Quarterly Report of the Gene Technology Regulator for the period 1 October to 31 December 2004

ISBN 0 642 82589 0

This report can be accessed through the Internet at www.ogtr.gov.au.

Produced by:

Office of the Gene Technology Regulator
MDP54 PO Box 100
WODEN ACT 2606

Email: ogtr@health.gov.au
Website: www.ogtr.gov.au
Telephone: 1800 181 030
Fax: 02 6271 4202

Inquiries about the content of this report may be directed to the Policy, Secretariat and Communications Section of the Office of the Gene Technology Regulator.

Commonwealth Department of Health and Ageing

Publications Approval Number 3576

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

The Hon Christopher Pyne MP
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*, I am pleased to present to you the Quarterly Report of the Gene Technology Regulator, covering the period 1 October to 31 December 2004.

During this quarter, key achievements included the issuing of one licence for dealings involving the intentional release of a genetically modified organism, 11 licences for dealings not involving intentional release of genetically modified organisms, five organisations were accredited and 72 contained facilities were certified.

Routine monitoring activities for this quarter have again been well above the minimum target rate and no significant risks to either human health or the environment were identified.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator
29 April 2005

Address: MDP 54 PO Box 100 Woden ACT 2606 Website: www.ogtr.gov.au
Telephone: 1800 181 030 Facsimile: 02 6271 4202

Contents

Glossary

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	*see* 'Non-compliance'
CCI	Confidential commercial information
Certified contained facility	A building or place certified by the Regulator to a specified containment level under section 84 of the Act
Clock stop	The period during which an application evaluation is suspended – usually whilst awaiting further information from the applicant
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 contained 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 advice to either GTTAC or GTEC to assist them in the performance of their functions (expert advisers are not committee members)
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 risk to human health or the environment
NLRD	Notifiable low risk dealing (e.g. plant or tissue culture work undertaken in a certified contained facility)
Non-compliance	A failure to comply with legislative requirements including licence, accreditation or certification conditions
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

Introduction

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:

- genetically modified organism (GMO) licences issued during the quarter
- any breaches of conditions of a GMO licence 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.

Structure of this report

This report is divided into four parts:

Part 1 outlines activities and outcomes achieved in relation to the implementation and management of the national regulatory system during the October - December 2004 quarter.

Part 2 details 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.

Part 3 reports on the activities of the three advisory committees established under the Act to assist the Regulator and the Gene Technology Ministerial Council (GTMC).

Part 4 summarises other activities undertaken by the Office of the Gene Technology Regulator (OGTR), including reviews and research, international collaboration and coordination, advice provided on gene technology regulation, freedom of information requests received and consultant contracts managed during this quarter.

Further information

Further information about regulation of GMOs can be obtained by contacting:

Office of the Gene Technology Regulator
MDP 54 PO Box 100
WODEN ACT 2606

Email: ogtr@health.gov.au
Website www.ogtr.gov.au
Telephone: 1800 181 030
Fax: (02) 6271 4202

PART 1 National regulatory system

Key achievements during this quarter

The key achievements of the October - December 2004 quarter were:

Licences and other instruments

- 1 licence issued for a dealing involving the intentional release of a GMO into the environment (DIR licence).
- 11 licences issued for dealings not involving intentional release of GMOs into the environment (DNIR licences).
- 63 Notifiable low risk dealing (NLRD) notifications received.
- 5 organisations accredited.
- 72 contained facilities certified.
- 29 surrender of certifications processed.
- 1 surrender of a DIR licence processed.
- 524 variations processed.

More information on licences and other instruments is contained in Part 2 of this report.

Monitoring and compliance

Approximately 52 per cent of current field trial sites and five per cent of post harvest field trial sites were subjected to routine monitoring during the quarter. This exceeds the target minimum rate of five per cent per quarter.

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

Working collaboratively with States and Territories

State and Territory consultation

The Regulator must consult with State and Territory Governments and relevant local councils twice during the evaluation of applications for DIR licences.

For each application for a DIR licence, 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.

More information is contained in Part 2.

Gene Technology Ministerial Council

The GTMC consists of one Minister from each State and Territory and one Minister from the Australian Government. Currently, the Ministerial Council comprises Ministers from a range of portfolios including health, agriculture, environment and innovation. The Council is chaired by Queensland.

