Quarterly Report of the Gene Technology Regulator

for the period
1 October to 31 December 2001

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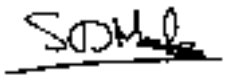
The Hon Trish Worth MP
Parliamentary Secretary to the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

Dear Parliamentary Secretary

In accordance with section 136A of the *Gene Technology Act 2000*, I am pleased to present to you the second Quarterly Report for the Office of the Gene Technology Regulator, covering the period 1 October to 31 December 2001.

The report illustrates the increasing breadth and volume of work as the Office successfully completed the first six months of operation of the new regulatory system for gene technology.

Yours sincerely



(Dr) Sue D Meek
Gene Technology Regulator

13 May 2002

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PART 4 - Other Activities

Abbreviations and Terms

Accredited organisation	An organisation that is accredited under section 92 of the *Gene Technology Act 2000*
Act	*Gene Technology Act 2000*
Breach	see Non-compliance
CCI	Confidential commercial information
Certified facility	A building or place certified by the Regulator, to a specified containment level, under section 84 of the GT Act
DIR	A dealing with a GMO involving the managed intentional release of a GMO *eg.* field trial
DNIR	A contained dealing with a GMO not involving the intentional release of a GMO into the environment *eg.* experiments in a laboratory
Expert advisers	Advisers appointed by the Minister to give advice to either GTTAC or GTEC to assist with the Committees in the performance of its functions. Expert advisers are not Committee members
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
GT Act	Commonwealth *Gene Technology Act 2000*
GTA	The Gene Technology Agreement between the Commonwealth, State and Territory governments, also known as an inter-governmental agreement
GTCCC	Gene Technology Community Consultative Committee

GTEC	Gene Technology Ethics Committee
GTMC	Gene Technology Ministerial Council
GTSC	Gene Technology Standing Committee of senior Commonwealth, State and Territory government officials
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
IOGTR	Interim Office of the Gene Technology Regulator
NLRD	Notifiable low risk dealing *eg.* plant or tissue culture work undertaken in contained facilities
Non Compliance	A failure to comply with licence, accreditation or certification conditions
OGTR	Office of the Gene Technology Regulator
PC2, PC3, PC4	Physical Containment levels of facilities as certified by the Regulator in accordance with the Regulator's *Guidelines for Certification of Facilities/Physical Containment Requirements*
PR	Planned release of a GMO into the environment
RARMP	Risk assessment and risk management plan
Regulator	Gene Technology Regulator
spot checks	Unannounced visits by the OGTR Monitoring & 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 GT 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 GT 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 GT Act by the Regulator or an inspector during the quarter.

Structure of this Report

This report is divided into 4 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 October - December 2001 quarter. This includes information about applications for, and action taken with respect to, new and deemed GMO licences and other instruments under the GT 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 GT Act to assist the Regulator.

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 the quarter.

Further Information

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

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PART 1 - National Regulatory System

Key achievements during the quarter

The key achievements of the October - December 2001 quarter were:

- **First application for a dealing involving intentional release (DIR) of a genetically modified organism (GMO)**

  In the quarter covered by this report, the Regulator received the first application for a dealing involving the intentional release of a GMO into the environment (known as a DIR). The application, by Cotton Seed Distributors Ltd, is for a two-year licence to trial genetically modified (GM) insect resistant cotton in Queensland.

  The process for assessing the application as laid down in the legislation requires a rigorous scientific assessment to identify any risks posed and how they can be managed. It involves extensive consultation with State and Territory Governments, the Gene Technology Technical Advisory Committee (GTTAC), the Federal Environment Minister, relevant government agencies and the public. During the period covered by this report, the Regulator invited the public and other stakeholders to be involved in the assessment process for this first application under the new regulatory system for a licence for the limited and controlled release of a genetically modified organism into the environment. For more detail, see Part 2.

- **Establishment of committees**

  Under the new regulatory system three key advisory groups have been established to assist the Regulator and the Gene Technology Ministerial Council in their decision making roles. These three committees are:

  - The **Gene Technology Technical Advisory Committee (GTTAC)** – provides scientific and technical advice to the Regulator and the Ministerial Council;
  - The **Gene Technology Ethics Committee (GTEC)** – provides advice to the Regulator and Ministerial Council on ethical issues relating to gene technology; and

- The **Gene Technology Community Consultative Committee (GTCCC)** – advises the Regulator and Ministerial Council on matters of general concern to the community in relation to GMOs.

On 8 October 2001 the then Minister for Health and Aged Care, the Hon. Dr Michael Wooldridge MP, appointed members and expert advisers to all three gene technology committees. During the quarter covered by this report, both GTTAC and GTEC held their inaugural meetings. The first meeting of GTCCC is scheduled for April 2002. For more details on the work of the committees see Part 3, Appendix A and Appendix B.

❖ Licences and other instruments

In the quarter the Regulator:

- received 38 applications for licences for dealings with GMOs including 6 applications for limited and controlled releases (DIR licences);
- received 107 applications seeking certification of facilities;
- received 4 applications for protection of confidential commercial information (CCI).
- received 1 application for accreditation of an organisation;
- was notified of 49 notifiable low risk dealings (NLRDs);
- certified 28 facilities;
- varied 19 DIR deemed licences; and
- varied 3 deemed licences for dealings not involving the intentional release of a GMO into the environment (DNIR).

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

❖ Monitoring and compliance

In the December quarter, the OGTR's target to monitor at least 5% of current and post harvest trial sites per quarter, was exceeded. A total of 40 licences were the subject of monitoring by the OGTR. Eighty-four (84) sites were monitored and 87 monitoring visits were conducted, including revisits as follow-ups to 3 of the 84 sites inspected. Of the 105 trial sites that were current in the quarter, 14% or 15 sites were monitored. Of the

518 sites subject to post-harvest monitoring during the quarter, 13% or 69 were monitored.

As input into a review of the Regulator's guidelines for certified facilities, a significant number of higher-level containment facilities were visited by the Monitoring and Compliance Section during the quarter. The target of 5% per quarter of higher level containment facilities receiving a monitoring visit was exceeded. In the quarter there were fifty-four (54) Physical Containment (PC) 4, PC3 and PC2 large-scale facilities operating under deemed certifications from the previous voluntary system. During the quarter 20% (11) of these facilities were visited. Lower level containment facilities were also inspected with ten (10) PC2 facilities and one PC1 facility visited.

A 'gene flow' study, commissioned to examine sites in Tasmania which the Interim Office of the Gene Technology Regulator (IOGTR) teams found in February 2001 to be non-compliant with voluntary guidelines, commenced during the quarter. The results of the study are expected in the first half of 2002. For more detail see Part 2 of this report.

❖ Commencement of major reviews

A review of risk assessment data requirements from GM cotton trials and a review of guidelines for the certification of facilities both commenced during the quarter. For more detail see Part 4 of the report.

❖ Institutional Biosafety Committee (IBC) training sessions

The OGTR completed a national series of training and individual information sessions for IBCs and researchers to explain how the new regulatory system will operate in practice. The issues covered in these sessions included the preparation of licence applications, NLRDs and other reports required by the Regulator. A total of 10 sessions were held across Australia between 28 September and 18 October 2001. These sessions were designed to assist IBCs to better understand and fulfil their role under the new regulatory system for GMOs.

❖ Commencement of the Gene Technology Regulator

Dr Sue Meek took up her position in Canberra as the inaugural Gene Technology Regulator on 3 December 2001.

Working collaboratively with States and Territories

Gene Technology Agreement

The Gene Technology Agreement (GTA) is an inter-governmental agreement which sets out the understandings between governments in relation to the national GMO regulatory scheme. Although the GTA took effect from the date when the majority of jurisdictions had signed the agreement (on 11 September 2001), during this reporting quarter the States of New South Wales and Tasmania signed the GTA. The Northern Territory, the last jurisdiction to receive the GTA, was forwarded the GTA in December 2001.

