

Interim Office of the Gene Technology Regulator

Quarterly Report

June 2001

Interim Office of the Gene Technology Regulator Quarterly Report

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The Hon. Dr Michael Wooldridge MP
Minister for Health and Aged Care
Parliament House
CANBERRA ACT 2600

Dear Minister

I am pleased to present to you the fifth and last Quarterly Report of the Interim Office of the Gene Technology Regulator (IOGTR). This report covers the period April - June 2001.

As you are aware, the *Gene Technology Act 2000* and the Gene Technology Regulations 2001 came into force on 21 June 2001, and the interim office became the Office of the Gene Technology Regulator (OGTR). This signified the end of the voluntary arrangements that Australia had for the past 25 years, and the start of a new regulatory system for dealings with genetically modified organisms (GMOs).

In this last quarter under the interim arrangements, much work was done and many milestones were achieved to ensure that the transitional arrangements worked smoothly and that systems were in place for the new regulatory regime. During the reporting period:

- approximately 1800 deemed licences, 1700 deemed certifications and 120 deemed accreditations were issued to bring the Genetic Manipulation Advisory Committee (GMAC) approvals in line with the new legislative requirements;
- the *Handbook on the Regulation of Gene Technology in Australia - a user's guide to the Gene Technology Act 2000 and related legislation* was prepared and published. The Handbook is a resource to help organisations conducting work with GMOs to understand and comply with the requirements of the new regulatory system;
- the new OGTR website (<http://www.ogtr.gov.au>) was launched on 21 June 2001 when information on field trial site locations was released for the first time; and
- the IOGTR maintained proactive monitoring of current field trials and sites subject to post-trial monitoring for compliance with GMAC recommendations.

During this quarter, GMAC and its subcommittees continued to provide advice on planned release applications and on non-compliance of GMAC recommendations identified during monitoring and inspection activities. GMAC met for the last time on 18 June 2001 and will now be superseded by a new committee, the Gene Technology Technical Advisory Committee.

Yours sincerely

Elizabeth Cain
Acting Gene Technology Regulator

November 2001

CONTENTS

ABBREVIATIONS AND TERMS		1
SUMMARY	Tracking commitments made in the previous Quarterly Report	2
	Structure of this Report	6
	Further Information	6
PART 1:	A NATIONAL REGULATORY FRAMEWORK	7
1.1	Key results during the reporting period	7
1.2	Key result 1 - The legislation - the Act and Regulations	8
1.3	Key result 2 - Deemed licences - advices and notices	9
1.4	Key result 3 - Handbook on the Regulation of Gene Technology in Australia	10
1.5	Key result 4 - OGTR Website	11
1.6	Other results	12
PART 2	GMAC AND THE VOLUNTARY SYSTEM	14
2.1	Appointments to GMAC	14
2.2	GMAC meetings	14
2.3	IOGTR monitoring strategy	15
2.4	Investigations completed	19
2.5	Investigations underway	24
2.6	Release of information	25
2.7	Audits underway	26
2.8	General release applications	26
2.9	Other activities under the interim arrangements	28
PART 3	THE QUARTER AHEAD	31
Attachment 1	DELIBERATE RELEASE PROPOSALS (FIELD TRIALS)	33

ABBREVIATIONS & TERMS

BA	Biotechnology Australia
CSCG	Commonwealth-State Consultative Group on Gene Technology
DIR	Dealing involving Intentional Release of a GMO
DNIR	Dealing Not involving Intentional Release of a GMO
EA	Environment Australia
GM	Genetically modified
GMAC	Genetic Manipulation Advisory Committee
GR	General Release
GMO	Genetically Modified Organism
GT Act	Gene Technology Act 2000
GTIMS	Gene Technology Information Management System
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
IOGTR	Interim Office of the Gene Technology Regulator
JPRG	Joint Policy Reference Group
NLRD	Notified Low Risk Dealings
NRA	National Registration Authority for Agricultural and Veterinary Chemicals
OGTR	Office of the Gene Technology Regulator
PR	Planned Release
Regulator	Gene Technology Regulator
RSC	Release Subcommittee
SSC	Scientific Subcommittee
Volunteer	Regrowth of plants from seed that has remained on a site after a trial has been completed.

SUMMARY

This is the fifth Quarterly Report of the Interim Office of the Gene Technology Regulator (IOGTR).

The main purpose of this report is to provide information about the function of the IOGTR during the period April - June 2001, as well as the activities undertaken by the Genetic Manipulation Advisory Committee (GMAC), the independent expert committee on the bio-safety of genetically modified organisms (GMOs).

This will be the last report from the IOGTR under the voluntary system. On 21 June 2001 the *Gene Technology Act 2000* (GT Act) came into force and the Office of the Gene Technology Regulator (OGTR) is now established.

In this report, the Office is referred to as IOGTR in relation to activities that occurred prior to 21 June 2001 and as OGTR for those activities that occurred between 21 and 30 June 2001.

Tracking commitments made in the previous Quarterly Report

The January - March 2001 Quarterly Report highlighted 8 key issues that the IOGTR anticipated addressing during the April - June 2001 quarter. A brief summary against those 8 issues follows.

- 1. Finalise the Gene Technology Regulations, in consultation with States and Territories, and make arrangements for them to be laid before Parliament. This final version of the Regulations will be signed by the Governor-General and tabled in Parliament by 21 June 2001.**

The Gene Technology Regulations 2001 were signed by the Governor-General on 30 May 2001 and gazetted on 31 May 2001. The Regulations were tabled in the House of Representatives on 4 June 2001 and in the Senate on 18 June 2001.

- 2. Continue the establishment of the new advisory and consultative committees by calling for nominations from a wide range of key stakeholder groups by early May. Selection of members will take place in late May and June 2001.**

In April 2001, over 400 scientific, consumer, health, environmental and industry groups/individuals were directly invited to submit nominations to new advisory and consultative committees. The list of organisations and individuals invited to nominate was compiled collaboratively with States and Territories. In addition, the call for nominations was posted on the IOGTR website. Nominations closed on 9 May 2001. 164 individual nominations (some for more than one committee) were received.

A working group comprising representatives from the Commonwealth-State Consultative Group (CSCG) was formed to shortlist the candidates. The final shortlist of candidates was then considered by CSCG as a whole. The final decision on membership will be made available on the IOGTR website.

- 3. Issue the Gene Technology Regulation Handbook, a comprehensive handbook on the regulation of gene technology, intended for release prior to the commencement of the new regulatory arrangements on 21 June 2001.**

The Handbook on the *Regulation of Gene Technology in Australia – a user's guide to the Gene Technology Act 2000 and related legislation* was prepared and distributed to key stakeholders (2 per Accredited Organisation) in the week of 21 June 2001. The Handbook was also made available for downloading from the IOGTR website in the same week.

- 4. Issue draft and final deemed licences for all proposals under the existing administrative system. The deemed licences allow work previously considered by GMAC under the current voluntary arrangements to proceed under the new regulatory system. These will apply to all small scale, contained, and deliberate and general release proposals still in progress, and to deliberate release proposals still undergoing post-trial monitoring.**

Draft GMAC advices to proceed with dealings and draft GMAC notices with respect to Notifiable Low Risk Dealings (NLRD), certification of facilities and accreditation of organisations were issued during April and May 2001. Organisations provided updates and corrections to this information during May and June 2001. After consideration of supplementary information from organisations, final advices to proceed and notices were issued by the IOGTR on behalf of GMAC prior to 21 June 2001.

- 5. Prepare standard operating procedures for the processing of applications under the legislative system.**

An application entry point was established within the OGTR to process the receipt of, and to track all applications received by the Gene Technology Regulator (Regulator).

- 6. Commence work on the development of agreements (Memoranda of Understanding) with existing regulatory agencies to cement cooperative arrangements with these bodies under the new regulatory system.**

Initial contact, and some preliminary discussions, in relation to future cooperative arrangements under the new regulatory system (including the placing of Genetically Modified (GM) products approved by other agencies on to the Record of GMOs and GM products) were undertaken with existing regulatory agencies during the reporting period. These relationships will be further clarified and strengthened during the next quarter.

7. Continue monitoring and surveillance activities.

Target rates for monitoring (ie 5% of current trials per quarter) were met during this quarter.

During the April - June 2001 quarter 8 current trial sites were inspected and all were compliant with GMAC recommendations. Additionally, 17 post-trial sites were inspected and 3 were found to require some level of remedial action. The issues observed at the 3 sites were assessed by GMAC and found to present negligible risks to human health safety or the environment in view of the fact that remedial action was taken, and will continue to be taken, to ensure compliance with GMAC recommendations.

The results of 5 completed investigations into alleged breaches are reported this quarter, as well as, an update on 3 investigations currently under way. Further information about monitoring and surveillance is set out at parts 2.3 to 2.7 of this report.

8. Continue preparations for Gene Technology Information Management System (GTIMS) to go live in June 2001, including consultation with, and training for, key users such as Institutional Biosafety Committees (IBCs).

