Australian Government

Department of Health

Office of the Gene Technology Regulator

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 APRIL TO 30 JUNE 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 April to 30 June 2015

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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 April to 30 June 2015.

During this period one licence was issued for dealings involving intentional release of GMOs, two licences were issued for dealings not involving intentional release of GMOs, and 26 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.

On 28 and 29 April 2015 OGTR hosted the 6th National Institutional Biosafety Committee Forum in Canberra, engaging with regulated organisations on current issues in GMO regulation.

The Gene Technology Amendment Bill 2015 was introduced to the House of Representatives on 18 June 2015 and referred to the Senate Community Affairs Legislation Committee for inquiry on 25 June 2015.

Yours sincerely

Robyn Cleland
Acting Gene Technology Regulator

15 September 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 April to 30 June 2015 quarter were:

Licences and other instruments

- 1 licence 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
- 26 physical containment facilities certified
- 38 instruments surrendered
- 67 certifications, 1 DIR licence and 10 DNIR licences varied.

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

Monitoring and Compliance

Approximately 23 per cent of current field trial sites and seven 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 sought advice from State and Territory governments on matters relevant to preparing two RARMPs, as well as comment on three 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 two RARMPs, as well as comment on three RARMPs.

During the quarter the OGTR and the Department of Agriculture initiated a joint project to explore opportunities to harmonise by better aligning requirements for containment facilities.

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. Three 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 April to 30 June 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*
Accreditation	2	5
DIR licence	1	1
DNIR licence	1	2
Certifications	19	26

**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 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 139	DIR 137	DIR 137	DIR 132	DIR 133
	DIR 138	DIR 138	DIR 135	
			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 one application for a DIR licence in the quarter**:**

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

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 two commercial 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 137 - GM Influenza (AstraZeneca Pty Ltd) Commercial supply of attenuated GM influenza vaccines
- DIR 138 - GM Canola (Bayer CropScience Pty Ltd) Commercial release of canola genetically modified for dual herbicide tolerance and a hybrid breeding system

Consultation 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 for the following applications:

- DIR 137 - GM Influenza (AstraZeneca Pty Ltd) Commercial supply of attenuated GM influenza vaccines
- DIR 138 - GM Canola (Bayer CropScience Pty Ltd) Commercial release of canola genetically modified for dual herbicide tolerance and a hybrid breeding system

Invitations to comment on three RARMPs 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

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

Five DIR licences were surrendered during the quarter:

- DIR 086 - GM Maize (CSIRO) Limited and controlled release of maize genetically modified to investigate gene function
- DIR 092 - GM Wheat (CSIRO) Limited and controlled release of wheat genetically modified for altered grain composition
- DIR 093 - GM Wheat and Barley (CSIRO) Limited and controlled release of wheat and barley genetically modified for altered grain starch composition
- DIR 094 - GM Wheat and Barley (CSIRO) Limited and controlled release of wheat and barley genetically modified for enhanced nutrient utilisation efficiency

- DIR 099 - GM Wheat and Barley (CSIRO) Limited and controlled release of wheat and barley genetically modified for altered grain composition or nutrient utilisation efficiency

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 not stopped on any DIR applications in this quarter.

Decisions on applications for Dealings involving Intentional Release

One DIR licence was issued during the quarter:

- DIR 133 - GM Cotton (Bayer CropScience Pty Ltd) Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance

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-555 - New studies on the virulence and physiology of *Burkholderia pseudomallei* (Griffith University)
- DNIR-556 – Factors controlling developmental transitions in the fungus *Candida albicans* (Monash University)

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	1	0
Surrender of certification	29	32
Surrender of DIR licence	0	5
Surrender of DNIR licence	1	1
Variation of accreditation	0	0
Variation of certification	117	67
Variation of DIR licence	3	1
Variation of DNIR licence	14	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 one CCI application. 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 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, 12 GM plant field trial sites under DIR licenses:

- **Current field trial sites:** Of the 30 sites current in the quarter, seven were monitored. This represents a monitoring rate of 23 per cent of all current sites for the quarter
- **Post-harvest field trial sites:** Of the 55 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 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
Nuseed Pty Ltd, Victoria	DIR 123	3	2 PHM 1 Current	Canola
Department of Economic Development, Jobs, Transport and Resources, Victoria	DIR 103 DIR 122	1 1	PHM PHM	Canola Wheat
Sugar Research Australia, Queensland	DIR 096	4	Current	Sugarcane
Queensland University of Technology, Queensland	DIR 107	2	Current	Banana

**PHM = post-harvest monitoring*

Monitoring of certified facilities:

