Quarterly Report of

the Gene Technology Regulator

for the period

1 April to 30 June 2002

ISBN

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Produced by:
The Office of the Gene Technology Regulator
MDP54 PO Box 100
Woden ACT 2606

Email: ogtr@health.gov.au
Website: www.ogtr.gov.au
Telephone: 1800 181 0303
Fax: 02 6271 4202

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

Commonwealth Department of Health and Ageing

Office of the Gene Technology Regulator
THERAPEUTIC GOODS ADMINISTRATION
PO Box 100 Woden ACT 2606 Tel **1800 181 030** Fax 02 6271 4202

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 the Fourth Quarterly Report of the Gene Technology Regulator, covering the period 1 April to 30 June 2002.

This quarter saw the continuation of the high level of regulatory activity experienced last quarter. In addition, a number of important milestones were achieved for Australia's nationally consistent gene technology regulatory system. The intergovernmental Gene Technology Agreement that underpins the nationally consistent framework for gene technology regulation was signed by the final jurisdiction, the Northern Territory, and the Victorian and South Australian legislation was declared as 'corresponding State law' to the Act.

In addition, the appointments of Professor Stephen Powles, as Chair of the Gene Technology Technical Advisory Committee, Professor Don Chalmers, as Chair of the Gene Technology Ethics Committee and Sir Ninian Stephen, as Chair of the Gene Technology Community Consultative Committee, were announced after the appointments were agreed to by a majority of State and Territory Governments (as required by the Act).

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator
27 September 2002

Contents

Acronyms 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 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
GTA	The Gene Technology Agreement between the Commonwealth, State and Territory governments
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 legislation requirements including 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 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 must include information on the following:

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

Structure of this Report

This report is divided into four (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 April - June 2002 quarter. This includes information about applications for, and action taken with respect to, new and deemed 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 this quarter.

Further Information

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

The Office of the Gene Technology Regulator
Commonwealth Department of Health and Ageing
Mail Drop Point 54
PO Box 100
WODEN ACT 2606

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

PART 1 - National Regulatory System

Key achievements during this quarter

The key achievements of the April to June 2002 quarter were:

1. Licences and other instruments

In the April-June 2002 quarter the Regulator:

- issued twelve (12) licences for dealings not involving the intentional release of a GMO (DNIRs);
- accredited two (2) organisations; and
- certified one hundred and eighteen (118) facilities.

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

2. State and Territory gene technology legislation

In the quarter, the Parliamentary Secretary to the Minister for Health and Ageing, the Hon Trish Worth MP, declared the *Gene Technology Act 2001* (Victoria), the Gene Technology Regulations 2001 (Victoria), the *Gene Technology Act 2001* (South Australia) and the Gene Technology Regulations 2002 (South Australia) to be 'corresponding State law' to the Act.

More information on State and Territory gene technology legislation is provided later in this part.

3. Monitoring and Compliance

In the quarter, the following Monitoring and Compliance Section targets were exceeded:

- at least 5% of current trial sites and sites subject to post trial monitoring per quarter; and

- at least 5% of containment facilities at Physical Containment (PC) 4, PC3 and PC2 large scale levels per quarter.

The Monitoring and Compliance Framework and the Monitoring Protocols were made available on the OGTR website.

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

4. Committee Operations

In this quarter, the appointments of the Chairs to the Gene Technology Technical Advisory Committee, the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee were announced after the appointments were agreed to by a majority of State and Territory Governments (as required by the Act).

Further information on committee operations is contained in Part 3 of this report.

Working collaboratively with States and Territories

Gene Technology Agreement

The Gene Technology Agreement (GTA) is an inter-governmental agreement which sets out the understanding between Commonwealth, State and Territory governments regarding the establishment of a nationally consistent regulatory system for gene technology. The effective date of commencement of the GTA was 11 September 2001, when the majority of jurisdictions (that is, the Commonwealth and at least three States and a Territory) signed the GTA. During this quarter, the final jurisdiction, the Northern Territory, signed the GTA.

Gene Technology Ministerial Council

The Act establishes the Gene Technology Ministerial Council which has responsibility for, among other things:

- 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 consists of one Minister from each State and Territory and one Minister from the Commonwealth.

In this quarter, the Ministerial Council held its inaugural meeting on 24 May 2002, chaired by the Commonwealth Minister for Health and Ageing, Senator Kay Patterson.

The Act provides for the Ministerial Council to issue policy principles in relation to recognising areas, if any, designated under State law for the purpose of preserving the identity of genetically modified (GM) or non-GM crops for marketing purposes. The Regulator may not issue a licence if doing so would be inconsistent with policy principles issued by the Ministerial Council.

Ministers agreed to start work on such a policy principle. Ministers also agreed that the policy principle must not detract from the clearly identified role of the Regulator in assessing and managing risks to protect the health and safety of people or the environment.

Ministers also agreed to work closely with the Primary Industry Ministerial Council to formulate the policy principle as members of both Councils have interlinking interests in the regulation of genetically modified organisms (GMOs).

Ministers agreed to the Operating Procedures that will govern the work of the Gene Technology Standing Committee.

Gene Technology Standing Committee

The Gene Technology Standing Committee (GTSC) 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 met in Melbourne on 30 April 2002 to finalise the agenda papers for the Ministerial Council meeting held on 24 May 2002.

It was agreed that the Standing Committee would reconvene after the Ministerial Council to progress issues arising from that meeting.

State and Territory gene technology legislation

The Act anticipates that each State and Territory will enact corresponding legislation to ensure a nationally consistent framework for the regulation of dealings with GMOs.

Where there is sufficient uniformity between the Commonwealth and State gene technology laws, the Commonwealth Minister can declare them to be ‘corresponding State law’ to the Act.

The *Gene Technology Act 2001* (Victoria) and Gene Technology Regulations (Victoria) commenced in December 2001. The *Gene Technology Act 2001* (South Australia*)* and Gene Technology Regulations (South Australia) commenced in February 2002.

During this quarter, the OGTR examined both the South Australian and Victorian gene technology acts and regulations and recommended to the Parliamentary Secretary to the Minister for Health and Ageing, the Hon Trish Worth MP, that they be recognised as corresponding State law.

By a notice in the Gazette on 29 May 2002, the Parliamentary Secretary declared the *Gene Technology Act 2001* (Victoria), the Gene Technology Regulations 2001 (Victoria), the *Gene Technology Act 2001* (South Australia) and the Gene Technology Regulations 2002 (South Australia) to be 'corresponding State law' to the Act. These laws now form part of the national scheme of laws for the regulation of gene technology and are enforced by the Regulator.

Commonwealth agency liaison

The close relationship between the OGTR, Commonwealth agencies and existing regulators continued during this quarter.

The Regulator must seek advice from prescribed Commonwealth agencies and authorities and the Commonwealth Environment Minister on matters relevant to the preparation of the risk assessment and risk management plans (RARMPs) in respect of each licence application for an intentional release into the environment[1].

In this context, the Regulator consults a range of regulators responsible for product approval, including GM products, comprising the Australia New Zealand Food Authority, National Industrial Chemicals Notification and Assessment Scheme, National Registration Authority for Agricultural and Veterinary Chemicals and Therapeutic Goods Administration, as well as the Australian Quarantine and Inspection Service and National Health and Medical Research Council.

