OPERATIONS OF THE GENE TECHNOLOGY REGULATOR
QUARTERLY REPORT
1 July to 30 September 2008

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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Senator the Hon Jan McLucas
Parliamentary Secretary to the Minister 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 July to 30 September 2008.

During this period I issued six licences for dealings involving intentional release of GMOs, three licences for dealings not involving intentional release of GMOs, and certified 67 physical containment facilities.

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

On 19 September 2008, the *Gene Technology (Equine Influenza Vaccine) Emergency Dealing Determination 2007* expired following an official declaration that Australia is free from equine influenza.

Yours sincerely

Elizabeth Flynn

A/g Gene Technology Regulator

1 December 2008

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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 Regulators' 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 and appendices.

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 July to 30 September 2008 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.

Appendices

The appendices contain information on the number of Dealings Not involving Intentional Release (DNIR) licences issued.

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 July to 30 September 2008 quarter were:

Licences and other instruments

- six licences issued for dealings involving the intentional release (DIR) of GMOs into the environment
- three licences issued for dealings not involving the intentional release (DNIR) of GMOs into the environment
- 67 physical containment facilities certified
- surrender of 12 certifications of certified facilities and five DNIR licences processed
- 82 variations processed.

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

Annual reporting for Accredited Organisations

All Accredited organisations are required to submit an annual report within three months of the end of each financial year. The purpose of the annual report is for Accredited Organisations to provide information to the Regulator to demonstrate that they are meeting obligations and responsibilities under the Act, Regulations and *Guidelines for Accreditation of Organisations* issued by the Regulator. Information within an annual report may be subject to monitoring and auditing by OGTR staff. Of the 154 organisations accredited on 30 June 2008, 126 had submitted their annual reports by the end of this reporting period.

Monitoring and Compliance

Approximately 26 percent of current field trial sites and five percent of post harvest field trial sites were subjected to routine monitoring during the quarter. This exceeds 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 Environment, Water, Heritage and the Arts
- Department of Foreign Affairs and Trade.

During the quarter, the Regulator sought advice and comment in respect of four 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. Four 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 July to 30 September 2008 quarter. This includes information about applications for GMO licences and other instruments under the Act. This section also 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 received after 1 July 2007 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 usually 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	6
DNIR licence	5	3
Accreditations	1	2
Certifications	66	67

* *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 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 and including 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 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 091 DIR 092	DIR 087 DIR 089	DIR 081/2007 DIR 084/2008 DIR 085/2008 DIR 086/2008	DIR 078/2007 DIR 079/2007 DIR 081/2007 DIR 082/2007 DIR 083/2007 DIR 084/2008

** Although not required under the Act, all new DIR applications are notified on the OGTR website under 'What's New' and notified to all individuals and organistations on the OGTR mailing list. For applications other than limited and controlled consultation with prescribed authorities is also conducted at this stage.*

Applications received for Dealings involving Intentional Release licences

The Regulator received two applications for a DIR licence in the quarter:

- DIR 090 – Commercial release of cotton genetically modified for insect resistance (Widestrike™ Insect Protection cotton) – Dow AgroSciences Australia Pty Ltd.
- DIR 091 – Commercial release of rose genetically modified for altered flower colour – Florigene Pty Ltd

Consultation on applications for Dealings involving Intentional Release licences

No consultations commenced on any DIR licence applications during this quarter as all under consideration were deemed by the Regulator to qualify as limited and controlled releases.

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

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

- DIR 081/2007 – Limited and controlled release of cotton genetically modified for enhanced water use efficiency – Monsanto Australia Limited
- DIR 084/2008 – Limited and controlled release of torenia genetically modified for enhanced phosphate uptake – Florigene Pty Ltd
- DIR 085/2008 – Limited and controlled release of cotton genetically modified for altered fatty acid composition of the cottonseed oil – CSIRO
- DIR 086/2008 – Limited and controlled release of maize genetically modified to investigate gene function - CSIRO

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

Withdrawn applications and surrendered licences for Dealings involving Intentional Release licences

No DIR licence application was withdrawn and no DIR licences were 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 were initiated in this quarter.

