Quarterly Report of

the Gene Technology Regulator

for the period

1 January to 31 March 2002

ISBN

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

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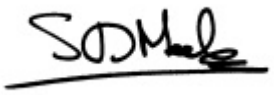
The Hon Trish Worth MP
Parliamentary Secretary to the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

Dear Parliamentary Secretary

In accordance with section 136A of the *Gene Technology Act 2000*, I am pleased to present to you the Third Quarterly Report of the Gene Technology Regulator, covering the period 1 January to 31 March 2002.

The first three months of 2002 saw the highest level of regulatory activity to date as the new regulatory system continues to evolve.

Yours sincerely



(Dr) Sue D Meek
Gene Technology Regulator

26 September 2002

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Abbreviations and Terms

Accredited organisation	An organisation that is accredited under section 92 of the *Gene Technology Act 2000*
Act	*Gene Technology Act 2000*
Breach	see Non-compliance
CCI	Confidential commercial information
Certified facility	A building or place certified by the Regulator, to a specified containment level, under section 84 of the 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:

- licences for dealings with genetically modified organisms (GMOs) 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 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 January - March 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:

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PART 1 - National Regulatory System

Key achievements during this quarter

The key achievements of the January to March 2002 quarter were:

First licence approved under the new regulatory system

The first approved dealing involving intentional release (DIR) of a genetically modified organism (GMO) licence was granted to Cotton Seed Distributors Ltd to carry out a limited and controlled release of two types of genetically modified cotton in Queensland. Three others were issued in the quarter. For more detail, see Part 2.

Licences and other instruments

In the January-March 2002 quarter the Regulator:

- issued 4 licences for DIRs;
- issued 9 licences for DNIRs;
- accredited 1 organisation; and
- certified 94 facilities.

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

Monitoring and compliance

In the March quarter, the Monitoring and Compliance Section's targets were to monitor:

- at least 5% of current trial sites and sites subject to post trial monitoring per quarter was exceeded; and
- at least 5% of containment facilities at Physical Containment (PC) 4, PC3 and PC2 large scale levels per quarter was exceeded.

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

Three investigations into suspected non-compliances with the Act were completed in this quarter. While non-compliances were identified in each case, the risk posed to human health and the environment was assessed as being negligible requiring no further action, and strategies to raise accredited organisations' understanding of the requirements under the Act were implemented.

Working collaboratively with States and Territories

Gene Technology Agreement

The Gene Technology Agreement (GTA) is an inter-governmental agreement which sets out the understandings between 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) had signed the GTA.

Gene Technology Ministerial Council and Standing Committee

The Act establishes the Gene Technology Ministerial Council (GTMC) which has responsibility for:

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

The Ministerial Council consists of one Minister from each State and Territory and one Minister from the Commonwealth. In this quarter the Commonwealth, States and Territories finalised 24 May 2002 as the date for the inaugural meeting of the GTMC and began preparation on agenda papers for this meeting. The outcomes of this meeting, which will be held in conjunction with the Australia New Zealand Food Standards Council meeting, will be reported in the next Quarterly report.

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 convened their first meeting in the last Quarter. The Standing Committee convened two teleconferences in this quarter, on 15 and 22 February 2002. The main issues discussed at these meetings included the finalisation of the date and agenda papers for the first Ministerial Council meeting. Finalisation of the Chairs of the gene technology advisory committees was also discussed. It was agreed that a face-to-face meeting of the Standing Committee would be held in April 2002, preceding the Ministerial Council meeting.

State and Territory gene technology legislation

The Act anticipates that each State and Territory would 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' for the purposes of the Act.

The *Gene Technology Act 2001* and Regulations (South Australia) were enacted in February 2002 and the *Gene Technology Act 2001* and Regulations (Victoria) were enacted in December 2001. The OGTR commenced examination of the South Australian and Victorian gene technology laws as a prelude to declaring those laws as corresponding State law.

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) that are prepared 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 stakeholers. In addition, however, input is sought from a range of 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.

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

In this quarter, the Regulator sought advice and comment from Commonwealth agencies on the evaluation of six (6) DIR applications. Further information is set out in Part 2.

Public Participation

In this quarter, the Regulator advised the public of the receipt of three (3) DIR applications through postings of 'early bird' notifications and summaries of applications on the OGTR website and via email or post to those persons who have registered on the OGTR mailing list. The notifications foreshadow the opportunity for the public to comment on the RARMP being prepared for each application and provide information on the consultation process.

The Regulator also sought public comment on three (3) RARMPs 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 January - March 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 non-compliance with 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.

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

- accreditations of organisations; and
  Organisations which conduct work with GMOs must be accredited. To achieve this, the Regulator must be satisfied that the organisation has, or has access to, a properly constituted and maintained Institutional Biosafety Committee and complies with the requirements of the Regulator's guidelines for accreditation.

- certifications of facilities.
  The purpose of certification is to satisfy the Regulator that the facility which is used to contain the GMO meets the Regulator's requirements for physical containment as described in the Regulator's certification guidelines.

The Act also requires the Regulator to receive notifications from organisations undertaking notifiable low risk dealings (NLRDs) work. As this category of dealings with GMOs has been assessed as posing low risks based on previous national and international experience, the Regulator is not required to make a decision in respect of NLRDs provided they comply with certain risk management conditions and the dealing is undertaken in facilities which meet at least physical containment level 2.

New licences and other instruments

The following table describes the number and type of applications received for new licences and other instruments, as well as the approvals made by the Regulator in the January - March 2002 quarter.

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

Applications for /Notification of		Number Approved #
Type	Number Received	
Accreditations	2	1
Certifications	46	94
Licence for a DNIR	11	9
Licence for a DIR	7	4
NLRD	42	43

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

Processing of DIR applications

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

- initial screening of the application for completeness;
- deciding, based on the level of risk to human health and safety and/or the environment, whether one or two rounds of public consultation will occur in the assessment process for the application;
- seeking comments from expert groups and key stakeholders on issues to consider in a Risk Assessment and Risk Management Plan (RARMP);
- preparing a RARMP including proposed licence conditions;
- consulting with both the public, expert groups and key stakeholders 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 licence application within 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 also required to undertake two mandatory consultation periods of at least 30 days each for each DIR application, therefore it is unlikely that a DIR application would be received and decided upon within the same three month reporting period.

