

Quarterly Report of the Gene Technology Regulator



for the period
1 July to 30 September 2001

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the Gene Technology Regulator
for the period
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ISSN 1446-4950

ISBN 0 642 50382 6

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Commonwealth Department of Health and Ageing
Publications Approval Number 2985



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Senator the Hon Kay Patterson
Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

Dear Minister

I present the Quarterly Report of the Gene Technology Regulator for the period 1 July to 30 September 2001 in accordance with section 136(A) of the *Gene Technology Act 2000*. In doing so I would like to acknowledge the work of Ms Liz Cain who was the Acting Gene Technology Regulator for the period covered by the Report.

During this first quarter:

- 51 applications were received in relation to licences for dealings with GMOs including the first application for a licence for a dealing involving intentional release of a GMO into the environment;
- the monitoring strategy was enhanced to ensure greater emphasis on risk profiling, to include unannounced spot checks of licenced dealings and to have a greater focus on inspecting sites subject to post-harvest monitoring;
- progress was made on complementary gene technology legislation by the Tasmanian, Victorian, Western Australian, Queensland, South Australian and New South Wales State Governments; and
- the public was consulted on the *Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator*.

Yours sincerely

(Dr) Sue D Meek

Gene Technology Regulator
25 January 2002

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Abbreviations and Terms

accredited organisation	an organisation that is accredited under section 92 of the Act
Act	<i>Gene Technology Act 2000</i>
breach	a failure to comply with licence, accreditation or certification conditions
CCI	confidential commercial information
certified facility	means a facility certified by the Regulator, under section 84 of the Act, to a particular containment level
COAG	Council of Australian Governments
DIR	dealing involving intentional release of a GMO into the environment
DNIR	dealing not involving intentional release of a GMO into the environment
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
GTA	Gene Technology Agreement
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
IOGTR	Interim Office of the Gene Technology Regulator
NLRD	notifiable low risk dealing
OGTR	Office of the Gene Technology Regulator

PC2	Physical Containment Level 2, as certified by the Regulator in accordance with the Regulator's <i>Guidelines for Certification of Facilities/Physical Containment Requirements</i>
PC3	Physical Containment Level 3, as certified by the Regulator in accordance with the Regulator's <i>Guidelines for Certification of Facilities/Physical Containment Requirements</i>
PC4	Physical Containment Level 4, as certified by the Regulator in accordance with the Regulator's <i>Guidelines for Certification of Facilities/Physical Containment Requirements</i>
PR	planned release (of an GMO into the environment)
Regulator	Gene Technology Regulator
spot checks	unannounced visits by the OGTR monitoring and compliance unit
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 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 must include information on the following:

- 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; and
- auditing and monitoring of dealings with GMOs under the Act by the Regulator or an inspector during the quarter.

As the Act came into force on 21 June 2001, this is the first quarterly report from the Regulator and covers the period 1 July to 30 September 2001. Prior to the commencement of the Act, the Interim Office of the Gene Technology Regulator (IOGTR) was established to develop and implement the new national system for the regulation of GMOs. The IOGTR published 5 quarterly reports describing its activities; the last IOGTR quarterly report being for the period April - June 2001. It should be noted, therefore, that activities for the first nine days of operation of the Office of the Gene Technology Regulator (OGTR) were reported in the fifth and final IOGTR quarterly report.

Structure of this report

This report is divided into 7 parts.

Part 1 details activities and outcomes achieved in relation to the implementation and management of the national regulatory system.

Part 2 outlines the regulatory activity undertaken during the July - September 2001 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, auditing and compliance activities by the Regulator during the quarter.

Part 3 reports on the activities of the three key advisory committees established under the Act to assist the Regulator.

Parts 4, 5 and 6 summarise, respectively, advice provided on gene technology regulation, reviews and research undertaken, and international collaboration and coordination activities undertaken by the Regulator.

Part 7 provides details on freedom of information requests received and consultant contracts managed during the quarter.