Once the RARMPs are prepared the Regulator must again seek comment on the RARMPs from the same expert groups and key stakeholders. In addition, comment is sought from a range of other Commonwealth agencies which, while not prescribed in the legislation, have maintained a strong interest in its implementation: Agriculture Fisheries Forestry Australia, the Department of Foreign Affairs and Trade, the Department of Industry, Tourism and Resources and Environment Australia.

In this quarter, the Regulator sought advice and comment from Commonwealth agencies on five (5) dealings involving the intentional release of a GMO (DIR) applications. Further information is set out in Part 2.

[1] Provision is also made for consultation with State and Territory Governments, GTTAC, relevant local councils and the public.

Public Participation

In this quarter, the Regulator issued an invitation to the public to comment on matters relevant to the protection of human health and safety and the environment in relation to two (2) DIR applications and on the RARMPs prepared for three (3) DIR applications 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
- OGTR website: www.ogtr.gov.au.

Further information is set out in Part 2.

PART 2 - The Regulation of Genetically Modified Organisms

This part of the Report outlines the regulatory activity undertaken during the April - June 2002 quarter. This includes information about applications for, and action taken with respect to, GMO licences, deemed licences and other instruments under the 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 Act during this quarter. 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:

- 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. These licences have a statutory timeframe of 170 days for processing.

- 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. These licences have a statutory timeframe of 90 days for processing.

- 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 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 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.

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

Type of Application	Number Received	Number Approved
Licence for a DIR	2	0
Licence for a DNIR	48	12
Accreditations	3	2
Certifications	333	118

Approvals reported in the current quarter will often relate to applications received in previous quarters.

Processing of DIR applications

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

- initial screening of the application for completeness;
- determination of whether the proposed dealings may pose a significant risk to human health and safety and/or 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 Risk Assessment and Risk Management Plan (RARMP);
- preparing a RARMP including proposed licence conditions;
- consulting with expert groups and key stakeholders, including the public, on the RARMP; and
- considering all comments received in 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 a DIR licence application within one hundred and seventy (170) working days of receiving the application. For example, for an application received on 1 January 2002 the Regulator is required to make a final decision by 4 September 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.

The Regulator is required to undertake two mandatory consultation periods of at least thirty (30) days on each DIR application and RARMP. Therefore it is unlikely that a DIR application would be received and decided upon within the same three month reporting period.

Table of DIR applications received, considered or decided during April - June 2002

The following table sets out the stages of processing of DIR applications undertaken in April - June 2002 quarter.

Application Received/Initial Screening	Application Received Last Quarter and Under Active Consideration	First Round of Consultation[1]	Second Round of Consultation[2]	Licence decision
DIR019/2002	DIR 014/2002	DIR 012/2002[2]	DIR 007/2001	
DIR020/2002	DIR 015/2002	DIR 013/2002	DIR 010/2001	
	DIR 016/2002		DIR 011/2001	
	DIR 017/2002			
	DIR 018/2002			

[1]included postings of 'early bird' notifications and summaries of applications on the OGTR website and to people on the OGTR mailing list.
[2]included public consultation 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 OGTR website: www.ogtr.gov.au.

New DIR licence applications

The OGTR received two (2) DIR licence applications in the April to June 2002 quarter with the following titles:

- DIR019/2002 "Agronomic assessment of transgenic sugarcane engineered with reporter genes" (Bureau of Sugar Experiment Stations); and
- DIR020/2002 "General release of Roundup Ready® canola (*Brassica napus*) in Australia" (Monsanto).

Both DIR applications received in the April - June 2002 quarter were screened for completeness and the applicants notified of the receipt of their applications within this quarter.

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

In-Progress DIR applications

In this quarter, the following DIR applications received last quarter were under consideration:

- DIR014/2002 “Agronomic assessment and seed increase of transgenic cotton expressing *cry1Ac* and *cry2Ab* genes from *Bacillus thuringiensis*” (CSIRO);
- DIR015/2002 “Agronomic assessments and seed increase of transgenic cotton expressing tolerance to the herbicide glufosinate-ammonium” (CSIRO);
- DIR 016/2002 “Evaluation under field conditions of sub-clover stunt virus promoters driving an insect tolerance gene (*cry1Ab*) from *Bacillus thuringiensis*” (CSIRO);
- DIR017/2002 “Agronomic assessments and efficacy studies of transgenic cotton expressing a new insecticidal protein gene” (CSIRO); and
- DIR018/2002 “Field assessment of alkaloids in modified poppy” (CSIRO).

First round consultations

In the previous quarter, the Regulator received two applications from Monsanto:

- DIR012/2002 “Commercial release of Bollgard II® cotton” (Monsanto) proposing a commercial release of GM cotton in potentially all cotton growing areas of Australia (NSW, QLD, NT and north western WA); and
- DIR013/2002 “Agronomic assessment and seed increase of INGARD® and Bollgard II® cotton” (Monsanto) proposing a limited and controlled release of GM cotton in New South Wales and Queensland. The proposed scale of this release was 10,000 hectares.

In this quarter, the Regulator invited submissions from the public on matters relevant to the preparation of the RARMPs for DIR 012/2002 and DIR 013/2002.

If the commercial release (DIR012/2002) was approved then the large scale release would not proceed (DIR 013/2002) as it would become redundant. Both applications proposed sizeable releases of GM cotton north of latitude 22º South.

The Regulator made an initial assessment of the applications as to whether the proposed releases may pose significant risks to human health or the environment in accordance with the Act. The Regulator decided that the proposed releases did not pose significant risks to human health or the environment south of latitude 22ºSouth. However, at this early stage of the evaluation process, the Regulator could not determine conclusively whether or not the proposed release poses a significant risk to the environment north of latitude 22ºSouth.

Consequently, the Regulator issued an invitation for the first of two (2) rounds of public comment on the development of the RARMPs for these two (2) DIR applications in accordance with the Act.

Second round consultations

In this quarter, the Regulator commenced second round consultations on the RARMPs for the following DIR applications:

- DIR007/2001 "Evaluation of the alkaloid production of oilseed poppy containing a modified gene involved in the pathway of alkaloid production" (Department of Agriculture (WA)) proposing a limited and controlled release of genetically modified (GM) oilseed poppy in Western Australia;

- DIR010/2001 "Small and large scale trialing of InVigor® canola (*Brassica napus*) for development for the Australian cropping system" (Bayer CropScience Pty Ltd (formerly Aventis CropScience Pty Ltd)); proposing limited and controlled releases of GM canola in New South Wales, Victoria, Western Australia and South Australia; and

- DIR 011/2001 "Field trials of Roundup Ready® canola (*Brassica napus*) in Australia in 2002" (Monsanto Australia Ltd) proposing limited and controlled releases of GM canola in New South Wales, Victoria, Western Australia and South Australia.

Finalised DIR Applications

No DIR application was finalised this quarter.