Table of DIR applications received, considered or decided during January – March 2002

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

Application Received – Initial Screening	**First Round of Consultation[1]**	**Second Round of Consultation[2]**	**Licence decision**
DIR 012/2002	DIR 007/2001	DIR 006/2001	Licence issued for DIR 005/2001
DIR 013/2002	DIR 010/2001	DIR 008/2001	Licence issued for DIR 006/2001
DIR 014/2002	DIR 011/2001	DIR 009/2001	Licence issued for DIR 008/2001
DIR 015/2002			Licence issued for DIR 009/2001
DIR 016/2002			
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 seven (7) DIR licence applications in the January to March 2002 quarter with the following titles:

- DIR012/2002 “Commercial release of Bollgard II® cotton” (Monsanto);
- DIR013/2002 “Agronomic assessment and seed increase of INGARD® and Bollgard II® cotton” (Monsanto);
- 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).

The seven (7) DIR applications received in the January - March 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 Regulator considered the following applications received in the October – December 2001 Quarter as to whether they proposed dealings which may pose significant risks to human health and safety or the environment:

- DIR010/2001 “Small and large scale trialing of InVigor® canola (*Brassica napus*) for development for the Australian cropping system” (Aventis CropScience Pty Ltd);
- DIR 011/2001 “Field trials of Roundup Ready® canola (*Brassica napus*) in Australia in 2002” (Monsanto Australia Ltd); and
- DIR007/2001 “Evaluation of the alkaloid production of oilseed poppy containing a modified gene involved in the pathway of alkaloid production” (Agriculture Western Australia).

The Regulator decided that no significant risks were posed by these applications. The Regulator's reasons for reaching these conclusions were that:

- under the previous voluntary system there were a number of limited and controlled releases of the same types of GM crops into the environment with no reports of adverse impacts on human health and safety or the environment associated with these releases;
- the total area of the proposed releases is within the range of previous releases; and
- based on information available from research and from previous releases, the potential risks of toxicity, allergenicity, pathogenicity, weediness and out-crossing to related species can be managed in such a way as to protect the health and safety of people and the environment.

This meant that the Regulator is not required to consult with the public on the development of these RARMPs. However, although not obliged to do so, in keeping with the spirit of the legislation, the Regulator decided to inform the public of receipt of these applications and of how the public would be able to contribute to the decision-making process via comment on the RARMP once it was prepared. The public was advised of this through postings of 'early bird' notifications and summaries of applications on the OGTR website and to people who have registered on the OGTR mailing list.

Finalised DIR Applications

The Regulator completed consultation and issued a licence for each of the following four applications:

- DIR 005/2001 from Cottonseed Distributors Ltd, proposing a limited and controlled release of insect resistant, and some herbicide tolerant cotton in Queensland;
- DIR 006/2001 from CSIRO proposing a limited and controlled release of GM insecticidal cotton into the environment in Western Australia and the Northern Territory; and
- DIR 008/2001 and DIR 009/2001 from Agriculture Western Australia proposing a limited and controlled releases of GM insecticidal cotton in Western Australia.

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.

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	Status
DNIR 001/2001	TVW Telethon Institute for Child Health Research, Western Australia	Murray Valley Encephalitis virus	The researchers are aiming to produce a more effective vaccine against Murray Valley encephalitis virus and to test potential vaccines in mice.	Approved 8 March 2002
DNIR 003/2001	Institute of Medical and Veterinary Science, South Australia	Construction of immortalized macrophage cell lines	This proposal aims to generate cell lines from macrophages isolated from patients who suffer from iron overload (haemochromatosis) to study the proteins involved in iron transport.	Approved 21 January 2002
DNIR 004/2001	CSL Limited, Victoria	Pilot scale fermentation and processing of ESO-1 antigen expressed in recombinant *E. coli*	The researchers will produce quantities of the protein coded for by the gene ESO-1, isolated from a human oesophageal carcinoma cell line, to be used to test the properties of the protein.	Approved 4 February 2002
DNIR 005/2001	Murdoch University, Western Australia (experiment to be conducted in Victoria)	Testing protection of cattle from fluoroacetate	This proposal aims to test if cattle can be protected against fluoroacetate, a poison found in some native plants, by inoculating them with genetically modified rumen bacteria.	Approved 11 February 2002
DNIR 006/2001	RMIT University, Victoria	Evaluation of chimeric influenza virus, incorporating the fusion glycoprotein of respiratory syncytial virus	The researchers aim to generate a virus strain with potential as a live vaccine by replacing a gene from an influenza A virus strain with a gene from the respiratory syncytial virus.	Approved 15 February 2002

Application number	Organisation and State	Project title	Project description	Status
DNIR 007/2001	RMIT University, Victoria	Cloning and inactivation of phospholipase gene from *Clostridium perfringens* to produce a non-toxic vaccine antigen	The researchers are aiming to produce a vaccine against the chicken disease, necrotic enteritis, which is caused by the bacterium *Clostridium perfringens*.	Approved 5 March 2002
DNIR 008/2001	St Vincent's Hospital, Victoria	The role of osteoclast inhibitory lectin in breast cancer mestases to bone	This research is to see if, in mice, an inhibitor of osteoclast formation can slow the spread of human breast cancer cells to bone.	Approved 18 February 2002
DNIR 009/2001	Biotech Australia, New South Wales	Production of humanised monoclonal antibodies from NSO cells	This proposal is to produce quantities of antibodies to be used in clinical trials.	Approved 11 March 2002
DNIR 016/2001	Biotech Australia, New South Wales	Production of domain 1 of the human plasma protein Beta 2-glycoprotein 1	The project will produce recombinant protein which will be chemically modified for use in preclinical studies	Approved 18 February 2002

Existing licences and other instruments

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

The following table describes the number and type of the applications received to vary existing licences and other instruments, as well as the approvals made by the Regulator in the January – March 2002 quarter. In summary, the Regulator varied 3 deemed DIR licences and 1 deemed DNIR licence[2] and approved the transfer of 1 licence.

[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.

Applications received and decisions made – Existing licences and other instruments

Type	Number Received	No. Approved #
Variation of accreditation	7	0
Surrender of certification	19	0
Variation of certification	4	0
Transfer of licence	3	1
Variation of DIR	11	3
Variation of DNIR	6	1

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 the seamless transfer into the new regulatory system of dealings with genetically modified organisms that were approved by the Genetic Manipulation Advisory Committee (GMAC) under the previous voluntary 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. In the case of 'deemed' certifications of PC3, PC4 and large-scale PC2 facilities, these instruments will operate for up to one year.

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.

