Interim Office of the Gene Technology Regulator

Quarterly Report

March 2001

The Interim Office of the Gene Technology Regulator Quarterly Report

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TGA THERAPEUTIC GOODS ADMINISTRATION

Health and Aged Care

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 fourth Quarterly Report of the Interim Office of the Gene Technology Regulator (IOGTR), covering the period January – March 2001

The Interim Office of the Gene Technology Regulator has given a commitment to you and to the Australian community to provide timely and comprehensive information about the operation of the IOGTR and the Genetic Manipulation Advisory Committee (GMAC).

In conducting several rounds of public consultations on the gene technology legislation, staff of the IOGTR have received much positive feedback that the reports are valued by a range of stakeholders. While this is the penultimate report to be provided by the Interim Office, quarterly reporting will continue as a legislative requirement when the permanent office is established at the end of June.

During the reporting period the IOGTR:

- Released the draft of the Gene Technology Regulations 2000 with the Explanatory Guide to the Regulations and consulted through meetings with key stakeholders and advertising for written submissions from members of the public;
- Continued the development of guidelines and licensing arrangements for the new Regulatory system for gene technology commencing on 21 June 2001; and
- Maintained proactive monitoring of current field trials and sites subject to post-trial monitoring for compliance with GMAC recommendations.

During the reporting period, GMAC

- has provided advice on:
  - 2 new proposals for field trials;
  - 5 extensions to proposals previously assessed by GMAC;
  - remedial actions to be undertaken in a number of non-compliances with GMAC conditions for field trials of GMO crops; and
- has played a key role in the development of:
  - the draft Gene Technology Regulations 2000; and
  - an explanatory paper for exempt and notifiable low risk dealings.

I look forward to reporting to you on the activities of the IOGTR and GMAC at the end of the next quarter.

Yours sincerely

Terry Slater
National Manager
Therapeutic Goods Administration
May 2001

CONTENTS

ABBREVIATIONS & TERMS

BA	Biotechnology Australia
CSCG	Commonwealth-State Consultative Group on Gene Technology
EA	Environment Australia
GM	Genetically modified
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically modified organism
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
GTIMS	Gene Technology Information Management System
GTR	Gene Technology Regulator
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
IDC	Inter-Departmental Committee
IGA	Inter-Governmental Agreement on Gene Technology
IOGTR	Interim Office of the Gene Technology Regulator
JPRC	Joint Policy Reference Group
MPC	Matthews Pegg Consulting
NHMRC	National Health and Medical Research Council
NLRD	Notified Low Risk Dealings
OGTR	Office of the Gene Technology Regulator
PR	Planned Release
RSC	Release Subcommitee
SOP	Standard Operating Procedure
SSC	Scientific Subcommitee
Volunteer	Regrowth of plants from seed that has remained on a site after a trial has been completed.
UWA	University of Western Australia

SUMMARY

This is the fourth 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 January - March 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).

Tracking commitments made in the previous Quarterly Report

The October – December 2000 Quarterly Report highlighted 6 key issues that the IOGTR anticipated addressing during the January - March 2001 quarter. A brief summary against those 6 issues follows:

1. Consultations on the revised draft Gene Technology Regulations 2000 to be made under the *Gene Technology Act 2000*

A revised draft of the Gene Technology Regulations 2000, along with an explanatory guide, were released for public comment in January. The IOGTR received over 75 written submissions in this second round of consultations on the Regulations.

In addition, the IOGTR conducted meetings with targeted stakeholders, including IBC members, researchers, consumer and environmental groups, in all capital cities to receive their input into the Regulations and to discuss the practicalities of the new regulatory scheme.

2. Finalisation of responses to the second round of consultations on the Regulations

As the date for receiving submissions on the second round of consultations was extended from 9 March 2001 to 23 March 2001 to provide more time for interested persons to fully consider the matter. Responses will therefore be finalised, and the Regulations further developed, in the next quarter.

3. Recruitment of the Gene Technology Regulator

Recruitment commenced for the position of Gene Technology Regulator with advertisements in the press on 27 January 2001.

4. The establishment of 3 new committees

In March the Commonwealth State Consultative Committee (CSCG) agreed an approach to nominating representatives on the Gene Technology Community Consultative Committee (GTCCC), the Gene Technology Ethics Committee (GTEC), and the Gene Technology Technical Advisory Committee (GTAC).

Arrangements were initiated to seek nominations from key stakeholder groups. Work to establish the committees will continue in the next quarter.

5. Monitoring and surveillance activities.

Target rates for monitoring and surveillance (ie 20% of current trials per annum) were exceeded during this quarter as the IOGTR continued to monitor compliance with GMAC conditions for the operation and management of crop trial sites involving GMOs.

During the January – March 2001 quarter 109 sites were inspected. Eleven sites containing trials currently underway and 98 sites subject to post–trial monitoring were selected for inspection. Twenty-four of the 109 sites required some level of remedial action to ensure compliance with GMAC recommendations.

GMAC advised that none of the sites represented a risk to human health or the environment as appropriate action was taken to remedy concerns.

Investigations into three alleged breaches were completed during the quarter. The Office investigated a site previously sown to genetically modified (GM) canola and currently subject to post-trial monitoring by Monsanto Australia Ltd. As a result of IOGTR routine quarterly monitoring in Tasmania, issues of non-compliance were observed at sites previously sown to GM canola and presently subject to post-trial monitoring. Two separate breach investigations, into Aventis CropScience and Monsanto Australia Ltd, were carried out for these sites. Further information about monitoring and surveillance is set out at parts 2.3 to 2.7 of this report

6. The Gene Technology Information System (GTIMS)

The work to develop GTIMS (the new information management system which will support the implementation of the *Gene Technology Act 2000*) continued. During the reporting period, existing information from the GMAC database was migrated into GTIMS.

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 January – March 2001 quarter in relation to the development and implementation of the national regulatory framework.

Part 2 outlines work undertaken during the January – March 2001 quarter under the current system of voluntary controls over GMOs, which will continue to operate until the new regulatory system is established. It focuses on GMAC's work, and the activities (such as monitoring) undertaken by the IOGTR to support the voluntary system.

In addition, **Part 3** points to activities expected to be undertaken, and outcomes to be achieved, in the April – June 2001 quarter.

Further information

This fourth 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 on the IOGTR or GMAC are encouraged to contact the Office:

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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 January – March 2001 quarter:

Key result 1
The Regulations to be made under the *Gene Technology Act 2000* were substantially finalised as a result of the second round of consultations. This included face-to-face meetings with targeted stakeholders (including Institutional Biosafety Committee (IBC) members, researchers, consumer and environmental groups, industry and persons having previously made submissions to the regulations) as well as extensive consultation with members of GMAC.

Key result 2
Model State/Territory legislation was finalised at officials' level to complement the *Gene Technology Act 2000* as the basis for the State and Territory component of the regulatory system.

Key result 3
Draft guidelines for activities concerning GMOs under the new regulatory arrangements were further developed.

Key result 4
GTIMS was further developed to enable on-line support of the client services and regulatory system mentioned in ***Key result 3***.

Key result 5
Consultation and information processes were established to advise jurisdictions, scientists, industry and the community of transitional arrangements for operating under the new regulatory system for gene technology.

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

1.2 Key result 1 - The draft Gene Technology Regulations 2000

A revised draft of the Gene Technology Regulations 2000, which underpin the Act, was released in early January 2001.

Copies of the revised Regulations, an Explanatory Guide and an invitation to make submissions was also made available on the IOGTR internet site (http://www.health.gov.au/tga/genetech.htm). Approximately 3,500 individuals and organisations listed on the IOGTR contact database were specifically invited to make submissions. (Persons or organisations wishing to be included on these contact lists can arrange this by contacting the IOGTR: email iogtr@health.gov.au or telephone 1800 181 030.)

Written submissions were originally required by 9 March 2001. The submission date was, however, extended to 23 March 2001 to provide more time for interested persons to fully consider the matter.

The IOGTR received 75 submissions in this second round of consultations on the revised regulations.

Consultations on the Regulations

In addition, the IOGTR invited 666 organisations and individuals to attend meetings held in each capital city, with a view to having detailed discussions on the technical and practical elements of the Regulations. Organisations invited included Institutional Biosafety Committee (IBC) members, researchers, consumer and environmental groups, industry and persons having previously made submissions to the regulations.

