Australian Government

Department of Health

Office of the Gene Technology Regulator

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 APRIL–30 JUNE 2013

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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The Hon Peter Dutton MP
Minister for Health
Minister for Sport
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 2013.

During this period one licence for dealings involving intentional release of GMOs was issued, five licences for dealings not involving intentional release of GMOs were issued and 26 physical containment facilities were certified.

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

This quarter saw the OGTR host the 5th National Institutional Biosafety Committee Forum in Canberra. The Forum provided a valuable opportunity for OGTR officers to meet with representatives from many of our accredited organisations to exchange information, receive feedback and provide updated information on regulatory issues.

The fifth version of the Risk Analysis Framework, a key strategic document for the OGTR, was also officially launched at the forum.

Yours sincerely

Dr Joe Smith

Gene Technology Regulator

26 September 2013

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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 April to 30 June 2013 quarter were:

Licences and other instruments

- two organisations issued with accreditation
- one licence issued for Dealings involving the Intentional Release (DIR) of GMOs into the environment
- five licences issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- 26 physical containment facilities certified
- 36 instruments surrendered
- variation of 219 certifications, six DIR licences and 18 DNIR licences.

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

Monitoring and Compliance

Approximately 11 per cent of current field trial sites and eight 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 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) (formerly the Gene Technology Ministerial Council) 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.

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, Fisheries and Forestry 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 which, while not prescribed in the legislation, have maintained a strong interest in its implementation including the:

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

During the quarter the Regulator sought advice in respect of three 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. Three invitations to the public to comment on RARMPs 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 April to 30 June 2013 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 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 of GMOs. DIR licence applications have a statutory timeframe of 255 working days for processing 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

It is a condition of DIR and DNIR licences that the organisation holding the licence is 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 complies with the requirements of the Regulator's guidelines for accreditation. These applications have a statutory timeframe of 90 working days for making a decision.

Certifications of containment facilities

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

GMO Register

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

New licences and other instruments

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

Application type	Number received	Number approved*
Accreditation	2	2
DIR licence	2	1
DNIR licence	3	5
Certifications	43	26

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

Processing of applications for Dealings involving Intentional Release licences

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

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

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 twelve 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	Notification of applications*	Consultation on RARMP	Licences issued
DIR 122 DIR 123	DIR 122 DIR 123	DIR 118 DIR 120 DIR 121	DIR 119

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

- DIR 122—Limited and controlled release of wheat genetically modified for enhanced yield stability—Department of Primary Industries and Environment (Victoria)
- DIR 123—Limited and controlled release of canola genetically modified for altered oil content—Nuseed Pty Ltd.

Consultation on applications for Dealings involving Intentional Release licences

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

- DIR 122—Limited and controlled release of wheat genetically modified for enhanced yield stability—Department of Primary Industries and Environment (Victoria)
- DIR 123—Limited and controlled release of canola genetically modified for altered oil content—Nuseed Pty Ltd

There were three invitations to comment on RARMPs issued during the quarter:

- DIR 118—Commercial release of herbicide tolerant (Roundup Ready Flex® MON 88913) pima cotton in Australia—Monsanto Australia Limited
- DIR 120—Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance—Monsanto Australia Limited
- DIR 121—Limited and controlled release of safflower genetically modified for increased levels of oleic acid—CSIRO.

Full copies of DIR applications can be obtained by contacting the OGTR. Summary information on DIR applications and full consultation 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 during the quarter.

No DIR licence was 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 any DIR applications were initiated in this quarter.

Decisions on applications for Dealings involving Intentional Release licences

One DIR licence was issued during the quarter:

- DIR 119—Limited and controlled release of narrow-leafed lupin genetically modified for herbicide tolerance—The University of Western Australia.

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.

Five DNIR licences were issued during the quarter:

- DNIR 523—A clinical trial to treat Hemophilia B using AAV-based gene therapy—Royal Prince Alfred Hospital
- DNIR 525—The role of gut-resident T cells in protecting against enteric Listeria infection—The University of Melbourne
- DNIR 527—Influenza A virus PB1-F2 protein: A virulence factor and initiator of inflammation—The University of Melbourne
- DNIR 528—Evaluation of a cytolysin expressed in Corynebacterium glutamicum—Zoetis Australia Research & Manufacturing Pty Ltd
- DNIR 529—Recombinant Viral Vaccines to Treat and Prevent Cancer, Allergy and Infectious Diseases—University of South Australia.

