Interim Office of the Gene Technology Regulator

Quarterly Report

December 2000

The Interim Office of the Gene Technology Regulator Quarterly Report

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TGA THERAPEUTIC GOODS ADMINISTRATION

Commonwealth Department of 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 third Quarterly Report of the Interim Office of the Gene Technology Regulator (IOGTR). I regret the delay in presenting this Report, which is due to the workload involved in implementing the new regulatory system by 21 June 2001.

The purpose of this Report is to provide information about the operation of the IOGTR and the Genetic Manipulation Advisory Committee (GMAC). This Report covers the October–December 2000 quarter. As you know, a major milestone was achieved during this reporting period when the *Gene Technology Act 2000* was passed in Parliament and received royal assent on 21 December 2000. While this event was the focus of activity in the Interim Office of the Gene Technology Regulator, the Office continued all other functions necessary to establish the regulatory system by 21 June 2001 when the Act comes into effect. Quarterly Reporting will continue when the new regulatory system begins operating.

During the reporting period the IOGTR:

- Continued to work with representatives from States and Territories to develop the Inter-Governmental Agreement on Gene Technology (IGA);
- Developed detailed responses to all public submissions made on the first draft of the Gene Technology Regulations 2000;
- Revised the draft of the Gene Technology Regulations 2000 and Explanatory Guide to the Regulations in the light of comment from the public;
- Continued the coordination of the risk assessment of the application for general release of insect resistant (INGARD) cotton; and
- Maintained a proactive monitoring of current field trial compliance with GMAC recommendations.

During the reporting period, GMAC has provided advice on:

- 3 new proposals for field trials;
- 3 extensions to proposals previously assessed by GMAC;
- 1 general release proposal; and
- 54 proposals for contained work with GMOs.

I am forwarding the report to you simultaneously with the fourth Quarterly Report and I look forward to providing you with the fifth and final report for the Interim Office in the middle of the year.

Yours sincerely

Terry Slater
National Manager
Therapeutic Goods Administration
May 2001

CONTENTS

ABBREVIATIONS

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
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
PR	Planned Release
RSC	Release Subcommitee
SOP	Standard Operating Procedure
SSC	Scientific Subcommitee

SUMMARY

This is the third 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 October - December 2000, 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).

A major milestone during the October - December 2000 Quarter was the passage of the *Gene Technology Act 2000,* which has as its object:

> To protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms.

The Act will take effect on 21 June 2001, underpinning a national regulatory system for gene technology, which will establish a new international benchmark for rigorous and progressive regulation of gene technology. Further details on the Act are provided at part 1.2 (Key result 1 – Legislation to underpin a national regulatory framework for GMOs*)* of this Report.

Tracking commitments made in the previous Quarterly Report

The July – September Quarterly Report 2001 highlighted six key issues that the IOGTR anticipated addressing during the October - December quarter. A brief summary against those six issues follows.

1. **Responses to submissions received on the Regulations**

   Fifty one submissions were received in response to a call for comment on the first draft of the Gene Technology Regulations 2000. These submissions were thoroughly analysed during the October - December quarter and resulted in a revised draft of the Regulations, made available in January 2001. An individual response to each submission was prepared. Further details on the Regulations are discussed at part 1.2 (Key result 1 – Legislation to underpin a national regulatory framework for GMOs*)* of this Report.

2. Regulations under the Gene Technology Bill 2000

During the July – September 2000 quarter, IOGTR had anticipated that a second round of consultation on the draft Regulations would commence in the period October – December 2000. This timeframe was revised however, to ensure that the second round of consultations and the revised Regulations could take account of the Senate Community Affairs References Committee Report on the Gene Technology Bill 2000 (*A Cautionary Tale: Fish Don't Lay Tomatoes*) and Parliamentary debate on the Gene Technology Bill 2000.

Revised drafting instructions for the Regulations took account of:

- Information from the 50 submissions from the public;
- The Senate Community Affairs References Committee report;
- Parliamentary debate on the Gene Technology Bill 2000;
- Detailed considerations of the draft Regulations by GMAC;
- Consultations with States and Territories;
- Contact with key users of the system such as representatives of Institutional Biosafety Committees (IBCs); and
- International approaches to the regulation of GMOs (such as the European Community directive governing deliberate releases of GMOs and the approach adopted by the Advisory Committee on Releases to the Environment in the United Kingdom).

