



Australian Government

Department of Health

Office of the Gene Technology Regulator

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 APRIL TO 30 JUNE 2014

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

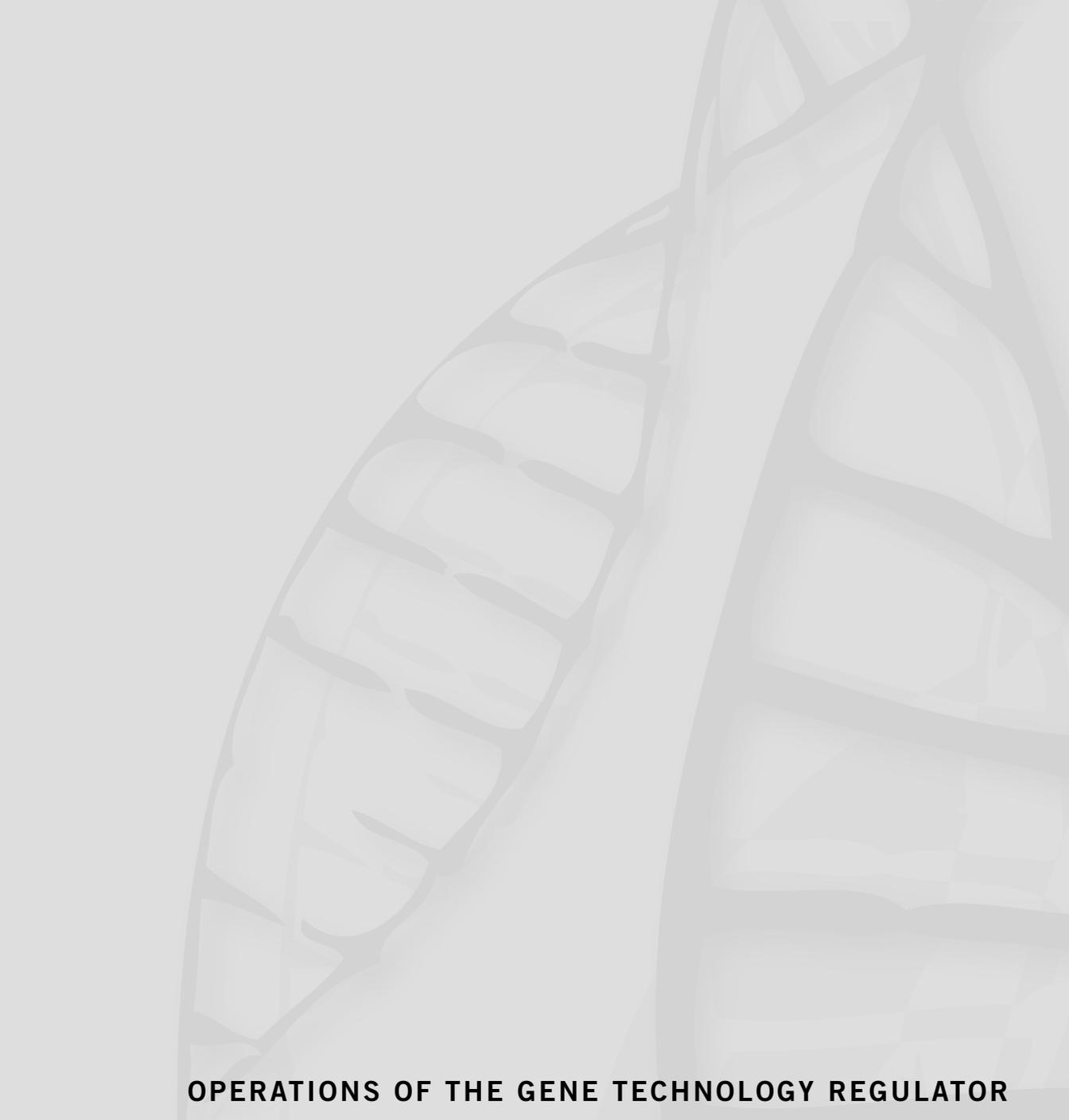
‘to protect the health and safety of people, and to protect

the environment, by identifying risks posed by or as a

result of gene technology, and by managing those risks through

regulating certain dealings with genetically

modified organisms’



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ISBN: 978-1-74186-213-3

Online ISBN: 978-1-74186-214-0

Publications approval number: 10933

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Paper-based publications

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

LETTER OF TRANSMITTAL

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

Dear Minister

In accordance with section 136A of the *Gene Technology Act 2000* (the Act), I am pleased to present to you the Quarterly Report of the Operations of the Gene Technology Regulator, covering the period 1 April to 30 June 2014.

During this period two licences were issued for dealings involving intentional release of GMOs, one licence was issued for dealings not involving intentional release of GMOs, and 63 physical containment facilities were certified.

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

Yours sincerely



Dr Robyn Cleland
Acting Gene Technology Regulator

17 September 2014

CONTENTS

LETTER OF TRANSMITTAL	III
ABOUT THIS REPORT	1
Gene technology regulatory system	1
Regulation of genetically modified organisms	1
Statutory committee operations	1
Other activities of the Gene Technology Regulator	1
SECTION 1	
NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM	4
Key achievements during this quarter	4
Licences and other instruments	4
Monitoring and Compliance	4
Working collaboratively with States and Territories	4
Legislative and Governance Forum on Gene Technology	4
State and Territory consultation	4
Australian Government Agency liaison	5
Public participation	5
SECTION 2	
REGULATION OF GENETICALLY MODIFIED ORGANISMS	8
Types of Applications	8
Dealings involving Intentional Release licences	8
Dealings Not involving Intentional Release licences	8
Accreditations of organisations	8
Certifications of containment facilities	8
GMO Register	9
New licences and other instruments	9
Processing of applications for Dealings involving Intentional Release licences	9
Applications received for Dealings involving Intentional Release licences	10
Consultation on applications and RARMPs for Dealings involving Intentional Release licences	10
Withdrawn applications and surrendered licences for Dealings involving Intentional Release licences	11
Clock stopped on Dealings involving Intentional Release licence applications	11
Decisions on applications for Dealings involving Intentional Release licences	11
Decisions on applications for Dealings Not involving Intentional Release licences	11
Changes to existing licences and other instruments	12

Emergency Dealing Determinations	12
Confidential Commercial Information	13
Monitoring and Compliance	13
Monitoring and Compliance Strategy	13
Monitoring of GMO Dealings involving Intentional Release	14
Monitoring of Dealing Not involving Intentional Release	15
Monitoring of Physical Containment Facilities	15
Monitoring Findings	16
Dealings involving Intentional Release	16
Findings for Dealings involving Intentional Release	17
Findings for Dealings Not involving Intentional Release	18
Findings for Physical Containment Facilities	19
Practice Reviews	19
Audits	19
Investigations	20
SECTION 3	
STATUTORY COMMITTEE OPERATIONS	22
Gene Technology Technical Advisory Committee	22
Gene Technology Ethics and Community Consultative Committee	22
SECTION 4	
OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR	24
International collaboration and coordination	24
OGTR website usage and statistics	24
Internet contacts and freecall number	26
OGTR email address and freecall number	26
Statutory Committee email inbox	26
Application and Licence Management email inbox	26
Contained Dealings Evaluation Section email inbox	26
APPENDIX 1:	28
Gene Technology Technical Advisory Committee Communiqué	28
GLOSSARY	

ABOUT THIS REPORT

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

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

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

This report has four key sections.

