Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 JULY–30 SEPTEMBER 2010

The object of the *Gene Technology Act 2000* is:

'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 genetically modified organisms'

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Inquiries about the content of this report may be directed to the Business Management and Communications Section, Regulatory Practice and Compliance Branch of the Office of the Gene Technology Regulator.

The Hon Catherine King MP
Parliamentary Secretary 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 Quarterly Report of the Operations of the Gene Technology Regulator, covering the period 1 July to 30 September 2010.

During this period four licences for dealings involving intentional release of GMOs and five licences for dealings not involving intentional release of GMOs were issued, while 43 physical containment facilities were certified.

Routine monitoring activities for this quarter exceeded the target rate and no significant risks to either human health or the environment were identified.

Yours sincerely

Dr Joe Smith
Gene Technology Regulator

22 November 2010

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ABOUT THIS REPORT

Sub-section 136A(1) of 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. Sub-section 136A(2) of the Act requires that the report include information on:

- GMO licences issued during the quarter
- breaches of conditions of a GMO licence that have come to the Regulator's attention during the quarter
- Emergency Dealing Determinations (EDDs) made by the Minister during the quarter
- any breaches of conditions of an EDD 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.

Its purpose is to inform the community of our roles and responsibilities and to provide a summary of our achievements over the past quarter.

This report has four key sections.

Gene technology regulatory system

Provides advice on the activities and outcomes achieved in relation to the implementation and management of the national regulatory system during the 1 July to 30 September 2010 quarter.

Regulation of genetically modified organisms

Provides details on the regulatory activity undertaken, including information about applications for, and action taken with respect to, GMO licences and other instruments under the Act. It also includes details of monitoring, auditing and compliance activities by the Regulator during this quarter.

Statutory committee operations

Reports on the activities of the two advisory committees established under the Act to assist the Regulator and the Gene Technology Ministerial Council.

Other activities of the Gene Technology Regulator

Describes other activities relating to the statutory functions of the Regulator that support the operations of the gene technology regulatory system.

SECTION 1

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 July to 30 September 2010 quarter were:

Licences and other instruments

- One organisation issued with accreditation.
- Four licences issued for Dealings involving the Intentional Release (DIR) of GMOs into the environment.
- Five licences issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- Forty three physical containment facilities certified
- Sixteen instruments surrendered
- Variation of 35 certifications, five DIR licences and 17 DNIR licences.

Further information on licences and other instruments is contained in Section 2 of this report.

Monitoring and Compliance

Approximately six percent of current field trial sites and seven percent of post-harvest field trial sites were subjected to routine monitoring during the quarter. This exceeded the target minimum rate of five percent per quarter.

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

Working collaboratively with States and Territories

Gene Technology Ministerial Council

The Gene Technology Ministerial Council (GTMC) oversees the implementation of the regulatory system and comprises one Minister from the Commonwealth and one Minister from each of the States and Territories. Currently, the GTMC includes Ministers from a range of portfolios including health, agriculture and environment.

State and Territory consultation

The Regulator must consult with State and Territory Governments and appropriate local councils during the evaluation of applications for all DIR licences.

For each application for a DIR licence other than a limited and controlled release, the Regulator is required to seek advice on matters relevant to the preparation of the Risk Assessment and Risk Management Plan (RARMP), and must also seek comment on the RARMP itself once it is prepared. For each application for a limited and controlled release, the Regulator is required to seek comment on the RARMP.

Further information is contained in Section 2 of this report.

Australian Government Agency liaison

The close relationship between the OGTR and other Australian Government authorities and agencies continued during this quarter.

Under the Act, the Regulator must seek advice from the Australian Government Environment Minister, and prescribed Australian Government authorities and agencies, on matters relevant to preparing the RARMP for each application for a DIR licence, except those that meet the criteria to be considered as a limited and controlled release.

The prescribed Australian Government authorities and agencies comprise:

- Australian Pesticides and Veterinary Medicines Authority
- Australian Quarantine and Inspection Service
- Food Standards Australia New Zealand
- National Industrial Chemicals Notification and Assessment Scheme
- Therapeutic Goods Administration.

Once a RARMP is prepared for any DIR licence application, the Regulator is required to seek comment on the RARMP from the same prescribed Australian Government authorities and agencies.

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

- Department of Agriculture, Fisheries and Forestry
- Department of Sustainability, Environment, Water, Population and Communities
- Department of Foreign Affairs and Trade.

During the quarter the Regulator sought advice in respect of one DIR RARMP.

Further information on the processing of DIR applications is contained in Section 2 of this report.

Public participation

The Act requires the Regulator to consult the public on the RARMPs for all DIR licence applications. One invitation to the public to comment on a RARMP was issued during the quarter.

Further information on the processing of DIR applications is contained in Section 2 of this report.

