Quarterly report of the Gene Technology Regulator for the period 1 October to 31 December 2002

ISBN

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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* (the Act), I am pleased to present to you my quarterly report, covering the period 1 October to 31 December 2002.

The key achievements in this quarter include issuing five licences for dealings involving intentional release of genetically modified organisms, 24 licences for dealings not involving intentional release of genetically modified organisms, accreditation of 39 organisations and certification of 228 facilities.

Routine monitoring activities for this quarter have again been well above the minimum rate.

During the quarter liaison regarding regulation of genetically modified organisms progressed with reciprocal regulatory agencies in various countries including the United States of America, Canada, Great Britain and China as well as with the European Commission.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator

2 April 2003

Contents

Glossary

Accredited organisation	An organisation that is accredited under section 92 of the Act
Act	*Gene Technology Act 2000*
AHEC	Australian Health Ethics Committee
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 Act
Clock Stop	Statutory timeframe for consideration of application is suspended pending provision of additional information by the applicant
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DIR	A dealing with a GMO involving intentional release of a GMO into the environment e.g. field trial or commercial release
DIR licence	A licence for a dealing involving intentional release of a GMO into the environment
DNIR	A contained dealing with a GMO not involving intentional release of a GMO into the environment e.g. experiments in a laboratory
DNIR licence	A licence for a dealing not involving intentional release of a GMO into the environment
Expert advisers	Advisers appointed by the Minister to give advice to either GTTAC or GTEC to assist them in the performance of their functions. (Expert advisers are not committee members.)
GM	Genetically modified
GM product	A thing (other than a GMO) derived or produced from a GMO
GMAC	Genetic Manipulation Advisory Committee

GMO	Genetically modified organism
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
GTTAC	Gene Technology Technical Advisory Committee
HREOC	Human Rights and Equal Opportunity Commission
IBC	Institutional Biosafety Committee
NLRD	Notifiable low risk dealing (e.g. plant or tissue culture work undertaken in contained facilities)
NHMRC	National Health and Medical Research Council
Non-compliance	A failure to comply with legislative requirements including licence, accreditation or certification conditions
NRA	National Registration Authority for Agricultural and Veterinary Chemicals
OGTR	Office of the Gene Technology Regulator
PC1, 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 and Compliance Section
Volunteer	Regrowth of plants from seed that has remained on a site after a trial has been completed.

Introduction

The *Gene Technology Act 2000* (the Act) requires the Gene Technology Regulator (the Regulator) to prepare and give to the Minister after each quarter a report on the operations of the Regulator during that quarter. Section 136A(2) of the Act requires that the report include information on:

- genetically modified organism (GMO) licences issued during the quarter
- any breaches of conditions of a GMO licence that have come to the Regulator's attention during the quarter
- auditing and monitoring of dealings with GMOs under the Act by the Regulator or an inspector during the quarter.

Structure of this report

This report is divided into four parts:

Part 1 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 2002 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 this quarter.

Part 3 reports on the activities of the three key advisory Committees established under the 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 regulation of GMOs can be obtained by contacting:

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PART 1 National regulatory system

Key achievements during this quarter

The key achievements of the October–December 2002 quarter were:

Licences and other instruments

In this quarter the Regulator:

- issued five licences for dealings involving intentional release of GMOs into the environment (DIR licences)
- issued 24 licences for dealings not involving intentional release of GMOs into the environment (DNIR licences)
- accredited 39 organisations
- certified 228 facilities.

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

International collaboration and coordination

The Regulator visited the United States, Canada, the United Kingdom, and the European Commission en route to an international symposium on the biosafety of GMOs in Beijing, China. These visits were undertaken to monitor international practice in relation to regulation of GMOs and to consolidate links with a number of relevant overseas regulatory agencies.

Further information on international collaboration and coordination is contained in Part 4 of this report

Monitoring and compliance

Approximately 18 per cent of current field trial sites and 11 per cent of post harvest field trial sites were subjected to routine monitoring during the quarter. This exceeds the target minimum rate of 5 per cent per quarter.

The Monitoring and Compliance Section completed two incident reviews which commenced following self reporting by organisations and one investigation into an alleged non-compliance reported by a third party.

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

Working collaboratively with States and Territories

Gene Technology Ministerial Council

The Gene Technology Ministerial Council consists of one Minister from each State and Territory and one Minister from the Commonwealth. Currently, the Council comprises Ministers from a range of portfolios including health, agriculture and environment.

The Gene Technology Ministerial Council did not meet this quarter.

Gene Technology Standing Committee

The Gene Technology Standing Committee supports 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 did not meet this quarter but progress was made on development of the draft Gene Technology (Recognition of Designated Areas) Policy Principle.

Commonwealth agency liaison

The close relationship between the OGTR and Commonwealth authorities and agencies continued during this quarter.

Under the *Gene Technology Act 2000,* the Regulator must seek advice from prescribed Commonwealth authorities and agencies and the Commonwealth Environment Minister. Advice is sought on matters relevant to preparation of the risk assessment and risk management plan (RARMP) for each application made to the Regulator for a DIR licence.[1]

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

- Food Standards Australia New Zealand
- the Australian Quarantine and Inspection Service
- the National Health and Medical Research Council
- the National Industrial Chemicals Notification and Assessment Scheme
- the National Registration Authority for Agricultural and Veterinary Chemicals

[1] Consultation is also required with State and Territory Governments, GTTAC, relevant local councils and the public.

- the Therapeutic Goods Administration.

Once a RARMP is prepared, the Regulator again seeks comment on the RARMP from the same prescribed Commonwealth authorities and agencies.[2]

In addition, comment is sought on each application and RARMP from a range of other Commonwealth agencies which, while not prescribed in the legislation, have maintained a strong interest in its implementation including:

- the Department of Agriculture, Fisheries and Forestry – Australia
- the Department of Foreign Affairs and Trade
- the Department of Industry, Tourism and Resources
- Environment Australia.

During the quarter, the Regulator sought advice and comment from Commonwealth agencies in respect of 14 applications for DIR licences. Further information is set out in Part 2.

Public participation

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

- the *Commonwealth Government Notices Gazette*
- *The Australian* newspaper
- relevant regional press and rural press, such as *The Land* and *The Weekly Times*
- OGTR website: <www.ogtr.gov.au>.

Further information is set out in Part 2.

[2] Consultation is also required with State and Territory Governments, GTTAC, relevant local councils and the public.

PART 2 Regulation of genetically modified organisms

Part 2 of the report outlines the regulatory activity undertaken during the October–December 2002 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. Information on the auditing and monitoring of dealings with GMOs and information on confidential commercial information (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:

- DIR licences

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

- DNIR licences

  DNIR licences authorise contained work carried out in laboratories and other facilities designed to prevent release of the GMO into the environment. These licences have a statutory timeframe of 90 days for processing.

