OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 JULY–30 SEPTEMBER 2007

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Publications Number P3 -2940

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 2007.

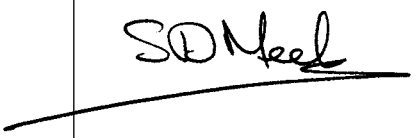
During the quarter changes to the gene technology regulatory system resulting from the All Governments' response to the *Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement 2001* were implemented smoothly, following the commencement of the provisions of the *Gene Technology Amendment Act 2007* and the Gene Technology Amendment Regulations 2007 on 1 July 2007.

Achievements relating to the discharge of my statutory functions include the issuing of one licence for a dealing involving the intentional release of genetically modified organisms (GMOs), two licences for dealings not involving intentional release of GMOs, and the certification of 40 physical containment facilities.

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

In addition, I prepared a risk assessment to assist the responsible minister in considering the first application for an Emergency Dealing Determination (EDD) in accordance with new powers under Section 72B(1) of the Act during the reporting period.

Yours sincerely



(Dr) Sue D Meek

Gene Technology Regulator

21 January 2008

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ABOUT THIS REPORT

Section 136 A (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. 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 2007 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 three 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.

Appendix

The appendix contains information on the number of Dealings Not involving Intentional Release (DNIR) licences issued during this quarter.

SECTION 1

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 July to 30 September 2007 quarter were:

Licences and other instruments

- one licence issued for a DIR of GMOs into the environment
- two licences issued for dealings not involving the intentional release (DNIR) of GMOs into the environment
- 40 physical containment facilities certified
- surrenders of 18 certifications and 16 DNIRs processed
- 201 variations processed.

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

Emergency Dealing Determination

The Regulator provided advice to the responsible Minister in relation to the making of the *Gene Technology (Equine Influenza Vaccine) Emergency Dealing Determination 2007*.

Monitoring and Compliance

Approximately 33 per cent of current field trial sites and 8 per cent of post harvest field trial sites were subjected to routine monitoring during the quarter. This exceeds the target minimum rate of 5 per cent per quarter.

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

Implementation of changes to the Gene Technology Legislation

During the quarter the OGTR assisted organisations and processed applications to effectively implement changes to the regulation of GMOs arising from the All Governments' Response to the *Statutory Review of the Gene Technology Act 2000* and the *Gene Technology Agreement 2001*.

Further information is contained in Section 4 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 relevant local councils twice during the evaluation of applications for all DIR licences, except limited and controlled releases.

For each application for a DIR licence other than a limited and controlled release, the Regulator seeks advice on matters relevant to the preparation of the Risk Assessment and Risk Management Plan (RARMP) and comment on the RARMP itself once it is prepared. For each application for a limited and controlled release, the Regulator is only required to seek comment on the RARMP.

More 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 prescribed Australian Government authorities and agencies and the Australian Government Environment Minister 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 (AQIS)
- 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 and Water Resources
- Department of Foreign Affairs and Trade
- Department of Industry, Tourism and Resources.

During the quarter, the Regulator sought advice and comment in respect of one RARMP.

Further information 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. During the quarter, the Regulator issued one invitation to the public to comment on one RARMP prepared in response to a DIR licence application. The invitation was issued via email or post to people who have registered on the OGTR mailing list and via advertisements in:

- The *Australian Government Gazette*
- *The Australian*
- The *Courier Mail*
- relevant regional or rural press including; *Queensland Country Life*, *Barrier Miner*, *Country Leader*, *The Rural*, *Western Magazine*
- OGTR website www.ogtr.gov.au

More information 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 July to 30 September 2007 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.

Applications received and decisions made

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. Then the timeframe for making a decision is 150 days or 170 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 processing.

- **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 processing.

- **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 processing.

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	0	1
DNIR licence	7	2
Accreditations	1	2
Certifications	82	40
GMO Register	0	0

* *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 the application is a limited and controlled release
- consideration of the applicant's suitability against disclosure of relevant convictions and/or revocations and suspensions of related licences and permits
- 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 determining whether the proposed dealings may pose a significant risk and proposed licence conditions to manage risks to human health and safety and the environment
- 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

- confirmation of the applicant's suitability, including capacity to meet licence conditions, and consideration of policy principles and any relevant policy guidelines.