Finalised DNIR Applications

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

Licences to conduct dealings not involving intentional release of the GMO into the environment (DNIR) issued in the quarter

Application number	Organisation and State	Project title	Project description	Date approved
DNIR 010/2001	Australian Water Quality Centre, South Australia	Rapid methods for the detection of toxic cyanobacteria	The aim of this project is to identify the genes associated with toxin synthesis in cyanobacteria and to construct cyanobacteria that do not produce the toxin.	Approved 2 April 2002
DNIR 011/2001	Western Sydney Area Health Service, New South Wales	Cryptococcal phospholipases: structure and potential targets for therapeutics	The structure and function of phospholipase proteins in the fungus *Cryptococcus neoformans* will be studied. Fungus without the proteins tested in mice.	Approved 16 April 2002
DNIR 012/2001	Western Sydney Area Health Service, New South Wales	Investigating TRAIL in the immune system	TRAIL is a molecule which is thought to specifically kill transformed and virus infected cells but not most normal human cells. The researchers are investigating the function of TRAIL within the immune system.	Approved 11 April 2002
DNIR 013/2001	Western Sydney Area Health Service, New South Wales	Studies of cell growth and survival	The researchers will genetically modify a number of cell lines and study the effects of the modifications on cell growth and survival.	Approved 16 April 2002
DNIR 015/2001	Biotech Australia, New South Wales	Production of NeoGARD antigens	The aim is to produce the antigens used in manufacturing a vaccine against neonatal scour in pigs.	Approved 2 April 2002
DNIR 017/2001	CSIRO–AAHL, Victoria	Reverse genetics of Newcastle Disease Virus (NDV)	The researchers will determine the role of the matrix protein gene in NDV.	Approved 20 May 2002
DNIR 019/2001	Deakin University, Victoria	B55 gene over-expression in *Psammonmys obesus* (Israeli sand rats)	The researchers will study the effects on obesity and diabetes of over-expression of the B55 gene.	Approved 10 May 2002

Application number	Organisation and State	Project title	Project description	Date approved
DNIR 020/2001	Biotech Australia, New South Wales	Production of members of the inhibin hormone family in mammalian, insect, yeast and bacterial cells	The project will produce recombinant hormones for research reagents, clinical research and commercial biopharmaceuticals.	Approved 16 April 2002
DNIR 021/2002	Royal Children's Hospital, Brisbane, Queensland	HIV replication and gene expression	This project aims to determine the role of virus regulatory proteins in HIV replication and gene expression.	Approved 16 May 2002
DNIR 022/2002	Peter MacCallum Cancer Research Institute, Victoria	Characterisation of the anti-apoptotic function of P-glycoprotein and transcriptional regulation of the MDR1 gene	The aim is to determine if the P-glycoprotein can protect tumour and normal cells against apoptosis (programmed cell death) produced by a variety of methods.	Approved 3 Jun 2002
DNIR 024/2002	Biotech Australia, New South Wales	Production of recombinant proteins in mammalian, insect, yeast and bacterial cells	The project will produce a large range of recombinant proteins for research reagents, clinical research and commercial biopharmaceuticals.	Approved 25 Jun 2002
DNIR 027/2002	University of Southern Queensland	Whooping cough vaccine IV	The aim is to create a safe non-invasive whooping cough vaccine which will neutralise consequences of the major toxin of *Bordetella pertussis*.	Approved 14 Jun 2002

Notifications of NLRDs received

The Act also 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 eighty (80) NLRD notifications in the quarter. A full listing of NLRDs is available from the OGTR website: www.ogtr.gov.au.

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 April to June 2002 quarter. The Regulator varied one (1) deemed DIR[2].

Applications received and decisions made – Existing licences and other instruments

Type	Number Received	No. Approved #
Variation of accreditation	2	6
Surrender of certification	35	0
Variation of certification	4	0
Transfer of licence	8	0
Transfer of certification	23	0
Variation of DIR	9	1
Variation of DNIR	2	0

Approvals reported in this 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.

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 field trials, contained and low risk work, accreditations of organisations and certifications of contained facilities are 'deemed' instruments under the Act for up to two years from commencement of the Act on 21 June 2001.

[2] 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 the case of 'deemed' certifications of PC4, PC3 and large-scale PC2 facilities, these instruments operated for one (1) year. All the deemed high-level facilities, except nine (9), were inspected by OGTR. Seven (7) of the nine (9) exceptions had ceased GM work and the holders were going to allow the certification to lapse. The remaining two (2) facilities were being refurbished. Thirty-two (32) high-level facilities were recertified by 21 June 2002 and the certification of fourteen (14) facilities lapsed until the recertification process was completed. The holders of lapsed certifications were notified that they must cease any dealings with GMOs in the facilities.

To minimise any disruption to industry and researchers, OGTR has initiated a staggered program of review, in consultation with instrument holders, to ensure that all deemed instruments can be reviewed before the expiry date set down in the legislation.

Organisations will be regularly reminded to renew applications as soon as possible to avoid any possible 'rush' of applications immediately prior to the expiry date.

Confidential commercial information (CCI)

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, but which may be released with the consent of the applicant or by order of a court.

In the April to June 2002 quarter the Regulator received two (2) CCI applications in relation to DIR licence applications, three (3) CCI applications in relation to DNIRs, two (2) CCI applications in relation to certifications and one (1) CCI application in relation to an NLRD. The Regulator approved one (1) CCI application in relation to a DNIR.

Monitoring and Compliance

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

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

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

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

Monitoring and compliance strategy

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

In the case of limited and controlled releases involving GMOs, the OGTR conducts routine monitoring visits to a minimum of 20% of all field trial sites on an annual basis. A minimum of 5% of current trial sites and 5% of trial sites subject to post-harvest monitoring are to be monitored each quarter. The purpose of this routine monitoring of field trials is to ensure compliance with licence conditions.

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

The monitoring program for contained dealings involving GMOs revolves around the inspection of certified facilities. A minimum of 20% of Physical Containment (PC) 4, PC3 and PC2 Large-Scale facilities per year are monitored. PC2 and PC1 facilities are monitored on a random basis.

A major review of the Guidelines for Certification of Facilities/Physical Containment Requirements (the current standard used for monitoring the compliance of certified facilities) continued during the quarter. The review was initiated as it was recognised that the current version of the guidelines was limited in its application as a standard for monitoring compliance (see Part 4, Reviews and Research).

The Monitoring and Compliance Section is continuing to develop and apply protocols and provide training that will assist accredited organisations to better understand the obligations and requirements under the new regulatory system. This is particularly important during this transitional period where organisations have moved from a voluntary system of regulation to a legislative framework under the *Gene Technology Act 2000*.

In this quarter, the Monitoring and Compliance Framework and the Monitoring Protocols were made available on the OGTR website (at http://www.ogtr.gov.au/monitoring/protocol.htm). These are working documents intended to offer guidance and facilitate continual improvements of monitoring and compliance activities. It is expected that they will evolve as systems are assessed and validated. Comments and feedback on these documents are welcomed.

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored. During the quarter, a total of sixty-seven (67) monitoring visits were carried out. Nineteen (19) visits were carried out as unannounced spot checks. Monitoring was carried out on 22 deemed licences and covered 3 plant species.

Current field trial sites monitored. Of the fifty-three (53) sites that were current in the quarter, fourteen (14) sites were monitored. This represents a monitoring rate of 26% of all current sites for the quarter. Seven (7) of the visits were unannounced spot checks.