Over 213 participants attended these meetings which were held in:

- Canberra, 16 February 2001, Australian National University;
- Perth, 20 - 21 February 2001, Technology Park Function Centre;
- Adelaide, 22 February 2001, Adelaide University;
- Canberra, 26 February 2001, Australian National University;
- Melbourne, 27 - 28 February 2001, University of Melbourne;
- Hobart, 2 March 2001, Salamanca Inn;
- Sydney, 5 - 6 March 2001, Sydney Masonic Centre;
- Brisbane, 8 - 9 March 2001, Brisbane City Novotel;
- Canberra, 23 March 2001, The Brassey; and
- Darwin, 26 March 2001, Exhibition Gallery.

The revised draft of the Regulations was considered in detail by GMAC. GMAC also considered scientific and/or technical issues raised in the written submissions.

Issues raised during consultations on the revised draft Regulations

Analysis of the submissions and of comments made during the consultation process has commenced, and will continue through the early part of the April-June 2001 quarter. Some of the main issues under consideration as a result of the second round of consultations are:

- the definitions for what does not constitute a GMO for the purposes of the Regulations;
- the appropriate dealings to be made exempt dealings and notifiable low risk dealings under the Regulations;
- the liability provisions relating to, and the responsibilities of, IBCs;
- the meeting procedures for the three advisory committees; and
- the appropriate information to be required from applicants in applications for licensed dealings.

This second round of consultations has been extremely useful, not only for enhancing the effectiveness of the Regulations, but in assisting users of the new regulatory system to understand their roles and responsibilities.

For example, during the national consultations on the revised Regulations, the IOGTR discussed transitional arrangements with IBC members and clients of GMAC/IOGTR, providing early notification of the arrangements to assist organisations in planning for the transition. Transitional arrangements are further discussed at section 1.6 Key result 5.

Further revision and redrafting of the Regulations will now proceed, with the penultimate draft to be considered by CSCG, the Commonwealth Interdepartmental Committee and GMAC.

1.3 Key result 2 - Model State/Territory legislation

All States and Territories are committed, as part of the national regulatory scheme for GMOs, to introduce legislation into their Parliaments to complement the Commonwealth's *Gene Technology Act 2000*.

This will ensure that the scheme covers all persons and organisations dealing with GMOs, including individuals, tertiary institutions and State research organisations, and not just those captured under the Commonwealth's constitutional powers.

Two models of State legislation to complement the Commonwealth legislation were agreed to by State, Territory and Commonwealth officials in the January-March 2001 quarter. The 2 models provide the options for:

- a simple State/Territory law adopting the Commonwealth legislation; or
- a longer form piece of State/Territory legislation essentially mirroring the Commonwealth legislation.

Processes are now in place in the majority of State and Territory jurisdictions to have legislation established by the end of 2001.

1.4 Key result 3 - Further development to underpin the legislative scheme

Preparation of guidelines to underpin the legislative scheme continued in the January – March 2001 quarter.

The guidelines cover a range of issues including:

- the accreditation of organisations; and
- the certification of facilities/requirements for physical containment;
- transport of GMOs.

The Guidelines:

- are based on the current GMAC Guidelines but adapted for the new regulatory requirements; and
- will also form part of the comprehensive Handbook on Gene Technology for users of the regulatory system.

The Gene Technology Regulation Handbook

The Handbook will serve as an ongoing resource for clients of the regulatory system. It will consolidate all Guidelines in one source, and will also include:

- answers to commonly asked questions about the regulatory system; and
- sections on each of the key aspects of the scheme including:
  - accreditation of organisations;
  - certification of facilities;
  - exempt dealings with GMOs;
  - notifiable low risk dealings with GMOs;
  - licensing of dealings with GMO;
  - treatment of commercial in confidence information;
  - importation of GMOs; and
  - transitional arrangements.

1.5 Key result 4 - Gene Technology Information Management System (GTIMS)

The information technology company developing GTIMS, Dialog, continued to develop the database to underpin the operation of the *Gene Technology Act 2000*.

Dialog is continuing to build functionality to match the administrative arrangements for organisations operating under the Act and Regulations. In the reporting period the IOGTR viewed prototypes of the system in preparation for user acceptance testing in the next quarter.

The system is to commence operation from 21 June 2001 and will be introduced in a phased manner. Public access will be available from 21 June 2001.

1.6 Key result 5 - Advising participants of transitional arrangements under the new regulatory system

An important element of IOGTR work during this quarter has been the consultation and information processes established to advise jurisdictions, scientists, industry and the community of transitional arrangements for operating under the new regulatory system for gene technology.

TRANSITIONAL ARRANGEMENTS FOR IMPLEMENTION OF THE NEW REGULATORY SYSTEM FOR GMOs

The *Gene Technology Act 2000* provides for special arrangements to apply in relation to dealings with GMOs that were approved by the GMAC prior to the commencement of the new regulatory scheme on 21 June 2001. In determining these transitional arrangements, an effort has been made to minimise the impact of the change to the new regulatory scheme on users of the previous system.

The transitional arrangements comprise two parts:

1. Cut-off dates for applications made to GMAC under the existing voluntary system

To ensure that GMAC has adequate time to consider applications made under the voluntary system before the new regulatory system takes effect, a series of "cut-off" dates have been identified.

These cut-off dates are based on the cut-off dates originally set by GMAC for this year, although the April cut-off dates in relation to field trials and unintentional release proposals have been brought forward to some extent.

As a result, no-one should be disadvantaged, and users were informed of these proposed dates at consultations held in relation to the revised draft of the Gene Technology Regulations during February and early March this year. The next set of cut-off dates would have occurred close to the start-up date for the new regulatory system, and it is therefore appropriate that they occur under the new Act.

Applications/notification type	Cut off date
• Applications for Category A (small scale work)	10 May 2001

• Applications for large scale work	10 May 2001
• Notification of category B work	10 May 2001
• Applications for Category C work	10 May 2001
• Applications for field trials of GMOs	26 March 2001
• Applications for work with GMOs involving the potential for unintended release	26 March 2001
• Cut-off date for applications for general release of GMOs	December 2000*

* Note: when the *Gene Technology Act 2000* was passed by the Senate, the IOGTR advised potential applicants that no further applications would be accepted in relation to the general release of GMOs under the voluntary arrangements.

After these dates, no new applications will be received by GMAC under the voluntary system. GMAC will consider all applications received by the cut-off dates and, if approved, "deemed licenses" (refer below) will be issued.

Any applications received by GMAC after the cut-off dates will be returned to the applicants. The applicants may submit an application after 21 June 2001 in accordance with the *Gene Technology Act 2000* and Regulations.

2. Carry over of existing approvals under the voluntary arrangements into the new regulatory system (deemed licences and other approvals)

(a) Category A (small scale work) and large scale work under the voluntary GMAC system

In summary, if an organisation receives an advice to proceed in relation to certain dealings with GMOs from GMAC before 21 June 2001, the dealing is deemed to be licensed under the Act. The dealing is taken to be subject to any recommended conditions imposed by GMAC, as well as subject to the statutory conditions prescribed under the *Gene Technology Act 2000*.

In April 2001, the IOGTR will write to all IBCs supervising projects that are the subject of a current GMAC approval for Category A small scale work and for large scale work. The IOGTR will also write to organisations to inform them of this process. The correspondence will include a draft deemed licence which will reflect the conditions to which the work is subject (based on GMAC's

records).

Organisations and IBCs will be given one month to review the deemed licences and notify the IOGTR of any changes that may be necessary. The IOGTR will consider requests for changes. New deemed licences will be issued where changes have been identified by the IBC or organisation and the IOGTR agrees to the proposed change.

Organisations, IBCs and principal researchers will be requested to review the draft deemed licences very carefully as they will operate as licences (subject to all of the provisions of the new regulatory system) once issued by GMAC/IOGTR.

The IOGTR will issue the deemed licences on behalf of GMAC before the commencement of the legislation on 21 June 2001. Deemed licences will operate for up to 2 years, subject to any expiration date set by GMAC, or to suspension/cancellation under the regulatory system.