Gene technology regulatory system

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

Regulation of genetically modified organisms

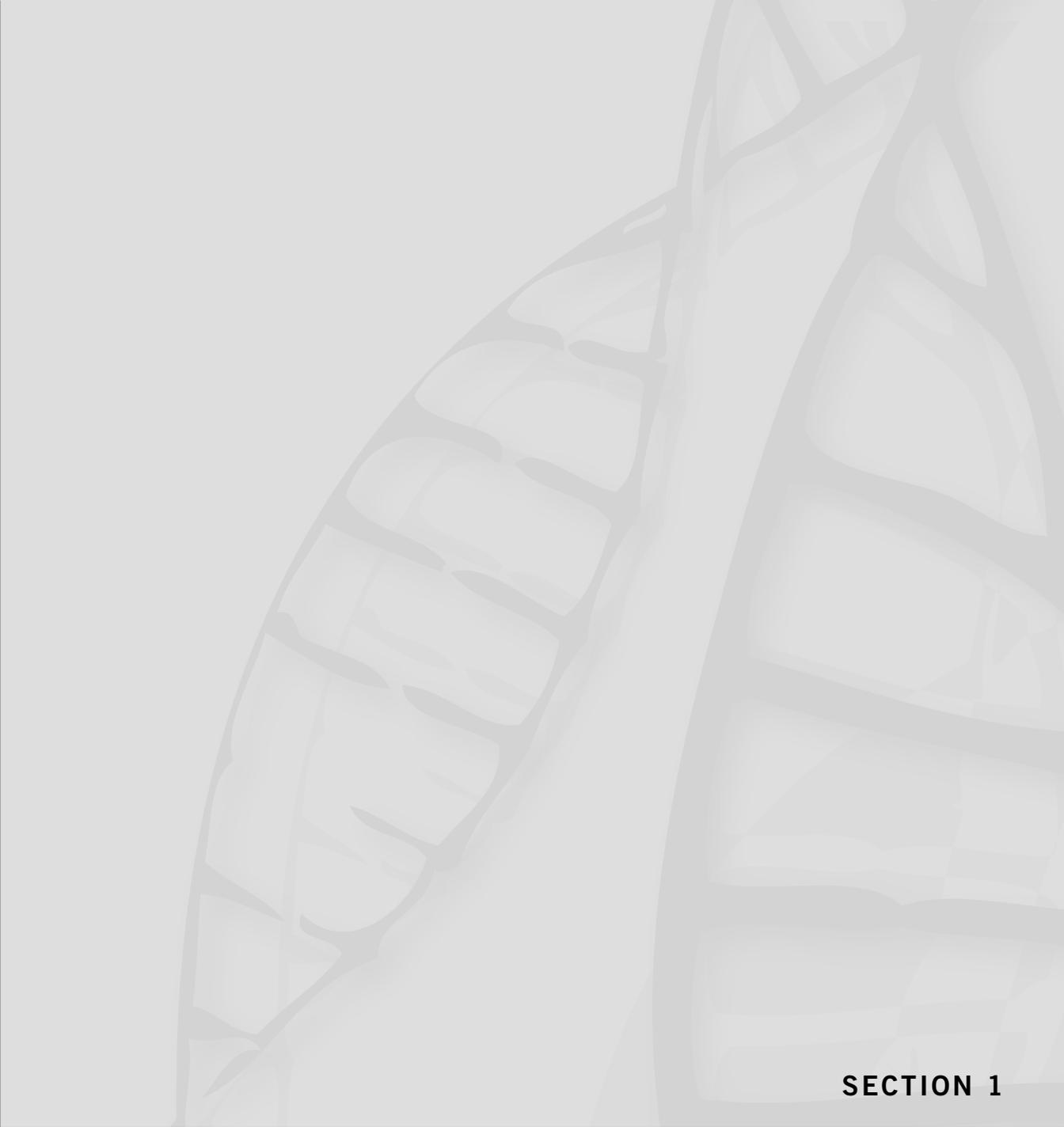
Provides details on the regulatory activity undertaken, including information about applications for, and action taken with respect to, GMO licences and other instruments under the Act. It also includes details of monitoring, auditing and compliance activities by the Regulator during this quarter.

Statutory committee operations

Reports on the activities of the two advisory committees established under the Act to assist the Regulator and the Legislative and Governance Forum on Gene Technology.

Other activities of the Gene Technology Regulator

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



SECTION 1

**NATIONAL GENE TECHNOLOGY
REGULATORY SYSTEM**



NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 April to 30 June 2014 quarter were:

Licences and other instruments

- one organisation accredited
- two licences issued for Dealings involving the Intentional Release (DIR) of GMOs into the environment
- one licence issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- 63 physical containment facilities certified
- 15 instruments surrendered
- 64 certifications, three DIR licences and 22 DNIR licences varied.

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

Monitoring and Compliance

Approximately 22 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 on one DIR RARMP.

Further information is contained in Section 2 of this report.

Australian Government Agency liaison

The close relationship between the OGTR and other Australian Government authorities and agencies continued during this quarter.

Under the Act, the Regulator must seek advice from the Australian Government Environment Minister, and prescribed Australian Government authorities and agencies, on matters relevant to preparing the RARMP for each application for a DIR licence, except those that meet the criteria to be considered as a limited and controlled release.

