OPERATIONS OF THE GENE TECHNOLOGY REGULATOR
QUARTERLY REPORT
1 April to 30 June 2010

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 Catherine King MP
Parliamentary Secretary for Health and Ageing
Parliament House
CANBERRA ACT 2600

Dear Parliamentary Secretary

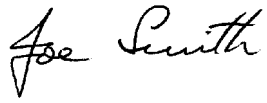
In accordance with section 136A of the *Gene Technology Act 2000* (the Act),
I am pleased to present to you the Quarterly Report of the Operations of the Gene Technology Regulator, covering the period 1 April to 30 June 2010.

During this period I issued three licences for dealings involving intentional release of genetically modified organisms (GMOs), four licences for dealings not involving intentional release of GMOs and 35 physical containment facilities certifications.

As part of the ongoing review of the Gene Technology Regulations 2001, I undertook a public consultation on Draft Gene Technology Amendment Regulations 2010, inviting submissions on proposed amendments pursuant to the requirements of section 142 of the Act.

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 Joe Smith
Gene Technology Regulator

17 September 2010

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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 1 April to 30 June 2010 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 Gene Technology Ministerial Council.

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.

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 April to 30 June 2010 quarter were:

Licences and other instruments

- Two organisations issued with accreditations
- Three licences issued for Dealings involving Intentional Release (DIR) of GMOs into the environment
- Four licences issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- 35 physical containment facilities certified
- 18 instruments surrendered
- 75 certifications, four DIR licences and 16 DNIR licences varied.

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

Monitoring and Compliance

Approximately 20 percent of current field trial sites and 11 percent of post-harvest field trial sites were subjected to routine monitoring during the quarter. This exceeded the target minimum rate of five percent per quarter.

Further information on monitoring and compliance is contained in Section 2 of this report.

Working collaboratively with States and Territories

Gene Technology Ministerial Council

The Gene Technology Ministerial Council (GTMC) 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 GTMC 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
- Biosecurity Services Group (Department of Agriculture, Fisheries and Forestry)
- 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, Fisheries and Forestry
- Department of Environment Water, Heritage and the Arts
- Department of Foreign Affairs and Trade.

During the quarter the Regulator sought advice in respect of six 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. Six 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.

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of the report outlines the regulatory activity undertaken during the 1 April to 30 June 2010 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 is also 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**

DIR and DNIR licences 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 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 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	1	2
DIR licence	3	3
DNIR licence	6	4
Certifications	27	35

* *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 30 day timeframe for each of the one or two rounds of consultation that the Regulator must undertake during the processing of each DIR application. 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. An application for a DIR licence cannot normally be received and decided upon within the same three month reporting period.

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 105	DIR 104	DIR 098	DIR 099
DIR 106		DIR 099	DIR 100
DIR 107		DIR 100	DIR 102
		DIR 101	
		DIR 102	
		DIR 103	

** Although not required under the Act, all new limited and controlled 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 three applications for a DIR licence in the quarter:

- **DIR 105 –** Limited and controlled release of canola genetically modified for herbicide tolerance – Monsanto Australia Limited
- **DIR 106 –** Limited and controlled release of sugarcane genetically modified for production of biopolymers and biopolymer precursors - University of Queensland
- **DIR 107 –** Limited and controlled release of banana genetically modified for disease resistance - Queensland University of Technology.

Consultation on applications for Dealings involving Intentional Release licences

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

- **DIR 104** – Limited and controlled release of canola and Indian mustard genetically modified for herbicide tolerance and/or a hybrid breeding system – Bayer CropScience Pty Ltd.

There were six invitations to comment on a RARMP issued during the quarter:

- **DIR 098 –** Commercial release of a genetically modified live viral vaccine to protect against Japanese encephalitis (IMOJEV™) – Sanofi Pasteur Pty Ltd
- **DIR 099** – Limited and controlled release of wheat and barley genetically modified for altered grain composition or nutrient utilisation efficiency – CSIRO
- **DIR 100** – Limited and controlled release of wheat genetically modified for enhanced carbon assimilation in drought and heat prone environments – CSIRO
- **DIR 101** – Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance - Monsanto Australia Limited
- **DIR 102** – Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance - The University of Adelaide
- **DIR 103** – Limited and controlled release of canola genetically modified for enhanced yield and delayed leaf senescence – Department of Primary Industries Victoria.