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 application, 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	4	3
Surrender of certification	58	32
Surrender of DIR licence	0	0
Surrender of DNIR licence	2	1
Variation of accreditation	160[b]	159
Variation of certification	198	219
Variation of DIR licence	9	6
Variation of DNIR licence	20	18

[a] *Numbers reported in this quarter often relate to applications received in previous quarters.*

[b] *159 of these were initiated by the Regulator in order to apply, to all accredited organisations, the conditions of accreditation of the revised Guidelines for the Accreditation of Organisations—Version 2.2—effective 31 August 2012.*

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 in accordance with section 185 for specified information to be declared confidential commercial information (CCI). 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 seven CCI applications in relation to DIR applications and one in relation to a DNIR application. The Regulator made no CCI declarations in 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.

The Monitoring Section conducts routine monitoring visits of a minimum of 20 per cent of field trial sites 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. In addition inspections are conducted on a minimum of 20 per cent of PC2 large-scale, PC3 and PC4 facilities per year.

Monitoring and Compliance Strategy

The purpose of routine inspections is to ensure compliance with licence conditions and includes 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).

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).

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

- **Current field trial sites:** Of the 27 sites current in the quarter, three were monitored. This represents a monitoring rate of 11 per cent of all current sites for the quarter.
- **Post-harvest field trial sites:** Of the 60 sites subject to post-harvest monitoring in the quarter, five were monitored. This represents a monitoring rate of eight per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection with contained dealings covered three organisations and six certified facilities. Monitoring of certified facilities encompassed three PC2 laboratories and three PC2 animal facilities.

Monitoring of contained dealings: During the quarter, the monitoring of the 6 certified facilities mentioned above included monitoring for compliance with the general practices that must be followed when undertaking dealings (e.g. DNIRs) that are required to be conducted within contained facilities.

Four DNIRs were monitored during the quarter.

Monitoring of Dealings involving Intentional Releases

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
CSIRO, Australian Capital Territory	DIR 111	2	PHM	Wheat and Barley
CSIRO, Western Australia	DIR 099	1	PHM	Wheat and Barley
	DIR 112	1	PHM	Wheat and Barley
Monsanto Australia Limited, New South Wales	DIR 101	3	Current	Cotton
Monsanto Australia Limited, Queensland	DIR 101	1	PHM	Cotton
Total		**8**	**Current = 3 PHM* = 5**	

* *PHM = post-harvest monitoring.*

Monitoring of Dealing Not involving Intentional Releases

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

Licensed Organisation Name	Licence Number
Peter MacCallum Cancer Centre, Victoria	DNIRs 110 and 384
Telethon Institute for Child Health Research, Western Australia	DNIR 482
The University of Western Australia, Western Australia	DNIR 415
Total	**4**

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
Peter MacCallum Cancer Centre, Victoria	PC2 laboratory	2
	PC2 animal facility	2
Telethon Institute for Child Health Research, Western Australia	PC2 laboratory	1
	PC2 animal facility	1
Total		**6**

Monitoring Findings

Dealings involving Intentional Release

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

Findings by inspectors of inconsistencies between an event or state of affairs and the requirements imposed by licence or certification conditions are called non-compliances in this report. However, non-compliances are not regarded as breaches of licence conditions unless proven to be so after investigation. Non-compliances with licence conditions are assessed

against a number of considerations before determining the OGTR response. The following aspects of the findings are taken into account as relevant:

- the extent of risk to the health and safety of people and the environment
- the severity of the issue or event involved in the finding
- the culpability of the licence holder or other relevant persons in bringing about the issue or event e.g. whether there was a bona fide mistake involved
- the types of mechanisms available to address the issue or event
- the compliance history of the licence holder or other relevant persons
- mitigating factors such as self-reporting or steps taken voluntarily by the licence holder to address the issue or event
- the need for deterrence.

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

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

Findings for Dealings involving Intentional Release

There were no non-compliances during the quarter.

Findings for Dealings Not involving Intentional Release

There was one non-compliance issue observed for a DNIR that was finalised in the quarter.