Consultations were undertaken within the quarter and resulted in positive feedback from key users. The initial release date of GTIMS was postponed due to the extension of user acceptance testing and the delays in the finalisation of the Regulations.

Structure of this Report

The structure of this Report reflects the two primary functions of the IOGTR.

Part 1 addresses activities undertaken and outcomes achieved in the April - June 2001 quarter in relation to the development and implementation of the national regulatory framework.

Part 2 outlines work undertaken during the April - June 2001 quarter under the voluntary system of controls over GMOs. It focuses on GMAC's work, and the activities (such as monitoring) undertaken by the IOGTR to support the voluntary system.

Part 3 points to activities expected to be undertaken, and outcomes to be achieved, in the July - September 2001 quarter.

Further information

This fifth Quarterly Report reflects the IOGTR's commitment to provide interested parties with comprehensive information about the oversight of GMOs in Australia. Readers seeking further information are encouraged to contact:

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PART 1: A NATIONAL REGULATORY FRAMEWORK

1.1 Key results during the reporting period

The following key results were achieved in the April - June 2001 quarter:

Key result 1

The GT Act received Royal Assent on 21 December 2000 and came into force on 21 June 2001.

The Gene Technology Regulations 2001 were signed by the Governor-General on 30 May 2001 and gazetted on 31 May 2001. The Regulations were tabled in the House of Representatives on 4 June 2001 and in the Senate on 18 June 2001.

Key result 2

On 21 June 2001, GMAC approved dealings with GMOs were brought into the new regulatory system under the transitional arrangements of the GT Act.

Key result 3

The Handbook on the Regulation of Gene Technology in Australia - A user's guide to the Gene Technology Act 2000 and related legislation has been developed as a resource for organisations that conduct work with GMOs. The Handbook will help organisations to understand and comply with the requirements of the new regulatory system for GMOs, which commenced on 21 June 2001.

Key result 4

On 21 June 2001, the OGTR launched its new website.

Further commentary, on these key result areas and other outcomes from this period, follows.

1.2 Key result 1 - The legislation - the Gene Technology Act and the Regulations

The GT Act, which received Royal Assent on 21 December 2000, came into force on 21 June 2001, replacing the previous administrative system of voluntary controls over dealings with GMOs.

The object of the GT Act 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 GMOs.

Under the GT Act persons are prohibited from dealing with GMOs (including research, manufacture, production, commercial release and import) unless the dealing with the GMOs is:

- Exempt;
- A notifiable low risk dealing;
- On the Register of GMOs; or
- Licensed by the Regulator.

Substantial penalties apply for those failing to comply with the GT Act.

To support the GT Act, the revised draft of the Gene Technology Regulations 2000 was further revised following the second round of public consultation conducted in the previous quarter. The Gene Technology Regulations 2001 were signed by the Governor-General on 30 May 2001 and gazetted on 31 May 2001. The Regulations were tabled in the House of Representatives on 4 June 2001 and in the Senate on 18 June 2001.

The Gene Technology Regulations 2001 give effect to the objects of the GT Act by:

- providing further information about the definitions in the GT Act;
- describing exemptions under the legislation;
- setting out the dealings with GMOs that are NLRD and the conditions which will apply to such dealings;
- describing the types of information that must be provided by an applicant for a licence to deal with a GMO; and
- setting out details of the operation of the three committees established under the GT Act.

The Regulations also prescribe time limits in which the Regulator must consider and decide applications for licences, certification of facilities and accreditation of organisations; prescribe the information which must be included on the public record of GMOs and GM product dealings; and enable facilities and organisations that were operating under the previous voluntary regulatory system to be certified and accredited under the new regulatory scheme.

An explanatory statement and a regulation impact statement were prepared and tabled in Parliament to accompany the Gene Technology Regulations 2001. These documents, along with GT Act and Regulations, can be accessed from the OGTR website (<http://www.ogtr.gov.au/publications/index.htm>).

1.3 Key result 2 - Deemed licences - advices and notices

On 21 June 2001, GMAC-approved dealings with GMOs were brought into the new regulatory system under the transitional arrangements of the GT Act.

Prior to the commencement of the GT Act on 21 June 2001, final GMAC advices and notices were issued to organisations by the IOGTR on behalf of GMAC. This gave effect to 'deemed' licences for dealings not involving the release of a GMO into the environment (DNIRs), dealings involving the release of a GMO into the environment (DIRs), and to deemed NLRD. Deemed certification of facilities to specified physical containment levels, and accreditation of organisations also came into effect on 21 June 2001. A summary of the number of deemed licences and notices that have been issued is shown below.

<u>Type</u>	<u>No. Issued</u>
Deemed DNIR licences	494
Deemed DIR licences	109
Deemed NLRD	1222
Deemed Certifications	1680
Deemed Accreditations	119

Further information on deemed licences, deemed NLRD, deemed certifications and deemed accreditations can be accessed from the OGTR website.

1.4 Key result 3 - Handbook on the Regulation of Gene Technology in Australia

The *Handbook on the Regulation of Gene Technology in Australia - A user's guide to the Gene Technology Act 2000 and related legislation* has been developed as a resource for organisations that conduct work with GMOs. The Handbook will help organisations to understand and comply with the requirements of the new regulatory system for GMOs, which commenced on 21 June 2001.

It is expected that the Handbook will be used as an ongoing resource for applicants or users of the regulatory system. It has been developed in a folder format to allow for easy replacement of sections as information is updated to reflect any amendments to the gene technology legislation. The Handbook is available from the OGTR website.

The Handbook includes chapters on each of the key aspects of the regulatory system including:

- dealings with GMOs that are, and are not, regulated under the national regulatory scheme;
- exempt dealings with GMOs;
- NLRD with GMOs;
- licensed dealings with GMOs not involving the intentional release of a GMO into the environment;
- licensed dealings with GMOs involving the intentional release of a GMO into the environment;
- dealings with GMOs on the GMO Register;
- import and transport of GMOs;
- accreditation of organisations;
- certification of facilities;
- review of decisions made under the legislation;
- reporting, monitoring and enforcement;
- the website and GTIMS; and
- fees and charges.

The Handbook also includes as appendices:

- Application forms for accreditation of organisations, certification of facilities, licences to deal with GMOs and NLRD;
- Guidelines for the Accreditation of Organisations;

- Guidelines for the Certification of Facilities/Physical Containment Requirements;
- Guidelines for Good Industrial Large Scale Practice; and
- Risk Analysis Framework for Licence Applications before the Office of the Gene Technology Regulator.

1.5 Key result 4 - OGTR Website

The new OGTR website (<http://www.ogtr.gov.au>) was fully operational on 21 June 2001. The website includes information on DIRs, DNIRs and NLRD as well as GMO field trial site locations.

The new website has facilities to provide information on:

- the OGTR;
- the GMO Record (including crop trial site information);
- publications;
- committees;
- media information;
- general information;
- accredited organisations;
- the former voluntary system;
- related sites; and
- contacting the OGTR.

On the first day of the OGTR internet site, Excite Australia (in partnership with the ABC) reported that the website had over 80,000 hits, despite technical difficulties encountered by the server. Community interest focused on GMO field trial sites and on companies seeking a Confidential Commercial Information status for field trial sites.

The OGTR recognised from the outset that enhancements to the public record of GMOs would be needed. Work has now commenced on a range of enhancements to the public record of GMOs, eg providing GM trial site locations in map format, the provision of summary information and improved searching facilities.

1.6 Other results

Working collaboratively with States and Territories

The IOGTR continued to work collaboratively with officials from all State and Territory Governments, meeting under the auspices of the CSCG to further develop the national regulatory framework.

During the reporting period, the CSCG met twice on 1 - 2 May and 7 June 2001.

Some of the key matters dealt with by the CSCG in the reporting period included the:

- development of the OGTR Handbook;
- finalisation of the Regulations and Explanatory Guide;
- final transitional arrangements necessary to move from the current voluntary system to the new regulatory system;
- recruitment of the Regulator;
- selection process for the Gene Technology Technical Advisory Committee (GTTAC), the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee;
- funding for the OGTR; and
- risk assessment process for the OGTR.

Commonwealth agency liaison

The close partnership between the IOGTR, Commonwealth agencies and existing regulators continued during the April - June 2001 quarter.

The partnership between these bodies and the IOGTR primarily operates through an Inter-departmental Committee which met twice on 1 May and 6 June 2001. Issues discussed were essentially those reported for the CSCG above.

The IOGTR continued to work closely with the Office of the National Health and Medical Research Council in this quarter on the issue of implementing the prohibitions on human cloning and on certain inter-species experiments involving human material. These prohibitions were introduced into the GT Act during parliamentary debate on the legislation.

The role and contribution of non-government organisations

A key focus of consultation with non-government stakeholders during the April - June 2001 quarter was nominations for the three gene technology advisory committees. Over 400 scientific, consumer, health, environmental and industry groups/individuals were directly invited to submit nominations to the committees. Additionally, the call for nominations was posted on the IOGTR website. Nominations closed on 9 May 2001.