- accreditations of organisations

  Licences require organisations which conduct work with GMOs to be accredited. To achieve accreditation, the Regulator must be satisfied that the organisation has, or has access to, a properly constituted and resourced 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 a facility which is proposed to be used to conduct a dealing with a GMO meets the guideline requirements for physical containment.

New licences and other instruments

The following table describes the number and type of applications received for new licences and other instruments, as well as the approvals made by the Regulator in the quarter.

Applications received and decisions made, new licences and other instruments 1 October–31 December 2002

Application type	Number received	Number approved[1]
DIR licence	5	5
DNIR licence	57	24
Accreditations	37	39
Certifications	367	228

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

Processing of applications for DIR licences

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

- initial screening of the application for completeness
- determining whether the proposed dealings may pose a significant risk to human health and safety and the environment
- seeking comments from expert groups and key stakeholders (including the public if a significant risk is identified) on issues to consider in a RARMP
- preparing a draft RARMP including proposed licence conditions
- consulting with expert groups, key stakeholders and the public, on the draft RARMP
- considering all comments received and finalising 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.

The Regulator must make a decision on an application for a DIR licence within 170 working days of receiving the application. For example, for an application received on 1 January 2003 the Regulator is required to make a final decision by 4 September 2003. This time limit is extended, that is, the 'clock is stopped', if the decision-making process is unable to continue, for example, because of an

unresolved application for declaration of CCI, or because additional information is sought from the applicant.

The Regulator is required to undertake two mandatory consultation periods of at least 30 days for processing each application for a DIR licence. Therefore an application for a DIR licence cannot normally be received and decided upon within the same three-month reporting period.

The following table shows the status as at 31 December 2002 of applications for a DIR licence that underwent evaluation during the quarter.

Status as at 31 December 2002 of applications for a DIR licence subject to evaluation during the quarter

First round of consultation[1]	Licence decision
DIR020/2002[2]	DIR015/2002
DIR021/2002[2]	DIR016/2002
DIR022/2002	DIR017/2002
DIR023/2002	DIR018/2002
DIR024/2002	DIR019/2002
DIR025/2002	
DIR026/2002	
DIR027/2002	
DIR028/2002	
DIR029/2002	
DIR030/2002	
DIR031/2002	
DIR033/2002	

1 Includes posting of 'early bird' notifications and summaries of applications on the OGTR website and to people on the OGTR mailing list.

2 Finalised first round of consultation during the quarter but clock stopped on these applications.

New applications for DIR licence

The OGTR received five applications for DIR licences in the October–December 2002 quarter as follows:

- DIR028/2002 'Field trial of pineapple plants modified for blackheart reduction and to delay flowering' (Department of Primary Industries (Qld))

- DIR030/2002 ‘Commercial release of colour modified carnation (replacement of deemed licence GR-2)’ (Florigene Pty Ltd)
- DIR031/2002 ‘Field trial of GM grapevines – Evaluation of berry colour, sugar composition, flower and fruit development and gene flow study’ (CSIRO)
- DIR032/2002 ‘Field trial – Seed increase and field evaluation of herbicide tolerant hybrid canola’ (Bayer CropScience Pty Ltd)
- DIR033/2002 ‘Recombinant live oral cholera vaccine (Orochol® Vaccine)’ (CSL Limited).

All applications for DIR licences received in the October–December 2002 quarter were screened for completeness and the applicants notified of the receipt of their applications within the quarter.

In-progress applications for DIR licence

In this quarter, the Regulator initiated consultation with expert groups and key stakeholders as part of first-round consultations for the following applications:

- DIR022/2002 ‘Commercial release of insecticidal (INGARD®) cotton’ (Monsanto)
- DIR023/2002 ‘Commercial release of herbicide-tolerant (Roundup Ready®) and herbicide tolerant/insect resistant (Roundup Ready®/INGARD®) cotton’ (Monsanto)
- DIR024/2002 ‘Agronomic assessment and seed increase in northern Australia of transgenic cotton expressing Cry1Ac or Cry1Ac and Cry2Ab’ (CSIRO)
- DIR025/2002 ‘Seed increase and efficacy studies in northern Australia of transgenic cotton expressing a new insecticidal protein gene (VIP3A)’ (CSIRO)
- DIR026/2002 ‘Field trial for evaluation of GM papaya to delay fruit ripening and to test the expression of the introduced gene’ (The University of Queensland)
- DIR027/2002 ‘Field test of pineapple plants modified to control flowering’ (The University of Queensland)
- DIR028/2002 ‘Field trial of pineapple plants modified for blackheart reduction and to delay flowering’ (Department of Primary Industries (Qld))
- DIR029/2002 ‘Defining sustainable production systems for transgenic cotton in the Kimberley, Western Australia’ (Department of Agriculture (WA))

- DIR030/2002 'On going commercial release of colour modified carnation (Extension of deemed licence GR-2)' (Florigene Pty Ltd)
- DIR031/2002 'Field trial of GM grapevines – Evaluation of berry colour, sugar composition, flower and fruit development and gene flow study' (CSIRO)
- DIR033/2002 'Commercial release – Recombinant live oral cholera vaccine (Orochol® Vaccine)' (CSL Limited).

Second round consultation commenced and was completed in the quarter for application DIR019/2002, 'Agronomic assessment of transgenic sugarcane engineered with reporter genes' (Bureau of Sugar Experiment Stations).

Clock stopped on applications for DIR licence

In the quarter, the Regulator 'stopped the clock' on two applications for a DIR licence:

- DIR020/2002 'General release of Roundup Ready® canola (Brassica napus) in Australia' (Monsanto)
- DIR021/2002 'Commercial release of InVigor® canola (Brassica napus) for use in the Australian cropping system' (Bayer CropScience).

The Regulator stopped the clock on these applications as they contained references to a number of documents relating to technology stewardship and crop management. These documents were under development during the quarter, in parallel with *Guidelines for Supply Chain Management of GM Canola* being prepared by the Gene Technology Grains Committee. The additional material was requested from the applicants to assist in the evaluation of risks to human health and safety and the environment posed by the proposed releases.

The public will be notified when these applications progress to the second round of consultation once the risk assessment and risk management plans have been prepared. An extended public consultation period of eight weeks is envisaged for feedback and input.

Finalised applications for DIR licence

During the quarter, the Regulator issued five DIR licences:

- DIR015/2002 'Agronomic assessments and seed increase of transgenic cotton expressing tolerance to the herbicide glufosinate-ammonium' (CSIRO). The licence authorises a limited and controlled release of GM cotton in the Shire of Narrabri in New South Wales. The release is for a maximum of 2 hectares at one site.