SECTION 2

REGULATION OF GENETICALLY MODIFIED ORGANISMS

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of the report outlines the regulatory activity undertaken during the 1 July to 30 September 2010 quarter. This includes information about applications for GMO licences and other instruments under the Act. This section details any EDDs made pursuant to the Act. It also includes details of monitoring activities and of alleged, admitted or self-reported non-compliances with the Act, or with the conditions imposed by the Regulator on GMO licences or other instruments issued pursuant to the Act. Summary reports on investigations completed during the quarter are supplied. Information on Confidential Commercial Information (CCI) applications has also been provided.

Types of Applications

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

- **Dealings involving Intentional Release licences**

DIR licences authorise dealings ranging from limited and controlled releases (e.g. field trials) through to more extensive general or commercial releases of GMOs. DIR licence applications have a statutory timeframe of 255 working days for processing unless the Regulator determines the application is a limited and controlled release application. Then the timeframe for making a decision is 150 working days, or 170 working days if the Regulator determines that the proposed dealings represent a significant risk to human health and the environment.

- **Dealings Not involving Intentional Release licences**

DNIR licences authorise contained dealings with GMOs carried out in laboratories and other containment facilities that are designed to prevent release of the GMO(s) into the environment. These licence applications have a statutory timeframe of 90 working days for making a decision.

- **Accreditations of organisations**

DIR and DNIR licences require organisations which conduct work with GMOs to be accredited. To achieve accreditation, the Regulator must be satisfied that the organisation has, or has access to, a properly constituted and resourced Institutional Biosafety Committee (IBC) and complies with the requirements of the Regulator's guidelines for accreditation. These applications have a statutory timeframe of 90 working days for making a decision.

- **Certifications of containment facilities**

Certification is required to satisfy the Regulator that a facility which is proposed to be used to conduct dealings with a GMO meets the guideline requirements for the particular level of physical containment specified. These applications have a statutory timeframe of 90 working days for making a decision.

GMO Register

The GMO Register is a list of dealings with GMOs that the Regulator is satisfied pose minimal risks to human health and safety and the environment and can therefore be undertaken by anyone, subject to any specified conditions, without the oversight of a licence holder. Under section 78 of the Act the Regulator may determine that dealings with a GMO previously authorised by a licence are to be included on the GMO Register. Such determinations are disallowable instruments.

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.

Application type	Number received	Number approved*
Accreditation	2	1
DIR licence	1	4
DNIR licence	7	5
Certifications	50	43

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

Processing of applications for Dealings involving Intentional Release licences

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

- initial screening of the application for completeness
- determining whether or not the application is a limited and controlled release
- considering the applicant's suitability to hold a licence, having regard to relevant convictions, revocations and suspensions of related licences and permits, and ability to meet conditions of the licence
- seeking comments from prescribed experts, agencies and authorities on issues to consider in the RARMP for all DIR applications except limited and controlled releases
- preparing a consultation RARMP, including proposed licence conditions to manage risks to human health and safety and the environment, and determining whether the proposed dealings may pose a significant risk

- seeking comments on the RARMP from prescribed experts, agencies and authorities and the public
- considering all comments relating to the protection of human health and safety and the environment in finalising the RARMP
- confirming the applicant's suitability, including their capacity to meet licence conditions, and considering policy principles and any relevant policy guidelines.

Once these actions are completed, the Regulator can make a decision on whether or not to grant a licence and the conditions which are to be included in the licence if issued.

The statutory timeframes for making decisions on DIR licences effectively extend over approximately twelve months, and eight or nine months for limited and controlled releases, as they exclude weekends and public holidays observed in the Australian Capital Territory.

This time limit may be extended, that is, the clock may be stopped, if the decision-making process is unable to continue, for example, because of an unresolved application for declaration of CCI or because additional information is sought from the applicant.

The Act and the Gene Technology Regulations 2001 (the Regulations) mandate a minimum 30 day timeframe for each of the one or two rounds of consultation that the Regulator must undertake during the processing of each DIR application. However, consultation periods longer than minimum timeframes are usually allowed to facilitate the provision of information and promote involvement in the decision-making process, particularly by the community. An application for a DIR licence cannot normally be received and decided upon within the same three month reporting period.

The following table shows the progress of applications for DIR licences undergoing evaluation during the quarter.

Applications received	Notification of applications*	Consultation on RARMP	Licences issued
DIR 108	DIR 105	DIR 104	DIR 098
	DIR 107		DIR 101
			DIR 103
			DIR 104

* *Although not required under the Act, all new limited and controlled DIR applications are notified on the OGTR website under 'What's New' and notified to all individuals and organisations on the OGTR mailing list*

Applications received for Dealings involving Intentional Release licences

The Regulator received one application for a DIR licence in the quarter:

- **DIR 108**—Commercial release of InVigor × Roundup Ready canola (*Brassica napus*) for use in the Australian Cropping System—Bayer CropScience Pty Ltd

Consultation on applications for Dealings involving Intentional Release licences

Although not required by the Act, the Regulator issued a 'Notification of Licence Application' for two DIR licence applications. These notifications were posted on the OGTR website and sent to people and organisations on the OGTR mailing list to advise receipt of the applications and when the RARMP is expected to be released for public comment.