Further information

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

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National Regulatory System

Key achievements during the quarter

The key achievements of the July - September 2001 quarter were:

1. Appointment of the Gene Technology Regulator

On 27 September 2001, the Governor-General of the Commonwealth of Australia, Dr Peter Hollingworth, appointed Dr Sue Meek as the Gene Technology Regulator for a period of 5 years commencing on 30 November 2001. The recommendation for the appointment was endorsed by the Federal and all State and Territory Governments. The Gene Technology Regulator is an independent statutory office holder responsible for administering and enforcing the regulatory system for GMOs in Australia.

Dr Meek has extensive experience in biotechnology-based industry development along with a proven track record in public sector administration and implementation of public policy in the science and technology arena. Dr Meek represented Western Australia in the national consultative process which established the Act, and also represented all States and Territories in international negotiations to develop a Biosafety Protocol under the United Nations Convention on Biological Diversity.

2. Activities under the new regulatory system - Licences and other instruments

In the first quarter of the new regulatory system the Acting Gene Technology Regulator (the Regulator):

- received 51 applications in relation to licences for dealings with GMOs including the first application for a licence for dealings involving intentional release of a GMO into the environment (DIRs);
- received 40 applications seeking certification of facilities; and
- was notified of 56 notifiable low risk dealings (NLRDs).

During the quarter the Regulator:

- certified 11 facilities;
- varied 23 DIR licences; and
- varied 2 DNIR licences.

The Regulator also received 38 applications for protection of confidential commercial information (CCI). Of the 12 decisions made on CCI applications during the quarter, all were refused. The refused applications sought to have the location of field trials of genetically modified crops declared CCI. However, the Regulator was not satisfied that significant damage to the health and safety of people, the environment or property would be likely to occur if the locations were disclosed. These trial site locations are now available from the OGTR website (www.ogtr.gov.au).

3. Activities under the new regulatory system – Monitoring and compliance

To support the transition from the voluntary system to the regulatory framework now in place, particular attention was given during the July - September 2001 quarter, to the consolidation of the monitoring and compliance processes of the OGTR. The monitoring strategy for example was enhanced to ensure a greater emphasis on risk profiling, to include unannounced spot checks of licenced dealings, and to have a greater focus on inspecting sites subject to post-harvest monitoring.

During this quarter, the OGTR exceeded its monitoring target of 5% of trial sites per quarter. Of the 105 sites that were current in the quarter, 15% or 16 sites were monitored. Of the 518 sites subject to post-harvest monitoring during the quarter, 13% or 68 were monitored.

4. State and Territory gene technology legislation

To ensure a nationally consistent scheme for the regulation of dealings with GMOs it is anticipated that each State and Territory will enact corresponding legislation.

During the quarter:

- the *Tasmanian Gene Technology Act 2001* was passed by the Tasmanian Parliament but had not commenced; and

- Gene Technology Bills were introduced into the Victorian, Western Australian, Queensland, South Australian and New South Wales Parliaments.

In order for the State gene technology laws to form part of the national system, the Minister needs to declare the State laws to be corresponding State laws for the purposes of the Act. As all States and Territories except Tasmania had not yet enacted their gene technology laws, no declaration by the Minister was possible. For the Tasmanian *Gene Technology Act 2001*, regulations under that Tasmanian Act will form an integral part of the Tasmanian regulatory system. However, as Tasmanian regulations had yet been made, it was not possible for the Minister to make a declaration in relation to the Tasmanian *Gene Technology Act 2001*.

5. Public consultations on the *Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator*

The Act provides that the Regulator must prepare a risk assessment and a risk management plan for all GMO licence applications. To guide this process a draft risk assessment framework for licence applications, *Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator*, was prepared. The purpose of the risk assessment framework is to provide general guidance to applicants, OGTR evaluators and other stakeholders in identifying and assessing the risks posed by GMOs and in determining the measures necessary to manage any such risks.