Gene Technology Ministerial Council and Standing Committee

The *Gene Technology Act 2000* establishes the Gene Technology Ministerial Council (GTMC) which will have responsibility for:

- issuing policy principles, policy guidelines and codes of practice to underpin the activities of the Regulator and the operation of the regulatory framework;
- considering and agreeing to changes, as required, to the national legislative framework;
- discussing matters related to gene technology regulation with other relevant Ministerial Councils;
- approving the appointment of the Regulator; and
- overseeing periodic reviews of the legislative framework.

The Ministerial Council will consist of one Minister from each State and Territory and one Minister from the Commonwealth. Decisions and outcomes from the Ministerial Council will be reported in future quarterly reports .

The Gene Technology Standing Committee (GTSC) will support the work of the Gene Technology Ministerial Council. The Standing Committee consists of senior government officials from all jurisdictions, with responsibility for gene technology issues. The Standing Committee convened their first meeting by teleconference on 10 December 2001. The main issues discussed at this meeting included the convening of the first Ministerial Council meeting and the terms of reference and standard operating procedures for both the Ministerial Council and the Standing Committee. It was agreed that a further meeting of the Standing Committee be held early in 2002.

State and Territory gene technology legislation

To establish 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 covered by this report, the Queensland, South Australian and Victorian Gene Technology Acts commenced.

Where there is sufficient uniformity between the Commonwealth and individual State gene technology laws and regulations, the Minister can declare them to be 'corresponding state laws' for the purposes of the GT Act. No State gene technology laws were declared to be corresponding state laws because, by the end of this reporting period, no regulations had been enacted in any State or Territory jurisdiction.

Commonwealth agency liaison

The close relationship between the OGTR, Commonwealth agencies and existing regulators continued during the quarter. The key focus was on the Risk Assessment and Risk Management Plan (RARMP) prepared for the first DIR application.[1]

As part of this process the Regulator sought input from Commonwealth stakeholders[2] for the preparation of the RARMP for the licence application. Once the RARMP was prepared the Regulator again sought comment on the RARMP from prescribed groups, including Commonwealth stakeholders, and the public. During the next quarter these comments will be taken into account by the Regulator in reaching a decision on whether or not to issue a licence. (See Status of DIR applications on page 3 for more detail.)

The Federal Environment Minister, Australia New Zealand Food Authority, Australian Quarantine and Inspection Service, National Health and Medical Research Council, National Industrial Chemical Notification and Assessment Scheme, National Registration Authority for Agricultural and Veterinary Chemicals and Therapeutic Goods Administration were all consulted.

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[1] Application number DIR005 - GM insect resistant cotton trial in Queensland.
[2] This consultation process also included the States and Territories, GTTAC and relevant local councils.

The role and contribution of non-government organisations

The key focus of consultation with non-government stakeholders during the quarter was in relation to the RARMP prepared for the first DIR application[3].

The Regulator sought comments from the public on the RARMP, addressing risks to health and safety and the environment, in mid-November 2001. Notices seeking public comment by 24 December 2001 were placed in the national and Queensland press, the Commonwealth Government Notices Gazette and on the OGTR website. Public comment was also sought through a mail-out and Email distribution to over 1,000 interested individuals who have requested to be notified via the OGTR mailing list. The OGTR received 16 submissions from the public. These comments will be taken into account by the Regulator in finalising the RARMP and reaching a decision on whether or not to issue a licence. (See Status of DIR applications on page 3 for more detail.)

Also in December 2001, the Regulator issued an early notification of the receipt by the OGTR of 3 new DIR licence applications. Each of the applications proposes a limited and controlled release of GM cotton. The purpose of the advance or 'Early Bird' notifications[4] is to foreshadow with the public and other stakeholders that the Regulator will be shortly seeking comment on the RARMP for each application. Early notifications were issued via press release, the OGTR website and mail-outs to individuals on the OGTR mailing list.

[3] Application number: DIR005.
[4] Early notifications are not required by legislation but rather are intended to enhance the openness of the new regulatory system.

PART 2 - The Regulation of Genetically Modified Organisms

This part of the Report outlines the regulatory activity undertaken during the October - December 2001 quarter. This includes information about applications for, and action taken with respect to, GMO licences, deemed licences and other instruments under the GT Act. It also includes details of any breaches of conditions of a GMO licence or deemed licence that have come to the Regulator's attention, and the auditing and monitoring of dealings with GMOs under the GT Act during the quarter. Information on CCI applications has also been included.

Applications received and decisions made

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

- licences or deemed licences authorising dealings involving intentional release of GMOs into the environment;
  Licences for DIRs cover work ranging from limited and controlled releases (field trials) at the initial stages of research and development through to more extensive commercial releases of GMOs.

- licences or deemed licences authorising dealings not involving intentional release of GMOs into the environment;
  Licences for DNIRs authorise contained work carried out in laboratories and other facilities designed to prevent the release of the GMO into the environment.

- accreditations of organisations; and
  Organisations which conduct work with GMOs must be accredited. To achieve this, The Regulator must be satisfied that the organisation has, or has access to, a properly constituted and maintained Institutional Biosafety Committee 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 GT 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 as long as they comply with certain risk management conditions and the dealing is undertaken in facilities which meet at least physical containment level 2. Each organisation notifying an NLRD must provide a report from their institutional biosafety committee (IBC) stating that the dealing meets the legislative requirements for a NLRD.

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 October - December 2001 quarter. In this quarter the Regulator certified 28 facilities.

Applications and notifications received and decisions made – new licences and other instruments

Applications for / Notification of		Number Approved #
Type	Number Received	
Accreditations	1	0
Certifications	107	28
Licence for a DNIR	13	0
Licence for a DIR	6	0
NLRD	49	not applicable

Approvals reported in the current quarter will often relate to applications received in previous quarters. For the purposes of this table, 'Approved' means a facility was certified.

New DIR licence applications

The OGTR received six (6) DIR licence applications in the October to December 2001 quarter:

- DIR006 – from CSIRO, to conduct seed increase and test the agronomic performance of insect resistant and insect resistant/herbicide tolerant cotton in Western Australia and the Northern Territory;

- DIR007 – from Agriculture Western Australia, to test the alkaloid production of oilseed poppies with modified alkaloid synthesis in Western Australia;
- DIR008 – from Agriculture Western Australia, to test agronomic performance and integrated pest management systems for insect resistant cotton in Western Australia and the Northern Territory;
- DIR009 – from Agriculture Western Australia, to test agronomic performance and integrated pest management systems for insect resistant cotton in Western Australia and the Northern Territory;
- DIR010 – from Aventis CropScience, to conduct seed increase and test the agronomic performance of herbicide tolerant canola in New South Wales, Victoria, Western Australia and South Australia; and
- DIR011– from Monsanto, to test the agronomic performance of herbicide tolerant canola in New South Wales, Victoria, Western Australia and South Australia

More information on these applications, including detailed summaries, can be accessed on the OGTR website at: ***www.ogtr.gov.au***.

Status of DIR applications

The key steps the Regulator takes when considering a DIR licence application are:

- initial screening of the application for completeness;
- deciding, based on the level of risk, whether one or two rounds of public consultation will occur in the assessment process for the application;
- seeking comments from prescribed stakeholders for the preparation of the Risk Assessment and Risk Management Plan (RARMP);
- preparing a RARMP (including proposed licence conditions);
- consulting with both the public and stakeholders on the RARMP; and
- considering all comments received in relation to the RARMP.

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.