- **DIR 105**—Limited and controlled release of canola genetically modified for herbicide tolerance—Monsanto Australia Limited
- **DIR 107**—Limited and controlled release of banana genetically modified for disease resistance—Queensland University of Technology.

There was one invitation to comment on a RARMP issued during the quarter:

- **DIR 104**—Limited and controlled release of canola and Indian mustard genetically modified for herbicide tolerance and/or a hybrid breeding system—Bayer CropScience Pty Ltd

Full copies of DIR applications can be obtained by contacting the OGTR. Summary information on DIR applications and full consultation RARMPs, including proposed licence conditions, are available via the OGTR website or directly from the OGTR.

Withdrawn applications and surrendered licences for Dealings involving Intentional Release licences

No DIR licence applications were withdrawn during the quarter.

Three DIR licences were surrendered during the quarter.

- **DIR 033/2002**—Commercial release of recombinant live oral cholera vaccine (Orochol® vaccine)—CSL Ltd
- **DIR 064/2006**—Limited and controlled release of water-efficient genetically modified cotton—Monsanto Australia Limited
- **DIR 084/2008**—Limited and controlled release of torenia genetically modified for enhanced phosphate uptake—Florigene Pty Ltd.

Clock stopped on Dealings involving Intentional Release licence applications

The Regulations determine that a day on which the Regulator is unable to proceed with the decision-making process, or a related function, because information requested from the applicant has not been received, is not counted as part of the prescribed timeframe for making a decision on an application.

One request for further information on a DIR application was initiated in this quarter:

- **DIR 106**—Limited and controlled release of sugarcane genetically modified for production of biopolymers and biopolymer precursors—University of Queensland.

Decisions on applications for Dealings involving Intentional Release licences

Four DIR licences were issued during the quarter:

- **DIR 098**—Commercial release of a genetically modified live viral vaccine to protect against Japanese encephalitis (IMOJEV™)—Sanofi-Aventis Australia Pty Ltd
- **DIR 101**—Limited and controlled release of Cotton Genetically Modified for Insect Resistance and Herbicide Tolerance—Monsanto Australia Limited
- **DIR 103**—Limited and controlled release of canola genetically modified for enhanced yield and delayed leaf senescence—Department of Primary Industries Victoria
- **DIR 104**—Limited and controlled release of canola and Indian mustard genetically modified for herbicide tolerance and/or a hybrid breeding system—Bayer CropScience Pty Ltd.

Summary information on DIR applications, finalised RARMPs, licences issued and copies of licences are available from the OGTR website or can be obtained by contacting the OGTR directly.

Decisions on applications for Dealings Not involving Intentional Release licences

These dealings must be conducted in appropriate containment facilities and the dealings must not involve intentional release of a GMO into the environment.

Five DNIR licences were issued during the quarter:

- **DNIR 485**—Mouse studies using EcoHIV—Queensland Institute of Medical Research
- **DNIR 486**—Gene Therapy for HIV—Calimmune Australia Pty Ltd
- **DNIR 487**—The use of short hairpin microRNAi lentiviral based constructs and libraries for functional analysis—Western Australian Institute for Medical Research

- **DNIR 488**—Identification of determinants of virulence and vector competence factors in Bluetongue virus—CSIRO
- **DNIR 489**—The Role of micro-RNAs in Cancer Models—St Vincent's Institute of Medical Research.

A full listing of DNIR licences and their current status is available from the OGTR website.

Changes to existing licences and other instruments

The Regulator can, directly or upon application, vary an issued licence or other instrument. Variations involve changes to conditions applied to an instrument or a licence. For example, the Regulator can vary a licence to manage risks if new information or data comes to light. The Regulator must not vary the licence unless he is satisfied that any risks posed by the dealings, proposed to be authorised by the licence as varied, are able to be managed in such a way as to protect the health and safety of people and the environment.

Most variations are made at the request of the instrument/licence holder. Applications for variation to licences have a statutory timeframe of 90 days for making a decision. Additionally, the Regulator can make a decision in relation to an application to transfer a licence/instrument to another person or consent to the surrender of a licence/instrument request by a licence/instrument holder.

The following table describes the number and type of applications for variation and surrender received in relation to existing licences and other instruments, as well as the number of variations and surrenders approved during the quarter.

Type	Number received	Number approved[b]
Surrender of accreditations	1	0
Surrender of certification	12	13
Surrender of DIR licence	2	3
Surrender of DNIR licence	1	0
Variation of accreditation	0	0
Variation of certification	62	35
Variation of DIR licence[a]	3	5
Variation of DNIR licence	20	17

a Also includes variations initiated by the Regulator

b Numbers reported in this quarter often relate to applications received in previous quarters.