Once these actions are completed, the Regulator can make a decision on whether to grant a licence and the conditions which are to be included in any licence.

The statutory timeframes for making a decision 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 is 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 minimum 30 days timeframes for the one or two rounds of consultation that the Regulator must undertake with 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.

Application received	Consultation on application	Consultation on RARMP	Withdrawn/ surrendered application	Licence Issued
		DIR 074/2007	DIR 018/2002	DIR 073/2007

Consultation on applications for Dealings involving Intentional Release licences

The Regulator invited comment from prescribed experts, agencies and authorities and the public, on the RARMP for the following application:

- DIR 074/2007—Limited and controlled release of GM insect resistant and/or herbicide tolerant Gossypium barbadense cotton—Monsanto Australia Limited.

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

Withdrawn/surrendered application for Dealings involving Intentional Release licences

One DIR licence was surrendered during the quarter following confirmation that all licence conditions had been met:

- DIR 018/2002—Field trial of oilseed poppy in Tasmania to evaluate alkaloid production—CSIRO.

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 170 day time-limit for a decision to be made on an application.

One request for further information was initiated in this quarter:

- DIR 072/2007—Commercial release of GloFish™ expressing red, green or yellow fluorescent proteins—Yorktown Technologies Limited Partnership (USA).

Decisions on applications for Dealings involving Intentional Release licences

During the quarter, the Regulator issued one DIR licence:

- DIR 073/2007—Limited and controlled release of GM insect resistant and insect resistant/herbicide tolerant cotton—Deltapine 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.

During the quarter the Regulator issued two 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.

Notifications of Notifiable Low Risk Dealings

This category of dealings with GMOs is defined in the Regulations and has been assessed as posing low risks based on national and international experience. Notifiable Low Risk Dealings (NLRDs) must comply with certain risk management conditions and be conducted by appropriately trained personnel in facilities certified to physical containment level PC2 or PC1, depending on which Schedule of the Regulations the dealings are listed in.

During the 1 July to 30 September 2007 quarter, the Regulator received nine NLRD notifications that related to dealings that commenced during the previous quarter.

As a result of amendments to the Act that took effect on 1 July 2007, NLRDs no longer need to be notified to the Regulator within 14 days of commencement.

NLRDs are now assessed by IBC's and do not require approval by the Regulator. The IBCs then advise the proponents of the dealing of their assessment and are required to provide a list of NLRDs in their Annual Reports to the Regulator.

Dealings placed on the GMO Register

Sections 78 and 79 of the *Gene Technology Act 2000* provides for the Regulator to place GMOs which have been previously licensed, pose minimal risks to people or the environment, and are safe to be used by anyone without the need for a licence on the GMO Register.

There were no applications to place any dealings on the GMO Register received during this quarter.

Emergency Dealing Determination

During this quarter, the first Emergency Dealing Determination (EDD) was issued in accordance with new powers in Part 5A of the Act which commenced on 1 July 2007, enabling the responsible Minister to expedite an approval of dealings with a GMO in an emergency.

The *Gene Technology (Equine Influenza Vaccine) Emergency Dealing Determination 2007* was made on 18 September 2007 and commenced on 20 September 2007, and temporarily authorised certain dealings with two genetically modified (GM) vaccines against equine influenza, ProteqFlu and ProteqFlu-TE. The dealings authorised by the EDD include the importation, transport, and disposal of the GM vaccines, and their possession and supply in the course of these dealings. Details of the EDD are available via the OGTR website at www.ogtr.gov.au/gmorecord/edd.htm

An EDD is a legislative instrument made under section 72B of the Act. EDDs are not made by the Regulator. The Gene Technology Ministerial Council's decision to amend the Act arose from recommendations made by the independent review panel, and recognition that situations may arise in which a rapid approval of dealings with a GMO may be required.

Before making an EDD the Minister must be satisfied that: (a) there is an actual or imminent threat to the health and safety of people or to the environment; (b) the dealings proposed to be specified in the EDD would, or would be likely to, adequately address the threat; and (c) any risks posed by the dealings proposed to be specified in the EDD are able to be managed in such a way as to protect the health and safety of people and to the environment.