In this quarter, the Regulator wrote to all accredited organisations reminding them of the need to make application for new instruments to replace deemed instruments where work was anticipated to continue beyond the expiry date. The letter also included a proposed schedule for a rolling program of renewals of instruments to spread the workload for researchers, industry and the regulatory system over the available time.

Organisations will be regularly reminded to renew applications as soon as possible to avoid any possible 'rush' of applications immediately prior to the relevant 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 may be released with the consent of the applicant or by order of a court.

In the January – March 2002 quarter the Regulator received four (4) CCI applications in relation to DIR licence applications. One (1) CCI application was approved by the Regulator during this quarter.

Monitoring and Compliance

The aim of OGTR monitoring and compliance activities is to ensure that dealings with GMOs comply with 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 field trial sites, the OGTR conducts routine monitoring visits of a minimum of 20% of the field trial sites involving GMOs on an annual basis. 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 routine monitoring is to ensure compliance with licence conditions.

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

The monitoring program for certified facilities monitors a minimum of 20% of PC4, PC3 and PC2 large-scale facilities per year or 5% per quarter. 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 contained facilities) continued during this 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).

Overview of monitoring and compliance for the reporting period

Total trial sites monitored. During this quarter, a total of seventy-seven (77) monitoring visits were carried out. Ten (10) visits were carried out as unannounced spot checks. Monitoring activities related to twenty-three (23) deemed licences and covered six (6) plant species.

Current trial sites monitored. Of the fifty-three (53) sites that were current in this quarter, ten (10) sites were monitored. This represents a monitoring rate of 20% of all current sites for this quarter. Two (2) of the visits were unannounced spot checks.

Post Harvest trial sites monitored. Of the five hundred and eight (508) sites that were subject to post harvest monitoring in this quarter, sixty-seven (67) sites were monitored. This represents a monitoring rate of 12% of all sites subject to post harvest monitoring in this quarter. Eight (8) of these visits were unannounced spot checks.

Monitoring of contained dealings. In this quarter, there were fifty-four (54) PC4, PC3 and PC2 large scale facilities in operation. Of these, five (5) or 9% were monitored. Of the lower level facilities, seven (7) facilities of lower level containment (ie PC2 facilities other than PC2 large scale facilities and PC1 facilities) were monitored.

Monitoring conducted

The total monitoring coverage for the January to March 2002 quarterly reporting period is shown in the following table.

Licensed Organisation name	Deemed licence (PR)	No. sites licensed	No. sites visited	Site status*	Crop type
Aventis CropScience	62X(4)	15	15	PHM	Canola
	63X(3)	62	1	PHM	Canola
	63X(4)	96	33	PHM	Canola
	63X(5)	39	1	PHM	Canola
	93	1	1	PHM	Canola
	110	2	1	PHM	Canola
	125	1	1	PHM	Tomato
Monsanto Australia Limited	77X	18	4	PHM	Canola
	77X(2)	30	3	PHM	Canola
	77X(3)	30	1	PHM	Canola
Department of Agriculture (Western Australia)	87X	7	2	PHM	Cotton
	144	24	1	PHM	Cotton

Licensed Organisation name	Deemed licence (PR)	No. sites licensed	No. sites visited	Site status*	Crop Type
CSIRO	89X(2)	26	2	C	Cotton
	73	2	1	PHM	Sugarcane
	136	2	1	PHM	Sugarcane
Cotton Seed Distributors	94X(3)	1	1	C	Cotton
	131X(3)	1	1	C	Cotton
University of Queensland	95	1	1	C	Pineapple
	68X	1	1	C	Sugarcane
Queensland Department of Primary Industries	108	1	1	C	Papaya
	137	2	2	C	Pineapple
	141	1	1	PHM	Cotton
	152	2	1	C	Pineapple
Totals	**23**	**365**	**77**	**C=10 PHM=67**	**6 species**

* C = current / PHM = post-harvest monitoring

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

Organisation	Physical Containment (PC) facility
Biotech Australia Pty Ltd	PC2 large scale
Department of Primary Industry and Fisheries, Northern Territory	2 x PC3
Johnson & Johnson Research	PC3, PC2
Centenary Institute	PC2, PC2 animal house, PC3
Deakin University	2 x PC2
James Cook University	2 x PC1

Monitoring Findings

This section reports on the final outcomes of routine monitoring activities. Significant findings for field trial sites, where there are no outstanding issues that are the subject of a review, are shown in the tables below.

PR & Site No.	141, site 1
Summary of Dealing	The licence, now in its post-harvest monitoring phase, relates to field trials of insecticidal cotton *(Gossypium hirsutum)* conducted by Queensland Department of Primary Industries.
Findings	The site contained approximately 200 volunteer plants that had passed flowering stage and had bolls with obvious lint. The Queensland Department of Primary Industries indicated that due to rainfall, the site was inaccessible for the purposes of control of volunteer plants.
Risk assessment	Without remedial action, the seed that had fallen on the site and the mature plants with lint seed attached may have contributed to the persistence of the GMO in the environment. However, the risk to human health and the environment was assessed to be negligible with follow-up management action.
Risk management	The strategy implemented by the deemed licence holder was the: 1) immediate destruction of cotton plants on the site; 2) monitoring of the site until 13 March 2003 - a further 12 months; 3) encouragement of germination of any seed at the site to facilitate its destruction, within the 12 month period; and 4) requirement for a monitoring schedule and monthly reports of the monitoring activities to the OGTR.

PR & Site No.	73, site 2 / 136, site 2
Summary of Dealing	The licence, now in its post-harvest monitoring phase, relates to field trials of sugarcane (*Saccharum* interspecific hybrids) modified for increased sugar production or altered juice colour and is held by CSIRO.
Findings	CSIRO staff reported that the site that was sown to transgenic sugarcane in October 1999 was harvested in July 2001. Sugarcane had regrown across the site after harvest. CSIRO indicated that due to rainfall, the site had been inaccessible for the purposes of herbicide application. Volunteers had grown to approximately 1-1.5m height but were several months away from flowering.
Risk assessment	Due to the absence of flowering volunteers, the risk of dissemination and persistence of the transgenic sugarcane in the environment is negligible provided the numerous volunteers are destroyed as soon as possible.
Risk management	The volunteers were to be destroyed by 30 April 2002.

In addition, observations from a monitoring visit in the October to December 2001 quarter to PR97 and PR58X(2) were under assessment and are subsequently reported here.

