Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 JANUARY–31 MARCH 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 Mark Butler MP
Parliamentary Secretary for Health
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 January to 31 March 2010.

During this period one licence for dealings involving intentional release of GMOs and five licences for dealings not involving intentional release of GMOs were issued, and 34 physical containment facilities were certified.

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

Yours sincerely

Dr Joe Smith

19 May 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 January to 31 March 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.

SECTION 1

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 January to 31 March 2010 quarter were:

Licences and other instruments

- Three organisations issued with accreditations
- 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
- Thirty four physical containment facilities certified
- Thirty nine instruments surrendered
- Variation of one accreditation, 47 certifications, two DIR licences and 19 DNIR licences.

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

Monitoring and Compliance

Approximately 14 percent of current field trial sites and seven 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
- Australian Quarantine and Inspection Service
- 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 the Environment, Water, Heritage and the Arts
- Department of Foreign Affairs and Trade.

During the quarter the Regulator did not seek advice in respect of any 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. However no invitations to the public to comment on a RARMP were issued during the quarter.

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

SECTION 2

REGULATION OF GENETICALLY MODIFIED ORGANISMS

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of the report outlines the regulatory activity undertaken during the 1 January to 31 March 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 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**

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 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*
DIR licence	2	1
DNIR licence	5	5
Accreditations	3	3
Certifications	41	34

* *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 103	DIR 099		DIR 097
DIR 104	DIR 100		
	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 two applications for a DIR licence in the quarter:

- **DIR 103**—Limited and controlled release of canola genetically modified for enhanced yield and delayed leaf senescence—Department of Primary Industries Victoria
- **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.

Consultation on applications for Dealings involving Intentional Release licences

Although not required by the Act, the Regulator issued a 'Notification of Licence Application' for five 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 when the RARMP is expected to be released for public comment.

- **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.

There were no invitations to comment on a RARMP issued during the quarter.

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.

One DIR licence was surrendered during the quarter.

- **DIR 010/2001**—Small and large scale trialing of InVigor® canola (*Brassica napus*) for development for the Australian cropping system—Bayer CropScience Pty Ltd.

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 request for further information on any DIR application was initiated in this quarter.

Decisions on applications for Dealings involving Intentional Release licences

One DIR licence was issued during the quarter:

- **DIR 097**—Limited and controlled release of a genetically modified vaccine for prevention of selected childhood respiratory diseases—PPD Australia Pty Ltd

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.

Five DNIR licences were issued during the quarter.

- DNIR 474—The impact of influenza A virus PB1-F2 protein on host immunity and potential for therapeutic targeting—University of Melbourne, Victoria
- DNIR 475—Targeting NADPH oxidase in angiogenesis—Bernard O'Brien Institute of Microsurgery, Victoria
- DNIR 476—Developing lentiviral vectors for gene therapy of Friedreich Ataxia—Murdoch Childrens Research Institute, Victoria
- DNIR 478—Interferon-adjuvanted flavivirus vaccine—Australian National University, ACT
- DNIR 479—Modulation of brain activity for understanding cardiovascular diseases—University of Melbourne, Victoria.

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*
Surrender of accreditations	1	1
Surrender of certification	31	36
Surrender of DIR licence	0	1
Surrender of DNIR licence	3	1
Variation of accreditation	1	1
Variation of certification	75	47
Variation of DIR licence	5	2
Variation of DNIR licence	16	19

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

Emergency Dealing Determinations

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

Confidential Commercial Information

Under section 184 of the Act a person may apply to the Regulator 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 five CCI applications in relation to DIR applications. The Regulator made one CCI declaration in relation to a DIR application and one CCI declaration in relation to a notifiable low risk dealing during the quarter.

Monitoring and Compliance

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

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

In particular, the Monitoring and Compliance Sections focus on management of dealings at field trial sites and within 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 1 January to 31 March 2010 quarter, 7 GM plant field trial sites under DIR licences were subjected to monitoring visits.

- **Current field trial sites:** Of the 28 sites current in the quarter, 4 were monitored. This represents a monitoring rate of 14 percent of all current sites for the quarter.
- **Post-harvest field trial sites:** Of the 41 sites subject to post-harvest monitoring in the quarter, 3 were monitored. This represents a monitoring rate of 7 percent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection to contained dealings covered 4 organisations and 8 PC facilities. Monitoring of PC facilities encompassed 3 PC2 laboratories, 3 PC2 animal containment facilities, 1 PC2 arthropod facility and, 1 PC3 laboratory.