The prescribed Australian Government authorities and agencies 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 :

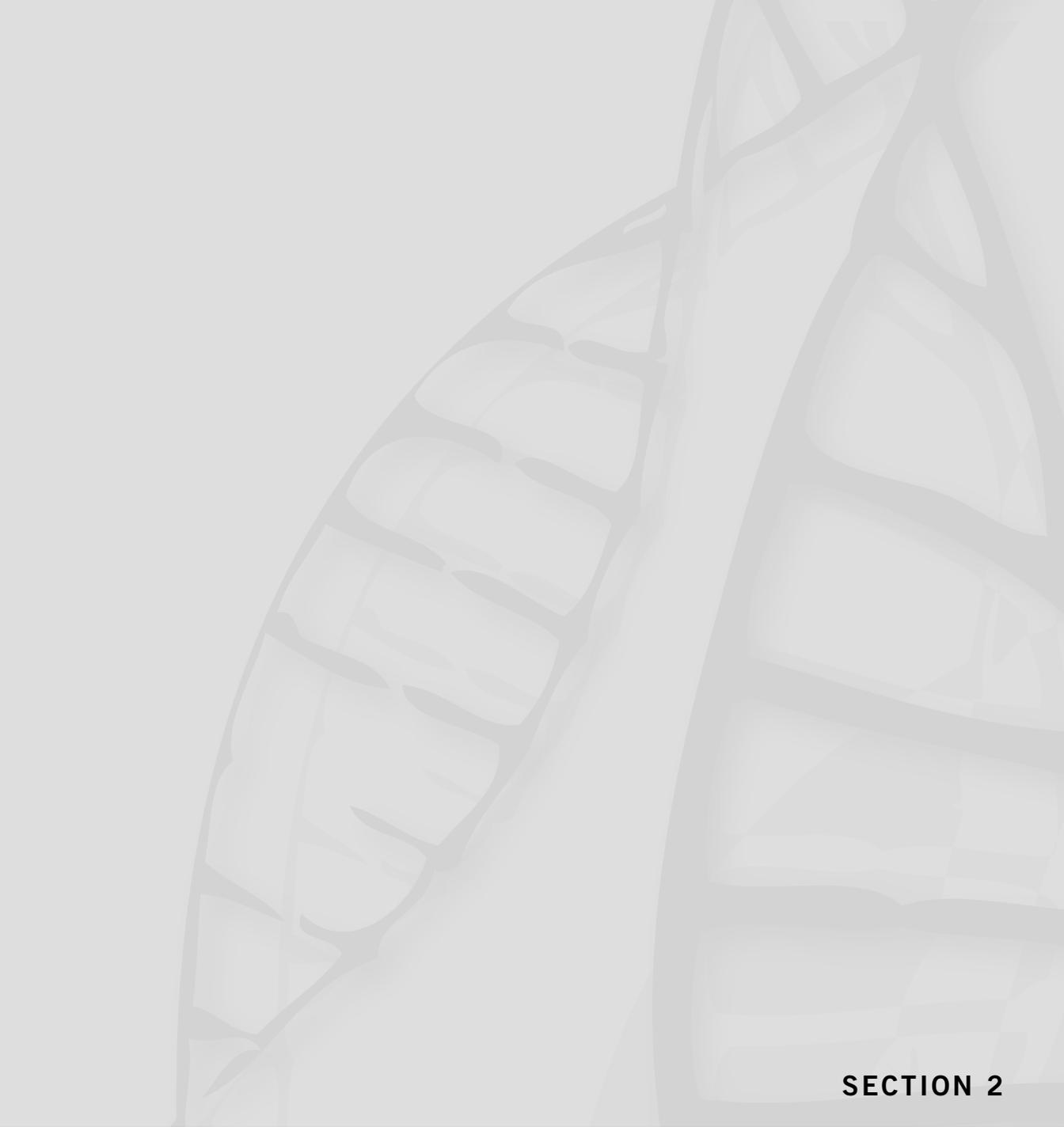
- Department of Agriculture
- Department of Environment
- Department of Foreign Affairs and Trade.

During the quarter the Regulator sought advice on one DIR RARMP. 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. One invitation to the public to comment on a RARMP was issued during the quarter.

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



SECTION 2



**REGULATION OF GENETICALLY
MODIFIED ORGANISMS**

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of the report outlines the regulatory activity undertaken during the 1 April 2014 to 30 June 2014 quarter. This includes information about applications for GMO licences and other instruments under the Act. This section details any EDDs made pursuant to the Act. It also includes details of monitoring activities and investigation of alleged, admitted or self-reported non-compliances with the Act, or with the conditions imposed by the Regulator on GMO licences or other instruments issued pursuant to the Act. Summary reports on investigations completed during the quarter are supplied. Information on Confidential Commercial Information (CCI) applications has also been provided.

Types of Applications

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

Dealings involving Intentional Release licences

DIR licences authorise dealings ranging from limited and controlled releases (e.g. field trials) through to more extensive general or commercial releases. DIR licence applications have a statutory timeframe of 255 working days for making a decision unless the Regulator determines the application is a limited and controlled release application. Then the timeframe for making a decision is 150 working days, or 170 working days if the Regulator determines that the proposed dealings represent a significant risk to human health and the environment.

Dealings Not involving Intentional Release licences

DNIR licences authorise contained dealings with GMOs carried out in laboratories and other containment facilities that are designed to prevent release of the GMO(s) into the environment. These licence applications have a statutory timeframe of 90 working days for making a decision.

Accreditations of organisations

DIR and DNIR licence conditions require organisations which conduct work with GMOs to be accredited. To achieve accreditation, the Regulator must be satisfied that the organisation has, or has access to, a properly constituted and resourced Institutional Biosafety Committee (IBC) and meets the requirements of the Regulator's guidelines for accreditation. These applications have a statutory timeframe of 90 working days for making a decision.

Certifications of containment facilities

Certification is required to satisfy the Regulator that a facility which is proposed to be used to conduct dealings with a GMO meets the guideline requirements for the particular level of physical containment specified. These applications have a statutory timeframe of 90 working days for making a decision.

GMO Register

The GMO Register is a list of dealings with GMOs that the Regulator is satisfied pose minimal risks to human health and safety and the environment and can therefore be undertaken by anyone, subject to any specified conditions, without the oversight of a licence holder. Under section 78 of the Act the Regulator may determine that dealings with a GMO previously authorised by a licence are to be included on the GMO Register. Such determinations are disallowable instruments.

New licences and other instruments

The following table describes the number and type of applications received for new licences and other instruments, as well as the approvals made by the Regulator in the quarter.

Application type	Number received	Number approved*
Accreditation	3	1
DIR licence	0	2
DNIR licence	4	1
Certifications	46	63

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

Processing of applications for Dealings involving Intentional Release licences

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

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

- confirming the applicant's suitability, including their capacity to meet licence conditions, and considering policy principles and any relevant policy guidelines issued by the LGFGT.

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

The statutory timeframes for making decisions on DIR licences effectively extend over approximately 12 months, and eight or nine months for limited and controlled releases, as they exclude weekends and public holidays observed in the Australian Capital Territory.

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

The Act and the Gene Technology Regulations 2001 (the Regulations) mandate a minimum timeframe for public consultation on the RARMP of 30 days, or 50 days if the Regulator identifies a significant risk to people or the environment from the proposed dealings. However, consultation periods longer than minimum timeframes are usually allowed to facilitate the provision of information and promote involvement in the decision-making process, particularly by the community. The following table shows the progress of applications for DIR licences undergoing evaluation during the quarter.

Applications received	Notifications of applications*	Consultation on application	Consultation on RARMP	Licences issued
	DIR 129		DIR 128	DIR 124 DIR 126

* Although not required under the Act, all new limited and controlled release DIR applications are notified on the OGTR website under 'What's New' and notified to all individuals and organisations on the OGTR mailing list

Applications received for Dealings involving Intentional Release licences

The Regulator received no applications for a DIR licence in the quarter.

