Quarterly report of
the Gene Technology Regulator
for the period
1 July to 30 September 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* (the Act), I am pleased to present to you the Fifth Quarterly Report of the Gene Technology Regulator, covering the period 1 July to 30 September 2002.

This quarter saw the continuation of the high level of regulatory activity undertaken last quarter.

The key achievements for the quarter covered in the report include the issuing of 4 licences for dealings involving the intentional release of genetically modified organisms (DIRs). These licences covered limited and controlled releases of a poppy, a cotton and two canolas. In addition, there were 45 licences for dealings not involving the intentional release of genetically modified organisms (DNIRs), 2 accreditations of organisations and 258 certifications of facilities.

Yours sincerely

(Dr) Sue D Meek
Gene Technology Regulator

29 November 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
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DIR	A dealing with a GMO involving the intentional release of a GMO into the environment e.g. field trial or commercial release
DNIR	A contained dealing with a GMO not involving the intentional release of a GMO into the environment e.g. experiments in a laboratory
Expert advisers	Advisers appointed by the Minister to give advice to either GTTAC or GTEC to assist the committees in the performance of their functions. Expert advisers are not committee members
GM	Genetically modified
GM product	A thing (other than a GMO) derived or produced from a GMO
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically modified organism
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
GTTAC	Gene Technology Technical Advisory Committee

HREOC	Human Rights and Equal Opportunity Commission
IBC	Institutional Biosafety Committee
NLRD	Notifiable low risk dealing e.g. plant or tissue culture work undertaken in contained facilities
Non-compliance	A failure to comply with legislative requirements including licence, accreditation or certification conditions
OGTR	Office of the Gene Technology Regulator
PC1, PC2, PC3, PC4	Physical containment levels of facilities as certified by the Regulator in accordance with the Regulator's *Guidelines for Certification of Facilities/Physical Containment Requirements*
PR	Planned release of a GMO into the environment
RARMP	Risk assessment and risk management plan
Regulator	Gene Technology Regulator
Spot checks	Unannounced visits by the OGTR Monitoring and Compliance Section
Volunteer	Regrowth of plants from seed that has remained on a site after a trial has been completed.

Introduction

The *Gene Technology Act 2000* (the Act) requires the Gene Technology Regulator (the Regulator) to prepare and give to the Minister after each quarter a report on the operations of the Regulator during that quarter. Section 136A(2) of the Act requires that the report include information on 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
- 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 July–September 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 (3) 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 July–September 2002 quarter were:

1 Licences and other instruments

In this quarter the Regulator:

- issued four (4) licences for dealings involving the intentional release of genetically modified organisms (DIRs)
- issued forty-five (45) licences for dealings not involving the intentional release of genetically modified organisms (DNIRs)
- accredited two (2) organisations
- certified two hundred and fifty-eight (258) facilities.

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

2 International collaboration and coordination

The Regulator embarked on an overseas trip that included visits to the United States, Canada, Great Britain and the European Union en route to an international symposium on the biosafety of GMOs in Beijing, China. These visits were undertaken as part of the Regulator's statutory functions.

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

3 Monitoring and compliance

Analysis of the results of the Tasmanian gene flow studies was finalised during the quarter. The Regulator determined from the results that the risks to human health and safety and the environment from gene flow and outcrossing to nearby brassicaceous plants were negligible at the twenty-one (21) non-compliant trial sites in Tasmania.

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

4 State and Territory gene technology legislation

The Gene Technology Regulations 2002 (Queensland) commenced operation on 24 July 2002 following the commencement of the *Gene Technology Act 2001* (Queensland) on 1 January 2002.

Working collaboratively with States and Territories

Gene Technology Ministerial Council

The Gene Technology Ministerial Council did not meet this quarter.

Gene Technology Standing Committee

The Gene Technology Standing Committee supports the work of the Gene Technology Ministerial Council. The Standing Committee consists of senior government officials from all jurisdictions, with responsibility for gene technology issues.

The Standing Committee met once in this quarter by teleconference on 27 August 2002 to consider progress on the development of the draft Gene Technology (Recognition of Designated Areas) Policy Principle.

Cost recovery

When the OGTR's legislation was enacted, the Commonwealth Government decided that the operations of the organisation should be 100 per cent cost recovered. However, the Government decided to fund the cost of the first two (2) years of operations of the OGTR from 21 June 2001. This period allowed time for the establishment of the office and consultation on the implementation of cost recovery arrangements with universities, other scientific and medical research institutions, and industries undertaking gene technology research, in conjunction with environmental, consumer and other interested stakeholders. Cost recovery is due to take effect on 1 July 2003.

In July 2002, the OGTR commissioned an independent consultant, Acumen Alliance, to consult on various options to cost recover the operation of the national gene technology regulatory scheme. A national consultation process involving both face-to-face consultation with key stakeholders and extensively advertised requests for written submissions on the options was undertaken in

July 2002, with the closing date for submissions being 26 July 2002. The results of the consultations will be considered by Government.

Commonwealth agency liaison

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

Under the *Gene Technology Act 2002,* the Regulator must seek advice from prescribed Commonwealth authorities and agencies 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 with the following prescribed Commonwealth authorities and agencies, including regulators responsible for product approval, including GM products:

- Food Standards Australia New Zealand (formerly Australia New Zealand Food Authority)
- the Australian Quarantine and Inspection Service
- the National Health and Medical Research Council
- the National Industrial Chemicals Notification and Assessment Scheme
- the National Registration Authority for Agricultural and Veterinary Chemicals
- the Therapeutic Goods Administration.

Once the RARMPs are prepared, the Regulator must again seek comment on the RARMPs from the same expert groups and key stakeholders and the public.

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

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

1 Consultation is also required 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 seven (7) applications for DIRs. Further information is set out in Part 2.

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 the RARMPs prepared for four (4) 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 rural press, such as *The Land* and *The Weekly Times*
- OGTR website: www.ogtr.gov.au.

Further information is set out in Part 2.

PART 2 The regulation of genetically modified organisms

Part 2 of the report outlines the regulatory activity undertaken during the July-September 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. Information on the auditing and monitoring of dealings with GMOs and information on confidential commercial information (CCI) applications has also been included.

Applications received and decisions made

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

- 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

  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 1 July – 30 September 2002

Application type	Number received	Number approved[1]
Licence for a DIR	8	4
Licence for a DNIR	34	45
Accreditations	28	2
Certifications	244	258

1 Approvals reported in the current quarter mainly 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 the environment
- seeking comments from expert groups and key stakeholders, including the public if a significant risk is identified, on issues to consider in a RARMP
- preparing a RARMP including proposed licence conditions
- consulting with expert groups and key stakeholders, including the public, on the RARMP
- 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 application 'clock' was stopped while additional information was sought from the applicant.

The Regulator is required to undertake two (2) mandatory consultation periods of at least thirty (30) days for the processing of each DIR application. Therefore a DIR application cannot normally be received and decided upon within the same three (3) month reporting period.

The following table sets out the stages of processing of DIR applications undertaken in July–September 2002 quarter.

Table of DIR applications received, considered or decided, 1 July – 30 September 2002

Application received/initial screening	Applications withdrawn	First round of consultation[1]	Second round of consultation[2]	Licence decision
DIR021/2002[3]	DIR013/2002	DIR019/2002	DIR015/2002	DIR007/2001
DIR022/2002	DIR014/2002	DIR020/2002	DIR016/2002	DIR010/2001
DIR023/2002		DIR021/2002[3]	DIR017/2002	DIR011/2001
DIR024/2002			DIR018/2002	DIR012/2002
DIR025/2002				
DIR026/2002				
DIR027/2002				
DIR029/2002				

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 rural press, such as *The Land* and *The Weekly Times*; and OGTR website: www.ogtr.gov.au.