Post Harvest field trial sites monitored. Of the five hundred and eight (508) sites that were subject to post harvest monitoring in the quarter, fifty-three (53) sites were monitored. This represents a monitoring rate of 10% of all sites subject to post harvest monitoring. Twelve (12) of these visits were unannounced spot checks.

Monitoring of contained dealings. During the quarter all PC4, PC3 and PC2 large scale facilities deemed certified and seeking renewal of certification were inspected by the OGTR under the Act. Of the lower level facilities, ten (10) PC2 and four (4) PC1 facilities were monitored as part of the routine monitoring program.

Refer to Part 2, ‘Existing licences and other instruments’ for further details.

Monitoring conducted

The total monitoring coverage for field trial sites during the April to June 2002 quarter is shown in the following table.

Licensed Organisation name	Deemed licence	No. sites licensed	No. sites visited	Site status*	Crop type
Bayer CropScience Pty Ltd(formerly Aventis CropScience)	PR62X(4)	15	9	PHM	Canola
	PR63X(4)	96	20	PHM	Canola
	PR63X(5)	39	2	PHM	Canola
	PR63X(6)	12	3	C	Canola
Monsanto Australia Limited	PR77X	18	4	PHM	Canola
	PR77X(2)	30	3	PHM	Canola
	PR77X(3)	30	1	PHM	Canola
Department of Agriculture (Western Australia)	PR87x	7	2	PHM	Cotton
	PR146	1	1	PHM	Poppy
CSIRO	PR89X(2)	26	8	4xC, 4xPHM	Cotton
	PR112X(2)	3	1	PHM	Cotton
	PR123X(2)	2	1	C	Cotton
	PR124X(2)	2	1	C	Cotton
	PR131	4	1	PHM	Cotton
	PR131X(2)	4	1	PHM	Cotton
	PR138X	2	1	C	Cotton
	PR151	2	1	C	Cotton
	DIR006	7	3	C	Cotton
Cotton Seed Distributors	PR94X(3)	1	1	PHM	Cotton
	PR131X(3)	1	1	PHM	Cotton
GlaxoSmithKline	PR129	1	1	PHM	Poppy
	PR129X	1	1	PHM	Poppy
Totals	**22**	**304**	**67**	**C=14 PHM=53**	**3 species**

* C = current / PHM = post-harvest monitoring

Monitoring Findings

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

A review of compliance with licence conditions at GMO canola field trial sites has been conducted and is reported in the Reviews section below.

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

The OGTR's current Guidelines for Certification of Facilities/Physical Containment Requirements are the subject of a review to remove ambiguity and make them more user-friendly and more easily enforceable. A draft version has been released for comment and feedback. In the meantime, the OGTR is focusing its monitoring efforts on educating organisations and gathering information to assist in the revision of these guidelines.

During the reporting period 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.

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 (2) types of reviews:

- Incident Reviews: are initiated when an organisation reports or an OGTR monitoring team identifies a particular incident that is suspected to be a non-compliance with the *Gene Technology Act 2000* and associated legislation; and

- Practice Reviews: are reviews relating to monitoring to determine if licence conditions can be, and are being, effectively implemented and include the identification of potential 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 *Gene Technology Act 2000* that needs to be referred for investigation. Completed Incident Reviews and ongoing Practice Reviews are reported below.

The following Incident Review was completed in this quarter and is outlined in the table below.

Issue	An accredited organisation, Murdoch University, reported an incident where a glass panel in a certified PC2 glasshouse was damaged during routine maintenance.
Risk assessment	The OGTR assessment was that this incident posed negligible risks to public health and environmental safety, and there was negligible potential for the spread or dissemination of GM material from within the facility due to the nature of the material and the remedial actions taken by Murdoch University.
Determination	Compliant: The review found that the incident was an unforeseeable event and that the organisation acted appropriately.
Risk management	The accredited organisation undertook repairs soon after the incident and the facility now meets the requirements set out in the *Guidelines for the Certification of Facilities/Physical Containment Requirements*.
Action	Not referred for investigation. OGTR is to conduct follow-up monitoring.

Practice/Incident Review: Post Harvest Monitoring Practices on canola sites

A review of Bayer CropScience (formerly Aventis CropScience Pty Ltd) and Monsanto monitoring and reporting information from July 2001 to March 2002 for GMO Canola field trials has been conducted. The review was conducted to verify compliance and further assure continual improvement in the licence holders' risk management of the GMO.

The review canvassed licence holder improvements in risk management, monitoring and reporting. The review found sites were managed at the *compliant* or *conceded compliant* level[3].

Over the nine (9) month review period, 96.6% of monitoring reports showed Bayer CropScience (formerly Aventis CropScience Pty Ltd) trial sites were managed to the extent that no flowering GM plants occurred on the sites. 274 sites were monitored over this period with approximately 2500 monitoring reports submitted. Approximately 3.4% of monitoring reports showed the occurrence of flowering GM plants.

Monsanto produced 756 monitoring reports over the nine (9) month review period showing approximately 97.2% of trial sites had no flowering GM plants on the 84 sites monitored. Approximately 2.7 % of monitoring reports showed the occurrence of flowering GM plants.

Most reports of flowering volunteers indicated the presence of less than ten (10) flowering plants.

Review of management practices at these sites indicates that appropriate action was taken to control the volunteers and the reported flowering occurrences posed a negligible risk to health and the environment.

The licence holders and the OGTR are continuing to monitor and achieve improvements in the control of flowering plants.

Practice Review: Post trial crops on canola sites

As mentioned in the previous Quarterly Report, the OGTR has reviewed past monitoring records to evaluate the feasibility and effectiveness of crop management programs in post trial crops (crops sown on sites once the trial is complete). A significant part of the review focussed on the licensees' ability to detect volunteers and prevent those plants from flowering (as required under current deemed licence conditions), in post trial crops other than cereals, grass pasture or where sites remained fallow.

A draft report on the review has been provided to accredited organisations (operating under deemed licences for GM canola) for comment and will be finalised in the next quarter.

[3] These terms are described in the *Monitoring and Compliance Framework* – in accordance with the *Gene Technology Act 2000 (Cth)* – available on the OGTR website (at *http://www.ogtr.gov.au/monitoring/protocol.htm*

Practice Review: Gene Flow Study for Post Harvest Canola Sites in Tasmania

As mentioned in previous Quarterly Reports, the OGTR is conducting a study examining whether gene flow had occurred on post harvest trial sites in Tasmania that were found not to comply with the previous voluntary guidelines. The non-compliant sites were detected by the Interim Office of the Gene Technology Regulator (IOGTR) monitoring teams in February 2001 and the study was commissioned to determine whether any gene flow from GM canola to sexually compatible species has occurred on or around the non-compliant sites. Most of the work for the project has been completed, with field observations subject to analysis and the final report currently in preparation. Results to-date do not show that gene flow to the sexually compatible species has occurred on the field trial sites.

Investigations

No investigations were initiated or completed in the quarter.

Audits

No audits were initiated or were ongoing in the quarter.