Consultation and Information sessions for IBCs on GTIMS

The following sessions were held to demonstrate the functionality of GTIMS and future enhancements and to gather feedback from key users:

- Canberra, 5 June 2001;
- Sydney, 6 June 2001;
- Brisbane, 7 June 2001; and
- Melbourne, 8 June 2001.

Presentations

Staff of the IOGTR endeavour to participate in discussions on gene technology wherever possible to inform the community about the new regulatory system. During the reporting period, in addition to the purpose specific consultations on the draft Gene Technology Regulations, the IOGTR made presentations at the following forums:

- Grains Week 2001 - Grains Council of Australia 5 April 2001, in Sydney;
- The Biotechnology Revolution Conference - Investment, skills, ethics and regulations, 6 April 2001, in Melbourne;
- South Australian Development Committee - Biotechnology Inquiry, 11 May 2001, in Adelaide;
- Grassland Society of Victoria Inc, 11 May 2001, in Launceston, Tasmania; and
- Mayors and CEOs of Strathbogie Shire Meeting, 21 June 2001 in Collingwood, Victoria.

PART 2: GMAC AND THE VOLUNTARY SYSTEM

2.1 Appointments to GMAC

Members of GMAC are appointed by the Minister for Health and Aged Care.

No new appointments were made during the April - June 2001 reporting period.

2.2 GMAC Meetings

GMAC

GMAC, chaired by Professor Nancy Millis, met once during the reporting period on 18 June 2001 and considered matters relating to planned releases of GMOs into the environment. This was the final GMAC meeting before the introduction of the new gene technology legislation on 21 June 2001. Under the new legislative system, GMAC will be replaced by the GTTAC.

The Scientific Subcommittee (SSC)

The SSC, chaired by Professor Jim Pittard, met once during the reporting period on 27 April 2001. The SSC:

- considered *ad hoc* scientific matters relating to genetic manipulation work in containment facilities; and
- reviewed 11 proposals for the release of GMOs into the environment, of which 3 were new proposals for field trials, and 8 were extensions to proposals previously assessed by GMAC. Summaries of the field trials are at Attachment 1.

The SSC worked on a number of matters out-of-session. The SSC played a key role in the development of the Gene Technology Regulations 2001 and developed an explanatory paper justifying exempt dealings and NLRD.

The Release Subcommittee (RSC)

The RSC met twice during the reporting period on 27 April and 25 May 2001. The 27 April 2001 meeting was chaired by Professor Millis. The 25 May 2001 meeting was chaired in Professor Millis' absence by Dr Ian Parsonson. The RSC reviewed 17 proposals for the release of GMOs into the environment, of which 7 were new proposals for field trials, and 10 were extensions to proposals previously assessed by GMAC. Summaries of the field trials are at Attachment 1 (note: of the 17 proposals presented in Attachment 1 all were reviewed the RSC and 11 were reviewed by the SSC).

The RSC worked on a number of matters out-of-session. The RSC:

- played a key role in the development of the Gene Technology Regulations 2001;
- provided advice on remedial actions to be taken in several instances where GMAC conditions for planned releases of GMOs were not complied with; and
- provided advice on requests from proponents for variation of conditions for the conduct of trials.

2.3 IOGTR monitoring strategy

The IOGTR has undertaken to carry out random inspections of 20% of the field trials involving GMOs in a calendar year to ensure compliance with GMAC recommendations for the management of trial sites. A minimum of 5% of trials are to be inspected each quarter. This monitoring strategy will continue under the OGTR. In addition, on the basis of experience over the last 12 months, the OGTR is revising the monitoring strategy to include risk profiling and a greater focus on monitoring of post-trial sites.

The purpose of GMAC's recommendations for the management of trial sites, both during current crop trials and for certain periods following these trials, is to:

- minimise dissemination of a GMO and its genetic material;
- minimise the persistence of the GMO in the environment; and
- ensure the full control of the GMO is maintained.

Terminology used in this section

The following terms are used in this section to describe observations by IOGTR monitoring staff.

Compliant: the trial site was found to be in compliance with GMAC recommendations at the time of the monitoring visit.

Issues: the trial site presented issues that may lead to non-compliance with GMAC recommendations and may therefore require remedial action to rectify potential problems.

Non-compliant: the trial site did not comply with GMAC recommendations and required remedial action to bring the site back into compliance. There are various degrees of non-compliance based on the risk posed, ie negligible, low, moderate and high risk.

Summary of current and post-trial monitoring in the reporting period

Of 8 current trial sites randomly inspected, all were compliant with GMAC recommendations. Of 17 post-trial sites that were inspected, 3 required some level of remedial action to ensure compliance with GMAC recommendations.

The issues observed at the 3 sites were assessed by GMAC and were found to present negligible risks to human health safety or the environment in view of the fact that remedial action was taken, and will continue to be taken, to ensure compliance with GMAC recommendations.

Inspection of current trial sites

In the April - June 2001 quarter, the IOGTR inspected 8 current sites for compliance with GMAC recommendations. These 8 sites represent approximately 5% of current trials, therefore, during this quarter, the minimum target of 5% of current trial sites to be inspected per quarter was met. Inspections of current trials spanned 7 Planned Release (PR) proposals (PRs: 73, 89x(2), 95, 104, 108, 136, 137) covering 5 crop types: sugarcane, cotton, pineapple, grapevine and papaya. All of the sites inspected were compliant with GMAC recommendations.

CURRENT TRIAL SITE INSPECTIONS

Quarter	Sites	Proponent	Crop type	No. of sites under PR	No. of sites inspected	No. of sites with 'issues'	No. of sites non-compliant
Quarter 2 Apr-Jun 01	73	CSIRO	Sugarcane	3	1	0	0
	89X(2)	CSIRO	Cotton	3	2	0	0
	95	University of QLD	Pineapple	1	1	0	0
	104	CSIRO	Grapevine	1	1	0	0
	108	Dept. Prim. Industries (QLD)	Papaya	1	1	0	0
	136	CSIRO	Sugarcane	3	1	0	0
	137	CSIRO	Pineapple	1	1	0	0
QUARTER 2, 2001 TOTAL				13	8	0	0

Inspection of sites subject to post-trial monitoring

In addition to inspections of current trial sites during the quarter, the IOGTR conducted inspections of 17 sites subject to post-trial monitoring. The trial sites covered cotton and canola crops.

Sites were selected for inspection on the basis of their location and suitability for the regrowth of the trial crop over the autumn period. Fewer sites were monitored during this quarter than in the previous quarter due to the seasonal change in growing conditions.

Inspections of sites subject to post-trial monitoring spanned 5 PR proposals (PRs: 62X(4), 63X(4), 77X, 77X(2) and 87X(2)).

None of the sites were found to be non-compliant with GMAC recommendations. However, PR87X(2) had 3 sites identified as having issues (more detailed information is provided in the following section).

POST TRIAL SITE INSPECTIONS

Quarter	Sites	Proponent	Crop type	No. of sites under PR	No. of sites inspected	No. of sites with issues	No. of sites non-compliant
Quarter 2 Apr-Jun 01	62X(4)	Aventis	Canola	15	5	0	0
	63X(4)	Aventis	Canola	95	4	0	0
	77X	Monsanto	Canola	18	1	0	0
	77X(2)	Monsanto	Canola	30	1	0	0
	87X(2)	AGWEST	Cotton	17	6	3	0
QUARTER 2, 2001 TOTAL				175	17	3	0

PR87X(2)Summary of the trial

PR-87X(2) relates to field trials of GM cotton conducted by Agriculture Western Australia (AGWEST). The cotton has been modified to be resistant to insects.

Conduct of the inspection

IOGTR inspected 6 sites out of 17 to ascertain compliance with GMAC recommendations.

Findings

The IOGTR found that 3 of the 6 sites had low numbers of plants that had survived cultivations and herbicide treatments during the wet season.

At three sites, a number of cotton plants were observed, ranging from 2 to 1000 plants, which had survived the wet season and reached seed set. This represents low survival rates in comparison to the numbers of plants on the site during the trial. In each case, the AGWEST was monitoring the site and ensuring that the collaborating farmers were destroying the plants when soils sufficiently dried out after the wet season to allow an opportunity to undertake more effective control.

GMAC found that the issue of plants surviving wet season conditions to reach seed set, presented negligible risks to human health safety or the environment.

Remedial action

At all three sites, cultivation, herbicides and hand chipping will be used to control any subsequent emergence of volunteer cotton plants.

At each of these three sites monthly inspections will be carried out for a period of twelve months after the last live cotton plant is found, and OGTR will conduct monitoring inspections of all sites under PR-87X(2).

The OGTR recognises the practical difficulties of destroying volunteer plants during wet season conditions when wet soils may make effective control difficult during this period of time. A review of conditions pertaining to PRs in tropical environments, including management procedures, will be conducted by the OGTR in consultation with AGWEST.