PR & Site No.	97, site 1 and 58X(2), site 2
Summary of Dealing	The licence, now in its post-harvest monitoring phase, relates to field trials of subterranean clover (*Trifolium subterraneum*) modified for increased nutritional benefits for grazing sheep with insertion of an additional protein and is held by CSIRO.
Findings	The two trials were sown adjacent to each other, and at the time of inspection were observed to have an unrelated forage species (*Trigonella balansa*) sown on the area previously occupied by the trial planting. Deemed licence conditions state that the trial site will be "sown to a competitive grass species and monitored for the emergence of volunteer clover plants". CSIRO indicated that the treatment and use of the forage species is an alternative means to control volunteer plants. No clover volunteers were observed on the site.
Risk assessment	As there were no clover volunteers present on the site at the time of monitoring, there were no additional risks posed to the environment or human health.
Risk management	The content and intent of the licence conditions were discussed with the deemed licence holder to ensure appropriate post-trial plantings take place on the sites in future.

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. 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 certified facilities found a variety of apparent deviations from the current guidelines. None of the observations compromised the containment of GMOs or posed a risk to human health or the environment. These findings have been conveyed to the Guidelines review team.

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 reports, or an OGTR monitoring team identifies, 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 in practice and include the identification of the occurrence of 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. Completed Incident Reviews and ongoing Practice Reviews are reported below.

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

Issue	An accredited organisation, CSIRO, reported an incident where 6 bags of plant material from a Notifiable Low Risk Dealing, involving genetically modified barley, were not disposed of in accordance with the OGTR's *Guidelines for Certification of Facilities/Physical Containment Requirements*. The bags of plant material were inadvertently removed from a CSIRO facility to a landfill site and buried without the required sterilisation process (autoclaving) having been conducted.
Risk assessment	The OGTR assessment was that this incident posed negligible risks to public health and environmental safety due to the manner of disposal.
Determination	Negligible risk non-compliance: it was determined that the plant material had not been disposed of in accordance with the OGTR's *Guidelines for Certification of Facilities/Physical Containment Requirements*.
Risk management	CSIRO is implementing procedures to minimise the occurrence of similar incidents. The current *Guidelines for Certification of Facilities/Physical Containment Requirements* are under review by the OGTR, in particular, the waste disposal options currently provided.
Action	Not referred for investigation.

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

A review of compliance with deemed licence conditions for canola field trial sites initiated in the third quarter of 2001 was extended into the first quarter of 2002. The report on the review is nearing completion and will include an analysis of the regular reporting provided by licensees of GM canola trials and the Monitoring and Compliance Section's observations at field trial sites. The purpose of the review is to consider two aspects of interest:

- the potential environmental risks posed by GM canola 'volunteers' on sites subject to post-harvest monitoring during the review period; and
- whether there has been a possible non-compliance for referral for investigation.

Observations from monitoring visits that are being analysed in the review will be reported on in subsequent quarterly reports. A number of GM canola trial sites subject to post-harvest monitoring were observed to have canola volunteers or sexually compatible species that presented issues requiring further examination.

Practice Review: A field survey on the effectiveness of deemed licence conditions for containment of canola

A significant component of any regulatory system based upon risk analysis is the link from the practical aspects of the risk management strategy back to the theoretical components of the risk analysis to ensure there is a 'feedback loop'. This allows determination of whether the theoretical assessment of risks has taken account of all risks that are present when dealings with GMOs are performed.

In the first quarter of 2002, the Monitoring and Compliance Section performed surveys on a number of properties that contained sites that were leased from landholders for trials of GM canola. The aim of the surveys was to determine the effectiveness of deemed licence conditions to prevent dissemination and persistence of canola through seed movement. This was achieved by surveying in all areas canola may have been vectored to (eg. along watercourses, areas where machinery movement was evident, animal movement corridors, etc). Field work has been completed for this particular survey and results are currently being analysed for reporting in a subsequent quarterly report.

Practice Review: Post trial crops on canola sites

Deemed licence conditions for dealings involving genetically modified canola state that canola shall not be grown on the trial site, for three years following harvest of the GM crop and if the trial site is to be planted within this period, only the following crops may be grown:

(a) grass pastures;
(b) cereal crops; or
(c) crops agreed to by the Regulator.

OGTR reviewed past monitoring records to evaluate the feasibility and effectiveness of crop management programs in post trial crops other than those specified above. A significant part of the review focussed on the licensee's 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.

The final report is in preparation and the results will be provided in a subsequent quarterly report.

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

A study continued during this quarter to determine 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 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 in the vicinity of non-compliant sites. Most of the work for the project has been completed, with field observations subject to analysis and the final report is currently in preparation.

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, by self-reporting by an accredited organisation or by third party reporting.

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

- jeopardise current or future investigations;
- be protected by legislation (eg. 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; and
- unfairly damage the reputation of third parties who have not themselves breached legislative requirements.

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

Three investigations were completed in the quarter. Action resulting from the investigations included implementation of strategies to raise accredited organisations' understanding of the requirements under the Act.

Summaries of the completed investigations are shown in the tables below.

Type	A legislative system investigation
Name	An investigation into the management and monitoring practices employed by the Department of Agriculture (Western Australia)
Current Status	Closed – with follow-up action being undertaken
Allegation	OGTR monitoring of a number of cotton trials, conducted under both the voluntary and legislative systems, found several occurrences of non-compliances in the form of low numbers of volunteer cotton plants that had flowered and/or produced seed within a period of 12 months.
Summary of Investigation	OGTR monitoring and compliance staff investigated each occurrence through inspection visits and performed a risk analysis on the basis of monitoring findings.
Findings	Investigation into the management and monitoring practices employed by the Department of Agriculture Western Australia found that the organisation could make procedural changes to improve

	the control of volunteer plants in certain areas.
Risk Assessment and Management	A risk assessment of the non-compliances determined that the risk to human health and the environment was negligible. The Department of Agriculture, Western Australia, has increased its monitoring frequency and is reporting to the OGTR on a regular basis. Improvements have been made to management and monitoring practices by the organisation. Follow-up monitoring by the OGTR is continuing.