All DIR applications received in the October - December 2001 quarter were screened for completeness and their receipt acknowledged within the quarter.

In the October to December 2001 quarter the Regulator also made a preliminary assessment of the risks to human health and safety and the environment which may be posed by dealings proposed to be authorised by cotton applications DIR005 (received in the July - September Quarter); DIR006; DIR008; and DIR009. This preliminary assessment determines whether or not the Regulator is required to undertake one or two rounds of public consultations. In these cases, the Regulator was satisfied that none of the dealings, proposed to be authorised by the licences, should pose significant risks.

The Regulator's reasons for reaching these conclusions were that:

- based on information available from research and from previous releases, any potential risks of toxicity, allergenicity, pathogenicity, weediness and out-crossing to related species would not be significant;
- under the previous voluntary system there were a number of limited and controlled releases of the same types of GM cotton into the environment with no reports of adverse impacts on human health and safety or the environment associated with these releases; and
- the total area of the proposed releases is within the range of previous releases.

Consequently, the Regulator was not required by the legislation to undertake two rounds of public consultation. However, in keeping with the spirit of the legislation, the Regulator decided to inform the public of receipt of these applications and of how the public would be able to contribute to the decision-making process via comment on the RARMP once it was prepared. The public was advised of this through postings of early notifications and summaries of applications on the OGTR website and to people on the OGTR mailing list.

The Regulator completed consultation on the RARMP for application DIR 005 from Cotton Seed Distributors Ltd, proposing a limited and controlled release of insect resistant, and some herbicide tolerant cotton in Queensland.

DIR applications 007, 010 and 011 were under active consideration during the quarter. The Regulator must make a decision on a licence application within 170 working days of receiving the applications. For example, for an application received on 1 October 2001 the Regulator is required to make a final decision by 12 June 2002. This time limit would be extended if the decision making process could not be continued because of an unresolved

application for declaration of CCI, or because the applicant has not supplied information requested by the Regulator in the required timeframe. However, in most cases the Regulator expects to be able to make a decision well within the legislated timeframe. The Regulator is also required to undertake mandatory consultation periods of at least 30 days each for each DIR application, therefore it is unlikely that a DIR application would be received and decided upon within the same three month reporting period.

Existing (deemed) 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 the applications received to vary existing licences and other instruments, as well as the approvals made by the Regulator in the October - December 2001 quarter. The Regulator varied 1 certification of a facility, 19 deemed DIR licences, and 3 deemed DNIR licences[5]. No instrument applications were refused in this quarter.

Applications received and decisions made – Existing (deemed) licences and other instruments

Type	Number Received	No. Approved #
Variation of accreditation	1	0
Surrender of certification	8	0
Variation of certification	5	1
Transfer of licence	1	0
Variation of DIR	15	19
Variation of DNIR	3	3

Approvals reported in the quarter often relate to applications received in previous quarter. For the purposes of this table, 'Approved' means that the Regulator varied a licence, deemed licence or other instrument.

[5] The majority of variations were made at the request of the licence holder. 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.

In order to facilitate a smooth transition from the previous voluntary (GMAC) arrangements, '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 Physical Containment (PC)3, PC4 and large-scale PC2 for which the instruments will operate for up to one year for facilities and other facilities. In the short term most changes reported in this section will relate to 'deemed' licences and other 'deemed' instruments.

During the October to December 2001 quarter, the Regulator wrote to all accredited organisations seeking to know which of their 'deemed' instruments would need to be replaced by new applications to enable work to continue past the expiry date set down in the legislation. Information in response to this request will be used to develop a rolling program of renewals of instruments to spread the workload for researchers, industry and the regulatory system.

Confidential commercial information (CCI)

The GT 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 from the Regulator that the information is confidential commercial information (CCI). CCI information is protected from disclosure until any appeal rights have been exhausted. If the Regulator declares information to be CCI, the Regulator can not publicly release that information.

In the October - December 2001 quarter the Regulator received 3 CCI applications in relation to DIR licence applications and 1 CCI application in connection with a NLRD. No CCI applications were either refused or approved by the Regulator during the quarter.

Monitoring and Compliance

The aim of OGTR monitoring and compliance activities is to ensure that dealings with GMOs comply with licence conditions that are consistent with the object of the GT 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 the management of dealings for field trial sites and within contained facilities to ensure that:

- the risk of persistence of a GMO in the environment is controlled; and
- the risk of dissemination of a GMO and its genetic material is minimised;

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 conducts routine monitoring visits of a minimum of 20% of the field trial sites involving GMOs on an annual basis. The purpose of routine monitoring is to promote compliance with licence conditions. A minimum of 5% of current trial sites and 5% of trial sites subject to post-harvest monitoring are monitored each quarter.

On the basis of experience, the OGTR has enhanced the effectiveness of its monitoring strategy to have a greater emphasis on risk profiling and to include unannounced spot checks. OGTR monitoring activity is scheduled, as far as possible, to coincide with inherently higher risk periods in dealings with gene technology *eg.* flowering and harvesting.

In order to meet legislative requirements for the re-certification of facilities, and to assist the process of re-certification, the Monitoring and Compliance Section has instituted a program of inspecting facilities, particularly Physical Containment (PC) 4, PC3 and PC2 large scale facilities.

The Monitoring and Compliance Section is continuing to develop and apply protocols and provide training to assist licence holders better understand obligations and requirements of the regulatory system.

This is particularly important during the period following 21 June 2001 where organisations are moving from a voluntary system of regulation to the legislative framework under the *Gene Technology Act 2000*.

A 'gene flow' study (to verify whether any gene flow to related weeds from GM canola has occurred around non-compliant sites) commenced this quarter on post harvest trial sites in Tasmania that were found in February 2001 to not comply with the previous voluntary guidelines. The results of the study are expected in the first half of 2002.

Over the course of the quarter, OGTR monitoring activities in Tasmania were conducted jointly with Tasmanian government officials in their capacity as quarantine officers under Tasmanian quarantine legislation. Discussions with Queensland officials continued on the details of a bilateral agreement to undertake monitoring at certain sites on behalf of the OGTR in that State.

Overview of monitoring and compliance for the reporting period

Total trial sites monitored. During the October to December 2001 quarter, a total of 87 monitoring visits were carried out on 84 sites (follow-up visits were undertaken at 3 of the 84 sites to ensure continued compliance with legislative and licence conditions). Eleven (11) visits were carried out as unannounced spot checks.

Current trial sites monitored. Of the 105 sites that were current in the quarter, sixteen (16) monitoring visits were carried out at fifteen (15) sites. This represents a monitoring rate of 14% of all current sites for the quarter. Nine (9) of the visits were unannounced spot checks and one (1) site was revisited to ensure continued compliance.

Post Harvest trial sites monitored. Of the 518 sites that were subject to post harvest monitoring in the quarter, 71 monitoring visits carried out at 69 sites. Two (2) of these visits were unannounced spot checks and 2 sites were revisited to ensure continued compliance. This represents a post harvest site monitoring rate of 13% in the quarter.

Monitoring conducted

The total monitoring coverage for the October to December 2001 quarterly reporting period is shown in the following table.

