Australian Government

Department of Health

Office of the Gene Technology Regulator

# OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

# QUARTERLY REPORT

## 1 JANUARY–31 MARCH 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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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 MP
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 January to 31 March 2014.

During this period no licences were issued for dealings involving intentional release of GMOs, three licences were issued for dealings not involving intentional release of GMOs, and 30 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

9 July 2014

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# ABOUT THIS REPORT

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

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

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

This report has four key sections.

**Gene technology regulatory system**

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

**Regulation of genetically modified organisms**

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

**Statutory committee operations**

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

**Other activities of the Gene Technology Regulator**

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

SECTION 1

# NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

# NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

## Key achievements during this quarter

The key achievements of the 1 January to 31 March 2014 quarter were:

**Licences and other instruments**

- no organisations accredited
- no licences issued for Dealings involving the Intentional Release (DIR) of GMOs into the environment
- three licences issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- 30 physical containment facilities certified
- 26 instruments surrendered
- 70 certifications, four DIR licences and 20 DNIR licences varied.

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

**Monitoring and Compliance**

Approximately 10 per cent of current field trial sites and 11 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 matters relevant to preparing RARMPs for two DIR 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 comprise:

- Australian Pesticides and Veterinary Medicines Authority
- Department of Agriculture, Biosecurity
- Food Standards Australia New Zealand
- National Industrial Chemicals Notification and Assessment Scheme
- Therapeutic Goods Administration.

Once a RARMP is prepared for any DIR licence application, the Regulator is required to seek comment on the RARMP from the same prescribed Australian Government authorities and agencies.

In addition, comment is sought on each DIR RARMP from a range of other Australian Government agencies that are not prescribed in the 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 matters relevant to preparing RARMPs for two DIR RARMPs. Further information on the processing of DIR applications is contained in Section 2 of this report.

## Public participation

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

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

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 January 2014 to 31 March 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 | 0 | 0 |
| DIR licence | 1 | 0 |
| DNIR licence | 1 | 3 |
| Certifications | 56 | 30 |

* *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 127 | DIR 124<br>DIR 126 | Nil |

* *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 one application for a DIR licence in the quarter:

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

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

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 application:

- DIR 127 – Commercial release of canola genetically modified for herbicide tolerance – Monsanto Australia Limited.

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

There were two invitations to comment on a RARMP 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 Aus Pty Ltd.

For DIR 126 as result of social media interest the Regulator tweeted calls for submission on the RARMP using the Department of Health Twitter handle every alternate week during the six weeks consultation period to enhance wider circulation of information and consultation with a broader cross section of the community.

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.

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

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

**Decisions on applications for Dealings involving Intentional Release licences**

No DIR licences were issued during the quarter.

Information on DIR applications, finalised RARMPs, licences issued and copies of licences are available from the OGTR website or can be obtained by contacting the OGTR directly.

## Decisions on applications for Dealings Not involving Intentional Release licences

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

Three DNIR licences were issued during the quarter:

- DNIR 539 – Development and use of a banana streak virus-based virus vector to investigate banana-Fusarium interactions – Queensland University of Technology
- DNIR 542 – The molecular determinants of pathogenicity, tissue tropism and transmissibility of influenza A virus – CSIRO
- DNIR 543 – HIV Biology of Latency and Assembly – University of New South Wales.

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

## Changes to existing licences and other instruments

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

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

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

| Type | Number received | Number approved[a] |
|---|---|---|
| Surrender of accreditations | 1 | 0 |
| Surrender of certification | 29 | 24 |
| Surrender of DIR licence | 0 | 0 |
| Surrender of DNIR licence | 2 | 2 |
| Variation of accreditation | 0 | 0 |
| Variation of certification | 73 | 70 |
| Variation of DIR licence | 5 | 4 |
| Variation of DNIR licence | 16 | 20 |

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

- **Current field trial sites:** Of the 49 sites current in the quarter, five were monitored. This represents a monitoring rate of 10 per cent of all current sites for the quarter.
- **Post-harvest field trial sites:** Of the 61 sites subject to post-harvest monitoring in the quarter, seven were monitored. This represents a monitoring rate of 11 per cent of all sites subject to post-harvest monitoring in this quarter.