The draft framework was developed in consultation with all States, Territories and relevant Commonwealth Government agencies. In its preparation, the requirements of the Act and the Gene Technology Regulations 2001, practices and guidelines of the former Genetic Manipulation Advisory Committee (GMAC), and the general principles of risk assessment strategies in use in related agencies both in Australia and overseas were considered.

Public consultation on the draft framework began early in September 2001. The consultation process involved inviting comment from the public (through the OGTR website and by writing to approximately 900 people on the OGTR's mailing list) and key stakeholders. The original closing date for comment on the draft framework was extended from 21 September to 5 October 2001. The framework will be revised in the light of the comments received and once finalised will be made available on the OGTR website or in hard copy from the OGTR.

6. OGTR vision and mission statements

To assist in conveying the purpose and directions of the OGTR to the public, clients and members of staff, a proposed vision and mission statement have been prepared for the Office. These are:

- Vision: A healthy, safe, sustainable future; and
- Mission: To remain at world's best practice in identifying and managing risks to human health and the environment posed by or as a result of gene technology.

The OGTR will be seeking public comments on the proposed vision and mission statements in the next quarter.

Working collaboratively with States and Territories

The OGTR continued to work collaboratively with officials from all State and Territory governments on the implementation and management of the national regulatory framework. Two of the key matters dealt with during the period were the appointment of the Regulator and the selection processes for the Gene Technology Technical Advisory Committee (GTTAC), the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC).

The Gene Technology Agreement (GTA), an inter-governmental agreement which sets out many of the understandings between governments in relation to the national GMO regulatory scheme, has been signed by a majority of the jurisdictions. At the end of the quarter signatories included the Commonwealth of Australia, the State of Victoria, the State of Western Australia, the State of Queensland, the State of South Australia and the Australia Capital Territory.

Also during the quarter the OGTR was given responsibility for the preparation of a report requested of Health Ministers by the Council of Australian Governments (COAG). The requested report was in relation to COAG's commitment to achieve, by June 2002, nationally consistent provisions in legislation to prohibit human cloning and to develop a nationally consistent approach to the regulation of assisted reproductive technology and related emerging technologies. In preparing the report the

OGTR worked in consultation with State and Territory government officials from Premiers'/Chief Ministers' Departments and Health Departments, as well as with experts in ethics, law and medical sciences.

Commonwealth agency liaison

The close relationship between the OGTR, Commonwealth agencies and existing regulators continued during this quarter. The key issues considered were the appointment of the Regulator and the selection processes for the GTTAC, the GTEC and the GTCCC. Work also continued on the formulation of working arrangements between the OGTR and other agencies involved in the regulation of genetically modified (GM) products.

The OGTR continued to work closely with representatives from the Department of the Prime Minister and Cabinet, the Therapeutic Goods Administration, the National Health and Medical Research Council, and Biotechnology Australia in this quarter in the preparation of the Report for the COAG on human cloning and assisted reproductive technologies (see previous section).

The role and contribution of non-government organisations

The key focus of consultation with non-government stakeholders during the July - September 2001 quarter was in relation to the draft *Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator* (see key achievement 5 for details).

With the receipt and acceptance of the first DIR licence application during the quarter, the quarter ahead will see the first DIR consultation process initiated under the new regulatory system.

The Regulation of Genetically Modified Organisms

This part of the Report outlines the regulatory activity undertaken during the July - September 2001 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 any breaches of conditions of a GMO licence that have come to the Regulator's attention, and the auditing and monitoring of dealings with GMOs under the Act during the quarter. Information on CCI applications has also been included.

Applications received and decisions made

Under the Act the Regulator is required to make decisions in relation to applications for the following instruments:

- licences authorising dealings involving intentional release of GMOs into the environment;
Licences for DIRs cover work ranging from limited releases (field trials) at the initial stages of research and development through to more extensive commercial releases of GMOs.
- licences authorising dealings not involving intentional release of GMOs into the environment (DNIRs);
Licences for DNIRs include contained work carried out in laboratories and other facilities designed to prevent the release of the GMO into the environment.
- accreditations of organisations; and
If an organisation is accredited, the Regulator is satisfied that the organisation has, or has access to, a properly constituted and maintained Institutional Biosafety Committee (IBC) and complies with the requirements of the Regulator's guidelines for accreditation.
- certifications of facilities.
The purpose of certification is to satisfy the Regulator that the facility, which is used to contain the GMO, meets the Regulator's requirements for physical containment as described in the Regulator's certification guidelines.