Organisation	Telethon Institute for Child Health Research
Licence number(s)	DNIR 482
Summary of dealing	The purpose of this dealing is to use Australian Leishmania as a tool to identify genes involved in pathogenesis of human Leishmania species.
Findings	At the time of inspection, the licence holder had not obtained signed statements from autoclave staff responsible for destruction of GMOs indicating that they understood and agreed to be bound by licence conditions or variations to those conditions.
Assessment	Although signed statements were not obtained from autoclave staff undertaking dealings, the autoclave staff had received appropriate training in destruction of GMOs. The risks to human health and safety and the environment have been assessed as negligible.
Compliance management	The Telethon Institute for Child Health Research 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 Physical Containment Facilities

The OGTR's monitoring of certified PC facilities in the quarter found no non-compliances with certification conditions in relation to work practices and structure.

	Non-Compliance Issue					
Number of PC Facilities inspected	Structure	PPE[1]	Equipment	Waste disposal	Work practices[2]	Transport
6	0	0	0	0	0	0

[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 management actions to be implemented. 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
- Gene Technology Ethics and Community Consultative Committee.

Call for nominations 2014–17

Current memberships of the Gene Technology Technical Advisory Committee (GTTAC) and Gene Technology Ethics and Community Consultative Committee (GTECCC) will expire on 31 January 2014. A public call for nominations for members to GTTAC and GTECCC for the 2014–17 opened on 22 February and closed on 28 March 2013. The selection and appointment process 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 the LGFGT on gene technology, GMOs, GM products, applications made under the Act, the biosafety aspects of gene technology and the need for policy principles, policy guidelines, codes of practice, technical and procedural guidelines in relation to GMOs and GM products and the content of such principles and codes.

GTTAC met once during the quarter on 11 June 2013. The communiqué for this meeting and the videoconference held on 21 March 2013 are at Appendix 1 and 2.

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.

GTECCC met once during the quarter on 24 May 2013. The Communiqué for this meeting and the meeting held by videconference on 24 January 2013 are at Appendix 3 and 4.

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 and national 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:

- 27th Meeting of the Organisation for Economic Co-operation and Development (OECD) Working Group for Harmonization of Regulatory Oversight in Biotechnology, April, Paris, France
- Asia Pacific Economic Cooperation Workshop: Regulatory Issues on Emerging Agricultural Technologies, June, Medan, Indonesia
- On-line discussions of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management under the UN Cartagena Protocol on Biosafety, June.

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:

- International Life Sciences Institute workshop on New Plant Breeding Technologies, June, Canberra
- Department of Finance & Deregulation—Regulators' Community of Practice Forum, June, Canberra.

OGTR officers also participated in the following meetings/conferences:

- CropLife Regulators Roundtable meeting, April, Canberra
- Opening of the Victoria Department of Primary Industries Centre for AgriBioscience, Melbourne, April, Melbourne
- Regulators Forum meeting April, Canberra
- Regulatory Science Network meetings, April, June, Canberra

- Workshop on Weed Risk Assessment in the context of Climate Change, April, Sydney
- 8th Australasian Gene Therapy Society meeting, May, Sydney
- Sugarcane Consultative Committee meeting, May, Brisbane
- Australian Agricultural Innovation Systems at the Crossroads Conference, May, Canberra.

Revision of the Risk Analysis Framework

During the quarter the OGTR finalised its review of the *Risk Analysis Framework* (RAF) with the publication of the revised version as a printed document and on the OGTR website.

The RAF is a key document for OGTR, setting out the approach to assessing and managing risks from GMOs. The revision has significantly updated the section of risk communication.

The main changes in this version are:

- major updating to the chapter on risk communication
- better aligning the approach to risk analysis with the Australian Standard/ New Zealand Standard ISO 31000:2009, *Risk Management—Principles and guidelines*
- incorporating recent amendments to legislation and regulatory practices
- clarifying the criteria for harm used in the assessment of consequences
- clarifying how uncertainty is addressed in risk analysis.

Accredited organisations and Institutional Biosafety Committee training

The fifth National Institutional Biosafety Committee Forum (IBC) was held in Canberra on 12 and 13 June 2013 at the National Gallery of Australia. Representatives of organisations and IBCs from all States and Territories except the Northern Territory and Tasmania attended with 166 delegates from 76 organisations.

The Forum was opened by the Parliamentary Secretary, who also launched the Regulator's revised Risk Analysis Framework. The keynote address was given by the Chief Scientist, Professor Ian Chubb, which was followed by the Regulator's presentation on "OGTR Directions".

A number of other guest speakers and panel members from organisations and IBCs, together with OGTR staff, contributed to the program.