- DIR016/2002 'Evaluation under field conditions of sub-clover stunt virus promoters driving an insect-tolerance gene (*cry1Ab*) from *Bacillus thuringiensis*' (CSIRO). The licence authorises a limited and controlled release of GM cotton in the Shire of Narrabri in New South Wales. The release is for a maximum of 1.5 hectares over two sites.
- DIR017/2002 'Agronomic assessments and efficacy studies of transgenic cotton expressing a new insecticidal protein gene' (CSIRO). The licence authorises a limited and controlled release of GM cotton in the Shires of Narrabri and Moree Plains in New South Wales. The release is for a maximum of 3 hectares over three sites.
- DIR018/2002 'Field assessment of alkaloids in modified poppy' (CSIRO). The licence authorises a limited and controlled release of GM poppy in the Meander Valley Municipality in Tasmania. The release is for a maximum of 0.064 hectares on one site.
- DIR019/2002 'Agronomic assessment of transgenic sugarcane engineered with reporter genes' (Bureau of Sugar Experiment Stations). The licence authorises a limited and controlled release of GM sugarcane in the City of Cairns local Government area in Queensland. The release is for a maximum of 0.7 hectares.

Finalised applications for DNIR licences

These dealings must be conducted in appropriate containment facilities and the dealings must not involve intentional release of a GMO into the environment. A full listing of DNIR licences and their current status is available from the OGTR website at <www.ogtr.gov.au>.

DNIR licences issued 1 October–31 December 2002

Application date	Application number	Organisation, State	Project title	Project description	Licence issued
21 June 02	DNIR076/2002	Murdoch University, WA	Generation of infectious cucumber mosaic virus clones	Cucumber mosaic virus is a disease of lupins and many other plants. Researchers intend to study the interactions between the virus and lupins.	25 Oct 2002

Continued

Application date	Application number	Organisation, State	Project title	Project description	Licence issued
24 June 02	DNIR077/2002	NSW Agriculture, NSW	Bioassay evaluation of bacteria expressing insecticidal genes	To identify proteins toxic to the rice bloodworm *Chironomus tepperi* from bacteria.	25 Oct 2002
24 June 02	DNIR078/2002	NSW Agriculture, NSW	Toxicity of modified rice callus to *Chironomus* larvae	To insert and test proteins toxic to the rice bloodworm *Chironomus tepperi* in tissue cultures of rice.	25 Oct 2002
21 June 02	DNIR079/2002	Centenary Institute, NSW	Development of new vaccines against tuberculosis	To develop and test vaccines to protect against the human bacterial disease tuberculosis.	25 Oct 2002
5 July 02	DNIR080/2002	Monash University, Vic.	Packaging of hepatitis delta virus (HDV) with modified envelope protein	Researchers propose to genetically modify HDV so it can infect cells other than liver cells, such as cancer cells, as a potential treatment.	8 Nov 2002
10 July 02	DNIR081/2002	Wollongong University, NSW	Molecular analysis of *Streptococcus pyogenes*	To understand the role of specific gene products of the bacteria *Streptococcus pyogenes* in the onset of disease and to develop vaccines to protect against the disease.	8 Nov 2002

Continued

Application date	Application number	Organisation, State	Project title	Project description	Licence issued
10 July 02	DNIR082/2002	Wollongong University, NSW	Molecular analysis of *Mycoplasma hyopneumoniae* and vaccine development	To understand the role of specific gene products of the bacteria *Mycoplasma hyopneumoniae* in the onset of disease and to develop vaccines to protect against the disease.	8 Nov 2002
11 July 02	DNIR083/2002	St Vincent's Hospital, Vic.	Breast cancer invasion and metastasis	Tagged breast cancer cells will be inoculated into mice to assess how tumours develop.	4 Nov 2002
18 July 02	DNIR084/2002	Western Sydney Area Health Service, NSW	The role of SDF-1 in normal and leukemic pre-B cell interactions with bone marrow stroma	SDF-1 is thought to be a key regulator of the behaviour of cells involved in acute lymphoblastic leukemia and this project aims to study how it works.	8 Nov 2002
18 July 02	DNIR085/2002	Western Sydney Area Health Service, NSW	Analysis of the effects of CD44 variant exon expression on adhesion and migration of human leukemia cells	CD44 is thought to affect cells involved in myeloid leukemia and this project aims to study how variations of CD44 act.	8 Nov 2002
19 July 02	DNIR086/2002	St Vincent's Hospital, NSW	HIV Biology	To understand the biology of the human immuno deficiency virus as the basis for better drug and vaccine development.	15 Nov 2002

Continued

Application date	Application number	Organisation, State	Project title	Project description	Licence issued
30 July 02	DNIR087/2002	Australian National University, ACT	Molecular genetic studies of *Shigella* virulence	*Shigella* can cause dysentery. Researchers hope to find the genes which are involved in disease development.	15 Nov 2002
1 August 02	DNIR088/2002	Monash University, Vic.	Cloning of genes from *Mycobacterium ulcerans* in other mycobacteria	*Mycobacterium ulcerans* can cause skin ulcers in people. The ulcers are thought to be due to production of mycolactone by the bacteria. Researchers are aiming to identify the genes responsible for mycolactone production.	29 Nov 2002
1 August 02	DNIR089/2002	Monash University, Vic.	Cloning of genes from *Mycobacterium ulcerans*	*Mycobacterium ulcerans* can cause skin ulcers in people. The ulcers are thought to be due to production of mycolactone by the bacteria. Researchers are aiming to identify the genes responsible for mycolactone production.	29 Nov 2002
1 August 02	DNIR090/2002	University of WA	Immunocontra-ception and antigen delivery by recombinant cytomegalovirus (CMVs)	To genetically modify various CMVs to contain reproductive proteins and other proteins as immunocontraceptives and as vaccines and to test the viruses in a number of animal species.	23 Dec 2002

Continued

Application date	Application number	Organisation, State	Project title	Project description	Licence issued
1 August 02	DNIR091/2002	University of WA	Recombinant vaccinia virus encoding CMV or hepatitis C virus (HCV) genes	To examine the host response to CMV and HCV proteins to test for protective immune responses.	25 Nov 2002
31 Jul 02	DNIR092/2002	Institute of Medical and Veterinary Science, SA	Molecular mechanisms of bone and tissue remodelling	To introduce genes of interest into primary human and rodent cell lines of bone origin to study the effects of their forced expression on the formation of bone and other connective tissue.	21 Nov 2002
31 Jul 02	DNIR093/2002	Institute of Medical and Veterinary Science, SA	Novel retroviral expression cloning strategies to isolate genes with roles in haemopoiesis and stromal biology	To isolate novel cDNAs which encode for proteins which regulate haemopoietic and stromal cell differentiation.	25 Nov 2002
9 Aug 02	DNIR094/2002	St Vincent's Hospital, NSW	Clinical protocol HVDDT NO1 Al-05395 – fowlpox virus	To determine the safety and immunogenicity of an HIV vaccine regimen.	27 Nov 2002