The Ministerial Council did not meet this quarter.

Gene Technology Standing Committee

The Gene Technology Standing Committee (GTSC) supports the work of the GTMC, and consists of a senior government official from each jurisdiction with responsibility for coordinating gene technology issues.

The GTSC held a teleconference on 10 November 2004.

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. Advice is sought on matters relevant to preparing the RARMP for each application made to the Regulator for a DIR licence.

In this context, the Regulator consults with the following prescribed Australian Government authorities and agencies:

- Food Standards Australia New Zealand
- Australian Quarantine and Inspection Service
- National Health and Medical Research Council
- National Industrial Chemicals Notification and Assessment Scheme
- Australian Pesticides and Veterinary Medicines Authority
- Therapeutic Goods Administration.

Once a RARMP is prepared, the Regulator again seeks comment on the RARMP from the same prescribed Australian Government authorities and agencies.

In addition, comment is sought on each application and 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 Heritage.
- Department of Foreign Affairs and Trade.
- Department of Industry, Tourism and Resources.

During the quarter, the Regulator sought advice and comment in respect of two applications for a DIR licence and two RARMPs.

Further information is set out in Part 2.

Public participation

During the quarter, the Regulator issued two invitations to the public to comment on RARMPs prepared for applications for a DIR licence. The invitations were issued via email or post to people who have registered on the OGTR mailing list and via advertisements in:

- the *Australian Government Notices Gazette*
- *The Weekend Australian* newspaper
- relevant regional press, such as *The Weekend Advertiser,* Wagga Wagga NSW, and rural press such as *Queensland Country Life* and *The Land.*
- OGTR website www.ogtr.gov.au.

Further information is set out in Part 2.

PART 2 Regulation of genetically modified organisms

Part 2 of the report outlines the regulatory activity undertaken during the October - December 2004 quarter. This includes information about applications for, and action taken with respect to, GMO licences and other instruments under the Act. It also includes details of monitoring activities and any breaches of conditions of a GMO licence that have come to the Regulator's attention. 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:

- **Dealing involving Intentional Release (DIR) licences**

  DIR licences authorise dealings ranging from limited and controlled releases (field trials) through to more extensive commercial releases of GMOs. These licence applications have a statutory timeframe of 170 working days for processing.

- **Dealing Not involving Intentional Release (DNIR) licences**

  DNIR licences authorise contained dealings carried out in certified laboratories and other contained facilities that are designed to prevent release of the GMO into the environment. These licence applications have a statutory timeframe of 90 working days for processing.

- **Accreditations of organisations**

  Licences may 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 contained facilities**

  Certification assists to satisfy the Regulator that a facility which is proposed to be used to conduct a dealing 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.

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.

Applications received and decisions made, new licences and other instruments 1 October - 31 December 2004

Application type	Number received	Number approved[1]
DIR licence	0	1
DNIR licence	9	11
Accreditations	6	5
Certifications	45	72

1. Approvals reported in the current quarter mainly relate to applications received in previous quarters.

Processing of applications for Dealings involving Intentional Release (DIR) 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 proposed dealings may pose a significant risk to human health and safety and the environment
- seeking comments from prescribed expert groups and key stakeholders (including the public if a significant risk is identified) on issues to consider in the RARMP
- preparing a consultation RARMP, including proposed licence conditions to manage risks to human health and safety and the environment
- seeking comments from prescribed expert groups and key stakeholders (including the public) on the RARMP
- considering all comments relating to the protection of human health and safety and the environment in finalising the RARMP
- consideration of applicant's suitability, 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 Regulator must make a decision on an application for a DIR licence within 170 working days of receiving the application. This timeframe effectively extends over approximately 9 months as it excludes weekends and public holidays in the Australian Capital Territory (ACT).

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 timeframes for the two rounds of consultation that the Regulator must undertake with prescribed expert groups and key stakeholders during the processing of each DIR application. However, longer periods are usually allowed to facilitate the provision of information and promote involvement in the decision-making process particularly by the community. Therefore an application for a DIR licence can not normally be received and decided upon within the same three month reporting period.

The following table shows the status of applications for DIR licences that underwent evaluation during the quarter.