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 or surrendered during the quarter.

Clock stopped on Dealings involving Intentional Release licence applications

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

No requests for further information leading to stopping the clock on any DIR application were initiated in this quarter:

Decisions on applications for Dealings involving Intentional Release licences

Three DIR licences were issued during the quarter:

- **DIR 099** – Limited and controlled release of wheat and barely genetically modified for altered grain composition or nutrient utilisation efficiency – CSIRO
- **DIR 100** – Limited and controlled release of wheat genetically modified for enhanced carbon assimilation in drought and heat prone environments – CSIRO
- **DIR 102** – Limited and controlled release of wheat and barely genetically modified for abiotic stress tolerance – University of Adelaide.

Summary information on DIR applications, finalised RARMPs 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.

Four DNIR licences were issued during the quarter:

- **DNIR 477 -** Children, Youth and Women's Health Service - Human immunodeficiency vaccine studies
- **DNIR 480** - The University of Queensland - In vivo modification of target cell populations to study signalling pathways
- **DNIR 482 –** Telethon Institute for Child Health Research - Comparative analysis of human and kangaroo Leishmania: defining human pathogenicity genes
- **DNIR 483 -** The University of Queensland - Manipulation of the immune system in mouse skin using immunoregulatory cytokines.

A full listing of DNIR licence applications 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 he is 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 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	2	1
Surrender of certification	15	13
Surrender of DIR licence	3	0
Surrender of DNIR licence	1	4
Variation of accreditation	0	0
Variation of certification	48	75
Variation of DIR licence	3[b]	4
Variation of DNIR licence	19	16

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

[b] *Includes applications initiated by applicants and by the Regulator*

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 one CCI application in relation to a DIR application. The Regulator made two CCI declarations in relation to DIR applications 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.

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

- the dissemination of a GMO and its genetic material is minimised
- the persistence of a GMO in the environment is managed
- 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 percent of field trial sites each year. To achieve this goal a minimum of five percent of current trial sites and five percent of trial sites subject to post-harvest monitoring are monitored each quarter.

Monitoring and Compliance Strategy

The purpose of routine monitoring of field trials is to ensure compliance with licence conditions and includes spot checks.

The OGTR strategy for conducting field trial 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 limit the spread and persistence of the GMOs is more likely to occur (for example, flowering and harvest of GM crops).

The monitoring program for contained dealings involves inspecting DNIRs and the facilities that those dealings are conducted in, as well as monitoring a minimum of 20 percent of PC2 large-scale, PC3 and PC4 facilities per year.

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).

Overview of monitoring and compliance for the reporting period

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

- *Current field trial sites:* Of the 20 sites current in the quarter, four were monitored. This represents a monitoring rate of 20 percent of all current sites for the quarter.
- *Post-harvest field trial sites:* Of the 46 sites subject to post-harvest monitoring in the quarter, five were monitored. This represents a monitoring rate of 11 percent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection to contained dealings covered six organisations and ten PC facilities. Monitoring of PC facilities encompassed six PC2 laboratories, two PC2 animal facilities, one PC2 plant facility and one PC3 laboratory.

Monitoring of contained dealings: During the quarter, the monitoring of the ten PC 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 period between 1 April to 30 June 2010.

Licensed Organisation Name	**Licence Number**	**No. sites visited**	**Site status***	**Crop type**
Queensland University of Technology	DIR 076/2007	1	Current	Banana
	DIR 079/2007	1	Current	Banana
CSIRO, Victoria	DIR 031/2002	1	PHM	Grapevines
BSES Limited, Queensland	DIR 070/2006	1	PHM	Sugarcane
	DIR 096	2	Current	Sugarcane
Hexima Ltd, New South Wales	DIR 063/2005	3	PHM	Cotton
Total		**9**	**Current = 4** ***PHM = 5**	**4 crop types**

* PHM = post-harvest monitoring.

Monitoring of Dealings Not involving Intentional Release

The following table summarises monitoring activities for DNIRs for the period between 1 April to 30 June 2010.