Continued

Application date	Application number	Organisation, State	Project title	Project description	Licence issued
9 Aug 02	DNIR095/2002	St Vincent's Hospital, NSW	Clinical protocol HVDDT NO1 AI-05395 – DNA vaccine	To determine the safety and immunogenicity of an HIV vaccine regimen.	18 Nov 2002
9 Aug 02	DNIR096/2002	The University of Sydney, NSW	Investigation into genes responsible for ochratoxin A production in *Aspergillus carbonarius* and *Aspergillus niger*	To clone and sequence the biosynthetic pathway genes involved in ochratoxin A synthesis in *Aspergillus carbonarius.*	29 Nov 2002
12 Aug 02	DNIR097/2002	Australian National University, ACT	Molecular biology of *Phytophthora* pathogenicity	To identify *Phytophthora* genes that are involved in the infection of host plants.	29 Nov 2002
15 Aug 02	DNIR098/2002	Royal Perth Hospital, WA	Construction of vaccinia virus recombinants carrying HCV antigens and their use in detecting cytokine responses in human peripheral blood leucocytes	To make recombinant vaccinia viruses that contain HCV genes and to use these viruses to observe the immunological responses of peripheral blood mononuclear cells (PBMCs) in vitro to endogenously synthesised HCV proteins.	27 Nov 2002
15 Aug 02	DNIR099/2002	Royal Perth Hospital, WA	Development and characterisation of viral hybrids containing various segments of *flaviviridae* genomes	To make recombinant attenuated hepatitis C viruses and to use these viruses to elucidate the replicative mechanisms of hepatitis C virus.	29 Nov 2002

Notifications of notifiable low risk dealings received

The Act requires the Regulator to receive notifications from organisations undertaking notifiable low risk dealings (NLRDs).

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

NLRDs are assessed by Institutional Biosafety Committees (IBCs) and do not require approval by the Regulator. Notifications are checked by the OGTR for compliance with legislative requirements.

The Regulator received 214 NLRD notifications in the quarter.

Confidential commercial information

Under the Act a person may apply for a declaration from the Regulator that specified information is confidential commercial information (CCI). The Act protects information that has been declared CCI from disclosure to anyone other than certain Commonwealth and State authorities and agencies, or with the consent of the applicant or by order of a court.

During the quarter the Regulator received four CCI applications in relation to applications for DIR licences, five CCI applications in relation to applications for DNIR licences and one CCI application in relation to an NLRD. The Regulator also received one application to revoke the status of CCI on information that was previously declared as CCI on licence application DIR017/2002.

The Regulator approved two CCI applications in relation to the certification of facilities, one in relation to an application for a DIR licence and one in relation to revocation of the status of CCI on information from licence application DIR017/2002.

Existing licences and other instruments

The Regulator can, directly or upon application, suspend, cancel or vary an issued licence or other instrument. For example, the Regulator can vary a licence to better manage risks if new information or data comes to light. Additionally, 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 2002 quarter.

Applications received and decisions made; existing licences and other instruments, 1 October–31 December 2002

Type	Number received	Number processed[1]
Surrender of accreditation	1	0
Surrender of certification	83	109
Variation of certification	8	19
Transfer of instruments	1	11
Surrender of DIR licence	2	0
Variation of DIR licence[2]	16	3
Surrender of DNIR licence	1	3
Variation of DNIR licence	7	10

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

2 The majority of variations are 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 additional risks to human health, safety or the environment that cannot be managed.

Renewal of transitional instruments

The transitional provisions in the Act enable dealings with GMOs that were approved by the Genetic Manipulation Advisory Committee (GMAC) under the previous voluntary system to be transferred into the new regulatory system.

'Advices to proceed' issued by GMAC for DIRs, DNIRs, NLRDs and transitional arrangements for accreditation of organisations and certifications of contained facilities are recognised under the Act until 21 June 2003.

To minimise any disruption to industry and researchers, OGTR has initiated a phased program of renewal, in consultation with instrument holders, to ensure that new approvals under the provisions of the Act can be considered before the expiry dates set down in the legislation.

Monitoring and compliance

The aim of OGTR monitoring and compliance activities is to ensure dealings with GMOs comply with legislative obligations and are consistent with the object of the Gene Technology Act:

> To protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

In particular, the Monitoring and Compliance Section focuses on management of dealings for field trial sites and within contained facilities to ensure:

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

Monitoring and compliance strategy

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

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

On the basis of experience, the OGTR field trial monitoring strategy emphasises risk profiling and includes unannounced spot checks. OGTR field trial monitoring activity is scheduled, as far as possible, to identify inherently higher risk periods in dealings with gene technology (for example, flowering and harvest) and to perform monitoring activities accordingly.

The monitoring program for contained dealings involving GMOs revolves around inspection of certified facilities. A minimum of 20 per cent of Physical Containment (PC) 4, PC3 and PC2 large-scale facilities per year are monitored. PC2 and PC1 facilities are monitored randomly. This monitoring approach is under review due to overlap with certification monitoring requirements in which all PC4, PC3 and PC2 large-scale facilities deemed certified and seeking renewal of certification are inspected by the OGTR.

As reported last quarter, a major review of the *Guidelines for Certification of Facilities/Physical Containment Requirements* was completed and a revised

draft document produced. Following this, a consultation phase was initiated and submissions were sought. During the October–December 2002 quarter, work was underway to review the submissions on the revised draft Guidelines (see Part 4, Reviews).

Monitoring and compliance protocols

The Monitoring and Compliance Section has developed a range of documents to provide organisations and interested parties with guidance on monitoring and compliance activities under the Act. Monitoring and compliance activities are under continual improvement and these protocols are recorded in working documents that will evolve as systems are assessed and validated. Links to the protocols are provided on the OGTR website at <www.ogtr.gov.au>.

Updated protocols for this quarter are:

- Mapping Protocol
- Practice Note: Mapping Checklist.

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored. During the October–December 2002 quarter, 79 monitoring visits were carried out. Monitoring was carried out on 19 licences and covered three plant species.

Current field trial sites monitored. Of the 66 sites current in the quarter, 12 were monitored. This represents a monitoring rate of 18 per cent of all current sites for the quarter.