The Forum prompted much discussion and facilitated the exchange of information between regulated organisations and the OGTR. It also provided an arena to discuss the activities that will be undertaken by the Department of Health following the announcement in the 2013–14 Budget to evaluate cost recovery for OGTR.

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]
April	283,807	35,311
May	289,502	35,733
June	291,249	34,133

[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:

- What's New
- 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
- List of Genetically Modified Product approvals
- About the OGTR
- Record of GMOs and GM Product Dealings
- Guidelines/Forms
- What are Notifiable Low Risk Dealings (NLRDs)?
- List of International Release Licence Applications under Evaluation

The most popular downloaded documents were:

- *Risk Analysis Framework*
- The Biology of *Carica papaya* L. (Papaya, pawpaw, paw paw)
- The Biology of *Saccharum spp* (Sugarcane)
- The Biology and Ecology of Rice (*Oryza sativa* L.) in Australia
- The Biology of *Ananas comosus* var. *comosus* (Pineapple)
- The Biology of *Gossypium hirsutum* L. and *Gossypium barbadense* L. (Cotton)

- The Biology of Hybrid Tea Rose (*Rosa x hybrida*)
- The Biology of *Zea mays* L. ssp *mays* (maize or corn)
- The Biology of *Triticum aestivum* L. em Thell. (Wheat)
- The Biology of *Musa* L. (banana)

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	91	110
May	238	92
June	202	125

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 155 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 373 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 981 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 66 emails during the quarter.

APPENDICES

APPENDIX 1:

Gene Technology Technical Advisory Committee Communiqué —Meeting 11 June 2013, Canberra ACT

This communiqué covers matters considered at the 43rd meeting of the Gene Technology Technical Advisory Committee (GTTAC) 11 June 2013

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 any other major issues discussed by GTTAC.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED ORGANISMS

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

The Regulator must seek GTTAC advice on RARMPs prepared in respect of 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 comment as part of the consultation process. Information on how to obtain copies of applications and RARMPs for DIR applications is provided at the end of this document.

1. ADVICE ON CONSULTATION RARMP—COMMERCIAL RELEASE

GTTAC considered the consultation RARMP prepared in response to the following commercial release application:

1.1 DIR 118—Commercial release of herbicide tolerant (Roundup Ready Flex® MON 88913) pima cotton in Australia

DIR 118 is an application from Monsanto Australia Ltd for the commercial release of herbicide tolerant (Roundup Ready Flex® MON 88913) GM pima cotton in Australia. GTTAC noted that they had previously provided advice on matters relevant to the preparation of the RARMP for licence application DIR 118, and that they were now being asked to provide advice on the RARMP prepared by the Regulator.

GTTAC noted that the GM pima cotton (*Gossypium barbadense*) proposed for release was produced using conventional breeding to transfer the genetic modification from approved Roundup Ready Flex® G. hirsutum cotton to non-GM pima cotton. GTTAC also noted that GM cotton and GM cotton-derived products from Roundup Ready Flex® pima cotton would enter general commerce, including use in human food and animal feed.

GTTAC discussed the RARMP prepared for DIR 118 and noted that the risk assessment concludes that this release poses negligible risks to the health and safety of people and to the environment. Key points that were discussed by GTTAC included:

- the similarity between *G. barbadense* and *G. hirsutum* and the application of data from one species to the other
- that the herbicide tolerance trait would not affect the weediness of the GM pima cotton in the absence of the herbicide.

RESOLUTION:

GTTAC advised the Regulator that:

1. the Committee agrees with the overall conclusions of the RARMP
2. the risk assessment identifies all relevant risk scenarios
3. there is no additional relevant information that should be considered.

2. ADVICE ON CONSULTATION RARMPS—LIMITED AND CONTROLLED RELEASE

GTTAC considered the consultation RARMPs prepared in response to the following limited and controlled release applications:

2.1 DIR 120—Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance

GTTAC noted that application DIR 120 from Monsanto Australia is for a limited and controlled release of GM cotton modified for insect resistance and herbicide tolerance. The trial is proposed to take place between October 2013 and October 2019, on up to ten sites per year at 10 ha/site for the first two years of the trial and up to 20 sites per year at 30 ha/site thereafter. Sites will be selected from 56 local government areas in Western Australia, NSW and Queensland.