Status, as at 31 December 2004, of applications for a DIR licence subject to evaluation during the quarter

Application received	First round of consultation[1]	Second round of consultation	Withdrawn applications	Licence Issued
	DIR 045/2004[2] DIR 046/2004[2] DIR 050/2004[2] DIR 053/2004 DIR 054/2004 DIR 055/2004 DIR 056/2004[2] DIR 057/2004	DIR 051/2004 DIR 052/2004		DIR 49/2004

1. Includes posting of 'Early Bird' Notifications and summaries of applications on the OGTR website and to people on the OGTR mailing list.

2. The clock was stopped on these applications

Applications received for DIR licences

The OGTR received no applications for DIR licences in the October - December 2004 quarter.

Consultation on applications for DIR licences

In this quarter, consultations with expert groups and key stakeholders took place as part of first round consultations to help identify risks to human health and safety and/or the environment to be considered in the RARMP for the following applications:

- DIR 053/2004 'Field trial of genetically modified salt tolerant wheat on saline land' (Grain Biotech Australia Ltd)
- DIR 054/2004 'Field trial of genetically modified wheat with altered grain starch' (CSIRO)
- DIR 055/2004 'Field trials of herbicide tolerant (Roundup Ready® Flex MON 88913) and herbicide tolerant/insect resistant (Roundup Ready® Flex Mon 88913/Bollgard II®) cottons' (Monsanto Australia Ltd)
- DIR 056/2004 'Commercial release of herbicide tolerant cotton (LLCotton25) for use in the Australian cropping system' (Bayer CropScience Pty Ltd)
- DIR 057/2004 'Field trials of genetically modified herbicide tolerant hybrid *Brassica juncea*' (Bayer CropScience Pty Ltd)

Although not required to by the Act, the Regulator also issued 'Early Bird Notifications' to people and organisations on the OGTR's mailing list to advise receipt of these applications and when the RARMPs are expected to be released for public comment

The Regulator invited comment from expert groups and key stakeholders, including the public, as part of the second round of consultations on RARMPs for the following applications:

- DIR 051/2004 'Field trial of genetically modified (GM) sugarcane expressing sucrose isomerase' (University of Queensland)
- DIR 052/2004 'Field trial of genetically modified rice (*Oryza sativa* L.) – functional characterisation of rice genome' (CSIRO)

Withdrawn applications for DIR licences

No DIR licences where withdrawn in this quarter.

Surrendered applications for DIR licences

One licence was surrendered during this quarter as the trial has finished

- DIR 006/2001 'Agronomic assessment and seed increase in northern Australia of transgenic cotton expressing Cry1Ac or Cry1Ac and Cry2Ab' (CSIRO).

Clock stopped on four applications for DIR licences

The statutory timeframe of 170 days for assessing an application for a DIR licence can be suspended for several reasons. For example, the clock may stop on an application because of an unresolved application for CCI, or while further information is sought from the applicant.

The 'clock' remains stopped on the assessment of the following applications while further information is sought from the applicant:

- DIR 045/2003 – 'Vaccine Trial - Development of Porcine Adenovirus (PAV) Vaccine Vectors' (Imugene Limited)
- DIR 046/2003 'Vaccine Trial - Development of Fowl Adenovirus (FAV) Vaccine Vectors' (Imugene Limited)
- DIR 050/2004 'Vaccination of cattle with recombinant bovine herpesvirus vaccines' (Queensland Government Department of Primary Industries and Fisheries)

The 'clock' was stopped during this quarter on the following application:

- DIR 056/2004 'Commercial release of herbicide tolerant cotton (LLCotton25)' (Bayer CropScience Pty Ltd)

Finalised applications for DIR licences

During the quarter, the Regulator issued one DIR licence:

- DIR 049/2004 'Field trial – Evaluation under field conditions of the cotton rubisco small subunit promoter driving a reporter gene' (CSIRO)

Summary information on DIR applications and RARMPs as well as the finalised RARMPs, including the licence conditions imposed are available from the OGTR website at www.ogtr.gov.au, or can be obtained by contacting the OGTR directly. Full copies of DIR applications can be obtained by contacting the OGTR directly.

Finalised applications for Dealings Not involving Intentional Release (DNIR) licences

These dealings must be conducted in appropriate certified containment facilities and the dealings must not involve intentional release of a GMO into the environment.

During the quarter the Regulator issued 11 DNIR licences. Further information about these licences is contained in Appendix A of this report.