Monitoring in connection with contained dealings covered eight organisations and 16 certified facilities. Monitoring of certified facilities encompassed seven PC2 laboratories, two PC2 animal facilities, one PC3 invertebrate facility, five PC3 laboratories, and one PC2 large scale 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
Monash University, Victoria	PC3 Invertebrate Facility	1
Macfarlane Burnet Institute of Medical Research and Public Health, Victoria	PC3 Laboratory	1
bioCSL Pty Ltd, Victoria	PC2 Large Scale Facility	1
The University of Queensland, Queensland	PC2 Laboratory	3
	PC3 Laboratory	1
	PC2 Animal Facility	1
Queensland Health Forensic and Scientific Services, Queensland	PC3 Laboratory	2
Department of Agriculture and Fisheries, Queensland	PC3 Laboratory	1
University of Tasmania, Tasmania	PC2 Laboratory	2
	PC2 Animal Facility	1
CSIRO, Tasmania	PC2 Laboratory	2
Total		**16**

Monitoring of contained dealings: During the quarter, the monitoring of the 16 certified facilities mentioned above included monitoring three DNIRs for compliance with licence conditions. Joint inspections with the Department of Agriculture were conducted at the University of Queensland as part of an ongoing pilot program of harmonisation of inspection activities between the two agencies.

Monitoring of Dealings Not involving Intentional Release

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

Licensed Organisation Name	Licence Number
The University of Queensland, Queensland	DNIR 518, 472 and 439
Total	3

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 one non-compliance. There was also one non-compliance issue identified for DIRs in the previous quarter that was finalised in this quarter.

Organisation	DuPont Pioneer
Licence number and site	DIR 114 Site 10 (Post-harvest phase)
Summary of GMO dealing	The purpose of the release is to evaluate the agronomic performance of GM canola modified for herbicide tolerance under field conditions.
Findings	DuPont Pioneer self-reported an incident which involved planting a commercial variety of canola over the planting area and monitoring zone at DIR 114 site 10 while the site was in the post-harvest phase. Canola is not permitted as a crop for planting post-harvest in the Planting Area or Monitoring zone under DIR 114. The farmer planted canola in paddocks surrounding the trial site as permitted under DIR 114, however at the same time planted the crop in the unapproved areas. DuPont Pioneer had previously provided training in the requirements of DIR licence 114 to the farmer. Once aware of the incident, DuPont Pioneer notified the OGTR that canola had been inadvertently planted at the post-harvest site, and sought advice on their proposed management strategies to bring the trial site back into compliance. They proposed a herbicide management strategy to destroy the incorrectly planted canola and will continue to provide monthly post-harvest monitoring reports to the OGTR.

Organisation	DuPont Pioneer
Assessment	The OGTR's Risk Assessment and Risk Management Plan (RARMP) for the DIR 114 licence application considered appropriate control measures to restrict the spread and persistence of the GM canola plants and their genetic material. These control measures included monitoring of the field trial sites and post-harvest control of volunteers. The licence prohibits certain post-harvest crops (e.g. canola) that may impede the licence holder's ability to detect GMO canola volunteers. In response to the incident, a herbicide strategy was implemented to destroy the incorrectly planted canola. The OGTR has not identified any additional risks associated with this non-compliance which had not been previously considered in the DIR 114 RARMP. There is a negligible risk posed to the health and safety of people and the environment by this non-compliance.
Compliance management	The post-harvest planting of canola in the monitoring zone is not considered to significantly impact the licence holder's ongoing ability to manage the site because any regrowth can be controlled. Suitable voluntary steps were taken by DuPont Pioneer, in consultation with the OGTR, to address the non-compliance including updated procedures and increased frequency of reminder training to raise farmer awareness and understanding of DIR114 licence conditions. DuPont Pioneer has been reminded of post-harvest crop restrictions under the licence and that persons covered under the licence must be fully aware of all their obligations.

Organisation	Monsanto Australia Limited
Licence number and site	DIR 120 Site 4 and Site 7
Summary of dealing	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance
Findings	During an unannounced monitoring inspection at Site 7, it was identified that a section of the pollen trap was delayed in development in relation to the rest of the pollen trap and planting area and that it may not flower at the same time as the GMOs and may not form a continuous barrier at least 20m wide around the planting area. The same issue was identified at Site 4 by Monsanto and confirmed during an announced monitoring inspection by the OGTR.
Assessment	Monsanto undertook mitigation strategies to minimise the potential for out-crossing to nearby commercial cotton occurring due to pollinating insects. Additionally, procedures were updated to enable the improved monitoring of pollen traps, and staff involved with DIR 120 were retrained in the requirements under the licence and Monsanto's procedures. The risks posed by these non-compliances to human health and safety or the environment are negligible.
Compliance management	Monsanto has been reminded that if the need to replant any section of the pollen trap or planting area is required, the OGTR should be contacted so the matter can be further analysed to determine if the pollen trap was suitable.