The Act also requires the Regulator to receive notifications of NLRDs. As this category of dealings with GMOs has been assessed as posing low

risks, the Regulator is not required to make a decision in respect of NLRDs provided they comply with certain risk management conditions and the dealing is undertaken in facilities which meet at least physical containment level 2.

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 July - September 2001 quarter. In this quarter the Regulator certified 11 facilities.

Applications and notifications received and decisions made - New licences and other instruments

Applications for /Notification of		Number Approved #
Type	Number Received*	
Certification of a facility	40	11
Licence for DNIR	7	0
Licence for DIR	1 (4)	0
NLRD	56	not applicable

* The figure in brackets indicates the number of additional applications received that were subsequently withdrawn by the applicant or not considered by the Regulator because the application was incomplete.

For the purposes of this table approved means that a licence was issued or a facility was certified.

New DIR licence applications

The Regulator received during this quarter the first application, under the new regulatory system, for a licence for a dealing involving the intentional release of a GMO into the environment. The application was for a licence to undertake certain activities with a GMO, including a controlled and limited release of the GMO into the environment. The genetically modified organism is a variety of cotton which has been modified by the introduction of genes from common bacteria. The aim of the genetic modification is to increase the cotton's resistance to insect pests. Some of the cotton has also been modified to make it resistant to a herbicide.

The process for assessing the application as laid down in the legislation involves a rigorous scientific assessment and extensive consultation with the GTTAC, relevant government agencies and the public. In the next quarter the Regulator will be inviting the public to be involved in the assessment process for this first application for a licence for the release of a genetically modified organism into the environment.

Existing licences and other instruments

The Regulator can, directly or upon application, suspend, cancel or vary an issued licence or other instrument, ie certifications and accreditations. Additionally, with respect to licences, the Regulator can make a decision in relation to an application to transfer a licence from the licence holder to another person and consent to the surrender of a licence by a licence holder.

The following table describes the number and type of applications received to vary existing licences and other instruments, as well as, the approvals made by the Regulator in the July - September 2001 quarter. The Regulator cancelled the certification of a facility at the request of the holder of the certification, and varied 23 DIR and 2 DNIR licences¹. Variations involve minor changes to licences where the Regulator is satisfied that the variation does not pose any risks to human health, safety or the environment that cannot be managed. No instrument applications were refused in this quarter.

¹ The majority of variations were made at the request of the licence holder.

Applications received and decisions made – Existing licences and other instruments

Applications for		Number Approved #
Type	Number Received*	
Variation of certification	1	0
Cancellation of certification	6	1
Variation of DIR licence	37	23
Variation of DNIR	5	2
Surrender of licence	1 (1)	0

* The figure in brackets indicates the number of additional applications received that were subsequently withdrawn by the applicant or not considered by the Regulator because the application was incomplete.

For the purposes of this table approved means that the Regulator consented to the surrender of a licence, cancelled or varied a licence or other instrument.

As a result of the transition from the prior voluntary to the new regulatory system for GMOs ‘deemed’ licences and other instruments were issued prior to the commencement of the new system on 21 June 2001. These ‘deemed’ licences and other instruments will operate for up to two years; the exception being ‘deemed’ certifications of facilities for which the instrument will operate for up to one year for Physical Containment (PC)3, PC4, large-scale PC2 facilities² and other facilities. In the short term most changes reported in this section will relate to ‘deemed’ licences and other instruments.