Monitoring of contained dealings: During the quarter, the monitoring of the 8 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.

Eight 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 January to 31 March 2010.

Licensed Organisation Name	Licence Number	No. sites visited	Site status*	Crop type
CSIRO, New South Wales	DIR 067/2006	1	PHM	Cotton
	DIR 083/2007	1	PHM	Cotton
	DIR 085/2008	1	PHM	Cotton
CSIRO, Australian Capital Territory	DIR 092	1	Current	Wheat
	DIR 093	1	Current	Wheat and Barley
	DIR 094	1	Current	Wheat and Barley
Monsanto, New South Wales	DIR 074/2007	1	Current	Cotton
Totals	**7**	**7**	**C = 4 *PHM = 3**	**Cotton, wheat, barley**

** PHM = post-harvest monitoring.*

Monitoring of Dealings Not involving Intentional Release

The following table summarises monitoring activities for DNIRs for the period between 1 January to 31 March 2010.

Licensed Organisation Name	Licence Number
Avexa Ltd, Victoria	DNIR 118/2002 and DNIR 302/2004
CSIRO, Victoria	DNIR 066/2002 and DNIR 067/2002
Griffith University, Queensland	DNIR 380/2005 and DNIR 426/2007
Queensland Institute of Medical Research (QIMR), Queensland	DNIR 222/2003 and DNIR 423/2007
Total	**8**

Monitoring of Physical Containment Facilities

The organisations and the facility types the OGTR visited during the 1 January to 31 March 2010 quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
Avexa Ltd, Victoria	PC2 laboratory	1
	PC3 laboratory	1
CSIRO, Victoria	PC2 animal containment	2
Griffith University, Queensland	PC2 animal facility	1
	PC2 laboratory	1
Queensland Institute of Medical Research, Queensland	PC2 arthropod facility	1
	PC2 laboratory	1
Total	**4 facility types**	**4**

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 two findings of non-compliances for DIRs that were finalised in the 1 January to 31 March 2010 quarter.

Organisation	Bayer CropScience
Licence number	DIR 069/2006 Site 4
Summary of dealing	Limited and controlled release of GM herbicide tolerant hybrid *Brassica napus* and hybrid *Brassica juncea*
Findings	A small area of unapproved crop (forage rape) was planted in the monitoring zone by a land owner at site 4 under DIR 069/2006. This was reported in a post-harvest monitoring report. The forage rape was sown in the outer 5–10 metres of the 50m monitoring zone on the western side of the site.
Assessment	Although informed of relevant licence conditions by the licence holder (Bayer CropScience), the land owner inadvertently overlooked conditions prohibiting the planting of unapproved crops on a post harvest site. Once aware of this issue during their monthly monitoring visits, Bayer CropScience ensured immediate action to destroy the crop and followed up by writing to all land owners under the licence reminding them of their licence obligations towards planting of unapproved Brassica crops. Risks to human health, safety and environment from this incident were assessed as negligible. In addition to this non-compliance, OGTR has been notified of a number of other instances where small amounts of unapproved forage Brassica crops were inadvertently planted at sites under DIR 069/2006. These plantings apparently occurred due to remnant forage *Brassica* seeds left in machinery. When Bayer became aware of these plantings they directed the land holders to remove the crops.
Compliance management	Bayer CropScience has informed land owners of licence conditions and has sent additional reminder letters in regards to incidents of unapproved *Brassica* plantings. OGTR has also written to the land owners to remind them of their obligations under the *Gene Technology Act 2000* as persons covered by a licence.