Consultation on applications and RARMPs for Dealings involving Intentional Release licences

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

- DIR 129 – Limited and controlled release of sugarcane modified for herbicide tolerance – Sugar Research Australia Limited

There was no consultation on issues to consider in the preparation of a RARMP during the quarter. However, prescribed experts, agencies and authorities and the public were invited to comment on one DIR RARMP:

- DIR 128 – Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance or micronutrient uptake – The University of Adelaide

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

Withdrawn applications and surrendered licences for Dealings involving Intentional Release licences

No DIR licence applications were withdrawn or surrendered during the quarter.

Clock stopped on Dealings involving Intentional Release licence applications

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

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

Decisions on applications for Dealings involving Intentional Release licences

Two DIR licences were issued during the quarter:

- DIR 124 - Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard®III and Bollgard®III x Roundup Ready Flex®) – Monsanto Australia Limited
- DIR 126 - Clinical trial of a genetically modified vaccine against Cholera – PaxVax Australia Pty Ltd

Decisions on applications for Dealings Not involving Intentional Release licences

These dealings must be conducted in appropriate containment facilities and the dealings must not involve intentional release of a GMO into the environment.

One DNIR licence was issued during the quarter:

- DNIR-546 – Investigation of the role of glia in the control of blood pressure (Macquarie University, NSW)

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

Changes to existing licences and other instruments

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

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

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

Type	Number received	Number approved ^a
Surrender of accreditations	0	1
Surrender of certification	38	13
Surrender of DIR licence	1	0
Surrender of DNIR licence	0	1
Variation of accreditation	0	0
Variation of certification	90	64
Variation of DIR licence	2	3
Variation of DNIR licence	18	22

^a Numbers reported in this quarter often relate to applications received in previous quarters.

Emergency Dealing Determinations

During this quarter the Regulator did not receive any requests for advice in relation to the making of any Emergency Dealing Determinations (EDD) and no EDDs were in effect.

Confidential Commercial Information

Under section 184 of the Act a person may apply to the Regulator for specified information to be declared confidential commercial information (CCI) in accordance with section 185 of the Act. Specified information awaiting a decision on an application for CCI is treated as if it were CCI until a decision is made. If the Regulator declares information to be CCI the information is protected from disclosure. More information on the protection of CCI is available on the OGTR website.

During the quarter, the Regulator received two CCI applications in relation to DNIR licences and one in relation to a DIR licence. The Regulator made six CCI declarations during the quarter.

Monitoring and Compliance

The aim of OGTR monitoring and compliance activities is to ensure that dealings with GMOs comply with legislative obligations and are consistent with the object of the Act:

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

In particular, the Monitoring and Compliance Sections focus on management of dealings at field trial sites and within containment facilities certified by the Regulator to ensure:

- the dissemination of a GMO and its genetic material is restricted
- the persistence of a GMO in the environment is restricted
- the containment of GMOs for dealings not involving intentional release
- effective management of the GMO is maintained.

OGTR monitoring activities comprise the functions of routine monitoring including spot checks, assessment of monitoring findings and, where necessary, recommending corrective action and follow-up activities.

OGTR compliance activities comprise reviews of potential compliance risks, investigations, audits and related enforcement activities.

Monitoring and Compliance Strategy

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

The OGTR strategy for conducting monitoring draws on accumulated operational experience of risk profiling in relation to compliance.

For example, OGTR field trial monitoring coincides, where possible, with periods or circumstances when non-compliance with licence conditions designed to restrict the spread and persistence of the GMOs is more likely to occur (for example, during flowering and harvest of GM crops). Post-harvest monitoring continues until the site is free of volunteers.

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

The monitoring program for contained dealings involves inspecting DNIRs and the facilities that those dealings are conducted in. These inspections focus on the integrity of the physical structure of the facility and on the general laboratory practices followed in that facility, including those practices followed for DNIRs and Notifiable Low Risk Dealings (NLRD). Inspections are conducted on a minimum of 20 per cent of PC2 large-scale, PC3 and PC4 facilities per year.

Total field trial sites monitored: During the quarter, 13 GM plant field trial sites under DIR licences were subjected to monitoring visits:

- **Current field trial sites:** Of the 37 sites current in the quarter, 8 were monitored. This represents a monitoring rate of 22 per cent of all current sites for the quarter
- **Post-harvest field trial sites:** Of the 72 sites subject to post-harvest monitoring in the quarter, 5 were monitored. This represents a monitoring rate of 7 per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection with contained dealings covered 7 organisations and 16 certified facilities. Monitoring of certified facilities encompassed 8 PC2 laboratories, 3 PC2 animal facilities, 2 PC3 animal facilities, 1 PC3 laboratory and 2 PC4 laboratories.

Monitoring of contained dealings: During the quarter, the monitoring of the 16 certified facilities mentioned above included monitoring of DNIRs for compliance with licence conditions that must be followed when undertaking dealings that are required to be conducted within contained facilities.

5 DNIRs were monitored during the quarter.

Monitoring of GMO Dealings involving Intentional Release

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

Licensed Organisation Name/Location of trial site	Licence Number	No. sites visited	Site status	Crop type
Sugar Research Australia Limited, Queensland	DIR 096	7	6 Current 1 PHM	Sugarcane
Pioneer Hi-Bred Australia Pty Ltd	DIR 114	6	2 Current 4 PHM	Canola
Total		13	Current = 8 PHM* = 5	

* PHM = post harvest monitoring

Monitoring of Dealing Not involving Intentional Release

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

Licensed Organisation Name	Licence Number
Western Sydney Local Health District, New South Wales	DNIR-52 DNIR-86
The University of Melbourne, Victoria	DNIR-519
Australian Institute of Marine Science, Queensland	DNIR-491
La Trobe University, Victoria	DNIR-26
Total	5

Monitoring of Physical Containment Facilities

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

Organisation	Physical Containment (PC) facility	No. facilities visited
Western Sydney Local Health District, New South Wales	PC2 Laboratory	3
	PC3 Laboratory	1
CSIRO, Victoria	PC3 Animal Facility	1
	PC4 Laboratory	2
Garvan Institute of Medical Research, New South Wales	PC2 Laboratory	1
	PC2 Animal Facility	2
Australian Institute of Marine Science, Queensland	PC2 Laboratory	2
Curtin University of Technology, Western Australia	PC3 Animal Facility	1
La Trobe University, Victoria	PC2 Laboratory	2
	PC2 Animal Facility	1
Total		16

Monitoring Findings

Dealings involving Intentional Release

The monitoring findings listed below indicate the monitoring activities of the OGTR with respect to dealings with GMOs, in accordance with paragraph 136A(2)(c) of the Act, and the Regulator's response to those findings.