Emergency Dealing Determinations

During this quarter the Regulator did not receive any requests for advice in relation to the making of any Emergency Dealing Determinations (EDD) and no EDDs were in effect.

Confidential Commercial Information

Under section 184 of the Act a person may apply to the Regulator in accordance with section 185 for specified information to be declared confidential commercial information (CCI). Specified information awaiting a decision on an application for CCI is treated as if it were CCI until a decision is made. If the Regulator declares information to be CCI the information is protected from disclosure. More information on the protection of CCI is available on the OGTR website.

During the quarter, the Regulator received two CCI applications in relation to DIR applications. The Regulator made three CCI declarations in relation to DIR 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 Sections focus on management of dealings at field trial sites and within contained facilities certified by the Regulator to ensure:

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

OGTR monitoring activities comprise the functions of routine monitoring including spot checks, assessment of monitoring findings and, where necessary, recommending corrective action and follow-up activities.

OGTR compliance activities comprise reviews of potential compliance risks, investigations, audits and related enforcement activities.

The Monitoring Section conducts routine monitoring visits of a minimum of 20 percent of field trial sites each year. To achieve this goal a minimum of five percent of current trial sites and five percent of trial sites subject to post-harvest monitoring are monitored each quarter.

Monitoring and Compliance Strategy

The purpose of routine monitoring of field trials is to ensure compliance with licence conditions and includes spot checks.

The OGTR strategy for conducting field trial monitoring draws on accumulated operational experience of risk profiling in relation to compliance.

For example, OGTR field trial monitoring coincides, where possible, with periods or circumstances when non-compliance with licence conditions designed to restrict the spread and persistence of the GMOs is more likely to occur (for example, flowering and harvest of GM crops).

The monitoring program for contained dealings involves inspecting DNIRs and the facilities that those dealings are conducted in, as well as monitoring a minimum of 20 percent of PC2 large-scale, PC3 and PC4 facilities per year.

These inspections focus on the integrity of the physical structure of the facility and on the general laboratory practices followed in that facility, including those practices followed for DNIRs and Notifiable Low Risk Dealings (NLRD).

Overview of monitoring and compliance for the reporting period

Total field trial sites monitored: During the 1 July to 30 September 2010 quarter, four GM plant field trial sites under DIR licences were subjected to monitoring visits.

- *Current field trial sites:* Of the 18 sites current in the quarter, one was monitored. This represents a monitoring rate of six percent of all current sites for the quarter.
- *Post-harvest field trial sites:* Of the 44 sites subject to post-harvest monitoring in the quarter, three were monitored. This represents a monitoring rate of seven percent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection with contained dealings covered five organisations and 10 PC facilities. Monitoring of PC facilities encompassed four PC2 laboratories, two PC2 animal containment facilities, three PC2 large scale facilities and, one PC3 laboratory.

Monitoring of contained dealings: During the quarter, the monitoring of the 10 PC facilities mentioned above included monitoring for compliance with the general practices that must be followed when undertaking dealings (e.g. DNIRs) that are required to be conducted within contained facilities.

Four DNIRs were monitored during the quarter.

Monitoring of Dealings involving Intentional Releases

The following table summarises monitoring activities for field trials with GM crop plants for the period 1 July to 30 September 2010.

Licensed Organisation Name	Licence Number	No. sites visited	Site status*	Crop type
Bayer CropScience Pty Ltd, Victoria	DIR 069/2006	3	PHM	Canola and Indian Mustard
Victorian Department of Primary Industries, New South Wales	DIR 089	1	Current	White Clover
Total	**2**	**4**	**Current = 1 *PHM = 3**	

** PHM = post-harvest monitoring.*

The following table summarises monitoring activities for limited and controlled release of GMOs other than plants for the period 1 July to 30 September 2010.

Licensed Organisation Name	Licence Number	No. sites visited	GMO
PPD Australia Pty Ltd, Australian Capital Territory	DIR 097	1	viral vaccine
Total	**1**	**1**	

Monitoring of Dealings Not involving Intentional Release

The following table summarises monitoring activities for DNIRs for the period between 1 July to 30 September 2010.

Licensed Organisation Name	Licence Number
Australian National University, Australian Capital Territory	DNIR 87 and DNIR 478
Bioproperties Australia Pty Ltd, New South Wales	DNIR 391
The University of Sydney, New South Wales	DNIR 376
Total	**4**

Monitoring of Physical Containment Facilities

The organisations and the facility types the OGTR visited during the 1 July to 30 September 2010 quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
Australian National University, Australian Capital Territory	PC2 laboratory PC2 animal containment	3 1
Bioproperties Australia Pty Ltd, New South Wales	PC2 large scale	2
Pfizer Australia Pty Ltd, Victoria	PC2 large scale	1
St Vincent's Hospital Melbourne, Victoria	PC3 laboratory	1
The University of Sydney, New South Wales	PC2 laboratory PC2 animal containment	1 1
Total	**4 facility types**	**10**

Monitoring Findings

Dealings involving Intentional Release

The monitoring findings listed below indicate both the monitoring activities of the OGTR with respect to dealings with GMOs under this Act, in accordance with paragraph 136A(2)(c) of the Act, and the Regulator's response to those findings.