Throughout the year prior to the expiration of the ‘deemed’ licences and other instruments, the Regulator will contact instrument holders informing them that their ‘deemed’ licences and other instruments will shortly expire and that if they wish to continue dealing with GMOs they will need to apply for the appropriate instrument. Therefore, the financial year 2002-03 is likely to contain a large number of new applications for licences and other instruments as ‘deemed’ instrument holders apply to the Regulator to continue ongoing work with GMOs.

² For PC2 facilities, except large-scale PC2 facilities, the ‘deemed’ certification lasts for up to two years.

Confidential commercial information

The Act provides that a person may apply to the Regulator for a declaration that specified information provided to the Regulator be protected from disclosure by a declaration that the information is CCI. If the Regulator declares information to be CCI, the Regulator must not publicly release that information.

The following table shows the number and type of CCI applications received in the July - September 2001 quarter. During the quarter the Regulator:

- did not make any declarations for the protection of CCI; and
- refused 12 CCI applications.

All of the CCI applications rejected by the Regulator in the quarter were in relation to the location of field trial sites of genetically modified crops. The Regulator was not satisfied that significant damage to the health and safety of people, the environment or property would be likely to occur if the locations were disclosed. These site locations are now available from the OGTR website.

Applications received and decisions made – Confidential commercial information

Type of licence or other activity to which CCI application relates	Number of CCI applications received*
NLRD	3
DIR	15 (9)
DNIR	20

* The figure in brackets indicates the number of additional applications received that were subsequently withdrawn by the applicant or not considered by the Regulator because the application was incomplete.

Monitoring and compliance

Purpose

The aim of OGTR monitoring and compliance activities is to ensure that dealings with GMOs comply with regulatory conditions 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 focus on the management of dealings for field trial sites and within contained facilities is to ensure the:

- minimisation of the risk of dissemination of a GMO and its genetic material;
- minimisation of the risk of persistence of a GMO in the environment; and
- full control of a GMO is maintained.

Monitoring and compliance strategy

OGTR monitoring and compliance activities comprise the functions of monitoring and auditing, reviews, risk assessment and management, investigations and reporting.

In the case of field trial sites, the OGTR will continue conducting the minimum rate of inspections carried out by the IOGTR. This involves random inspections of at least 20% of the field trial sites involving GMOs on an annual basis. A minimum of 5% of current trial sites and 5% of trial sites subject to post-harvest monitoring are to be inspected each quarter.

On the basis of experience over the last 12 months, the OGTR has enhanced its monitoring strategy to have a greater emphasis on risk profiling, to include unannounced spot checks of licenced dealings, and to have a greater focus on inspecting sites subject to post-harvest monitoring. OGTR monitoring activity is scheduled, as far as possible, to identify inherently higher risk periods in dealings with gene technology and to perform monitoring activities accordingly. These risks are related to:

- the type of GMO and its biology;

- the facilities and procedures of the organisations conducting work with GMOs; and
- seasonal/geographical/ecological risk factors for both current and post-harvest field trial sites.

In preparation for meeting legislative requirements for the re-certification of facilities, and to assist the necessary considerations in re-certification, the Monitoring and Compliance Unit is initiating a program of monitoring facilities, particularly PC3, PC4 and large-scale PC2 facilities.

Under the GTA, States that wish to assist in the administration and enforcement of the national regulatory scheme for gene technology can enter into a bilateral agreement with the Commonwealth. Arrangements for developing a bilateral agreement with Queensland was successfully negotiated during the quarter. As part of the in-principle agreement, aspects of monitoring would be carried out by Queensland State Government officials on behalf of the OGTR. The in-principle agreement outlines the scope of involvement by State officials in monitoring of licenced dealings. Further negotiation towards a final agreement will develop, among other things, monitoring procedures and protocols and reporting guidelines. Discussions with Tasmanian officials on a bilateral agreement also commenced during the quarter.

Preparation commenced on a guideline for the provision of site location information to the Regulator. This will ensure that uniform technical and scientifically credible standards for geographic information apply across Australia for site information collected and provided by proponents.

Since the Act came into force on 21 June 2001, investigation standards are now under the guidance of the Heads of Commonwealth Operational Law Enforcement Agencies. These standards are being implemented into the Monitoring and Compliance Unit through procedural guidelines and through the appointment of qualified investigation staff.