Licenced Organisation name	Deemed licence (PR)	No. sites licenced	No. sites visited	Site status*	Crop type
Aventis CropScience	62X(3)	2	1	PHM	Canola
	62X(4)	15	4	PHM	Canola
	63X(3)	62	1	PHM	Canola
	63X(4)	96	15	PHM	Canola
	63X(5)	39	1	PHM	Canola
	90X	6	1	PHM	Canola
Monsanto Australia	77X	18	4	PHM	Canola
	77X(2)	30	7	PHM	Canola
	77X(3)	30	3	PHM	Canola
	77X(4)	6	1	PHM	Canola
Department of Agriculture, Western Australia	87X	7	1	PHM	cotton
	87X(2)	17	1	PHM	cotton
	144	24	5	3xC, 2xPHM	cotton
	146	1	1	C	poppy
Cotton Seed Distributors	94X(3)	1	1	C	cotton
	131X(3)	1	1	C	cotton
CSIRO	58X	2	1	PHM	subterranean clover
	58X(2)	2	1	PHM	subterranean clover
	69X(5)	1	1	PHM	cotton
	89X(2)	26	1	C	cotton
	97	1	1	PHM	subterranean clover
	99X(3)	1	1	PHM	cotton
	102X	1	1	PHM	wheat
	123X	6	2	PHM	cotton
	123X(2)	2	2	C	cotton
	124X	1	1	PHM	cotton
	124X(2)	2	1	C	cotton
	138	1	1	PHM	cotton
	138X	2	1	C	cotton
	150	1	1	C	subterranean clover
	151	2	1	C	cotton
Deltapine	51X(5)	2	1	PHM	cotton
	112X(2)	3	1	C	cotton
	140	16	5	PHM	cotton
	143	1	1	C	cotton
Qld Dept Primary Ind	24X	1	1	PHM	apple
University of Western Australia	74	7	7	PHM	lupin
	75	1	1	PHM	lupin
GlaxoSmithKline	129	1	1	PHM	poppy
	129X	1	1	PHM	poppy
Totals	**40**	**439**	**84**	**C15/PHM69**	**7 species**

* C = current / PHM = post-harvest monitoring

In addition to monitoring field trial sites, the Monitoring and Compliance Section has also initiated a program of monitoring contained facilities. Higher risk GMO dealings are undertaken in physical containment (PC) 4, PC3 and large-scale PC2 certified facilities. As a minimum, the OGTR is committed to monitor 20% of these facilities per year. As monitoring and reporting is structured on a quarterly basis, a minimum of 5 % of these certified facilities will be monitored per quarter. In addition, PC2 and PC1 certified facilities will also be monitored on a random basis.

In the quarter there were fifty-four (54) PC4, PC3 and PC2 large-scale facilities operating under 'deemed' certifications from the previous voluntary system. Of these, eleven (or 20%) were visited during the quarter. Of the low level facilities, ten (10) PC2 and one (1) PC1 facility were also visited. During the inspections, the Monitoring and Compliance Section gathered as part of the review of the Regulator's guidelines for certified facilities.

The organisations that were visited by the OGTR during this quarter are detailed in the table below.

Organisation	**Physical Containment (PC) facility**
Australian National University	PC2 Laboratory PC2 Plant House (x2) PC2 Animal Containment Facility
CSIRO	PC2 Laboratory (x2) PC2 Plant House PC2 Animal Containment Facility
James Cook University	PC2 Laboratory PC1 Laboratory
Queensland Health Scientific Services	PC4 Laboratory PC3 Laboratory (x2) PC4 Animal House PC4 Insectory PC2 Laboratory
Progen Industries	PC2 Large Scale Laboratory
Queensland Dept of Primary Industry	PC3 Animal House PC3 Laboratory
Queensland Institute of Medical Research	PC3 Laboratory PC3 Animal House (x2)
Total no. organisations visited - 7	**PC1 – 1 / PC2 – 10 PC2(large) – 1 / PC3 – 7 / PC4 – 3**

Monitoring Findings

This section reports on the outcomes of monitoring activities. A review of compliance with licence conditions at field trial sites initiated in the last quarter continues and has been extended to include observations at field trial sites by monitoring teams during this quarter. The purpose of the review is to consider two aspects of interest:

- potential environmental risks using monitoring observations; and
- whether there has been a possible non-compliance for referral for investigation.

Observations from monitoring visits that constitute the review will be reported on in subsequent quarterly reports. A number of GM canola trial sites subject to post-harvest monitoring were observed to have canola volunteers or brassicaceous species which required further examination. In addition, observations from a monitoring visit to PR97 is currently under assessment and will be reported in the next quarterly report.

OGTR's monitoring of certified facilities found a variety of minor non-compliances with the certification guidelines. None of the observed non-compliances compromised the containment of GMOs or posed a risk to public health or the environment. The current certification guidelines, which are based on the previous GMAC requirements, are also being reviewed (see Part 4, Reviews and Research) to make them more user-friendly and more easily enforceable. In the meantime, the OGTR is focusing efforts on educating organisations and scrutinising the waste management systems within certified facilities based on potential risks from this activity.

Findings for field trial sites arising from monitoring activity

PR & Site No.	**87X, Site 1**
Summary of Dealing	The licence, now in its post-harvest monitoring phase, relates to field trials of cotton (*Gossypium hirsutum*) modified to express a toxin lethal to certain insect species conducted by the Department of Agriculture (Western Australia).
Findings	Less than 10 volunteer cotton plants with seed were observed in an area immediately adjacent to the site.
Risk assessment	Without remedial action, the plants may have dropped seed and contributed to the persistence of the GMO in the environment. As the plants were removed at the time of the monitoring visit, there was a negligible risk posed to the environment.
Risk management	As noted, the plants were removed at the time of the monitoring visit. The proponent is to continue performing monitoring as per licence conditions.

PR & Site No.	74, Site 1
Summary of Dealing	The licence, now in its post-harvest monitoring phase, relates to field trials of lupins (*Lupinus angustifolius)* modified for tolerance to the herbicide glufosinate-ammonium and is held by CLIMA (University of Western Australia). One of the cultivars trialed also carries a gene for a sunflower seed albumin, a protein rich in sulphur-containing amino acids.
Findings	Less than ten volunteer plants with mature seed were observed to be on, or immediately adjoining, the site. The site had its post-harvest crop of cereal mown and retained on site.
Risk assessment	There was a negligible risk posed to the environment by the small number of mature plants observed, as each plant was removed and destroyed. However, there was potential for mature genetically modified lupin plants to have been present on the site within the mown material.
Risk management	The mown material is to be held on site so that any seed present in mown plant material is destroyed or subjected to ongoing monitoring.

PR & Site No.	74, Site 3
Summary of Dealing	The licence, now in its post-harvest monitoring phase, relates to field trials of lupins (*Lupinus angustifolius)* modified for tolerance to the herbicide glufosinate-ammonium and is held by CLIMA (University of Western Australia). One of the cultivars trialed also carries a gene for a sunflower seed albumin, a protein rich in sulphur-containing amino acids.
Findings	Six volunteer plants with mature seed were observed in the area immediately adjoining the site.
Risk assessment	Lupin plants observed in the vicinity of the site had reached maturity, however were not expected to be genetically modified lupins given their location in relation to the site. There was a negligible risk posed to the environment as the small number of mature plants observed were collected for destruction.
Risk management	As noted, the plants were removed at the time of the monitoring visit. The proponent is to continue performing monitoring as per licence conditions.

PR & Site No.	74, Site 5
Summary of Dealing	The licence, now in its post-harvest monitoring phase, relates to field trials of lupins (*Lupinus angustifolius)* modified for resistance to the herbicide glufosinate-ammonium and is held by CLIMA (University of WA). One of the cultivars trialed also carries a gene for a sunflower seed albumin, a protein rich in sulphur-containing amino acids.
Findings	Representatives of the licence holder responsible for monitoring to date appeared to have been monitoring an area immediately adjacent to the site rather than the trial site.

Risk assessment	From information provided to the OGTR, it was assessed that a negligible risk was posed to the environment due to the monitoring of the adjacent area, as the entire field, including the trial site, was subject to the same management strategies to control volunteer growth.
Risk management	The entire area, the trial site and the adjacent area, is to be monitored as Site 5.