**Monitoring of certified facilities:** Monitoring in connection with contained dealings covered four organisations and seven certified facilities. Monitoring of certified facilities encompassed four PC2 laboratories, two PC3 laboratories and one PC2 large scale facility.

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

Five DNIRs were monitored during the quarter.

**Monitoring of GMO Dealings involving Intentional Release**

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

| Licensed Organisation Name/Location of trial site | Licence Number | No. sites visited | Site status | Crop type |
|---|---|---|---|---|
| Monsanto Australia Limited, New South Wales | DIR 101 | 1 | PHM | Cotton |
| Bayer CropScience Pty Ltd, New South Wales | DIR 113 | 2 | Current | Cotton |
| CSIRO, Australian Capital Territory | DIR 092 | 1 | PHM | Wheat |
| | DIR 093 | 1 | PHM | Wheat and Barley |
| | DIR 094 | 1 | PHM | Wheat and Barley |
| | DIR 111 | 4 | 2 PHM<br>2 Current | Wheat and Barley |
| | DIR 121 | 1 | Current | Safflower |
| Monsanto Australia Limited, Queensland | DIR 101 | 1 | PHM | Cotton |
| **Total** | | **12** | **Current = 5<br>PHM* = 7** | |

* *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 |
|---|---|
| The University of Melbourne, Victoria | DNIR519 |
| | DNIR520 |
| Macfarlane Burnet Institute for Medical Research and Public Health, Victoria | DNIR328 |
| | DNIR524 |
| Zoetis Australia Research & Manufacturing Pty Ltd, Victoria | DNIR528 |
| **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 |
|---|---|---|
| The University of Melbourne, Victoria | PC2 Laboratory | 1 |
| Macfarlane Burnet Institute for Medical Research and Public Health, Victoria | PC2 Laboratory | 1 |
| | PC3 Laboratory | 1 |
| Zoetis Australia Research & Manufacturing Pty Ltd, Victoria | PC2 Laboratory | 1 |
| | PC2 Large Scale | 1 |
| Defence Science and Technology Organisation – Melbourne, Victoria | PC3 Laboratory | 1 |
| University of Wollongong | PC2 Laboratory | 1 |
| **Total** | | **7** |

## 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 | CSIRO |
|---|---|
| Licence number | DIR111 Site 1a |
| Summary of GMO dealings | Limited and controlled release of wheat and barley genetically modified for altered grain composition, nutrient utilisation efficiency, disease resistance or stress tolerance |
| Findings | At the time of inspection six volunteer wheat plants that had grown past flowering stage were growing on the site. The licence requires that all volunteer plants are destroyed prior to flowering. |
| Assessment | CSIRO staff were aware of the requirement to destroy these plants and had conducted routine schedules inspections as required, including an additional inspection three weeks prior to OGTR inspection. The mature plants were approximately 30 cm high, had a single stem and a single head, consistent with the plants germinating and quickly maturing due to stressful agronomic circumstances. At the time of the inspection all plants were hand rogued and destroyed immediately. No other mature wheat/barley or similar species plants were within the location or isolation zone during the period in which the volunteer plants were likely to have been flowering. Therefore the likelihood of gene flow from the volunteer plants is extremely low. The risks to human health and safety and the environment have been assessed as negligible. |
| Compliance management | The CSIRO was reminded of the requirement to destroy volunteer wheat/barley plants prior to them flowering. |

