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

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 JANUARY–31 MARCH 2008

The object of the *Gene Technology Act 2000* is:

'to protect the health and safety of people, and 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 January to 31 March 2008.

During this period the then Gene Technology Regulator, Dr Sue Meek issued five licences for dealings not involving intentional release of GMOs, and certified 51 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.

The provisions of the *Gene Technology Amendment Act 2007* (the Amendment Act) establishing the Gene Technology Ethics and Community Consultative Committee, replacing the former Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee commenced on 1 January 2008. The appointment process for the gene technology advisory committees was finalised during the quarter.

In February, Dr Meek advised the Gene Technology Ministerial Council of her intention to resign as the Gene Technology Regulator with effect from 30 April 2008. Dr Meek will take on a new role with the Australian Academy of Science from May.

Yours sincerely

Elizabeth Flynn
A/g Gene Technology Regulator

14 May 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 January to 31 March 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.

SECTION 1

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 January to 31 March 2008 quarter were:

Licences and other instruments

- five licences issued for DNIRs of GMOs into the environment
- 51 physical containment facilities certified
- processing surrenders of 23 certifications and 12 licences
- 299 variations processed.

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

Monitoring and Compliance

Approximately 25 percent of current field trial sites and 6 percent of post harvest field trial sites were subjected to routine monitoring during the quarter. This exceeds the target minimum rate of 5 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 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.

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 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 Water, Heritage and the Arts
- Department of Foreign Affairs and Trade
- Department of Innovation, Industry, Science and Research.

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

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. One invitation to the public to comment on a RARMP was issued during the quarter.

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

SECTION 2

REGULATION OF GENETICALLY MODIFIED ORGANISMS

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of the report outlines the regulatory activity undertaken during the 1 January to 31 March 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. 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 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	2	0
DNIR licence	8	5
Accreditations	3	3
Certifications	76	51

* *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 considering 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
- confirming the applicant's suitability, 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 licence if issued.

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 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*	Withdrawn applications	Surrendered licence
DIR 084/2008	DIR 078/2007	DIR 072/2006	DIR 017/2002
DIR 085/2008	DIR 079/2007		
	DIR 080/2007		
	DIR 081/2007		
	DIR 082/2007		
	DIR 083/2007		
	DIR 084/2007		

* *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.*

Applications received for Dealings involving Intentional Release licences

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

- 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.

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 seven 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.

One invitation to comment on a RARMP was issued during the quarter—DIR 076/2007 Limited and controlled release of banana genetically modified for enhanced nutrition.

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 applications and surrendered licences for Dealings involving Intentional Release licences

One DIR licence application was withdrawn during the quarter. One DIR licence was surrendered, following confirmation by the Monitoring Section that all licence conditions had been met:

- DIR 072/2006—Commercial release of GloFish™ expressing red, green or yellow fluorescent proteins was withdrawn
- DIR 017/2002—Field trials of insect resistant cotton was surrended.

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.

No requests for further information were initiated in this quarter.

Decisions on applications for Dealings involving Intentional Release licences

No DIR licences were issued during this quarter.

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 five 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 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[1]
Surrender of certification	15	23
Surrender of DIR licence	1	1
Surrender of DNIR licence	7	11
Variation of certification[2]	317	283
Variation of DIR licence	1	1
Variation of DNIR licence	25	15
Applications for CCI	5	6

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.*

2 *Large number of applications to vary certifications of contained facilities in response to recent revisions to guidelines and often coincides with pending expiry of existing instruments.*

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 four CCI applications in relation to DIR licence applications, and one CCI application in relation to a DNIR licence application. The Regulator also made six CCI declarations in relation to DIR applications.

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 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 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 January to 31 March 2008 quarter, eight field trial sites with GM plants were subjected to monitoring visits.