Overview of monitoring and compliance for the reporting period

A total of 18 licences were identified for monitoring and auditing purposes during the reporting period. Eighty-four (84) sites were monitored and 87 monitoring visits were conducted, which included revisits to three of the 84 sites. Of the 105 sites that were current in the quarter, 15% or 16 sites were monitored. Of the 518 sites subject to post-harvest monitoring during the quarter, 13% or 68 were monitored.

Monitoring conducted

The total monitoring coverage for the July - September 2001 quarterly reporting period is shown in the table below.

Licensed organisation	'Deemed' licence no. (PR No.)	No. of sites under 'deemed' licence	No. of sites visited	Site status C=Current PHM=Post-Harvest Monitoring	Crop type
Aventis CropScience	62X(4)	15	9	PHM	Canola
	63X(2)	28	28	PHM	Canola
	63X(4)	96	16	PHM	Canola
	63X(5)	39	2	PHM	Canola
	63X(6)	10	7	C	Canola
	85X(2)	5	1	PHM	Canola
	90X(3)	2	2	C	Canola
Monsanto Australia	77X	18	3	PHM	Canola
	77X(2)	30	2	PHM	Canola
	77X(3)	30	1	PHM	Canola
	77X(4)	6	5	C	Canola
CSIRO	102X	1	1	PHM	Wheat
	105	3	1	PHM	Field Pea
	105X	2	2	PHM	Field Pea
	135	1	1	PHM	Field Pea
	139	1	1	PHM	Barley
	150	1	1	C	Clover
La Trobe University	64X(2)	2	1	C	Clover
Totals	18	290	84	C = 16 PHM = 68	5

Monitoring findings

This section reports the final outcomes of monitoring activities. No findings of non-compliance with licence conditions (breaches) were found during this quarter. However, monitoring activities lead to the commencement, during this quarter, of reviews of some sites against organisations' monitoring reports. If findings of non-compliance are found as a result of a review, these will be published in subsequent quarterly reports.

Although there were no findings of non-compliance in this quarter, the following tables report significant findings for the July - September 2001 period ie findings that resulted in remedial action to ensure compliance was maintained.

PR No. and Site No.	63X(6) Site 1
Summary of Dealing	Licence relates to field trials of canola (<i>Brassica napus</i>) modified for resistance to gluphosinate-ammonium conducted by Aventis CropScience.
Findings	The pollen trap/buffer was observed to be of sufficient width to meet licence conditions at the time of sowing, however, the western edge of the buffer had significant gaps through poor initial establishment of plants within the buffer.
Risk assessment	Without remedial action, the pollen trap would not have been at an appropriate density to function as the licence intended when flowering of the trial occurred. As the trial had not reached flowering, there was a negligible risk posed to the environment.
Risk management	The proponent proposed to transplant vigorously growing plants from other parts of the buffer to the areas where poorer establishment had occurred with the aim to have a complete and densely growing buffer that met licence conditions. From evidence viewed, OGTR is satisfied that this occurred.

PR No. and Site No.	63X(6) Site 4
Summary of Dealing	Licence relates to field trials of canola (<i>Brassica napus</i>) modified for resistance to gluphosinate-ammonium conducted by Aventis CropScience.
Findings	Pollen trap/buffer was observed to have poor establishment and growth on southern side of trial site. Although planting of pollen trap met the requirement of 15m in width, the establishment of plants in the pollen trap was not at similar density to that of the trial. Trial and buffer were at the vegetative growth stage, however a small proportion of plants had bud initiation.
Risk assessment	Without remedial action, the pollen trap would not have been at an appropriate density to function as the licence intended when flowering of the trial occurred. As the trial had not reached flowering, there was a negligible risk posed to the environment.
Risk management	OGTR explored and outlined a number of management options that could be undertaken by the proponent in order to meet the intended outcome of limiting the spread of genetic material that may occur through pollen flow. The proponent erected tenting over the southern end of the trial to contain pollen flow for the duration of flowering. OGTR monitored the site when tenting was erected and was satisfied that the spread of genetic material was minimised.