Decisions on applications for Dealings involving Intentional Release licences

Six DIR licences were issued during this quarter.

- DIR 078/2007 – Limited and controlled release of sugarcane genetically modified for altered sugar production – The University of Queensland
- DIR 079/2007 – Limited and controlled release of banana genetically modified for disease resistance – Queensland University of Technology
- DIR 081/2007 – Limited and controlled release of cotton genetically modified for enhanced water use efficiency – Monsanto Australia Limited
- DIR 082/2007 – Limited and controlled release of perennial ryegrass and tall fescue genetically modified for improved forage qualities – Department of Primary Industries (Victoria)
- DIR 083/2007 – Limited and controlled release of cotton genetically modified for enhanced waterlogging tolerance – CSIRO
- DIR 084/2008 – Limited and controlled release of torenia genetically modified for enhanced phosphate uptake – Florigene 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.

During the quarter the Regulator issued three DNIR licences. More information about these licences is contained in Appendix 1 of this report.

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 better manage risks if new information or data comes to light. The Regulator must not vary the licence unless she 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 and those applications 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 to another person or consent to the surrender of a licence by a licence holder.

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

Type	Number received	Number processed[1]
Surrender of certification	13	12
Surrender of DIR licence	0	0
Surrender of DNIR licence	5	5
Variation of certification	74	66
Variation of DIR licence	6	3
Variation of DNIR licence	15	13
Applications for CCI	2	1

[1]Numbers reported in this quarter often relate to applications received in previous quarters. For the purposes of this table, 'processed' means that action on the authorisation was completed.

Emergency Dealing Determinations (EDD)

During this quarter, the *Gene Technology (Equine Influenza Vaccine) Emergency Dealing Determination 2007* expired. This instrument was originally made on 18 September 2007 by the then Parliamentary Secretary to the Minister for Health and Ageing, Senator the Hon Brett Mason, coming into effect on 20 September 2007 and due to expire on 19 March 2008. On 11 March 2008 the EDD was extended for six months by the Parliamentary Secretary to the Minister for Health and Ageing, Senator the Hon Jan McLucas, and expired on 19 September 2008. The Regulator had provided advice on risk management in relation to both the making of the EDD and its extension. Details of the EDD are still available from the OGTR website.

Australia's Chief Veterinary Officer, Dr Andy Carroll, officially declared Australia free from equine influenza on 30 June 2008.

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 commercial confidential 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 two CCI applications in relation to DIR licence applications. The Regulator also made one CCI declaration in relation to a DIR application.

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, PC4, PC3 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 NLRDs.

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored: During the 1 July to 30 September 2008 quarter, six GM plant field trial sites under DIR licences were subjected to monitoring visits.

- *Current field trial sites:* Of the 15 sites current in the quarter, four were monitored. This represents a monitoring rate of 26 percent of all current sites for the quarter
- *Post-harvest field trial sites:* Of the 39 sites subject to post-harvest monitoring in the quarter, 2 were monitored. This represents a monitoring rate of five percent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection to contained dealings covered three organisations and five PC facilities. Monitoring of PC facilities encompassed PC2 laboratories (one visited), PC3 laboratories (one visited), PC2 plant containment facilities (three visited).

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

Two 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 July to 30 September 2008.

Licensed Organisation Name	Licence Number	No. sites visited	Site status *	Crop type
The University of Queensland, Queensland	DIR 051/2004	1	Current	Sugarcane
BSES Limited, Queensland	DIR 070/2006	3	Current	Sugarcane
Monsanto Australia Limited, Queensland	DIR 064/2006	2	PHM	Cotton
Totals		6	C = 4 PHM = 2	2 crop types

* C = current PHM = post-harvest monitoring.