3. Guidelines for certification and accreditation

Preparation of guidelines for certification and accreditation commenced in the October – December 2000 quarter. The guidelines will be part of a comprehensive handbook for users of the regulatory system, which is discussed in Part 3 (The Quarter Ahead).

4. Senate inquiry: Gene Technology Bill 2000 and related legislation

As flagged in the July - September 2000 Quarterly Report, and as discussed in the context of the revised draft Regulations (point 2. above), the legislation was the subject of a Senate inquiry conducted by the Senate Community Affairs References Committee. During the October - December 2000 quarter, the IOGTR:

- responded to further questions from the Committee and its Secretariat; and
- provided additional information to the Committee such as KPMG's report on cost recovery.

The Committee handed down its report on 1 November 2000.

5. Committees

In the reporting period (October – December 2000), work continued to establish the three statutory committees specified in the *Gene Technology Act 2000*:

- the Gene Technology Technical Advisory Committee (GTTAC);
- the Gene Technology Community Consultative Committee (GTCCC); and
- the Gene Technology Ethics Committee (GTEC).

A paper outlining a process and timeframe for establishing the Committees was considered by Commonwealth agencies, States and Territories in November as set out in part 1.6 (Other results: Working collaboratively with the States and Territories) of this Report.

6. Monitoring and surveillance

Monitoring during the October – December 2000 quarter saw 35 sites randomly inspected (22 current sites and 13 past sites) by the IOGTR. Four of the 35 sites required some level of remedial action to ensure compliance with GMAC recommendations. None of the sites represented an additional risk to human health or the environment as appropriate action was taken to remedy concerns.

Investigations into two alleged breaches were also completed during this quarter. As foreshadowed in the July - September Quarterly Report, the final report on the Audit of Aventis CropScience was publicly released during The October – December quarter.

Further information about monitoring and surveillance is set out at parts 2.3 to 2.7 of this Report.

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 October - December 2000 quarter in relation to the development and implementation of the national regulatory framework.

Part 2 outlines work undertaken during the October – December 2000 quarter under the current system of voluntary controls over GMOs, which will continue to operate until the new regulatory system is established. It highlights the work of the GMAC and its subcommittees.

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

Further information

This third Quarterly Report reflects the IOGTR's commitment to provide interested parties with comprehensive information about the oversight of GMOs in Australia. The release of the Report has been delayed somewhat as a result of the workload required to implement the new regulatory system by 21 June 2001 and in particular by the need to thoroughly analyse submissions on the draft Gene Technology Regulations 2000. The IOGTR is, however, in the process of recruiting new staff which should assist in ensuring the timely release of Quarterly reports in the future. 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 October - December 2000 quarter:

Key result 1.
The passage through Parliament of the *Gene Technology Act 2000*, the *Gene Technology (Consequential Amendments) Act 2000*, and the *Gene Technology (Licence Charges) Act 2000*.

Key result 2.
The Inter-Governmental Agreement on Gene Technology was amended to reflect changes to the *Gene Technology Act 2000* resulting from Parliamentary debate.

Key result 3.
The Regulations under the *Gene Technology Act 2000* were re-drafted to take account of comments received and agreed by the Commonwealth State Consultative Group (CSCG) on Gene Technology and the Parliamentary debate on the primary legislation.

Key result 4.
Significant progress was made on the development of the new information technology system, which will support the regulatory system.

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

1.2 Key result 1 - Legislation to underpin a national regulatory framework for GMOs

On 8 December 2000, the Commonwealth Parliament passed three pieces of legislation which comprise the Commonwealth's contribution to the national regulatory framework for gene technology:

- the *Gene Technology Act 2000*;
- the *Gene Technology (Consequential Amendments) Act 2000*; and
- the *Gene Technology (Licence Charges) Act 2000*.

Date of effect

The Acts will take effect on 21 June 2001. Copies of these Acts are available on the IOGTR Website (www.health.gov.au/tga/genetech.htm).

Amendments

The amendments to this legislation made during Senate debate are described below.

SUMMARY OF AMENDMENTS

1. Precautionary Principle – Section 4

A new paragraph has been added to section 4 as follows:

(aa) provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost effective measures to prevent environmental degradation.

2. Definition of Gene Technology Agreement – Section 10

The definition of Gene Technology Agreement has been changed to mean the agreement between the Commonwealth and at least 4 States, as in force from time to time. Since the introduction of the Gene Technology Bill 2000 into Parliament, the text of the gene technology agreement has been settled between officials from the Commonwealth and all States and Territories. The final text provides that the agreement commences on signature by the Commonwealth and at least four States (including Territories), rather than on signature of all States and Territories (as was previously set out in the Bill that was introduced into Parliament). The Act has therefore been amended to reflect this change.