Post-harvest field trial sites monitored*.* Of the 602 sites that were subject to post-harvest monitoring in the quarter, 67 were monitored. This represents a monitoring rate of 11 per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of contained dealings*.* During the October–December 2002 quarter, 22 PC1 and PC2 facilities were monitored as part of the routine monitoring program. This encompassed PC1 laboratories (1 visited), PC2 laboratories (16 visited), PC2 plant houses (4 visited) and PC2 Animal house (1 visited) across six organisations.

Monitoring conducted

The total monitoring coverage for field trial sites during the October–December 2002 quarterly reporting period is shown in the following table.

Licensed Organisation name	Licence number	No. sites licensed	No. sites visited	Site status*	Crop type
Department of Agriculture (WA)	DIR008/2001	12	2	C	Cotton
Bayer CropScience	PR 62X(4)	15	14	PHM	Canola
	PR 63X(3)	39	2	PHM	Canola
	PR 63X(4)	96	28	PHM	Canola
	PR 63X(5)	62	2	PHM	Canola
	PR 63X(6)	12	2	PHM	Canola
	PR 90X(3)	2	1	PHM	Canola
	PR 93	1	1	PHM	Canola
	PR 110	2	1	PHM	Canola
	DIR 010/2001	10	2	C	Canola
Monsanto Australia Limited	PR 77X	18	3	PHM	Canola
	PR 77X(2)	30	3	PHM	Canola
	PR 77X(3)	30	3	PHM	Canola
	PR 77X(4)	7	1	C	Canola
	DIR011/2001	1	1	C	Canola
CSIRO	PR 89X(2)	26	3PHM/1C	PHM/C	Cotton
	PR 105X	2	1	PHM	Field Peas
	PR 131X(2)	4	3	PHM	Cotton
	DIR 006/2001	7	5	C	Cotton
Totals	**19**	**376**	**79**	**C=12 PHM=67**	**3 species**

* C = current; PHM = post-harvest monitoring.

Inspection of PC1 and PC2 facilities

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

Organisation	Physical Containment (PC) facility	No. facilities visited
Charles Sturt University	PC2 Laboratory	5
Charles Sturt University	PC2 Plant House	1
Victorian Department of Natural Resources and Environment[1]	PC2 Plant House	1
Victorian Department of Natural Resources and Environment	PC2 Laboratory	2
Victorian Department of Natural Resources and Environment	PC2 Animal House	1
Florigene Limited	PC2 Plant House	1
Florigene Limited	PC2 Laboratory	2
La Trobe University	PC1 Laboratory	1
La Trobe University	PC2 Laboratory	3
South Australian Research and Development Institute	PC2 Laboratory	3
CSIRO	PC2 Laboratory	1
CSIRO	PC2 Plant House	1
Totals	**4 facility types**	**22**

[1] The Victorian Department of Natural Resources and Environment was replaced by the Department of Primary Industries and the Department of Sustainability and Environment in December 2002

Monitoring findings

This section reports on the final outcomes of routine monitoring activities.

There were no outstanding issues or significant findings for field trial sites monitored in this quarter.

OGTR's monitoring of PC1 and PC2 facilities found a variety of issues and non-compliances with the certification guidelines. None of the observed non-compliances compromised the containment of GMOs or posed a risk to human health and safety or the environment. The certification guidelines are currently under review to remove any ambiguities associated with them.

Reviews

The Monitoring and Compliance Section carries out reviews of incidents or practices in dealing with GMOs that come to the notice of the section through a

report by the accredited organisation or routine monitoring. There are two types of reviews:

- ***incident reviews***: are initiated when an organisation self reports a particular incident that is suspected to be a non-compliance with the Act and associated legislation
- ***practice reviews***: are reviews relating to monitoring to determine if licence conditions can be, and are being, effectively implemented and include identification of potentially adverse effects of a GMO.

The primary focus of the review process is to determine whether the incident that has occurred, or practice being used, has a potential human health or environmental risk that requires management actions to be implemented or whether there has been a non-compliance with the Act that needs to be referred for investigation. Reported below are two incident reviews (completed between October and December 2002 and one ongoing practice review.

Incident Review: Self reported flowering occurrences

Bayer Cropscience reported ongoing occurrences of flowering GM canola plants at three former GM trial sites in Tasmania (63x4 site 73 and 62x4 site 13 and 14). Destruction of the volunteers was hampered by cover crops (poppies and lupini beans). A risk assessment conducted by the OGTR determined that at two of these sites, detection of volunteer GM canola was difficult due to the cover crops and could lead to a risk of persistence of the GMO in the environment and possible dissemination of the GMO.

Bayer CropScience therefore arranged to destroy the cover crops at these sites, resulting in the simultaneous elimination of the volunteer canola. The OGTR determined that continued monitoring by Bayer CropScience at the remaining site would enable adequate control of GM volunteer canola growth. The OGTR determined that following these actions the incident did not pose a risk to human health and safety, and that the risk to the environment was negligible.

Incident Review: Self reported presence of GM cotton seed variety in stored GM cotton seed

The recent availability of new polymerase chain reaction tests now makes possible monitoring for very small amounts of specific unintended GM events in seed stocks. CSIRO advised that their own internal testing arrangements had revealed the unintended presence of a small amount (in total less than 0.1 per cent) of a GM Roundup Ready® cotton seed variety. The seed was identified in stored GM Roundup Ready® cotton seed intended for commercial use. Further assessment revealed that the unintended presence occurred during breeding of

the cotton under the voluntary arrangements in place prior to the *Gene Technology Act 2000* being introduced.

The OGTR risk assessment established that the GM Roundup Ready® seed found to be inadvertently present was virtually identical to, and posed no different risks to, GM Roundup Ready® cotton seed licenced under deemed licence GR-9 for commercial release for Roundup Ready® cotton. The seed found to be inadvertently present had not yet been evaluated by Australia for human food purposes. However, the unintended GM Roundup Ready® cottonseed was assessed by the OGTR as safe for use as stockfeed and disposal has now been completed.

CSIRO advised that all other current CSIRO GM varieties of cotton seed stocks tested clear of unintended presence. An OGTR assessment of the site where the seed was held, and of CSIRO risk mitigation actions (for one site where the seed varieties have been sown), concluded that the risks to the health and safety of people and the environment are negligible.

Practice Review: Field surveys on the effectiveness of deemed licence conditions for containment of canola

As previously reported, the OGTR undertook whole-farm surveys in the Mt Gambier region in February–March 2002. These surveys were performed at four properties that had previously conducted GM canola trials to determine if dissemination and persistence of GM canola had occurred, and to assess whether risk assessment and risk management strategies had been adequate.

Monitoring staff from the OGTR re-visited survey sites in October 2002 as part of the ongoing review of the adequacy of OGTR risk assessment and risk management strategies in minimising the risk of persistence and dissemination of GM canola over the long-term.

The survey continues to find no evidence that GM canola is persisting or has spread. The review confirmed that the OGTR risk assessment and risk management strategies continue to be valid.

