmful to people through toxicity or allergenicity
- the potential for the GM canola to be harmful to other desirable organisms through toxicity
- whether the introduced herbicide tolerance trait will increase the potential for the GM canola to spread and persist, leading to harm to the environment
- the potential for gene flow to other canola, including other GM or non-GM herbicide tolerant canola, and whether this could lead to harm to the environment
- GTTAC was also asked to provide advice on any other key issues that should be considered in the preparation of the RARMP.
- GTTAC discussed the potential for the introduced gene to acetylate amino acids including non-protein amino acids in the context of presence in the food chain. GTTAC noted that acetylation is a natural process that occurs in cells including human.

RESOLUTION

GTTAC advised the Regulator that:

1. GTTAC agrees that the RARMP should consider issues identified [by the Regulator] in the agenda paper.
2. GTTAC recommends that the Regulator consider the potential for acetylation of other amino acids and their role in the food chain

2. ADVICE ON CONSULTATION RARMP – COMMERCIAL

2.1 DIR 134 - Commercial import and distribution of genetically modified carnations with altered flower colour

International Flower Developments Pty Ltd has applied for a licence for the commercial import and distribution of GM carnations that have been modified for altered flower colour. The aim of the application is to import cut carnation flowers for use in the commercial flower trade in Australia. There is no intention to grow these GM flowers in Australia. If a licence is issued, harvested cut-flowers of the GMOs would be imported and distributed in the same way as other cut carnation flowers in the floristry industry.

Members noted that this application relates to cut flowers only and not whole plants. Similar GM carnation varieties already exist on the GMO Register in Australia and can be propagated, grown and distributed.

GTTAC was provided a draft consultation RARMP prepared by the Regulator which concluded that the proposed release poses negligible risks to the health and safety of people and the environment as a result of gene technology. Advice was sought by the Regulator from GTTAC on the following issues:

- Does the risk assessment identify all the risk scenarios by which the proposed release could potentially give rise to risks relating to the health and safety of people or the environment?
- Is the characterisation of the risk scenarios identified adequate?
- Is there additional relevant information that should be considered?

GTTAC considered whether the GMO would require labelling in Australia as a GMO not intended for use as a therapeutic or food. The committee discussed the potential for people to eat the GM carnations, noting that the GMOs produce increased levels of some anthocyanins, which are claimed to be beneficial to health. GTTAC agreed that consuming anthocyanins would not pose a risk, particularly if consumed in low doses.

GTTAC discussed the effect of glyphosate treatment on pollen in the GMO, agreeing that glyphosate reduces pollen production.

RESOLUTION

GTTAC advised the Regulator that:

1. GTTAC agrees with the overall conclusions of the RARMP

3. ADVICE ON CONSULTATION RARMP – LIMITED AND CONTROLLED

3.1 DIR 136 – Limited and controlled release of cotton genetically modified for enhanced fibre quality

Commonwealth Scientific and Industrial Research Organisation (CSIRO) has applied for a licence to conduct a limited and controlled release of GM cotton. The GM plants have been modified for altered fibre quality.

The field trial is proposed to take place between October 2015 and May 2018 on a site belonging to CSIRO in New South Wales. The maximum area of the trial would be one hectare per year. The aim of this field trial is to evaluate the field performance and fibre quality of the GM cotton. CSIRO has proposed a number of controls to restrict the spread and persistence of the GM cotton plants and their genetic material in the environment. GM cotton from the trial would not be used for human food or animal feed.

GTTAC noted that the GM cotton lines in DIR 136 are new and have not been previously approved by the Regulator or other authorities in Australia or internationally.

GTTAC was provided a draft consultation RARMP prepared by the Regulator which concluded that the proposed release poses negligible risks to the health and safety of people and the environment as a result of gene technology. Advice was sought by the Regulator from GTTAC on the following issues:

- Does the risk assessment identify all plausible risk scenarios by which the proposed release could give rise to risks to the health and safety of people or the environment?
- Are the measures to limit and control the release appropriate for the trial?
- Is there any additional key information that should be considered?
- Does the committee agree with the overall conclusions of the RARMP?

GTTAC discussed the potential for allergenicity to the pectin methylesterase proteins (PME) expressed in the GMOs and the effectiveness of proposed personal protective equipment for individuals working with the GMO during processing to limit contact or inhalation of PMEs.

RESOLUTION

GTTAC advised the Regulator that:

1. GTTAC agrees with the overall conclusions of the RARMP.
2. GTTAC recommends that the Regulator consider the effectiveness of proposed use of personal protective equipment in limiting exposure to GM material

INFORMATION ITEMS AND REPORTS

GTTAC received a report from the acting Regulator that provided updates on activities undertaken by the Regulator and the OGTR since the previous GTTAC meeting (April 2015).

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 the OGTR 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*
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
GM	Genetically modified
GM product	A thing (other than a GMO) derived or produced from a GMO
GMO	Genetically modified organism
GTECCC	Gene Technology Ethics and Community Consultative Committee

GTSC	Gene Technology Standing Committee
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
Incident	A self-reported event which may constitute a non-compliance with regulatory requirements and a public health or environment risk
LGFGT	Legislative and Governance Forum on Gene Technology
Limited and controlled release	A type of DIR which meets certain criteria relating to limiting and controlling the dealings with the GMO (e.g. a field trial)
NLRD	Notifiable low risk dealing (work with transgenic plants, animals or microorganisms undertaken in certified containment facilities)
Non-compliance	An inconsistency between an event or state of affairs and the requirements imposed by licence accreditation or certification conditions, or any of the requirements of the Act or Regulations
OGTR	Office of the Gene Technology Regulator
PC1, PC2, PC3, PC4	Physical containment levels of facilities as certified by the Regulator
PHM	Post-harvest monitoring - 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
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 4.12.15