Findings by inspectors of inconsistencies between an event or state of affairs and the requirements imposed by licence or certification conditions are called non-compliances in this report. However, non-compliances are not regarded as breaches of licence conditions unless proven to be so after investigation. Non-compliances with licence conditions are assessed against a number of considerations before determining the OGTR response. The following aspects of the findings are taken into account as relevant:

- the extent of risk to the health and safety of people and the environment
- the severity of the issue or event involved in the finding
- the culpability of the licence holder or other relevant persons in bringing about the issue or event e.g. whether there was a bona fide mistake involved

- the types of mechanisms available to address the issue or event
- the compliance history of the licence holder or other relevant persons
- mitigating factors such as self-reporting or steps taken voluntarily by the licence holder to address the issue or event
- the need for deterrence.

After having regard to those matters, the OGTR has a range of options including additional investigation to determine if further action is warranted e.g. a recommendation of prosecution for an alleged breach of a licence condition or that a licence be suspended or cancelled. A proven breach of a licence condition will be reported in accordance with paragraph 136A (2)(b) of the Act.

In the case of all matters reported below it was decided that the findings of non-compliances with licence conditions were minor in nature, involved negligible or nil culpability, and could be resolved by reminders, education and/or cooperative compliance.

Findings for Dealings involving Intentional Release

There were two non-compliance issues observed for DIRs in the quarter.

Organisation	Pioneer
Licence number and site	DIR 114 Site 12 and Site 5 (Post-harvest phase)
Summary of dealings	The purpose of the release is to evaluate the agronomic performance of GM canola line under field conditions.
Findings	<p>Pioneer self-reported two incidents which involved planting a conventional variety of canola in part of the monitoring zone at DIR 114 site 12 and site 5 while the sites were in the post-harvest phase.</p> <p>Canola is not a permitted crop for planting post-harvest in the Monitoring zone under DIR 114.</p> <p>Both incidents arose from miscommunication between the licence holder and farmers.</p>
Assessment	<p>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 incidents, a herbicide strategy was implemented to destroy the incorrectly planted canola.</p> <p>There is a negligible risk posed to the health and safety of people and the environment by this non-compliance.</p>

Organisation	Pioneer
Compliance management	<p>Pioneer proposed a herbicide management strategy to destroy the incorrectly planted canola and continues to provide monthly post-harvest monitoring reports to the OGTR.</p> <p>The voluntary steps taken by Pioneer, in consultation with the OGTR, suitably address the non-compliance. In addition, Pioneer has implemented a new 'Site plan' for each site under the DIR 114 licence to increase farmer awareness and understanding of DIR114 licence conditions.</p> <p>Pioneer has been reminded of post-harvest crop restrictions under the licence and that persons covered under the licence must be fully aware of their obligations.</p>

Findings for GMO Dealings Not involving Intentional Release

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

Organisation	Australian Institute of Marine Science
Licence number	DNIR 491
Summary of dealing	This study aims to elucidate the mechanism of action of a virulence factor from the coral pathogen <i>Vibrio coralliilyticus</i> . The virulence factor, a metalloprotease, will be overexpressed in an attenuated vaccine strain of <i>V. cholerae</i> .
Findings	The licence holder did not obtain signed statements from staff, prior to commencing the dealings, indicating that they understood and agreed to be bound by licence conditions
Assessment	Although signed statements were not obtained from staff prior to the commencement of dealings, staff received appropriate training and were informed of licence conditions. The risks to human health and safety and the environment have been assessed as negligible.
Compliance management	The Australian Institute of Marine Science was reminded of the requirement to have signed statements from each person covered by the licence acknowledging that the licence holder has informed the person of the conditions of the licence, or variations to those conditions, that apply to that person before that person commences work on the dealing.

Findings for Dealings Not Involving Intentional Release

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

Findings for Physical Containment Facilities

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

It was found to pose negligible risks to human health and safety and the environment.

Number of PC Facilities inspected	Non-Compliance Issue					
	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. Their objective is to determine if licence conditions can be, and are being, effectively implemented.

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

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

There were no practice reviews completed in the quarter.

Audits

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

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

These activities are conducted to:

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

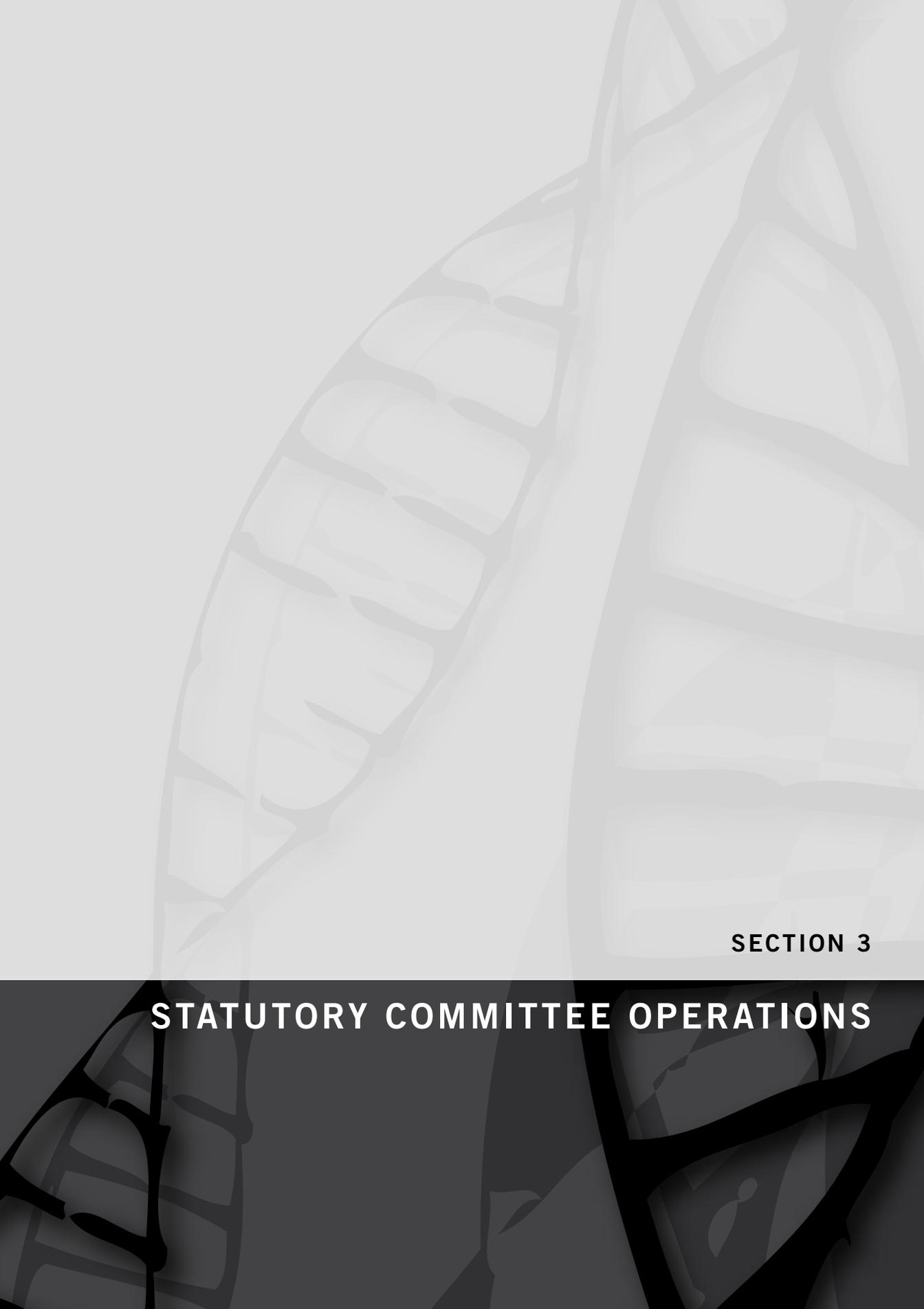
Audits are an opportunity for accredited organisations and the OGTR to share information to improve the risk management of dealings with GMOs under the Act. Audits may focus on a single dealing, a range of dealings (e.g. dealings with a common host organism or dealings within a common climatic zone),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