Organisation	BSES Limited
Licence number	DIR 070/2006: Site 1
Summary of dealing	Limited and controlled release of GM sugarcane with altered plant architecture, enhanced water or improved nitrogen use efficiency.
Findings	BSES self reported the planting of four GMO lines sourced from DIR 070/2006 plant material for further growing and release at Meringa under a different licence DIR 095. This action contravenes licence condition 35 of DIR 070/2006 that prohibits the use and release of plant material under other licences.
Assessment	BSES stated that at the time of planting they believed the use of plant material from DIR 070/2006 was allowed as the four GMO lines sourced from DIR 070/2006 are identical and permitted lines under DIR 095. The Risk Assessment and Risk Management Plan for DIR 095 did not identify any additional risks associated with these four GMO lines other than those already identified and documented under DIR 070/2006. Risks to human health, safety and environment from this incident were assessed as negligible.
Compliance management	BSES has admitted responsibility for this unintentional mistake and has fully cooperated with OGTR in identifying ways to continue to improve their operational capabilities in line with licence conditions. BSES Ltd was reminded of its obligation to licence conditions with respect to various licences they hold. BSES Ltd have since destroyed the sugarcane material. No further action is required.

Findings for Dealings Not involving Intentional Release

No non-compliance issues were observed for DNIRs in the 1 January to 31 March 2010 quarter.

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	PPE[1]	Equipment	Waste disposal	Work practices[2]	Transport
8	0	0	2[3]	0	4[3]	0

1 *PPE = Personal Protective Equipment.*

2 *Work practices include personnel training, record keeping, or other actions affecting compliance with certification instruments.*

3 *Numbers listed include non-compliance issues observed during the 1 October–31 December 2009 quarter that were finalised during the 1 January–31 March 2010 quarter.*

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 1 January to 31 March 2010 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 1 January to 31 March 2010 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 1 January to 31 March 2010 quarter.

SECTION 3

STATUTORY COMMITTEE OPERATIONS

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 did not meet during the quarter.

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 2010.

GTECCC met once during the quarter, on 18 February 2009. The communiqué is at Appendix 1.

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

SECTION 4

OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

International collaboration and coordination

Under the Act the Regulator's functions include:

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

International collaboration and coordination activities undertaken during the quarter involved participation in or presentation to:

- Canadian Food Inspection Agency symposium, 8–9 February 2010, Canada.

The OGTR also received visitors and a presentation from Forestry and Fisheries Research Council Secretariat, Japanese Ministry of Agriculture, Forestry and Fisheries, 11 March 2010.

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 attended a Regulators' forum with the prescribed agency regulators who are involved in Australia's regulatory system for gene technology, 25 March 2010.

The OGTR provided presentations to the following:

- Department of Agriculture, Fisheries and Forestry risk assessment training, 20 January 2010
- Sub-committee on Animal Health Laboratory Standards workshop, 19 March 2010.

OGTR officers also attended the following meetings/conferences:

- Australian Bureau of Agricultural and Resource Economics—Outlook 2010 Conference, 2 March 2010, Canberra
- Biocontainment workshop "Bio2IC", 22–26 March 2010, Perth.

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 reviewed the quality assurance systems of one agency (Department of Primary Industries, Victoria) and did not identify any issues of concern.

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

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

The Framework was published in 2006 to provide a resource that would 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.

Stakeholders that were invited directly to participate in the survey included:

- 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.

The survey was open to the public via a notice on the OGTR website, and link to the online survey.

ORIMA Research designed the survey in consultation with GTECCC and will analyse the responses to the survey. The analysis and results will be provided to GTECCC to assist in the review of the Framework.

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

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 January to 31 March 2010 quarter.

MONTH	HITS[1]	VISITS[2]
January	182,882	34,912
February	165,524	30,844
March	203,861	36,471

DAY OF THE WEEK PATTERN FOR THE QUARTER	HITS [1]	VISITS[2]
Sunday	45,457	13,042
Monday	88,790	14,626
Tuesday	88,807	14,729
Wednesday	85,791	13,833
Thursday	82,557	12,905
Friday	90,876	14,279
Saturday	69,989	13,010

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
- Record of GMOs and GM Product Dealings
- List of applications and licences for Dealings involving Intentional Release (DIR) of GMOs into the environment
- About the OGTR
- Licence application forms
- Publications and Legislation

- Annual and Quarterly Reports
- IBC & Accredited Organisations Information
- Fact Sheets

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 and Ecology of Sugarcane (*Saccharum spp.*) in Australia
- The Biology of *Musa L.* (banana) in Australia
- The Biology of *Zea mays* L. ssp *mays* (maize or corn) in Australia
- The Biology of *Triticum aestivum* L. em Thell. (Bread Wheat) in Australia

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

Internet contacts and freecall number

OGTR email address and freecall number

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

MONTH	EMAILS	OGTR 1800 NUMBER
January	117	60
February	91	89
March	128	99

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 123 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 280 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 319 emails during the quarter.