3 Received and progressed to the first round of consultation during the quarter.

New DIR licence applications

The OGTR received eight (8) DIR licence applications in the July–September 2002 quarter as follows:

- DIR021/2002 'Commercial release of InVigor® canola (*Brassica napus*) for use in the Australian cropping system' (Bayer CropScience)
- DIR022/2002 'Commercial release of insecticidal (INGARD®) cotton' (Monsanto)
- DIR023/2002 'Commercial release of herbicide-tolerant (Roundup Ready®) and herbicide tolerant/insect resistant (Roundup Ready®/INGARD®) cotton' (Monsanto)
- DIR024/2002 'Agronomic assessment and seed increase in northern Australia of transgenic cotton expressing *Cry1Ac* or *Cry1Ac* and *Cry2Ab*' (Commonwealth Scientific and Industrial Research Organisation (CSIRO))
- DIR025/2002 'Seed increase and efficacy studies in Northern Australia of transgenic cotton expressing a new insecticidal protein gene' (CSIRO)
- DIR026/2002 'Genetic improvement of papaya to enhance post-harvest quality of the fruit and resistance to viral pathogens' (The University of Queensland)
- DIR027/2002 'Field test of pineapple plants modified to control flowering and ripening' (The University of Queensland)
- DIR029/2002 'Defining sustainable production systems for transgenic cotton in the Kimberley, Western Australia' (Department of Agriculture (WA)).

All DIR applications received in the July–September 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.

Withdrawn DIR applications

In this quarter the following applications were withdrawn:

- DIR013/2002 'Agronomic assessment and seed increase of INGARD® and Bollgard II® cotton' (Monsanto); and
- DIR014/2002 'Agronomic assessment and seed increase of transgenic cotton expressing *Cry1Ac* and *Cry2Ab* genes from *Bacillus thuringiensis*' (CSIRO).

Approval to undertake these dealings is covered by DIR012/2002 'Commercial release of Bollgard II® cotton' (Monsanto).

In-progress DIR applications

First-round consultations

In this quarter, the Regulator commenced first-round consultations on the applications with expert groups and key stakeholders for the following DIR applications:

- DIR019/2002 'Agronomic assessment of transgenic sugarcane engineered with reporter genes' (Bureau of Sugar Experiment Stations)
- DIR020/2002 'General release of Roundup Ready® canola (*Brassica napus*) in Australia' (Monsanto)
- DIR021/2002 'Commercial release of InVigor® canola (*Brassica napus*) for use in the Australian cropping system' (Bayer CropScience).

Second-round consultations

In this quarter, the Regulator commenced second-round consultations with expert groups, key stakeholders and the public on the RARMPs for the following DIR applications:

- DIR015/2002 'Agronomic assessments and seed increase of transgenic cotton expressing tolerance to the herbicide glufosinate-ammonium' (CSIRO)
- DIR016/2002 '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)
- DIR018/2002 'Field assessment of alkaloids in modified poppy' (CSIRO).

Finalised DIR applications

In this quarter, the Regulator issued four (4) DIR licences:

- DIR007/2001 'Improved alkaloid production in *Papaver somniferum'* (Department of Agriculture (WA)). The licence authorises a limited and controlled release of GM oilseed poppy at 1 site of 0.2 hectares in the shire of Wyndham/East Kimberley (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). The licence

authorises a limited and controlled release of GM canola in New South Wales, Victoria and Western Australia. The release is for a maximum of 318 hectares at 90 sites over 3 years, comprising 106 hectares at 30 sites in each year including 61 hectares at 13 sites in each winter season and 45 hectares at 17 sites in each summer season. The maximum area for any individual site will be 9 hectares. In the 2002 winter season, Bayer planted a total of 38.5 hectares over 10 sites in South Australia (Grant, Naracoorte–Lucindale and Wattle Range shires), Victoria (Horsham and Southern Grampians shires) and New South Wales (Wagga Wagga shire).

- DIR011/2001 'Field trials of Roundup Ready® canola (*Brassica napus*) in Australia in 2002' (Monsanto Australia Ltd). The licence authorises a limited and controlled release of GM canola in the shires of Ararat and Surf Coast in Victoria and Naracoorte–Lucindale in South Australia. The release is for a maximum of 4 hectares at 4 sites in winter 2002. (Monsanto originally sought approval for a release of 34 hectares over 26 sites in New South Wales, Victoria, South Australia and Western Australia, but reduced the scope of their licence application.) Monsanto advised that because of the lateness of planting, only 1 site of 1 hectare in the shire of Naracoorte–Lucindale (South Australia) was planted under this licence.
- DIR012/2002 'Commercial release of Bollgard II® cotton' (Monsanto). Under the Act, the Regulator is able to impose conditions upon general or commercial releases. The licence authorises the commercial release of Bollgard II® cotton and Bollgard II/Roundup Ready® cotton in the cotton growing regions of New South Wales and Queensland south of 22 degrees South. Monsanto originally sought approval for commercial release of GM cotton in potentially all cotton growing areas of Australia (New South Wales, Queensland, the Northern Territory and north-western Western Australia). The Regulator decided that further field trials are required to collect more data on the behaviour of GM cotton in northern 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. 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 1 July – 30 September 2002

Application number	Application date	Organisation and State	Project title	Project description	Licence issued
DNIR 025/2002	25 Feb 2002	Royal Perth Hospital, Western Australia	Meningococcal virulence genes	The aim is to characterise the function and expression levels of virulence genes of the human bacterial pathogen *Neisseria meningitidis.*	5 Jul 2002
DNIR 026/2002	26 Feb 2002	Ludwig Institute for Cancer Research, Victoria	The mechanisms of establishing and maintaining immunological memory	The aim is to investigate the development and maintenance of cytotoxic T lymphocyte (CTL) immunological memory against influenza virus proteins.	9 Jul 2002
DNIR 028/2002	28 Feb 2002	University of Southern Queensland	Whooping cough vaccine V	The aim is to study *Bordetella pertussis* genes that are important in developing immune responses and protection from infection in mice.	5 Jul 2002
DNIR 029/2002	8 Mar 2002	The Australian National University, Australian Capital Territory	A drug screen for anti-viral compounds	The aim is to screen compounds for their ability to inhibit the *human immunodeficiency virus (type 1)* budding process.	19 Jul 2002
DNIR 030/2002 (same as DNIR 029/2002)	8 Mar 2002	Biotron Ltd, Australian Capital Territory	A drug screen for anti-viral compounds	The aim is to screen compounds for their ability to inhibit the *human immunodeficiency virus (type 1)* budding process.	19 Jul 2002
DNIR 032/2002	16 Apr 2002	CSIRO – Sustainable Ecosystems, Australian Capital Territory	*In vivo* analysis of modified *myxoma virus* for immuno-contraception and vaccine development.	The purpose of the proposed dealings is to produce recombinant myxoma viruses that could be used in the development of immuno-contraceptives and/or vaccines.	23 Jul 2002