PART 3 - Committee Operations

The Act establishes three new advisory committees:

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

On 22 May 2002, the Parliamentary Secretary to the Minister for Health and Ageing, the Hon Trish Worth MP, announced the appointments of Professor Stephen Powles, as Chair of the Gene Technology Technical Advisory Committee, Professor Don Chalmers, as Chair of the Gene Technology Ethics Committee and Sir Ninian Stephen, as Chair of the Gene Technology Community Consultative Committee after the appointments were agreed to by a majority of State and Territory Governments (as required by the Act).

Gene Technology Technical Advisory Committee

During this quarter, GTTAC held two (2) face-to-face meetings on 24 April and 27 June 2002 in Canberra. Two (2) teleconference meetings of the Committee were also held on 10 April and 30 May 2002. At these meetings the Committee considered:

DIRs - seven (7) licence applications;
- three (3) risk assessment and risk management plans.

DNIRs - nineteen (19) risk assessment and risk management plans.

During this quarter, the Committee also considered twenty-four (24) applications for DNIRs out of session.

Further information about the dealings considered by GTTAC can be obtained from the Communique attached to this Report **(Appendix A).**

Other significant matters considered in this period were:

GM Canola

During this quarter, the Committee began to give more detailed consideration to the issues surrounding the possible commercial release of GM Canola in Australia as an application seeking the general release of GM Canola had been foreshadowed. To this end the teleconference held on 10 April 2001

was dedicated to the identification and initial consideration of the possible impacts the release of GM Canola may have on the health and safety of people and the environment and of any of the data that would be required for the Committee to fully assess an application seeking the general release of GM Canola.

Antibiotic Resistance Marker Genes

GTTAC was advised that the Regulator intended to review the use of antibiotic resistance marker genes (ARMGs) in GMOs. In considering this issue, GTTAC noted that there was no scientific evidence supporting the view that the use of ARMGs in GMOs contributed to the development of antibiotic resistance and advised the Regulator that the risk to human health and safety and/or the environment from the use of ARMGs in GMOs is minimal.

Gene Technology Ethics Committee

During this quarter, GTEC held its second meeting on 15-16 May 2002, at which the major focus was on five (5) priority work areas agreed at the inaugural meeting in December 2001. The working groups presented draft papers for consideration by the members and the Regulator. Following discussion, the Committee resolved that the areas currently under consideration and the draft papers warranted further development. It was agreed that revised papers, incorporating the comments received from the members and expert advisers, would be considered at the next GTEC meeting later in 2002.

Further information about the issues considered by GTEC can be obtained from the Communique attached to this Report **(Appendix B)**.

Gene Technology Community Consultative Committee

The GTCCC held its inaugural meeting in Melbourne on the 17th and 18th of April 2002. The GTCCC was established by the Act as a statutory advisory committee to the Regulator and the Gene Technology Ministerial Council. All committee members hold office on a part-time basis.

At its first meeting the Committee discussed the role of the GTCCC and the future development of a work plan. The discussion covered a range of issues facing the gene technology regulatory system. The GTCCC agreed to meet in July 2002 to discuss these issues further.

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 including intentional release of GM cotton, particularly large scale releases. This review is still on-going; and
- A review of the *Guidelines for the Certification of Facilities/Physical Containment Requirements*. OGTR 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 next quarter.

International Collaboration and Coordination

Under the Act, two (2) 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 quarter, an officer from the OGTR travelled to the United Kingdom and to Canada to gather data and information relating to:

- scientific and anecdotal information on environmental and health risks associated with the release of GMOs in these countries;
- monitoring and compliance operational practices used by the respective regulatory authorities; and
- developing closer communication links between the OGTR and the UK and Canadian regulatory authorities to enhance all parties' understanding of scientific and regulatory issues for GMOs.

Information from the visit has been used in the development of protocols for the Monitoring and Compliance Section, in the preparation of risk assessment and risk management plans, and in developing parameters for closer communication activities between the United Kingdom and Canada.

The OGTR 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.

Advice on Gene Technology Regulation

Briefings

The OGTR provided briefings to organisations and agencies on aspects of the legislation relevant to their work:

- Meeting with the Victorian Health Department on Monitoring & Compliance protocols;
- Meeting with the National Registration Authority;
- Meeting with the Cooperative Research Centre for Weed Management; and
- Meeting with the RSPCA on Transgenic Animals.

Presentations

Staff of the OGTR endeavour to participate in public discussions and forums on gene technology wherever possible to inform the community and users about the regulatory system. During the quarter the OGTR made presentations to, or at the:

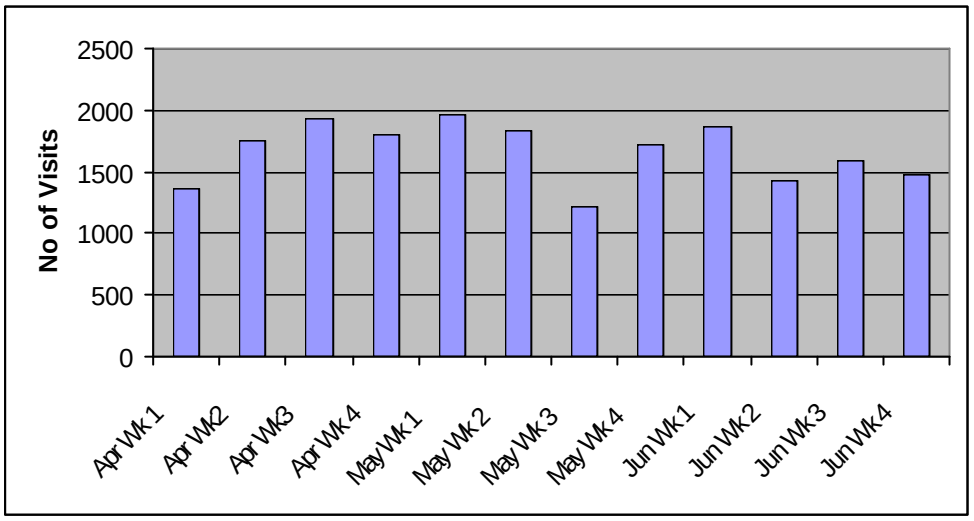
- AusBiotech Fermentation and Bioprocessing Special Interest Group annual conference "The New Gene Technology Legislation" Implications for commercial dealings with GMOs";
- Biosafety 2002 conference on regulation of biotechnology research & application process;
- Horticulture Australia/Agrifood Awareness Australia Gene Technology Forum;
- Australian Landcare Council; and
- AVCC Deputy & Pro-Vice chancellors (research) committee meeting.

Institutional Biosafety Committee (IBC) training sessions

The OGTR completed a training session for the Australian National University institutional biosafety committee and researchers on 27 June 2002. This session was designed to explain the new regulatory system and assist IBCs and researchers in applying to the Regulator for licences, certifications and accreditations.

OGTR website: www.ogtr.gov.au

The OGTR website received 419,416 'hits'[4] during the quarter, which represents an average of 4,608 hits per day. The table below illustrates the pattern of individual visits[5] 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; and
- OGTR 'What's new'.