Type	A legislative system investigation
Name	An investigation into an allegation regarding a laboratory at James Cook University
Current Status	Closed – with follow-up action being undertaken
Allegation	An allegation was made that a PC1 laboratory at James Cook University was not disposing of GM material correctly in conducting exempt dealings.
Summary of Investigation	OGTR monitoring and compliance staff investigated the allegation through an inspection visit and performed a risk analysis on the basis of monitoring findings. The facility visited was a PC1 facility in which exempt dealings are conducted and under the Act it is required to comply with Australian Standard 2243.3:1995.
Findings	The facility was inspected against the AS2243.3:1995 criteria and it was found that the means of waste disposal did not meet the criteria, substantiating the allegation.
Risk Assessment and Management	The risk was found to be negligible, however, James Cook University was required to restore the laboratory to PC1 standard for the exempt dealings to continue. Recent follow-up monitoring by the OGTR has confirmed that the facility now meets requirements.

Type	A legislative system investigation
Name	An investigation of the waste disposal practices of the Australian National University, Canberra
Current Status	Closed – with follow-up action being undertaken
Allegation	An allegation was made that the ANU was not complying with OGTR requirements in relation to waste disposal practices.
Summary of Investigation	OGTR monitoring and compliance staff investigated the allegation as part of an inspection visit to several certified facilities at ANU and performed a risk analysis on the basis of monitoring findings.
Findings	ANU was found not to autoclave all microbiological waste as specified in the current *Guidelines for Certification of Facilities/Physical Containment Requirements*.
Risk Assessment and Management	The method of waste disposal employed by ANU posed a negligible risk to human health and the environment. Pending revision of the *Guidelines for Certification of Facilities/Physical Containment Requirements* ANU has been advised to follow the current Guidelines or consult the OGTR on appropriate alternative procedures. Follow up monitoring is continuing.

Audits

No audits were initiated or were ongoing in this quarter.

PART 3 - Committee Operations

The Act establishes three new 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; and
- The **Gene Technology Ethics Committee (GTEC)** – provides advice on ethical issues relating to gene technology to the Regulator and Ministerial Council.

On 21 February 2002, the Parliamentary Secretary to the Minister for Health and Ageing, the Hon Trish Worth MP, appointed Professor Stephen Powles to Chair the GTTAC and Professor Don Chalmers to Chair the GTEC with the support of a majority of State and Territory Governments. Ms Worth also appointed Sir Ninian Stephen on 25 March 2002 as a member of the GTCCC and to the position of acting Chair. Subject to formal confirmation by a majority of jurisdictions (as required by the Act), ratification of the appointment is expected to occur in the next quarter.

Gene Technology Technical Advisory Committee

During this quarter, GTTAC held one face-to-face meeting on 1 March 2002 in Canberra. At this meeting the Committee considered:

DIRs - 3 licence applications
- 3 risk assessment and risk management plans

DNIRs - 1 application
- 1 risk assessment and risk management plan.

During this quarter the Committee also considered 16 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).

Gene Technology Ethics Committee

In the previous quarter, GTEC held its inaugural meeting on 12-13 December 2001. At that time, the Committee agreed to form five working groups that will look at each of the five priority issues identified by GTEC. In this quarter, the working groups have been progressing their research for papers to be presented at the next meeting in May 2002.

Gene Technology Community Consultative Committee

Sir Ninian Stephen was appointed as the acting Chair of GTCCC and the date was set for the inaugural meeting (17 and 18 April 2002). The outcomes of this meeting will be reported in the next Quarterly report.

PART 4 - Other Activities

Reviews and Research

The following reviews, initiated last quarter, 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 monitoring activities found practical difficulties in implementing the current Guidelines and gathered specific information for input into the review. The revised Guidelines will be released as a draft for comment and feedback from experts and stakeholders.

International Collaboration and Coordination

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

During the January-March 2002 quarter, the OGTR provided briefings to representatives of a number of countries interested in learning about Australia's new regulatory system. Briefings included:

- Presentation organised by AVCARE to discuss issues relating to biotechnology and the OGTR; and
- Presentation to Singapore health officials on the regulation of genetically modified organisms in Australia.

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

- preparing papers relating to Australia's regulatory system for GMOs for the Biosafety Protocol Secretariat;
- answering OECD questionnaires on the regulation of GM stockfeed and GM identification/detection methods in Australia; and

- assisting the Department of Foreign Affairs and Trade to provide briefings to Australian industry on outcomes from the second meeting of the Inter-governmental Committee of the Cartegena Protocol relating to the proposed Biosafety Clearing House mechanism and GMO unique identifier.

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

Advice on Gene Technology Regulation

Presentations

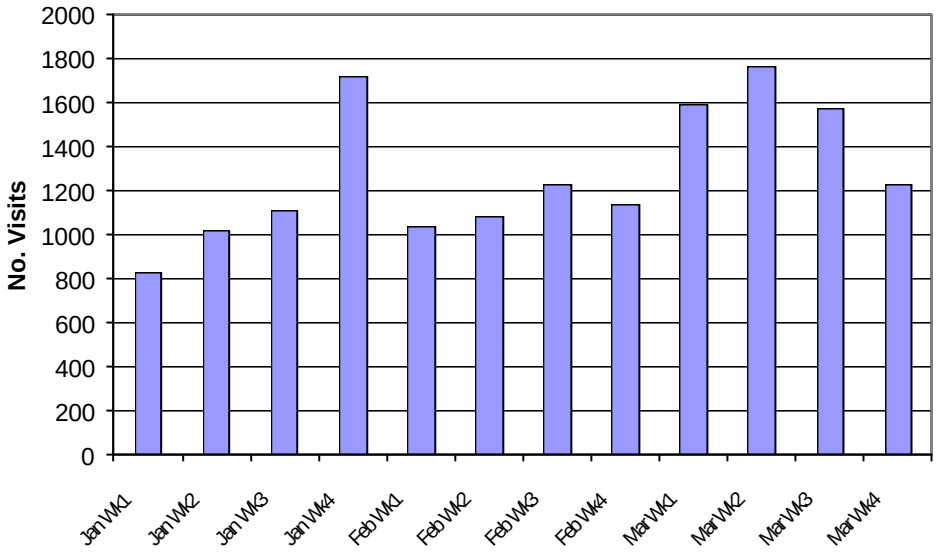
Staff of the OGTR endeavour to participate in discussions on gene technology wherever possible to inform the community about the regulatory system. During the reporting period the OGTR made the following presentations to or at the:

- Meeting with OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology;
- Presentation on Gene Technology Regulatory Scheme to City of Mitcham Council;
- Presentation to Combined Rural Traders (CRT) agronomists in Cowra on OGTR monitoring and compliance roles and on the application process for dealings involving intentional releases into the environment;
- Meeting on Grains Research Update for Advisers;
- RSPCA Annual General Meeting Dinner;
- ABARE Outlook 2002 Conference on the role of government in biotechnology;
- AVCC Deputy & Pro-Vice-Chancellors (Research) Committee meeting on the gene technology regulatory scheme; and
- Presentation to internal Environment Australia seminar on risk communication.