Investigations

An investigation is an inquiry into a suspected non-compliance with the Act and corresponding state laws with the aim of gathering evidence. Such investigations are not restricted to purely criminal aspects – in the wider context they may include advice on detected flaws and vulnerabilities in policies, practices and procedures. An investigation may be initiated as a consequence of monitoring by the OGTR, self-reporting by an accredited organisation or third party reporting.

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

- jeopardise current or future investigations
- be protected by legislation (for example, the *Privacy Act 1988*)
- contain confidential commercial information
- unfairly damage the reputation of a company or individual under investigation if the allegation is not subsequently proven
- unfairly damage the reputation of third parties who have not themselves breached legislative requirements.

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

Where a non-compliance is found, action taken is commensurate with the level of risk posed by the non-compliance.

One investigation was completed in the reporting period. Action resulting from the investigation included implementation of strategies to raise accredited organisations' understanding of the requirements under the Act.

A summary of the completed investigation is shown in the table below.

Type	A legislative system investigation
Name	An investigation into an allegation regarding a GroPep laboratory at Roseville, Sydney, NSW
Current status	Closed – Certification of facility has been surrendered as of 11 December 2002.
Allegation	A third party allegation was made to the OGTR that GroPep may have caused an unacceptable risk to human health and safety by conducting a public auction within their PC2 and PC2 Large Scale laboratories at the Roseville site.
Summary of investigation	OGTR monitoring and compliance staff investigated the allegation and performed a risk analysis. GroPep management was fully cooperative during interviews and readily supplied requested documentation relating to the allegation.
Findings	Prior to the allegation, GroPep had informed the OGTR that the Roseville site was closed and all operations had ceased. GroPep had decontaminated the facilities and the GMOs had been removed prior to public access. However, PC2 signage was inappropriately displayed during the auction, which pre-empted the allegation; and while GroPep had provided written advice of their arrangements to close the laboratory; GroPep had not formally surrendered the certification of the Roseville

	GroPep facilities to the OGTR prior to the auction.
Risk assessment and management	A risk assessment of the alleged non-compliance determined that the risk to human health and the environment was negligible. All equipment auctioned had been appropriately cleaned. All GMO dealings had ceased and had been removed prior to the auction. Improvements have been made to management and monitoring practices by the organisation.

Audits

No audits were initiated or completed in the quarter.

PART 3 Committee operations

The Act established three advisory committees:

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

Gene Technology Technical Advisory Committee

During the quarter, GTTAC held two face-to-face meetings in Canberra on 24 October 2002 and 5 December 2002. At these meetings the Committee considered:

- 12 applications for DIR licences;
- 1 RARMP in connection with an application for a DIR licence; and
- 21 applications for DNIR licences and associated RARMPs.

Due to the current drought, the GTTAC also considered two applications for importing soybeans and corn from the United States of America as stockfeed, a proportion of which may be GM. (A decision on this application was not made during the quarter). GTTAC members also met with their GTEC counterparts when the two meetings were scheduled concurrently in October.

Further information about the dealings considered by GTTAC can be obtained from the communiqués that are published on the OGTR website at <www.ogtr.gov.au>. The sixth GTTAC Communiqué, outlining the discussions held at the October meeting, and the seventh GTTAC Communiqué, outlining the discussions held at the December meeting, as well as a January 2003 teleconference, will be attached to the next quarterly report covering the January–March 2003 period. The GTTAC web pages have been redesigned to include a photograph of the Committee members and can be accessed through the OGTR website at <www.ogtr.gov.au>.

Gene Technology Ethics Committee

During the quarter, GTEC held its third meeting on 23–24 October 2002.

At the request of the Regulator, GTEC is continuing its work on a range of agreed priority areas. The working groups reported to the full Committee on their progress between meetings and are due to report again at the fourth meeting in early 2003. GTEC members also met with their GTTAC counterparts when the two meetings were scheduled concurrently in October 2002. This was an opportunity for members to meet face-to-face for the first time to discuss matters of mutual interest.

Also during the quarter, GTEC published on the Internet its submission in response to the National Health and Medical Research Council's (NHMRC) release of *Draft guidelines and discussion paper on xenotransplantation* for public comment.

Further information about the issues under consideration by GTEC can be obtained from the October 2002 meeting communiqué attached to this report (Appendix A). The GTEC web pages have been redesigned to include a photograph of the Committee members and can be accessed through the OGTR website at <www.ogtr.gov.au>.

Gene Technology Community Consultative Committee

At its third meeting, held in Melbourne on 19 November 2002, the GTCCC considered reports from five working groups established in July 2002 and provided advice to the Regulator in relation to this work. The Committee endorsed a number of current OGTR activities reviewed by the working groups, for example, documentation and communication matters, and agreed to consider a further review of these activities in 12 months.

Members also received a presentation from the OGTR on the current version of the Office's website. The working group reviewing the website design and other electronic communication congratulated the OGTR on the current format.

The GTCCC is scheduled to meet again early in 2003. Further information about the Committee's activities and current work plan can be obtained from the November 2002 meeting communiqué attached to this report (Appendix B). The GTCCC web pages also contain a recent photograph of the Committee members and can be accessed through the OGTR website at <www.ogtr.gov.au>.

PART 4 Other activities

Reviews

The following reviews continued during this quarter:

- A review to develop a strategy to identify data required for future risk assessments and risk management plans for dealings involving intentional release of GM cotton, particularly large-scale releases. This review is ongoing.
- A review of the *Guidelines for the Certification of Facilities/Physical Containment Requirements* found practical difficulties in implementing the current guidelines. Draft revised guidelines were released for wide consultation last quarter. A total of 57 submissions were received and evaluated. Another version of the guidelines is now being prepared to incorporate suggested improvements with the assistance of independent expert advice.

International collaboration and coordination

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

International collaboration and coordination activities undertaken during the quarter include:

- the Regulator visited the United States, Canada, the United Kingdom, China and the European Commission to discuss gene technology and regulatory processes with relevant agencies and interest groups. The Regulator met with a range of politicians, government officials, consumer groups and industry representatives which provided an invaluable resource of international contacts and initiated discussions regarding collaborative links with other regulatory agencies.
- the Regulator attended the 7th International Symposium on the Biosafety of GMOs in Beijing, China
- a delegation from China visited the OGTR to gather information on regulation of gene technology in Australia

- the Canadian Canola Council met with the OGTR to discuss Canadian experiences with GM canola
- New Zealand Opposition Minister, Dr Hutchence, National Party spokesperson for science, research and biotechnology visited the OGTR to discuss gene technology
- Research Chair in Global Governance and Public Policy, Professor Coleman from McMaster University, Canada, met with the OGTR to discuss gene technology regulation.