A full listing of DNIR licence applications and their current status is available from the OGTR website at www.ogtr.gov.au.

Notifications of Notifiable Low Risk Dealings (NLRD) received

The Act requires organisations to notify the Regulator when conducting NLRDs.

This category of dealings with GMOs has been assessed as posing low risks based on previous national and international experience. NLRDs must comply with certain risk management conditions and be contained in facilities deemed suitable by the Regulator.

NLRDs are assessed by the submitting organisation's Institutional Biosafety Committee (IBC) and do not require approval by the Regulator. The OGTR checks notifications for compliance with legislative requirements.

The Regulator received 63 NLRDs in the quarter. A full listing of NLRDs and their date of notification is available from the OGTR website at www.ogtr.gov.au.

Existing licences and other instruments

The Regulator can, directly or upon application, vary an issued licence or other instrument. For example, the Regulator can vary a licence to better manage risks if new information or data comes to light. 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 vary existing licences and other instruments, as well as the number of applications processed during the October to December 2004 quarter.

Applications received and decisions made; existing licences and other instruments 1 October – 31 December 2004

Type	Number received	Number processed[1]
Surrender of certification	19	29
Surrender of DIR licence	0	1
Surrender of DNIR licence	1	0
Surrender of accreditation	1	2
Variation of certification[2]	124	498
Variation of accreditation	1	0
Variation of DIR licence[3]	7	11
Variation of DNIR licence[3]	18	15

1 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.

2 The increased volume of certification variation requests received in this quarter is due to the Guidelines being revised resulting in current holders of certifications progressively varying these to meet the new requirements.

3 The majority of variations are made at the request of the licence holder. Variations involve changes to licences where the Regulator is satisfied that the variation does not pose any additional risks to human health and safety and the environment that cannot be managed.

Confidential commercial information (CCI)

Under s.184 of the Act a person may apply to the Regulator in accordance with s.185 for specified information to be declared CCI. 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 two CCI applications relating to DNIR applications (DNIR 342/2004 and DNIR 275/2004) and one CCI application relating to a DIR application. (DIR 057/2004)

The Regulator made three declarations in relation to applications for a DNIR licence (DNIR 328/2004, DNIR 336/2004 and DNIR 342/2004), and no declarations in relation to NLRDs.

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 Section focuses on management of dealings at field trial sites and within contained facilities to ensure:

- the risk of dissemination of a GMO and its genetic material is minimised
- the risk of persistence of a GMO in the environment is managed
- effective management of the GMO is maintained.

Monitoring and compliance strategy

OGTR monitoring and compliance activities comprise the functions of routine monitoring, reviews of potential risks, investigations and audits.

The OGTR conducts routine monitoring visits of a minimum of 20 per cent of field trial sites each year. 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. The purpose of routine monitoring of field trials is to ensure compliance with licence conditions, and includes spot checks.

The OGTR field trial monitoring strategy utilises risk profiling, which incorporates the accumulated operational experience of the office to date. OGTR field trial monitoring activity is scheduled, as far as possible, during inherently higher risk periods in dealings with gene technology (for example, flowering and harvest of GM crops) and to perform monitoring activities accordingly.

The monitoring program for dealings conducted in contained facilities involves inspecting and monitoring:

- a minimum of 20 per cent of physical containment (PC) 4, PC3 and PC2 large-scale facilities per year; and
- selected PC2 and PC1 facilities.

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored. During the October - December 2004 quarter, 17 field trial sites were subject to monitoring visits. Monitoring was carried out on six DIR licences and covered one plant type.

Current field trial sites monitored. Of the 23 sites current in the quarter, 12 were monitored. This represents a monitoring rate of 52 per cent of all current sites for the quarter.

Post-harvest field trial sites monitored. Of the 98 sites subject to post-harvest monitoring in the quarter, five were monitored. This represents a monitoring rate of five per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of contained dealings. During the October - December 2004 quarter, monitoring in connection to contained dealings covered 10 organisations and 30 PC facilities. Monitoring of PC facilities encompassed PC2 laboratories (17 visited), PC2 animal containment facilities (nine visited), PC2 plant containment facilities (one visited), PC3 laboratory re-certifications (one visited) and PC3 laboratory pre-certification inspections (two visited).

Monitoring of dealings involving intentional releases conducted

The total monitoring coverage for field trial sites during the October - December 2004 quarter is shown in the following table.