Findings by inspectors of inconsistencies between an event or state of affairs and the requirements imposed by licence or certification conditions are called non-compliances in this report. However, non-compliances are not regarded as breaches of licence conditions unless proven to be so after investigation. Non-compliances with licence conditions are assessed against a number of considerations before determining the OGTR response. The following aspects of the findings are taken into account as relevant:

- the extent of risk to the health and safety of people and the environment
- the severity of the issue or event involved in the finding
- the culpability of the licence holder or other relevant persons in bringing about the issue or event e.g. whether there was a bona fide mistake involved
- the types of mechanisms available to address the issue or event

- the compliance history of the licence holder or other relevant persons
- mitigating factors such as self-reporting or steps taken voluntarily by the licence holder to address the issue or event
- the need for deterrence.

After having regard to those matters, the OGTR has a range of options including additional investigation to determine if further action is warranted e.g. a recommendation of prosecution for an alleged breach of a licence condition or that a licence be suspended or cancelled. A proven breach of a licence condition will be reported in accordance with paragraph 136A(2)(b) of the Act.

In the case of all matters reported below it was decided that the findings of non-compliances with licence conditions were minor in nature, involved negligible or nil culpability, and could be resolved by reminders, education and/or cooperative compliance.

Findings for Dealings involving Intentional Release

There was one finding of non-compliance for a DIR that was finalised in the 1 July to 30 September 2010 quarter.

Organisation	Victorian Department of Primary Industries
Licence number	DIR 089 Site 1
Summary of dealing	Limited and controlled release of white clover genetically modified to resist infection by Alfalfa mosaic virus.
Findings	At the time of inspection, OGTR inspectors noticed that signed copies of training statements had not been updated to reflect the licence conditions as varied on 16 November 2009. The variation included a new method of disposal via a decomposition pit. Updated signed statements were required prior to those dealings taking place.
Assessment	The DPI had informed staff of the new method of disposal, and GM material was being disposed of appropriately, however DPI had overlooked the need to obtain new signed statements. Risks to human health, safety and environment were assessed as negligible.
Compliance management	Following the inspection, a copy of updated signed statements was provided to OGTR by the DPI. The matter has already been addressed by the organisation and no further action is required.

Findings for Dealings Not involving Intentional Release

There was one finding of non-compliance for a DNIR that was finalised in the 1 July to 30 September 2010 quarter.

Organisation	The Australian National University
Licence number	DNIR 478
Summary of dealing	The aim of this dealing is to create interferon-adjuvanted flavivirus vaccines.
Findings	At the time of inspection, the licence holder had not obtained signed statements from all staff undertaking dealings indicating that staff understand and agree to follow licence conditions. It is a Licence condition that signed statements are obtained before dealings commence.
Assessment	The ANU had informed staff of Licence conditions and Licence conditions were being adhered to. The ANU supplied the signed statements for all staff undertaking dealings within two weeks of the inspection. The risks to human health and safety and the environment have been assessed as negligible.
Compliance management	The ANU was reminded of the requirement to have signed statements from each person covered by the licence acknowledging that the licence holder has informed the person of the conditions of the licence that apply to that person and that the person understands and agrees to follow the conditions.

Findings for Physical Containment Facilities

The OGTR's monitoring of certified PC facilities in the quarter found three minor non-compliances with certification conditions in relation to work practise (conditions relating to washing of hands/equipment for washing hands) within facilities. All were found to pose negligible risks to human health and safety and the environment.

Practice Reviews

The OGTR may initiate Practice Reviews in response to observations made during monitoring activities, or to follow up incident reports that may relate to non-compliance with licence conditions by accredited organisations. Their objective is to determine if licence conditions can be, and are being, effectively implemented.

An accredited organisation may request a Practice Review to assess the effectiveness of systems used by its IBC(s) to ensure that dealings are being conducted in accordance with the Act.

The primary focus of the review process is to determine whether or not practices being used pose potential human health or environmental risks that require management actions to be implemented. In certain instances, where a suspected non-compliance with the Act is identified, the issue may be referred for investigation.

There were no practice reviews completed in the 1 July to 30 September 2010 quarter.

Audits

Audits can be initiated by the OGTR or an accredited organisation. An audit can entail:

- documentary evidence
- observations
- assessments of procedures and practices.