(b) Category B work under the voluntary GMAC system

Under the new regulatory system Category B work will become Notifiable Low Risk Dealings (NLRDs). The categories of NLRDs are set out in the Gene Technology Regulations. In transferring Category B work into the Regulations, some minor changes have been made and some work that was previously Category B work may require licensing under the new regulatory system.

Once the Regulations are finalised in early May, the IOGTR will be reviewing all existing Category B work and identifying any work that may have changed status.

The IOGTR will identify whether the work will be considered to be a NLRD under the new system or whether it will require a deemed licence. If the work requires a deemed licence, the IOGTR, on behalf of GMAC, will write to IBCs and organisations in early May, providing draft deemed licences to review.

IBCs and organisations will be given three weeks to review these draft deemed licences provided by GMAC/IOGTR and to notify the IOGTR of any changes to the information before the final deemed licence is issued.

If the work will be an NLRD under the new regulatory system, the IOGTR/GMAC will write to IBCs and the organisation in May confirming that the work will be classified as NLRD.

If the work is confirmed as a NLRD, the organisation must comply with the conditions set out in the Regulations as applying to NLRDs (for example, the

work must be undertaken in a facility certified to at least Physical Containment Level 2 and the work must be overseen by an IBC). Details of the conditions applying to NLRDs will be provided to IBCs and organisations, and will be set out in the Gene Technology Regulations 2000.

The correspondence will include details of the work that GMAC/IOGTR currently holds. The correspondence will be copied to the parent organisation, the relevant IBC and to the principal researcher/project supervisor.

(c) Category C work under the voluntary GMAC system (special exemptions)

Under the new regulatory system there is no equivalent category to the GMAC Category C (special exemptions).

As such, all work that is currently Category C will either be exempt, a NLRD or require licensing under the new system.

The IOGTR and GMAC will be reviewing all existing Category C work and identifying what category the work will fall under in the new regulatory system.

Organisations holding a Category C approval from GMAC will be notified in May 2001 and advised as to what category the work now falls under. If the work is required to be licensed under the new system, GMAC/IOGTR will provide the organisation with a draft deemed licence, reflecting the conditions of the GMAC approval.

Organisations will have three weeks to review the draft deemed licence (or details of the NLRD or exemption, depending on which category the work falls under) and advise the IOGTR regarding any changes that may be necessary.

The IOGTR will then notify organisations (and relevant IBCs and principal researchers) again in June confirming the details of the dealings with the GMO and, if necessary, issuing the deemed licence.

(d) Work with GMOs involving unintentional release, field trials and general releases under the voluntary GMAC system

In summary, if an organisation receives an advice to proceed in relation to these types of dealings with GMOs from GMAC before 21 June 2001, the dealing is deemed to be licensed under the Act.

The dealing is taken to be subject to any recommended conditions imposed by GMAC, as well as subject to the statutory conditions prescribed under the *Gene Technology Act 2000*.

In May 2001, the IOGTR will write to all organisations that hold a current approval from GMAC for work with GMOs involving unintentional release, field trials or general releases.

The correspondence from the IOGTR will be on behalf of GMAC and will include a draft deemed licence which will reflect the conditions to which the work is subject (based on GMAC's records). The correspondence will be copied to the parent organisation, the relevant IBC and the principal researcher/project supervisor.

Organisations will be given one month to review the deemed licences and notify the IOGTR of any changes that may be necessary. It is very important that organisations, IBCs and principle researchers review the draft deemed licences very carefully as they will operate as licences (subject to all of the provisions of the new regulatory system) once issued by GMAC/IOGTR.

GMAC/IOGTR will issue the deemed licences before the commencement of the legislation on 21 June 2001. Deemed licences will operate for up to 2 years, subject to any expiration date set by GMAC or suspension/cancellation under the regulatory system.

(e) Certification of facilities (PC2, PC3 and PC4)

Transitional arrangements will also operate in relation to the certification of containment facilities.

Where there is in force at the time of commencement of the Act a notice from GMAC that a facility provides for a specified physical containment level, under the special transitional arrangements, the facility will be taken to be certified to that physical containment level for the purposes of the legislation.

In April/May 2001, organisations will receive confirmation from IOGTR/GMAC of the facilities under their control that are to receive deemed certification under the new regulatory scheme.

Notifications of any amendments to these listings are to be provided to the IOGTR by the end of May 2001.

Deemed certification will operate for up to 2 years for PC2 facilities (excluding large scale) and 1 year in the case of PC3, PC4 and PC2 large scale facilities.

(f) Deemed accreditation

If, at the commencement of the legislation, there is in force in relation to an

existing organisation a notice from GMAC that, under guidelines issued by the GTR, the organisation is an accredited organisation, the organisation is taken to be an accredited organisation for the purposes of the legislation.

In April/May 2001, organisations currently undertaking dealings with GMOs will receive from the IOGTR/GMAC a summary of information that GMAC/IOGTR holds regarding that organisation and its relevant IBC(s) and a request for certain additional information. Included with the correspondence will also be the Accreditation Guidelines setting out the roles and responsibilities of IBCs under the new regulatory system, and the conditions of accreditation that organisations will be expected to observe.

Organisations and IBCs will have one month to review the information and provide the supplementary information requested to the IOGTR.

Following this process, the IOGTR/GMAC will issue each organisation with a notice "deeming" the organisation to be accredited under the new regulatory system.

The "deemed" accreditation will operate for up to two years (subject to suspension or cancellation by the Gene Technology Regulator).

Summary

- All organisations dealing with GMOs, and IBCs will be notified by the IOGTR about the transitional arrangements for:

- Deeming of licences (for Category A small scale work, large scale work, unintentional releases, field trials, general releases and certain Category C work);

- NLRDs (for work that was previously Category B work);

- Certification of containment facilities; and

- Accreditation of organisations (recognising the existence of an IBC within the organisation or overseeing work undertaken by another organisation).

- The first notification from IOGTR will be in April 2001 and will:

- set out how the transitional arrangements will work;

- contain the information that the IOGTR holds about the relevant GMAC approval;

- include a draft deemed licence, accreditation or certification and, in the case of NLRDs, details about the conditions applying to NLRDs;
-
- identify a contact person with the IOGTR who may be contacted for further clarification or advice; and

- be copied to the relevant organisation, IBC and principal researcher.

- Having received notification from GMAC/IOGTR, organisations/IBCs/principal researchers will be expected to:

- review the information carefully;

- contact the identified IOGTR contact person if they have any queries;

- notify the IOGTR, in writing (by letter, fax or email) if the information is correct or requires amendment, by the due date notified in the GMAC/IOGTR correspondence.

- Once GMAC/IOGTR are satisfied that all of the information is complete and correct, GMAC/IOGTR will write to organisations/IBCs/principal researchers again issuing the relevant notices (deemed licences, accreditations, certifications etc) that will take effect from 21 June 2001.

1.7 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 Commonwealth State Consultative Committee (CSCG) to further develop the national regulatory framework.

During the reporting period, the CSCG met once on 20 March 2001.

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

- the transitional arrangements necessary to move from the current voluntary system to the new regulatory system;

- revisions of the draft Regulations and Explanatory Guide;

- recruitment of the Gene Technology Regulator (GTR);

- establishing the Gene Technology Technical Advisory Committee, the Gene Technology Ethics Committee and the Gene Technology Community Consultative Group;

- funding for the OGTR; and

- human cloning.

- **Commonwealth agency liaison**

The close partnership between the IOGTR, Commonwealth agencies and existing regulators continued during the January – March 2001.

The partnership between these bodies and the IOGTR primarily operates through an Inter-departmental Committee which met once on 16 March 2001. Issues discussed were primarily those reported for CSCG above.

Additionally, the IOGTR has worked closely with the Office of the National Health and Medical Research Council (ONHMRC) in this quarter.

Liaison with NHMRC focused on the issue of implementing and further developing the prohibitions on human cloning and on certain inter-species experiments involving human material. These legislative prohibitions were introduced into the *Gene Technology Act 2000* 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 January-March quarter was the revised draft of the Gene Technology Regulations 2000.

- **Presentations**

Staff from 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 the IOGTR made presentations at the following forums:

- A briefing to the Health Advisory Committee of the National Health and Medical Research Council on the new regulatory scheme on 19 February 2001, in Brisbane.