Advice on gene technology regulation

Presentations and meetings

Staff of the OGTR endeavour to participate in presentations and meetings on gene technology wherever possible to inform the community and users about the regulatory system. During the quarter the OGTR:

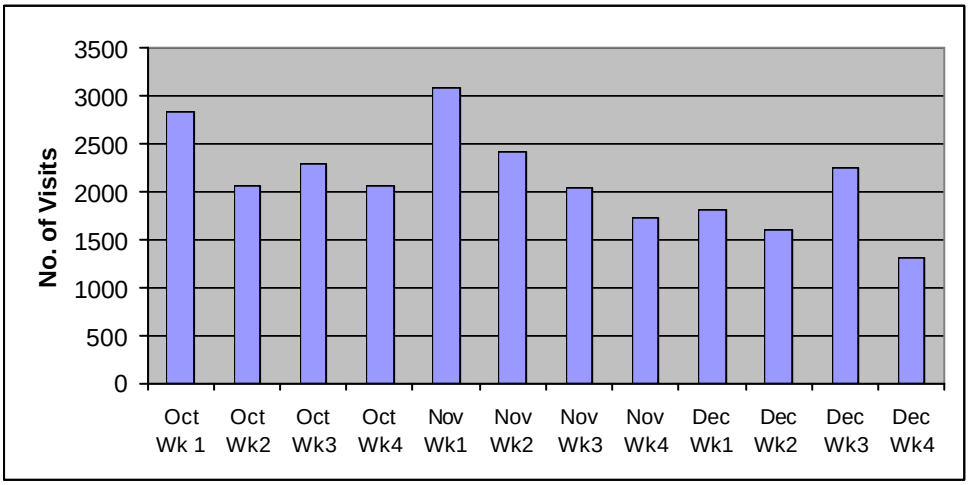
- hosted a GM cotton research review forum and Commonwealth, State and Territory technical officers meeting
- met with the South Australian Minister for Agriculture, Food and Fisheries the Hon. Paul Holloway
- gave a presentation about the regulatory system at the GM Cropping Forum held in Temora, New South Wales
- gave a lecture, *Regulation of gene technology in Australia*, to the University of Third Age in Canberra, Australian Capital Territory
- gave a presentation, *Changes to the regulation of genetically modified animals – the Gene Technology Act 2000,* to the Australian and New Zealand Society for Laboratory Animal Science and Australian Animal Technician's Conference
- gave a presentation to *ClubBio 2002* in Coolum, Queensland
- attended the *AVCARE Summit 2000* in Sydney, New South Wales.

Institutional Biosafety Committees training sessions

OGTR regularly provides training sessions to organisations and institutional biosafety committees (IBCs). During the October–December 2002 quarter, sessions were conducted at the Royal Children's Hospital, Melbourne and at the University of Wollongong.

OGTR website

The OGTR website received 479 765 'hits'[3] during the quarter, which represents an average of 5 214 hits per day.



The graph above illustrates the pattern of individual visits[4] to the OGTR website, by week over the reporting period.

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

- What's New
- Maps of current field trial locations
- Media Releases.

The most popular downloaded documents were:

- *Handbook on the regulation of gene technology in Australia*
- *GM products approved as food, food additives and processing aids*
- *Application for licence dealing with a GMO not involving intentional release of a GMO into the environment (DNIR).*

Complaint to the Human Rights and Equal Opportunity Commission

In July 2002 the OGTR's website was the subject of a complaint to the Human Rights and Equal Opportunity Commission (HREOC). The complaint arose from

[3] Hits = Total number of pages and images accessed on the website

[4] Visits = Total number of visitors that entered the website

difficulties being experienced by a member of the community who is vision-impaired and uses 'screen-reader' software to access documents available on the Internet. Since the complaint, the OGTR has implemented measures to help the complainant access the website, and formally responded to HREOC. In December 2002 the OGTR participated in a telephone conciliation conference with the complainant and HREOC. During the conference it was acknowledged that the OGTR had taken action to increase the accessibility of the website and the complaint was withdrawn.

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

OGTR email address and freecall number

The 1800 line (1800 181 030) and the OGTR email address (ogtr@health.gov.au) are points of contact for members of the public and other interested parties. Assistance for specific questions and additional mechanisms for public feedback are among some of the benefits provided by the 1800 line and email facilities.

OGTR received 278 calls and 355 emails in October 2002, 133 calls and 237 emails in November 2002, and 206 calls and 232 emails in December 2002.

Freedom of Information

During the quarter the OGTR received a freedom of information request from the Total Environment Centre Inc. (TEC). The request related to correspondence between the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), the Minister for Environment and Heritage, the Secretary of the Department of Health and Ageing and the OGTR concerning development of risk assessments and risk management plans of pesticide use in application of GM cotton and canola, between 1 December 2001 and 15 October 2002.

TEC originally made the request to the NRA on 22 October 2002 and it was referred to the OGTR on 15 November 2002. Given the size of the request, OGTR and TEC have negotiated timeframes for production of documents that are satisfactory to both. The OGTR is working towards producing all documents relevant to the request.

Consultants

During the reporting period, the OGTR managed four consultancy contracts worth a total of $89 113 (GST exclusive). The table below lists the consultants,

describes the purpose of the consultancy and states the amount paid during the quarter.

Consultant	Amount paid (GST exclusive)	Purpose
Dialog Information Technology	$46 890	Develop Gene Technology Information Management System (GTIMS)
Agronico Pty Ltd	$5 998	Services to determine gene flow, if any, from herbicide resistance GM canola to weedy relatives (*brassica rapa*) in Tasmania
Adelaide Research & Innovation	$17 775	Study into the potential gene flow from GM *brassica napus*
Acumen Alliance	$18 450	Review of cost recovery options
Total Consultants for quarter	**$89 113**	

Appendix A

Gene Technology Ethics Committee Meeting
23-24 October 2002, Canberra
COMMUNIQUÉ

The Gene Technology Ethics Committee (GTEC) held its third meeting in Canberra on the 23rd and 24th of October 2002. GTEC was established by the *Gene Technology Act 2000* (the Act) as a statutory advisory committee to the Gene Technology Regulator (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 communiqué includes 'expert advisers').

At its third meeting GTEC focused on the consideration of revised draft reports from working groups established at its inaugural meeting in December 2001. (Details of the agreed priority areas are listed below). Members were informed of relevant work from other national committees via cross-member reports and the Committee received a detailed update from the Regulator on activities undertaken by the Office of the Gene Technology Regulator (OGTR) since their last meeting.

Meeting with the Gene Technology Technical Advisory Committee

A concurrent meeting of the Gene Technology Technical Advisory Committee (GTTAC) on 24 October in Canberra provided an opportunity for members to meet face-to-face for the first time to discuss matters of mutual interest.