PR & Site No.	**74, Site 6**
Summary of Dealing	The licence, now in its post-harvest monitoring phase, relates to field trials of lupins (*Lupinus angustifolius)* modified for tolerance to the herbicide glufosinate-ammonium and is held by CLIMA (University of Western Australia). One of the cultivars trialed also carries a gene for a sunflower seed albumin, a protein rich in sulphur-containing amino acids.
Findings	Volunteer plants had been removed or destroyed on the site prior to the monitoring visit. At the time of the monitoring visit it was observed that the site had its post-harvest crop of cereal mown.
Risk assessment	There was potential for mature genetically modified lupin plants to have been present on the site within the mown material.
Risk management	The mown material is to be held on site so that any seed present in mown plant material is destroyed or subjected to ongoing monitoring.

Investigations

As at 31 December 2001, three investigations into alleged non-compliances had been initiated under the new regulatory system. Details of these investigations will be reported in a subsequent quarterly report once investigations are complete.

The OGTR may not release information about ongoing investigations because the information may:

- jeopardise current or future investigations;
- be protected by legislation (*eg.* the *Privacy Act 1988*);
- be 'confidential commercial information';
- unfairly damage or unfairly treat persons who may be assisting, or may be the subject of, an investigation; or
- unfairly damage the reputation of third parties who have not themselves breached legislative requirements.

However, if there are imminent risks of danger to the health and safety of people or the environment, the Regulator would consider whether the release of the information may be appropriate.

The three investigations that were initiated under the voluntary system, and reported on in the March and June 2001 quarterly reports, were completed during the quarter. As the incidents that lead to these investigations occurred under the voluntary system, legislative provisions within the *Gene Technology Act 2000* do not apply. Summaries of the completed investigations are shown in the tables below.

Type	A voluntary system investigation
Name	Aventis CropScience Pty Ltd past canola trial sites in Tasmania. Investigation of breaches found during IOGTR monitoring in Tasmania and risk assessment advice from GMAC
Current Status	Closed – with follow-up action being undertaken
Allegation	IOGTR monitoring activities in February 2001 detected volunteer canola that had not been controlled before flowering.
Summary of Investigation	The investigation by the IOGTR included monitoring of all sites involved in GM canola trials in Tasmania, discussions with Aventis CropScience personnel and their contracted agent, and discussions with the Tasmanian Department of Primary Industries, Water and Environment.
Findings	As a result of IOGTR monitoring in Tasmania, it was found that 18 of the 49 Aventis CropScience GM canola trial sites did not comply with GMAC advice.
Risk Assessment and Management	The risk of gene flow or continued persistence in the environment was considered negligible as management actions were put into place to mitigate such risks. In addition to immediate remedial action to remove flowering or seeding volunteers, further remedial action included: - extension of the post-trial monitoring period for a further 3 years at all non-compliant sites; - the monitoring and removal of weedy relatives within 100 m of non-compliant sites for 3 years; and - increased independent monitoring of sites by the OGTR. These requirements are now part of Aventis Crop Science's licence under the new regulatory system and include a general strengthening of provisions such as frequency of monitoring by the company. In addition, the Regulator has commissioned an independent study to verify whether any gene flow to related weeds from GM canola has occurred around the non-compliant sites. Following the completion of the gene flow study, all risk management actions will be reviewed to reflect the results of the study.

Type	A voluntary system investigation
Name	Monsanto Australia Ltd past canola trial sites in Tasmania. Investigation of breaches found during IOGTR monitoring in Tasmania and risk assessment advice from GMAC
Current Status	Closed – with follow-up action being undertaken
Allegation	IOGTR monitoring activities in February 2001 detected volunteer canola that had not been controlled before flowering.
Summary of Investigation	The investigation involved IOGTR monitoring of all sites used in GM canola trials in Tasmania, discussions with Monsanto personnel and their contracted agent, and discussions with the Tasmanian Department of Primary Industries, Water and Environment.
Findings	As a result of IOGTR monitoring in Tasmania, it was found that 3 of the 7 Monsanto GM canola trial sites subject to post harvest monitoring did not comply with GMAC advice.
Risk Assessment and Management	The risk of gene flow or continued persistence in the environment was considered negligible as management actions were put into place to mitigate such risks. In addition to immediate remedial action to remove flowering or seeding volunteers, further remedial action included: - extension of the post-trial monitoring period for a further 3 years at all non-compliant sites; - the monitoring and removal of weedy relatives within 100 m of non-compliant sites for 3 years; and - increased independent monitoring of sites by the OGTR. These requirements are now part of Monsanto's licence under the new regulatory system and include a general strengthening of provisions such as frequency of monitoring by the company. In addition, the Regulator has commissioned an independent study to verify whether any gene flow to related weeds from GM canola has occurred around the non-compliant sites. Following the completion of the gene flow study, all risk management actions will be reviewed to reflect the results of the study.

Type	A voluntary system investigation
Name	Aventis CropScience canola trial sites. Seeds being transported off trial sites in boots and clothing of workers
Current Status	Closed – with follow-up action being undertaken
Allegation	An allegation was made that canola seed was being transported off genetically modified (GM) canola trial sites in the Mount Gambier area in or on boots or clothing of casual workers employed at the trial sites for hand harvesting purposes. There was also an allegation that workers were not adequately informed of the nature of their work or the requirements for managing GM trial sites.

Summary of Investigation	The investigation involved interviews with company personnel, the original source of the allegations, and independent observations of the harvesting activities and sites by Interim OGTR monitoring teams.
Findings	This investigation, initiated by the Interim Office of the Gene Technology Regulator (IOGTR) under the voluntary system arrangements and finalised by the OGTR, could not, beyond reasonable doubt, make a conclusive finding in relation to the allegations. However, in weighing up the information collected by IOGTR monitoring teams, the balance of probability supports the conclusion that small amounts of seed were transported off trial sites in boots and on clothing of workers.
Risk Assessment and Management	As it is possible that some seeds were leaving sites in workers' boots, a risk assessment was undertaken. The investigation concluded that no risks existed to human health and safety and risks to the environment were negligible. To follow-up on the outcomes of the risk assessment, the OGTR made the following recommendations: • Aventis CropScience should contact each of the casual workers contracted for hand harvesting activities in the Mount Gambier region offering to collect seeds or plants growing on the workers' property, or a property visited by the workers, if they believe the seed or plants may be GM canola. • For future crop trials, Aventis CropScience should implement their suggestion to provide documentary evidence to demonstrate that each worker is aware of their obligations in relation to GM canola field trial sites. • The harvesting process should be reviewed as a potential point of seed loss and movement of seed off-site. • The OGTR to undertake follow-up monitoring of gateways and access tracks to detect any movement of seed off-site. Aventis CropScience has agreed to undertake all risk management actions relevant to the company.

Audits

An audit of the University of Western Australia management of previous lupin trial sites, initiated under the former voluntary system, was completed during the October to December 2001 quarter. Under the voluntary system, GMAC received Planned Release Proposals (PR74, PR75 & PR76) for transgenic lupin trials to be conducted by the Centre for Legumes in Mediterranean Agriculture (CLIMA), a Cooperative Research Centre (CRC) involving the University of Western Australia, Agriculture Western Australia and others.

The CRC was discontinued and CLIMA was subsumed in the University of Western Australia's Faculty of Agriculture.

As a result of this transition there was a need to clarify the roles and responsibilities for the ongoing management of the GM lupin trial sites. IOGTR monitoring activities highlighted non compliance with GMAC advice and a number of issues of concern regarding the organisation's monitoring and management of post-trial sites. The audit initiated by the IOGTR, and completed by the OGTR, was conducted to ensure that these sites were being appropriately managed and to identify any areas needing improvement.