| Organisation | Monsanto Australia |
|---|---|
| Licence number and site | DIR101 Site 14 |
| Summary of GMO dealings | The purpose of the trial is to generate data for future submissions to regulatory agencies, to breed and develop varieties using elite germplasm suitable for use under Australian conditions, and for seed increase. |
| Findings | Monsanto self-reported the occurrence of approximately 80 flowering cotton volunteers on the post-harvest trial site. Upon finding, all plants were hand rogued and destroyed immediately. Volunteers on a post-harvest trial site must be destroyed prior to flowering in accordance with licence condition 58 of DIR101. |

| Organisation | Monsanto Australia |
|---|---|
| Assessment | Outcrossing of GM volunteers to commercial cotton crops is highly unlikely as cotton is a self-pollinating crop. There is a negligible risk posed to human health and safety and the environment by this non-compliance. |
| Compliance management | Monsanto attributed this incident to miscommunication between the landholder and Monsanto staff overseeing the site resulting in failure to follow-up the previously planned site cultivation. Monsanto has since implemented additional measures to avoid similar occurrence such as fortnightly calls to each site compliance manager to confirm that any required control actions have been implemented. |

**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.

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

| | Non-Compliance Issue | | | | | |
|---|---|---|---|---|---|---|
| Number of PC Facilities inspected | Structure | PPE[1] | Equipment | Waste disposal | Work practices[2] | Transport |
| 5 | - | - | 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 3 audits completed in the quarter.

| Audit | Austin health |
|---|---|
| Aim | This audit is part of the OGTR ongoing audit program and was conducted to:<br>• trace, assess and reinforce Austin Health compliance management arrangements for meeting compliance obligations under the Act;<br>• promote an internal audit framework for assessing and managing compliance risks;<br>• provide compliance risk education and communication to Austin Health Institutional Biosafety Committee (IBC) and compliance / risk management personnel and decision makers;<br>• recognise and take best practice principles from current Austin Health compliance risk management arrangements; and<br>• include Austin Health as a party to ongoing Practice Reviews. |

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

| Audit | Murdoch University, Western Australia |
|---|---|
| Aim | This audit is part of the OGTR ongoing audit program and was conducted to:<br>• trace, assess and reinforce Murdoch University's compliance management arrangements for meeting compliance obligations under the Act;<br>• promote an internal audit framework for risk assessment and management of compliance risks to Murdoch University's Institutional Biosafety Committee (IBC) and compliance risk management personnel and decision makers; and<br>• include Murdoch University as a party to ongoing Practice Reviews. |
| Determination | The audit found that;<br>• there were no non-compliances or breaches evident; and<br>• Murdoch University has effective arrangements to meet national gene technology regulatory requirements. |
| Action | The audit team proposed a number of compliance risk management techniques to be considered as part of ongoing Murdoch University development of their compliance arrangements. The audit promoted:<br>• the benefits of internal risk management and auditing in compliance and containment arrangements; and<br>• organisational arrangements to link risk management and internal auditing expertise with scientific and biosafety expertise. |

| Audit | University of Queensland (UQ) |
|---|---|
| Aim | This audit is part of the OGTR ongoing audit program and was conducted to:<br>• trace, assess and reinforce UQ compliance management arrangements as they relate to meeting compliance obligations under the Act;<br>• promote an internal audit framework for assessing and managing compliance risks;<br>• provide compliance risk education and communication to UQ Institutional Biosafety Committee (IBC) and compliance / risk management personnel and decision makers;<br>• recognise and take best practice principles from any current UQ compliance risk management arrangements; and<br>• include UQ as a party to ongoing CIS Practice Reviews. |
| Determination | The audit found that:<br>• there were no non-compliances or breaches evident; and<br>• UQ has efficient tailored arrangements to meet national gene technology regulatory requirements. |
| Action | The audit team proposed a number of compliance performance risk management techniques to be considered as part of ongoing UQ improvement and in any internal auditing of compliance. The audit promoted:<br>• the benefits of internal risk management and auditing in organisational compliance and containment arrangements; and<br>• organisational arrangements to link and deploy risk management and internal auditing expertise with scientific and biosafety expertise. |

## Investigations

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

There were no investigations completed in the quarter.