The primary purpose of the trial is to assess the agronomic performance of the GM cottons under Australian field conditions and generate data for possible future commercial release. The GM cotton would not be permitted for use in human food or animal feed.

GTTAC noted the key points in the consultation RARMP including that the risk assessment concludes that this release poses negligible risks to the health and safety of people and to the environment. GTTAC also noted that the draft licence conditions are similar to those used for other recent GM cotton licences with the exception of the proposed isolation zone, which has been reduced from 3km to 1.5km on the basis of recent literature on gene flow.

Key points that were discussed by GTTAC included:

- Issues that may need further consideration in the risk assessment for an application for commercial release of these GM cotton lines, including potential effects on non-target invertebrate species and the implication of multiple herbicide tolerance traits for control of volunteers.

RESOLUTION:

GTTAC advised the Regulator that:

1. the Committee agrees with the overall conclusions of the RARMP
2. the risk assessment identifies all relevant risk scenarios
3. there is no additional relevant information that should be considered.

2.2 DIR 121—Limited and controlled release of safflower genetically modified for increased levels of oleic acid

GTTAC noted that application DIR 121 from CSIRO is for a limited and controlled release of GM safflower modified for increased levels of oleic acid, and that this is the first application for release of GM safflower in Australia.

The trial is proposed to take place over three growing seasons between September 2013 and March 2016. The GM safflower would be grown only in the ACT in the first season, and in the ACT, in Wagga Wagga in NSW, and near Narrabri in NSW in the second and third seasons. A maximum area of 1 hectare per season would be grown in each locality.

The primary purpose of the trial is to evaluate the agronomic performance of up to 190 lines of GM safflower under field conditions. The GM safflower would not be permitted for use in human food or animal feed.

GTTAC noted the key points in the consultation RARMP including that the risk assessment concludes that this release poses negligible risks to the health and safety of people and to the environment. GTTAC also noted the draft licence conditions, some of which are novel because this is the first licence application for a limited and controlled release of GM safflower.

Key points that were discussed by GTTAC included:

- the likelihood of seed dispersal by birds, and the potential consequence if it occurred, in the context of the scale of the proposed release and the draft licence conditions;
- the limits and controls for the trial, including the basis for the distance of the proposed exclusion zone; and
- the potential ambiguity of the wording in the RARMP arising from the fact that the marker genes express a protein although the silencing construct does not.

RESOLUTION:

GTTAC advised the Regulator that:

1. the Committee agrees with the overall conclusions of the RARMP
2. the Regulator should further consider measures to limit dispersal
3. the Regulator should consider clarifying the potential for the silencing construct to produce a protein.

OTHER ADVICE

Double stranded RNA (dsRNA) techniques

GTTAC considered recent publications related to dsRNA mediated gene silencing, including Zhang et al 2011[1] and Heinemann et al 2013[2] (referred to as the Environment International paper) and discussed the risk assessment by the Office of the Gene Technology Regulator (OGTR) of GM crops developed using these techniques.

GTTAC noted that Food Standards Australia New Zealand (FSANZ) had published a comprehensive response[3] to the Environment International paper, which concluded that the weight of scientific evidence published to date does not support the view that small dsRNAs in foods are likely to have adverse consequences for humans. GTTAC were advised that the OGTR had discussed the Environment International paper with FSANZ and had reached the same conclusions.

GTTAC further noted that all limited and controlled releases of GM plants developed using dsRNA techniques approved to date include licence conditions preventing the use of plant material from the trials in the human food or animal feed supply.

GTTAC were advised that the OGTR's approach to future risk assessment of crops developed using dsRNA silencing techniques is to continue to monitor the literature on this topic, and to assess licence applications on a case-by-case basis taking into account all relevant literature available at the time. GTTAC noted that the committee provides advice on the assessment of all DIR licence applications, including those involving the use of dsRNA techniques

RESOLUTION:

GTTAC advised the Regulator that:

1. the Committee agrees with the current and proposed future approach of the OGTR to the assessment of GM plants modified using gene silencing
2. the Regulator should continue to monitor and review the relevant scientific literature and include any developments in future applicable DIR risk assessments.

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1 Zhang, L., et al. "Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA." *Cell Res* 22 (2011): 107–26.

2 Heinemann, J. A., Sarah. Z. Agapito-Tenfen, and J. A. Carman. "A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments." *Environment International* 55 (2013): 43–55.