Licensed Organisation Name	Licence Number	No. sites visited	Site status[1]	Crop type
CSIRO	DIR 038/2003	3	C	Cotton
		3	PHM	Cotton
Dow AgroSciences	DIR 044/2003	3	C	Cotton
Hexima Limited	DIR 048/2003	2	C	Cotton
Monsanto Australia Limited	DIR012/2001	2	C	Cotton
	DIR035/2003	2	C	Cotton
		1	PHM	Cotton
Queensland Department of Primary Industries	DIR 028/2002	1	PHM	Cotton
Totals	6	17	C=12	1 type
			PHM=5	

1 C= current, PHM = post-harvest monitoring

Monitoring of dealings not involving intentional release (DNIR)

There were no DNIRs monitored in this quarter.

Monitoring of physical containment facilities conducted

The organisations and the facility types the OGTR visited during this quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
AgriQuality	PC2 Laboratory	1
Alfred Hospital	PC2 Laboratory	5
CSIRO	PC3 Laboratory +	1
Macquarie University	PC2 Laboratory	1
Monash University	PC2 Laboratory	5
	PC2 Animal House	8
Platforms Sciences Laboratory	PC3 Laboratory +	1
Prince Henry's Institute for Medical Research	PC2 Laboratory	1
St Vincent's Hospital Sydney	PC2 Laboratory	1
The University of Newcastle	PC2 Laboratory	3
	PC2 Plant House	1
	PC2 Animal House	1
The University of Western Australia	PC3 Laboratory +	1
Totals	**4 Facility Types**	**30**

+ - Joint inspection with Contained Dealings Evaluation Section

Monitoring findings

Dealings involving intentional release

There were no non-compliances with licence conditions observed during this quarter.

Physical containment facilities

OGTR's monitoring of PC2 facilities and DNIR licences in the quarter found a number of minor non-compliances and issues with certification instruments. Each observed non-compliance was assessed for risks posed to human health and safety and the environment. All issues observed posed negligible or no additional risk to human health and safety and the environment.

In most instances, issues observed arose from the imprecise wording of Version 1 of the *Guidelines for Certification of Facilities/Physical Containment Requirements* (the Guidelines) and did not jeopardise the secure containment of GMOs. The Guidelines are subject to an ongoing review and Version 2.2 of the requirements for PC2 laboratories, PC2 animal containment and PC2 plant containment facilities were issued on 7 August 2003. Whilst the OGTR is managing a program where these facilities are being progressively re-certified according to the Version 2.2 Guidelines, a small number of facilities are still certified under Version 1 of the Guidelines.

Guidelines for the remaining facility types (PC1, PC2 aquatic, PC2 arthropod and PC2 large scale, PC3 and PC4) continue to be reviewed and consulted on.

This quarter, monitoring staff were involved in joint inspections (re-certification and pre-certification) of three PC3 facilities with officers from the Contained Dealings Evaluation Section of the OGTR. These inspections are usually undertaken when these facilities are shutdown which enables safe examination of the physical structure of these facilities (including air ventilation systems) as well as inspection for compliance with procedural requirements, including training, maintenance documentation and waste management processes.

Monitoring and compliance reviews

The Monitoring and Compliance Section carries out reviews of incidents or practices in dealings with GMOs that come to the notice of the section through monitoring activities or reports by accredited organisations. There are two types of reviews:

- ***incident reviews*** are initiated when an organisation reports a particular incident that may present a potential risk to human health and/or the environment and may be suspected to be a non-compliance with the Act and associated regulations
- ***practice reviews*** are initiated by an accredited organisation or the OGTR to determine if licence conditions can be, and are being, effectively implemented and include identification of potentially adverse effects of a GMO. This may be prompted by observations made during monitoring activities.

The primary focus of the review process is to determine whether the incident that has occurred, or practice being used, has a potential human health or environmental risk that requires management actions to be implemented. In certain instances where there has been a suspected non-compliance with the Act, the issue may be referred for investigation.

No incident or practice reviews were completed in the October to December 2004 quarter.

The following summary of an incident review conducted in February and finalised in April 2004 should have been reported in the April to June 2004 Quarterly Report.