There were no audits completed in the quarter.

Investigations

An investigation is an inquiry into a suspected non-compliance with the Act and corresponding state laws with the aim of gathering evidence. Such investigations are not restricted to purely criminal aspects – in the wider context they may include advice on detected flaws and vulnerability in policies, practices and procedures. An investigation may be initiated: as a consequence of monitoring by the OGTR; self-reporting by an accredited organisation; or by third party reporting.

There were no investigations completed in the quarter.



SECTION 3

STATUTORY COMMITTEE OPERATIONS

STATUTORY COMMITTEE OPERATIONS

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

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

Committee appointments 2014-17

The appointment process of new members to GTECCC for the 2014 – 17 triennium is ongoing.

Gene Technology Technical Advisory Committee

The function of the GTTAC under the Act is to provide scientific and technical advice, on the request of the Regulator or LGFGT on gene technology, GMOs, GM products, applications made under the Act, the biosafety aspects of gene technology and the need for policy principles, policy guidelines, codes of practice, technical and procedural guidelines in relation to GMOs and GM products and the content of such principles and codes.

GTTAC met by videoconference on 21 May 2014. The Communiqué for this meeting is at Appendix 1.

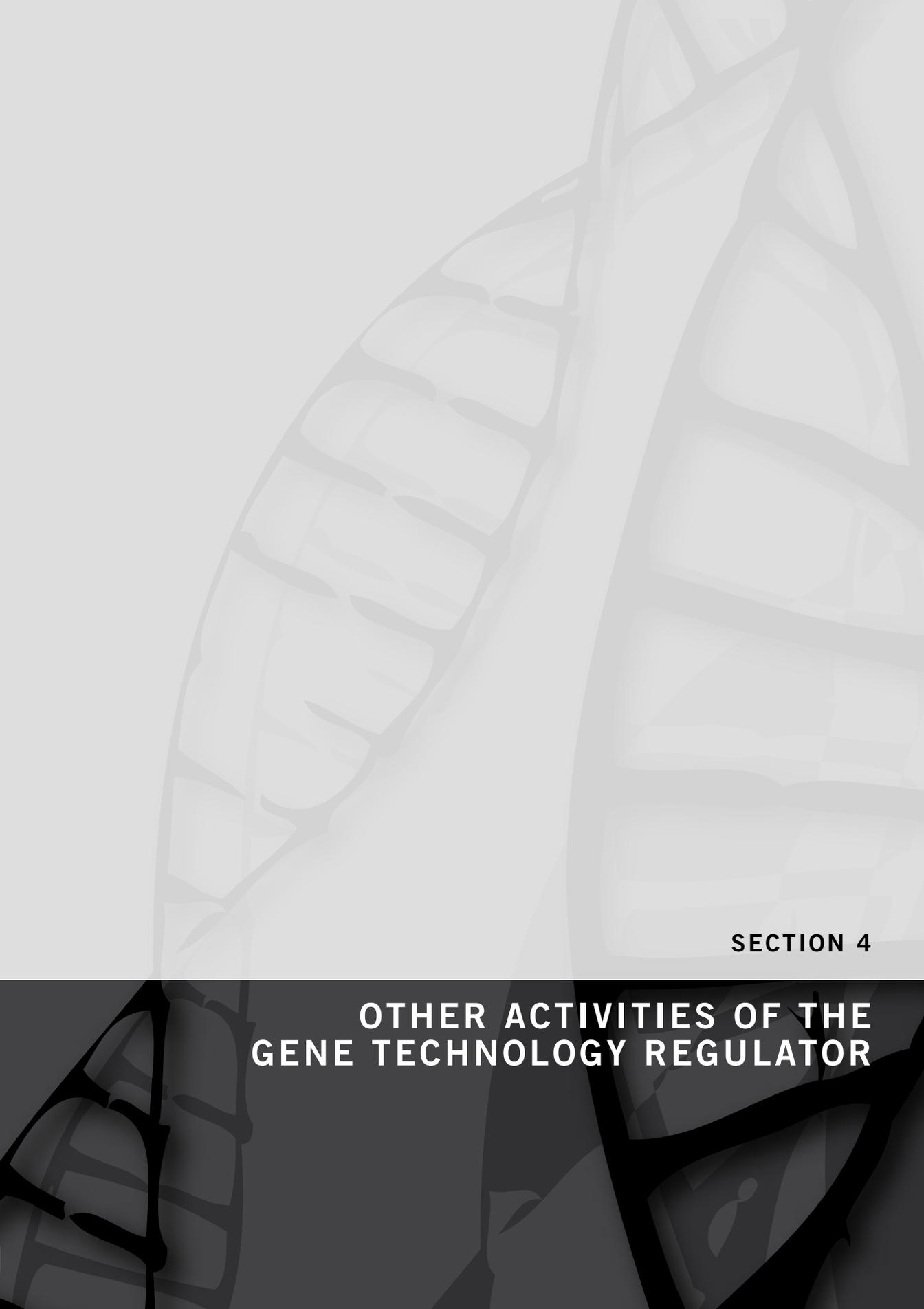
Further information about the work of GTTAC is available from the OGTR website www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gttac-2

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.

There were no GTECCC meetings in this quarter.

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



SECTION 4

**OTHER ACTIVITIES OF THE
GENE TECHNOLOGY REGULATOR**

OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

International collaboration and coordination

Under the Act the Regulator's functions include:

- monitoring international practice in relation to regulation of GMOs
- maintaining links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia
- promoting the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies.

International collaboration and coordination activities undertaken during the quarter included:

- Presentation at a European Commission workshop The Global Pipeline of GM Crops: An Outlook for 2020, Seville, Spain, June 2014 National collaboration and coordination.