Licensed Organisation Name	Licence Number
Macfarlane Burnet Institute for Medical Research and Public Health	DNIR 190 and DNIR 224
Murdoch University	DNIR 076
The University of Western Australia	DNIR 210
Total	4

Monitoring of Physical Containment Facilities

The organisations and the facility types the OGTR visited during the 1 April to 30 June 2010 quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
Baker Medical Research Institute	PC2 animal facility	1
Curtin University of Technology	PC3 laboratory	1
Macfarlane Burnet Institute for Medical Research and Public Health	PC2 laboratory	2
Monash University	PC2 laboratory	1
Murdoch University	PC2 laboratory	1
	PC2 plant facility	1
The University of Western Australia	PC2 laboratory	2
	PC2 animal facility	1
Total	4 facility types	10

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-compliance issues observed for DIRs that were inspected in the 1 April to 30 June 2010 quarter.

Findings for Dealings Not involving Intentional Release

Two non-compliance issues were observed for DNIRs in the 1 April to 30 June 2010 quarter.

Organisation	Murdoch University
Licence number(s)	DNIR 076
Summary of dealing	The aim of the proposed dealings is to study host-virus interactions of Cucumber mosaic virus in lupins.
Findings	At the time of the inspection OGTR staff observed that there were no signed statements demonstrating that staff had been informed of, and understood, licence conditions
Assessment	The non-compliance poses no immediate risks to the health and safety of people or the environment. However, unmanaged the non-compliance may pose risks to the environment once the dealings progress to the experimental stage in the plants.
Compliance management	The potential risks to the environment can be managed by ensuring that people conducting licensed dealings are aware of all licence conditions that apply to them.

Organisation	The University of Western Australia
Licence number(s)	DNIR 210
Summary of dealing	The aim of this dealing is to determine if recombinant Vaccinia virus can induce long term protection against tumour growth and induce tumour regression.
Findings	At the time of the inspection OGTR staff noted that one of the project supervisors had left the University and the Regulator had not been notified of this change. The University of Western Australia also did not have up to date training records or signed statements indicating that the licence holder had informed all staff of the conditions of the licence that apply to that person.
Assessment	Currently the only licensed dealing being undertaken for DNIR 210 is storage of GMOs. The University of Western Australia has since submitted a variation to the licence to update the contact details of the project supervisors. The risks to human health and safety and the environment have been assessed as negligible.
Compliance management	The University of Western Australia was reminded of the requirement to have up to date training records and signed statements from each person covered by the licence acknowledging that the licence holder has informed the person of the conditions of the licence that apply to that person.

Findings for Physical Containment Facilities

The OGTR's monitoring of certified PC facilities in the quarter found a small number of minor non-compliances 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**	**Personal Protective Equipment**	**Equipment**	**Waste disposal**	**Work practices[1]**	**Transport**
10	4	1	1	0	7	0

[1] 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 was one practice review completed in the 1 April to 30 June 2010 quarter.

	People Management Practice Review
Issues	This review is part of the OGTR ongoing audit/review program and was conducted to: • trace and assess the policies, instructions, procedures and corporate culture of organisations in relation to people management risks to meeting compliance obligations under the *Gene Technology Act 2000* • provide compliance risk advice to participants • recognise and take best practice principles from any well developed compliance and containment risk management arrangements. The review included information from previously reported investigations, reviews and audits together with site visits to the following organisations: • Telethon Institute for Child Health Research • Ozgene • University of Tasmania • University of Melbourne • The University of South Australia • Hospira • Cargill Australia • Imugene • Flinders University.
Findings	The review found that: • there were no non-compliances or breaches evident • participants generally had efficient tailored arrangements to meet national gene technology regulatory requirements • there are human behaviour/people management risks which can impede effective compliance performance management arrangements, for example: o less effective performance practices or clear designation of responsibilities through changes to staff o less clarity in instructions, and barriers to compliance awareness, due to changes to the diversity/scale of an organisation's dealings o human error due to lapses and misunderstandings developing over time • the interviews and the documentation, provided as part of the audit interview and site visits, are valuable inclusions to data on organisation compliance techniques which would be drawn upon in future OGTR education and awareness activities such as IBC Forums.

Outcomes	The review team proposed to participants that they adopt a number of compliance risk management techniques to be considered as part of ongoing organisational improvement and internal auditing. This review theme will be applied routinely as part of the OGTR audit and review program, and related information will continue to be disseminated through OGTR compliance management and awareness activities.

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 three audits completed in the 1 April to 30 June 2010 quarter.