Issue	The CSIRO Plant Industry Division Canberra, reported an incident at its Black Mountain Laboratory it occurred on 7 February 2004. A localised windstorm struck the glasshouse complex damaging a total of 19 glasshouses, nine of these being Physical Containment level 2 (PC2) (planthouse) facilities. Although PC2 glasshouses were damaged, the plants and their pots were not disturbed by the storm. The majority of the dealings involved NLRD and exempt dealings.
Risk assessment	The OGTR risk assessment concluded that this incident posed negligible risk to human health and the environment due to plants being fully contained within the damaged glasshouses. Gene transfer via pollen was considered extremely unlikely as the limited number of plants that were flowering were either self-fertilising or obligate outcrossers, with no related species in the immediate area. Any possible adverse consequences were further mitigated by CSIRO's swift response to the incident.
Determination	That CSIRO Plant Industry acted expeditiously to repair the damaged glasshouses within 24 hours of the wind damage occurring.
Risk management	CSIRO Plant Industry will determine the feasibility of installing a high wind speed warning system to signal such storms and are investigating the possible use of other glasshouse cladding materials such as polycarbonate.
Action	No further action is required.

Audits

Audits can be initiated by an accredited organisation or by the OGTR, an audit can entail:

- documentary evidence; and/or
- observations; and
- 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; and
- where appropriate suggest improvements to procedure 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.

No audits were completed in the October to December 2004 quarter.

The following audit was finalised in July 2004 and should have been reported in the July to September 2004 Quarterly Report

Audit Subject	The OGTR conducted an audit with Monsanto Australia Ltd (Monsanto) following a self-report in July 2003 of the possible presence of minute quantities of an unapproved genetic material in GM canola seeds used to plant a small trial plot. Although the results from the tests that indicated the possible presence of unapproved GM material were ambiguous, Monsanto immediately destroyed the GM plants and worked closely with the OGTR's Monitoring and Compliance Investigations Unit to conduct a thorough audit of the company's seed management processes.
Aims	To identify any potential source of an unintended presence, in the context of a broad assessment of the effectiveness of procedures and practices in maintaining separation between conventional and GM lines at every stage of Monsanto's canola breeding operations.

Type	Systems Audit.
Coverage	Comprehensive examination of Monsanto's canola breeding operations in Australia.
Findings	At the completion of the audit, no clear source for the possible introduction of an unintended presence was established. However, it was evident that Monsanto: • had a well-developed risk and compliance management system which had the capacity to be adaptive and cautious in preventing and managing risk; and • was able to provide quality examples of documentation to validate its procedures and practices and responses to the audit queries. A small number of opportunities for improving Monsanto procedures and practices were identified during the audit.
Completed actions	Monsanto provided revised procedures and practices to address the small number of opportunities for improvement identified during the audit.

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.

The OGTR provides summarised accounts of investigations, once completed, in the relevant quarterly report. However, the OGTR does not release information about ongoing investigations because the information may:

- jeopardise current or future investigations
- be protected by legislation (for example, the *Privacy Act 1988*)
- contain confidential commercial information
- unfairly damage the reputation of third parties who have not themselves breached legislative requirements.

However, if there was an imminent risk to the health and safety of people and the environment, the Regulator would consider whether release of information may be appropriate.

No investigations were completed in the October to December 2004 quarter.

PART 3 Committee operations

The Act established three advisory committees:

- The **Gene Technology Community Consultative Committee** (GTCCC)
  - provides advice on matters of general concern to the community, in relation to GMOs, to the Regulator and the GTMC
- The **Gene Technology Ethics Committee** (GTEC)
  - provides advice on ethical issues relating to gene technology to the Regulator and the GTMC
- The **Gene Technology Technical Advisory Committee** (GTTAC)
  - provides scientific and technical advice to the Regulator and the GTMC.

Gene Technology Community Consultative Committee

The inaugural membership of the Gene Technology Community Consultative Committee (GTCCC) expired on 8 October 2004. The appointment process for new membership of the GTCCC was ongoing at the end of this quarter.

There were no meetings held by GTCCC during this quarter.

Further information about the work of the GTCCC is available from the OGTR website www.ogtr.gov.au

Gene Technology Ethics Committee

The inaugural membership of the Gene Technology Ethics Committee (GTEC) expired on the 8 October 2004. The appointment process was finalised in late December 2004.

There were no meetings held by GTEC during this quarter.