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
16	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 was 1 audit completed in the quarter.

Audit	Department of Agriculture and Food Western Australia (DAFWA)
Aim	This audit is part of the OGTR ongoing audit program and was conducted to: • trace, assess and reinforce DAFWA's compliance management arrangements; and • examine the potential for emerging compliance risks to arise from new operations on agricultural research stations.
Determination	The audit found that DAFWA has effective arrangements to meet national gene technology regulatory requirements.
Action	The OGTR proposed a number of compliance risk management techniques to be considered by DAFWA as part of ongoing development of its 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 8 April 2015.The Communiqué is at Appendix 1.

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

Gene Technology Ethics and Community Consultative Committee

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 June 2015, the appointment process for the 2014-17 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:

- Participation in the 29th meeting of the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology, 20-22 April 2015, Paris, France
- Participation in online forum on 'synthetic biology' under the UN Convention on Biological Diversity, April-June 2015
- Study visit from a regulatory official from Ghana, June – July 2015 under MOU between OGTR and International Centre for Genetic Engineering and Biotechnology.

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 also provided a presentation to the following:

- Harmonisation Workshop with Department of Agriculture, 10 April 2015
- Gene editing workshop, University of Adelaide, 14 April 2015
- 6th National IBC Forum, Canberra, 29-30 April 2015
- Regulatory Science Network meeting, Canberra, 13 May 2015
- Stakeholder visit to Tasmania, 24 June 2015

On 18 June 2015, the Government introduced the Gene Technology Amendment Bill 2015 to the House of Representatives and on 25 June the Bill was referred to the Senate Community Affairs Legislation Committee for inquiry. The Bill proposes minor and technical amendments to the *Gene Technology Act 2000*, as recommended by the 2011 independent review of the Act and agreed by the Legislative and Governance Forum on Gene Technology in the 2013

all of governments response. OGTR supported the Department of Health and the Office of Parliamentary Counsel in the preparation of the Bill. Further information about the Bill and the Senate Inquiry are available from the Australian Parliament House website:

http://www.aph.gov.au/Parliamentary_Business/Bills_LEGislation/Bills_Search_Results/Result?bId=r5489 and http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Gene_Technology

Accredited organisations and Institutional Biosafety Committee training

The 6th National Institutional Biosafety Committee Forum was held in Canberra on 29-30 April 2015 at the National Gallery of Australia. Representatives of IBCs and accredited organisations from most states and territories attended. There were 141 delegates from 77 organisations. The forum was opened by the Assistant Minister for Health, Senator the Hon Fiona Nash who has portfolio responsibility for gene technology. The keynote address was given by Professor Fiona Wood AM, Director of the Burns Service of Western Australia. A number of other guest speakers and panel members from organisations and IBCs, together with OGTR staff, contributed to an engaging and well-received program. The IBC forum provides an important opportunity for feedback and exchange of information between the IBCs and OGTR to enhance regulation of gene technology. The forum also allows IBCs to share experiences and learn from each other.

Other major topics for discussion highlighted the steps being taken by the OGTR towards regulatory harmonisation and regulatory issues relating to emerging technologies.

For the first time, the IBC Forum program included a half-day plant DIR workshop presented by OGTR staff. The workshop provided information about licence variations and what constitutes confidential commercial information (CCI) as well as discussing the proposed new DIR application form and pro formas for monitoring inspections. It was attended by approximately 40 stakeholders with an interest in releases of GM plants.

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]
April	313,641	44,087
May	365,655	47,535
June	280,956	38,911

[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:

Legislation

Gene Technology Amendment Regulations 2011

List of applications and licences for Dealings involving Intentional Release (DIR) of GMOs into the environment

Maps of Trial Sites

List of Genetically Modified Product approvals

DIR 109 – Gene Technology Regulation in Australia

Guidelines and forms for Certification of Physical Containment Facilities

What's New

Record of GMOs and GM Product Dealings

Guidelines for the Transport, Storage and Disposal of GMOs

The most popular downloaded documents were:

Risk Analysis Framework

DIR 020/2002 – Risk Assessment and Risk Management Plan

The Biology of *Saccharum spp* (Sugarcane)

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

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

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

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

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

The Biology of Hybrid Tea Rose (*Rosa* x *hybrida*)

The Biology of *Musa* L. (banana)

Internet contacts and freecall number

OGTR email address and freecall number

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

MONTH	EMAILS	OGTR 1800 NUMBER
April	98	100
May	45	60
June	41	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 227 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 144 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 336 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 180 emails during the quarter.