2.4 Investigations completed

The IOGTR completed 5 investigations into allegations that GMAC recommendations for GM crop trials had been breached.

Non-Compliance

Unaccounted for seeds in pea field trial in Western Australia

Notification of the alleged breach

On 4 January 2001 the AGWEST IBC informed IOGTR that a 1 kg bag of transgenic field peas was missing. The bag of peas was harvested from a transgenic field pea trial conducted under PR-113. The trial site was located at Northam in Western Australia.

GMAC recommendations for trial

The current GMAC recommendations for this trial state:

- that the seed shall be carried in a primary container, which is packed in a secondary unbreakable container;
- the outer container shall be labelled to indicate that it contains transgenic plant material, and the label shall include the telephone number of a person to contact should the package be lost or damaged. Labels on seed packets shall include the quantity of seed being transported;

- accounting procedures shall be in place to ensure that the same number of plants or containers sent is delivered; and
- harvested seed will be either destroyed or used in subsequent experiments.

The investigation

As well as the IOGTR investigation, an internal audit was conducted by AGWEST of the harvesting and storage processes and the disappearance of the bag. Investigations indicated that the bag did exist and that appropriate accounting procedures were in place.

The Western Australian Police Service is currently conducting an investigation into the disappearance of the bag of peas. The IOGTR investigation will be reopened if new information becomes available as a result of the police investigation.

The findings

The IOGTR investigation found that the accounting procedures used during the harvest and transport of the peas were satisfactory and that these procedures determined that the bag of peas was missing.

The most likely scenario is that the bag was collected as garbage and subsequently buried at a landfill. Disposal of genetic material in landfill is considered an acceptable method for destruction of genetic material, however, AGWEST is unable to confirm that this was indeed the fate of the missing bag of peas. Therefore AGWEST is considered to have breached the GMAC recommendations for this trial.

Risk assessment and management

GMAC expressed satisfaction at the level of concern expressed by the Project Supervisor and that appropriate steps have been taken to avoid a similar event in the future.

In the event that the peas in the bag do germinate either in a land-fill situation or some other situation, GMAC has noted that the level of out-crossing of field peas under field conditions in Australia is very low, and that hybridisation of the transgenic pea plants with surrounding plants is therefore unlikely. Results from previous field trials in Australia support this conclusion. GMAC has also noted that neither peas nor any other members of the genus *Pisum* are regarded as weeds in Australia.

Based on the information provided, GMAC concluded that the breach posed negligible risk to human health safety or the environment.

Volunteer GM cotton at Shamrock Gardens, Broome Western Australia

Notification of alleged breach

The alleged breach was reported in the *West Australian* newspaper on 11 April 2001. The article stated that a GM cotton trial on a property 150km south of Broome had resulted in seeds being left behind allowing volunteers to grow on the site. The claim was made by Broome based environmental agency Environs Kimberley.

GMAC recommendations for trial

The current GMAC recommendations for this trial state:

- that plant material remaining after harvest will be destroyed by stalk pulling and mulching prior to incorporation into the soil;
- the field sites will either remain fallow or be planted to a rotation crop the following winter; and
- volunteer plants will be killed by cultivation and/or herbicide treatment.

The investigation

Investigations by the IOGTR determined the site the newspaper article was most likely referring to was a trial conducted by AGWEST under PR-87X on the property at Shamrock Gardens. The management of the site for AGWEST was undertaken by Western Agricultural Industries (WAI) on land leased from the owners of Shamrock Gardens. The last trial occurred on the site in 1999.

Officers from the IOGTR attended the site on 2 May 2001 in the company of WAI representatives and an independent expert from CSIRO. A number of sites were inspected which had been operated under PR-87 and PR-87X. The site identification numbers are A1, A2, H1 and J1.

The findings

The IOGTR officers observed five volunteers around the perimeter of site H1 under PR-87X. Two of the volunteers had reached maturity with seed set occurring. The bolls had opened and lint was clearly visible outside the bolls and both plants were approximately 45- 60 cm in height. Remedial action was taken with all the volunteers being removed from the site to be burnt by WAI representatives.

Risk assessment and management

GMAC considers that this breach represents negligible risk to the human health safety or the environment.

The risk associated with the mature volunteers located at Shamrock Gardens is that once cotton reaches seeding stage, viable seed can drop to the ground and new plants can emerge as volunteers.

The GM cotton volunteers found at Shamrock Gardens were removed and destroyed and GMAC recommends that the site be monitored until there have been 12 months clear of volunteers.

Other Investigations

Alleged presence of GM canola along roadsides in Tasmania

It was brought to the attention of the IOGTR on Wednesday 4 October 2000 that volunteer canola plants growing on the sides of roads in north-east Tasmania may be of GM origin.

Discussions between the IOGTR, the Tasmanian Department of Primary Industries, Water and Environment, and the companies involved in GM canola research in Tasmania resulted in a consensus opinion that the roadside canola is more than likely commercial non-GM canola (the majority of commercial non-GM canola in Tasmania is grown in the north-east and would be transported over the roads in question).

The companies involved agreed to monitor the roadside and remove any brassica plant found in a 300 km section of the roadside for the 2000-01 summer and for a further two seasons.

The OGTR is seeking to undertake independent testing of any suspected plant material found on the roadside. The companies involved in monitoring the roadsides have committed to notify OGTR of any findings of significant populations of canola. The OGTR will also be undertaking monitoring of the roadsides.

Given this level of continual monitoring of the roadside there is a very low risk to the environment in the unlikely event that any volunteers are found to be of GM origin.

Allegations that crop residue removed from GM trial site and sold

On 14 December 2000, the IOGTR received correspondence raising concerns that GM crop residue had been mistakenly sold and that harvesting equipment had not been properly cleaned following harvest of a transgenic crop.

One of the GMAC requirements for this particular trial site was that any residual material be incinerated.

The IOGTR investigated the allegation and found that the management practices used throughout the harvest of the GM crop and during post harvest destruction of the crop residue had been satisfactory. The crop residue had been destroyed according to GMAC recommendations and the harvesting equipment had also been cleaned appropriately.

The information relating to the type of GM crop, the location of the trial and the organisation involved has not been provided as the provision of this information may unfairly damage the reputation of third parties who have not breached GMAC recommendations.

Use of mis-identified DNA construct

On 22 March 2001, the IOGTR received information from a research organisation stating that an incident had occurred during a transgenic project. A DNA construct with human growth hormone had been used instead of a DNA construct with human serum albumin.

The use of a mis-identified DNA construct was discovered when testing of the DNA construct used in the project revealed it contained human growth hormone. Further testing revealed that the DNA construct had not been successfully incorporated during the transgenic project.

The IOGTR sought and received detailed information from the research organisation on the procedures used throughout this project and on steps taken to prevent similar incidents from occurring in the future.

GMAC has considered the incident and believes that there was no risk either to human health safety or the environment as a result of the use of this mis-identified DNA construct.

As a GMO was not created, a case of non-compliance was not found during the investigation. The specific information relating to the type of transgenic project and the organisation involved has not been provided as the provision of this information may unfairly damage the reputation of third parties where a non-compliance was not found.

2.5 Investigations underway

As at 30 June 2001, the OGTR had 3 ongoing investigations into alleged breaches of GMAC recommendations which were carried over from the voluntary system. The 3 investigations, described below, are expected to be finalised later this year.

Update on post-trial Aventis CropScience and Monsanto canola trial sites in Tasmania

On 6 April 2001, the Minister for Health and Aged Care publicly released the penultimate draft investigation reports into non-compliances at 21 canola trial sites in Tasmania. The reports specified detailed findings and actions for 18 Aventis CropScience non-compliant sites and 3 Monsanto non-compliant sites.

Since the release of the penultimate draft reports the IOGTR has revisited the non-compliant sites on several occasions. The IOGTR conducted further monitoring of non-compliant sites from 4 April to 10 April 2001 and again on 19-20 June 2001. All sites exhibited a high level of compliance with GMAC recommendations at the time of the visits. Post 21 June 2001, the recommendations within the penultimate draft reports became conditions for the relevant Aventis CropScience and Monsanto deemed licenses under the new regulatory system.

The OGTR began work to put in train a gene flow study around the 21 non-compliant sites in Tasmania. A draft experimental protocol has been

developed and a study will commence later in the year when conditions are suitable for both weed development and herbicide use.

Seeds being transported off Aventis CropScience canola trial sites in boots of workers

On 18 April 2001, the IOGTR was informed of a possible breach of GMAC recommendations at canola trial sites in the Mount Gambier area. Allegations were made that seed was being inadvertently transported off trial sites in or on the boots and clothing of workers harvesting the GM seed from the trial sites.

An IOGTR monitoring team visited trial sites in Mount Gambier and viewed a demonstration of harvesting techniques to ascertain the likelihood of significant amounts of seed leaving sites in or on boots and clothing of workers. IOGTR monitoring of sites including access tracks, roadways and farm gates where seeds could be expected to be deposited if being carried off trial sites in or on boots and clothing of workers, found no volunteer canola growth to-date.