Monitoring of Dealings Not involving Intentional Release

The following table summarises monitoring activities for DNIRs for the period between 1 July to 30 September 2008.

Licensed Organisation Name	Licence Number
South Eastern Sydney and Illawarra Area Health Service, New South Wales	DNIR 100/2002 DNIR 291/2004
Total	2 DNIR licences

Monitoring of Physical Containment Facilities

The organisations and the facility types the OGTR visited during the 1 July to 30 September 2008 quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
South Eastern Sydney and Illawarra Area Health Service, New South Wales	PC2 laboratory	1
CSIRO, South Australia	PC2 plant containment	3
Monash University, Victoria	PC3 laboratory	1
Totals	3 facility types	5

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 was one finding of non-compliance for a DIR for the 1 July to 30 September 2008 quarter.

Organisation	Monsanto Australia Ltd
Licence number and site	DIR 064/2006
Summary of dealing	Licence relates to limited and controlled release of water-efficient GM cotton
Findings	During a routine monitoring inspection, OGTR inspectors noted that Monsanto Australia Ltd compliance staff were not fully informed of their obligations with respect to relevant conditions of licence DIR064/2006. This was evident from the failure to provide an annual report to the Regulator for DIR064/2006 licence activities for the period 2006-07.
Assessment	Whilst Monsanto Australia Ltd failed to appreciate the relevant conditions of licence DIR064/2006 relating to the failure to provide an annual report, it was found that this was an oversight due to recent staff changes. Monsanto Australia Ltd quickly put in place remedial measures to correct this non-compliance and an annual report was duly submitted. Risks to human health and safety and the environment as a result of this non-compliance were determined to be negligible.
Compliance management	Monsanto Australia Limited is to ensure that an annual report is sent to the Regulator at the end of each anniversary of the licence.

Findings for Dealings Not involving Intentional Release

There were no findings of non-compliance for DNIRs for the 1 July to 30 September 2008 quarter.

Findings for Physical Containment Facilities

The OGTR's monitoring of certified PC facilities in the quarter found a small number of minor structural 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**
5	2	0	0	0	0	0

[1]. PPE = Personal Protective Equipment.

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

Practice Reviews

The OGTR may initiate Practice Reviews in response to observations made during monitoring activities, or to follow up incident reports that may relate to non-compliance with licence conditions by accredited organisations. Their objective is to determine if licence conditions can be, and are being, effectively implemented.

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

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

There was no practice Review completed in the 1 July to 30 September 2008 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 July to 30 September 2008 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 July to 30 September 2008 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 Parliamentary Secretary to the Minister for Health and Ageing, Senator the Hon Jan McLucas, in January 2008.

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.

During this quarter GTTAC considered the following items out-of-session:

- RARMP for licence application DIR 078/2007 (a limited and controlled release of sugarcane genetically modified for altered sugar production); and
- RARMP for licence application DIR 081/2007 (a limited and controlled release of cotton genetically modified for enhanced water use efficiency)

GTTAC did not meet during this quarter.

Further information about the work of GTTAC, including its communiqués, is available from the OGTR website www.ogtr.gov.au/committee/gttac

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 this quarter.

Further information about GTECCC is available from the OGTR website www.ogtr.gov.au/committee/gteccc

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 and presentation to:

- Environment Risk Assessment Workshop – 19-21 August 2008, Brasilia, Brasil.

Representatives of the OGTR met with the Research Director, Biosciences, Eastern and Central Africa on 2 September 2008, and with a Kazakhstani trade and agriculture delegation on 23 September 2008.

During the quarter the office continued to liaise with New Zealand (NZ) officials on arrangements for the 10th International Symposium on the Biosafety of Genetically Modified Organisms. This conference, co-sponsored by the OGTR will be held in Wellington NZ in November 2008.

A review entitled *Risks from GMOs due to Horizontal Gene Transfer* prepared by Dr Pual Keese from the OGTR was published in the online journal of *Environmental Biosafety Research* in September 2008.