- National Outlook Conference, Canberra, 27 February 2001;
- Avcare Biotechnology Committee (ABC) Melbourne, 23 March 2001;
- The Australian Weeds Committee, 23 March 2001, in Canberra;
- Current Trends in the Biotechnology Industry, 27-28 March 2001, in Sydney;
- Grains Week 2001 - Grains Council of Australia 5 April 20001, in Sydney; and
- The Biotechnology Revolution Conference - Investment, skills, ethics and regulations, 6 April 2001, in Melbourne.

PART 2: GMAC AND THE CURRENT VOLUNTARY SYSTEM

The current system of voluntary controls over GMOs will remain in place until the new regulatory system takes effect on 21 June 2001. The GMAC underpins the current administrative arrangements, providing risk assessment advice on proposals for genetic manipulation work and making recommendations concerning the conduct of dealings with GMOs.

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 January-March 2001 reporting period.

2.2 GMAC meetings

- **The Scientific Subcommittee (SSC)**

The SSC, chaired by Professor Jim Pittard, met twice during the reporting period on 29 January 2001 and on 30 March 2001. The SSC:

- considered *ad hoc* scientific matters relating to genetic manipulation work in containment facilities; and

- reviewed 13 proposals for the release of GMOs into the environment, of which 6 were new proposals for field trials, and 7 were extensions to proposals previously assessed by GMAC.

Summaries of the field trials are at **Attachment 1**.

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

- provided a key advisory role in the development of the draft Gene Technology Regulations; and

- developed an explanatory paper for exempt and notifiable risk dealings.

- **The Release Subcommittee (RSC)**

The RSC, chaired by Professor Nancy Millis, met once during the reporting period on 2 March 2001. The RSC:

- discussed breaches of GMAC recommendations; and

- reviewed 7 of the proposals discussed at Attachment 1 of this Report.

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

- played a key advisory role in the development of the Gene Technology Regulations 2000; and
- provided advice on remedial actions to be taken where GMAC conditions for planned releases of GMOs were not complied with. These are discussed in this report under 2.3 (IOGTR monitoring strategy).

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 that GMAC recommendations for the management of trial sites are complied with. A minimum of 5% of current trials are to be inspected each quarter.

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.

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

In summary, in conducting monitoring the IOGTR:

1. contracted appropriate experts to undertake site inspections of current trials in the company of officials from the IOGTR;
2. conducted site inspections from 30 January to 14 March 2001.

Of 11 current trial sites randomly inspected, 1 required some level of remedial action to ensure compliance with GMAC recommendations. Of 98 sites that are subject to post–trial monitoring, 23 required some level of remedial action to ensure compliance with GMAC recommendations.

However, the issues of non–compliance observed at the sites were assessed by GMAC and were found to present negligible risks to human health or the environment in view of the fact that:

- immediate remedial action was taken to ensure compliance with GMAC recommendations; and
- further remedial action was undertaken to ensure compliance with GMAC recommendations continues to be met.

A description of the remedial action taken at the sites is set out below under each relevant Planned Release (PR) proposal.

- **Inspection of current trial sites**

In the January – March 2001 quarter, the IOGTR inspected 11 current sites for compliance with GMAC recommendations. These 11 sites represent approximately 7% of current trials, therefore, during the January – March 2001 quarter, the minimum target of 5% of current trial sites to be inspected per quarter was exceeded. Inspections of current trials spanned five PR proposals (PRs: 63X(5), 77X(3), 90X(2), 129, 129X) covering two crop types: canola (*Brassica napus* and *B. juncea*) and opium poppies (*Papava somniferum*). The following is a summary of the one issue of non-compliance that required some form of remedial action.

PR77X(3)

Summary of the trial

PR77X3 refers to a trial of transgenic canola conducted in NSW, Victoria, South Australia and Western Australia and Tasmania conducted on several sites. The aim of this trial is to continue breeding and variety–testing of potential commercial lines of canola modified for tolerance to the herbicide glyphosate (Roundup®), including seed production in preparation for a possible general release.

Conduct of the inspection

IOGTR inspected 2 sites currently sown to canola and two sites subject to post–trial monitoring (noted below) out of 31 to ascertain compliance to GMAC recommendations. PR77X(3) was extensively reviewed during the last quarter (October to December 2000), where 13 of 31 sites had been inspected.

Findings

At 1 site a single flowering wild radish (*Raphanus raphanistrum*) was observed within the site sown to canola. Several other wild radish plants were observed in pre–flowering stages. GMAC found the risks to the environment and human health were negligible.

Remedial action

The flowering wild radish was hand pulled at the time of inspection. Further occurrences of wild radish were to be spot sprayed with a herbicide suitable for destroying the plants before flowering occurred.

- **Inspection of sites subject to post–trial monitoring**

In addition to inspections of current trial sites during the quarter, the IOGTR conducted inspections of 98 of approximately 320 sites subject to post-trial monitoring for canola (*Brassica napus and Brassica juncea)*.

Sites were selected for inspection on the basis of their location and suitability for the growth of canola over the southern Australia summer. Inspections of sites subject to post–trial monitoring spanned 9 planned release proposals (PRs: 60X(2), 62X(4), 63X(3), 63X(4), 77X, 77X(2), 77X(3), 93, 110).

Due to the level of non-compliance observed in Tasmania, a full investigation was initiated by IOGTR. Findings from inspections in Tasmania are included in this section under specific PR numbers.

A summary of the Tasmanian investigation can be found in 2.4 (Investigations completed) below, and in reports investigating Aventis CropScience Pty Ltd and Monsanto Australia Ltd into issues of non–compliance at 21 sites in that state available on the IOGTR website (www.health.gov.au/tga/genetech.htm).

(1) PR63X(4)

Summary of the trial

PR63X(4) refers to a deliberate release of transgenic canola, conducted on several sites in New South Wales, South Australia, Victoria, Western Australia and Tasmania, with the aim of producing seed from lines of canola that have been genetically modified for tolerance to the herbicide glufosinate-ammonium.

Conduct of the inspection

IOGTR inspected 44 sites out of 92, across three states, to ascertain compliance to GMAC recommendations.

Findings

One site in South Australia was found to have 2 flowering canola volunteers within the area previously sown to GM canola.

Twelve sites in Tasmania were found to have to varying numbers of volunteer canola plants, including over 1000 at one site, present from early flowering to later stages of growth. One site had 50 flowering and/or seed set plants present, another had 20 flowering and/or seed set plants present and the remaining 9 sites had less than 10 flowering and/or seed set plants present.

The finding represented a potential environmental risk. GMAC found that the environmental risks were negligible. No human health risks were identified.

Remedial action

At the single site in South Australia, the flowering volunteer plants were hand–pulled and contained for disposal in accordance with GMAC guidelines.

In Tasmania, a combination of hand–pulling, herbicide treatment and cultivation was employed. Due to the level of non-compliances, a full investigation was initiated by IOGTR. A summary of the findings of the investigation can be found in 2.4 (Investigations completed), below. A full account can be found in the penultimate draft report to the Minister of Aged Care: Investigation of breaches fund during the IOGTR monitoring in Tasmania and risk assessment advice from GMAC, date 29 March 2001, available on the IOGTR website (http://www.health.gov.au/tga/genetech.htm).

(2) PR63X(5)

Summary of the trial

PR63X(5) refers to a deliberate release of transgenic canola, conducted on several sites in New South Wales, South Australia, Victoria, Western Australia and Tasmania, with the aim of producing seed from lines of canola that have been genetically modified for tolerance to the herbicide glufosinate-ammonium.

Conduct of the inspection

IOGTR inspected 10 sites out of 38, across three states, to ascertain compliance to GMAC recommendations.

Findings

One site in Victoria was observed to have had sheep grazing occurring on a site containing canola and wheat stubble. It is possible that sheep may have grazed on canola trash containing viable seed. There is a risk of dissemination of GM canola seed from the trial site via the action of grazing sheep. This might occur if sheep ingested viable GM canola seed and that seed passed through the digestive system and was voided in droppings after the sheep were moved from the trial site. There is no threat to the health and wellbeing of the sheep in terms of ingesting GM seed, as glufosinate-ammonium tolerant canola has been approved as stock feed in Canada, Japan and the USA. Furthermore, there is no threat to the health and wellbeing of humans arising from consumption of sheep products (ie meat, cheese or milk) where the sheep may have ingested this modified canola.