SECTION 3

# STATUTORY COMMITTEE OPERATIONS

## STATUTORY COMMITTEE OPERATIONS

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

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

**Committee appointments 2014-17**

Appointments to GTTAC for February 2014- January 2017 were made on 8 December 2013, by the Assistant Minister for Health, Senator the Hon Fiona Nash. 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 face-to-face on 20 February 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:

- Technical Consultation on Low Levels of Genetically Modified Crops in International Food and Feed Trade, UN Food and Agriculture Organisation, March 2014, Rome, Italy
- 28th meeting of the Organisation for Economic Co-operation and Development (OECD) Working Group on the Harmonisation of Regulatory Oversight in Biotechnology, February 2014, Paris, France
- OECD Focus Session on Biotechnology during 51st Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, February 2014, Paris, France
- OECD Workshop on Environmental Risk Assessment of Products Derived from Novel Plant Breeding Techniques, February 2014, Paris, France
- Workshop on Genetic Basis of Unintended Effects in Modified Plants, Canadian Food Inspection Agency, January 2014, Ottawa, Canada.

## National collaboration and coordination

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

The OGTR provided a presentation to the following:

- Presented at the Regulatory Science Network meeting, February 2014, Canberra
- Presentation to Therapeutic Goods Administration, March 2014, Canberra.

OGTR officers also participated in the following meetings/conferences:

- CropLife meeting - LLP, AHTEG, Review response, February 2014, Canberra

- 45th GTTAC meeting, February 2014
- Canberra Biological Weapons Convention & Chemical Weapons Convention IDC – Department of Foreign Affairs and Trade, March 2014, Canberra

## OGTR website usage and statistics

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

| MONTH | HITS[1] | VISITS[2] |
|---|---|---|
| January | 309,920 | 42,465 |
| February | 302,530 | 40,179 |
| March | 355,648 | 52,266 |

[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:

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

The most popular downloaded documents were:

- *Risk Analysis Framework*
- The Biology of *Saccharum spp* (Sugarcane)
- The Biology of *Carica papaya* L. (Papaya, pawpaw, paw paw)
- The Biology of *Ananas comosus* var. *comosus* (Pineapple)
- PC2 Laboratory guidelines
- The Biology of *Zea mays* L. ssp *mays* (maize or corn)
- The Biology and Ecology of Rice (*Oryza sativa* L.) in Australia
- The Biology of *Gossypium hirsutum* L. and *Gossypium barbadeuse* L. (Cotton)
- The Biology of *Trifolium repens* L. (White Clover)
- DIR 126 - Receipt of licence application (DIR 126) from PaxVax Australia Pty Ltd for a clinical trial of a GM cholera vaccine

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 |
|---|---|---|
| January | 88 | NA* |
| February | 92 | NA* |
| March | 171 | 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 169 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 324 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 596 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 61 emails during the quarter.

# APPENDIX

# APPENDIX 1:

## Gene Technology Technical Advisory Committee Communiqué 45th Meeting 20 February 2014, Canberra Communiqué

**This Communiqué covers matters considered at the 45th meeting of the Gene Technology Technical Advisory Committee (GTTAC)**

GTTAC is a statutory advisory committee established under the *Gene Technology Act 2000* (the Act) to provide scientific and technical advice to the Gene Technology Regulator (the Regulator) and the ministerial Legislative and Governance Forum on Gene Technology. All Committee members and expert advisers hold office on a part-time basis.

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

### DEALINGS INVOLVING THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED ORGANISMS

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

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

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

## 1. ADVICE ON LICENCE RARMP – LIMITED AND CONTROLLED RELEASE

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

**DIR 126 RARMP - Clinical trial of a genetically modified vaccine against Cholera (PaxVax Australia Pty Ltd)**

PaxVax Australia Pty Ltd (PaxVax) has applied for a licence for a clinical trial in Australia of a genetically modified (GM) vaccine against Cholera. 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 addressed.