The Minister must have received advice in relation to (a) (the threat) and (b) (addressing the threat) from: the Commonwealth Chief Medical Officer; the Commonwealth Chief Veterinary Officer; or the Commonwealth Chief Plant Protection Officer; and in relation to (c) (management of risks) from the Gene Technology Regulator. The States and Territories must also have been consulted.

In this case the Minister received advice regarding (a) and (b) from the Chief Veterinary Officer. The Regulator provided advice in relation to (c) based on a risk assessment which concluded that risks to people and the environment posed by the dealings proposed to be authorised by the EDD are able to be managed. Additional approvals were required from the Australian Quarantine Inspection Service and the Agricultural Pesticides and Veterinary Medicines Authority to import and administer the vaccine.

An EDD can only be made to have effect for up to six months but may be extended by the Minister with the majority agreement of the States and Territories.

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 processing. 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 the applications received to change existing licences and other instruments, as well as the number of applications processed during the quarter.

Type	Number received	Number processed*
Surrender of certification	24	18
Surrender of DIR licence	1	1
Surrender of DNIR licence	17	16
Surrender of accreditation	1	1
Variation of certification	189	186
Variation of accreditation	0	1
Variation of DIR licence	7	3
Variation of DNIR licence	12	11

* *Numbers reported in this quarter often relate to applications received in previous quarters. For the purposes of this table, 'processed' means the action on the licence or instrument was completed.*

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 can be found in Chapter 15 of the *Handbook on the Regulation of Gene Technology* which is available on the OGTR website.

During the quarter, the Regulator received one CCI application in relation to an application for a DIR licence application. The Regulator also made one CCI declaration in relation to an existing DIR application and one in relation to an existing DNIR application.

Monitoring and Compliance

The aim of OGTR monitoring and compliance activities is to ensure 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 per cent of field trial sites each year. To achieve this goal a minimum of five per cent of current trial sites and five per cent of trial sites subject to post-harvest monitoring are monitored each quarter.

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 per cent of PC4, PC3 and PC2 large-scale 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 2007 quarter, eight field trial sites with GM plants were subjected to monitoring visits.

- **Current field trial sites:** Of the 15 sites current in the quarter, five were monitored. This represents a monitoring rate of 33 per cent of all current sites for the quarter
- **Post-harvest field trial sites:** Of the 40 sites subject to post-harvest monitoring in the quarter, three were monitored. This represents a monitoring rate of 8 per cent of all sites subject to post-harvest monitoring in this quarter.

Other limited and controlled releases (eg animal trials) monitored: No monitoring of other limited and controlled releases occurred during the quarter.

Monitoring of certified facilities: Monitoring in connection to contained dealings covered five organisations and seven PC facilities. Monitoring of PC2 large scale laboratories (two visited), PC2 laboratories (four visited), and a PC2 plant containment facility (one visited).

Monitoring of contained dealings: During the quarter, the monitoring of the seven PC facilities mentioned above included monitoring for compliance with the general practices that must be followed when undertaking dealings (eg 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 July to 30 September 2007.

Licensed Organisation Name	Licence Number	No. sites visited	Site status *	Crop type
Queensland Department of Primary Industries and Fisheries	DIR 028/2002	3	C	Pineapple
Bureau of Sugar Experiment Stations	DIR 070/2006	2	C	Sugarcane
Dow AgroScience	DIR 044/2003	1	PHM	Cotton
Monsanto Australia	DIR 064/2006	2	PHM	Cotton
Totals	4 licences	8 sites	C = 5 PHM = 3	3 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 2007.

Licensed Organisation Name	Licence Number
Hospira Adelaide	DNIR 138/2002
Queensland Institute of Medical Research	DNIR 221/2003 DNIR 356/2005
Queensland University of Technology	DNIR 161/2002 DNIR 162/2002
Xenome	DNIR 165/2002
CSL Limited	DNIR 352/2005 DNIR 397/2006
Total	8 DNIR licences

Monitoring of Physical Containment Facilities

The organisations and the facility types the OGTR visited during the 1 July to 30 September 2007 quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
Queensland Institute of Medical Research	PC2 laboratory	2
Queensland University of Technology	PC2 laboratory PC2 plant containment facility	1 1
Xenome	PC2 laboratory	1
Pfizer Australia	PC2 large scale laboratory	1
Hospira Adelaide	PC2 large scale laboratory	1
Totals	3 facility types	7

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 for DIR's for the 1 July to 30 September 2007 quarter.