The OGTR completed a training session for the Charles Sturt University (Wagga Wagga campus) institutional biosafety committee and researchers on 20 February 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 322,640 'hits'[3] during the period 1 January to 31 March 2002, which represents an average of 3,584 hits per day. The table below 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:

- OGTR Publications;
- OGTR General information;
- GMO record; and
- Committees pages.

The most popular downloaded documents were:

- Media Release – Gene Technology Regulator issues first licence under new laws;
- Media Release – Gene Technology Regulator takes up new position; and
- Handbook on the Regulation of Gene Technology in Australia.

During the reporting period, a facility on OGTR electronic maps was added allowing hyperlinks from the trial site labels on each map to view the related licence conditions. The OGTR welcomes any feedback on ways to improve the provision of information on gene technology regulation.

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

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

Over the reporting period, a total of 382 e-mail messages were sent to the OGTR general e-mail account, 95 in January 2002, 128 in February 2002 and 159 in March 2002.

Of the e-mails received, approximately 85 per cent were requests for information; 10 per cent were provision of information from other organisations; and approximately 5 per cent provided feedback and comments.

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

In January 2002, there were 232 calls to the OGTR 1800 line; 187 calls in February 2002; and 137 calls in March 2002.

Freedom of Information (FOI)

No FOI requests were received during the reporting period.

Consultants

During the reporting period, the OGTR managed 8 consultancy contracts worth a total of $242,273. 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**
Dept of Natural Resources & Environment	$2,416	Site inspections of GMO Canola Sites
Dialog Information Technology	$111,351	Develop Gene Technology Information Management System (GTIMS)
Hassall & Assoc	$22,728	Review of OGTR's Certification Guidelines
Luminis P/L	$54,727	Gene Flow Study
Mathews Pegg Consulting	$27,557	Provide legal policy support for the development of recommendations for achieving nationally consistent legislation prohibiting human cloning and a nationally consistent approach to the regulation of assisted reproductive technologies and related matters
McNiece Communications	$20,000	Public affairs
Outlook Biotec	$494	Weed survey of GM crop trials
University of Melbourne	$3,000	Environment risk analysis
Total Consultants for quarter	$242,273	

Appendix A

GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE

COMMUNIQUE

This is the second communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the second and third meetings of GTTAC held on 17 December 2001 (teleconference) and 1 March 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 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 (DNIRs)

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

Murray Valley Encephalitus Virus (DNIR 001/2001)

The TVW Telethon Institute for Child Health Research has applied for a licence for work to develop a more effective vaccine against Murray Valley encephalitis virus and to test potential vaccines in mice.

GTTAC considered and endorsed the RARMP for this application out of session.

Gene Therapy for Hypertension (DNIR 002/2001)

The University of Queensland has applied for a licence to develop a new model for gene therapy by treating rats with hypertension (high blood pressure) with a gene which produces atrial natriuretic peptide.

GTTAC noted there was a remote possibility of replication competent retroviruses being produced.

GTTAC resolved to advise the Regulator:

- The measures proposed in this application will be adequate to contain the GMOs.

- To assess the risks posed to human health and safety as part of the RARMP the applicant should be requested to test for the presence of replication competent retroviruses.

Construction of Immortalised Macrophage Cell lines (DNIR 003/2001)

The Institute of Medical and Veterinary Science has applied for a licence to generate cell lines from macrophages isolated from patients who suffer from iron overload (haemochromatosis) to study the proteins involved in iron transport.

GTTAC noted that there was a remote possibility of replication competent retroviruses being produced.

GTTAC resolved to advise the Regulator:

- The measures proposed in this application will be adequate to contain the GMOs.

- To assess the risks posed to human health and safety as part of the RARMP the applicant should be requested to test for the presence of replication competent retroviruses.

Pilot Scale Fermentation and Processing of ESO-1 Antigen Expressed in Recombinant E coli (DNIR 004/2001)

Commonwealth Serum Laboratories Ltd has applied for a licence to produce quantities of the protein coded for by the gene ESO-1, isolated from a human oesophageal carcinoma cell line, to be used to test the properties of the protein.

GTTAC noted that the applicant had not provided information on the antibiotic resistance genes being used as marker genes.

GTTAC resolved to advise the Regulator:

- The measures proposed in this application will be adequate to contain the genetically modified organisms (GMOs).

- To assess the risks posed to human health and safety as part of the RARMP information should be sought on the antibiotic resistance genes being used as marker genes.

Testing Protection of Cattle from Fluoroacetate (DNIR 005/2001)

Murdoch University has applied for a licence for a dealing that involves inoculating cattle with rumen bacteria (*Butyrivibrio fibrisolvens*) which have been genetically modified to detoxify fluoroacetate (a compound poisonous to cattle which occurs in some native plants) and contain antibiotic resistance genes. The cattle will be monitored to see if the bacteria colonise the rumen in the cattle. The cattle will then be challenged with fluoroacetate.

GTTAC considered and endorsed the RARMP for this application out of session. GTTAC requested that some minor amendments be made to the RARMP.

Evaluation of Chimeric Influenza Virus, Incorporating the Fusion Glycoprotein of Respiratory Syncytial Virus (DNIR 006/2001)

The Royal Melbourne Institute of Technology (RMIT) has applied for a licence to generate a virus strain with potential as a live vaccine by replacing a gene from an influenza A virus strain with a gene from the respiratory syncitial virus.

GTTAC considered and endorsed the RARMP for this application out of session. GTTAC requested that some minor amendments be made to the RARMP.

Cloning and Inactivation of Phospholipase Gene from *Clostridium perfringens* to Produce a Non-toxic Vaccine Antigen (DNIR 007/2001)

RMIT is aiming to produce a vaccine against the chicken disease, necrotic enteritis, which is caused by the bacterium *Clostridium perfringens*.

GTTAC noted that ampicillin would not be effective treatment in the case of accidental ingestion of the pathogen.

GTTAC resolved to advise the Regulator that:

- The measures proposed in this application will be adequate to contain the GMOs.

- To assess the risks posed to human health and safety, the RARMP should include advice regarding the choice of an appropriate antibiotic treatment should accidental ingestion of the bacterium occur.