Following introductions from the Regulator and the respective committee Chairs, coordinators from two of the GTEC working groups gave brief presentations to GTTAC outlining their work in relation to; the ethical context in which gene technology should be viewed; and managing risk ethically in OGTR risk assessment and risk management work.

GTEC Submission on Xenotransplantation

In the period between its second and third meetings GTEC members prepared a submission in response to the National Health and Medical Research Council's (NHMRC) release of *Draft guidelines and discussion paper on xenotransplantation* for public comment.

The Committee resolved to make its work, 'Gene Technology Ethics Committee Submission on the Draft Guidelines on Xenotransplantation Research', publicly available and it can be accessed on the OGTR website at <www.ogtr.gov.au> under the GTEC information page or by telephoning the Committee Secretariat on free-call 1800 181 030.

GTEC's Work Plan

As detailed in GTEC's first Communiqué from its inaugural meeting in December 2001, the priority areas agreed by the Committee are as follows:

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[5] including animal welfare considerations; and
5. Ethical matters in relation to transkingdom gene transfer.[6]

Since December 2001 internal working groups of members have been working on draft documents in relation to these matters.

At the Regulator's request, the Committee resolved at its most recent meeting to continue with their present work plan and to incorporate the comments received from members at the meeting into further versions of the draft papers. This new work will be considered at the fourth meeting of the Committee in early 2003.

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

6 *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).

GTEC and Relationships with Other Committees

GTEC received verbal reports on activities from the cross-members with GTTAC and the Gene Technology Community Consultative Committee (GTCCC). Communiqués from meetings of these committees are also published on the OGTR website.

The cross-member report from the NHMRC Australian Health Ethics Committee (AHEC) focused on points of common interest between the two committees. The report identified recent AHEC work in the areas of xenotransplantation and assisted reproductive technology, and developments in relation to legislation to regulate research involving embryos and human cloning activities. The importance of Human Research Ethics Committees in AHEC's work was highlighted to GTEC.

GTEC was updated on recent activities in relation to two other relevant NHMRC committees: the Gene and Related Therapies Research Advisory Panel and the Code Liaison Group (undertaking a review of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (1997)*).

The cross-member reports are an important part of GTEC's communication process and feature as standing items at each meeting.

Next Meeting

GTEC is scheduled to meet again early in 2003.

For all inquiries, please contact the Office of the Gene Technology Regulator on

1800 181 030 (free-call)

Appendix B

Gene Technology Community Consultative Committee Meeting
19 November 2002, Melbourne
COMMUNIQUÉ

The Gene Technology Community Consultative Committee (GTCCC) held its third meeting in Melbourne on 19 November 2002. GTCCC was established by the *Gene Technology Act 2000* (the Act) as a statutory advisory committee to the Gene Technology Regulator (the Regulator) and the Gene Technology Ministerial Council. All committee members hold office on a part-time basis.

At its third meeting the GTCCC covered a full agenda of business during the day. The Committee considered reports from five working groups established in July 2002 and provided advice to the Regulator in relation to their work. Members received a presentation from the Office of the Gene Technology Regulator (OGTR) on the Office's website and heard a report on recent OGTR activities from the Regulator as well as reports from the cross-members with the Gene Technology Ethics Committee and the Gene Technology Technical Advisory Committee. The outcomes of these discussions are summarised below.

GTCCC's Work Plan

In July 2002 GTCCC discussed its key priorities and identified five areas as the basis for its future work plan. Working groups were formed for each of the five identified areas and draft reports were considered at the third meeting of the GTCCC in November 2002. The groups are as follows:

1. Review of documentation in regard to applications

The working group reviewed all of the OGTR's documentation associated with lodging an application for a dealing involving intentional release of a GMO into the environment (DIR) including the Early-Bird Notification, Invitation to Comment and a selection of Risk Assessment and Risk Management Plans. Comments from the group have already been incorporated into current application documentation leading to improvements in the quality and accessibility of the documents.

The Committee endorsed the current OGTR documentation for applications for DIR licences and is to consider the need for a further review in twelve months time.

2. Review of the OGTR website design and other electronic communication

Mr Garth Powell, OGTR Web Master, attended the meeting in the morning and demonstrated the website to the working group and the Committee. Mr Powell discussed navigation features; highlighted updated areas and enhancements; and explained further planned reviews to members. In particular, the Intentional Release table was drawn to members' attention as being a useful summary for regular users of the OGTR site.

The Committee noted the improvements that had been made since the working group's review had been undertaken and congratulated the OGTR on the current website design. The working group also noted that their initial work related to the design of the website rather than the content. Further reviews may be undertaken in the future.

3. Review of processes by which the OGTR can improve community consultation and participation including review of the effectiveness of information and communication provided to the community in general and to the regions involved in limited and controlled releases

The working group provided the Committee with preliminary advice and indicated that the group would report in more detail at the next meeting.

4. Write an overview of the public understanding of science literature

The working group tabled a brief discussion paper and outlined the work they would be doing in the next few months to prepare a background paper for the Committee. The group will report again at the next meeting.

5 Consideration of issues relating to the interpretation of 'the environment' under the Act.

The Committee received the working group's report and discussed the content in detail. A conclusion was not reached in relation to future work on the issues raised in the paper.

Future Work

1. Risk Analysis Framework Review

In 2003 the GTCCC will assist the OGTR in a planned review of the *Risk Analysis Framework for Licence Applications to the OGTR* (the Framework). The Framework is available from the OGTR free-call telephone number and on the website.

The Framework was published in 2002 by the OGTR to assist organisations and individuals who intend to make an application under the Act or who otherwise have an interest in the potential for, and assessment of, risks from GMOs. The document was developed in consultation with all States and Territories, other Commonwealth agencies and targeted stakeholders and incorporates material received in response to a public invitation to comment on the draft.

2. Communicating with the Community

As agreed at the July GTCCC meeting, the Committee's Chair, Sir Ninian Stephen, has written to a number of key stakeholders advising them of the setting up of the GTCCC and the Committee's interest in hearing any views they may have about consultations undertaken by the Regulator. The GTCCC will continue to look for opportunities to interact with these organisations with a view to providing advice to the Regulator in this area.

GTCCC and Relationships with Other Committees

At each meeting the Committee receives verbal reports from the cross-members with the Gene Technology Ethics Committee and the Gene Technology Technical Advisory Committee on meetings held and activities undertaken by those committees since GTCCC last met. Communiqués from meetings of these committees are also published on the OGTR website.

Next Meeting

GTCCC is scheduled to meet again early in 2003.

For all inquiries, please contact the Office of the Gene Technology Regulator on

1800 181 030 (free-call)