GTTAC noted that the proposed trial would involve the inoculation of volunteers via oral ingestion of the GMOs. GTTAC also noted that, in addition to a licence from the Regulator, PaxVax would need to meet the Therapeutic Goods Administration (TGA) requirements for the clinical trial. The same vaccine strain was previously approved by the Regulator and the TGA and marketed in Australia, but that manufacturer ceased production of the vaccine in 2004 for commercial reasons. No adverse risks to health were previously reported in relation to the vaccine.

GTTAC noted that this application had attracted significant comment in social media, largely as a result of misunderstandings about the trial. The OGTR's actions in response to this included providing updated information on the OGTR website to correct the misinformation.

GTTAC agreed that the GM vaccine poses a low risk of transmission; however GTTAC advised that the RARMP could include more detail on management of potential transmission to young children. GTTAC also suggested that co-vaccination, particularly with the typhoid vaccine, should be considered in the RARMP.

Additional key points discussed by the Committee:

- there would be negligible risk of reversion of the vaccine strain to wild type during clinical trials
- preparation and batch testing method proposed by PaxVax was adequate

**RESOLUTION:**

GTTAC advised the Regulator that:

- GTTAC agrees with the overall conclusion of the RARMP [that the risks to the health and safety of people or the environment from the proposed trial are negligible]
- The Regulator should further consider potential exposure of contacts under two years of age
- The Regulator should further consider other possible exclusions relating to other vaccinations

**2. ADVICE ON LICENCE APPLICATION – COMMERCIAL RELEASE**

GTTAC considered the following commercial release application:

**DIR 127 - Commercial release of canola genetically modified for herbicide tolerance (Monsanto Australia Pty Ltd)**

Monsanto Australia Pty Ltd has applied for a licence for the commercial release of GM herbicide tolerant canola variety MON 88302 in Australia. GTTAC was provided an agenda paper that outlined key issues for consideration in the risk assessment, and was asked for advice on any other key issues that should be addressed in the preparation of the RARMP.

GTTAC suggested that the RARMP should make it clear that the applicant is seeking approval to grow the GM canola in any part of Australia, although not all areas are currently suited to growing canola, in particular the northern parts of the country.

GTTAC discussed the potential increase in the use of glyphosate on the GM crop and possible resulting impacts on the environment. In particular, GTTAC discussed the potential increase in selective pressure for development of herbicide tolerant weeds. GTTAC suggested the RARMP could include consideration of these issues, but noted that the Australian Pesticides and Veterinary Medicines Authority has regulatory responsibility for herbicide use and resistance management.

Additional key points discussed by the Committee:

- the potential for gene flow to other canola, including other commercially approved GM canola and non-GM herbicide tolerant canola
- the potential allergenicity and toxicity of the GM canola

**RESOLUTION:**

GTTAC advised the Regulator that, when preparing the RARMP, in addition to the issues outlined in the agenda paper, the Regulator should consider:

- Clarifying whether the assessment will consider growing of the GM canola in canola growing areas or all of Australia
- Potential for development of herbicide resistant weeds and related environmental impacts

**REPORTS/UPDATES**

The Committee was updated on the progress towards implementation of the recommendations from the 2011 review of the Act. GTTAC received a report from the Regulator that provided updates on activities undertaken by the Regulator and the OGTR since the previous face-to-face GTTAC meeting (18 December 2013). GTTAC members offered best wishes to the Regulator, Dr Joe Smith, who retired on 21 March 2014. The Chair thanked the Dr Smith for his contributions to the regulatory scheme and noted that the Australian regulatory system for gene technology is highly regarded by international stakeholders.

**ENQUIRIES AND RISK ASSESSMENT AND RISK MANAGEMENT PLANS**

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

## GLOSSARY

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

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

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