See <www.ebr-journal.org/index.php?option=article&access=doi&doi=10.1051/ebr:2008014>

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 1 July to 30 September 2008 quarter the OGTR provided the following presentations:

- World Poultry Congress, 3 July 2008, Brisbane Queensland
- CSIRO Group Meeting , 7 August 2008, Adelaide, South Australia
- Society for Risk Analysis Conference, 29 September – 1 October 2008, Canberra, ACT.

The office held a training session for Institutional Biosafety Committees in Adelaide. The office also participated in technical subcommittee meetings to review Australian Standards, Safety in Laboratories – Microbiology.

The office also attended the following meetings:

- Australian Society for Microbiology Conference, 7 August 2008, Melbourne, Victoria
- Australian Seed Federation Conference, 19-21 August 2008, Hobart, Tasmania
- Agriculture in Climate Change – Crawford Fund Conference, 3 September 2008, Canberra, ACT
- ComBio, 22-25 September 2008, Canberra, ACT
- BSES Limited & CSIRO Sugarcane Projects, 23 October 2008, Canberra, ACT.

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 interdepartmental 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 no reviews were conducted as the OGTR and the ASF continued development of the next stage of the program. The OGTR also attended the ASF annual conference and presented on plans to expand the program to involve additional companies and to broaden the reach of the program across additional segments of the industry.

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OGTR website usage and statistics

The OGTR's 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 web site and the number of visitor sessions by month, and day of week pattern during the 1 July to 30 September 2008 quarter.

MONTH	HITS [1]	VISITORS[2]
July	1263457	40756
August	273922	53600
September	222987	17835

DAY OF THE WEEK PATTERN FOR THE QUARTER	HITS [1]	VISITORS[2]
Sunday	320897	6247
Monday	539962	10890
Tuesday	622519	11748
Wednesday	634267	9864
Thursday	517174	9411
Friday	44088	8088
Saturday	363698	5851

1 'A hit is a request made to the server. Each file that is requested is counted as a hit

2 "Visitors" is the number of times the OGTR website has been visited.

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The most popular pages viewed on the OGTR website during the period were:

List of applications and licences for Dealings involving Intentional Release (DIR) of GMOs into the environment
Licence Application Forms
About the OGTR
Licence Application and Assessment Process
What's New

Guidelines and Forms for Certification of Physical Containment Facilities
Record of GMOs and GM Product Dealings
Classes of dealings involving Genetically Modified Organisms (GMOs)
Forms & Guidelines
Publications

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
Record of GMO and GM Product Dealings - Fact sheets
The Biology and Ecology of Pineapple (*Ananas comosus var. comosus*) in Australia
PC2 Laboratory guidelines
The Biology of Carnation (*Dianthus caryophyllus*)
What dealings with GMOs are classified as exempt dealings
GM products approved as food, additives and processing aids
Guidelines for transport of GMOs

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
July	139	123
August	133	126
September	135	120

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 100 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 133 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 555 emails during the quarter.

Appendix 1

DNIR licences issued 1 July to 30 September 2008.

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR-441	15 July 2008	Queensland Institute of Medical Research, QLD	Characterizing Host Immunity to Plasmodium	The aims of this dealing are to characterise Plasmodium antigens in vitro and in vivo, to assess their suitability in the development of a malaria vaccine.
DNIR-442	18 July 2008	Children, Youth and Women's Health Service, SA	Lentivirus Gene Transfer to Treat Cystic Fibrosis Airway Disease	The purpose of this dealing is to test lentiviral HIV-1 vector systems for the treatment of cystic fibrosis.
DNIR-443	7 August 2008	CSIRO, VIC	Avian Influenza: A Study of Molecular Pathogenesis	The purpose of this dealing is to identify sequence changes in H5N1 influenza viral genes that cause differences in the severity of disease symptoms in avian and mammalian hosts.

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 contained 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 (for example, 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 (for example, 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 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