3. Name of Gene Technology Community Consultative Group – Section 10

The name of the Gene Technology Community Consultative Group has been changed to the Gene Technology Community Consultative Committee, in order to better reflect its function under the national scheme.

4. GM-free zones – Section 21

Section 21 of the Act has been amended to allow the Ministerial Council to issue policy principles recognising areas, if any, designated under State or Territory law for the purpose of preserving the identity of GM crops and non-GM crops for marketing purposes.

5. Penalties – Sections 32 and 34 (not 33 and 35)

Imprisonment terms have been included in the legislation for someone who deals with a GMO without a licence (maximum 2 years, or 5 years in the case of an aggravated offence), or who breaches a condition of a GMO licence (again, a maximum of 2 years, or 5 years in the case of an aggravated offence).

6. Continuing Offences – Section 34

A new provision has been included in the Act to provide that where a person has breached a condition of a licence, the person is guilty of a separate offence for each day that the breach occurred.

7. Insurance – Section 62

Section 62 has been amended to include an additional subsection as follows:

(3) Licence conditions may also include conditions requiring the licence holder to be adequately insured against any loss, damage, or injury that may be caused to human health, property or the environment by the licensed dealing.

8. GMO Register – Section 78

The Act has been amended to allow GM Products that have not previously been licensed to be placed on the GMO Register.

This ensures that an appropriate level of regulation is also able to be applied to non-viable GM products that pose negligible biosafety risks (for example, non-viable stockfeed derived from GM plants).

9. GTTAC – Section 100

The Act has been amended to ensure that the Gene Technology Technical Advisory Committee includes a member of the Consultative and of the Ethics Committees.

10. Function of the Community Consultative Committee – Section 107

An additional subsection has been included in this section providing that one of the functions on the Gene Technology Community Consultative Committee is to provide advice on the request of the Regulator or the Ministerial Council on matters of general concern identified by the Regulator in relation to applications made under the Act.

11. Appointment of the GTR – Section 118

Section 118 has been amended to include two additional subsections as follows:

(5) The Governor-General must not appoint a person as the Regulator if, at any time during the period of 2 years immediately before the proposed period of appointment, the person was employed by a body corporate whose primary commercial activity relates directly to the development and implementation of gene technologies.

(6) The Governor-General must not appoint a person as the Regulator if the person has a pecuniary interest in a body corporate whose primary commercial activity relates directly to the development and implementation of gene technologies.

12. Quarterly Reports to Parliament – Section 136A

A new section has been added to require the GTR to, as soon as practicable after the end of each quarter, prepare and give to the Minister a report on the operations of the Regulator during that quarter.

The report must include information on GMO licenses issued during the quarter, any breaches of conditions of a GMO dealing during the quarter, and the auditing and monitoring of dealings.

The Minister must cause a copy of this report to be laid before both Houses of Parliament within 15 sitting days of receiving the report.

13. Extended Standing for Judicial Review – Section 183A

This amendment explicitly states that a State is taken to be a person aggrieved of a decision for the purposes of the *Administrative Decisions (Judicial Review) Act 1977*, meaning that States may seek review by the Federal Court of a decision made by the GTR under the Act, or of the failure of the GTR to make a decision, or of the conduct engaged in for the purpose of making a decision.

14. Confidential commercial information – Section 185

Two new subsections have been added as follows:
(2A) The Regulator must refuse to declare that information is confidential commercial information if the information relates to one or more locations at which field trials involving GMOs are occurring, or are proposed to occur, unless the Regulator is satisfied that significant damage to the health and safety of people, the environment or property would be likely to occur if the locations were disclosed."

(3A) If:

a) the Regulator declares that particular information is confidential commercial information, and

b) the information relates to one of more locations at which field trials involving GMOs are occurring, or are proposed to occur;

the Regulator must make publicly available a statement of reasons for the making of the declaration, including but not limited to:

c) the reasons why the Regulator was satisfied as mentioned in subsection (1); and

d) the reasons why the Regulator was not satisfied under subsection (2) that the public interest in disclosure of the information outweighed the prejudice that the disclosure would cause; and

e) the reasons why the Regulator was satisfied under subsection (2A) that significant damage to the health and safety of people, the environment or property would be likely to occur if the locations were disclosed.