Organisation	Monsanto Australia Ltd
Licence number and site	DIR 064/2006, Sites 1 & 2
Summary of dealing	Licence relates to the limited and controlled release of water efficient genetically modified cotton (Gossypium hirsutum)
Findings	OGTR inspectors observed that 8 GMO cotton plants up to approximately 60cm in height had not been removed from the sites during the cleaning process. Although the plants were dry and appeared dead some had open bolls, with lint and seed present. The OGTR had been previously notified that the site had been cleaned and planted to wheat. The site was in the post harvest monitoring phase.
Assessment	It was established that the staff responsible for cleaning the sites believed that appropriate measures had been taken. However Monsanto Australia acknowledged that the sites had not been cleaned adequately and stated that they would revise their protocols regarding the cleaning of trial sites to ensure that similar incidents do not occur in the future. The 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 was required to remove and destroy the remaining plants. Monsanto Australia was reminded that it must ensure that trial sites are cleaned in accordance with licence requirements. No further action is required.

Findings for Dealings Not involving Intentional Release

There were no findings for DNIRs for the 1 July to 30 September 2007 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*	Equipment	Waste disposal	Work practices	Transport
7	3	0	0	0	0	0

**. PPE = Personal Protective Equipment*

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 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.

A Practice Review was conducted by the OGTR in this quarter which is summarised in the table below:

Organisation	Genetically Modified Ornamental Fish Practice Review
Issue	From June to August 2007 the OGTR conducted a practice review into the importation and supply of ornamental fish in Australia, with a particular focus on fish that have been genetically modified (GM) to express fluorescent proteins. This followed correspondence that the Regulator sent to importers of ornamental fish on 5 May 2007 providing details of the restrictions that apply to GM fish imports under the *Gene Technology Act 2000* (the Act) (see also www.ogtr.gov.au/moncomp/imports.htm). The review was also intended to provide information relevant to the consideration of a current application (DIR 072/2007) for a commercial release licence for fluorescing GM ornamental fish (GloFish™). The practice review included: • an assessment of quarantine arrangements for imported ornamental fish and situations where fluorescing ornamental fish had been intercepted and quarantined • an assessment of the supply chain of ornamental fish in Australia (including the inspection of 29 key premises across Australia) • a desk audit of Australian and overseas sources of supply of ornamental fish (including sale via the internet).
Determination	The review found that AQIS systematically examines ornamental fish imported through bulk air and sea shipments to Australia. Possible GM ornamental fish referred by AQIS to the OGTR have consistently been demonstrated to be GM (reported separately in the investigations section of this quarterly report). No fluorescent GM ornamental fish were found during the OGTR inspections. A desk audit of a sample of overseas exporters revealed an awareness of the restrictions applying to the import of GM fish into Australia. The Practice Review provided an opportunity to raise awareness through discussion of the requirements of the Act with key suppliers.
Action	The OGTR will continue to: • maintain communication and awareness raising regarding compliance requirements with key suppliers, the industry and enthusiasts • work in co-operation with AQIS on quarantine import interventions.

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 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 (eg, 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 2007 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 was one investigation completed in the 1 July to 30 September 2007 quarter which is summarised in the table overleaf.