A report of the audit has been completed and is available on the OGTR website at *http://www.ogtr.gov.au/publications/bulletins.htm*

No other audits were initiated or were ongoing in the October to December 2001 quarter.

PART 3 - Committee Operations

The GT Act establishes three new advisory committees:

1. The **Gene Technology Technical Advisory Committee** – provides scientific and technical advice to the Regulator and the Ministerial Council;
2. The **Gene Technology Community Consultative Committee** – advises the Regulator and Ministerial Council on matters of general concern to the community in relation to GMOs; and
3. The **Gene Technology Ethics Committee** – provides advice to the Regulator and Ministerial Council on ethical issues relating to gene technology.

The Minister for Health and Aged Care, the Hon. Dr Michael Wooldridge MP, appointed members and expert advisers[6] to all three committees on 8 October 2001. Formal appointment of the Committee Chairs, ratified by all jurisdictions is expected to occur in the next quarter. In accordance with the GT Act, committee member and Chair appointments are not made unless a majority of jurisdictions endorse the appointment.

As soon as possible following each meeting, committees must produce a communique of the resolutions agreed to at the meetings. The communiques will be publicly available via the OGTR website and are reproduced in the quarterly reports (see Appendix A and B).

During the quarter, both GTAC and GTEC held their inaugural meeting in Canberra. The inaugural meeting of GTCCC is anticipated in the first half of 2002.

Details on the committee membership and meetings follow.

[6] Expert advisers are to give advice to assist with the Committees in the performance of its functions; expert advisers are not Committee members.

Gene Technology Technical Advisory Committee

Gene Technology Technical Advisory Committee appointments:

- Dr Gerald Both, BSc(Hons), PhD;
- Professor James Dale, BSc(Hons), PhD;
- Professor Ashley Dunn, MPhil, PhD;
- Associate Professor Eric Haan, BMedSc, MBBS, FRACP;
- Ms Judy Jones, B.Sc, LL.B (Cross member with GTEC);
- Professor James Kirkpatrick, BA(Hons), PhD;
- Professor Peter Langridge, BSc, PhD;
- Professor Marjory-Dore Martin, BSc, BEd, MSc, PhD (Cross member with GTCCC);
- Emeritus Professor Nancy Millis, AC MBE BSc, MSc, PhD, DSc;
- Dr John Oakeshott, BSc(Hons), PhD;
- Dr Philip O'Brien, BSc(Hons), PhD;
- Dr John Rasko, BSc, MBBS(Hons), PhD, FRCPA, FRACP;
- Dr Franklin Panetta, BA, PhD;
- Emeritus Professor Alfred James Pittard, AM, Dip Pharm, BSc, MSc, DSc, MD, PhD;
- Professor Hugh Possingham, BSc(Hons), PhD;
- Professor Stephen Powles, BAppSc, MSc, PhD;
- Dr Nancy Schellhorn, BSc, MSc, PhD;
- Associate Professor Peter Upcroft, BSc (Hons), PhD; and
- Associate Professor Richard Roush, BSc, PhD (Expert Adviser).

GTTAC held its inaugural meeting on the 14-15 November 2001. The communique from the first GTTAC meeting can be found at Appendix A Communique from the Gene Technology Technical Advisory Committee Meeting of 14-15 November 2001.

GTTAC agreed it should hold face to face meetings six times a year, supplemented with teleconferences where necessary. GTTAC held its first teleconference on 17 December 2001. Resolutions agreed to either through teleconferences or out-of-session agreement will be contained in the communique issued for the next face to face meeting. The next GTTAC meeting is scheduled for March 2002.

Gene Technology Ethics Committee

Gene Technology Ethics Committee appointments:

- Dr Gavin Ash, BSc(Hons), PhD;
- Ms Belinda Byrne;
- Professor Don Chalmers, LLB, LLM;
- Reverend Dr Brian Edgar, BTh (Hons), MTh, PhD;
- Dr Neville Hicks, BA (Hons), PhD;
- Dr Kees Hulsman BSc (Hons), PhD;
- Dr Bidda Jones, BSc (Hons), PhD;
- Ms Judy Jones, BSc, LLB (Cross member with GTTAC);
- Dr Simon Longstaff, BEd, MPhil, PhD;
- Associate Professor Ariel Salleh, BA (Hons), MA, PhD;
- Dr Sandy Webb, BSc, MSc, PhD (Cross member with Australian Health Ethics Committee);
- Dr Rosemary Robins, BA (Hons), PhD (Cross member with GTCCC);
- Dr John Fleming, B.A, ThL (Hons), PhD (Expert Adviser); and
- Mr Max Griffiths, MBE BA, BCom, BD (Expert Adviser).

GTEC held its inaugural meeting on 12-13 December 2001. The communique from the first GTEC meeting can be found at Appendix B Communique from the Gene Technology Ethics Committee Meeting of 12-13 December 2001.

GTEC agreed to form five working groups that will look at each of the five priority issues identified by the committee. GTEC agreed to hold face to face meetings twice a year, supplemented with teleconferences where necessary. The next GTEC meeting is scheduled for May 2002.

Gene Technology Community Consultative Committee

Gene Technology Community Consultative Committee appointments:

- Ms Elaine Attwood;
- Mr Donald Coles, Dip FM, MBA;
- Mrs Margaret Cover;
- Dr John Keniry, BSc (Hons), PhD;
- Mr Bruce Lloyd;
- Professor Marjory-Dore Martin, BSc, BEd, MSc, PhD (Cross member with GTTAC);
- Mrs Juliet McFarlane;
- Mr Robert Errol Phelps, BA (Hons);
- Councillor Clive Robartson, OAM, BAppSc., DipAgricTech.;
- Dr Rosemary Robins, BA (Hons), PhD (Cross Member with GTEC); and
- Associate Professor Frank Vanclay, BSc(Hons), MSocSci, PhD.

The inaugural meeting of GTCCC is anticipated to be held in the first half of 2002.

PART 4 - Other Activities

Reviews and Research

The Regulator initiated two reviews during this quarter:

- The Regulator requested a review be undertaken to develop a strategy to identify data required for future risk assessments and risk management plans for dealings including intentional release of GM cotton, particularly large scale releases. The review will also identify the most appropriate mechanism by which information to fill any data gaps could be acquired. To help the Regulator in this review a panel of experts, known as the Cotton Review Panel, was established to provide technical advice.
- To facilitate re-certification of contained facilities, the Regulator has also initiated a review of the *Guidelines for the Certification of Facilities/Physical Containment Requirements*. OGTR monitoring activities has found practical difficulties in implementing the current Guidelines and has gathered specific information for input into the review. Draft revised Guidelines are expected to be released for consultation in the first half of 2002.

International Collaboration and Coordination

Under the GT 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 October-December 2001 quarter, the OGTR provided briefings to representatives of a number of countries interested in learning about Australia's new regulatory system. Briefings included:

- presentation to an APEC workshop organised by AusAID;
- meetings with a delegation from the Hong Kong Food and Environmental Hygiene Department;
- presentation to a European parliamentarian;
- briefing to the new officer from the Department of Foreign Affairs and Trade posted to New Zealand with responsibility for gene technology issues;

- briefing material on the *Gene Technology Act 2000* to a visiting Chinese environment delegation; and
- responses to questions from the Japanese government on the applicability and scope of the new regulatory system.

The OGTR also participated in the workings of a number of ongoing international bodies and agreements such as the OECD, the UN Biosafety Protocol and the Codex Alimentarius. This included:

- preparing papers relating to Australia's regulatory system for GMOs for the Biosafety Protocol Secretariat;
- answering OECD questionnaires on the regulation of GM stockfeed and GM identification/detection methods in Australia; and
- providing briefing to Australian industry on outcomes from the second meeting of the Inter-governmental Committee of the Cartegena Protocol relating to the proposed Biosafety Clearing House mechanism and GMO unique identifier.