Further information about the work of the GTEC and the new membership is available on the OGTR website www.ogtr.gov.au.

Gene Technology Technical Advisory Committee

The inaugural membership of the Gene Technology Technical Advisory Committee expired on 8 October 2004. The appointment process was finalised in late December 2004.

There were no meetings held by GTTAC during this quarter.

Further information about the work of the GTTAC and the new membership is available from the OGTR website www.ogtr.gov.au.

PART 4 Other activities

Reviews

The following reviews continued during this quarter:

- A review to identify common data requirements for future applications for DIRs, particularly large-scale limited and controlled releases.
- A review of the OGTR's *Risk Analysis Framework*.
- A review of *Guidelines for the Certification of Facilities/Physical Containment Requirements* to address practical difficulties that have been encountered in their implementation. In this quarter:
  - drafting continued on revisions to guidelines for PC3 laboratory facilities; the draft revised PC2 arthropod and PC2 aquatic facility guidelines were circulated to stakeholders for comment; drafting of revised PC2 large scale facility guidelines commenced

International collaboration and coordination

Under the Act, two of the Regulator's functions are to monitor international practice in relation to regulation of GMOs, and to maintain links with international organisations that regulate GMOs in countries outside Australia.

International collaboration and coordination activities undertaken during the quarter include:

- 8th APEC Workshop on Technical Cooperation, Capacity Building, Risk Management and Emerging Issues in Agricultural Biotechnology / Australia's Experience with GMOs: Development and Regulation, Field Trials and Commercial Applications, and Labelling. 10 November Seoul Korea

Advice on gene technology regulation

Presentations and meetings

The Gene Technology Regulator and the OGTR endeavour to participate in presentations and meetings on gene technology wherever possible to inform the community and users about the regulatory system. During the quarter the following presentations were given:

- Academy of Technological Science and Engineering Symposium on GM Crops, 'Regulation of gene technology in Australia' 1 October, Perth, WA

- Australian Society for Microbiology - Annual Scientific Meeting 'Biosafety and Ethics - Regulation of gene technology in Australia' 1 October, Sydney, NSW
- University of Wollongong 'The Regulation of Gene Technology in Australia' 8 October, Wollongong, NSW
- FSANZ Food Safety Conference 2004, 'Australian Gene Technology Regulation: Form and Function' 11 October, Southport, Queensland
- Farmers Symposium 'GM Crops – Challenges' 21 October, Orange, NSW
- Safety and security in a hi-tech world conference 'Cloning, genetic engineering and biotechnology' 1 November, Adelaide, SA
- University of NSW 'Regulation of Gene Technology - Past, present and future issues' 3 November, Sydney, NSW
- AusBiotech 2004 'Regulation of Gene Technology - an OGTR perspective' and 'Biopharming GMOs and GM products' 8 November, Brisbane, Queensland
- LABbuild 2004 'Research facilities for the future - Who is monitoring?' 9 November, Brisbane, Queensland
- CSIRO IBC Forum 'Australia's Gene Technology Regulatory System' 23 November, Canberra, ACT
- Victorian Department of Primary Industries 'Gene Technology Regulation in Australia: Monitoring and Compliance Activities' 14 December, Bundura, Victoria

Institutional Biosafety Committee training sessions

The OGTR regularly provides training sessions to accredited organisations and their IBCs.

No training sessions were conducted in this quarter.

Consultants

During the reporting period, the OGTR managed two consultancy contracts worth a total of $46,460. The table below lists the consultants, describes the purpose of the consultancy and the amount paid during the quarter. The amount paid is net of GST.

Consultant	Amount paid (GST exclusive)	Purpose
Acumen Alliance	$17,905	Development of an appropriate cost recovery model for the Office of the Gene Technology Regulator
Dialog Information Technology	$28,555	Ongoing work on the Gene Technology Information System (GTIMS)
Total Consultants for quarter	$46,460	

Gene Technology Information Management System

The GTIMS rollout to date has migrated the following number of organisations to electronic application lodgment and tracking in each state.