These activities are conducted to:

- verify that an accredited organisation has relevant and effective management procedures and practices to meet requirements under the Act, including accreditation requirements, guidelines and any licence conditions applicable to a dealing under the Act
- assess whether or not procedures and practices provide mechanisms to identify and resolve emerging risks
- where appropriate suggest improvements to procedures and practices.

Audits are an opportunity for accredited organisations and the OGTR to share information to improve the risk management of dealings with GMOs under the Act. Audits may focus on a single dealing, a range of dealings (e.g. dealings with a common host organism or dealings within a common climatic zone), the activity of an organisation across a range of dealings, or an activity common to a range of organisations.

There were no audits completed in the 1 July to 30 September 2010 quarter.

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 vulnerability in policies, practices and procedures. An investigation may be initiated as a consequence of monitoring by the OGTR, self-reporting by an accredited organisation or by third party reporting.

There were no investigations completed in the 1 July to 30 September 2010 quarter.

SECTION 3

STATUTORY COMMITTEE OPERATIONS

STATUTORY COMMITTEE OPERATIONS

The Act establishes two committees to provide advice to the Regulator and the Gene Technology Ministerial Council:

- Gene Technology Technical Advisory Committee
- Gene Technology Ethics and Community Consultative Committee.

Appointments to the two gene technology advisory committees were made in 2007 by the then Parliamentary Secretary to the Minister for Health and Ageing, Senator the Hon Jan McLucas.

Gene Technology Technical Advisory Committee

The function of the Gene Technology Technical Advisory Committee (GTTAC) under the Act is to provide scientific and technical advice, on the request of the Regulator or the Ministerial Council, on gene technology, GMOs, GM products, applications made under the Act, the biosafety aspects of gene technology and the need for policy principles, policy guidelines, codes of practice, technical and procedural guidelines in relation to GMOs and GM products and the content of such principles and codes.

GTTAC did not meet during the quarter.

Further information about the work of GTTAC is available from the OGTR website www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gttac-2

Gene Technology Ethics and Community Consultative Committee

The function of the Gene Technology Ethics and Community Consultative Committee (GTECCC) under the Act is to provide advice on the request of the Regulator or the GTMC, on a number of matters, including ethical issues relating to gene technology, the need for and content of policy principles, policy guidelines, codes of practice, community consultation in respect of the process for applications for licences covering dealings involving the intentional release of a GMO into the environment, and risk communication matters in relation to those dealings.

In July 2010, members of GTECCC presented a paper on environmental ethics at the Australasian Association of Bioethics and Health Law (AABHL) Conference.

GTECCC did not meet during the quarter.

Further information about GTECCC is available from the OGTR website www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gteccc-2

SECTION 4

OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

International collaboration and coordination

Under the Act the Regulator's functions include:

- monitoring international practice in relation to regulation of GMOs
- maintaining links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia
- promoting the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies.

International collaboration and coordination activities undertaken during the quarter involved participation in or presentation to:

- 17th Australasian Weeds Conference, Christchurch, New Zealand, 26–30 September 2010
- International biotechnology and risk assessment workshop, Seoul, Korea, 7 September 2010
- Training Workshop 'Confined Field Trial (CFT) for Genetically Modified Crops: A Theoretical and Practical course for regulators, applicant, reviewers and inspectors of CFTs', Accra, Ghana, 30 August–3 September 2010.
- International Risk Assessment Workshop, Brasilia, Brazil, 16–17 August 2010.

Advice on gene technology regulation

The Regulator and the OGTR endeavour to participate in events that inform stakeholders, the Australian community and/or users about the regulatory system.

During the quarter the Regulator attended a Regulators' forum with the prescribed agency regulators who are involved in Australia's regulatory system for gene technology, 25 March 2010.

The OGTR provided presentations to the following:

- Society for Risk Analysis Conference, Sydney, 27–29 September 2010
- CSIRO Protein Expression Workshop, Melbourne, 27 July 2010.

OGTR officers also participated in the following meetings/conferences:

- CropLife Australia forum, Sydney, 23 September 2010
- Australian Food Safety Conference 2010, Risk Communication Master Class, Melbourne, 7 September 2010

- Australian Seed Federation Conference, Cairns, 16–19 August 2010
- International Congress on Parasitology XII, Melbourne, 15–20 August 2010
- Australian Society for Microbiology 2010 Conference, Sydney, 4–8 July 2010
- Australasian Association of Bioethics and Health Law Conference, Adelaide, 2 July 2010.

Reviews

During the quarter the Regulator conducted stakeholder consultation on the draft revised *Guidelines for Certification of a Physical Containment Level 2 Culture Facility*, Version 2.1. These guidelines are intended to replace the *Requirements for Physical Containment Level 2 (PC2) Constant Temperature Rooms*, Version 1.1, which were issued on 7 August 2003.

OGTR website usage and statistics

The OGTR website is a comprehensive source of information on activities of the office. The tables below provide information on the number of hits on the OGTR website and the number of visitor sessions by month and day of week pattern during the 1 July to 30 September 2010 quarter.