Continued

Application number	Application date	Organisation and State	Project title	Project description	Licence issued
DNIR 033/2002	17 Apr 2002	Western Sydney Area Health Service, New South Wales	Mechanisms by which CD44 variant exon 6 promotes disease progression in acute leukemia	The aim of the proposed dealings is to investigate the effect of the protein CD44v6 on the proliferation and survival of leukemic cells in culture and in mice.	12 Jul 2002
DNIR 034/2002	24 Apr 2002	Australian National University, Australian Capital Territory	Modification of myxoma virus for immunocontraception and vaccine development	The purpose of the proposed dealings is to produce recombinant myxoma viruses that could be used in the development of immuno-contraceptives and/or vaccines.	23 Jul 2002
DNIR 035/2002	26 Apr 2002	Macfarlane Burnet Centre for Medical Research and Public Health, Victoria	A replicon-based vaccine for *hepatitis C virus*	The purpose of the proposed dealings is to develop a vaccine for *hepatitis C virus* using a novel RNA-based replicon system.	23 Aug 2002
DNIR 036/2002	26 Apr 2002	Macfarlane Burnet Centre for Medical Research and Public Health, Victoria	A cell culture system for *hepatitis C virus*	The aim of the proposed dealings is to develop a mammalian cell culture system to study *hepatitis C virus* using recombinant baculoviruses.	23 Aug 2002
DNIR 037/2002	26 Apr 2002	Macfarlane Burnet Centre for Medical Research and Public Health, Victoria	Replication of GB virus and related chimeras	The aim of this study is to develop a mammalian cell culture system to study *hepatitis C virus* (HCV) using chimerics of HCV and GB viruses.	23 Aug 2002
DNIR 038/2002 039/2002 040/2002	26 Apr 2002	Macfarlane Burnet Centre for Medical Research and Public Health, Victoria	Molecular interactions between retroviruses and host gene products	The aim of the proposed dealings is to test the impact of the expression of cellular proteins on HIV-1 and MLV replication in mammalian cell culture.	02 Sep 2002

Continued

Application number	Application date	Organisation and State	Project title	Project description	Licence issued
DNIR 041/2002	30 Apr 2002	Peter MacCallum Cancer Institute, Victoria	Characterisation of the signalling and cell biology of CD46 and the Dlg family	The aim of the proposed dealing is to study the effects on immune cell function of the protein CD46 and its Dlg family in human and mouse cells.	02 Sep 2002
DNIR 043/2002	02 May 2002	CSIRO – Sustainable Ecosystems, Australian Capital Territory	*In vivo* testing of immunocontraceptive effects and species specificity of a recombinant murine cytomegalovirus (MCMV) expressing mouse ZP3	The aim of this dealing is to test the efficacy and specificity of a recombinant murine cytomegalovirus (MCMV) containing a mouse reproductive protein as an immuno-contraceptive in house mice and a number of native and exotic rodent species.	7 Aug 2002
DNIR 045/2002	13 May 2002	BresaGen, South Australia	Production of recombinant pST and amino acid analogues of that hormone	The proposed dealings are to produce the protein pig somatotropin.	17 Sep 2002
DNIR 046/2002	13 May 2002	BresaGen, South Australia	Production of recombinant met-human growth hormone	The proposed dealings are to produce the therapeutic protein human growth hormone.	17 Sep 2002
DNIR 047/2002	13 May 2002	BresaGen, South Australia	Production of recombinant human granulocyte macrophage colony stimulating factor (GM-CSF) and amino acid analogues of this hormone	The proposed dealings are to produce the therapeutic protein human granulocyte macrophage colony stimulating factor (GM-CSF) or analogue.	17 Sep 2002
DNIR 048/2002	13 May 2002	BresaGen, South Australia	Production of recombinant human interleukin 5 (IL-5) and amino acid analogues of this cytokine	The proposed dealings are to produce the protein human interleukin 5 (IL-5).	17 Sep 2002

Continued

Application number	Application date	Organisation and State	Project title	Project description	Licence issued
DNIR 049/2002	22 May 2002	Western Sydney Area Health Service, New South Wales	A preclinical model of pancreatic islet xenotransplantation as treatment for Type 1 diabetes	This dealing aims to produce pig and mouse pancreatic islet cells that can avoid the human immune system.	26 Sep 2002
DNIR 050/2002	22 May 2002	Western Sydney Area Health Service, New South Wales	HIV immunopatho-genesis and immune cell function	The aim of the proposed dealings is to study one possible mechanism whereby HIV depletes the immune cells in people.	26 Sep 2002
DNIR 051/2002	22 May 2002	Western Sydney Area Health Service, New South Wales	Growth of tissue culture cells genetically modified to express cytokine receptor subunit	The aim is to study the function of lymphocytes (white blood cells) and the effect of cytokine receptors on the development or treatment of severe combined immunodeficiency.	26 Sep 2002
DNIR 052/2002	22 May 2002	Western Sydney Area Health Service, New South Wales	Molecular pathogenesis of *Bartonella henselae*	The aim of the proposed dealings is to study *Bartonella henselae*, a bacterium which causes cat scratch disease.	26 Sep 2002
DNIR 054/2002	22 May 2002	Queensland Health Scientific Services	Cell complemented viruses as non-infectious diagnostic reagents and candidate vaccines, *Australian bat lyssavirus*	The dealings propose to produce diagnostic reagents and potential vaccines for the viral disease *Australian bat lyssavirus.*	20 Sep 2002
DNIR 055/2002	22 May 2002	Queensland Health Scientific Services	Cell complemented hendra virus as a non-infectious diagnostic reagent and as a model for studying genetic and phenotypic changes affecting pathogen-icity and host range	The dealings propose to produce diagnostic reagents and potential vaccines for the disease caused by *Hendra virus*.	20 Sep 2002

Continued

Application number	Application date	Organisation and State	Project title	Project description	Licence issued
DNIR 056/2002	22 May 2002	Queensland Health Scientific Services	Cell complemented viruses as non-infectious diagnostic reagents and candidate vaccines, Ross River virus	The dealings propose to produce diagnostic reagents and potential vaccines for the disease caused by Ross River virus.	20 Sep 2002
DNIR 057/2002	28 May 2002	Walter and Eliza Hall Institute of Medical Research, Victoria	Transfection of *Plasmodium falciparum*	These dealings aim to study the parasite that causes malaria, *Plasmodium falciparum*.	09 Sep 2002
DNIR 058/2002	28 May 2002	Walter and Eliza Hall Institute of Medical Research, Victoria	Expression of genes in *Leishmania*	The aim of the proposed dealing is to study the parasite *Leishmania* and immune responses to the parasite in mice.	13 Sep 2002
DNIR 063/2002	28 May 2002	Walter and Eliza Hall Institute of Medical Research, Victoria	Retroviral mediated gene transfer into murine haematopoietic cells	The researchers propose to transfer and study genes thought to be involved in cell growth, proliferation, apoptosis (programmed cell death) and differentiation in cell cultures.	26 Sep 2002
DNIR 064/2002	31 May 2002	Peter MacCallum Cancer Institute, Victoria	Negative regulation of haematopoiesis by P-selectin	The aim is to determine a signal transduction pathway and see how this results in suppression of blood cell production.	26 Sep 2002
DNIR 065/2002	31 May 2002	Peter MacCallum Cancer Institute, Victoria	Immunotherapy of cancer using recombinant viruses	This project aims to assess the anti-tumour potential of a melanocyte protein vaccine.	26 Sep 2002
DNIR 066/2002	5 June 2002	CSIRO – AAHL, Victoria	Porcine adenovirus viral vectors	Adenovirus from pigs will be genetically modified for use as vaccines and therapeutics for a range of animal diseases.	26 Sep 2002

Continued

Application number	Application date	Organisation and State	Project title	Project description	Licence issued
DNIR 067/2002	5 June 2002	CSIRO – AAHL, Victoria	Development of vaccines to protect against members of the Pasturellaceae	This project aims to develop vaccines against Pasteurellaceae associated diseases in production animal species.	26 Sep 2002
DNIR 068/2002	5 June 2002	CSIRO – AAHL, Victoria	Fowl adenovirus recombinants	The proponents intend to construct and test different genetically modified fowl adenoviruses as potential vaccines against diseases in chickens and dogs.	26 Sep 2002
DNIR 069/2002	5 June 2002	CSIRO – AAHL, Victoria	Identification of virulence factors for *infectious bursal disease virus* (IBDV)	The researchers are planning to identify what parts of the virus makes IBDV infectious to chickens.	26 Sep 2002
DNIR 070/2002	7 June 2002	CSL Ltd, Victoria	Expression of *Helicobacter pylori* proteins in *Escherichia coli*	The dealing is to produce quantities of proteins from the 'stomach-ulcer' bacterium *Helicobacter pylori* for potential use as vaccines.	26 Sep 2002
DNIR 071/2002	12 June 2002	Australian Army Malaria Institute, Queensland	JE Chimerivax	The aim is to test the safety and efficacy of a yellow fever vaccine genetically modified to vaccinate against Japanese encephalitis in human volunteers.	26 Sep 2002
DNIR 072/2002	24 June 2002	CSIRO – Livestock Industries, Victoria	Construction of recombinant ranaviruses	Ranaviruses are viruses of fish, frogs and reptiles and this project aims to develop technology to genetically modify these viruses.	26 Sep 2002

Notifications of NLRDs received

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

This category of dealings with GMOs has been assessed as posing low risks based on previous national and international experience. The NLRDs must

comply with certain risk management conditions and be contained in facilities deemed suitable by the Regulator.