3 See http://www.foodstandards.gov.au/consumer/gmfood/Pages/Response-to-Heinemann-et-al-on-the-regulation-of-GM-crops-and-foods-developed-using-gene-silencing.aspx

REPORTS

The Committee received a report from the Regulator that provided updates on activities undertaken by the Regulator and the OGTR since the previous GTTAC meeting (19 December 2012). A report was also received from the committee's cross-member with the Gene Technology Ethics and Advisory Committee (GTECCC) on recent GTECCC activities.

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>.

APPENDIX 2:

Gene Technology Technical Advisory Committee Communiqué —Videoconferences 21 March 2013, Canberra ACT

This communiqué covers matters considered at the meetings of the Gene Technology Technical Advisory Committee (GTTAC) held by video conference on 21 March 2013

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 Legislative and Governance Forum on Gene. 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.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF GMOs (DIR)

The Regulator must seek GTTAC advice on RARMPs prepared in respect of all DIR applications.

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

A DIR may involve a limited and controlled release (field trial) or a commercial release (general) of a GMO.

1. Advice on Consultation RARMPs—Limited and Controlled Release

GTTAC considered the consultation RARMP prepared by the Regulator in respect of an application from the University of Western Australia (UWA) for a limited controlled release:

DIR 119—Limited & controlled release of narrow-leafed lupin GM for herbicide tolerance

GTTAC noted that the application was for a limited and controlled release of narrow-leafed lupin, genetically modified (GM) for tolerance to the herbicide glyphosate. The trial is proposed to take place at the New Genes for New Environments (NGNE) facility, run by the Department of Agriculture and Food Western Australia, at Merredin, WA. The purpose of the trial is to test for glyphosate tolerance under

field conditions. The GM narrow-leafed lupin would not be permitted to enter the human food or animal feed supply chains. GTTAC considered the proposed licence conditions, which include a pollen trap and isolation zone to limit the potential for transfer of the GM trait by bee mediated pollination.

RESOLUTION:

GTTAC advised the Regulator that:

- GTTAC agreed with the overall conclusions of the RARMP
- the Regulator should further consider bee-mediated pollination in the RARMP.

DEALINGS NOT INVOLVING INTENTIONAL RELEASE OF GMOs (DNIR)

The Regulator may seek GTTAC advice on RARMPs prepared in respect of a DNIR application.

DNIRs are dealings that a licence applicant undertakes within a facility where the GMO is physically contained.

2. Advice on Consultation RARMPs: Dealings not Involving Intentional Release

GTTAC considered the RARMP prepared by the Regulator in respect of the application from the Royal Alfred Hospital (RPAH) for a dealing not involving intentional release:

DNIR 523—A clinical trial to treat Hemophilia B using AAV-based gene therapy

GTTAC noted that the application involves gene therapy using a GM adeno-associated virus (AAV) -based vector to treat patients with severe Hemophilia B. GTTAC considered the safety features of the AAV-based vector, noting that the proposed vector system is replication defective, non-pathogenic, and self-limiting. GTTAC addressed the safety of the AAV-based vector for participants in the clinical trial and other humans. Additional safety considerations under the proposed licence conditions included:

- use of appropriate containment protocols and disposal of clinical waste during the clinical trial
- any information relevant to patient safety obtained in the course of OGTR assessment and/or advice would be provided to the Therapeutic Goods Administration (TGA), and the Human Research Ethics Committee (HREC).

GTTAC noted that the clinical trial also requires:

- approval by a HREC
- authorisation under the TGA's Clinical Trial Notification scheme.

RESOLUTION:

GTTAC advised the Regulator that:

- GTTAC agreed with the overall conclusions of the RARMP for DNIR 523.

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 Office of the Gene Technology Regulator (OGTR) on 1800 181 030. RARMPs are also available electronically from our website at <http://www.ogtr.gov.au>

APPENDIX 3:

Gene Technology Ethics and Community Consultative Committee Communiqué —Meeting 24 May 2013, Canberra ACT

The Gene Technology Ethics and Community Consultative Committee (GTECCC) held its third face-to-face meeting of the 2011–2014 triennium in Canberra on 24 May 2013.

GTECCC is a statutory advisory committee established under the *Gene Technology Act 2000* (the Act) to provide advice to the Gene Technology Regulator (the Regulator) and the ministerial Legislative and Governance Forum on Gene Technology (LGFGT). The function of GTECCC is to provide advice to the Regulator and the LGFGT on request, on issues of ethical or community concern relating to gene technology. All Committee members and expert advisers hold office on a part-time basis.