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

OGTR officers also participated in the following meetings/conferences:

- CSIRO Biosecurity Futures Workshop, Canberra, May 2014.

OGTR website usage and statistics

The OGTR website is a comprehensive source of information on activities of the office. The table below provides information on the number of hits on the OGTR website and the number of visitor sessions by month during the quarter.

MONTH	HITS ¹	VISITS ²
April	301,751	54,838
May	304,748	46,199
June	310,009	41,754

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:

- DIR 126 - Clinical trial of a genetically modified vaccine against Cholera - PaxVax Australia Pty Ltd
- Maps of Trial Sites
- List of applications and licences for Dealings involving Intentional Release (DIR) of GMOs into the environment
- Guidelines and forms for Certification of Physical Containment Facilities
- Record of GMOs and GM Product Dealings
- What's New
- About the OGTR
- Fact sheets
- List of Genetically Modified Product approvals
- Guidelines

The most popular downloaded documents were:

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

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

Internet contacts and freecall number

OGTR email address and freecall number

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

MONTH	EMAILS	OGTR 1800 NUMBER
April	83	NA*
May	71	NA*
June	75	NA*

* due to change of suppliers these figures were not available for this quarter.

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 345 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 233 emails during the quarter.

Application and Licence Management email inbox

This electronic mail inbox provides a central, shared communication point to allow efficient coordination of responses for correspondence and queries about applications received by the Application and Licence Management Section. The inbox received 436 emails during the quarter.

Contained Dealings Evaluation Section email inbox

This email inbox provides a central common point for efficient coordination of responses to queries relating to classification of GMO dealings, certification requirements for higher level containment facilities and GMO licences accessed by the contained dealings evaluation section. The inbox received 111 emails during the quarter.



APPENDIX

APPENDIX 1:

Gene Technology Technical Advisory Committee Communiqué 21 May 2014 Videoconference¹ Communiqué

**This Communiqué covers matters considered at the 5th videoconference of the
Gene Technology Technical Advisory Committee (GTTAC) (21 May 2014)**

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 conduct dealings with genetically modified organisms (GMOs) and on Risk Assessment and Risk Management Plans (RARMPs) prepared in respect of applications. The purpose of this Communiqué is to provide a brief overview of GTTAC's consideration of applications and RARMPs and, in accordance with Regulation 29 of the Gene Technology Regulations 2001, any Committee resolutions given to the Regulator. The Communiqué also provides an overview of any other major issues discussed by GTTAC.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED ORGANISMS

Dealings involving the Intentional Release (DIR) of a GMO can involve the limited and controlled release (clinical trial or field trial) of a GMO 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 are not assessed 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 The videoconference was held at Department of Health facilities in Canberra, Sydney, Brisbane, Adelaide, Hobart, Melbourne and Perth.

1. ADVICE ON CONSULTATION RARMPs – LIMITED AND CONTROLLED RELEASE

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

DIR 128 – Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance or micronutrient uptake

GTTAC noted that application DIR 128 from the University of Adelaide is for a limited and controlled release of wheat and barley genetically modified (GM) for abiotic stress tolerance or micronutrient uptake. The applicant proposes to trial up to 1262 lines of GM wheat and barley between June 2014 and December 2019 in South Australia and Western Australia on a maximum total area of 2.5 hectares per year. The purpose of the trial is to evaluate candidate genes for improving yield potential under field conditions.

GTTAC noted the key points in the consultation RARMP including the conclusions that this release poses negligible risks to the health and safety of people and the environment. GTTAC also noted that the draft licence conditions are similar to those for previous GM wheat and barley trials. The licence would impose stringent controls during the trial and extensive monitoring and management post-harvest to ensure the GMOs do not persist after the trial.

Key points discussed by the committee:

- The large number of lines in the application in the context of the proposed limits and controls;
- Uncertainty about the function of some of the introduced genes and their potential effect on traits of the GMOs, and the need to address this uncertainty for future large scale or commercial releases;
- The low likelihood that GM seed or pollen could leave a trial site and result in any harm.

RESOLUTION:

GTTAC advised the Regulator that:

1. The committee agrees with the overall conclusions of the RARMP and the proposed limits and controls;
2. The Regulator should consider further acknowledging uncertainty regarding potential for the introduced genes for abiotic stress tolerance and micronutrient uptake to result in increased survival of the GMOs or increases in toxicity or allergenicity, including in the summary table [Table 5];
3. The committee notes that this application involves a large number of lines, and suggests the Regulator consider the upper limits of what qualifies as a limited and controlled release;
4. The Regulator should consider seeking information on the results of the trial to inform future applications for release of any of these GM lines, with respect to the potential risks to human health and the environment;
5. The Regulator should consider clarifying the text in RARMP regarding other government approvals;
6. The committee commends Table 5 as a useful device to summarise causal pathways.

2. ADVICE ON CONSULTATION RARMPS – COMMERCIAL RELEASE

GTTAC considered the consultation RARMP prepared for the following commercial release application:

DIR 124 – Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard®III and Bollgard®III x Roundup Ready Flex®)

DIR 124 is an application from Monsanto Australia Ltd for the commercial release two types of GM cotton: Bollgard® III cotton, which contains three genes that confer insect resistance (*cry1Ac*, *cry2Ab* and *vip3A*); and Bollgard® III x Roundup Ready Flex® cotton, which contains the same three insect resistance genes and also two copies of the cp4 epsps gene that confers herbicide tolerance. GTTAC noted that they had previously provided advice on matters relevant to the preparation of the RARMP and that they were now being asked for advice on the consultation RARMP prepared by the Regulator.

GTTAC noted that the GMOs were produced by conventional breeding between other GM cottons; two approved for commercial release (Bollgard® II and Roundup Ready Flex® cottons) and a third that has been grown in Australian field trials (VIP3A cotton). If approved, the GM cottons and cotton-derived products would enter general commerce, including use in human food and animal feed. GTTAC noted that Food Standards Australia New Zealand has approved the use of material from these GM cottons in food. The GM cottons would also be subject to regulation by the Australian Pesticides and Veterinary Medicines Authority as an agricultural chemical product due to their production of insecticidal substances.

GTTAC advised the Regulator that:

RESOLUTIONS:

1. The committee agrees with the overall conclusions of the RARMP;
2. The committee agrees that the RARMP identifies all plausible risk scenarios by which the proposed release could give rise to risks to human health and safety or the environment;
3. The Regulator should further consider the potential for interaction between the introduced Cry and Vip proteins;
4. The Regulator should consider clarifying the wording in the RARMP regarding Vip3A specificity and conclusions about potential toxicity;
5. The Regulator should consider clarifying the description in the RARMP of weed management practices undertaken by Councils on roadsides.