Aventis CropScience provided information to the IOGTR to assist in the investigation. The original source of the allegations also provided additional information to the IOGTR to assist in the investigation. As at 30 June 2001, investigations are continuing into the allegations.

2.6 Release of information

On the advice of the Australian Government Solicitor, the IOGTR releases limited information about an alleged breach while it is under investigation because the information may:

- be protected by legislation (eg. the *Privacy Act 1988*);
- be commercial-in-confidence information;
- unfairly damage the reputation of a company or individual under investigation if the allegation is not subsequently proven; and
- unfairly damage the reputation of third parties who have not themselves breached GMAC recommendations.

The application of this policy does not apply to breaches or alleged breaches that the IOGTR (on expert advice from the GMAC and other relevant sources) believes present a serious risk to human health safety or the environment. All such breaches will be notified immediately, pending the outcome of any investigation.

2.7 Audits underway

Report on audit of University of Western Australia (UWA)

During the quarter, the IOGTR continued its audit into the management of GM lupin trials in 1997 and 1998 conducted by the UWA. The objectives of the audit are:

- to identify whether there are any deficiencies in the processes employed to control sites which were the subject of field trials under PR74, PR75 and PR76, and that this control was in accordance with the post-trial recommendations made by the GMAC; and
- to identify and consider options for action in relation to any deficiencies identified in the above process.

The audit was in response to the findings of two previous breach investigations of UWA lupin trials by the IOGTR. The audit report will be made publicly available when completed.

2.8 General Release Applications

Assessments completed/approvals granted

No general release application assessments were completed during this reporting period, and no approvals for general release applications were granted.

The risk assessment of the general release proposal for insect-resistant (INGARD[®]) cotton, was carried over from the last quarter.

The use of INGARD[®] cotton is currently regulated by the *Agricultural and Veterinary Chemicals (Code) Act 1994* which is administered by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA). INGARD[®] was registered for commercial use by the NRA, following consultation with GMAC, in 1996.

In 2000, the NRA advised the IOGTR that it intended to amend the *Agricultural and Veterinary Chemicals (Code) Act 1994* to remove references to macroorganisms. This amendment would have limited the NRA's capacity to regulate INGARD[®] cotton. These amendments were intended, at the time, to take effect from the time the *Gene Technology Act 2000* took effect, clarifying responsibility for the regulation of this GMO.

On this basis, Monsanto submitted an application for General Release of INGARD[®] cotton on 5 September 2000 seeking approval for a further five years and the IOGTR commenced a reassessment of risks associated with INGARD[®] cotton.

The NRA has advised that amendments excluding macroorganisms have not progressed according to the timetable anticipated in 2000 and that they will not be finalised in the foreseeable future. In the absence of changes to the NRA legislation, the registration of INGARD[®] by the NRA will continue for at least another two years.

The draft risk assessment prepared by the IOGTR concluded the continued general release of INGARD cotton did not constitute significant risks to human health safety or the environment. GMAC approved this assessment. An assessment by Environment Australia (EA) of the proposed continuation of general release of INGARD[®] cotton also concluded that the general release should be extended.

The GT Act establishes a process for moving all GMOs considered by GMAC under the voluntary system into the new legislative system. Section 190 of the GT Act provides for those dealings for which an Advice to Proceed had been issued by the GMAC to be 'deemed' to be licensed for the purposes of the GT Act. The specific conditions of the advice to proceed constitute the conditions of the licence. These deemed licences are for a period of two years.

Guided by the provisions of section 190 of the GT Act, GMAC issued an Advice to Proceed prior to 21 June 2001 in relation to the general release of INGARD[®] cotton under proposal GR-3, to bring it under the regulatory requirements set out in GT Act. The conditions of the deemed licence address issues of concern identified through the risk assessment process, including issues raised by the States and Territories.

INGARD[®] cotton is one of the few GMOs that is subject to dual regulation, as the NRA registration of this GMO will continue to be in force for the foreseeable future.

New general release applications

No new general release applications were received in this quarter.

2.9 Other activities under the interim arrangements

Freedom of Information (FOI)

No FOI requests were received during the reporting period.

Information Bulletins

No information bulletins were issued during this quarter.

International coordination activities

During the April - June 2001 quarter, the IOGTR continued to build and maintain international contacts on gene technology regulatory matters with Australian officers in Australia's overseas posts and with interested officials from other Governments. New Zealand's Royal Commission on Genetic Modification and the development of new gene technology regulatory requirements in the European Union were particular focal points.

The IOGTR provided briefing and/or information on the proposed new regulatory system for GMOs to Government officials from China, the European Commission and the United States.

Also during the reporting period the IOGTR:

- coordinated Commonwealth Government input into the June 2001 meeting of the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology;
- continued to provide input into activities stemming from agreement of a final version of the Biosafety Protocol in Montreal on 28 January 2000, including analysis of the potential impact of the Protocol on Australia's proposed domestic legislation; and
- continued to provide input into activities relating to the development of a protocol under the Biological Weapons Convention. The IOGTR's participation in this effort is to ensure that Australia's experience in gene technology assists in harmonising biotechnology-related definitions and risk assessment processes internationally, and to assist in analysing the potential impact on Australia's proposed domestic legislation.

Collaboration in other regulation-related activities

Research program on environmental risk of GMOs

The aim of this program is to fund research that will:

- enhance our knowledge of environmental risks relating to GMOs; and
- develop or improve risk assessment tools that may be used by regulatory agencies, research organisations and commercial organisations.

The OGTR participates in the Joint Policy Reference Group (JPRG) which was formed to enhance collaboration and coordination between the collaborating agencies. The JPRG includes representatives from OGTR, CSIRO and EA. The JPRG has identified common priorities for research within this program. Work has commenced on several projects and the JPRG monitors progress.

The JPRG did not meet during this reporting period.

Biotechnology Australia coordination activities

Biotechnology Australia (BA) is the Commonwealth Government's coordinating agency for the portfolios having an interest in biotechnology issues.

The BA portfolios are the Department of Industry, Science and Resources; Agriculture, Fisheries and Forestry Australia; EA; the Department of Health and Aged Care; and the Department of Education, Training and Youth Affairs.

During the April - June 2001 reporting period, the IOGTR continued to coordinate Health portfolio input to BA public information products and services, BA programs (such as the Biotechnology Innovation Fund), BA working groups and participated in the BA regional forum on 11 May 2001 in Launceston. The IOGTR also coordinated the Department of Health and Aged Care's input into the BA Cabinet submission on progress with implementing the National Biotechnology Strategy.

Further information on BA can be obtained at its website (<http://www.biotechnology.gov.au/>).

Consultants

During the reporting period, the IOGTR managed 9 existing contracts with:

- Matthews Pegg Consulting for strategic legal/policy advice on developing a national regulatory framework for GMOs;
- Dialog for the development of the database system to facilitate the national regulatory system;
- Luminis Pty Ltd, a consultancy company, for expert support (weed/crop production experts) to IOGTR inspection teams in relation to canola and poppy trials;
- McNiece Communications Pty Ltd for continued communications support and advice to the IOGTR;
- Cordiner King Hever, an executive search agency, for undertaking the recruitment of the Gene Technology Regulator;
- Acumen Alliance (ACT) Pty Ltd for the purpose of providing project management for development of the database system to facilitate the national regulatory system;
- Outlook Biotech for undertaking inspections of biocontainment facilities to produce a report assessing their compliance with certification requirements;
- Oceania Health Consulting for assistance in the development of the Risk Assessment Guidelines; and
- Swell Design for developing graphics for the IOGTR stationery and website.

PART 3: THE QUARTER AHEAD

During the forthcoming quarter (July - September 2001), the OGTR will undertake the following activities:

- Further develop the procedures and guidelines for processing:
 - applications to conduct dealings involving an intentional release of a GMO into the environment;
 - applications to conduct dealings not involving an intentional release into the environment;
 - notices in respect of Notifiable Low Risk Dealings;
 - applications for certification of facilities;
 - applications for accreditation of organisations;
 - variations to licence conditions; and
 - applications for protection of confidential commercial information.
- Finalise any outstanding matters from the voluntary system.
- Develop a schedule for review of deemed licences, NLRD, accreditations and certifications.
- Prepare a tender brief and contract for review of the certification guidelines.
- Develop proformas for:
 - accredited organisations annual reports;
 - IBC record of exempt dealings; and
 - incident reporting.
- Finalise the membership for the Gene Technology Technical Advisory Committee, the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee. Set the dates and agendas for the first meetings of each committee.
- Finalise the recruitment for the appointment of the first Regulator.
- Respond to all persons or organisations, where possible, who are seeking advice on the new regulatory system.