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

The Regulator received one hundred and twenty-eight (128) 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 July–September 2002 quarter.

Applications received and decisions made, existing licences and other instruments, 1 July – 30 September 2002

Type	Number received	Number approved[1]
Variation of accreditation	2	4
Surrender of certification	53	19
Variation of certification	1	4
Transfer of licence	2	3
Transfer of certification	0	0
Variation of DIR[2]	11	2
Variation of DNIR	5	1

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.

2 The majority of variations are made at the request of the licence holder. Variations involve minor changes to licences where the Regulator is satisfied that the variation does not pose any risks to human health, safety or the environment that cannot be managed.

The transitional provisions in the Act enable dealings with genetically modified organisms 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' instrument under the Act for up to two (2) years from commencement of the Act on 21 June 2001.

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

Confidential commercial information

Under the Act a person may apply for a declaration from the Regulator that specified information is 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 quarter the Regulator received two (2) CCI applications in relation to DIR licence applications, one (1) CCI application in relation to a DNIR licence application and six (6) CCI applications in relation to NLRDs. The Regulator did not approve any CCI applications during the quarter.

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 managed; and
- effective management of the GMO is maintained.

Monitoring and compliance strategy

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

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 monitored each quarter. The purpose of routine monitoring of field trials is to ensure compliance with licence conditions.

On the basis of experience, the OGTR 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 identify inherently higher risk periods in dealings with gene technology (e.g. flowering and harvest) and to perform monitoring activities accordingly.

The monitoring program for contained dealings involving GMOs revolves around inspection of certified facilities. A minimum of 20% of physical containment (PC) 4, PC3 and PC2 large-scale facilities per year are monitored based on risk profiling. PC2 and PC1 facilities are monitored on a random basis.

A review of the Guidelines for Certification of Facilities/Physical Containment Requirements was initiated as it was recognised that the current version of the guidelines was limited in its application as a standard for monitoring compliance. The guidelines were redrafted with the intention of making the guidelines more user friendly and more easily enforceable. The redrafting was completed at the end of July 2002 (see Part 4, Reviews).

The Monitoring and Compliance Section is continuing to develop and apply protocols and provide training that will assist accredited organisations to better understand 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*.

Monitoring and compliance protocols

The Monitoring and Compliance Section has developed a range of documents to provide organisations and interested parties with guidance on monitoring and compliance activities under the *Gene Technology Act 2000*. Monitoring and compliance activities are under continual improvement and these protocols are recorded in working documents that that will evolve as systems are assessed and validated. Links to the protocols are provided on the OGTR website: www.ogtr.gov.au.

Updated protocols for this quarter are:

- Accredited Organisation Compliance Management Systems Protocol
- Risk Analysis Protocol
- Review Protocol.

Tasmanian gene flow studies

Following breaches of GMAC conditions at twenty-one (21) post-harvest GM canola sites in Tasmania in February 2001, a gene flow study was commissioned by the OGTR.

The findings of that study conducted by Luminis Pty Ltd and a subsequent smaller study conducted by Agronico Pty Ltd were released in July 2002.

In summary the findings revealed that:

- no gene flow from canola to weedy relatives was detected within the trial sites
- brassicaceous species were in low abundance at trial sites
- there is no evidence of gene flow from canola to *Brassica rapa* within 1 kilometre of trial sites.

Consequently the OGTR concluded that the risks to human health and safety and to the environment from gene flow and outcrossing to nearby brassicaceous plants were negligible at the twenty-one (21) non-compliant trial sites in Tasmania.

The OGTR has therefore decided to bring the monitoring conditions for these non-compliant sites into line with those for other former GM canola sites in Australia. The 100 metre monitoring zone will be reduced to 50 metres. A monitoring zone is an area extending from the outer edge of the trial site (or pollen trap if the trial was surrounded by a pollen trap). This area is monitored for the presence of canola and *Brassica rapa.* If any of these plants are identified in the monitoring zone, those plants will be removed and destroyed before flowering.

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored. During the quarter a total of eighty-seven (87) monitoring visits were carried out. Monitoring covering six (6) plant species was carried out on nineteen (19) deemed licences for planned release of a GMO into the environment (PR) and four (4) DIR licences.

Current field trial sites monitored. Of the seventy-two (72) sites that were current in the quarter, twenty-one (21) sites were monitored. This represents a monitoring rate of 30% of all current sites for the quarter.

Post-harvest field trial sites monitored. Of the 578 sites that were subject to post-harvest monitoring in the quarter, sixty-six (66) sites were monitored. This represents a monitoring rate of 21% of all sites subject to post-harvest monitoring.

Monitoring of contained facilities. During the July–September 2002 quarter, nineteen (19) PC2 facilities were monitored as part of the routine monitoring program. This encompassed visiting thirteen (13) PC2 laboratories, five (5) PC2 plant houses and one (1) PC2 animal containment facility across five (5) organisations.

Monitoring conducted

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

Licensed organisation name	Licence	No. sites licensed	No. sites visited	Site status[1]	Crop type
Department of Agriculture (Western Australia)	DIR009/2001	3	3	C	Cotton
	DIR008/2001	12	12	C	Cotton
	PR87x	7	2	PHM	Cotton
	PR113	32	24	PHM	Field pea
Bayer CropScience (formerly Aventis CropScience)	DIR010/2001	10	2	C	Canola
	PR63X(4)	96	11	PHM	Canola
	PR63X(5)	39	9	PHM	Canola
	PR79X	1	1	PHM	Canola
	PR85X(2)	5	1	PHM	Canola
Bayer CropScience (formerly Aventis CropScience) *contd*	PR90X	6	1	PHM	Canola
	PR90X(2)	8	1	PHM	Canola
	PR93X	1	1	PHM	Canola
	PR110	2	1	PHM	Canola
Monsanto Australia Limited	PR60X(2)	5	1	PHM	Canola
	PR77X	18	2	PHM	Canola
	PR77X(2)	30	3	PHM	Canola
	PR77X(3)	30	2	PHM	Canola
CSIRO	DIR006/2001	7	4	C	Cotton
	PR73	2	1	PHM	Sugarcane
	PR89X(2)	26	2	PHM	Cotton
	PR136	2	1	PHM	Sugarcane

Continued

Licensed organisation name	Licence	No. sites licensed	No. sites visited	Site status[1]	Crop type
University of Adelaide	PR106	1	1	PHM	Barley
	PR107	1	1	PHM	Wheat
Totals	22	344	87	C=21 PHM=66	6 species

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

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

Inspection of PC2 facilities

Organisation	Physical containment (PC) facility	No. facilities visited
University of Western Australia	PC2 Laboratory	1
	PC2 Plant House	1
	PC2 Animal Containment	1
South Australian Research and Development Institute (SARDI)	PC2 Laboratory	1
Monash University	PC2 Laboratory	4
	PC2 Plant House	1
Murdoch University	PC2 Plant House	1
	PC2 Laboratory	2
University of Tasmania	PC2 Laboratory	5
	PC2 Plant House	2
Totals	3 facility types	19

Monitoring findings

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

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

OGTR's monitoring of 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.