The most popular downloaded documents were:

- Handbook on the Regulation of Gene Technology in Australia;
- The first draft of the Gene Technology Regulations 2000; and
- Explanatory Guide to the draft Commonwealth Gene Technology Regulations 2000.

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

[4] Hits = Total number of pages and images requested from the website
[5] Visits = Total number of visitors that entered the website

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

During the quarter, a total of 806 e-mail messages were sent to the OGTR general e-mail account. 150 e-mails were received in April 2002, 216 in May 2002 and 440 in June 2002.

Of the e-mails received, approximately 80 per cent were requests for information; 5 per cent were provision of information from other organisations; and approximately 15 per cent provided feedback and comments.

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

During the quarter, there were 201 calls in April 2002, 268 in May 2002 and 317 in June 2002 to the OGTR 1800 line.

Freedom of Information (FOI)

No FOI requests were received during the reporting period.

Consultants

During the quarter the OGTR managed three (3) consultancy contracts worth a total of $128,343 (GST exclusive). The table below lists the consultants, describes the purpose of the consultancy and the amount paid during this quarter.

Consultant	**$ Amount paid** *GST exclusive*	**Purpose**
Dialog Information Technology	$123,123	Develop Gene Technology Information Management System (GTIMS)
McNiece Communications	$4,800	Public affairs
Outlook Biotec	$420	Undertake laboratory inspections
Total Consultants for quarter	$128,343	

Appendix A

GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE COMMUNIQUE

This is the third communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the fourth and fifth meetings of GTTAC held on 26 March 2002 (teleconference) and 24 April 2002 respectively.

GTTAC is a statutory advisory committee to the Gene Technology Regulator and the Gene Technology Ministerial Council. All committee members and expert advisers hold office on a part-time basis.

The Regulator receives input from GTTAC on all applications for licences to conduct dealings with GMOs and comment on the Risk Assessment and Risk Management Plan (RARMP) that is prepared in respect of each application.

The purpose of this Communique is to provide a brief overview of the applications and RARMPs considered by GTTAC and the advice the Committee has provided to the Regulator on those applications and RARMPs.

The Communique also provides an overview of any other major issues discussed by GTTAC.

RARMPs for licence applications for Dealings involving the Intentional Release of genetically modified organisms (DIRs) are released for public comment as part of the consultation process for these applications. Information on how to obtain copies of applications and RARMPs for DIRs is provided at the end of the document.

1. Dealings Not Involving the Intentional Release of Genetically Modified Organisms

1.1 Input to the preparation of, and advice on, RARMPS for DNIRs (in numerical order of receipt)

Rapid Methods for the Detection of Toxic Cyanobacteria (DNIR 010)

The Australian Water Quality Centre has applied for a licence to identify the genes associated with toxin synthesis in cyanobacteria and to construct cyanobacteria that do not produce the toxin.

GTTAC noted that there were several minor issues requiring further information with respect to this application. While they did not affect the level of risk involved, the applicant should be requested to provide the information.

GTTAC resolved to advise the Regulator:

- The risk assessment identifies all the risks associated with the proposed dealings.

- The measures proposed in the risk management plan are adequate to deal with the identified risks.

- The following matters should be considered in finalising the RARMP:

    - Clarification of the statement concerning the destruction of cyanobacteria and toxins by chlorination, microfiltration or oxonation.
    - Clarification of the statement in the RARMP about possible production of the toxin in *E. coli*.
    - Explanation of the statements concerning the ability of *E. coli* to survive in the environment and to cause disease.
    - Provision of references to support the statement that '… the precursors and cofactors required for synthesis of the toxin are unlikely to be present *in E. coli*.'

Cryptoccal phospholipases: Structure and Potential Targets for Therapeutics (DNIR 011)

Western Sydney Area Health Service has applied for a licence to study the structure and function of the phospholipase proteins in the fungus *Cryptococcus neoformans*.

GTTAC resolved to advise the Regulator:

- The risk assessment identifies all the risks associated with the proposed dealings.

- The measures proposed in the risk management plan are adequate to deal with the identified risks.

Investigation of the Roles of TNFα-related apoptosis-inducing ligand (TRAIL) in the Immune System (DNIR 012)

Western Sydney Area Health Service has applied for a licence to investigate the function of TRAIL in the immune system. TRAIL is a molecule which is thought to specifically kill transformed and virus infected cells but not most normal human cells.

GTTAC resolved to advise the Regulator:

- The risk assessment identifies all the risks associated with the proposed dealings.

- The measures proposed in the risk management plan are adequate to deal with the identified risks.

Studies of Cell Growth and Survival (DNIR 013)

Western Sydney Area Health Service has applied for a licence to investigate the biological processes that regulate cell growth and survival.

GTTAC resolved to advise the Regulator:

- The risk assessment identifies all the risks associated with the proposed dealings.

- The measures proposed in the risk management plan are adequate to deal with the identified risks.

Reverse Genetics of Newcastle Disease Virus (DNIR 017)

The Commonwealth Scientific and Research Organisation (CSIRO), Australian Animal Health Laboratory, has applied for a licence to determine the role of the matrix protein gene in Newcastle Disease Virus.

GTTAC noted that there were several minor issues requiring further information with respect to this application. While they did not affect the level of risk involved, the applicant should be requested to provide the information.

GTTAC resolved to advise the Regulator:

- The risk assessment identifies all the risks associated with the proposed dealings.

- The measures proposed in the risk management plan are adequate to deal with the identified risks.

- In finalising the RARMP, additional information should be sought on the following matters:

    - The methods used to transfer genes.
    - Scientific literature on whether the modification made to the matrix gene could impact on virus virulence.
    - The details of the animal facility in which the work would be carried out; and the proposed disposal methods for infected animals.

Bone Repair (DNIR 018)

CSIRO, Division of Molecular Sciences, has applied for a licence to identify genes that regulate bone growth and their most effective routes for administration in order to enhance bone repair.

GTTAC resolved to advise the Regulator:

- The risk assessment identifies all the risks associated with the proposed dealings.

- The measures proposed in the risk management plan are adequate to deal with the identified risks.

B55 Gene Over-expression in *Psammomys obesus* (DNIR 019)

Deakin University has applied for a licence to study the effects on obesity and diabetes of over-expression of the B55 gene.

GTTAC resolved to advise the Regulator:

- The risk assessment identifies all the risks associated with the proposed dealings.

- The measures proposed in the risk management plan are adequate to deal with the identified risks.

HIV Replication and Gene Expression (DNIR 021)

The Royal Children's Hospital, Brisbane has applied for a licence to investigate the role of virus regulatory proteins in HIV replication and gene expression.

GTTAC noted that there were several issues related to the handling of HIV that required further clarification by the applicant.

GTTAC resolved to advise the Regulator:

- The risk assessment identifies all the risks associated with the proposed dealings.

- The measures proposed in the risk management plan are adequate to deal with the identified risks.

- In finalising the RARMP, additional information should be sought from the applicant on the measures proposed to avoid the production of a virus with increased virulence and those aspects of the work which will be carried out in PC3 conditions.

Characterisation of the Anti-apoptotic Function of P-glycoprotein and Transcriptional Regulation of the MDR1 Gene (DNIR 022)

The Peter MacCallum Cancer Institute has applied for a licence to determine if the P-glycoprotein can protect tumour and normal cells against cell death.