Audit	**Cargill Australia**
Issues	This audit is part of the OGTR ongoing audit program and was conducted to: • trace and assess the policies, instructions, procedures and corporate culture of Cargill Australia in relation to meeting compliance obligations under the national regulatory system for gene technology in Australia • provide compliance risk advice to Cargill Australia • recognise and take best practice principles from any well developed Cargill Australia compliance and containment risk management arrangements.

Determination	The audit found that: • there were no non-compliances or breaches evident • Cargill Australia has efficient tailored arrangements to meet national gene technology regulatory requirements • the interviews and the records/documentation, provided as part of the audit interview and site visits, are valuable inclusions to data on organisation compliance techniques which would be drawn upon in future OGTR education and awareness activities such as IBC Forums.
Action	The audit team proposed a number of compliance performance risk management techniques to be considered as part of ongoing Cargill Australia continual improvement and in any internal auditing of compliance.

Audit	**Imugene Ltd**
Issues	This audit is part of the OGTR ongoing audit program and was conducted to: • trace and assess the policies, instructions, procedures and corporate culture of Imugene in relation to meeting compliance obligations under the national regulatory system for gene technology in Australia • provide compliance risk advice to Imugene • recognise and take best practice principles from any well developed Imugene compliance and containment risk management arrangements.
Determination	The audit found that: • there were no non-compliances or breaches evident • Imugene has efficient tailored arrangements to meet national gene technology regulatory requirements • the interviews and the records/documentation, provided as part of the audit interview and site visits, are valuable inclusions to data on organisation compliance techniques which would be drawn upon in future OGTR education and awareness activities such as IBC Forums.
Action	The audit team proposed a number of compliance performance risk management techniques to be considered as part of ongoing Imugene continual improvement and in any internal auditing of compliance.

Audit	Flinders University
Issues	This audit is part of the OGTR ongoing audit program and was conducted to: • assist and provide guidance to the Flinders University, particularly the Institutional Biosafety Committee (IBC), with their processes and procedures as foreshadowed in the quarterly report of 1 January to 31 March 2009; • trace and assess the policies, instructions, procedures and corporate culture of Flinders University in relation to meeting compliance obligations under the national regulatory system for gene technology in Australia; • provide compliance risk advice to Flinders University IBC and compliance management personnel and decision makers; • recognise and take best practice principles from any well developed Flinders University compliance and containment risk management arrangements; and • confirm compliance related to the matter reported in the 1 January to 31 March 2009 quarterly report.
Determination	The audit found that: • there were no non-compliances or breaches evident; • Finders University has efficient tailored arrangements to meet national gene technology regulatory requirements; • continued compliance was confirmed in the matter quarterly reported in the 1 January to 31 March 2009 quarterly report; and • the interviews and the records/documentation, provided as part of the audit interview and site visits, are valuable inclusions to data on organisation compliance techniques which would be drawn upon in future OGTR education and awareness activities such as IBC Forums.
Action	The audit team proposed a number of compliance performance risk management techniques to be considered as part of ongoing Flinders University continual improvement and in any internal auditing of compliance.

The OGTR audit program will continue to assess licencee compliance management arrangements and operational practices. Such information contributes to the continual improvement of:

- OGTR compliance management processes
- the prevention of practices and arrangements that could lead to non-compliance
- improved compliance capacity of organisations operating under the regulatory scheme.

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 1 April to 30 June 2010 quarter.

STATUTORY COMMITTEE OPERATIONS

The Act establishes two committees to provide advice to the Regulator and the Gene Technology Ministerial Council:

- Gene Technology Technical Advisory Committee
- Gene Technology Ethics and Community Consultative Committee.

Appointments to the two gene technology advisory committees were made by the then Parliamentary Secretary to the Minister for Health and Ageing, Senator the Hon Jan McLucas.

Gene Technology Technical Advisory Committee

As set out in section 101 of the Act, the functions of the Gene Technology Technical Advisory Committee (GTTAC) are to provide scientific and technical advice, on the request of the Regulator or the Ministerial Council, 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 10 May 2010. The communiqué is at Appendix 1.

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

Gene Technology Ethics and Community Consultative Committee

As set out in section 107 of the Act, the function of GTECCC is to provide advice on the request of the Regulator or the GTMC, on a number of matters, including ethical issues relating to gene technology, the need for and content of policy principles, policy guidelines, codes of practice, community consultation in respect of the process for applications for licences covering dealings involving the intentional release of a GMO into the environment, and risk communication matters in relation to those dealings. The appointment process for this new Committee was finalised in January 2008.