Total emails received by OGTR during the quarter, 887.

APPENDIX

APPENDIX 1

Gene Technology Technical Advisory Committee Communiqué 47th Meeting 8 April 2015 Canberra Communiqué

This Communiqué covers matters considered at the 47th meeting of the Gene Technology Technical Advisory Committee (8 April 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. All committee members and expert advisers hold office on a part-time basis.

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 GMOS (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 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 genetically modified (GM) carnations that have been genetically 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.

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. 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.

RESOLUTION

GTTAC advised the Regulator that:

The Regulator should consider in the RARMP:

1. the effect of any proposed treatment of the GM carnations for devitalisation or lack of propagation; and
2. the potential for people to eat the GM carnations.

2. ADVICE ON CONSULTATION RARMPS – COMMERCIAL

2.1 DIR 132 - Commercial supply of a tumour-selective genetically modified virus for cancer therapy

Amgen Australia Pty Ltd (Amgen) has applied for a licence for the commercial supply of an attenuated (reduced virulence) GM *herpes simplex* virus 1 (HSV-1), referred to as Talimogene laherparepvec, for use as a prescription medicine in the treatment of cancer. The GMO would be administered to patients by injection directly into the tumour, and has been modified by removing specific viral genes to reduce its virulence and pathogenicity. GTTAC provided advice on matters the Regulator should take into account in preparing the RARMP for this application in September 2014 and members were now being asked for advice on the RARMP prepared by Regulator.

GTTAC noted that Amgen is proposing to use the GMO as a prescription only cancer treatment for patients with suitable solid tumours. Before the GMO can be used as a therapeutic, Amgen must also obtain regulatory approval from the Therapeutic Goods Administration (TGA), which has responsibility for assessing the safety and efficacy of the GMO for therapeutic use in humans.

Key issues discussed by the committee included:

- the interface between the gene technology legislation and the *Therapeutic Goods Act 1989*
- the potential for the GMO to persist in a dormant state (latency). However GTTAC agreed that the potential for latency is significantly reduced as a result of the attenuation of the GMO. In any case, potential latency would not affect the conclusion of the RARMP that any risks to the health and safety of people or the environment from the proposed dealings are negligible.

RESOLUTION

GTTAC advised the Regulator that:

1. The committee agrees with the overall conclusions of the RARMP; and
2. The Regulator should consider clarification in the RARMP of background information and control measures regarding latency and containment of the GMO.

3. ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED

3.1 DIR 133 – Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance

Bayer CropScience Pty Ltd (Bayer) has applied for a licence to conduct a limited and controlled release of GM cotton modified for insect resistance and tolerance to the herbicides glyphosate and/or glufosinate ammonium. The field trial is proposed to take place between July 2015 and July 2021 at sites in New South Wales, Queensland and Western Australia. In the first year, up to 14 sites of up to 10 ha each would be grown, and in each of the following five years up to 20 sites of up to 30 ha. The total maximum planting area proposed is 3140 ha over the period of the trial[1].

GTTAC noted the key points in the consultation RARMP, including the conclusion that this field trial poses negligible risks to human health and safety and the environment. GTTAC discussed the draft licence conditions including that they permit Bayer to sell lint from GM cotton (cotton lint is used in textiles and clothing), but that no GM plant material from the trial is permitted to be used in human food or animal feed.

The committee also discussed the large scale of the proposed trial and referred to the operational policy document being prepared by the OGTR to clarify the criteria for considering a GM plant licence to be limited and controlled (see Section 4 under 'Other Advice' below).

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[1] The final DIR 133 licence issued to Bayer permits a maximum planting area of 120 hectares per year in the first two years and 600 hectares per year in the following four years, which is smaller than initially proposed by the applicant and considered by GTTAC.

RESOLUTION

GTTAC advised the Regulator that:

1. The committee agrees with the overall conclusions of the RARMP; and
2. The Regulator should consider clarification in the RARMP of:
   a. the potential for spread and dispersal of the GMO due to extreme weather events in northern Australia
   b. the definition of a natural waterway.