GTTAC resolved to advise the Regulator:

- The risk assessment identifies all the risks associated with the proposed dealings.
- The measures proposed in the risk management plan are adequate to deal with the identified risks.

Production of Recombinant Proteins in Mammalian, Insect, Yeast and Bacterial Cells (DNIR 024)

Biotech Australia Pty Ltd has applied for a licence to produce a large range of recombinant proteins for research reagents, clinical research and commercial biopharmaceuticals.

GTTAC noted that the purpose of the application was to streamline the application process for dealings that would otherwise be exempt from licensing if it were not for the fact they involved production volumes of greater than 10 litres of culture. The licence issued for these dealings would require that the OGTR is notified of the protein to be produced and the host/vector system to be employed before production commences.

GTTAC resolved to advise the Regulator:

- The risk assessment identifies all the risks associated with the proposed dealings.
- The measures proposed in the risk management plan are adequate to deal with the identified risks.

2. Dealings Involving the Intentional Release of Genetically Modified Organisms

2.1 Advice on Applications (in numerical order of receipt)

Commercial Release of Bollgard II® Cotton (DIR 012)

Monsanto Australia Ltd has applied for a licence for the commercial release of a genetically modified insecticidal type of cotton registered under the trade name Bollgard II® cotton and a type of genetically modified insecticidal cotton that is also herbicide tolerant, referred to as Bollgard II®/Roundup Ready® cotton.

The GM cotton plants and their by-products would be used in the same manner as conventional cotton, including for human food. The Australian New Zealand Food Authority (ANZFA) has approved the use of INGARD®, Bollgard II® and Roundup Ready® cotton and relevant by-products in human food. In two previous assessments of Bollgard II® cotton, ANZFA indicated that it considers products from Bollgard II® cotton to be as safe for human consumption as those from conventional cotton. There is no protein or DNA in cotton seed oil or linters after processing for either GM or non-GM cotton.

The proposed releases would be carried out in all cotton growing areas including potential areas north of latitude 22° South in Queensland, the Northern Territory and Western Australia. It is proposed that ultimately, the total release would comprise a high proportion of Australia's cotton growing hectarage (currently about 484, 000 ha), although the exact area would be subject to an insect resistance management strategy.

GTTAC resolved to advise the Regulator:

- The following potential hazards should be addressed in the RARMP for application DIR 012.

  (a) The potential for the genetically modified cotton to be harmful to other organisms because it is toxic or allergenic.
  (b) The potential for the genetically modified cotton to be harmful to agricultural or natural environments because of inherent weediness or increased potential for weediness.

- In addition, the following data should be obtained:

  - a copy of the report on the potential weediness of GM cotton in northern Australia
  - information on the extent to which cotton growers have complied with insect resistance management strategies (IRM) for INGARD® cotton
  - data, at a regional scale and from an existing tropical cotton growing area such as Emerald, QLD, on the efficacy of the IRM strategy developed for INGARD® cotton
  - more detailed data on the potential linkage of the Cry1Ac, Cry2Ab and CP4 EPSPS transgenes and associated segregation ratios.

Agronomic Assessment and Seed Increase of INGARD® and Bollgard II® Cotton (DIR 013)

Monsanto Australia Ltd has applied for a licence for the limited and controlled release of a genetically modified insecticidal type of cotton registered under the trade name Bollgard II® cotton, INGARD® cotton and a type of genetically modified insecticidal cotton that is also herbicide tolerant, referred to as Bollgard II®/Roundup Ready® cotton.

The purpose of the proposed release is to continue the agronomic and varietal assessment of promising cotton lines; increase seed of the most promising Bollgard II® and Bollgard II/Roundup Ready® cotton lines for future releases (which would be subject to additional applications); further the development of the Insect Resistance Management Plan for Bollgard II®.

The GM cotton plants and their by-products would be used in the same manner as conventional cotton, including for human food. The Australian New Zealand Food Authority (ANZFA) has approved the use of INGARD®, Bollgard II® and Roundup Ready® cotton and relevant by-products in human food. In two previous assessments of Bollgard II® cotton, ANZFA indicated that it considers products from Bollgard II® cotton to be as safe for human consumption as those from conventional cotton. There is no protein or DNA in cotton seed oil or linters after processing for either GM or non-GM cotton.

The releases would be carried out in all cotton growing areas of New South Wales and Queensland including potential cotton growing areas near Richmond, QLD, north of latitude 22° South. The release would be over a total area of 10 000 hectares. No limitations on transportation, cultivation or storage are proposed, other than compliance with an insect resistance management strategy, which is yet to be finalised.

GTTAC resolved to advise the Regulator:

- The following potential hazards should be addressed in RARMP for application DIR 013.

    (a) The potential for the genetically modified cotton to be harmful to other organisms because it is toxic or allergenic.
    (b) The potential for the genetically modified cotton to be harmful to agricultural or natural environments because of inherent weediness or increased potential for weediness.

Agronomic Assessment and Seed Increase of Transgenic Cotton Expressing the *Cry1Ac* and *Cry2Ab* Genes from *Bacillus thuringiensis* (DIR 014)

The Commonwealth Scientific and Industrial Research Organisation (CSIRO) has applied for a licence for the limited and controlled release of a genetically modified insecticidal type of cotton registered under the trade name INGARD®, Bollgard II® and a type of genetically modified insecticidal cotton that is also herbicide tolerant, referred to as Bollgard II®/Roundup Ready® cotton.

The purpose of the proposed release is for agronomic assessment, to produce seed for future releases and to assess the efficacy of insect control in unsprayed plots. The release would be carried out on 20 sites and involve a total area of 42 hectares in NSW and Queensland.

GTTAC resolved to advise the Regulator:

- The following potential hazards should be addressed in the RARMP for application DIR 014.

    (a) The potential for the genetically modified cotton to be harmful to other organisms because it is toxic or allergenic.
    (b) The potential for the genetically modified cotton to be harmful to agricultural or natural environments because of inherent weediness or increased potential for weediness.

Agronomic Assessment and Seed Increase of Transgenic Cotton Expressing Tolerance to the Herbicide Glufosinate Ammonium (DIR 015)

CSIRO has applied for a licence for the limited and controlled release of a genetically modified insecticidal type of cotton expressing tolerance to glufosinate-ammonium, the active constituent of herbicides Basta® and Liberty® (hence the name Liberty® cotton), which would be carried out in New South Wales.

The purpose of the proposed release is to trial Liberty® cotton for agronomic assessment, and to produce seed for future releases (which would be subject to further approvals). The release would be carried out on one site over a total area of two hectares in New South Wales.

GTTAC resolved to advise the Regulator:

- The following potential hazards should be addressed in the RARMP for application DIR015.

    (a) The potential for the genetically modified cotton to be harmful to other organisms because it is toxic or allergenic.
    (b) The potential for the genetically modified cotton to be harmful to agricultural or natural environments because of inherent weediness or increased potential for weediness.