As previously noted, the certification guidelines are currently under review to remove any ambiguities associated with them. The findings of the monitoring visits have been used to inform the review process. The results of the review and progress on their implementation will be reported on in subsequent quarterly reports.

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 *Gene Technology Act 2000* and associated legislation
- ***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.

No incident reviews were completed between July–September 2002. Ongoing practice reviews are reported below.

Practice review: post-trial crops on canola sites

OGTR reviewed past monitoring records to evaluate the feasibility and effectiveness of crop management programs in detecting and preventing canola volunteers from flowering (as required under current deemed licence conditions), in post trial crops other than those specified in the deemed licence.

A draft report on the review was provided to accredited organisations (operating under deemed licences for GM canola) for comment. The review itself, and comments gathered from the organisations has initiated the development of an administrative process which will streamline licence variations for growing crops other than those specified in the licence. This process will vary according to the risk profile given to that crop type. For instance, the ability to grow those crops which make detection and control of flowering volunteers difficult will need to be

assessed on a case-by-case basis and may involve a size restriction to the area of planting. It is proposed that the restrictions placed on lower risk crops will be less stringent. This process will be implemented in the next quarter.

Practice review:* Brassica *Gene Flow Research Project

In assessing environmental risks from GMOs, the *Gene Technology Act 2000* specifies that the Gene Technology Regulator must have regard for, among other things, 'the potential for spread or persistence of the GMO or its genetic material in the environment'. In light of the importance of conducting scientific risk assessments in this area, the OGTR has become a partner in a PhD project currently being conducted in conjunction with the Department of Primary Industries, Water and Environment and the Tasmanian Institute of Agricultural Research.

The project will be conducted over three (3) years and will investigate various aspects of gene flow between *Brassica* species, aspects of seed dormancy and volunteer management. The results from this research will complement existing data on the likelihood and extent of *Brassica* gene flow as well as providing scientific data for consideration in future risk assessments on GM canola, particularly in Tasmania. It is also envisaged that an important outcome of this project will be practical, scientific-based solutions for managing GM canola volunteers, which can be readily adopted in crop management plans by GM crop licence holders and industry.

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 established three (3) 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.

Gene Technology Technical Advisory Committee

During this quarter, GTTAC held one (1) face-to-face meeting on 22 August 2002 in Canberra. One (1) teleconference meeting of the Committee was also held on 19 September 2002. At these meetings the Committee considered:

DIRs three (3) licence applications;

six (6) RARMPs; and

DNIRs eighteen (18) RARMPs.

During this quarter, the Committee also considered twenty (20) applications for DNIRs out of session.

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

Gene Technology Ethics Committee

During this quarter, the working groups established by GTEC at its second meeting in May 2002 continued their work out of session preparing draft papers on previously identified priority issues for consideration at the next meeting of

the Committee. The next meeting will be held in the final quarter of 2002 (1 October to 31 December 2002).

Further information about the issues under consideration by GTEC can be found on the Committee's section of the OGTR website: www.ogtr.gov.au.

Gene Technology Community Consultative Committee

The GTCCC held its second meeting in Melbourne on 15–16 July 2002.

At its second meeting the Committee continued its deliberations from the first meeting on the role of the GTCCC and the development of a work plan. Before the start of the meeting, the Committee took part in an information session conducted by Dr TJ Higgins, Deputy Chief, Division of Plant Industry, CSIRO. The session addressed the science of gene technology, an overview of its current and possible future applications, and the potential benefits and risks associated with the technology.

At the request of the Regulator, GTCCC discussed its key priorities and identified the following areas as the basis for its future work plan:

- to review documentation in regard to applications
- to review the OGTR website (www.ogtr.gov.au) design and other electronic communication
- to review processes by which the OGTR can improve community consultation and participation, including review of the effectiveness of information and communication provided to the community in general and to the regions involved in limited and controlled releases
- to write an overview of the public understanding of science literature
- to consider the issues relating to the interpretation of 'the environment' under the Act.

Working groups have been formed for each of the five (5) identified areas and draft reports will be considered at the third meeting of the GTCCC later in 2002.

Further information about the Committee can be obtained from the combined July–September 2002 meeting communiqué attached to this report (Appendix B).

PART 4 Other activities

Reviews

The following reviews continued during this quarter:

- A review to develop a strategy to identify data required for future risk assessments and risk management plans for dealings involving the intentional release of GM cotton, particularly large scale releases. This review is still ongoing
- A review of the *Guidelines for the Certification of Facilities/Physical Containment Requirements* found practical difficulties in implementing the current guidelines. Draft revised guidelines were released for wide consultation with users and other expert organisations on 23 July 2002 with comments due by 30 September 2002.

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.

International collaboration and coordination activities undertaken this quarter include:

- the commencement of the Regulator's visits to the United States, Canada, the United Kingdom, the European Union and China to discuss gene technology regulatory processes with relevant agencies and interest groups and attend the 7th International Symposium on the Biosafety of GMOs in Beijing
- a presentation to a Singapore delegation regarding the operations of the OGTR
- a visit to OGTR and seminar to government agencies and industry groups by Associate Professor Rene Van Acker, Weed Science and Crop Management, University of Manitoba, Canada.

Advice on gene technology regulation

Briefings

The OGTR provided briefings to:

- the Gene Technology Community Consultative Committee
- the Plant Breeders' Rights Office
- the Biotechnology Australia Public Awareness Rural Communications Meeting

on the regulatory activities of the OGTR.

Presentations and meetings

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 Regulator attended the Crawford Foundation for International Agricultural Research's 'Food for the future, opportunities for a crowded planet' Conference on 8 August 2002, regarding current trends and prospects for GM crops
- the Regulator made the following presentations at the AusBiotech 2002 'Building excellence through partnership' conference in Melbourne on 19–20 August 2002:
  - 'The building blocks of GMO regulation'
  - 'Gene technology regulation'
- the OGTR co-presented with Environment Australia and CSIRO a meeting regarding United Kingdom farming practices
- the OGTR made the following presentations at the 13th Australian Weeds Conference in Perth on 9–12 September 2002:
  - 'Spread, epidemic development and impact of the bridal creeper rust in Australia: summary of results'
  - 'Predictability and acceptability: potential for damage to non-target native plant species by biological control agents for weeds'.

Institutional Biosafety Committees training sessions

Throughout the quarter, the OGTR held IBC training sessions in a number of cities across Australia including Melbourne, Brisbane, Sydney, Perth, Adelaide,

Canberra, Hobart and Townsville. The OGTR also contributed to a biosafety training course run by Monash University on 18 September 2002.

The IBC Awareness Sessions are a national training and seminar series targeted towards educating IBCs about the role of the OGTR and their obligations under the *Gene Technology Act 2000.* The training was conducted by staff from the OGTR's Monitoring and Compliance Section and Contained Dealings Section. The Sessions were held at 13 different venues across each State and Territory between 2 August 2002 and 19 September 2002. The training sessions complemented previous training sessions, with participants totalling 620 people and representing approximately 86% (79 of 92) of IBCs across Australia.