Remedial action

The sheep that had grazed the site were held for 3 weeks in a confined area on the property to allow any grazed seed to pass through the digestive tract of the sheep. The area where the sheep were held for the three week period will be monitored for volunteers for 3 years.

(3) PR62X(4)

Summary of the trial

PR62X4 refers to a deliberate release of transgenic canola conducted in Tasmania with the aim of producing seed, for further evaluation, from lines of canola that have been genetically modified for tolerance to the herbicide glufosinate–ammonium.

Conduct of the inspection

IOGTR inspected 15 sites out of 15, in Tasmania, to ascertain compliance to GMAC recommendations.

Findings

Six sites were found to have numbers of volunteer canola plants from early flowering to later stages of growth, including 4 sites that had over 1000

volunteers each that were at flowering and/or seed set. Of the remaining sites, one had 10 flowering and/or seed set plants present and the other was estimated to have had hundreds of shattered seed pods present.

The findings represented a potential environmental risk. GMAC found that the environmental risks were negligible. No potential human health risks were identified.

Remedial action

A combination of hand–pulling, herbicide treatment and cultivation was employed to remove all volunteers which had flowered. Due to the level of non-compliances, a full investigation was initiated by IOGTR. A summary of the findings of the can be found in 2.4 (Investigations completed), below.

A full account can be found in the penultimate draft report to the Minister for health and Aged Care: investigation of breaches found during the IOGTR monitoring in Tasmania and risk assessment advice from GMAC, date 29 March 2001, available on the IOGTR website (http://www.health.gov.au/tga/genetech.htm).

(4) PR77X

Summary of the trial

PR77X refers to a trial of transgenic canola conducted at a number of sites in New South Wales, Tasmania, Queensland and Victoria.

The aim of this trial was to continue breeding and variety–testing of potential commercial lines of canola modified for tolerance to the herbicide glyphosate (Roundup®).

Conduct of the inspection

IOGTR inspected 4 sites, in Tasmania, out of 19 to ascertain compliance to GMAC recommendations.

Findings

Two sites were observed to have numbers of volunteer canola plants at various stages of growth. One site was estimated to have had over 1000 flowering and seed set plants. The other site had 2 flowering plants present.

The findings represented a potential environmental risk. No potential human health risks were identified. GMAC found that the environmental risks were negligible.

Remedial action

A combination of hand–pulling, herbicide treatment and cultivation was employed. Due to the level of non-compliances, a full investigation was initiated by IOGTR. A summary of the findings of the investigation is at 2.4 (Investigations completed), below. A full account can be found in the penultimate draft report, available on the IOGTR website (http://www.health.gov.au/tga/genetech.htm).

(5) PR77X(2)

Summary of the trial

PR77X(2) refers to a trial of transgenic canola conducted in South Australia, Western Australia, Queensland, New South Wales, Tasmania and Victoria. The aim of this trial is to continue breeding and variety–testing of potential commercial lines of canola modified for tolerance to the herbicide glyphosate (Roundup®).

Conduct of the inspection

IOGTR inspected 14 sites, across three states, out of 37 to ascertain compliance to GMAC recommendations.

Findings

One site in Tasmania was estimated to have 30 flowering canola plants present. The finding represented a potential environmental risk. GMAC found that the environmental risks were negligible. No potential human health risks were identified.

Remedial action

A combination of hand–pulling, herbicide treatment and cultivation was employed. Due to the level of non-compliances, a full investigation was initiated by IOGTR. A summary of the findings of the investigation is at 2.4 (Investigations completed), below. A full account can be found in the penultimate draft report, available on the IOGTR website (http://www.health.gov.au/tga/genetech.htm).

2.4 Investigations completed

- **Past Monsanto canola trial site oversown with broadleaf crop**

Notification of alleged breach

On 28 September 2000, Monsanto Australia Ltd notified the IOGTR that Monsanto had conducted a routine post-trial monitoring visit to a 1998 site used in a PR 77X trial of Roundup Ready® canola. During this visit Monsanto staff discovered the farmer had planted lupins on the past trial site. Planting lupins as a post-trial crop is contrary to the current GMAC recommendations for uses of past canola trial sites.

Monsanto chose to inform the IOGTR of this potential breach given that the latest recommendations from GMAC indicate that broadleaf crops should not be grown. Monsanto indicated in their correspondence that the risks, including control of volunteer canola, were being appropriately managed at the site. The site, in Victoria, falls under planned release proposal PR77X (as discussed above).

GMAC recommendations for the canola trial site

The GMAC advice provided for PR77X, under which the trial was conducted, on 24 March 1998 stated that "The field will be planted in the following year to a cereal crop and in the year after that to a crop other than canola. GMAC advises that, as for PR77, the sites should be monitored for the emergence of volunteer canola plants for the three years following the trial, and that any volunteer plants should be destroyed by cultivation or appropriate herbicide treatment."

GMAC has recently updated its recommendations for post-trial planting on past canola sites. The current GMAC recommendations for canola sites advise that post-trial planting of crops be with either cereals or pasture or other crops with GMAC approval. GMAC no longer allows broadleaf crops, such as lupins, to be grown on past canola trial sites for 3 years after the completion of the trial. This recommendation is to minimise risk of volunteer canola not being observed and controlled (canola seed may lay dormant in the ground and germinate in subsequent years). It may, in some cases, be difficult to detect canola, a broadleaf crop, in other broadleaf crops. It may also be difficult to chemically control volunteer canola in broadleaf crops.

The investigation

The Monsanto trial manager responsible for compliance at the site conducted an inspection on 4 September 2000. The monitoring report from that inspection indicated a number of flowering canola volunteers (approximately nine volunteer

plants were detected) had been found in the lupin crop and destroyed during that visit.

GMAC requires that canola volunteers are destroyed before they reach the flowering stage in order to prevent dissemination of the GMO in the environment through cross-pollination or continuation of the GMO through seed production.

The Monsanto trial site manager advised that the canola volunteers found in early September 2000 are believed to have had low levels of flowering and therefore pollen production.

Further more, the nearest canola crop was approximately 2 km away, beyond the 1km isolation distance advised by GMAC. Related brassica weeds within 50 m of the trial had also been controlled. Therefore the risks from pollen escaping to related crops from the flowering volunteers would be negligible. No potential human health risks were identified.

On 22 November 2000, an IOGTR staff member and an independent expert inspected the site in the presence of the Monsanto trial site manager. The site was small in size and the whole site was easily inspected. No flowering canola volunteers were detected.

Findings

The finding of the IOGTR investigation was that a breach of GMAC recommendations had occurred. The breach was a failure to remove volunteers before they flowered. However, due to management action taken by Monsanto, the risks to human health and the environment were considered negligible.

In addition, a point of clarification is to be made regarding a second potential non-compliance. The point of clarification is made in relation to the growing of broadleaf crops such as lupins on past trial sites. GMAC's more recent advice recommends past canola sites, that are subject to post-trial monitoring, be planted to either cereals or pastures or other crops with GMAC approval.
It should be noted that this advice precludes the use of broadleaf crops, such as lupins, on past canola sites due to the difficulty in detecting and controlling volunteers (compared to cereals and pastures). This particular recommendation (relating to the growing of broadleaf crops) applied to the sites covered under the original release proposal.

Risk Assessment and Management

GMAC advised that lupins should not be grown in future on past canola sites due to the difficulty in detecting and controlling canola volunteers compared to that of cereals and pastures.

- **Post-trial Aventis CropScience canola trial sites in Tasmania with non-compliant flowering or seeding volunteer growth**

Notification of alleged breach

The IOGTR conducted routine monitoring of 5 sites used by Aventis CropScience for trialing of genetically modified (GM) canola (*Brassica napus*) in Tasmania. The monitoring took place on 13, 14 and 15 February 2001. One of the sites inspected was a current trial, the remaining four were sites previously sown to canola, now subject to post-trial monitoring.

It was observed that 3 of the 4 sites previously sown to GM canola had significant amounts of volunteer canola growth which had reached flowering and, therefore, represented a non-compliance with GMAC recommendations.

Following the 13, 14 and 15 February 2001 inspection, an IOGTR monitoring team returned to inspect all Tasmanian GM canola sites currently in post-trial monitoring periods to assess compliance with GMAC recommendations.