MONTH	HITS[1]	VISITS[2]
July	185,257	23,272
August	206,331	24,676
September	200,194	23,994

DAY OF THE WEEK PATTERN FOR THE QUARTER	HITS [1]	VISITS[2]
Sunday	46,207	8,154
Monday	90,108	9,672
Tuesday	101,456	10,938
Wednesday	98,466	10,502
Thursday	103,908	11,554
Friday	101,367	9,838
Saturday	50,270	7,785

1 'A hit' is a request made to the server. Each file that is requested is counted as a hit

2 'Visits' is the number of times the OGTR website has been visited

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

- What's New
- Maps of Trial Sites
- List of applications and licences for Dealings involving Intentional Release (DIR) of GMOs into the environment
- Guidelines and forms for Certification of Physical Containment Facilities
- About the OGTR
- Forms and Guidelines
- Record of GMOs and GM Product Dealings
- IBC & Accredited Organisations Information
- What are Dealings involving an Intentional Release (DIR) of a GMO into the environment?
- Licence Application & Assessment Process

The most popular downloaded documents were:

- *Risk Analysis Framework*
- The Biology and Ecology of Rice (*Oryza sativa*) in Australia
- The Biology and Ecology of Papaya (*Carica papaya*) in Australia
- The Biology and Ecology of Cotton (*Gossypium hirsutum L.*) in Australia
- PC2 Laboratory guidelines
- The Biology and Ecology of Sugarcane (*Saccharum spp.*) in Australia
- The Biology and Ecology of Pineapple (*Ananas comosus var. comosus*) in Australia
- The Biology of Hybrid Tea Rose (*Rosa x hybrida*)
- The Biology of *Zea mays* L. ssp *mays* (maize or corn)
- The Biology and Ecology of *Dianthus caryophyllus* L. (Carnation)

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

Internet contacts and freecall number

OGTR email address and freecall number

The OGTR's 1800 number and email address are points of contact for members of the public and other interested parties to obtain information about the regulation of GMOs. Assistance with specific questions and additional mechanisms for public feedback are among some of the services provided by the 1800 line and email facilities. The table below describes the activity of these facilities throughout the quarter.

MONTH	EMAILS	OGTR 1800 NUMBER
July	76	130
August	79	100
September	76	74

Monitoring and compliance email inbox

The OGTR maintains an email inbox to provide a central point for accredited organisations to contact the OGTR regarding monitoring and compliance matters, such as queries, notifications required under licences, and self reporting of non-compliances. The email inbox ensures that all communications are answered efficiently while monitoring staff are away from the office. The inbox received 150 emails during the quarter.

Statutory Committee email inbox

The Regulatory Practice and Secretariat Section maintain an email inbox to facilitate efficient communication between committee members and secretariat staff.

The inbox ensures that all communications are answered in a timely manner by secretariat staff. The inbox received 282 emails during the quarter.

Application and Licence Management email inbox

This electronic mail inbox provides a central, shared communication point to allow efficient coordination of responses for correspondence and queries about applications received by the Application and Licence Management Section. The inbox received 545 emails during the quarter.