The OGTR maintained a watching briefing on gene technology developments overseas, including the New Zealand government's response to the Royal Commission on Genetic Modification, New Zealand's implementation of a contamination threshold on imported seeds, and the latest regulatory developments in the European Union. The watching brief entailed liaison with Australian diplomatic staff and with officers in relevant overseas regulatory authorities.

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 regulatory system. During the reporting period the OGTR made the following presentations to or at the:

- AusAID Public Policy and Biotechnology Training Program, 24 October 2001, in Melbourne;
- GMO Forum, 22 November 2001, in Mount Gambier, South Australia;
- Clayton Utz Bioethical 2001, 4 December 2001, Sydney;
- Biotechnology Industry Forum, 4 December, Melbourne; and
- Canberra Hospital, 13 December 2001, Canberra.

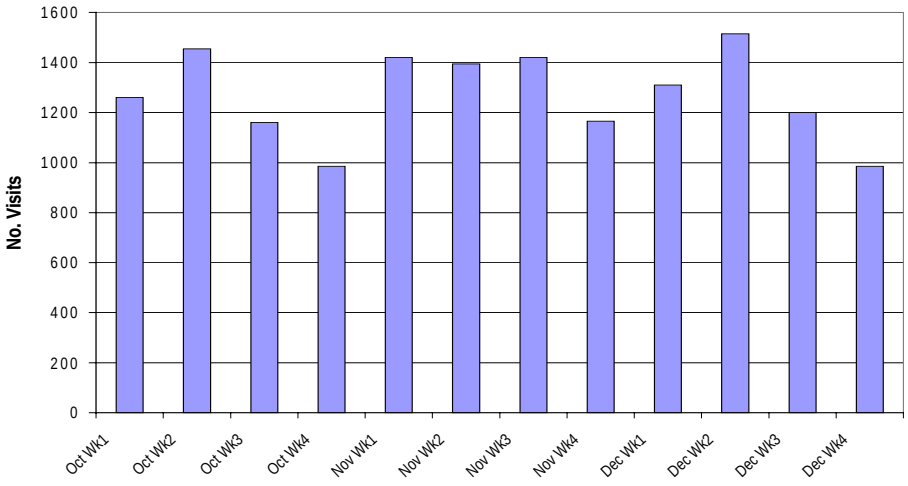
In addition, the OGTR completed training sessions for institutional biosafety committees (IBCs) which commenced in the previous quarter. Training sessions were conducted in all capital cities except Darwin[7] over the period 28 September to 18 October 2001.

A total of 10 sessions were held across Australia between 28 September and 18 October 2001. These sessions were designed to assist IBCs to better understand and fulfil their role under the new regulatory system for GMOs.

During the quarter, the final quarterly report for the Interim Office of the Gene Technology Regulatory was released. The *Interim Office of the Gene Technology Regulator Quarterly Report June 2001* is available from the OGTR website.

OGTR website *www.ogtr.gov.au*

The OGTR website received 340,442 'hits'[8] during the period 1 October to 31 December 2001, which represents an average of 3,704 hits per day. The table below illustrates the pattern of individual visits[9] to the OGTR website, by week over the reporting period.



The most popular pages viewed on the OGTR website during the period were: OGTR Publications; OGTR General information; GMO record; and Committees pages. During the reporting period, an on-line search facility was introduced to the website to assist the public in locating specific

[7] The OGTR paid travel costs for a participant from Darwin to attend the Adelaide presentation.
[8] Hits = Total number of pages and images requested from the website
[9] Visits = Total number of visitors that entered the website

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

OGTR e-mail enquiries to *ogtr@health.gov.au*

Over the reporting period, a total of 315 e-mail messages were sent to the OGTR general e-mail account. In October 2001, 120 e-mails were received, in November 107 were received and in December 88 were received.

Of the e-mails received, approximately 80 per cent were requests for information; 16 per cent were provision of information from other organisations; and approximately 4 per cent provided feedback and comments.

Calls to OGTR toll-free telephone number *1800 181 030*

In October 2001 there were 184 calls to the OGTR 1800 line; in November 201 calls; and in December 191 calls.

Freedom of Information (FOI)

No FOI requests were received during the reporting period.

Consultants

During the reporting period, the OGTR managed 8 consultancy contracts worth a total of $515,868. The table below lists the consultants, describes the purpose of the consultancy and the amount paid during the quarter.

Consultant	Amount paid	Purpose
Cordiner King	$29,307	Executive recruitment of the Regulator
Dialog Information Technology	$293,159	Develop Gene Technology Information Management System (GTIMS)
Environmental Resources Management	$8,850	Environment risk analysis of dissemination of genetically modified seed.
Luminis P/L	$45,455	Gene flow study
Matthews Pegg Consulting	$109,197	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	Assistance with information and media
NSW Agriculture	$2,000	Weed survey of GM crop trials
Oceania Health	$1,500	Assistance with preparation of risk assessment guidelines

Appendix A
Communique from the Gene Technology Technical Advisory Committee Meeting of 14-15 November 2001

The GTTAC held its inaugural meeting in Canberra on 14-15 November 2001. GTTAC was established by the GT Act as a statutory advisory committee to the Regulator and the Gene Technology Ministerial Council. All committee members and expert advisers hold office on a part-time basis.

At the first meeting the Committee discussed a risk analysis framework for licence applications and provided scientific and technical advice at the request of the Acting Regulator[10] on two applications for gene technology work currently before the Office of the Gene Technology Regulator (OGTR). The outcomes of these discussions are summarised below.

1. Risk Analysis Framework for Licence Applications Before the OGTR

The GT Act requires the Regulator to prepare a risk assessment and risk management plan for all licence applications. This Framework was developed to provide general guidance to applicants, evaluators and other stakeholders when identifying and assessing the risks posed by dealings of genetically modified organisms and to assist in determining the measures necessary to manage any such risks.

The Framework was developed by the OGTR in consultation with all States, Territories, Commonwealth Government Agencies, key stakeholders and the public. It takes into account the requirements of the GT Act, the Gene Technology Regulations 2001 (the Regulations), and guidelines and risk assessment strategies in use in related agencies both in Australia and overseas.

[10] Ms Elizabeth Cain, Acting Regulator from 21 June to 30 November 2001.

GTTAC Resolved:

GTTAC agreed that the Risk Assessment Framework should make clear the roles and responsibilities of other agencies such as Agriculture Fisheries and Forestry Australia (AFFA), the National Registration Authority (NRA) and the Australia New Zealand Food Authority (ANZFA) in the context of the new national regulatory system. GTTAC noted that the risk assessment framework would be formally reviewed in 12 months.

2. Agronomic Assessments and Seed Increase in Eastern Australia of Transgenic Cotton Expressing Cry1Ac and Cry 2Ab Genes from *Baccillus thuringiensis*

Cotton Seed Distributors have applied for a licence for a large-scale field trial of genetically modified insect resistant cotton (Bollgard II®). The cotton is derived from INGARD® (Bt) cotton which was approved for commercial release by the NRA, with the advice of the Genetic Manipulation Advisory Committee (GMAC), in 1996.

The trial is for seed increase and large-scale evaluation of agronomic performance of Bollgard II® cotton. Varieties crossed with Roundup Ready® cotton (approved for general release by the Minister for Health and Aged Care in September 2000, with advice from GMAC) are also to be trialled.