GMAC recommendations for trial

GMAC recommendations for the post-trial management of sites requires canola volunteers to be controlled before flowering to prevent the risk of pollen escape and gene flow.

Volunteer canola must also be controlled before reaching the seed development stage to prevent the continued persistence of the genetically modified organism (GMO) in the environment.

The investigation

Correspondence on 16 February 2001 from the IOGTR to Aventis CropScience sought immediate remedial action at the 3 sites observed to be non-compliant and also advised Aventis CropScience that the IOGTR intended to inspect all Tasmanian GM canola sites currently in post-trial monitoring periods. Aventis CropScience responded to the correspondence indicating that some remedial action had commenced on 15 February 2001, commencing as soon as the monitoring visits revealed issues of non-compliance.

On 20 February 2001, the IOGTR sent two monitoring teams to Tasmania for a 4-day period during which 48 Aventis GM canola sites currently in post-trial monitoring periods were inspected. This included re-visiting the four past GM canola sites monitored between 13 and 15 February 2001.

The findings

As a result of monitoring GM canola sites conducted by IOGTR in Tasmania, it was found that 18 of the 49 sites inspected did not comply with GMAC advice in that Aventis CropScience had not prevented volunteers at past canola sites before flowering occurred.

Of the 44 additional Aventis CropScience sites visited, a further 15 sites were found to be non-compliant with GMAC recommendations. Of these sites:

- 11 sites had low numbers of flowering volunteer plants (between 1 and 30 flowering plants);
- 1 site was found with over 1000 volunteers at various stages of growth up to seed pod development; and
- 3 sites had obviously undergone some remedial work by Aventis CropScience or their agents, but residual material left at the sites indicated that the sites had contained canola volunteers at the flowering or seed pod stage.

Risk assessment and management

Over the period 22 February to 16 March 2001, GMAC assessed the risks of flowering volunteers present at the non-compliant sites in Tasmania. GMAC concluded that the non-compliance represented negligible risk of gene flow or continued dissemination in the environment. GMAC advised that gene flow risks were negligible as there were limited numbers of recipient plants and a low likelihood of viable hybrids being produced.

The risk of continued dissemination in the environment was negligible as management actions could be put in to place to mitigate such dissemination. However, GMAC considered that the results of the monitoring visit clearly showed that Aventis CropScience had failed to maintain an appropriate level of control over the trial sites in question. In addition to immediate remedial action to remove flowering or seeding volunteers, GMAC further concluded that the further remedial action should include:

- extension of the post-trial monitoring period for a further 3 years at all non-compliant sites;

- the monitoring and removal of weedy relatives within 100 m of non-compliant sites for 3 years;

- increased frequency of company monitoring of past sites – once every four weeks during periods of likely canola germination and once every 2 months at all other times; and

- increased independent monitoring of sites by the IOGTR.

In addition, the IOGTR will commission an independent study to verify whether any gene flow to related weeds from GM canola has occurred around the non-compliant sites. Following the completion of the gene flow study, all risk management actions will be reviewed to reflect the results of the study.

In addition to the risk management mechanisms now being implemented on the advice of GMAC, the IOGTR has asked GMAC to consider how the continued lack of demonstrated capacity to comply with GMAC recommendations impacts on GMAC's assessments of risks associated with applications for trials involving GM canola which are currently under consideration by GMAC.

The IOGTR has asked GMAC to include advice on this issue in any recommendations made by GMAC in the future.

- **Post-trial Monsanto canola trial sites in Tasmania with volunteer growth**

Notification of the alleged breach

The IOGTR conducted routine monitoring of 2 sites used by Monsanto Australia for the trialing of genetically modified (GM) canola (*Brassica napus*) in Tasmania. The monitoring took place on 13 February 2001.

One of the sites inspected was a current trial, the remaining site was previously sown to canola, now subject to post-trial monitoring. On 16 February, the IOGTR decided to extend monitoring to encompass all sites previously sown to canola, subject to post-trial monitoring in Tasmania.

The IOGTR monitoring team found issues of non-compliance at 3 of seven sites subject to post trial monitoring.

GMAC recommendations for trial

As discussed above, GMAC recommendations for the post-trial management of sites requires that canola volunteers be controlled before flowering to prevent the risk of pollen escape and gene flow. Volunteer canola must also be controlled before reaching the seed development stage to prevent the continued persistence of the GMO in the environment.

The investigation

As noted previously, on 16 February 2001 the IOGTR decided to extend monitoring to encompass all past canola trial sites in Tasmania. Monsanto was notified on 19 February 2001 that the IOGTR intended to inspect such sites for

compliance with GMAC recommendations. A monitoring team visited 6 additional sites on 20 and 21 February 2001.

The findings

As a result of monitoring of GM canola sites conducted by Monsanto Australia Ltd in Tasmania, the IOGTR found that three of the seven sites subject to post-trial monitoring did not comply with GMAC advice regarding destruction of volunteers at past canola sites before flowering occurred.

Of the 2 sites inspected on 13 February 2001, the monitoring team did not identify any non–compliance issues at either site. Of the six additional Monsanto sites visited, three sites were found to be non-compliant with GMAC recommendations:

- one site had approximately 30 volunteer canola plants flowering (2 plants);
- one site had less than 100 canola volunteers flowering or with pod formation; and
- one site was found to have what is estimated to be over 1000 canola volunteers at various stages of growth up to seed pod development.

Risk assessment and management

Over the period 22 February to 16 March, GMAC assessed the risks associated with the presence of flowering volunteers at the three sites in Tasmania and the Monsanto advice on remedial actions. GMAC concluded that the non-compliance represented negligible risk of gene flow or continued dissemination in the environment.

GMAC advised that gene flow risks are negligible as there are limited numbers of recipient plants and a low likelihood of viable hybrids being produced.

The risk of continued dissemination in the environment is negligible as management actions can be put in place to mitigate such dissemination. However, GMAC considered that the results of the monitoring visit clearly showed that Monsanto Australia had failed to maintain appropriate levels of control over the trial sites in question. In addition to immediate remedial action to remove volunteers, GMAC further concluded that the further remedial action should include:

- extension of the post-trial monitoring period for a further 3 years at all non-compliant sites;

- the monitoring and removal of weedy relatives within 100 m of non-compliant sites for 3 years;

- increased frequency of company monitoring of past sites – once every four weeks during periods of likely canola germination and once every 2 months at all other times; and

- increased independent monitoring of sites by the IOGTR

In addition, the IOGTR will commission an independent gene flow study of related weeds around the non-compliant sites to verify whether any gene flow has occurred.

In addition to the risk management mechanisms now being implemented on the advice of GMAC, the IOGTR has asked GMAC to consider how the continued lack of demonstrated capacity to comply with GMAC recommendations impacts on GMAC's assessments of risks associated with applications for trials involving GM canola which are currently under consideration by GMAC. The IOGTR has asked GMAC to include advice on this issue in any recommendations made by GMAC in the future.

2.5 Investigations underway

As at 31 March 2001, IOGTR had 4 ongoing investigations into alleged breaches of GMAC recommendations.

Details will be reported in a subsequent quarterly report, once investigations are complete.

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*); and

- may be commercial-in-confidence information; and

- may unfairly damage the reputation of a company or individual under investigation if the allegation is not subsequently proven; and

- may 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 presents a serious risk to human health, or the environment. All such breaches will be notified immediately, pending the outcome of any investigation.

2.7 Audits underway

Background to the audit

In 1997 GMAC received Planned Release Proposals (PS74, 75, 76) for transgenic lupin trials to be conducted in Western Australia.

The lupin trials conducted by the Centre for Legumes in Mediterranean Agriculture (CLIMA), a Cooperative Research Centre (CRC) between the University of Western Australia, Agriculture Western Australia and others.

The CRC was discontinued but CLIMA was subsequently subsumed into the Faculty of Agriculture, University of Western Australia as a research centre. Details of the post-trial monitoring requirements are set out below.

- **PR74**

  This proposal was for the release of herbicide resistant lupins (*Lupinus angustifolius*). The post-trial monitoring conditions for PR74 state that there will be a two-year break before lupins are able to be grown on the sites and that the sites will be monitored for volunteer lupin plants during this period to ensure that any plants found are removed and destroyed before flowering.