ENQUIRIES AND RISK ASSESSMENT AND RISK MANAGEMENT PLANS

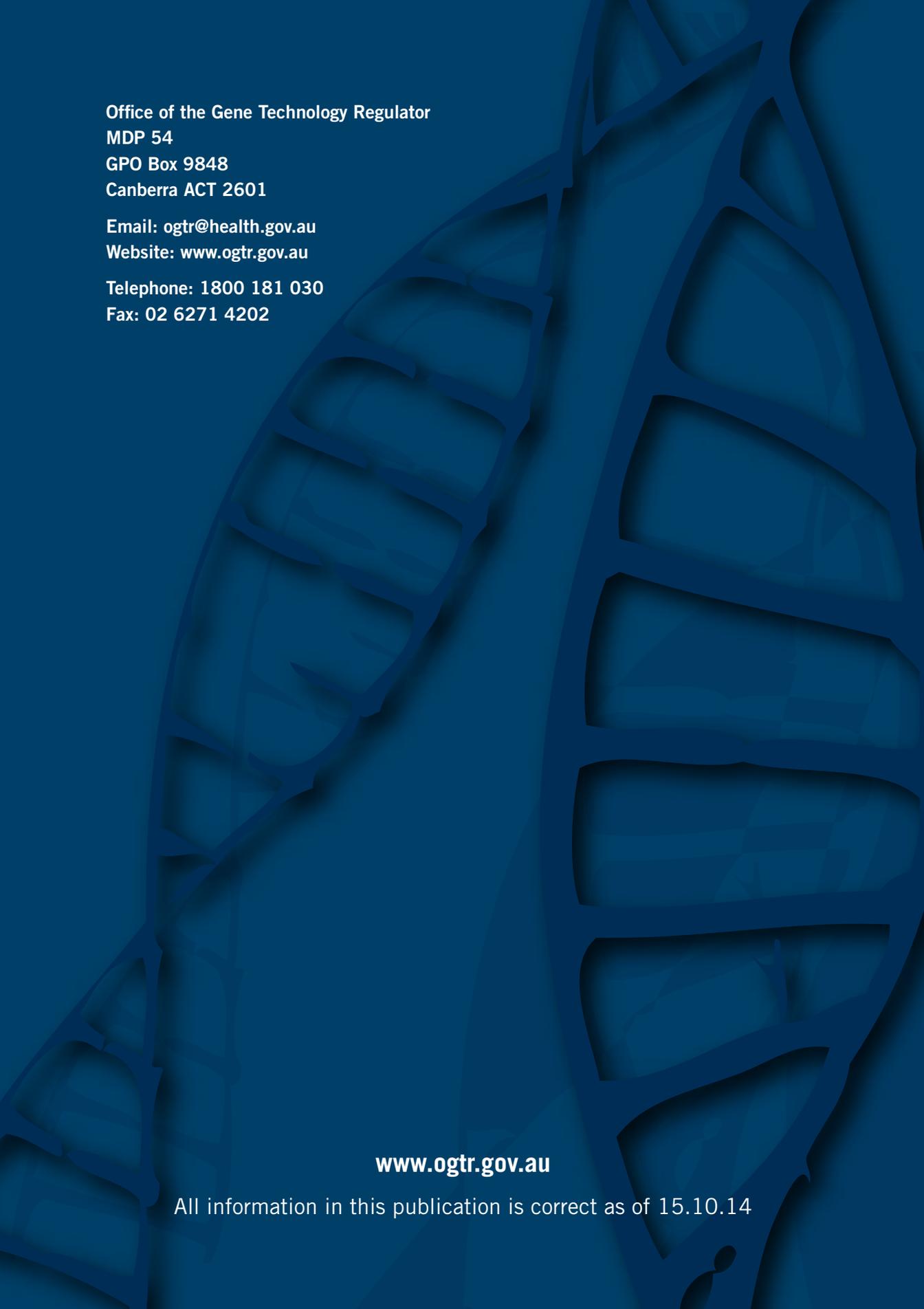
For all enquiries and to obtain copies of applications or RARMPs for dealings involving the intentional release of GMOs into the environment, please phone the OGTR on 1800 181 030. RARMPs are also available electronically from our website at <<http://www.ogtr.gov.au>>.

GLOSSARY

This section contains a brief description of terms relevant to an understanding of this quarterly report. They do not substitute for definitions of terms relevant to the operation of the gene technology regulatory system that are contained in section 10 of the *Gene Technology Act 2000*.

Accredited organisation Act	An organisation that is accredited under section 92 of the Act <i>Gene Technology Act 2000</i>
APVMA	Australian Pesticides and Veterinary Medicines Authority
Breach of a licence condition	A breach of a licence condition which has been proven either in court or by way of admission following investigation
CCI	Confidential commercial information
Certified facility	A building or place certified by the Regulator to a specified containment level under section 84 of the Act
Clock stop	The period during which days are not counted for purposes of the statutory time limit for making a decision – usually because evaluation cannot proceed until additional information requested from the applicant is received
CSIRO	Commonwealth Scientific and Industrial Research Organisation
Current	In relation to a field trial location (planted under a DIR Licence) refers to a location that has been planted with a GMO and has not yet been harvested.
DIR	A dealing involving intentional release of a GMO into the environment (e.g., field trial or commercial release)
DNIR	A contained dealing with a GMO not involving intentional release of the GMO into the environment (e.g. experiments in a certified facility such as a laboratory)
Expert advisers	Advisers appointed by the Minister to give expert advice to either GTTAC or GTECCC to assist them in the performance of their functions (expert advisers are not committee members)
EDD	Emergency Dealing Determination
FSANZ	Food Standards Australia New Zealand
GM	Genetically modified
GM product	A thing (other than a GMO) derived or produced from a GMO
GMO	Genetically modified organism
GTECCC	Gene Technology Ethics and Community Consultative Committee

GTMC	Gene Technology Ministerial Council
GTSC	Gene Technology Standing Committee
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
Incident	A self-reported event which may constitute a non-compliance with regulatory requirements and a public health or environment risk
LGFGT	Legislative and Governance Forum on Gene Technology
Limited and controlled release	A type of DIR which meets certain criteria relating to limiting and controlling the dealings with the GMO (e.g. a field trial)
NLRD	Notifiable low risk dealing (work with transgenic plants, animals or microorganisms undertaken in certified containment facilities)
Non-compliance	An inconsistency between an event or state of affairs and the requirements imposed by licence accreditation or certification conditions, or any of the requirements of the Act or Regulations
OGTR	Office of the Gene Technology Regulator
PC1, PC2, PC3, PC4	Physical containment levels of facilities as certified by the Regulator
PHM	In relation to a field trial location (planted under a DIR Licence) refers to a location that has been harvested but is still subject to regular monitoring by the licence holder
RARMP	Risk assessment and risk management plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator
Spot checks	Unannounced visits by the OGTR Monitoring or Compliance Sections
Volunteer	Regrowth of plants or other plant parts e.g. sugarcane that has remained on a site after a trial has been completed



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All information in this publication is correct as of 15.10.14