Type	Unauthorised importation
Name	GM zebrafish (*Brachydanio rerio*) and Japanese Rice Fish (*Oryzias latipes*).
Current status	Investigation finalised.
Allegation	Inquiries instigated as a result of the AQIS referrals of instances of importation of ornamental fish suspected to be GM.
Summary of Investigation	Ornamental fish that have been modified to express fluorescent proteins which enhance their colour are known to be commercially available internationally. The genes that encode these proteins have been isolated from marine organisms including jellyfish, anemone coral and include genes for green, yellow and red fluorescent proteins. The OGTR conducted a thorough investigation which also aimed to improve compliance with import requirements. AQIS has arrangements in place to actively monitor imports of ornamental fish. Any ornamental fish that are suspected to be GM are referred to the OGTR.
Findings	Some overseas exporters claimed that the fluorescent colours were created by either dyeing the fish or feeding them hormones. However, when seized fish were tested they were confirmed to be GM. The importers voluntarily handed the fish to AQIS Inspectors for humane destruction prior to release from quarantine. The importers would otherwise have required a licence under the *Gene Technology Act 2000* to keep and sell the GM fish commercially.
Risk Assessment and Management	OGTR investigations have ensured that shipments containing GM fish were humanely destroyed with the agreement of importers. A Risk Assessment found negligible risk to human health and safety and the environment from these importation incidents. The OGTR has conducted a practice review with exporters, importers, industry and enthusiasts (as reported in the Practice Review Section of this Quarterly Report). The OGTR will continue to work in co-operation with AQIS on quarantine import interventions in accordance with each agency's operational requirements and responsibilities.

SECTION 3

STATUTORY COMMITTEE OPERATIONS

STATUTORY COMMITTEE OPERATIONS

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

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

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 073/2007 (a limited and controlled release of genetically modified insect resistant and insect resistant/herbicide tolerant cotton from Deltapine Australia)
- RARMP for licence application DIR 074/2007 (a limited and controlled release of genetically modified insect resistant and/or herbicide tolerant Gossypium barbadense cotton from Monsanto Australia)

Feedback on the advice received will be provided at the next meeting of GTTAC on 4 December 2007.

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

Gene Technology Community Consultative Committee

As set out in section 107 of the Act, the functions of the Gene Technology Community Consultative Committee (GTCCC) are to provide advice on the request of the Regulator or the GTMC, on matters of general concern identified by the Regulator in relation to applications made under this Act, matters of general concern in relation to GMOs 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.

The term of the current GTCCC membership expired on 30 June 2007.

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

Gene Technology Ethics Committee

As set out in section 112 of the Act, the functions of the Gene Technology Ethics Committee (GTEC) are to provide advice on the request of the Regulator or the Ministerial Council, ethical issues relating to gene technology, the need for, and content of codes of practice in relation to ethics in respect of contained dealings with GMOs and the need for and content of policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons.

GTEC did not meet during this quarter. GTEC will next meet in Canberra on 22 November 2007.

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

SECTION 4

OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

Implementation of the *Gene Technology Amendment Act 2007* and the Gene Technology Amendment Regulations 2007

The *Gene Technology Amendment Act 2007* and the Gene Technology Amendment Regulations 2007 commenced on 1 July 2007. These amendments implement legislative changes as agreed in the All Governments' response to the recommendations of an independent statutory review of the Act commissioned by the Gene Technology Ministerial Council.

Pursuant to preparatory work, including national IBC training and issuing of related guidelines, conducted in the previous quarter, the Regulator wrote to all accredited organisations to formally advice them of the commencement of the amended legislation. Over the quarter the OGTR responded to a range of queries from instrument holders and received approximately sixty applications for PC1 certified facilities and related changes to DNIR licences.

The OGTR also continued to progress the nomination process for membership of the GTTAC and the new advisory committee created by the Amendment Act—the Gene Technology Ethics and Community Consultative Committee (GTECCC). The GTECCC will combine the functions of the current GTEC and GTCCC and will commence from 1 January 2008. Following a call for nominations which closed on 4 June 2007, a shortlisting process was undertaken by the Gene Technology Standing Committee.

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 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 presentations to and/or participation in:

- APEC Workshop on Liability and Redress under the Biosafety Protocol—Gene Technology Regulation in Australia: Structure and Scope of the *Gene Technology Act 2000*—19 to 21 Sept 2007, Hanoi, Vietnam
- International Congress of Insect Biotechnology—19 to 24 August 2007, Daegu, Republic of Korea.