- **Current field trial sites:** Of the 24 sites current in the quarter, 6 were monitored. This represents a monitoring rate of 25 percent of all current sites for the quarter
- **Post-harvest field trial sites:** Of the 32 sites subject to post-harvest monitoring in the quarter, 2 were monitored. This represents a monitoring rate of 6 percent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection to contained dealings covered six organisations and 15 PC facilities. Monitoring of PC facilities encompassed PC2 laboratories (eight visited), PC3 laboratories (two visited), PC2 animal containment facilities (three visited), PC2 plant containment facility (one visited) and PC2 arthropod facility (one visited).

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

Eight DNIRs were monitored during the quarter.

Monitoring of Dealings involving Intentional Release

The following table summarises monitoring activities for field trials with GM crop plants for the period between 1 January to 31 March 2008.

Licensed Organisation Name	Licence Number	No. sites visited	Site status*	Crop type
Bayer CropScience Pty Ltd, South Australia	DIR 032/2002	1	PHM	Canola
Bayer CropScience Pty Ltd, South Australia	DIR 069/2006	2	Current	Canola
CSIRO, New South Wales	DIR 067/2006	1	Current	Cotton
CSIRO, New South Wales	DIR 067/2006	1	PHM	Cotton
CSIRO, Australian Capital Territory	DIR 054/2004	1	Current	Wheat
Hexima Limited, New South Wales	DIR 063/2005	1	Current	Cotton
Monsanto Australia Limited, New South Wales	DIR 074/2007	1	Current	Cotton
Totals		8	C = 6 PHM = 2	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 January to 31 March 2008.

Licensed Organisation Name	Licence Number
Peter MacCallum Cancer Research, Victoria	DNIR 314/2004
RMIT University, Victoria	DNIR 007/2001
The University of Melbourne, Victoria	DNIR 204/2003
	DNIR 205/2003
Australian National University, Australian Capital Territory	DNIR 097/2002
	DNIR 159/2002
CSIRO, Australian Capital Territory	DNIR 164/2002
	DNIR 358/2005
Total	8 DNIR licences

Monitoring of Physical Containment Facilities

The organisations and the facility types the OGTR visited during the 1 January to 31 March 2008 quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
Peter MacCallum Cancer Research, Victoria	PC2 laboratory	1
RMIT University, Victoria	PC2 laboratory	1
	PC2 animal containment	1
The University of Melbourne, Victoria	PC2 laboratory	2
	PC3 laboratory	1
Macfarlane Burnet Institute for Medical Research & Public Health, Victoria	PC3 laboratory	1
Australian National University, Australian Capital Territory	PC2 laboratory	3
	PC2 animal containment	1
CSIRO, Australian Capital Territory	PC2 laboratory	1
	PC2 animal containment	1
	PC2 plant containment	1
	PC2 arthropod	1
Totals	5 facility types	15

Monitoring Findings

Dealings involving Intentional Release

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

Findings by inspectors of inconsistencies between an event or state of affairs and the requirements imposed by licence or certification conditions are called non-compliances in this report. However, non-compliances are not regarded as breaches of licence conditions unless proven to be so after investigation. Non-compliances with licence conditions are assessed against a number of considerations before determining the OGTR response. The following aspects of the findings are taken into account as relevant:

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

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

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

Findings for Dealings involving Intentional Release

There were no findings for DIRs for the 1 January to 31 March 2008 quarter.

Findings for Dealings Not involving Intentional Release

There was one finding for a DNIR for the 1 January to 31 March 2008 quarter.

Organisation	Australian National University, Australian Capital Territory
Licence number and site	DNIR 097/2002
Summary of dealing	The permitted experiments include identification and characterisation of *Phytophthora* genes that are involved in the infection of host plants.
Findings	OGTR inspectors observed that a glass flask was used as the primary container for transporting liquid GMO waste out of the facility to the autoclave room for destruction. The flask was not adequately sealed and unbreakable as required by the Regulator's *Guidelines for the Transport of GMOs*.
Assessment	Whilst the primary container was not appropriate it was packed inside a secondary container that was sealed and unbreakable. The compliance history of the Australian National University is good, and they have made the necessary changes to their transport procedures. The risk to human health and safety and the environment as a result of this non-compliance was assessed as negligible.
Compliance management	Australian National University was reminded of the requirement that all transport of GMOs out of the facility must be in accordance with the Regulator's *Guidelines for the Transport of GMOs*.