- Assist the Minister for Health and Aged Care in responding to queries from Parliamentarians in relation to the Gene Technology Regulations 2001.
- Continue work on the development of agreements with existing regulatory agencies to cement cooperative arrangements with these bodies under the new regulatory system.
- Ensure GM product information from existing regulators is adequately and accurately captured on the Record of GMOs and GM products.
- Fully implement and maintain an efficient applications entry point for all new applications received by the OGTR.

ATTACHMENT 1

DELIBERATE RELEASE PROPOSALS (FIELD TRIALS)

Public Information Sheets are not yet available for the proposals. The summaries that appeared in the Government Notices Gazette have been provided.

PR-147: Control small scale limited field trial of transposon marked derivatives of *Pseudomonas* (bacteria) on wheat roots in soil

Organisation proposing release: Australian National University
Canberra ACT 0200

Organism to be released: *Pseudomonas fluorescens* sp., strain AN5

Purpose of the release: Take-all disease affects the roots of plants such as wheat. Currently there are no control methods for this disease and biological control methods using bacteria such as *Pseudomonas* are the subject of intensive research worldwide.

In this field trial genetically modified strains of *Pseudomonas* bacteria will be evaluated for their ability to protect wheat plants against the fungal disease take-all. A total of 13 different *Pseudomonas* strains will be evaluated in this trial.

Brief description of the nature and effect of the genetic modification: Bacteria of *Pseudomonas fluorescens* sp., strain AN5 have been modified by the insertion of Tn5-derived transposons. The transposons contain marker genes which confer resistance to the antibiotics kanamycin and neomycin; and to tetracycline, respectively. An additional marker gene coding for the enzyme β -glucuronidase (GUS) has also been introduced to some of the strains.

Location and size of trial: The bacteria will be applied to a maximum of 3 million of wheat seeds which will be planted in an area approximately 0.75 hectare within a 2.46 hectare compound, at a site near Galong, NSW. A maximum of 10^{20} genetically modified bacteria will be released in this trial.

Further information: The institution's contact officer for this proposal is Dr Murali Nayudu, telephone (02) 6125 3643, facsimile (02) 6125 5573; email Murali.Nayudu@anu.edu.au.

PR-148: Biological control small scale limited field trial of partial diploid constructions of *Pseudomonas* bacteria on wheat roots in soil

Organisation proposing release: Australian National University
Canberra ACT 0200

Organism to be released: *Pseudomonas fluorescens* sp., strain AN5

Purpose of the release: Take-all disease affects the roots of plants such as wheat. Currently there are no control methods for this disease and biological control methods using bacteria such as *Pseudomonas* are the subject of intensive research worldwide.

In this field trial genetically modified strains of *Pseudomonas* bacteria will be evaluated for their ability to protect wheat plants against the fungal disease take-all by measuring wheat yield. The colonisation ability and stability on wheat roots in soil will also be tested. A total of 18 different *Pseudomonas* strains will be evaluated in this trial.

Brief description of the nature and effect of the genetic modification:

Bacteria of *Pseudomonas fluorescens* sp., strain AN5 have been modified to produce partial diploid strains that contain extra copies of genes already present in this organism. The extra gene copies have been introduced on extra-chromosomal plasmid constructs. These constructs confer altered characteristics of protection against the take-all fungus of wheat.

Selectable marker genes have also been introduced to these strains, conferring resistance to the antibiotics kanamycin and neomycin; and to tetracycline, respectively.

Location and size of trial: The bacteria will be applied to a maximum of 3 million of wheat seeds which will be planted in an area approximately 0.75 hectare within a 2.46 hectare compound, at a site near Galong, NSW. A maximum of 10^{20} genetically modified bacteria will be released in this trial.

Further information: The institution's contact officer for this proposal is Dr Murali Nayudu, telephone (02) 6125 3643, facsimile (02) 6125 5573; email Murali.Nayudu@anu.edu.au.

PR-149: Biological control of partial diploid constructions of *Pseudomonas* bacteria on wheat roots in soil

Organisation proposing release: Australian National University
Canberra ACT 0200

Organism to be released: *Pseudomonas fluorescens*

Purpose of the release: Take-all disease affects the roots of plants such as wheat. Currently there are no control methods for this disease and biological control methods using bacteria such as *Pseudomonas* are the subject of intensive research worldwide.

In this field trial genetically modified strains of *Pseudomonas* bacteria will be evaluated for their ability to protect wheat plants against the fungal disease take-all. A total of 18 different *Pseudomonas* strains will be evaluated in this trial.

Brief description of the nature and effect of the genetic modification: Bacteria of *Pseudomonas fluorescens* sp., strain AN5 have been modified to produce partial diploid strains that contain extra copies of genes already present in this organism. The extra gene copies have been introduced on extra-chromosomal plasmid constructs. These constructs confer altered characteristics of protection against the take-all fungus of wheat.

Selectable marker genes have also been introduced to these strains, conferring resistance to the antibiotics kanamycin and neomycin; and to tetracycline, respectively.

Location and size of trial: The bacteria will be applied to a maximum of 3000 of wheat seeds which will be planted in an area approximately 3 m² at Acton, ACT. A maximum of 10¹² genetically modified bacteria will be released in this trial.

Further information: The institution's contact officer for this proposal is Dr Murali Nayudu, telephone (02) 6125 3643, facsimile (02) 6125 5573; email Murali.Nayudu@anu.edu.au.

PR-150: Competitive ability and growth characteristics of transgenic *Trifolium subterraneum* subsp. *subterraneum* cv. Leura expressing sunflower seed albumin

Organisation proposing release: CSIRO Division of Plant Industry
GPO Box 1600
Canberra ACT 2601

Organism to be released: Subterranean clover (*Trifolium subterraneum* subsp. *subterraneum* cv. Leura)

Purpose of the release: The aim of the release is to assess whether the agronomic performance of transgenic clover which has been modified to improve its nutritional quality differs from that of the non-transgenic parental strain. This trial will address whether the transgenic clover has any increased competitive ability that would allow it to invade or persist in natural grassland ecosystems.

Brief description of the nature and effect of the genetic modification:

Three genes have been inserted into a commercial cultivar of subterranean clover. Two of the genes encode a protein, sunflower seed albumin, which is rich in sulfur-containing amino acids, and is resistant to breakdown in the rumen of sheep. It is expected that this protein will improve the nutritional quality of subterranean clover, and increase wool growth in sheep and ruminant live weight gains.

The third gene is a selectable marker gene conferring resistance to the antibiotics kanamycin and neomycin.

Location and size of trial: A total of 20,000 plants in 25m X 25m plot located within a 1 hectare containment area at the Ginninderra Experiment Station, ACT.

Further information: The institution's contact officer for this proposal is Dr Robert C. Godfree, telephone (02) 6246 4956, facsimile (02) 6246 5000.

PR-151: Field evaluation of transgenic cotton expressing a new insecticidal gene from *Bacillus thuringiensis*

Organisation proposing release: CSIRO Plant Industry
GPO Box 1600
Canberra ACT 2601

Organism to be released: Cotton (*Gossypium hirsutum*)

Purpose of the release: The aim of the release is to examine the field performance of a cotton line modified to express a novel insecticidal protein that confers resistance to caterpillar pests. In addition, seed increase of this new cotton line for subsequent trials and for an on-going breeding program will also be undertaken. The use of insect-resistant cotton plants has the potential to reduce the use of chemical pesticides on cotton crops.

Brief description of the nature and effect of the genetic modification: The cotton plants contain a new insecticidal gene derived from the bacterium *Bacillus thuringiensis*. The new insecticidal gene is a possible alternative to the Cry toxin gene that is present in the insect tolerant transgenic cotton (INGARD[®]) currently available to cotton growers. The insecticidal gene produces a protein that is toxic to the major caterpillar pests (*Helicoverpa armigera* and *H. punctigera*) that attack cotton.

In addition to the insecticidal gene, the plants contain a selectable marker gene that confers resistance to the antibiotic hygromycin.

Location and size of trial: Approximately 3000 plants in an area under 0.5 hectare spread over 2 fields at one site in the cotton-growing region of Narrabri (NSW).

Further information: The institution's contact officer for this proposal is Dr Danny Llewellyn, telephone (02) 6246 5470.

PR-152: Field test of pineapple plants modified for control of natural flowering

Organisation proposing release: Qld Department of Primary Industries
Maroochy Research Station
PO Box 5083
Nambour Qld 4560

Organism to be released: Pineapple (*Ananas comosus* (L.) Merrill) cultivar Smooth Cayenne

Purpose of the release: The aim of the trial is to assess the control of natural flowering in genetically modified pineapple plants. The proponent's ultimate aim is to develop pineapple plants with uniform time of flowering and ripening characteristics. This would allow a reduction in harvesting costs.

Brief description of the nature and effect of the genetic modification: The pineapple plants have been modified by suppressing the expression of an endogenous pineapple gene. This gene *acacs2* encodes for an enzyme S-adenosyl-L-methionine methylthioadenosine-lyase (ACC synthase), which is involved in the control of the time of flowering. This has been achieved by cloning the appropriate gene from pineapple and reintroducing it in the sense and/or antisense (opposite) orientation in order to suppress ACC2 expression in pineapple plants. The transgenic pineapple plants therefore have reduced ACC synthase activity.