Contained Dealings Evaluation Section email inbox

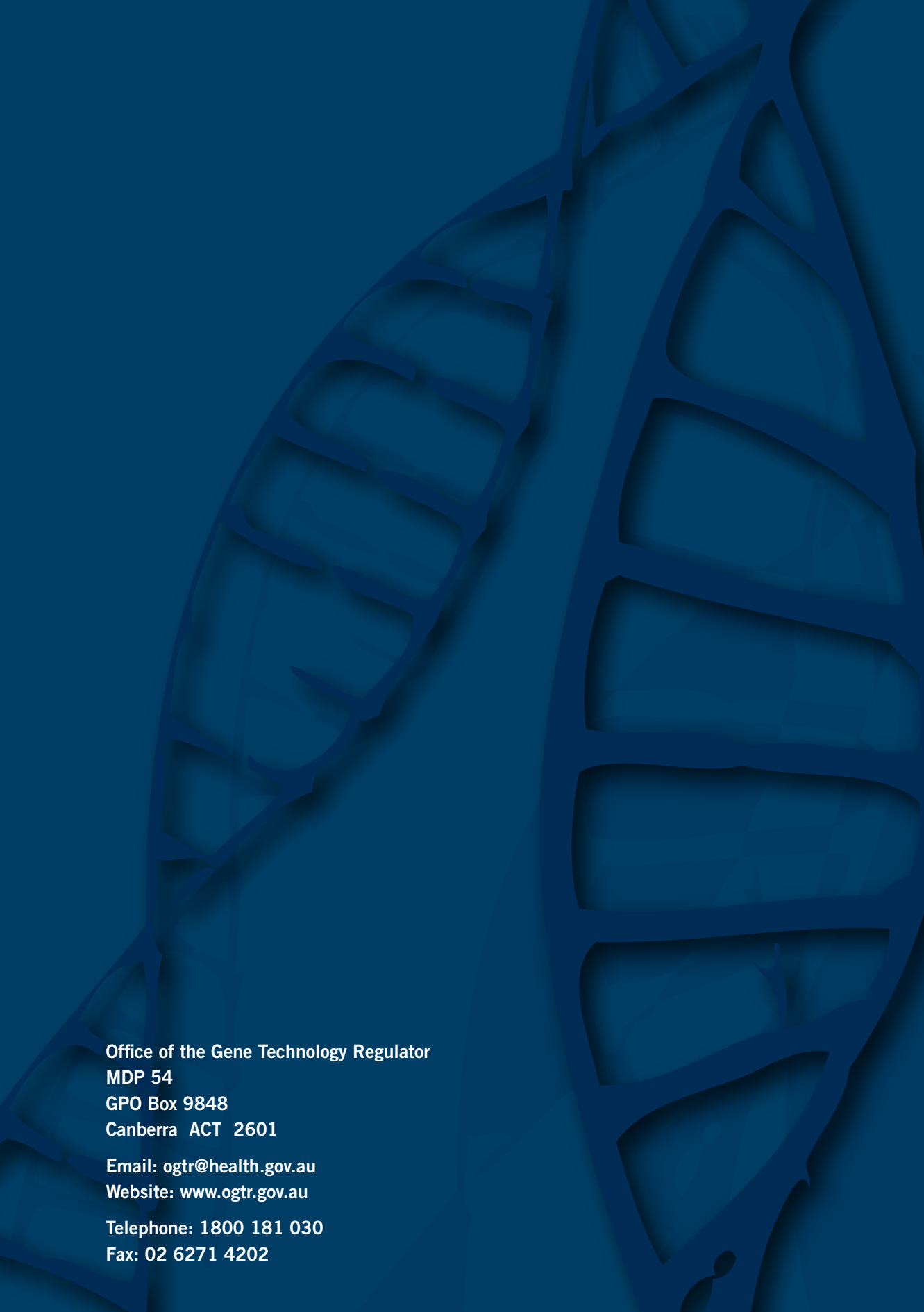
The Contained Dealings Evaluation Section has established an email inbox to provide a central common point for efficient coordination of responses to queries relating to classification of GMO dealings, certification requirements for higher level containment facilities and GMO licences accessed by the contained dealings evaluation section. The inbox received 83 emails during the quarter.

GLOSSARY

This section contains a brief description of terms relevant to an understanding of this quarterly report. They do not substitute for definitions of terms relevant to the operation of the gene technology regulatory system that are contained in section 10 of the *Gene Technology Act 2000*.

Accredited organisation	An organisation that is accredited under section 92 of the Act
Act	*Gene Technology Act 2000*
APVMA	Australian Pesticides and Veterinary Medicines Authority
BSG	Biosecurity Services Group of the Department of Agriculture, Fisheries and Forestry
Breach of a licence condition	A breach of a licence condition which has been proven either in court or by way of admission following investigation
CCI	Confidential commercial information
Certified containment facility	A building or place certified by the Regulator to a specified containment level under section 84 of the Act
Clock stop	The period during which time does not run for purposes of the statutory time limit for making a decision—usually because evaluation cannot proceed until additional information requested from the applicant is received
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DIR	A dealing involving intentional release of a GMO into the environment (e.g. field trial or commercial release)
DIR licence	A licence for a dealing involving intentional release of a GMO into the environment
DNIR	A contained dealing with a GMO not involving intentional release of the GMO into the environment (e.g. experiments in a certified facility such as a laboratory)
DNIR licence	A licence for a dealing not involving intentional release of a GMO into the environment
Expert advisers	Advisers appointed by the Minister to give expert advice to either GTTAC or GTECCC to assist them in the performance of their functions (expert advisers are not committee members)
EDD	Emergency dealing determination

FSANZ	Food Standards Australia New Zealand
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
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTMC	Gene Technology Ministerial Council
GTSC	Gene Technology Standing Committee
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
Incident	A self-reported event which may constitute a non-compliance with regulatory requirements and a public health or environment risk
Limited and controlled release	A type of DIR which meets certain criteria relating to limiting and controlling the dealings with the GMO (e.g. a field trial)
NLRD	Notifiable low risk dealing (work with transgenic plants, animals or microorganisms undertaken in certified contained facilities)
Non-compliance	An inconsistency between an event or state of affairs and the requirements imposed by licence accreditation or certification conditions, or any of the requirements of the Act or Regulations
OGTR	Office of the Gene Technology Regulator
PC1, PC2, PC3, PC4	Physical containment levels of facilities as certified by the Regulator
RARMP	Risk assessment and risk management plan
Regulations	Gene Technology Regulations 2001
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



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