- **PR75 and PR76**

  This proposal was for the development of herbicide and virus resistant lupins (*Lupinus luteus*). GMAC's advice for post-trial monitoring is that no *L. luteus* will be grown on the sites for at least four years after the trial and any lupins that grow on the sites during these four seasons will be destroyed before flowering.

Audit Objectives

The audit aims to:

1. identify whether there are any deficiencies in processes employed to control sites which were the subject of field trials under PR74, PR75 and PR76 and that this control is in accordance with the post-trial recommendations made by the GMAC; and

2. identify and consider options for action in relation to any deficiencies identified in 1 above.

Context of the audit

In the absence of regulatory underpinning, the IOGTR and GMAC operate within an administrative system. Organisations dealing with GMOs choose to voluntarily comply with GMAC recommendations.

The IOGTR and GMAC do not have any legislative basis to access documents or information necessary for the conduct of this audit and will rely on the cooperation of the UWA, and other parties involved in the management of the trials, to provide such information.

Reasons for audit

There appears to be a need to clarify the roles and responsibilities for ongoing management since discontinuation of CLIMA as a CRC.

The cumulative effect of a breach reported in the October – December 2000 Quarterly Report and further issues of concern that have been identified suggests that there is a weakness in the operation of post-trial monitoring for these proposals.

The IOGTR needs to be satisfied that the sites are being appropriately managed. An audit of these proposals would ascertain if improvements can be made to give greater certainty in the management of field trials.

Scope

The Audit Committee will review the post-trial monitoring for PR74, PR75 and PR76 and the processes for managing the sites to determine if there are any deficiencies and make recommendations for improvements. A complete copy of the Audit Plan is available at the IOGTR website (HTTP://www.health.gov.au/tga/genetech.htm).

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.

New general release applications

No new general release applications were received in this quarter. The risk assessment of the general release proposal for insect-resistant (Ingard®) cotton, has carried over from the last 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 released during this quarter.

- **Website**

Documents made available on the IOGTR internet website (http://www.health.gov.au/tga/genetech.htm) during the January – March 2001 quarter were:

- Notice on transitional arrangements for implementing the *Gene Technology Act 2000*;

- Nomination information for new gene technology committees;

- Investigations into non-compliance at past trial sites in Tasmania;

- Summary of major amendments to the Gene Technology Bill 2000;

- Second Draft of the Commonwealth Gene Technology Regulations 2000 (January 2001);

- Invitation to make a submission on the Second Draft of the Commonwealth Gene Technology Regulations 2000 (January 2001);

- Explanatory Guide to the second Draft of the Commonwealth Gene Technology Regulations 2000 (January 2001);

- The *Gene Technology Act 2000*; and

- Audit of management of Planned Releases 74, 75, 76.

Throughout the reporting period, the website was consistently in the top 10 Department of Health and Aged Care websites visited, with approximately 11,940 visits recorded to the IOGTR home page during the reporting period with an average of over 100 visits per day.

This brings the total number of home-page hits since recording began in March 2000 to 36,000.

During the reporting period, the IOGTR also responded to 303 emails to the IOGTR Website on gene technology related issues – this brings the total number of emails responded to since the beginning of the 2000-2001 financial year to 884.

- **International coordination activities**

During the January – March 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

- interested officials from other Governments.

Also during the reporting period the IOGTR continued to participate in:

- a Government working group coordinating Australia's involvement in the new *Codex Alimentarius ad hoc intergovernmental taskforce on food derived from biotechnology* (the IOGTR's aim in participation is to ensure that Australia's experience in gene technology assists in harmonisation of international biotechnology-related definitions and risk assessment processes);

- 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 public consultation processes; and

- activities relating to the development of a protocol under the Biological Weapons Convention. The IOGTR's participation in this effort aims 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.

The IOGTR also provided briefing on the proposed new regulatory system for GMOs to Government officials from China, Japan, Canada, New Zealand and from the European Commission.

- **Collaboration in other regulation-related activities**

a) Research program on environmental risk of genetically modified organisms

This research program is a collaboration between the IOGTR and the CSIRO and Environment Australia (EA). The program will fund a number of research programs aimed at:

- enhancing our knowledge of environmental risks relating to GMOs; and

- the development or improvement of risk assessment tools that may be used by regulatory agencies, research organisations and commercial organisations.

The IOGTR participates in a Joint Policy Reference Group (JPRG). The JPRG consists of representatives from CSIRO, EA and IOGTR and aims to enhance collaboration and coordination between the agencies.

As proposals for projects to be funded by this research program are still being drafted for comment by the organisations involved in the program, there was no meeting of the JPRG during the reporting period.

b) Biotechnology Australia (BA) coordination activities

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

The Biotechnology Portfolios are the Department of Industry, Science and Resources; Agriculture, Fisheries and Forestry Australia; Environment Australia; the Department of Health and Aged Care; and the Department of Education, Training and Youth Affairs. During the January- March 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), and BA working groups. Further information on Biotechnology Australia can be obtained at their internet website (http://www.biotechnology.gov.au/).

- **Consultants**

During the reporting period, the IOGTR managed 5 existing contracts with:

- Matthews Pegg Consulting (MPC) for legal policy advice;

- Dialog, for the development of the database system to facilitate the national regulatory system;

- Luminis Pty Ltd, a consultancy company providing expert support (weed/crop production experts) and contracted to accompany IOGTR inspection teams to canola and poppy trials;

- Acumen Alliance (ACT) Pty Ltd for the purpose of providing project management for development of the database system to facilitate the national regulatory system;

- McNiece Communications Pty Ltd providing continued communications support and advice to the IOGTR.

PART 3: THE QUARTER AHEAD

During the forthcoming quarter (April to June 2001) the IOGTR will undertake the following activities:

- Finalise the 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.

- 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.

- 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.

- 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.

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

- 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.

- Continue monitoring and surveillance activities.

- Continue preparations for GTIMS to go live in June 2001, including consultation with and training for, key users (such as IBCs).

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-145: Evaluation of transgenes in grapevine No.3

Organisation proposing release: CSIRO Plant Industry Horticulture Unit
PO Box 350
Glen Osmond SA 5064

Organism to be released: Grapevine (*Vitis vinifera*)

Purpose of the release: The aim of the release is to evaluate the long-term stability and field performance of transgenic grapevine plants with modified berry colour and tannin levels or sugar composition.

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

Two types of transgenic grapevines are being tested. They contain extra copies of genes derived from grapevine. One of the genes that has been introduced is for an enzyme that is part of the pathway that synthesises tannins and the anthocyanin pigments present in red grapes. Alteration of the expression of this gene is expected to result in a decrease in these compounds in the grape berry.

In a second set of plants, the genetic modification is aimed at reducing the levels of an enzyme involved in sugar accumulation in grape berries. This should result in an increase in berry sucrose levels due to reduced sucrose cleavage.

In addition, the transgenic plants contain a selectable marker gene that confers resistance to the antibiotics kanamycin and neomycin. This gene is used to aid identification and selection of transgenic plant cells in the laboratory.

Location and size of trial: Merbein, Victoria. Approximately 0.15 hectare.

Further information: The institution's contact officers for this proposal are Dr Simon Robinson and Dr Christopher Davies, telephone (08) 8303 8600, facsimile (08) 8303 8601.

PR-146: Planned release of GMO (*P. somniferum*) oilseed poppy

Organisation proposing release: Glaxo Wellcome Australia Ltd
PO Box 189
Latrobe TAS 7307

Supervising Biosafety Committee: Agriculture Western Australia

Organism to be released: Oilseed poppy (*Papaver somniferum*)

Purpose of the release: Oilseed poppy is a source of alkaloids for the production of morphine, codeine and thebaine for the pharmaceutical market. This release is investigating alkaloid production and cross-pollination within the oilseed poppy.

Brief description of the nature and effect of the genetic modification:
The transgenic plants contain either
i) the gene for an enzyme, β-glucuronidase (GUS), from the bacterium *Escherichia coli*, to investigate the degree of pollen transfer to non-transgenic oilseed poppy plants; *or*
ii) the tyrosine decarboxylase gene or the berberine bridge enzyme gene both from the opium poppy, with the aim of increasing alkaloid levels in the plant.
In addition, the transgenic plants contain a selectable marker gene that confers resistance to the antibiotic hygromycin.