15. Interference with dealings with GMOs – Section 192A

A provision has been added to the Act providing as follows:

A person is guilty of an offence if:

(a) the person engages in conduct; and

(b) the conduct:

(i) results in damage to, destruction of, or interference with, premises at which dealings with GMOs are being undertaken; or

(ii) involves damaging, destroying, or interfering with, a thing at, or removing a thing from, such premises; and

(c) the owner or occupier of the premises, or the owner of the thing (as the case requires) has not consented to the conduct; and

(d) engaging in the conduct, the person intends to prevent of hinder authorised GMO dealings that are being undertaken at the premises or facility; and

(e) the person knows, or is reckless as to, the matters mentioned in paragraphs (b) and (c).

Authorised GMO dealings are defined, in relation to premises or a facility, as meaning dealings with GMOs being undertaken at the premises or facility that:

(a) are authorised to be undertaken at the premises or facility by a GMO licence; or

(b) are notifiable low risk dealings; or

(c) are exempt dealings; or

(d) are on the GMO register.

16. Human cloning – Section 192B

A new section has been included in the Act to make it an offence if a person:
(a) engages in conduct; and
(b) the person knows that, or is reckless as to whether, the conduct will result in the cloning of a whole human being.

The maximum penalty for the offence is 2,000 penalty units or imprisonment for 10 years.

Cloning of a whole human being is defined in the Act as the use of technology for the purpose of producing, from one original, a duplicate(s) or descendant(s) that is genetically identical to the original.

17. Experiments involving animal eggs – Section 192C

A new section as been inserted into the Act to make it an offence if a person:
(a) engages in conduct; and
(b) the person knows that, or is reckless as to whether, the conduct involves carrying out experiments or research that involves putting human cells, or a combination of human cells and animal cells, into animal eggs.

The maximum penalty for the offence is 2,000 penalty units or imprisonment for 10 years.

18. Experiments involving putting human and animal cells into a human uterus – Section 192D

A new section has been inserted into the Act to make it an offence if a person:
(a) engages in conduct; and
(b) the person knows that, or is reckless as to whether, the conduct involves carrying out experiments or research that involves putting a combination of human cells and animal cells into a human uterus.

The maximum penalty for the offence is 2,000 penalty units or imprisonment for 10 years.

19. Review of the Act – Section 194

The Act has been amended to ensure that the Ministerial Council must cause an independent review of the Act (including the OGTR) to be undertaken after four years of operation.

The section provides as follows:
(1) The Ministerial Council must cause an independent review of the operation of this Act, including the structure of the Office of the Gene Technology Regulator, to be undertaken as soon as possible after the fourth

anniversary of the commencement of this Act.

(2) A person who undertakes such a review must give the Ministerial Council a written report of the review.

(3) The Minister, on behalf of the Ministerial Council, must cause a copy of the report of the review to be tabled in each House of the Parliament within 12 months after the fourth anniversary of the commencement of this Act.

(4) In this section:

independent review means a review undertaken by persons who:

(a) in the opinion of a majority of the Ministerial Council possess appropriate qualifications to undertake the review; and

(b) include one or more persons who are not employed by the Commonwealth or a Commonwealth authority.

SOME ADDITIONAL ISSUES

Cost Recovery

No amendment was made to the Act on cost recovery. The ALP had proposed amendments but agreed to withdraw them after the Government agreed that cost recovery for the OGTR would not be introduced for 2 years after the commencement of operations.

Consensus Conference

The Democrats proposed that the Community Consultative Committee should be able to appoint a citizens' jury on an ad hoc basis to assist its work. This jury would have been operated along the lines of the consensus conference. Whilst this amendment was not supported, the Government did agree to hold another consensus conference on a gene technology within the first 12 months of the OGTR's operation.

Access to the record of the debate and the Acts

The Senate debate on the legislation is available on the Parliament of Australia Website: *Commonwealth Of Australia Parliamentary Debates Senate - 2000* (http://www.aph.gov.au/hansard/hanssen.htm). Hard copies of Hansard are available from AusInfo bookshops.

1.3 Key result 2 - The Inter-Governmental Agreement on Gene Technology

In the September – December 2000 quarter, the IOGTR continued to work with States and Territories on the Inter-Governmental Agreement on Gene Technology (IGA). The IGA underpins the national legislative scheme.