The purpose of this Communiqué is to provide a brief overview of the key matters considered by GTECCC and resolutions of the committee at its meeting on 24 May 2013.

***In memoriam*—Professor Nancy Millis**

GTECCC acknowledged the passing in September 2012 of Professor Nancy Millis, AC FAA FTSE. GTECCC recalled that Professor Millis made an extraordinary and abiding contribution to the development of science-based regulation of gene technology in Australia over more than two decades as Chair of the Recombinant DNA Monitoring Committee and the Genetic Manipulation Advisory Committee. GTECCC members and guests at the meeting joined the Chair in paying their respects to Professor Millis by observing a moment of silence.

New appointments

GTECCC welcomed two new members to the committee: Professor Susan Dodds has been appointed as the cross-member with the NHMRC's Australian Health Ethics Committee, and Ms Judy Jones has been appointed as an Expert Adviser. These appointments were made in March 2013 by the Hon Catherine King MP, the then Parliamentary Secretary to the Minister for Health and Ageing.

GTECCC Work Plan

National Framework of Ethical Principles in Gene Technology

The revised National Framework of Ethical Principles in Gene Technology 2012 (the National Framework), agreed to by GTECCC in May 2012, was published in July 2012 and widely distributed to stakeholders including all Institutional Biosafety Committees and accredited organisations, as well as biotechnology course coordinators. The National Framework sets out key principles and values to inform ethical considerations for gene technology and provides a reference point for promoting the ethical conduct of dealings with genetically modified organisms consistent with the national regulatory scheme.

Members were provided with positive feedback on the National Framework that had been received by the OGTR from stakeholders.

Synthetic biology

Whether synthetic biology raises new ethical issues has been discussed by GTECCC at previous meetings. At its 6th meeting in May 2012, GTECCC concluded that synthetic biology does not raise any new ethical issues, and that the known proposed applications of synthetic biology would be regulated under the *Gene Technology Act 2000* (the Act). GTECCC also agreed to maintain a watching brief on developments and reports regarding synthetic biology.

At the 7th GTECCC meeting, members were provided with a presentation from a PhD candidate from the Australian National University Law School on research into the ethical and legal issues around synthetic biology and its regulation. Members also received a report on a Scoping Workshop on "Synthetic Biology Futures in Australia?" from an officer from the National Enabling Technology Strategy (NETS; Department of Industry, Innovation, Climate Change, Science, Research and Tertiary Education).

GTECCC noted the updates in the area of synthetic biology and agreed that:

- GTECCC will continue to maintain a watching brief on developments and reports regarding synthetic biology, noting the rapid and ongoing developments in this field
- most techniques related to synthetic biology to date would be regulated under the Act, noting that this is predicated on the definitions in the legislation. GTECCC understands that the 2011 review of the Act considered the issue of the definitions keeping pace with technological advances, and would be interested in being consulted on future proposals to change the definitions
- GTECCC notes that synthetic biology in relation to animals is subject to additional regulation by animal ethics committees

- GTECCC has considered several reports by expert groups that discuss synthetic biology. These reports have comprehensively covered scientific issues and also underline the importance of continuing social and ethical responsibility of scientists
- the reports all discuss deliberative democracy and emphasize the need not only for public consultation, but for public engagement
- GTECCC notes that the context for this issue also includes the debate around traditional intellectual property and the rapid expansion of open access science.

Community Consultation

An officer from the NETS provided GTECCC with a presentation of the key findings from the 2012 survey of Australian public attitudes towards biotechnology. Members noted that views for and against GM foods and crops have remained fairly consistent over the past few years, and that there are differences in attitudes to GM foods depending on gender, age and general attitude to science and technology.

GTECCC also received an update from the OGTR regarding the ongoing development of its communications strategy.