Location and size of trial: 81,000 plants grown at the Frank Wise Institute Kununurra in the shire of Wyndham and East Kimberley, Western Australia.

Further information: The institution's contact officer for this proposal is Dr M J Doyle, telephone (03) 6426 5722, facsimile (03) 6426 2300

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 *Pseudomanas* are the subject of intensive research worldwide.

In this field trial genetically modifed 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 *Pseudomanas 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 *Pseudomanas* 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 flourescens* 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 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 *Pseudomanas* 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 flourescens* 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 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 m^2 at Acton, ACT. A maximum of 10^{12} 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-63X(6): Release of glufosinate-ammonium tolerant hybrid and open-pollinated canola cultivars

Organisation proposing release: AventisCropScience Pty Ltd
391-393 Tooronga Road
East Hawthorn VIC 3123

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

Purpose of the extension to the release: Canola plants genetically modified for tolerance to the herbicide glufosinate-ammonium are to be trialled under this extension to the original proposal. Use of the herbicide-tolerance gene would allow the application of glufosinate-ammonium on canola crops to control broadleaf and grass weeds.

During the winter season, agronomic features of the herbicide-tolerant canola will be assessed along with a new system developed for making hybrid varieties of canola. Hybrid varieties of canola may provide higher yields.

During the Australian spring/summer 'contraseason', seed from open-pollinated glufosinate-ammonium-tolerant canola will be obtained and supplied to Aventis CropScience Canada for use in the Canadian breeding program.

Brief description of the nature and effect of the genetic modification: The transgenic plants to be released in both the winter and spring/summer season contain the phosphinothricin acetyltransferase gene from the bacterium *Streptomyces hygroscopicus*, which confers resistance to the herbicide glufosinate-ammonium.

The hybridisation system comprises two genetically modified lines of canola - a male-sterile line and a fertility-restorer line. The genes conferring these properties were introduced from the bacterium *Bacillus amyloliquefaciens*.

Some of the plants also contain a selectable marker gene conferring resistance to the antibiotics kanamycin and neomycin.

Location and size of trial: A total area of approximately 1100 hectares will be grown at a number of sites in the canola-growing regions of Western Australia, NSW, South Australia, Queensland and Victoria in May 2001 and in Victoria, South Australia and Tasmania in September 2001.

Further information: The institution's contact officer for this proposal is Mr Peter Whitehouse, telephone (03) 9248 6888, facsimile (03) 9248 6605.

PR-64X(2): Evaluation of transgenic white clover for field resistance to alfalfa mosaic virus

Organisation proposing release: Plant Biotechnology Centre
Agriculture Victoria
Victorian Department of Natural Resources and Environment

Organism to be released: White clover (*Trifolium repens*)

Purpose of the extension to the release: White clover plants have been produced that are immune to infection by at least two strains of alfalfa mosaic virus. This virus causes large economic losses to dairy farmers. The aims of this proposal are a) to determine whether the immunity to alfalfa mosaic virus observed in the primary transgenic plants under glasshouse and planned field release conditions also occurs in elite offspring from these plants under field conditions; and b) to establish a breeding nursery for selection of elite plants for the development of experimental cultivars.

Brief description of the nature and effect of the genetic modification: The DNA inserted into the plants is derived from alfalfa mosaic virus and includes the sequence that encodes the virus coat protein.

A marker gene from the bacterium *Escherichia coli*, encoding resistance to the antibiotics kanamycin and neomycin, was also transferred to the transgenic plants.

Location and size of trial: A total of 1300 transgenic plants will be planted at Hamilton, Victoria and a total of 336 transgenic plants will be planted at Howlong, NSW.

Further information: The institution's contact officer for this proposal is Professor German Spangenberg, telephone (03) 9479 3851 or (03) 9479 2995 and facsimile (03) 9479 3618.

PR-77X(4) : Planned release of transgenic canola expressing tolerance to the herbicide glyphosate (Roundup Ready® canola)

Organisation proposing release: Monsanto Australia Ltd
PO Box 6051
St Kilda Road
CENTRAL VIC 8008

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

Purpose of the extension to the release: The aim of this extension is to continue breeding and variety-testing of canola modified for tolerance to the herbicide glyphosate (Roundup®). The use of herbicide-tolerant canola would allow the application of glyphosate for the control of weeds that emerge following crop planting. The trial is for seed production and, in addition, options for weed management in glyphosate-tolerant canola will be examined during the trial. Seed production in preparation for a general release will also take place.

Brief description of the nature and effect of the genetic modification: The transgenic canola plants have been modified to contain two new genes that are found naturally in common soil microorganisms. The proteins produced by the two genes together confer tolerance to glyphosate, the active ingredient of the herbicide Roundup®.

Location and size of trial: A total area of approximately 100 hectares will be planted on up to 60 sites in NSW, Victoria, Tasmania, Queensland, Western Australia and South Australia.

Further information: The institution's contact officer for this proposal is Helen Arthur, telephone (03) 9522 7122, facsimile (03) 9525 2253.

PR-85X(4): Small and large scale seed increase of a genetically modified canola (*Brassica rapa*) with a new hybridisation system

Organisation proposing release: Aventis CropScience Pty Ltd
391-393 Tooronga Road
East Hawthorn VIC 3123

Organism to be released: Canola (*Brassica rapa*)

Purpose of the extension to the release: The aim of this extension is to continue the evaluation of a new genetic system for making hybrid varieties of canola (*Brassica rapa*) and to increase seed stocks for use in Aventis' global breeding program. Part of the trial is aimed at investigating the level of tolerance to Blackleg, a fungal disease.

The canola plants have also been genetically modified for tolerance to the herbicide glufosinate-ammonium. The herbicide-tolerance gene would allow the use of glufosinate-ammonium in canola crops as a post-emergent application to control broadleaf and grass weeds.

Brief description of the nature and effect of the genetic modification: The hybridisation system comprises two genetically modified lines of canola - a male-sterile line and a fertility-restorer line. The genes conferring these properties were introduced from the bacterium *Bacillus amyloliquefaciens*.

The herbicide-tolerance gene introduced into the canola plants is the phosphinothricin acetyltransferase gene from the bacteria *Streptomyces viridichromogenes* or *Streptomyces hygroscopicus*.

Location and size of trial: A total of 121 hectares will be planted at a number of sites in NSW, Queensland and Victoria in May 2001 and in Victoria, South Australia and Tasmania in September 2001.

Further information: The institution's contact officer for this proposal is Mr Peter Whitehouse, telephone (03) 9248 6888, facsimile (03) 9248 6605.

PR-90X(3): Development of herbicide tolerant *Brassica juncea*

Organisation proposing release: Aventis CropScience Pty Ltd
391-393 Tooronga Road
East Hawthorn VIC 3123

Organism to be released: Indian mustard (*Brassica juncea*)

Purpose of the extension to the release: The Indian mustard plant (*Brassica juncea*) is closely related to commercially grown canola (*Brassica napus*). Plant breeders are keen to develop canola-quality lines of *B. juncea* would be interchangeable with *Brassica napus* for processing. Features of non-canola quality *Brassica juncea* lines, such as greater tolerance to heat and drought and early maturity, are sought-after in canola quality breeding.

The aim of this extension to the original proposal is to continue trialing in the field a new system for making hybrids in suitably modified Indian mustard plants. The plants have also been modified for tolerance to the herbicide glufosinate-ammonium. The herbicide-resistance trait would also enable glufosinate-ammonium to be used to assist weed control in the crop.

Brief description of the nature and effect of the genetic modification: The hybridisation system comprises two genetically modified lines of canola - a male-sterile line and a fertility-restorer line. The genes conferring these properties were introduced from the bacterium *Bacillus amyloliquefaciens*.

The gene conferring resistance to the herbicide glufosinate-ammonium was introduced from the bacterium *Streptomyces hygroscopicus*. Some of the plants also contain a selectable marker gene coding for resistance to the antibiotics kanamycin and neomycin.

Location and size of trial: A total area of 10 hectares comprising less than 1 hectare per site will be planted at a number of sites in May 2001 in NSW, Queensland and Victoria, and in September 2001 in Victoria, South Australia and Tasmania.

Further information: The institution's contact officer for this proposal is Mr Peter Whitehouse, telephone (03) 9248 6888, facsimile (03) 9248 6605.

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-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