The IGA does 5 key things:

- describes the main components of the cooperative national scheme and commits all Governments to introduce substantially similar legislation in each jurisdiction;

- establishes a Ministerial Council with responsibility for:
    - ♦ issuing policy principles, policy guidelines and codes of practice to underpin the activities of the GTR and the operation of the regulatory framework;
    - ♦ considering and agreeing to changes, as required, to the national legislative framework;
    - ♦ discussing matters related to gene technology regulation with other relevant Ministerial Councils;
    - ♦ providing advice on the appointment and dismissal of the GTR; and
    - ♦ overseeing periodic reviews of the legislative framework;

- provides for the maintenance of a nationally consistent scheme over time, including provisions for the amendment of the gene technology legislation;

- describes the roles and responsibilities of each of the jurisdictions in the administration and enforcement of the scheme, including arrangements for the reimbursement of costs incurred by jurisdictions for services provided as part of the legislative scheme; and

- provides for the review of the implementation and effectiveness of the national scheme no later than 4 years after the commencement of the scheme.

The IGA has now been agreed by Officials through the Commonwealth State Consultative Group on Gene Technology (CSCG).

1.4 Key result 3 - The draft Gene Technology Regulations 2000

A key focus of consultation with non-government stakeholders during the October – December quarter was the draft Regulations:

- Draft Regulations were released in August 2000 and comment was requested by 6 October 2000. Fifty one submissions were received.

- During October and November, the submissions were thoroughly analysed and a new draft of the Regulations was developed.

- The draft Regulations were considered in detail by GMAC, as were the scientific and technical issues raised in written submissions. In reviewing the Regulations, we also revisited the GMAC guidelines to ensure that, where appropriate, the Regulations aligned closely with the guidelines.

- The draft Regulations were also made available to the Senate Community Affairs References Committee and other parliamentarians. A number of recommendations to improve the Regulations were made by the Committee and during debate on the Gene Technology Bill 2000.

The following extract from the revised Explanatory Guide to the Draft Commonwealth Gene Technology Regulations 2000 explains the key issues raised during consultations.

The changes made to the draft Regulations can be grouped into five major categories.

1. Substantive changes of a policy nature. For example, a number of stakeholders felt that it is important that resolutions of the expert committees are made publicly available. Commonwealth, State and Territory officials considered this proposal and thought that it was important for ensuring the transparency and openness of the scheme. As such, an amendment to the Regulations was made to explicitly provide for the public disclosure of committee resolutions.

2. Substantive changes clarifying matters of science. For example, through submissions provided by scientists and others, our attention was drawn to areas, particularly in the Schedules, where the language was not scientifically certain or where there were "gaps" or inconsistencies in the exemptions and notifiable low risk dealings. For example, one scientist raised concerns about how the Regulations dealt with dealings with virus genes and virus recombination. This was considered by GMAC and, as a result, changes were made to the Regulations to make the exemptions more restrictive.

3. Inclusion of additional matters that had been inadvertently left out or correction of inadvertent errors. A number of written submissions noted "gaps" in the information requirements for applications, described in the Schedules. For example, little information was requested on disposal of GM microorganisms at the end of a contained experiment. This has been rectified in the revised draft.

4. Consequential changes as a result of Senate amendments to the Gene Technology Bill 2000. For example, during debate of the Bill, the Australian Democrats proposed amendments to change the name of the Gene

Technology Community Consultative Group to the Gene Technology Community Consultative Committee. These amendments were passed and consequential changes have therefore been made to the referencing of the Committee in this draft of the Regulations.

5. Drafting changes to make the Regulations simpler and easier to read. For example, many people found the Schedules describing exempt dealings and notifiable low risk dealings very difficult to follow because of the use of double-negatives. This has been changed and we believe that the reworded Schedules are much easier to read.

Issues that were raised in written submissions but have not been addressed in the revised draft of the Regulations include:

- The role, function and membership of IBCs. A number of stakeholders considered that it would be useful to include more information about the role, function and membership of the IBCs in the Regulations. We discussed this with the drafters of the Regulations and while it is not possible to include this detail in the Regulations, we are currently drafting detailed guidelines that will describe the role, function and membership of the IBCs. These guidelines will be included in a comprehensive handbook on the regulation of gene technology that will be released, in the first half of 2001.

- Risk assessment guidelines. Many people also sought more detail on the process of risk assessment. For example: How will the GTR conduct risk assessments? What matters will be taken into account? Will a comparative scale of risk be employed? All of these issues will be addressed in Risk Assessment Guidelines that are currently being prepared by the IOGTR and will be released, in draft form, in the first half of 2001;

- Ethics. A key issue raised by stakeholders was how ethical issues will be dealt with by the GTR. A number of stakeholders also made valuable suggestions about the types of ethical issues that should be taken into account.