The transgenic plants also contain a selectable marker gene conferring resistance to the antibiotic geneticin.

Location and size of trial: A total of 2,000 plants in an area of 0.1 hectare at Redlands and Maroochy Research Stations, Queensland.

Further information: The institution's contact officer for this proposal is Dr Michael Kevin Smith, telephone (07) 5441 2211, facsimile (07) 5441 2235.

PR-153: Fungal disease resistant canola (*B. napus*)

Organisation proposing release: Natural Resources and Environment
Agriculture Victoria
c/o Institute of Land and Food Resources,
University of Melbourne
PARKVILLE VIC 3052

Organism to be released: Canola (*Brassica napus* subsp *oleifera*)

Purpose of the extension to the release: The aim of the trial is to examine the field performance of defence related genes for fungal disease tolerance in canola. Modified canola plants will be tested in an area where there is substantial infestation with fungal diseases.

Development of fungal disease resistance would assist canola growers in managing major fungal diseases such as blackleg and Sclerotinia in canola crops. Blackleg and Sclerotinia cause huge losses in canola production.

Brief description of the nature and effect of the genetic modification: The canola lines to be released contain either a peroxidase gene from the plant *Stylosanthes humilis* or a glucose oxidase gene from the bio-control fungus *Talaromyces flavus*. Some canola lines also contain four different antifungal genes from *Macadamia integrifolia*. The expression of these genes in canola plants is expected to reduce the susceptibility of plants to infection by blackleg fungus.

Selectable marker genes from the bacterium *Escherichia coli*, conferring resistance to antibiotics hygromycin or kanamycin, neomycin and geneticin, were also transferred to the transgenic plants.

Location and size of trial: The trial will be conducted in an area less than 1 hectare at Wonwondah and Lake Bolac, Victoria.

Further information: The institution's contact officer for this proposal is Dr Phil Salisbury, telephone (03) 9884 8068.

PR-69X(5): Release of transgenic cotton expressing tolerance to the herbicide bromoxynil - weed management studies

Organisation proposing release: CSIRO Plant Industry
GPO Box 1600
Canberra ACT 2601

Organism to be released: Cotton (*Gossypium hirsutum*)

Purpose of the release: The aim of this extension is to continue integrated weed management studies and examine long-term weed ecology issues with cotton plants modified for resistance to the herbicide bromoxynil. It is expected that the use of bromoxynil-tolerant cotton plants will allow more effective weed control in cotton crops by allowing spraying of the crop with bromoxynil to kill broadleaf weeds without damaging the crop itself.

Brief description of the nature and effect of the genetic modification: The herbicide resistance gene introduced into the transgenic plants is a nitrilase gene from a soil bacterium (*Klebsiella ozaenae*) that normally degrades bromoxynil in soil. When over-expressed in the plant, this enzyme breaks down the herbicide before it can cause any damage to the plant. In addition, the plants contain a selectable marker gene that confers resistance to the antibiotics kanamycin and neomycin.

Location and size of trial: Approximately 80 000 plants in an area under 0.8 hectares at the Australian Cotton Research Institute, Myall Vale, NSW.

Further information: The institution's contact officers for this proposal are Dr Danny Llewellyn, telephone (02) 6246 5470; Dr Greg Constable, telephone (02) 6799 1522; and Mr Graham Charles, telephone (02) 6799 1524.

PR-94X(3): Seed increase of INGARD cotton expressing glyphosate tolerance

Organisation proposing release: Cotton Seed Distributors Ltd
PO Box 117
Wee Waa NSW 2388

Organism to be released: Cotton (*Gossypium hirsutum*)

Purpose of the extension to the release: The aim of the extension is to evaluate and increase seed stocks of commercial cotton cultivars of transgenic cotton for possible commercial release to the Australian cotton industry. The transgenic Roundup Ready[®]/INGARD[®] cotton plants are tolerant to the herbicide glyphosate (Roundup[®]) and to insect pests (INGARD[®]).

Brief description of the nature and effect of the genetic modification:

The transgenic cotton has been modified to contain a gene from the bacterium *Agrobacterium* strain CP4 encoding the enzyme 5-enolpyruvyl shikimate-3-phosphate synthase (CP4 EPSPS) which confers tolerance to the herbicide glyphosate, the active ingredient of Roundup[®]; and a gene from the bacterium *Bacillus thuringiensis* encoding delta endotoxin CryIA(c), an insecticidal protein, which is toxic to the major insect pests of cotton (INGARD[®]). In addition, the plants contain selectable marker genes conferring resistance to the antibiotics kanamycin and neomycin; and streptomycin and spectinomycin.

Location and size of trial: Approximately 4,000,000 plants, in an total area of less than 40 hectares at Kununurra, WA.

Further information: The organisation's contact officers for this proposal are Mr Robert Eveleigh telephone (02) 6795 0000, fax (02) 6795 4966 and Dr Danny Llewellyn, telephone (02) 6246 5470.

PR-99X(3): Field evaluation of transgenic cotton for enhanced tolerance to waterlogging

Organisation proposing release: CSIRO Plant Industry
GPO Box 1600
Canberra ACT 2601

Organism to be released: Cotton (*Gossypium hirsutum*)

Purpose of the release: The aim of this extension is to continue agronomic studies of cotton plants that have been genetically modified for increased tolerance to waterlogging. Yield losses due to waterlogging are common in Australian cotton crops when heavy rain follows irrigation of the crop.

Brief description of the nature and effect of the genetic modification: The cotton plants have been modified to over-produce two plant enzymes that are normally involved in helping plants survive long periods of waterlogging. The two enzymes are alcohol dehydrogenase from cotton and pyruvate decarboxylase from rice. The modified plants contain an extra copy of either or both of these genes.

For comparison, genetically modified cotton plants are also being trialed which contain the alcohol dehydrogenase gene in the opposite or antisense orientation. This results in plants that have lower levels of the alcohol dehydrogenase enzyme than normal.

In addition, all of the genetically modified plants contain a selectable marker gene conferring resistance to the antibiotics kanamycin and neomycin.

Location and size of trial: Approximately 40,000 plants in an area under 0.5 hectares at the Australian Cotton Research Institute, Myall Vale, NSW.

Further information: The institution's contact officers for this proposal are Dr Marc Ellis, telephone (02) 6246 5306; Dr Greg Constable, telephone (02) 6799 1522; and Dr Ian Rochester, telephone (02) 6799 1574.

PR-118X(2): Regulatory trials for efficacy, crop safety and environmental impact with CryIA(c)/CryX 2001-2003

Organisation proposing release: Deltapine Australia Pty Ltd
PO Box 196
Narrabri NSW 2390

Organism to be released: Cotton (*Gossypium hirsutum*)

Purpose of the release: The aim of the release is to continue field assessment of lines of cotton plants that have been modified for resistance to insect pests. Specifically, assessments will be made of the insecticidal efficacy of the plants, the impact of the CryX gene (see below) on non-target insects occurring in cotton crops, and agronomic performance of the plants.

Brief description of the nature and effect of the genetic modification: The genes introduced into the cotton plants are either one or both of the insect tolerant genes CryIA(c) and CryX. The CryIA(c) and CryX genes are derived from the bacterium *Bacillus thuringiensis*. These genes encode toxins which act against lepidopteran (caterpillar) larvae, including two *Helicoverpa* species which are major pests of cotton.

The plants also contain a marker gene, which confers resistance to the antibiotics kanamycin and neomycin.

Location and size of trial: A maximum of 150 hectares at 21 sites in the cotton-growing regions of New South Wales and Queensland.

Further information: The institution's contact officer for this proposal is Stewart Addison, telephone (02) 6742 4251.

PR-123X(2): Field evaluation of transgenic cotton expressing the CryIA(c) and Cry2A(b) (formerly CryX) delta-endotoxins from *Bacillus thuringiensis*

Organisation proposing release: CSIRO Plant Industry
GPO Box 1600
Canberra ACT 2601

Organism to be released: Cotton (*Gossypium hirsutum*)

Purpose of the release: The purpose of this extension is to continue evaluation of the field performance and selection of breeding material of transgenic cotton expressing two different insecticidal genes over a variety of sites and environments. The insecticidal genes control caterpillar pests of cotton. 'Stacking' of the two genes in a single plant is expected to enhance the control of the pests and minimise the potential for the insects to become resistant to the insecticidal proteins. The use of insect-resistant cotton plants has the potential to reduce the use of chemical pesticides on cotton crops.

Brief description of the nature and effect of the genetic modification: The transgenic plants contain either the CryIA(c) or the Cry2A(b) gene from the bacterium *Bacillus thuringiensis*, or both genes. These genes produce insecticidal proteins that are toxic to the major caterpillar species that attack cotton.