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
15	5	1	0	3	1	1

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 practices being used pose potential human health or environmental risks that require management actions to be implemented. In certain instances, where a suspected non-compliance with the Act is identified, the issue may be referred for investigation.

There was one Practice Review completed in the 1 January to 31 March 2008 quarter.

Practice Review	Waste Management Practice Review
Issues	The OGTR has conducted a practice review into the management of GMO waste containing GMOs. The review aimed to: • examine the likelihood and consequences of the unauthorised dissemination of GMOs and/or non-compliances under the *Gene Technology Act 2000* by examining the waste disposal practices of licence holders and commercial waste services • gain an understanding of the structure and operations of the waste management industry in Australia • apply the findings to the development of licence conditions and guidelines.

Determination	The review: • took account of applicable regulatory arrangements for clinical and related wastes in states and territories and at the national level • included the assessment of the waste management practices and arrangements of licencees responsible for contained dealings and field trials • confirmed that the majority of GMO waste is rendered inert or destroyed in an approved way at the site of the research as required by licences and guidelines and as monitored by the OGTR • confirmed that in the few exceptional circumstances where GMO waste can not be rendered inert within the research facility/containment area, licencees arrange to transport the GMOs in an appropriately contained form to final destruction (e.g. high temperature incineration) as required by licences and guidelines • assessed the Australian commercial infrastructure for waste collection, transport, containment and destruction, available to licencees and found that there is adequate infrastructure and expertise to provide for compliance in meeting waste management licence requirements and guidelines • found that effective licencee management of GMO waste is supported by routine auditing by Institutional Biosafety Committees of internal waste management practices and service providers • confirmed that audits, practice reviews and routine monitoring appear to play an important role in keeping licencee/accredited organisation awareness and concern for GMO waste management compliance high • found no additional considerations that warrant amendments to licence conditions or for the development and maintenance of additional guideline requirements at this time.
Action	This issue will continue to be subject to ongoing OGTR monitoring, periodic practice reviews and audits.

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 (e.g. dealings with a common host organism or dealings within a common climatic zone), the activity of an organisation across a range of dealings, or an activity common to a range of organisations.

There were no audits completed in the 1 January to 31 March 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 January to 31 March 2008 quarter.

SECTION 3

STATUTORY COMMITTEE OPERATIONS

STATUTORY COMMITTEE OPERATIONS

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

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

Appointments to the two gene technology advisory committees were made by the 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.

The term of the second GTTAC triennium expired on 8 December 2007 and appointment of members for the third GTTAC triennium was finalised in January 2008.

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

The Gene Technology Ethics and Community Consultative Committee (GTECCC) is a new Committee that replaces the former Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC). The terms of GTEC and GTCCC expired on 8 December 2007 and 30 June 2007 respectively.

GTECCC was established through changes to the Act introduced by the *Gene Technology Amendment Act 2007* (the Amendment Act). The Amendment Act gave effect to the response agreed by Commonwealth, State and Territory Governments to the recommendations made by the *Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement 2001*. Most of the provisions of the Amendment Act commenced on 1 July 2007, however the date for the commencement of GTECCC was 1 January 2008.

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 Information about the work of the former GTEC and GTCCC, including their communiqués, is available from the OGTR website www.ogtr.gov.au/committee

SECTION 4

OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

International Collaboration and Coordination

Under the Act the Regulator's functions include:

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

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.

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 January to 31 March 2008 quarter the OGTR provided the following presentation:

- Agricultural Subcommittee of the Finance Committee of the Parliament of Finland at the Department of Agriculture, Fisheries and Forestry—the regulation of gene technology in Australia—6 February 2008, Canberra, ACT.