The sessions were conducted with a view to:

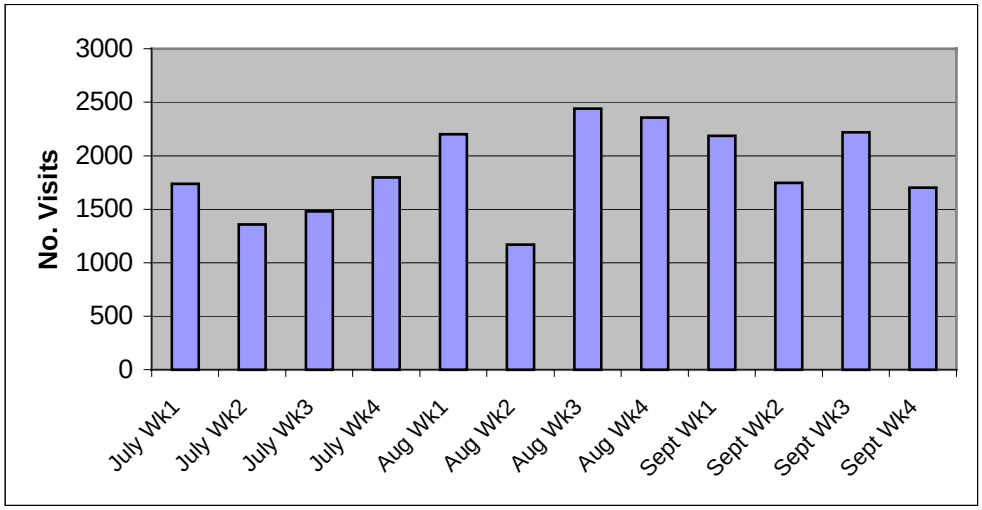
- achieving an increase in awareness of monitoring and compliance activities, protocols and related requirements for organisations
- contributing to organisations' capacity to meet legislative requirements under the *Gene Technology Act 2000* and associated legislation
- ensuring, through community/organisation awareness raising, that monitoring and compliance objectives and requirements are not confounded due to a lack of understanding
- achieving an increase in awareness of information that must be supplied in notifications and applications to the Regulator
- providing individual organisations or persons involved with dealings with GMOs an opportunity to discuss specific issues with an OGTR representative
- receiving feedback for organisations and IBCs on the general operation of the legislative system, the Office and the monitoring and compliance approach.

The awareness sessions coincided with the release of several revised documents including the proposed new *Guidelines for Certification of Facilities/Physical Containment Requirements*. The awareness sessions enabled IBCs, accredited organisations and their staff to ask questions and provide feedback on the drafts.

OGTR website www.ogtr.gov.au

The OGTR website received 579,348 'hits'[2] during the period 1 July to 30 September 2002, which represents an average of 6,297 hits per day.

2 Hits = Total number of pages and images accessed on the website



The graph above illustrates the pattern of individual visits[3] to the OGTR website, by week over the reporting period.

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

- What's New;
- OGTR publications
- OGTR general information.

The most popular downloaded documents were:

- KPMG report *A model for cost recovery in the Office of the Gene Technology Regulator*
- *Handbook on the regulation of gene technology in Australia*
- *GM products approved as food, food additives and processing aids*.

Complaint to the Human Rights and Equal Opportunity Commission

The OGTR's website was the subject of an accessibility complaint to the Human Rights and Equal Opportunity Commission (HREOC). The complaint arose from difficulties that were being experienced by a member of the community who is vision-impaired and utilises 'screen reader' software to access documents available on the site. The OGTR has implemented measures to assist the complainant's access to the OGTR's website and has formally responded to the HREOC.

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

3 Visits = Total number of visitors that entered the website

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

During the quarter, a total of 1477 e-mail messages were sent to the OGTR general e-mail account. Nearly one thousand (989) e-mails were received in July 2002, 246 in August 2002 and 242 in September 2002.

The large number of e-mails received in July 2002 were in response to the call for comment on the applications for the controlled and limited release of GM canola, DIR010/2001 and DIR011/2001.

Calls to OGTR toll-free telephone number 1800 181 030

The 1800 line is a point of contact for members of the public and other interested parties. Assistance for specific questions and an additional mechanism for public feedback are among some of the benefits provided by the 1800 line.

During the quarter, OGTR received 281 calls in July 2002, 192 in August 2002 and 240 in September 2002 to the 1800 line.

Freedom of Information

No Freedom of Information requests were received during the reporting period.

Consultants

During the reporting period, the OGTR managed three (3) consultancy contracts worth a total of $63,270 (GST exclusive). The table below lists the consultants, describes the purpose of the consultancy and the amount paid during the quarter.

Consultant	$ amount paid (GST exclusive)	Purpose
Dialog Information Technology	$10,463	Develop Gene Technology Information Management System (GTIMS)
Acumen Alliance	$34,625	Prepare financial statements and cost recovery report
Hassall & Associates	$18,182	Review of guidelines for the certification of facilities
Total consultants for quarter	$63,270	

Appendix A

GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE

COMMUNIQUE

This is the fifth communique of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the eighth meeting of GTTAC held on 22 August 2002.

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 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 (DNIRs)

DNIRs are dealings usually undertaken within a certified facility (so that the organism is physically contained) and where the personnel involved in the dealing have been assessed as having adequate training and experience for the task. These are typically laboratory based projects.

GTTAC has advised that all researchers involved with DNIRs need to follow the appropriate laboratory guidelines relating to their facility certification. In particular, GTTAC has advised that the use of sharp instruments should be avoided where the possibility of accidental inoculation exists. However, when sharps are required, extra care should be taken.

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

Molecular interactions between HIV-1 and host gene products

(DNIR 038)

Impact of host gene products on HIV-1 replication in mammalian cells (DNIR 039)

Effect of host gene products that interact with HIV-1 reverse transcriptase on MoMLV replication (DNIR 040)

GTTAC considered three applications from the Macfarlane Burnet Institute for Medical Research and Public Health for licences to test the impact of the expression of cellular proteins on HIV-1 and MLV replication in mammalian cell culture.

GTTAC agreed that the risk assessment identifies all the risks associated with the proposed dealing and that the measures proposed in the risk management plan are adequate to deal with the identified risks. GTTAC recommended that the development of separate RARMPs for these applications would assist in more clearly delineating the risks involved with each individual dealing and the precautions that should be followed by operators.

Characterisation of the signalling and cell biology of CD46 and the Dlg family (DNIR 041)

The aim of the proposed dealing is to study the effects on immune cell function of the protein CD46 and the Dlg family in human and mouse cells.

GTTAC agreed that the risk assessment identifies all the risks associated with the proposed dealing and that the measures proposed in the risk management plan are adequate to deal with the identified risks.

A preclinical model of pancreatic islet xenotransplantation as treatment for Type 1 diabetes (DNIR049)

This dealing aims to produce pig and mouse pancreatic islet cells that do not provoke a response in the human immune system.

GTTAC agreed that the risk assessment identifies all the risks associated with the proposed dealing and that the measures proposed in the risk management plan are adequate to deal with the identified risks.

Molecular pathogenesis of *Bartonella henselae* (DNIR 052)

The aim of the proposed dealing is to study *Bartonella henselae*, a bacterium which causes cat-scratch disease. GTTAC suggested the immunocompromised people should be advised against working on the project and that a contingency plan should be developed in the event of accidental injection.

GTTAC agreed that the risk assessment identifies all the risks associated with the proposed dealing and that the measures proposed in the risk management plan are adequate to deal with the identified risks.

Transfection of *Plasmodium falciparum* (DNIR 057)

The aim of the proposed dealing is to study the parasite which causes malaria, *Plasmodium falciparum*.

GTTAC agreed that the risk assessment identifies all the risks associated with the proposed dealing and that the measures proposed in the risk management plan are adequate to deal with the identified risks.

Expression of genes in *Leishmania* (DNIR 058)

The aim of the proposed dealing is to study the parasite *Leishmania* and immune responses to the parasite in mice.