3.2 DIR 135 – Limited and controlled release of sugarcane genetically modified for enhanced sugar content (The University of Queensland)

The University of Queensland has applied for a licence to conduct a limited and controlled release of GM sugarcane modified for enhanced sugar content. The field trial is proposed to take place between August 2015 and May 2020 in two locations in Queensland. The maximum area of the trial would be five hectares of field planting plus an area of 0.125 hectares for plant handling, analysis and waste storage per growing season. GM sugarcane from the trial would not be used for human food or animal feed.

GTTAC noted the key points in the consultation RARMP, including the conclusion that this field trial poses negligible risks to the health and safety of people and the environment as a result of gene technology. GTTAC discussed the draft licence conditions which require a 6 m isolation zone around the GM sugarcane, but the RARMP concluded that a guard row of non-GM sugarcane was not necessary.

RESOLUTION

GTTAC advised the Regulator that:

1. The committee agrees with the overall conclusions of the RARMP;
2. The Regulator should consider a provision that allows removal of developing flower heads that occur early on specific plants; and
3. The Regulator should consider clarifying in the RARMP:
   a. outcomes and likelihood of crosses with GM plants from other field trials
   b. the total area to be planted
   c. the description regarding restrictions on the use of the GMO in food or feed.

OTHER ADVICE

4. Limited and controlled release operational policy development

GTTAC was updated on the development of an operational policy about what constitutes a limited and controlled DIR licence application for GM plants. Section 50A, which defines the category of limited and controlled DIRs, was introduced in the 2007 amendments to the Act. Limited and controlled DIR applications (typically field trials) have a streamlined assessment process compared to 'standard' DIR applications (eg commercial release). In order to be considered a limited and controlled release, a licence application must meet specific criteria: that the principal purpose of the application is to conduct experiments, and that the applicant proposes appropriate limits and controls on the dealings with the GMO.

GTTAC discussed the policy document being developed by the OGTR to assist the Regulator to determine whether a GM plant licence application meets the criteria of a limited and controlled release. The document will consider the legislation, consistency with current practice in the OGTR, information collected from monitoring inspections, advice received on limited and controlled RARMPs and comparable policies of international gene technology regulatory agencies.

RESOLUTION

GTTAC advised the Regulator that:

1. The Regulator should take into account in the development of an operational policy on limited and controlled release applications the following:
   a. clarification of interpretation of section 50A (4)(a) of the *Gene Technology Act 2000*
   b. eliciting from applicants greater clarification of intent with regard to experimentation
   c. exploring scale as a proxy for assessing whether a given licence application qualifies as a limited and controlled release.

5. Commercial plant DIR licence application form

GTTAC considered a draft DIR licence application form for commercial or general releases of GM plants. GTTAC noted that this form complements the updated DIR licence application form for limited and controlled releases of GM plants, which was introduced in December 2013. Two draft documents were provided to GTTAC for comment: a new application form and a set of example answers. The example answers are intended to provide guidance for applicants and illustrate the kind of information used in conducting risk analysis.

RESOLUTION

GTTAC advised the Regulator that:

1. The Regulator should consider:
   a. in the example answers the reference should be to any area in Australia not just current growing areas
   b. adding other organisms to P31 – 13.4, as in 13.1 and 13.2
   c. giving opportunity for applicants to add new information or alternative interpretations in Part 14
   d. clarifying the rationale and examples for unintended changes in Part 9.11

6. New technologies

GTTAC was provided with background information relating to new technologies, including new plant breeding techniques, and the scope of Australian regulation of GMOs as determined by the legal definitions in the Act and the Regulations. The broad definitions in the Act are moderated by technical exclusions in Schedules to the Regulations. It was noted that these exclusions were drafted prior to the advent and use of these new techniques and that in light of technology developments, the clarity of the wording of some these exclusions could be improved. The presentation sought GTTAC's views on a technical review of the Regulations by the Regulator to address the clarity of regulatory coverage of organisms generated with new technologies and to ensure regulation is commensurate with risk. It was also noted that the Regulator had conducted two previous technical reviews of the Regulations. GTTAC was informed that policy approval would be required from the Commonwealth Minister responsible for gene technology, and that any amendments would also require agreement of a majority of states and territories.

RESOLUTION

GTTAC advised the Regulator that:

1. The committee supports a review of the Regulations.
2. Technical issues to consider:
   a. ability to detect the modification from some technologies may not be feasible, and differentiating changes obtained through gene technology from random events may be difficult in some cases
   b. similar technologies may produce modified organisms that differ in whether or not they are considered to be classified as GMOs
   c. focus on risk as the starting consideration to determine the need for regulatory oversight.

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 (September 2014). The committee was reminded of the upcoming 6th National Institutional Biosafety Committee Forum on 29-30 April 2015, and members of GTTAC were encouraged to attend.

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*
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
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

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