APPENDIX

APPENDIX 1:

Gene Technology Ethics and Community Consultative Committee 18th February 2010, Canberra COMMUNIQUÉ

The Gene Technology Ethics and Community Consultative Committee (GTECCC) held its third meeting of the Triennium in Canberra on 18 February 2010.

GTECCC is a statutory advisory committee to the Gene Technology Regulator (the Regulator) and the Gene Technology Ministerial Council. All Committee members hold office on a part-time basis.

The function of GTECCC is to provide advice to the Regulator (and the GTMC) on request, on issues of ethical or community concern relating to gene technology.

The purpose of this Communiqué is to provide a brief overview of the key matters considered by GTECCC at its third meeting on 18 February 2010.

Professor Michael Burgess

Michael Burgess, Professor and Chair in Biomedical Ethics at the University of British Columbia, was an invited guest speaker. He gave an interesting and informative talk on his work with a GE^{3}LS (Genomics, Ethics, Economics, Environment, Legal and Social Issues) research project funded by Genome Canada. Professor Burgess explained the deliberative democracy methods used in his research and gave some insights into different models of community engagement.

GTECCC's Work Plan

GTECCC reviewed progress in the following key areas, which had been identified as priorities at the previous meeting:

National Framework for the Development of Ethical Principles in Gene Technology (the Framework)

The Working Group established to undertake consultation with stakeholders to obtain feedback on the usefulness of the Framework's nine principles reported that they had agreed on a list of stakeholders to be targeted and some questions to be asked, and that a research company had been contracted to carry out a survey within these terms of reference.

Representatives from the survey company presented their survey plan to the committee. GTECCC suggested some additional questions to be included and noted that the survey results were expected to be available by the end of April 2010.

Environmental Ethics and Gene Technology

GTECCC noted that the final editing of the background paper on Environmental Ethics had now been completed. They recommended that the paper should be submitted for inclusion in the program of the inaugural conference of the Australasian Association of Bioethics and Health Law, to be held in Adelaide from 1 to 4 July 2010. They also recommended that three independent experts from relevant fields be invited to attend the workshop session at which the paper is presented and provide commentary on the paper. Following any further editing indicated by the reviewers the paper will then be published on the OGTR website.

Community Consultation

The Committee received an update on the Australian Government's New and Enabling Technologies Strategy (NETS) and noted that part of the strategy involved the continuation of a series of surveys designed to track changes in public attitudes to biotechnology over time. GTECCC resolved to pursue input to future NETS biotechnology surveys and asked to be kept informed of activities and results.

GTECCC were informed about the work of the International Association for Public Participation (IAP2) and noted that the organisation is working towards the establishment of standards for best practice in stakeholder engagement. They noted that one of the key messages is that different types of consultation or engagement may be appropriate in different circumstances, depending on the issues under discussion.

Do-it-Yourself Biology

GTECCC were informed that concerns had been raised that some individuals and groups may be conducting biological experiments outside of the containment and control of an institutional framework. The committee also noted that some school classes may involve gene technology techniques and that concerns had been raised that the disposal of waste may not always be appropriately carried out. The Regulator confirmed that there was no evidence to suggest that any unlawful activities were being carried out, and that information for schools and for individuals interested in DIY biological research was published on the OGTR website.

Request for Advice from the Regulator

The Committee considered a request for advice from the Regulator relating to licence application DIR 098. The application was for the commercial release of a live GM vaccine against Japanese Encephalitis (JE). GTECCC were informed about the consultation process normally undertaken by the Regulator for DIR applications and were asked to advise on whether any additional consultation should be undertaken in this case. GTECCC recommended several professional medical groups for inclusion in the consultation process. They also recommended that steps be taken to ensure that non-technical summary information is included in the public consultation.

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).