GTTAC agreed that the risk assessment identifies all the risks associated with the proposed dealing and that 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 Cotton

Commercial release of Bollgard II® Cotton (DIR 012)

Monsanto Australia Ltd has applied for a licence for the commercial release of an insecticidal cotton (Bollgard II®) and an insecticidal/herbicide tolerant combination cotton (Bollgard II®/Roundup Ready®). Bollgard II®/ Roundup Ready® was produced by the conventional crossing of genetically modified Bollgard II® with genetically modified Roundup Ready® that contains the gene for tolerance to the herbicide glyphosate (Roundup®).

The application sought to cover all Australian cotton growing areas, including areas north of latitude 22°South, in the Northern Territory, Western Australia and Queensland. The OGTR, however, advised that due to concerns expressed about the potential weediness of GM cotton in northern Australia, it was proposed that the release be restricted to cotton growing areas below 20° South and only limited and controlled releases would be permitted in areas above 20° South.*

GTTAC:

(a) endorsed the Risk Assessment and Risk Management Plan for DIR 012;

(b) agreed with the proposal to restrict the growing of GM cotton to areas below 20° South and that a roadside sampling program to monitor for the presence of volunteer GM cotton should be required; and

(c) endorsed the proposed licence conditions for DIR 012 with the recommendation that the following additional matters be considered in finalising the RARMP:

- monitoring dairies and their immediate surrounds for the presence and destruction of volunteers;
- double bagging, or covering of GM cotton seed and seed material by tarpaulins while being transported in areas above latitude 20° South;
- approaching the Cotton Research and Development Corporation to discuss the conduct of research into gene flow and environmental impacts of GM cotton; and
- permitting crop size to be determined by market forces and any conditions set by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA).

** NB. Based on additional information received during the consultation on the RARMP, the release was restricted to south of latitude 22º South, because of concerns about the potential weediness of the cotton in tropical areas, as well as the potential for out-crossing to native cotton species in areas north of that latitude.*

2.2 Advice on Sugarcane

Agronomic Assessment of Transgenic Sugarcane engineered with Reporter Genes (DIR 019)

The Bureau of Sugar Experiment Stations (BSES) has applied for a licence for the limited and controlled release of genetically modified sugarcane. The sugarcane has been produced through a new rapid tissue culture process combined with genetic modification.

The GM sugarcane contains three new genes. The first gene, *nptII* is derived from the bacterial Tn5 transposon and encodes resistance to the antibiotics kanamycin, neomycin and geneticin. This antibiotic resistance trait was used as a selectable marker in the initial laboratory stages to select sugarcane plants that were genetically modified. A second gene, *bla* from the bacterium *Escherichia coli*, encodes ampicillin resistance. It is linked to a bacterial promoter that does not function in plants, so the protein is not produced in sugarcane. The third gene, *gfp*, is derived from the jellyfish *Aequorea victoria* and encodes a reporter protein, green fluorescent protein. The protein is readily detected due to its fluorescent properties and provides an indication of whether, and to what extent, the gene is expressed.

Short regulatory sequences that control the expression of the *nptII* and *gfp* genes are also present in the GM sugarcane. These are derived from maize and a

common soil bacterium, *Agrobacterium*. Although *Agrobacterium* is a plant pathogen, the regulatory sequence comprises only a small part of its total genome and is not capable of causing disease.

The aim of the proposed release is to test the effect of both the new tissue culture process and genetic modification on the agronomic performance of the GM sugarcane. The release would be carried out over four growing seasons on one site over a total area of 0.7 ha in the Cairns district in North Queensland.

GTTAC advises the Regulator:

(a) The following risks or potential risks should be assessed in relation to the GM sugarcane application from the BSES:

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

(b) The risk management plan should include measures to prevent the spread or persistence of the GMO or its genetic material in the environment.

(c) In addition, GTTAC recommends that monitoring for volunteers be carried out for a period of six months.

2.3 Advice on Canola

GTTAC considered two applications for the proposed release of GM canola in Australia.

General Release of Roundup Ready® Canola (*Brassica napus*) in Australia (DIR 020)

The OGTR has received an application from Monsanto Australia Ltd (Monsanto) for a licence for the intentional release of GM Canola that has been modified to tolerate glyphosate, the active ingredient in the herbicide Roundup®.

Monsanto proposes the commercial cultivation of Roundup Ready® canola in all the current and future canola growing regions of Australia, which potentially includes New South Wales, Victoria, South Australia, Western Australia, Queensland, Tasmania and the Australian Capital Territory. The Tasmanian State Government currently has a moratorium on the planting of GM plants in

that State through the *Plant Quarantine Act 1997* (TAS). Accordingly, in addition to a licence issued under the Gene Technology Act 2000 (CWLTH) and corresponding State laws, any release of Roundup Ready® canola in Tasmania would also require approval from the Tasmanian State Government. The use of genetically modified crops in Tasmania is currently restricted to approved research trials and no approval would be considered for any commercial planting.

Monsanto proposes a phased introduction of Roundup Ready® canola which enables the use of glyphosate for weed control with a limited release of approximately 5000 hectares in the first year (2003) in the canola growing regions of south eastern Australia. Monsanto expects a steady increase in the area sown to Roundup Ready® canola over a number of years across the canola growing regions of Australia, with the rate of increase being determined by market acceptance and seed and variety availability. Monsanto proposes to continue to work closely with the grains industry to manage the introduction of Roundup Ready® canola. Glyphosate is not currently registered for use on canola by the NRA.

The canola plants and their by-products, would be used in the same manner as conventional canola, including for human food and animal feed. After harvest of the Roundup Ready® canola, the grain will enter the general commerce supply chain in Australia for domestic and export markets. Canola is grown commercially primarily for its seeds which yield about 40% oil and a high protein animal feed. Canola oil, which does not contain genetic material, is used in the manufacture of a variety of food products. Canola meal is primarily used as a feed for livestock, but it is also used in poultry and fish feed, pet foods and fertilisers.

Monsanto proposes a systematic and strategic approach to risk management and product stewardship through the implementation of its Roundup Ready Canola Technology Stewardship Strategy, which includes a Roundup Ready Canola Crop Management Plan. These will be consistent with the Guidelines for Industry Stewardship Programs and Crop Management Plans proposed by the Plant Industries Committee of the Primary Industries Standing Committee (under the Primary Industries Ministerial Council) and the Guidelines for Supply Chain Management of GM Canola being developed by the Gene Technology Grains Committee.

GTTAC advises the Regulator that:

(a) The following risks or potential risks, especially given the commercial scale of the release, should be assessed in relation to the Roundup Ready canola application from Monsanto:

- toxicity or allergenicity of Roundup Ready canola;
- weediness or increased potential for weediness, including the persistence of canola in non-agricultural habitats and the factors determining such persistence;
- potential for the introduced genes to be transferred to into other organisms by cross pollination; and
- any other potential hazards, including whether commercial release is likely to result in changes to agricultural practices that may have an environmental impact.

(b) The potential for glyphosate tolerant canola to occur along roadsides does not present a significant risk to the environment.

(c) In addition, the applicant should be requested to provide further information on glucosinolate production and to provide a crop management plan.

(d) The inclusion of data on the chromosomal location of the transgenes in the molecular characterisation of the GMO would be useful if available. However, is not absolutely required for the assessment.

(e) The applicant should be required to provide a detailed herbicide resistance management plan and any recommendations made regarding supply chain management.

Commercial Release of InVigor® Hybrid Canola (*Brassica napus*) for use in the Australian Cropping System (DIR 021)

The OGTR has received an application from Aventis CropScience Pty Ltd (Aventis) for a licence for the intentional release of a GMO into the environment. The aim of the proposed release is to allow the commercial use of InVigor® canola lines T45, Topas 19/2, MS1, MS8, RF1, RF2 and RF3 in Australian agriculture and continuing product research and development programs based on these lines.