The office continued to hold training sessions for Institutional Biosafety Committees in Melbourne and Sydney. The office also participated in technical subcommittee meetings to review Australian Standards, Safety in Laboratories—Microbiology.

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; 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 assessed the effectiveness of the first stage of reviews.

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 January to 31 March 2008 quarter.

MONTH	HITS[1]	VISITORS[2]
January	1307728	30468
February	1244956	30853
March	1353703	35425

DAY OF THE WEEK PATTERN FOR THE QUARTER	HITS [1]	VISITORS[2]
Sunday	492004	12433
Monday	595715	15591
Tuesday	586811	15165
Wednesday	596206	14711
Thursday	581921	14418
Friday	558058	13344
Saturday	495672	11084

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 how many times the OGTR website has been visited.

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

- Home Page
- What's New
- Handbook on the Regulation of Gene Technology in Australia
- GMO Record
- Intentional Release and Evaluation Process
- About the OGTR
- Media Information
- Publication and Forms—Certification of Physical Containment Facilities.

The most popular downloaded documents were:

- Risk Analysis Framework
- The Biology and Ecology of Wheat (*Trifolium repens L.*) in Australia
- Handbook on the Regulation of Gene Technology in Australia
- The Biology and Ecology of Pineapple (*Ananas comosus var. comosus*) in Australia
- The Biology and Ecology of Carnation (*Dianthus caryophyllus*) in Australia
- DIR 069/2007 Risk Assessment and Risk Management Plan
- Annual Report 2006–07
- The Biology and Ecology of Papaya (*Carica papaya*) in Australia
- The Biology and Ecology of Canola (*brassica napus*) in Australia
- The Biology and Ecology of Cotton (*Gossypium hirsutum L.*) in Australia.

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

Internet Contacts and Freecall Number

OGTR Email Address and Freecall Number

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

MONTH	EMAILS	OGTR 1800 NUMBER
January	130	97
February	134	142
March	89	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 whilst monitoring staff are away from the office. The inbox received 43 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 96 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 402 emails during the quarter.

APPENDICES

APPENDIX 1

DNIR Licences issued 1 January to 31 March 2008.

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 427/2007	7 February 2008	CSIRO, Victoria	Molecular identification and characterisation of the virulence and host range determinants of SARS and SARS-like *coronaviruses*	The aims of this dealing are to investigate the role of virulence and host-range determinants *in vitro* in Severe Acute Respiratory Syndrome (SARS) and SARS-like *coronaviruses*
DNIR 428/2007	7 February 2008	CSIRO, Victoria	Identification of virulence factors for *Henipaviruses*	This study aims to generate recombinant *Hendra virus* and *Nipah virus* that include mutations or deletions in viral genes or the non-coding regions to determine their role in *Henipavirus* pathogenesis and transmission