Plants with the Cry2A(b) gene also express a marker gene, β -glucuronidase (GUS), from the bacterium *Escherichia coli*. This gene enables visual identification of tissues expressing the Cry2A(b) gene. Plants with the CryIA(c) gene contain a selectable marker gene which confers resistance to the antibiotics kanamycin and neomycin.

Location and size of trial: A total of approximately 6 hectares over sixteen sites, at the Australian Cotton Research Institute, Myall Vale; the Plant Breeding Institute, Narrabri; and private farms at Boggabilla, Bourke, Breeza, Collarenbri, Hillston, Merah, Moree and Warren (NSW), and Biloela, St George, Moura, Dalby and Emerald (Queensland).

Further information: The institution's contact officers for this proposal are Dr Danny Llewellyn, telephone (02) 6246 5470; Dr Gary Fitt, telephone (02) 6799 1514; and Dr Greg Constable, telephone (02) 6799 1522.

PR-124X(2): Release of transgenic cotton expressing tolerance to the herbicide Basta®

Organisation proposing release: CSIRO Plant Industry
GPO Box 1600
Canberra ACT 2601

Organism to be released: Cotton (*Gossypium hirsutum*)

Purpose of the release: The aim of the extension is to continue the field evaluation and breeding of new lines of cotton that have been modified to be tolerant to the herbicide glufosinate ammonium (phosphinothricin, Basta®). As well, seed will be increased for subsequent trials. In addition, weed management studies will examine how the herbicide-tolerant cotton would fit into the cotton production system in Australia. It is expected that use of glufosinate ammonium-tolerant cotton plants will allow more effective weed control in cotton crops by allowing the crop to be sprayed with glufosinate ammonium to kill problem weeds without damaging the crop itself.

Brief description of the nature and effect of the genetic modification: The plants contain one of two genes conferring tolerance to glufosinate ammonium. Both genes encode the enzyme phosphinothricin acetyltransferase, which acts to detoxify the active ingredient of Basta®. The two genes have been isolated from two different species of the soil bacterium *Streptomyces*.

Location and size of trial: Approximately 220,000 plants in an area under 2.2 hectares at the Australian Cotton Research Institute, Myall Vale, NSW.

Further information: The institution's contact officers for this proposal are Dr Danny Llewellyn, telephone (02) 6246 5470; and Dr Greg Constable, telephone (02) 6799 1522.

PR-131X(3): Seed increase of transgenic cotton expressing Cry1A(c) and Cry2A(b)

Organisation proposing release: Cotton Seed Distribution Ltd
PO Box 117
Wee Waa NSW 2388

Organism to be released: Cotton (*Gossypium hirsutum*)

Purpose of extension to the release: The aim of this extension is to evaluate insect-resistant transgenic cotton and to produce commercial quantities of seed for further evaluation prior to general release. The use of insect-resistant cotton has the potential to reduce the use of chemical pesticides on cotton crops and to extend the useful life of the previously released INGARD[®] cotton that contains only a single insecticidal gene, Cry1A(c).

Brief description of the nature and effect of the genetic modification: The transgenic cotton plant express two delta endotoxin genes Cry1A(c) and Cry2A(b) derived from the bacterium *Bacillus thuringiensis*. The insecticidal proteins produced by these genes protect the plant from major caterpillar pests such as the cotton bollworm. The presence of more than one insecticidal gene in a single plant may give better insect control and reduce the potential for the insect pests to become resistant to the toxins.

The plants also contain a marker gene coding for the enzyme β -glucuronidase (GUS) which enables visual identification of plant tissues in which the gene is being expressed and a selectable marker gene conferring resistance to the antibiotics kanamycin and neomycin.

Location and size of trial: A total area of less than 40 hectares (approximately 4,000,000 transgenic cotton plants) at Kununurra (WA)

Further information: The institution's contact officers for this proposal are Mr Robert Eveleigh telephone (02) 6795 0000, fax (02) 6795 4966 and Dr Danny Llewellyn, telephone (02) 6246 5470.

PR-131X(4): Seed increase of transgenic cotton expressing CryX and CryIA(c)

Organisation proposing release: Cotton Seed Distributors Ltd
GPO Box 117
Wee Waa NSW 2388

Organism to be released: Cotton (*Gossypium hirsutum*)

Purpose of extension to the release: The aim of this extension is to evaluate insect-resistant cotton lines and produce commercial quantities of seed for further evaluation prior to a possible general release. The use of insect-resistant cotton has the potential to reduce the use of chemical pesticides on cotton crops.

Brief description of the nature and effect of the genetic modification: The genes introduced into the cotton plants are the CryIA(c) and CryX [Cry2A(b)] genes from the bacterium *Bacillus thuringiensis*. These genes produce proteins that are toxic to certain insects, including the major caterpillar pests that attack cotton. INGARD[®] cotton, which has been released commercially, contains only a single insecticidal gene, CryIA(c). The presence of more than one insecticidal gene in a single plant may give better insect control and reduce the potential for the insect pests to become resistant to the toxins.

Location and size of trial: A maximum of 3000 hectares (approximately, 300,000,000 modified cotton plants) at seventeen sites in the cotton growing regions of New South Wales and Queensland.

Further information: The institution's contact officer for this proposal is Mr Robert Eveleigh, telephone (02) 6795 0000.

PR-138X: Evaluation of sub-clover stunt virus promoters in cotton plants under field conditions

Organisation proposing release: CSIRO Plant Industry
GPO Box 1600
Canberra ACT 2601

Organism to be released: Cotton (*Gossypium hirsutum*)

Purpose of the release: The aim of the extension is to continue field trial of cotton plants containing two novel promoters isolated from a virus that infects subterranean clover plants. Promoters are genetic 'switches' which, when coupled to a gene of interest, control the expression of the gene in particular tissues of a plant.

Many of the genes, such as insect-resistance and herbicide-resistance genes, that have been used in field trials of genetically modified plants in the past have used a promoter from a virus that infects cauliflowers, the cauliflower mosaic virus. In glasshouse tests, the new promoters from sub-clover stunt virus seem to work as well as the cauliflower mosaic virus promoter. This trial aims to test the performance of the new promoters under field conditions.

Brief description of the nature and effect of the genetic modification: Most of the modified cotton plants to be trialed contain one of two promoters from the sub-clover stunt virus coupled to a marker gene. The marker gene encodes an enzyme, β -glucuronidase, from the bacterium *Escherichia coli* which enables the visual identification of plant tissues where the promoter is driving the expression of this gene. The plants also contain another marker gene which confers resistance to the antibiotics kanamycin and neomycin.

A small number of the modified cotton plants to be trialed will contain the same set of promoters driving the expression of an insecticidal gene (CryIA(b), derived from the bacterium *Bacillus thuringiensis*) that is toxic to caterpillar pests of cotton. These plants also contain a marker gene that confers tolerance to the herbicide Basta.

Location and size of trial: Approximately 6,000 plants in two different fields on an area of less than 0.5 hectares at the Australian Cotton Research Institute, Myall Vale, NSW.

Further information: The institution's contact officers for this proposal are Dr Danny Llewellyn, telephone (02) 6246 5470; and Dr Greg Constable, telephone (02) 6799 1522.

PR-140X: Agronomic selection and seed increase of INGARD® (Bt)/ CryX and INGARD® / CryX/ Roundup Ready® (RR) cotton plants 2001-2003

Organisation proposing release: Deltapine Australia Pty Ltd
PO Box 196
Narrabri NSW 2390

Organism to be released: Cotton (*Gossypium hirsutum*)

Purpose of the release: The aim of the trial is to continue agronomic evaluation and selection of new breeding lines of cotton which have been modified for resistance to insect attack, as well as lines expressing the insect-resistance genes in combination with a gene conferring tolerance to the herbicide glyphosate (Roundup Ready®). This includes multi-site yield and fibre trials, and seed increase of new crossbred selections. It is expected that use of the herbicide-tolerant cotton will permit more effective control of weeds in cotton crops, while the insect-resistance trait has the potential to reduce the amount of insecticide applied to cotton crops.

Brief description of the nature and effect of the genetic modification: The cotton plants have been modified to contain the 5-enolpyruvyl shikimate-3-phosphate synthase (EPSPS) gene from *Agrobacterium* and an insect-resistance gene CryIA(c) from the bacterium *Bacillus thuringiensis*. The EPSPS gene confers tolerance to the herbicide glyphosate, the active ingredient of Roundup®. The CryIA(c) gene confers tolerance to the major insect pests of cotton. In addition, some plants contain a combination of three genes: EPSPS, CryIA(c) and CryX. The CryX gene, derived from the bacterium *Bacillus thuringiensis*, also produces an insecticidal protein.

All the plants also contain a selectable marker gene that confers resistance to the antibiotics kanamycin and neomycin.

Location and size of trial: A total of 60 hectares in 2001/2002 season and up to 400 hectares in 2002/2003 season in the cotton-growing regions of New South Wales and Queensland.

Further information: The institution's contact officer for this proposal is Richard Leske, telephone (07) 4671 3136.