GTECCC did not meet during the quarter

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

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 involved participation in or presentation to:

- Training workshop on Risk Analysis of GMOs. 10-16 April 2010, Vietnam
- Meeting of the Ad Hoc Technical Experts Group on Risk Assessment & Risk Management under the UN Cartagena Protocol on Biosafety. 19-23 April 2010, Slovenia
- Biotechnology Regulatory Workshop. 13 May 2010, New Zealand
- 2010 Australia Group Plenary meeting. 31 May-4 June 2010, France
- OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology (WGHROB). 7-10 June 2010, OECD Task Force for the Safety of Novel Foods and Feeds 10-11 June 2010, France

Australia has undertaken to lead the drafting of an OECD WGHROB consensus document on the biology of *Eucalyptus*. In June 2010, OGTR hosted a two day workshop to obtain input from leading eucalypt experts. Participants included prominent researchers in Brazil, South Africa, Japan and Australia. Excellent contributions were provided on the taxonomy, genetics, breeding, silvicultural practices, weediness, pests, pathogens and biotechnology of *Eucalyptus.*

Advice on gene technology regulation

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

During the quarter the Regulator participated in a Regulators' Forum involving the prescribed agency regulators who have complementary role in the regulation of gene technology in Australia.

OGTR officers also attended the following meetings/conferences:

Australia New Zealand School of Government Workshop - Managing Regulation and Compliance, 2-7 May 2010, Melbourne

Australian Society of Sugar Cane Technologists 2010 Conference, 11-14 May 2010, Bundaberg

Australian Association for Professional and Applied Ethics - The Ethical Challenges of New Technologies, 17 June 2010, Sydney.

National Strategy for Unintended Presence of Unapproved GMOs

The Australian Government Biotechnology Ministerial Council has endorsed a risk-based national strategy to manage the unintended presence of unapproved GMOs in imported seeds for sowing (the UP strategy). The strategy was developed by an inter-departmental working group chaired by Biotechnology Australia and comprised of the then Department of Agriculture, Fisheries and Forestry; the Department of the Environment and Heritage; Department of Foreign Affairs and Trade; Department of Education, Science and Training; Department of Industry, Tourism and Resources; Department of Health and Ageing; FSANZ; and the OGTR.

The OGTR is responsible for implementing the UP strategy and has liaised closely with the Australian Seed Federation (ASF) to develop a voluntary auditing and testing program of existing industry quality assurance measures.

During the quarter the OGTR continued quality assurance reviews of Australian and State Government breeding programs, conducting reviews of the breeding programs of the Tasmanian Department of Primary Industries, Parks, Water and Environment, and the Australian Commonwealth Scientific and Research Organisation's Plant Industry Division. No issues of concern were identified.

Stakeholder survey on the Framework for the Development of Ethical Principles in Gene Technology (Framework)

The National Framework for the Development of Ethical Principles in Gene Technology (the Framework) was published in 2006 and was developed by the former Gene Technology Ethics Committee and published to provide a resource to inform and facilitate the consideration of ethical issues in decision making at all levels of gene technology activity. The Framework aims to provide the Australian community, and particularly scientists working in gene technology, with a national reference point for ethical considerations.

The Gene Technology Ethics and Community Consultative Committee (GTECCC) is currently reviewing the Framework. ORIMA Research Pty Ltd (ORIMA Research) was commissioned to undertake an online survey in March/April 2010 to obtain stakeholders' views to inform the review.

The survey was open to the public via a notice on the OGTR website. Stakeholder input was also sought by direct invitation, including from:

- accredited organisations regulated under the Act and related arrangements
- relevant Commonwealth and state and territory government agencies
- ethics organisations
- university biotechnology departments
- registered clients on the OGTR Client Register.

GTECCC is incorporating the information obtained from the survey responses in its review of the Framework. Comments confirmed that respondents felt that the Framework was a useful source of guidance.

The Framework is available at
www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/commpub-1

Public consultation on the draft Gene Technology Amendment Regulations 2010

In May-June 2010, as part of a review of the Regulations initiated in 2008, the Regulator undertook a public consultation on the Draft Gene Technology Amendment Regulations 2010 (Draft Amendment Regulations) in accordance with the requirements of section 142 of the Act.