Evaluation under Field Conditions of Sub-clover Stunt Virus Promoters Driving an Insect Tolerance Gene (*Cry1Ac*) from *Bacillus thuringiensis* (DIR 016)

CSIRO has applied for a licence for the limited and controlled release of a genetically modified cotton containing the *cry1Ab* and *bar* genes which confer insecticidal activity and herbicide tolerance, respectively. The proposed trial would mainly involve the evaluation of a novel set of promoters from the sub-clover stunt virus which were used to drive the *cry1Ab* gene and to produce seed for future releases (which would be subject to further approvals).

The trial would be carried out on 2 sites over a total area of 1.5 hectares in New South Wales.

GTTAC resolved to advise the Regulator:

- The following potential hazards should be addressed in the RARMP for application DIR 016.

    (a) The potential for the genetically modified cotton to be harmful to other organisms because it is toxic or allergenic.
    (b) The potential for the genetically modified cotton to be harmful to agricultural or natural environments because of inherent weediness or increased potential for weediness.

Agronomic Assessments and Efficacy Studies of Transgenic Cotton Expressing a New Insecticidal Tolerance Gene (DIR 017)

CSIRO has applied for a licence for the limited and controlled release of a genetically modified cotton expressing a new insecticidal gene which is subject to an application for protection as commercial confidential information.

The purpose of the proposed release is to trial the new insecticidal cotton for agronomic assessment and efficacy studies, and to produce seed for future releases (which would be subject to further approvals). The release would be carried out on 3 sites over a total area of 3 hectares in New South Wales. GTTAC resolved to advise the Regulator:

- The following potential hazards should be addressed in the RARMP for application DIR 016.

    (a) The potential for the genetically modified cotton to be harmful to other organisms because it is toxic or allergenic.
    (b) The potential for the genetically modified cotton to be harmful to agricultural or natural environments because of inherent weediness or increased potential for weediness.

- In addition, the following information should be requested from the applicant:

    - data on the toxicity of the new insecticidal genes to non-target insects and their expression levels and efficacy on target insects.

3. Other Matters

Antibiotic Resistance Marker Genes

GTTAC was advised that the Office of the Gene Technology Regulator proposed to undertake a review of the use of antibiotic resistance marker

genes (ARMGs) in Australia. The Committee noted that there was public concern about the development of antibiotic resistance. ARMGs in genetically modified organisms were thought, by some, to contribute to the development of antibiotic resistance and reduce the usefulness of antibiotics in treating infections.

GTTAC advised the Regulator that there was no evidence to support this view and that the risk to human health and safety or the environment from the use of antibiotic resistance marker genes is negligible.

Genetically Modified Canola

At the request of the Regulator GTTAC has begun to give more detailed consideration to the issues surrounding the possible commercial release of GM Canola in Australia as an application seeking the general release of GM Canola had been foreshadowed. To this end the Committee held a teleconference held on 10 April 2001 dedicated to the identification and initial consideration of the possible impacts the release of GM Canola may have on the health and well being of people and the environment and of any the data that would be required for the Committee to fully assess an application seeking the general release of GM Canola.

Enquiries and Risk Assessment and Risk Management Plans

For all enquiries and to obtain copies of Risk Assessment and Risk Management Plans for dealings involving the intentional release of GMOs into the environment please phone the OGTR on 1800 181 030. The Plans are also available electronically from our website at http://www.ogtr.gov.au/publications/riskassessments.htm

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Appendix B

Communique from the Gene Technology Ethics Committee Meeting

Gene Technology Ethics Committee Meeting
15-16 May 2002, Canberra

COMMUNIQUE

The Gene Technology Ethics Committee (GTEC) held its second meeting in Canberra on the 15th and 16th of May 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 communique includes 'expert advisers').

At its second meeting, GTEC's major focus was on progressing five agreed priority work areas. GTEC also considered reports from a number of national committees, whose work is directly related to GTEC, and information from the Regulator and the GTEC Chairman. A presentation by Biotechnology Australia provided the Committee with an overview of recent studies showing trends in public attitudes to gene technology including changes in areas of concern; ethical issues; and views of regulatory agencies over the past few years. This presentation complemented the Committee's later discussion of progress on the priority work areas. The outcomes of these discussions are summarised below.

GTEC's Work Plan

GTEC's major focus for the meeting was to work on progressing five agreed priority work areas. As detailed in GTEC's first Communique in December 2001 the priority areas are:

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 genetically modified organisms (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[6] including animal welfare considerations; and
5. Ethical matters in relation to transkingdom gene transfer[7].

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

In December the Committee formed working groups of members, based on relevant expertise and interests, to research and prepare issues papers.

At the May meeting, the working groups presented the draft papers for consideration by the members and the Regulator. Following discussion, the Committee resolved that the areas currently under consideration and the draft papers warranted further development and the working groups, at the request of the full Committee, have agreed to review their work and incorporate the comments received from members at the meeting. Revised papers will be considered at the next GTEC meeting.

Genetic Modification of Animals

As an example of GTEC's current work, the Committee considered a working group paper on 'Ethical Issues Arising from the Genetic Modification of Animals'. The paper covered three aspects of the genetic modification of animals: the techniques involved and their use; the ethical issues arising from the application of these techniques; and the regulatory framework surrounding this type of work. GTEC resolved that the genetic modification of animals is relevant to their agenda and will continue to seek opportunities to participate both formally, as part of any public consultations, and informally, via the cross-member, as part of a review of the National Health and Medical Research Council's (NHMRC) *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (the Code). GTEC further resolved to send a copy of the finalised working group paper to the NHMRC's Australian Health Ethics Committee and the Animal Welfare Committee, members of which are on the Code Liaison Group reviewing the Code.

GTEC and Relationships with Other Committees

GTEC received verbal reports on activities from the cross-members with the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Community Consultative Committee (GTCCC), which recently held its inaugural meeting. GTEC reconfirmed the valuable role of the cross-members as a conduit for sharing information across the national regulatory scheme. (Copies of the GTTAC and GTCCC communiques are also published on the OGTR web site.)

Members were kept informed of communication between the gene technology advisory committee chairs by the GTEC Chairman and were informed by the Regulator of recent activities and work undertaken by the OGTR.

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[7] *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 molds).

GTEC received a report from the cross-member with the NHMRC Australian Health Ethics Committee in relation to activities of mutual interest. GTEC also received an update on recent activities in relation to two other relevant NHMRC committees: the Gene and Related Therapies Research Advisory Panel and the Animal Welfare Committee.

GTEC resolved to continue to actively pursue opportunities for enhanced communication with the other gene technology advisory committees and appropriate NHMRC committees in order to avoid duplication of resources and ensure quality outcomes relating to the ethics of gene technology under the Act.

Committee Operating Procedures

GTEC considered a revised draft of its Committee Operating Procedures and, following final revisions, agreed to adopt the procedures as an additional level of detail to assist the working of the Committee. The operating procedures include extracts from the Act, the Gene Technology Regulations 2001, the Remuneration Tribunal and Department of Health and Ageing Financial Operating Procedures. The operating procedures will be reviewed in 12 months time in May 2003.

Copies of the Committee Operating Procedures are available from the OGTR on 1800 181 030 (free-call).

Next Meeting

GTEC is scheduled to meet again later in 2002.

For all inquiries, please contact the Office of the Gene Technology Regulator on
1800 181 030 (free-call)