In July, an OGTR staff member was also invited to participate in a consultation to draft an international guidance paper on definitions and processes for problem formulation in GMO risk assessments. This exercise is being coordinated by the International Life Sciences Institute Research Foundation, a non-profit organization with funding from the US Environmental Protection Agency and Health Canada.

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 2007 quarter the OGTR provided the following presentations:

- Weed Risk Assessment Workshop—Post-Border Weed Risk Management Systems —3–4 July 2007, Adelaide South Australia
- Australasian Biosafety Association—Certification of Containment Facilities by the OGTR—–9 July 2007, Adelaide, South Australia
- AusBiotech: BioForum '07: Shaping the Future—Update on Australia's Gene Technology Regulation—17 August 2007, Geelong, Victoria
- University of Sydney—IBC Training—24 September 2007, Sydney, New South Wales.

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 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; Food Standards Australia and New Zealand; and the OGTR.

The OGTR is responsible for implementing the UP strategy and has liaised closely with the Australian Seed Federation to develop a voluntary auditing and testing program of existing industry quality assurance measures. During the quarter, OGTR reviewed the quality assurance systems of two companies (HSR Group Pty Ltd and Pioneer Hi-Bred Australia Pty Ltd) and did not identify any issues of concern.

OGTR Website Usage and Statistics

The OGTR's website is a comprehensive and increasingly popular 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 2007 quarter.

MONTH	HITS[1]	VISITORS[2]
July	1414544	60990
August	1471145	48574
September	1344532	35218

DAY OF THE WEEK PATTERN FOR THE QUARTER	HITS [1]	VISITORS[2]
Sunday	560206	19319
Monday	653466	20864
Tuesday	636174	21771
Wednesday	657945	21650
Thursday	633367	22199
Friday	609423	20620
Saturday	510608	17402

1 'Hits' are the number of times the files started to download or did not fully download.
2 'Visitors' are actual downloads.

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

- Index/Home
- What's New
- Search
- Handbook on the Regulation of Gene Technology in Australia
- About the OGTR
- GMO Record
- IBC and Accredited Organisations
- Intentional Release and Evaluation Processes
- Media Information
- Publications and Forms.

The most popular downloaded documents were:

- Risk Analysis Framework (2nd edition)
- Handbook on the Regulation of Gene Technology in Australia
- DIR 069/2006 RARMP for limited and controlled release of GM herbicide tolerant canola and Indian mustard
- The Biology & Ecology of Wheat (*Triticum aestivum L.*) in Australia
- Risk Analysis Framework (1st edition)
- The Biology & Ecology of White Clover (*Trifolium repens L.*) in Australia

- DIR 066/2006 RARMP for Commercial release of GM herbicide tolerant and/or insect resistant cotton lines north of latitude 22° South
- OGTR Media Releases
- The Biology & Ecology of Pineapple (*Ananas comosus var. comosus*) in Australia
- The Biology & Ecology of Carnation (*Dianthus caryophyllus*) in Australia
- Forms.

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	86	976
August	117	145
September	145	145

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 whilst monitoring staff are away from the office. The inbox received 50 emails during the quarter.

Statutory Committee Email inbox

The Regulatory Practice and Secretariat Section maintain an email inbox to facilitate efficient communication between committee members and secretariat staff.

The inbox ensures that all communications are answered in a timely manner by secretariat staff. The inbox received 56 emails during the quarter.

Freedom of Information Requests

No freedom of information request was received by the OGTR during the reporting period.

APPENDICES

APPENDIX 1

DNIR Licences issued 1 July to 30 September 2007

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 418/2007	17 September 2007	Biotron Limited, Australian Capital Territory	Anti Viral Drugs	The purpose of this dealing is to use GM viruses to understand how novel anti-HIV drugs act against HIV-1 and confirm the target site of drug activity
DNIR 415/2007	2 July 2007	The University of Western Australia, Western Australia	A phase I/II human gene therapy trial to establish the base line safety and efficacy following a single subretinal injection of rAAV. sFlt-1 for the treatment of exudative age related macular degeneration (AMD)	The purpose of this dealing is to conduct a phase I/II clinical trial of a genetically modified replication defective *Adeno-associated virus* in patients suffering exudative age related macular degeneration

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 (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
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics 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 (eg 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