Proposals for amendment were developed based on operational experience of the office and a targeted stakeholder consultation undertaken in 2008-09 and policy approval for drafting amendments was provided by the Gene Technology Ministerial Council in May 2009. The Draft Amendment Regulations were prepared by the Office of Legislative Drafting & Publishing based upon instructions from the Regulator. The proposed changes are intended to: ensure that dealings with GMOs continue to be classified appropriately according to current understanding of risks which they may pose; improve the efficiency and effectiveness of the system; and assist users to better understand and comply with their legislative obligations.

The consultation was supported by comprehensive papers explaining the rationale and intended operation of proposed changes in five key areas of amendment: classification of Exempt and notifiable low risk dealings (NLRDs); classification of dealings with viral vectors; oversight of NLRDs; and administrative changes. Advice was sought from a wide range of stakeholders including all regulated organisations and Institutional Biosafety Committees, State and Territory Governments, Australian Government agencies, the Gene Technology Technical Advisory Committee, and the general public. Submissions were received from a range of stakeholders including regulated organisations and the public. The majority of submissions indicated broad

support for the proposed changes. A number of technical and other issues have been raised that will be taken into account in finalising the amendment regulations.

Pending agreement of the Gene Technology Ministerial Council it is anticipated that amendments will be made in mid-2010-11 and take effect by the end of 2010-11.

Nomination process for reappointment of gene technology advisory committees

The Act provides that the term of appointment for members of the two statutory advisory committees, GTTAC and GTECCC, is for up to three years and appointments are made by the Minister. In 2009-10, the process was initiated for nomination, selection and appointment of members for the next triennium of GTTAC and GTECCC with the OGTR providing the secretariat support for the process. A call for nominations was placed in newspapers, on the OGTR website, and circulated to some 400 organisations and individuals in April 2010. Nominations closed on 31 May 2010. It is anticipated that new appointments will be made by the Minister by mid 2010-11.

Reviews

During the quarter the Regulator issued revised *Guidelines for Certification of a Physical Containment Level 3 Animal Facility*, Version 2.1 – Effective 28 June 2010.

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 and day of week pattern during the 1 April to 30 June 2010 quarter.

MONTH	HITS[1]	VISITS[2]
April	173099	31066
May	209244	31710
June	199472	23495

DAY OF THE WEEK PATTERN FOR THE QUARTER	HITS[1]	VISITS[2]
Sunday	45881	9784
Monday	88590	12210
Tuesday	94861	12429
Wednesday	99162	12149
Thursday	92405	12248
Friday	97525	12020
Saturday	63391	10222

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
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
About the OGTR
Forms and Guidelines
Record of GMOs and GM Product Dealings
Review of the Gene Technology Regulations
Publications and Legislation
IBC & Accredited Organisations Information
List of Genetically Modified Product approvals

The most popular downloaded documents were:

Risk Analysis Framework
The Biology and Ecology of Cotton *(Gossypium hirsutum L.)* in Australia
The Biology and Ecology of Papaya *(Carica papaya)* in Australia
The Biology and Ecology of Rice *(Oryza sativa)* in Australia
PC2 Laboratory guidelines
The Biology and Ecology of Pineapple *(Ananas comosus var. comosus)* in Australia

The Biology of Hybrid Tea Rose (*Rosa x hybrida*)
The Biology of *Triticum aestivum* L. em Thell. (Bread Wheat) in Australia
The Biology and Ecology of Sugarcane *(Saccharum spp.)* in Australia
The Biology and Ecology of *Dianthus caryophyllus* L. (Carnation)

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	112	101
May	118	113
June	107	112

Monitoring and compliance email inbox

The OGTR maintains an email inbox to provide a central point for accredited organisations to contact the OGTR regarding queries, legislative notifications 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 95 emails during the quarter.

Statutory Committee email inbox

The Regulatory Practice and Secretariat Section maintains 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 413 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 381 emails during the quarter.

APPENDIX 1:

Gene Technology Technical Advisory Committee

Communiqué
No. 27

This is the 27th communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 37th meeting of GTTAC, held on 10 May 2010.

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 Gene Technology Ministerial Council. All Committee members and expert advisers hold office on a part-time basis.

The Regulator receives 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 the applications and RARMPs considered by GTTAC and, in accordance with Regulation 29 of the Gene Technology Regulations 2001, any resolutions the Committee has provided to the Regulator with regard to 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 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.

GTTAC Advice

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.