State	Total Number of Organisations	Number Completed
ACT	8	6
TAS	2	2
NT	3	3
SA	13	7
WA	13	5
NSW	35	13
VIC	49	12
QLD	22	11
Total	145	59

OGTR website

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

- Maps of current field trial locations
- What's New
- Office of Gene Technology Regulator Handbook
- About the OGTR
- Intentional Release
- GMO Record

The most popular downloaded documents were:

- The Handbook on Gene Technology Regulation in Australia
- The Biology and Ecology of Cotton (*Gossypium hirsutum*) in Australia
- The Biology and Ecology of White Clover (*Trifolium repens* L.) in Australia
- The Biology and Ecology of Pineapple (*Ananas comosus* var. *comosus*) in Australia
- The Biology and Ecology of Papaya (paw paw, *Carica papaya* L.), in Australia
- Risk Analysis Framework Consultation Version August 2004

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

OGTR email address and freecall number

The 1800 number and the OGTR email address are points of contact for members of the public and other interested parties. 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 OGTR 1800 number and website received approximately 110 calls and 1520 emails in October 2004, 100 calls and 1450 emails in November 2004, and 115 calls and 915 emails in December 2004.

Freedom of information

The OGTR received no freedom of information requests during the quarter.

Appendix A

DNIR Licences issued October - December 2004

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 305/2004	5 Oct 04	Peter MacCallum Cancer Centre, VIC	Wnt/FZD in human cancer	The aim of this dealing is to define the role of two particular proteins in colon cancer metastasis by modulating the expression of these proteins in colon cancer cell lines *in vitro.*
DNIR 307/2004	5 Nov 04	St. Vincent's Hospital Melbourne, VIC	Molecular studies of HIV and HCV	The proponents intend to study the fusion and entry of human immunodeficiency virus and hepatitis C virus into human cell lines *in vitro* in order to develop antivirals and vaccines targeting this process.
DNIR 308/2004	5 Nov 04	University of Canberra, ACT	Storage and maintenance of bacterial strains and plasmids for future use	The aim of this dealing is to store and maintain an array of bacterial strains and plasmids for future use.
DNIR 310/2004	9 Nov 04	Institute of Medical and Veterinary Science, SA	Mechanisms of cell survival and apoptosis in multiple myeloma	The aim of this dealing is to investigate the role of various proteins involved in apoptosis and cell survival in multiple myeloma cells and to identify potential targets for therapy.
DNIR 313/2004	18 Nov 04	Institute of Medical and Veterinary Science, SA	Study of breast cancer tumour suppressor genes	The aim of this dealing is to investigate the function of breast tumour suppressor genes and their interacting proteins in human breast cell lines *in vitro*.

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 314/2004	19 Nov 04	Peter MacCallum Cancer Centre, Vic	Viral mediated approaches to examine cell growth and proliferation	The aim of this dealing is to use viral vectors to introduce genes into cultured cells and animals to determine their role in cancer.
DNIR 315/2004	26 Nov 04	Peter MacCallum Cancer Centre, Vic	Expression and function of HIN 200 proteins	The aim of this dealing is to use viral vectors to introduce genes encoding HIN-200 proteins into mice and cultured cells to determine their role in cellular differentiation.
DNIR 316/2004	29 Nov 04	The University of Adelaide, SA	Storage of Salmonella GMOs	The storage of genetically modified *Salmonella enterica* Serovar Typhimurium.
DNIR 319/2004	5 Nov 04	Institute of Drug Technology Ltd.	Randomised, double blind, placebo controlled phase 2 dose-ranging study of the safety, tolerability and immunogenicity of live attenuated ChimeriVax™-JE vaccine (lyophilised).	The aims of this study are to assess the safety, tolerability and immunogenicity of a new formulation of lyophilised ChimeriVax™-JE, given at three dose levels, compared with the placebo.
DNIR 320/2004	5 Nov 04	Melbourne Health, Vic	Randomised, double blind, placebo controlled phase 2, dose-ranging study of the safety, tolerability and immunogenicity of live ChimeriVax™ JE vaccine (lyophilised).	The aims of this study are to assess the safety, tolerability and immunogenicity of a new formulation of lyophilised ChimeriVax™-JE, given at three dose levels, compared with a placebo.

Application number	Licence issued	Organisation and State	Project title	Project description
DNIR 321/2004	3 Dec 04	Ludwig Institute for Cancer Research, Vic	Storage of GM cell lines that would require a licence if dealings with those GMOs were undertaken.	Storage of GM cell lines that would require a licence if dealt with. The GMOs will be stored in certified facilities or in other restricted access areas (such as a locked freezer or liquid nitrogen store).