Resurrection of extinct species

The OGTR provided GTECCC with an overview presentation and some recent publications on scientific progress towards the resurrection of extinct vertebrate and virus species. Members noted the publication by Dewannieux et al. (2006), which reported the successful generation of a retrovirus that was calculated to have integrated into the human lineage around 5 million years ago, through use of bioinformatics analysis of the human genome and DNA synthesis. Members discussed the possible ethical considerations that the resurrection of extinct species may raise and concluded:

- some work in the area of resurrection of extinct species would be regulated under the *Gene Technology Act 2000*
- there may be ethical issues in the viral work for further consideration, however the resurrection of vertebrate species will not be considered further by GTECCC at this time
- the potential benefit of research is an important ethical consideration, noting however that the Regulator cannot take benefits of the technology into account when making licence decisions

- the technical context, for example the level of containment, would be an important component of the assessment by the OGTR of any licence application for work relating to the resurrection of extinct viruses
- GTECCC notes that the Regulator can seek advice on a specific application from the Gene Technology Technical Advisory Committee and GTECCC
- GTECCC will consider doing some further work on this topic.

Nuffield Council on Bioethics publication

GTECCC discussed a recent publication from the Nuffield Council on Bioethics on *Emerging biotechnologies: technology, choice and the public good*. This document examines how we think about emerging biotechnologies and addresses the question of how a society should determine the conditions through which to foster socially and ethically responsible innovation in biotechnology.

GTECCC agreed the paper from the Nuffield Council on Bioethics is relevant to their work and links to several areas of interest to the committee including synthetic biology. Members commented that the paper provides a lot of useful information including clarification of definitions, precision of language, and comment on consultation and public engagement. GTECCC noted that the paper is set in the European context around public ethics, including the legal framework, which is different to that in Australia. GTECCC agreed to contact the Nuffield Council on Bioethics to inform them of the committee's consideration of the paper.

ISSUES FOR FUTURE CONSIDERATION

GTECCC discussed several other areas of potential work, including contributing to ongoing communications activities of the OGTR.

REPORTS

The Committee received a report from the Gene Technology Regulator regarding the activities of the Office of the Gene Technology Regulator. Reports were also received from the committee's cross-members with the Gene Technology Technical Advisory Committee (GTTAC) and the Australian Health Ethics Committee (AHEC).

REFERENCES

Dewannieux, M., Harper, F. Richaud, A., Letzelter C., Ribet D., Pierron G., Heidmann T. (2006). Identification of an infectious progenitor for the multiple-copy HERV-K human endogenous retroelements. *Genome Research* 16: 1548–1556.

For all inquiries, please contact the Office of the Gene Technology Regulator on 1800 181 030 (free call)

APPENDIX 4:

Gene Technology Ethics and Community Consultative Committee Communiqué —Videoconference 24 January 2013

The Gene Technology Ethics and Community Consultative Committee (GTECCC) held a meeting by video conference on 24 January 2013.

GTECCC is a statutory advisory committee established under the *Gene Technology Act 2000* (the Act) to provide advice to the Gene Technology Regulator (the Regulator) and the Legislative and Governance Forum on Gene Technology (LGFGT, formerly the Gene Technology Ministerial Council). The function of GTECCC is to provide advice to the Regulator and the LGFGT on request, on issues of ethical or community concern relating to gene technology. All Committee members and expert advisers hold office on a part-time basis.

The purpose of this Communiqué is to provide a brief overview of the key matters considered by GTECCC at its meeting held by video conference (VC) on 24 January 2013.

GTECCC WORKPLAN

Risk Communication

GTECCC considered a draft revised version of the *Risk Analysis Framework* (RAF). The RAF describes the Regulator's rationale and approach to risk analysis of genetically modified organisms. GTECCC noted that the primary audience of the RAF is OGTR staff, but that it is also intended to provide transparency on the use of risk analysis for decision-making on licence applications.

GTECCC also noted that the risk communication chapter relied on important contributions from the GTECCC Risk Communication Working Group. The revision also took into account comments arising from a discussion at the GTECCC meeting in May 2012, and contributions from the Gene Technology Technical Advisory Committee (GTTAC).

GTECCC discussed the possibility of having a short, accessible summary of the RAF made publically available. The OGTR is considering a separate process to develop such a summary.

RESOLUTION:

GTECCC advised the Regulator that:

- the Regulator should consider whether the balance of the document would be improved by moving some detail to an Appendix
- the Regulator should consider ways to improve the accessibility of the document
- the Regulator should consider pre-meeting comments provided by members.

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
BSG	Biosecurity Services Group of the Department of Agriculture, Fisheries and Forestry
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
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
RARMP	Risk assessment and risk management plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator
Spot checks	Unannounced visits by the OGTR Monitoring and Compliance Section
Volunteer	Regrowth of plants from seed 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 October 2013

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