PR No. and Site No.	77X(4) Site 3
Summary of Dealing	Licence relates to field trials of canola (<i>Brassica napus</i>) modified for resistance to glyphosate conducted by Monsanto Australia.
Findings	The pollen trap/buffer was observed to be of sufficient width to meet licence conditions at the time of sowing, however, the southern and northern edges of the buffer had significant gaps in the buffer and the southern side in particular displayed symptoms of herbicide damage that had caused the death of significant proportions of the buffer.
Risk assessment	Without remedial action, the pollen trap would not have been at an appropriate density to function as the licence intended when flowering of the trial occurred. As the trial had not reached flowering, there was a negligible risk posed to the environment.
Risk management	OGTR explored and outlined a number of management options that could be undertaken by the proponent in order to meet licence conditions. The proponent decided, of its own volition, to destroy the trial crop. The site was later monitored by OGTR and verified that destruction had occurred.

PR No. and Site No.	77X(4) Site 6
Summary of Dealing	Licence relates to field trials of canola (<i>Brassica napus</i>) modified for resistance to glyphosate conducted by Monsanto Australia.
Findings	The pollen trap/buffer was observed to be of sufficient width to meet licence conditions at the time of sowing, however, the western edge of the buffer displayed symptoms of herbicide effect that had damaged growth of small sections of the buffer.
Risk assessment	While the opinion of the independent weed and canola expert engaged by OGTR was that the buffer had a reasonable chance of surviving the effects of the herbicide that had affected its growth, it was considered prudent to return to the site later in its growing phase to ensure the buffer was sufficient to meet licence conditions. As the trial had not reached flowering, there was a negligible risk posed to the environment.
Risk management	The site was later monitored and OGTR was satisfied that the trial met licence conditions.

Investigations

No investigations into non-compliances with the Act were initiated during this quarter.

During the quarter, work continued on the three investigations reported in the previous IOGTR quarterly report (June 2001). All these investigations relate to alleged breaches reported under the voluntary system prior to 21 June 2001. One of the major outcomes of this ongoing work was the finalisation of the parameters for a comprehensive gene flow study. The gene flow study is being undertaken to determine whether gene flow occurred in two of the trials under investigation. The study is expected to commence in the next quarter.

Committee Operations

The Act establishes three new advisory committees:

1. The **Gene Technology Technical Advisory Committee** – which will provide scientific and technical advice to the Regulator and the Ministerial Council;
2. The **Gene Technology Community Consultative Committee** – which will advise the Regulator and Ministerial Council on matters of general concern to the community in relation to GMOs; and

3. The **Gene Technology Ethics Committee** – which will provide advice to the Regulator and Ministerial Council on ethical issues relating to gene technology.

The recommended membership of three committees was put to the then Minister for Health and Aged Care, the Hon Dr Michael Wooldridge MP, for his consideration during this quarter. The recommendations were based on the shortlist of candidates developed by the Commonwealth-State Consultative Group during the April - June 2001 quarter.

In future quarterly reports this section will report on the activities of the three gene technology committees including meeting dates and key decisions made by the committees.

Advice on Gene Technology Regulation

Presentations

Staff of the OGTR endeavour to participate in discussions on gene technology wherever possible to inform the community about the new regulatory system. During the reporting period the OGTR made presentations at the following forums:

- Risk Engineering Society, 26 July 2001, in Sydney;
- Regional GMO information session, 9 August 2001, in Harden, New South Wales;
- Regional GMO information session, 28 August 2001, in Dubbo, New South Wales;
- Shire Councils Association 'G' Division, 13 September 2001, Corowa, New South Wales;
- Symposium on Biotechnology and the Environment, 22 September 2001, in Canberra; and
- Lecture at the Melbourne Institute of Technology, 25 September 2001, Melbourne.