The Role of Osteoclast Inhibitory Lectin in Breast Cancer Metastases to Bone (DNIR 008/2001)

St Vincent's Hospital Melbourne has applied for a licence to study the role of osteoclast inhibitory lectin in breast cancer metastasis to bone. This research is to see if, in mice, an inhibitor of osteoclast formation can slow the spread of human breast cancer cells to bone.

GTTAC considered and endorsed the RARMP for this application out of session. GTTAC requested that some minor amendments be made to the RARMP.

Production of humanised monoclonal antibodies from NSO cells (DNIR 009/2001)

Biotech Australia Pty Ltd has applied for a licence to produce antibodies to be used in clinical trials.

This dealing is a DNIR and not an exempt dealing only because it involves greater than 10 litres of GMO culture.

GTTAC considered and endorsed the RARMP for this application out of session.

2. Dealings Involving the Intentional Release of Genetically Modified Organisms

2.1 Advice on Applications (in numerical order of receipt)

Agronomic Assessment and Seed Increase in Northern Australia of Transgenic Cotton Expressing *Cry1 Ac* or *Cry 1 Ac* and *Cry 2 Ab* Gene from *Bacillus thuringiensis* (DIR 006/2001)

CSIRO has applied for a licence for the limited and controlled release of genetically modified insect resistant types of cotton registered under the trade names INGARD® cotton, Bollgard II® cotton and Bollgard II ®/Roundup Ready® cotton.

INGARD® and Bollgard II® cotton are resistant to the major caterpillar pests that attack cotton. They contain one or two insecticidal genes, respectively, that produce proteins that are toxic to specific insects. Bollgard II®/Roundup Ready® cotton was produced by conventional breeding of Bollgard II® cotton with genetically modified Roundup Ready® cotton which contains a gene for tolerance to the herbicide glyphosate (Roundup®). Bollgard-II®/Roundup Ready® cotton therefore contains the two insecticidal genes from Bollgard II® as well as the glyphosate tolerance gene from Roundup Ready®cotton.

CSIRO is proposing to carry out a limited and controlled release on a total of ten sites in northern Western Australia and the Northern Territory (above latitude 22° South), over a total area of 210 hectares. The purpose of these trials is to continue large-scale evaluation of the agronomic performance of a number of different genetically modified cotton varieties and to produce seed for possible future releases, which would be subject to a separate application and assessment process.

GTTAC resolved to advise the Regulator:

- That the following potential hazards should be addressed in the risk assessment and risk management plan:

    (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.
    (c) The potential for the new genes introduced into the cotton to cross into other organisms with adverse consequences.
    (d) The potential for resistance to the insecticidal proteins produced by the genes to develop in target insects in the long term.

Improved Alkaloid Production in Oilseed Poppy (*Papaver somniferum*) (DIR 007/2001)

Agriculture Western Australia has applied for a licence for the limited release of an oilseed poppy which has been genetically modified by the introduction of a modified gene involved in the alkaloid production pathway, and a gene conferring resistance to the antibiotic hygromycin.

The purpose of the release is identify whether the alkaloid production of oilseed poppy is altered by the introduction of the genetic modifications. The proposed trial will be carried out on one site in Western Australia covering a total area of 0.2 hectares.

GTTAC noted that without containment poppy may be capable of establishing itself in the region selected for the trial as the seed is capable of long periods of dormancy. GTTAC also questioned the need for a field trial to test for improved alkaloid production when contained cultivation in a glass house may be able to achieve the same result.

GTTAC resolved to advise the Regulator:

- The following risks or potential risks should be assessed in relation to the application

    - toxicity or allergenicity of the genetically modified poppy and its products
    - weediness or increased potential for weediness
    - potential for the introduced genes to cross into other organisms.

- The RARMP should also include measures to prevent the spread or persistence of the GMO or its genetic material in the environment.

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

    - the purpose or justification for the release
    - information concerning the effect of the genetic modification on the production of other alkaloids, and the distribution of alkaloids within the plant
    - data from previous trials on the emergence and management of volunteers, and the longevity of poppy seed in and around release sites.

Integrated Pest Management Systems for INGARD® Cotton in the Kimberley, WA (DIR 008/2001)

Agriculture Western Australia 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® cotton.

The proposed trial will be carried out on 30 sites in northern Western Australia (above latitude 22° South) over a total area of 500 hectares. The purpose of the trial is to conduct experiments/research on integrated pest management strategies for INGARD® cotton; evaluate the agronomic performance of new varieties of INGARD® cotton; assess the effects of releasing INGARD® cotton on key pests and beneficial insects and to assess the potential development of pests resistant to the insecticidal activity of the cotton.

GTTAC resolved to advise the Regulator:

- That the following potential hazards should be addressed in the risk assessment and risk management plan.

    (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.
    (c) The potential for the new genes introduced into the cotton to cross into other organisms with adverse consequences.
    (d) The potential for resistance to the insecticidal proteins produced by the genes to develop in target insects in the long term.

Preliminary Field Evaluation of Bollgard II® Cotton in the Kimberley Region of WA (DIR 009/2001)

Agriculture Western Australia 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.

The proposed trial will be carried out over a total of 80 hectares. The purpose of the trial is to conduct experiments/research on integrated pest management strategies for Bollgard II® cotton; evaluate the agronomic performance of new varieties of Bollgard II® cotton; assess the effects of releasing Bollgard II® cotton on key pests and beneficial insects and to assess the potential development of pests resistant to the insecticidal activity of the cotton.

GTTAC resolved to advise the Regulator:

- That the following potential hazards should be addressed in the risk assessment and risk management plan.

    (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.
    (c) The potential for the new genes introduced into the cotton to cross into other organisms with adverse consequences.
    (d) The potential for resistance to the insecticidal proteins produced by the genes to develop in target insects in the long term.

Small and Large Scale Trialing of InVigor canola for the Australian cropping system (DIR 010/2001)

Aventis CropScience Pty Ltd has applied for a licence for the intentional release of genetically modified canola into the environment. The male sterility line of the modified canola contains the *barnase* gene conferring male sterility and the fertility restorer line contains the *barstar* gene, which inhibits the enzyme produced in the male sterile line. Crossing of the male sterile line with the fertility restorer line results in hybrids which are fertile. Both the male sterile and fertility restorer lines of the modified canola contain the *bar* gene involved in conferring tolerance to the herbicide glufosinate ammonium.