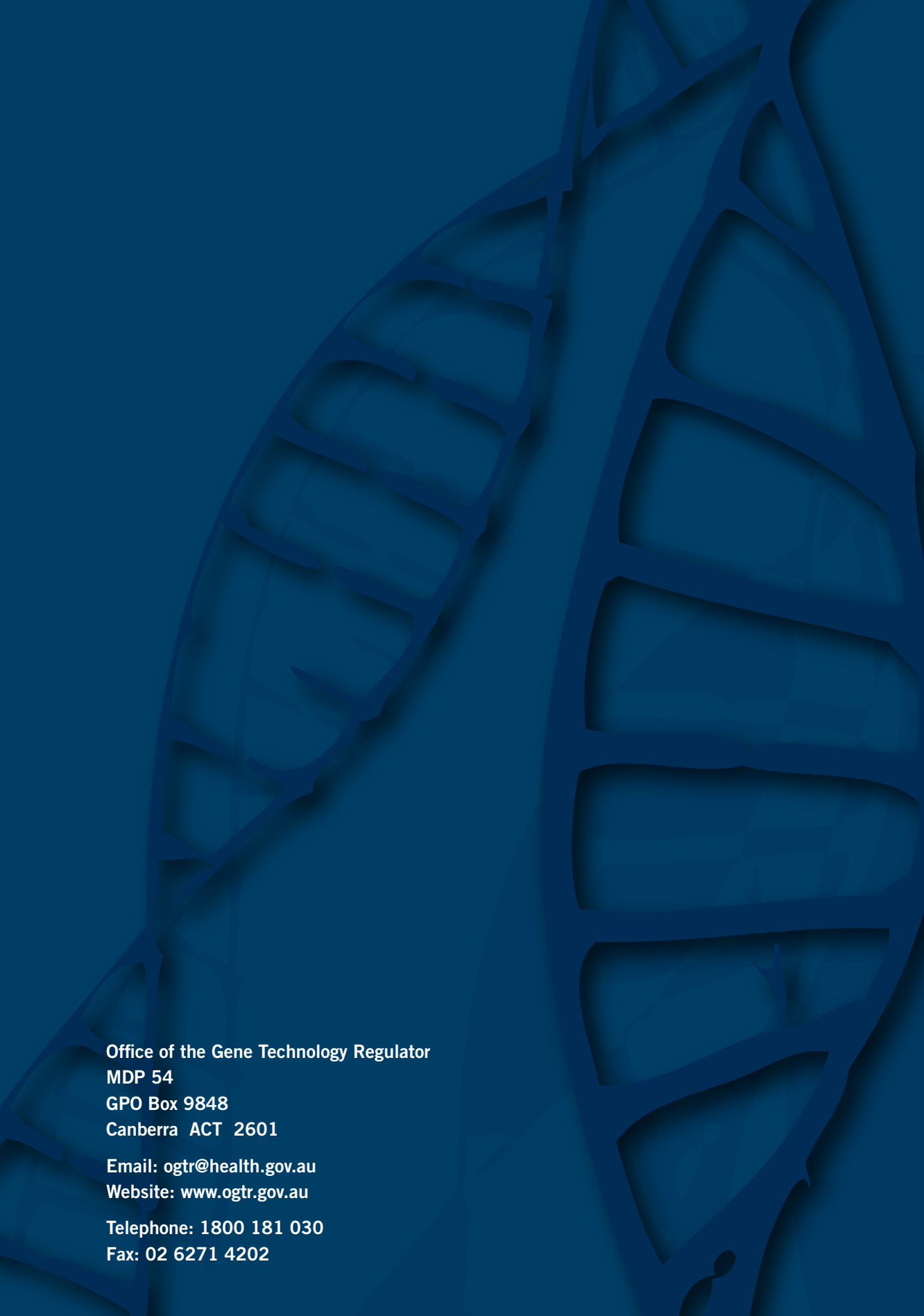
For all inquiries, please contact the Office of the Gene Technology Regulator on 1800 181 030 (free-call)

GLOSSARY

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

Accredited organisation	An organisation that is accredited under section 92 of the Act
Act	*Gene Technology Act 2000*
APVMA	Australian Pesticides and Veterinary Medicines Authority
Breach of a licence condition	A breach of a licence condition which has been proven either in court or by way of admission following investigation
CCI	Confidential commercial information
Certified 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 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
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 contained 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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