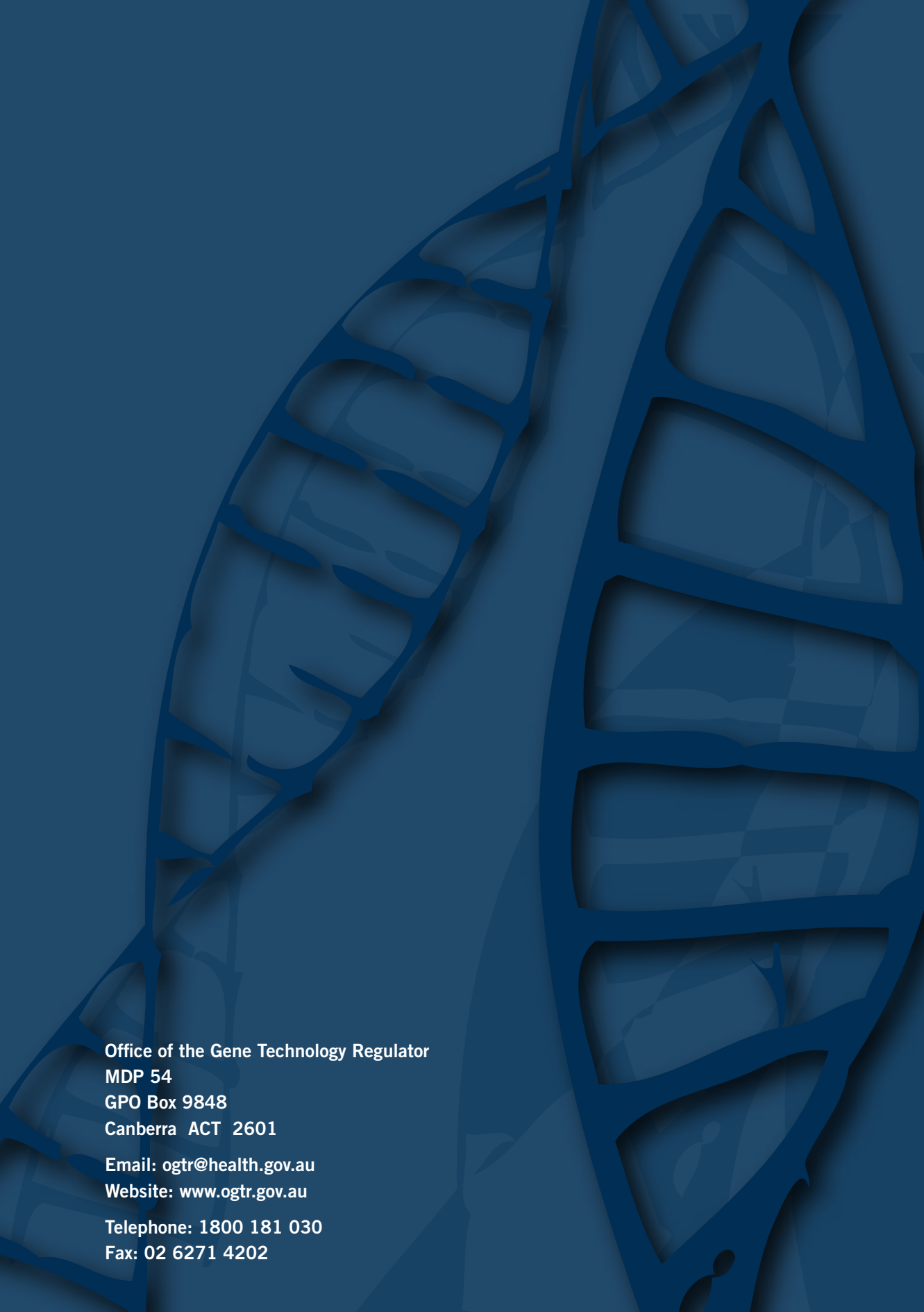
Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 429/2007	21 February 2008	Cargill Australia Limited, Victoria	Importation of US Corn for further processing into stockfeed	The aim of this dealing is to import corn which potentially includes GM lines into Newcastle and Melbourne for processing to produce domestic stockfeed
DNIR 431/2007	8 March 2008	Children, Youth and Women's Health Service, South Australia	Lentiviral-mediated gene therapy	Development and testing of lentiviral HIV-1 vector systems for the treatment of monogenic diseases
DNIR 432/2007	31 March 2008	University of Technology, Sydney, New South Wales	Insulin storage and release from liver hepatocytes	The purpose of the proposed dealings is to develop a somatic cell gene therapy system using lentiviral vectors for the treatment of diabetes

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 GTECCC to assist them in the performance of their functions (expert advisers are not committee members)
EDD	Emergency Dealing Determination
FSANZ	Food Standards Australia New Zealand
GM	Genetically modified
GM product	A thing (other than a GMO) derived or produced from a GMO

GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically modified organism
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
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 (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



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