The purpose of the release is to evaluate the agronomic performance of the modified canola and to produce seed for future releases both here (subject to further licence applications) in Australian conditions and overseas. The proposed release would be carried out over three years covering a total of 318 hectares of GM canola on 90 different sites, comprising 106 hectares at 30 sites in each year.

GTTAC noted that glufosinate ammonium herbicide is not widely used in weed control in Australia and therefore the impact of the release on current agricultural and weed control practices would be limited. One exception is the use of glufosinate ammonium in the control of weeds in vineyards, and this might represent one instance where there was potential for an impact on current agricultural practices.

GTTAC resolved to advise the Regulator:

- The following risks or potential risks should be assessed in relation to the application:
    - toxicity or allergenicity of the genetically modified canola;
    - weediness or increased potential for weediness; and
    - potential for the introduced genes to cross into other organisms.
- The following measures should be addressed in the RARMP to prevent the spread of the GMO or its genetic material in the environment:
    - the trials not be conducted within 5 kilometres of vineyards and other horticultural pursuits where the introduction of glufosinate ammonium tolerant plants had the potential to interfere with current agricultural practices.

- In addition, the following information should be requested from the applicant. It was noted that the licence could be issued for a period of one year with the second and third years contingent upon receipt of the information:

    - information on the potential impact of glufosinate resistance on the viticulture and horticultural industries
    - information on seed longevity, including data from overseas studies
    - identification of measures to manage a persistent seedbank
    - confirmation that the resources available to the company are sufficient to adequately manage the large size and number of trial sites involved
    - the provision of information on measures for detecting and managing volunteers
    - the provision of data on gene flow and on the persistence and population dynamics of GM canola within and around release sites.

Field trials of Roundup Ready® canola (*Brassica napus*) in Australia in 2002 (DIR 011/2001)

Monsanto Australia Ltd has applied for a licence for the intentional release of genetically modified canola into the environment. Roundup Ready® canola is tolerant to glyphosate, the active constituent of the proprietary herbicide Roundup®. Roundup Ready® canola has been genetically modified by the introduction of two genes, the CP4 EPSPS and *gox* genes that confer tolerance to the herbicide glyphosate.

The purpose of the release is to continue development and evaluation of potential commercial lines of genetically modified Roundup Ready® canola, including seed production in preparation for possible commercial release (subject to future licence application). The proposed release would be carried out on a total area of 34 hectares over 26 sites in winter 2002.

GTTAC noted that glyphosate is widely used in weed control in Australia and that the introduction of glyphosate tolerant plants into the environment has the potential to impact on weed control practices.

GTTAC resolved to advise the Regulator:

- The following risks or potential risks should be assessed in relation to the application

    - toxicity or allergenicity of the genetically modified canola
    - weediness or increased potential for weediness
    - potential for the introduced genes to cross into other organisms.

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

    - information on seed longevity, including data from overseas studies
    - identification of measures to manage a persistent seedbank

- data on gene flow and on the persistence and population dynamics of GM canola within and around release sites
- the measures that would be taken to exclude large animals from the release site.

2.2 Advice on Risk Assessment and Risk Management Plans (in numerical order of receipt)

Agronomic Assessment and Seed Increase in Eastern Australia of Transgenic Cotton Expressing *Cry1Ac* and *Cry 2Ab* Genes from *Bacillus thuringiensis* (DIR 005/2001)

Cotton Seed Distributors have applied for a licence for large-scale field trial of genetically modified insect resistant cotton (Bollgard II®) and insect resistant/herbicide tolerant cotton (Bollgard II®/Roundup Ready®). The cotton is derived from INGARD® (Bt) cotton.

INGARD® cotton contains the *Cry1Ac* insect resistance gene and two antibiotic resistance genes. An extra insect resistance gene (*cry2Ab*) and a marker gene (*GUS*) were inserted into INGARD® cotton to produce Bollgard II®. The Bollgard II® modification has been backcrossed into a number of commercial cotton varieties developed for Australian farming systems and these are the varieties proposed for the trial.

The purpose of the trial is for seed increase and for large-scale evaluation of agronomic performance, in preparation for a licence application for commercial release of Bollgard II® cotton in 2003. The proposed trials will be carried out over a total of 480 hectares at six sites in the Shires of Balonne and Emerald in Queensland (below latitude 22° South).

GTTAC resolved to advise the Regulator:

- GTTAC agrees with the conclusions of the risk assessment management plan.

- The following additional measures should be taken to manage the risks associated with the release:

    - monitoring of the plants to determine if gene expression is stable over a period of time
    - the applicant be requested to conduct a study to provide information on the effectiveness of the 50 metre isolation zone.

Agronomic Assessment and Seed Increase in Northern Australia of Transgenic cotton Expressing *Cry1Ac or Cry 1Ac* and *cry2Ab* Genes from *Bacillus thuringiensis* (DIR 006/2001)

The details of this application are provided in Section 2.1.

GTTAC resolved to advise the Regulator:

- GTTAC agrees with the conclusions of the risk assessment management plan.

Integrated Pest Management Systems for INGARD® Cotton in the Kimberley, WA (DIR 008/2001)

The details of this application are provided in Section 2.1.

GTTAC resolved to advise the Regulator:

- GTTAC agrees with the conclusions of the risk assessment management plan.

Preliminary Field Evaluation of Bollgard II® Cotton in the Kimberley Region of WA (DIR 009/2001)

The details of this application are provided in Section 2.1.

GTTAC resolved to advise the Regulator:

- GTTAC agrees with the conclusions of the risk assessment management plan.

3. Other Matters

Introduction of Antibiotic Resistance into *S. pyogenes*

GTTAC was requested to provide advice on the risk and appropriate category for dealings with GMOs in which an antibiotic resistance gene is inserted into a human pathogen.

GTTAC resolved to advise the Regulator:

- The introduction of kanamycin or spectomycin resistance genes into *S. pyogenes* as part of NLRD 037/2001 does not increase its virulence.

- The introduction of antibiotic resistance genes into potential pathogens does not increase their virulence.

- The appropriate category for the dealing was Schedule 3, Part 1.1(d), of the Gene Technology Regulations 2001. Consideration should be given to amending that regulation to give effect the principle that if a proposed dealing impairs in any way the treatment of a disease it should not be classified as an NLRD.

Enquiries and Risk Assessment and Risk Management Plans

For all enquiries and to obtain copies of applications and 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 documents are also available electronically from our website at http://www.ogtr.gov.au/publications/riskassessments.htm

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