The Australian Government Solicitor sponsors the Government Law Group which meets monthly in Canberra. During August 2001 there was a

presentation on the Act by the General Counsel to the Regulator, Australian Government Solicitor and the Regulator.

In addition, the OGTR began a series of training and individual information sessions for IBCs and researchers to explain how the new regulatory system will operate in practice. Some of the issues covered include the preparation of licence applications, NLRDs and other reports required by the Regulator. The first session was on 28 September 2001 at the Australian National University in Canberra; another 9 sessions will occur in capital cities around Australia in the next quarter.

Publications

No publications were issued during this quarter.

OGTR website

The OGTR website received 576,936 hits during the quarter, with an average of 6,281 hits per day. The most popular documents downloaded from the OGTR website were the:

- Handbook on the Regulation of Gene Technology in Australia;
- IOGTR Quarterly Report March 2001; and
- licence for PR63X4 canola field trial.

Attention was given to enhancing the website during the quarter with a particular focus on improving public access to information about the location of trial sites. Enhancements made included:

- listing trial sites by Local Government areas;
- including coloured maps of every state and territory with field sites marked in the correct geographic areas; and
- having sites marked with a reference number that allows the public to find full details of the trial.

Reviews and Research

The purpose of this section is to describe major reviews undertaken by the Regulator as well as a summary of any research undertaken or commissioned by the Regulator.

Research undertaken in this quarter was mainly used to inform the implementation of the new regulatory system; for example research was undertaken for the preparation of the draft *Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator* (see key achievement 5 for details).

No reviews were undertaken during the quarter. However, the following three areas were identified for review and the review process will commence in the next quarter:

- conditions of cotton licences;
- guidelines for the certification of facilities; and
- guidelines for the accreditation of organisations.

International Collaboration and Coordination

Under the Act, two of the functions of the Regulator are to monitor international practice in relation to the regulation of GMOs, and to maintain links with international organisations that deal with the regulation of gene technology as well as with agencies that regulate GMOs in countries outside Australia.

During the July - September 2001 quarter, the OGTR continued the work undertaken by the IOGTR to build and maintain international contacts on gene technology regulatory matters, both with officers in Australia's overseas posts and with interested officials from overseas governments. The OGTR responded to queries from the Chinese and Japanese governments, and liaised with government officials from New Zealand over the state of play of its Royal Commission on Genetic Modification and their implementation of a testing protocol for GM contamination of sweet corn imports. Additionally, regular updates on developments in the European Union were sought from the Australian post in Brussels, and international news and cables routinely monitored for international developments in the area of gene technology regulation.

The OGTR also provided input into activities relating to the development of the Biosafety Protocol under the United Nations Convention on Biological Diversity. This included the preparation of briefing material on information requirements under the new regulatory system for GMOs for

Australia's delegation to the second meeting of the Intergovernmental Committee on the Cartagena Protocol (ICCP2) and participating in industry consultation forums prior to ICCP2.

Other Activities

Freedom of information (FOI)

The OGTR received and actioned one FOI request during the reporting period.

Consultants

During the reporting period, the OGTR managed 8 consultancy contracts worth a total of \$384,333. The table below lists the consultants, describes the purpose of the consultancy and the amount paid during the quarter.

Consultant	Amount paid during quarter	Purpose
Acumen Alliance (ACT)	\$3,520	Independent quality assurance services for Gene Technology Information Management System (GTIMS) project
Animal & Plant Commission S.A	\$2,182	Provide scientific, technical and control specialised advice
Dialog Information Technology	\$294,542	Develop GTIMS
Matthews Pegg Consulting	\$28,195	Provide legal policy support for the development of recommendations for achieving nationally consistent legislation prohibiting human cloning and a nationally consistent approach to the regulation of assisted reproductive technologies and related matters
McNiece Communications	\$26,400	Public affairs
Oceania Health	\$14,850	Prepare risk assessment guidelines
Outlook Biotec	\$4,554	Undertake laboratory inspections
Swell Design Group	\$10,090	Website development



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