1. ADVICE ON CONSULTATION RARMP – COMMERCIAL RELEASE

GTTAC considered the consultation RARMP prepared in response to the following commercial release application: DIR 098 – GM live viral vaccine to protect against Japanese encephalitis (IMOJEV™)

Sanofi Pasteur Ltd have applied for a licence to release the live GM viral vaccine IMOJEV™ as a prescription medicine. GTTAC noted that they had previously provided advice to the Regulator on this application prior to the development of the RARMP, as required for commercial releases.

RESOLUTION:

GTTAC advised the Regulator:

- *That risks to people and the environment have been adequately characterised and assessed in the RARMP prepared for DIR 098.*
- *That no additional information that should be considered was identified.*

2. ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

GTTAC considered the Consultation RARMPs prepared in response to the following applications for limited and controlled releases:

2.1 DIR 101 – Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance

GTTAC noted that the application from Monstanto Australia Limited involved the intentional release of GM cotton lines with stacked insect resistance traits derived by conventional breeding of existing GM cottons previously licensed by the Regulator. The trial was proposed to take place on up to 50 sites per season in up to 34 local government areas in Queensland, New South Wales and Western Australia over four years.

RESOLUTION:

- *GTTAC advised that the Regulator should consider clarifying which sites will have a 20m pollen trap and which sites will have a 3km isolation zone.*
- *GTTAC advised the Regulator that data on the effects on non-target arthropods, specifically pollen beetles, bees and hover flies should be considered as a requirement to support any future application for commercial release.*

2.2 DIR 102 – Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance

GTTAC was informed that the purpose of the proposed dealing is to assess growth and yield characteristics under field conditions. The trial will take place on three sites, two in the LGAs of Marion and Wakefield (SA) and one in Corrigin (WA), of up to 0.75 ha/growing season from 2010 to 2015.

RESOLUTION:

- *GTTAC advised the Regulator that risks to people and the environment have been adequately characterised and assessed in the RARMP prepared for DIR 102.*
- *GTTAC advised that the Regulator should consider re-wording of the licence conditions to reflect that the fence at the site is to keep out 'domestic livestock' rather than 'large animals'.*

2.3 DIR 099 – Limited and controlled release of wheat and barley genetically modified for altered grain composition or nutrient utilisation efficiency

GTTAC noted that the trial involves two sites in the Shire of Narrabri (NSW) and the Shire of Corrigin (WA) of up to 2.0 ha from 2010 to 2013. The purpose of the trial is to assess the growth and yield characteristics of the GMOs, and assess changes in grain composition.

RESOLUTION:

- *GTTAC advised the Regulator that risks to people and the environment have been adequately characterised and assessed in the RARMP prepared for DIR 099.*
- *GTTAC advised the Regulator that the wording of the RARMP and licence conditions be modified to reflect that access by livestock is to be prevented at the proposed site in Narrabri.*

2.4 DIR 100 – Limited and controlled release of wheat genetically modified for enhanced carbon assimilation in drought and heat prone environments

GTTAC was informed that the proposed release would be conducted at a 0.1ha site in the Redland local government area in Queensland from 2010 to 2013. The purpose of the trial is to evaluate the agronomic properties of the GM wheat lines grown under field conditions (i.e rain fed, drought prone).

RESOLUTION:

- *GTTAC advised the Regulator that risks to people and the environment have been adequately characterised and assessed in the RARMP prepared for DIR 100.*
- *GTTAC advised the Regulator that no additional information that should be considered was identified.*

3 OTHER ADVICE:

Review of The Gene Technology Regulations 2001

The Committee was given a presentation on the progress of the review of the Gene Technology Regulations 2001, with particular reference to the discussion documents which had been prepared for the public consultation on the review. GTTAC noted that the information was being presented for discussion only and that the Committee was not being asked for advice as a formal request for advice would be sent out-of-session when the discussion documents had been finalised.

RESOLUTION:
GTTAC noted that a formal request for advice would be circulated following the meeting.

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. The 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
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 containment 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 time does not run 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)
DIR licence	A licence for a dealing involving intentional release of a GMO into the environment
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)
DNIR licence	A licence for a dealing not involving intentional release of a GMO into the environment
Expert advisers	Advisers appointed by the Minister to give expert advice to either GTTAC or GTEC 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
GMAC	Genetic Manipulation Advisory Committee
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
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