Aventis only proposes to commercialise InVigor® hybrid canola derived from MS8 and RF3 lines for use by Australian farmers. Canola derived from T45,

Topas 19/2, MS1, RF1 and RF2 lines has been approved for food and environmental release in a number of other countries and Aventis is also seeking approval for these lines to achieve consistency with existing overseas regulatory approvals.

InVigor® canola plants have been genetically modified to introduce a hybrid breeding system based on male sterile (MS) and fertility restorer (RF) lines, and to be tolerant to the herbicide glufosinate ammonium, the active ingredient in the herbicides Liberty® and Basta®. Lines T45 and Topas 19/2 have been genetically modified to introduce glufosinate ammonium tolerance, but do not contain the hybrid breeding system. Aventis have indicated that the use of InVigor® canola will also provide the option of using herbicides which have glufosinate ammonium as their active ingredient, in conjunction with other measures, for the control of weeds in the crop. Liberty® is not currently registered by the NRA for use on canola. Basta® is registered by the NRA for use in horticulture.

The canola lines Topas 19/2, MS1, RF1 and RF2 also contain the *nptII* gene from the bacterium *Escherichia coli* which confers resistance to some aminoglycosides including the antibiotics neomycin, kanamycin and gentamicin. The antibiotic resistance trait was used as a selectable marker in the initial laboratory stages to select canola plants that were genetically modified.

Aventis proposes the commercial cultivation of InVigor® canola potentially over all the current and future canola growing regions of Australia, which includes New South Wales, Victoria, South Australia, Western Australia, Queensland, Tasmania and the Australian Capital Territory. However, as noted for DIR 020, release in Tasmania would also require the approval of the Tasmanian Government which has imposed a moratorium on the cultivation of GM food crops under its Plant Quarantine Act.

Aventis proposes a phased introduction of InVigor® canola with a limited release in the first year (2003), including seed increase and demonstration sites. Aventis expects that the scale of the release will expand slowly and that the scale of the expansion will be dependent on market acceptance, seed and variety availability. Aventis proposes to work closely with the canola industry to manage the introduction of InVigor® canola.

Aventis proposes to implement a stewardship program for the management of InVigor® canola. The stewardship program, including the Crop Management Plan for InVigor® canola, will be consistent with the Guidelines for Supply

Chain Management of GM Canola being developed by the Gene Technology Grains Committee.

GTTAC advises the Regulator:

(a) The following risks or potential risks, especially given the commercial scale of the release, should be assessed in relation to the InVigor® canola application from Aventis:

- toxicity or allergenicity of InVigor canola;
- weediness or increased potential for weediness, including the persistence of canola in non-agricultural habitats and the factors determining such persistence;
- potential for the introduced genes to be transferred to into other organisms by cross pollination;
- any other potential hazards, including whether commercial release is likely to result in changes to agricultural practices that may have an environmental impact; and
- any hazards associated with the *nptII* gene.

(b) The RARMP should include a provision that glufosinate-ammonium tolerant canola should not be grown in vineyards. Glufosinate-ammonium is used to control weeds in vineyards.

(c) Inclusion of data on the chromosomal location of the transgenes in the molecular characterisation of the GMO, would be useful if available. However, this is not absolutely required for the assessment.

(d) In addition, the applicant should be requested to provide a detailed crop management plan, including a resistance management plan and any provisions made regarding supply chain management.

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

GENE TECHNOLOGY COMMUNITY CONSULTATIVE COMMITTEE MEETING

COMMUNIQUE

This is the first communique of the Gene Technology Community Consultative Committee (GTCCC). It covers matters considered at the first and second meetings of the GTCCC held on 17-18 April 2002 and 15-16 July 2002 respectively.

The GTCCC was established by the *Gene Technology Act 2000* (the Act) as a statutory advisory committee to the Gene Technology Regulator (the Regulator) and the Gene Technology Ministerial Council. All committee members hold office on a part-time basis.

At its first and second meetings the Committee considered the role of the GTCCC and the development of a work plan. The discussions covered a broad range of issues facing the new gene technology regulatory system. The outcomes of these discussions are summarised below.

Role and Future Work of the Committee

Following discussions at both meetings, the Committee decided to frame and adopt an agreed purpose to guide their deliberations and future work as follows:

'We collectively reflect a broad spectrum of community views and bring forward community concerns. In that capacity we advise on the processes of the Office of the Gene Technology Regulator (OGTR) and matters of general concern in relation to genetically modified organisms (GMOs) and also respond to requests for advice from the Regulator and the Gene Technology Ministerial Council.'

At the request of the Regulator, GTCCC discussed its key priorities and identified the following areas as the basis for its future work plan:

1. Review of documentation in regard to applications;
2. Review of the OGTR website design and other electronic communication;
3. Review of processes by which the OGTR can improve community consultation and participation including review of the effectiveness of information and communication provided to the community in general and to the regions involved in limited and controlled releases;
4. Write an overview of the public understanding of science literature; and
5. Consideration of issues relating to the interpretation of "the environment" under the Act.

Working groups have been formed for each of the five identified areas and draft reports will be considered at the third meeting of the GTCCC later in 2002.

GTCCC and Relationships with Other Committees

The GTCCC, in considering its role in the new regulatory system for GMOs in Australia, recognised that it was one of three gene technology advisory committees. The GTCCC discussed written communiques from the two other committees, the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics Committee (GTEC) set up under the new regulatory system, and heard verbal reports from the cross- members of these committees. The Committee agreed that this exchange of information from GTTAC and GTEC will be a feature of all GTCCC meetings.

Presentations

At the April meeting, Mr Craig Cormick, Manager of the Public Awareness Program for Biotechnology Australia, provided the Committee with an overview of recent studies showing trends in public attitudes - including changes in areas of concern, ethical issues, and views of regulatory agencies over the past few years. The GTCCC will participate in the development of the next questionnaire that will contribute to this ongoing research.

Prior to the start of the July meeting, the Committee took part in an information session conducted by Dr TJ Higgins, Deputy Chief, Commonwealth Scientific and Industrial Research Organisation Plant Industry, on the science of gene technology, an overview of its current and possible future applications, and the potential benefits and risks associated with the technology.

Delivering Accountable Regulation and Encouraging Community Participation

Consultation and community feedback is a consistent feature of the national regulatory system. Therefore, it was decided at the first meeting that GTCCC members and the OGTR would undertake a range of information gathering exercises to inform discussions at future meetings, with particular emphasis on the following areas:

1. The determination of the level of knowledge, communication channels and scope for participation for farmers and local government;
2. Possible ways farmers near GM crop releases could be targeted for information distribution and encouraged to participate; and
3. The quality, clarity, timeliness and accessibility of the information made available about proposed intentional releases of GMOs.

In seeking to encourage further consultation and community participation, the Committee focussed in their meetings on some specific areas of the new system. Examples of two areas of discussion are summarised below.

Communicating with the Community

As the GTCCC is a community consultative committee, members believe that it is very important to work strongly towards fulfilling this role and it was decided that the Committee would write to a range of relevant stakeholders. The letter will introduce the Committee and invite organisations to express any views they may have about the extent of consultations that have been undertaken by the Regulator. The Committee anticipates that this will only be the beginning in developing strong communication channels with a wide range of key groups.

Notifiable Low Risk Dealings

Notifiable Low Risk Dealings (NLRDs) are dealings with GMOs that have been assessed on the basis of long and extensive experience as posing low risks and are required to be conducted within certified contained facilities. Although NLRDs do not involve any intentional release into the environment, they must still be assessed and approved by an Institutional Biosafety Committee and must be notified to the Regulator.

The Committee proposed that public notification of NLRDs would benefit from a fuller description in more accessible language and accordingly requested that the OGTR explore ways to provide a plain English description of NLRDs on the public record for new and renewed dealings. The OGTR is currently reviewing the application form with a view to achieving improvements in the format and content.

Meetings in 2002

GTCCC 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)