The release is proposed to be carried out on a total area of 480 hectares, at six sites in the Shires of Balonne and Emerald in Queensland. The field locations will all be south of latitude 22° South, that is within the area approved by the NRA for commercial release of INGARD® cotton and designated by the Minister for Health and Aged Cared for the release of Roundup Ready® cotton.

GTTAC Resolved:

GTTAC recommended that the Regulator request additional information from Cotton Seed Distributors (CSD) regarding:

- the levels of expression of the Cry1Ac and Cry2Ab proteins; and
- the efficacy of the INGARD® and Bollgard II® genes endowing resistance to cotton plants against the target pest.

GTTAC recommended that the Regulator request that Cotton Seed Distributors provide more detail on the mechanisms they intend to use to ensure segregation of seed both at the gin and for any associated transport.

3. Testing Protection of Cattle from Fluoroacetate

Murdoch University has applied for a licence for a dealing that does not involve the intentional release of a GMO into the environment. The dealing involves inoculating cattle with rumen bacteria (*Butyrivibrio fibrisolvens*) which have been genetically modified to detoxify fluoroacetate (a compound poisonous to cattle which occurs in some native plants) and contain antibiotic resistance genes. The cattle will be monitored to see if the bacteria colonise the rumen in the cattle. The cattle will then be challenged with fluoroacetate.

The applicant has previously applied to GMAC for field trials of these GMOs (PR-45, PR-130 and PR130-X). GMAC's advice was that these trials should not proceed. This application differs from the previous ones in that the cattle will be housed in PC2 animal facilities in Werribee, Victoria. These facilities are managed by Commonwealth Scientific and Research Organisation (CSIRO).

GTTAC Resolved:

GTTAC recommended that the Regulator seek additional information from the applicant with regard to:

- the effective containment of the bacteria within the facility (in accordance with the Regulations, Schedule 4, Part 1, 1.1.4).
- the management of unintentional release (in accordance with the Regulations, Schedule 4, Part 1, 1.1.4) including:
- proposed methods of avoiding the unintentional release of the bacteria;
- impacts that any unintentional release may have on human health and the environment; and
- contingency plans that will be implemented in the event of an unintentional release.

GTTAC emphasised that any advice on this application should not be taken as an endorsement, or otherwise, of any future such applications.

Appendix B
Communique from the Gene Technology Ethics Committee Meeting of 12-13 December 2001

GTEC held its inaugural meeting in Canberra on the 12-13 December 2001. GTEC was established by the GT Act as a statutory advisory committee to the Regulator and the Gene Technology Ministerial Council. All committee members and expert advisers hold office on a part-time basis. (A reference to 'members' in the communique includes 'expert advisers').

At its first meeting the Committee discussed the development of a work plan for GTEC including ethical guidelines for the new gene technology regulatory system. The discussion covered the current and likely future ethical issues in gene technology. The outcomes of these discussions are summarised below.

GTEC and Relationships with Other Committees

GTEC, in considering its role in the new regulatory system for GMOs in Australia, recognised that there are many agencies and committees already operating across a range of biotechnology and health ethics issues. GTEC acknowledged the need to clarify areas of responsibility and pursue effective communication with these other agencies and committees.

For example, GTEC is one of three gene technology advisory committees established under the GT Act. The other committees are GTTAC and GTCCC. The GT Act provides for cross membership between the committees.

Therefore, at its first meeting GTEC received a copy of the written communique issued following the inaugural meeting of GTTAC in November 2001 and a verbal report from the cross member. This exchange of information from GTTAC will be a feature of forthcoming GTEC meetings when a similar report and presentation will be made by the GTCCC cross member.

Another significant stakeholder in this area is the National Health and Medical Research Council (NHMRC) formed under the *National Health and Medical Research Council Act (1992).* The NHMRC has established a number of committees as an integral part of its grant allocation and health advice processes. These committees include the Australian Health Ethics Committee (AHEC), the Gene and Related Therapies Research Advisory Panel (GTRAP) and the Animal Welfare Committee (AWC).

In recognition of the important links between GTEC, the other gene technology advisory committees and the NHMRC, GTEC resolved to develop ongoing relationships with these committees as follows:

- A standing item will be included on every GTEC agenda for consideration of committee reports from GTTAC and GTCCC;
- The Office of the Gene Technology Regulator will develop a paper on the role of the member in common with AHEC (with a view to developing clear communication links between the two committees) and will provide this advice at GTEC's next meeting;
- A standing item will be included on every GTEC agenda for consideration of relevant AHEC matters;
- The efficacy of the GTEC/GTRAP relationship will be reviewed in twelve months time by GTEC and the Committee considers that GTTAC may find a similar review of assistance;
- The GTEC/GTTAC cross member will act as the conduit for information from GTRAP when matters from that committee are discussed at GTTAC meetings;
- The AWC will be advised of the outcome of GTEC's December meeting and will be invited to explore the possibility of progressing joint work in 2002; and
- The possibility of future work with the AWC on the NHMRC review of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* will be included in the GTEC work plan.

GTEC will monitor developments in the ethics of gene technology and noted that its work will be of interest to other agencies.

Development of Ethical Guidelines for the New Gene Technology Regulatory System

There is a wide range of ethical matters in gene technology. Not all of these areas fall within the purview of the new regulatory system, the objective of which is to protect the health and safety of people and the environment. A number of relevant issues were raised during the extensive public consultation that preceded the new legislation. GTEC, at the request of the Regulator, was asked to examine the range of ethical areas applicable to the new system in order to identify priorities that should be addressed. GTEC identified the following priority areas:

1. An assessment of the need to establish an ethical review process for all types of applications for genetic modification work in relation to plants and animals;
2. The ethical aspects of risk in relation to GMOs;
3. The institutional and commercial context of consent in relation to GMOs and their possible impacts on the community;
4. Ethical matters in relation to transgenic animals[11] including animal welfare considerations; and
5. Ethical matters in relation to trans-kingdom gene transfer[12].

GTEC's Work Plan

At the request of the Regulator, GTEC developed a work plan based on the priority areas identified above that will lead to the development of recommendations for the Regulator in the following areas:

- To research the need to establish an ethical review process for all types of applications for genetic modification work in relation to plants and animals;
- Consideration of the ethical aspects of risk associated with gene technology with a view to providing advice to the Regulator that extends

[11] *Transgenic animals* are produced when individual genes from the same or a different species are inserted into another animal.

[12] *Transkingdom gene transfer* involves the transfer of DNA into the cells of an organism from a different 'kingdom'. Organisms are grouped on the basis of fundamental similarities and common ancestry into a taxonomic system. One widely accepted taxonomic system designates five such kingdoms: animals; plants; fungi; prokaryotes (bacteria); and protista (algae and moulds).

beyond the scientific aspects of risk as referred to in the *Gene Technology Act 2000*;

- Consideration of both the institutional and commercial context of consent in relation to GMOs. This includes consideration of the ethical implications that may arise from individual contracts and in relation to the wider community;
- The Committee recognises the need to examine ethical matters in relation to transgenic animals and associated animal welfare considerations and wishes to exercise prevision in this area; and
- Trans-kingdom gene transfer is also a significant emergent area that the Committee will consider immediately.

The Committee has formed working groups of members based on relevant expertise and interests. These working parties will research and prepare issues papers on these five topics for consideration at GTEC's next meeting in May 2002.

As part of its work plan GTEC:

- Will also seek to work jointly with the NHMRC Animal Welfare Committee on a review of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (the Code) via a member in common on GTEC and the Code Liaison Group; and
- Will support participation of the member in common on a working party of the AWC Code Liaison Group specifically examining new technologies and transgenic mice as part of a review of the Code.

Meetings in 2002

The GTEC is scheduled to meet again in May and September 2002 (dates yet to be determined).

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