  Parliament has determined that there are two ways that ethical issues will be dealt with under the legislative scheme. The Ministerial Council may issue policy principles dealing with ethical issues. These policy principles, will be developed in consultation with the Gene Technology Ethics Committee and the broader community. Once a policy principle has been issued by the Ministerial Council, the GTR must not act inconsistently with the policy principle. In other words, the GTR may not accept an application for a licence to conduct an activity that is contrary to a policy principle.

  The Ministerial Council will also issue codes of practice (with advice from the

ethics committee) describing procedures to be followed by researchers to ensure that dealings with GMOs are conducted in an ethical manner.

The ethical issues identified by stakeholders, as part of the consultation on the Regulations, will be referred to the Gene Technology Ethics Committee and will inform the development of policy principles and codes of practice;

- Clarifying the application of the legislation. In submissions made on the Regulations, a number of people sought clarification of how various provisions of the legislation would operate. These queries were addressed in correspondence directly to the individuals and will also be addressed in the handbook on the legislative scheme which will include answers to commonly asked questions about the national scheme;

- Matters that were addressed in amendments to the Gene Technology Bill 2000. One of the issues that was raised consistently, particularly by consumer groups, environmental groups and other individuals, was the need for the Regulations to include a reference to the precautionary principle.

  Other suggestions included providing for prison terms for people who breach the legislation, excluding certain people from being appointed as the GTR because of previous involvement with the gene technology industry and releasing the location of field trial sites. All of these issues were addressed in amendments to the Gene Technology Bill 2000 and as such, it is not necessary to also include them in the Regulations. A summary of amendments made to the Gene Technology Bill 2000 is at part 1.2 of this Report.

- Examples of exempt dealings and notifiable low risk dealings. During debate of the Gene Technology Bill 2000, a number of Senators expressed concern that the Schedules to the Regulations are difficult to read and that it would assist the layperson if examples could be included in the Regulations.

  As noted above, the Schedules have been redrafted to make them easier to read. Wherever possible, examples have also been included in this Explanatory Guide. However, the IOGTR will also be including many examples in the handbook on the legislative scheme which will be released shortly; and

- Cost recovery. One of the aspects of the legislation, which was of great interest to people, was the fees and charges to be applied to companies, research institutions and individuals who use the regulatory system. During debate on the Gene Technology Bill 2000, the Government announced that cost recovery would be deferred for a period of two years. During that time Government will undertake further work on cost recovery, in consultation with

clients of the system, and develop a system for the recovery of the costs of the regulatory scheme for implementation in two years time. The Regulations, therefore, do not prescribe any fees or charges.

As discussed in Part 1 of this Report, the timeframe for releasing the revised draft Regulations, was amended to ensure that the second round of consultations and the revised Regulations could take account of:

- the Senate Community Affairs References Committee Report on the Gene Technology Bill 2000, "A Cautionary Tale: Fish Don't Lay Tomatoes" (November 2000)*;* and

- Parliamentary debate on the new legislation.

Public consultations on the Act and the earlier draft of the Regulations have been very constructive and the IOGTR will continue to consult widely on the detail of the revised draft Regulations. A comprehensive explanatory guide to the revised draft Regulations is being prepared for release with the revised Regulations in the January – March 2001 quarter. Advertisements will be placed in newspapers calling for submissions on the draft Regulations in the next quarter (January to March). Following this second round of public feedback, it is expected that the Regulations will be revised to take account of any final issues prior to the Regulations being taken to Executive Council in May 2001 and laid before Parliament shortly afterwards.

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

In 2000, the IOGTR contracted an information technology company, Dialog, to develop a database to underpin the new Regulatory System. The database is being developed using Lotus Notes technology.

Users of the regulatory system will be able to maintain their own information online and track the progress of applications made to the OGTR.

The general public will be able to access publicly available information, including the record of GMOs and GM product dealings, through the new database system.

It is anticipated that training with clients of the OGTR will be held over the next two quarters. The system is to operate from 21 June 2001.

1.6 Other results

- **Working collaboratively with States and Territories**

The IOGTR continued to work collaboratively with officials from all State and Territory Governments to further develop the national regulatory framework through the Commonwealth State Consultative Group (CSCG), a group of officials representing each State and Territory Government, as well as the Commonwealth Government. Detail on the form and function of the CSCG is set out in the IOGTR's first Quarterly Report (for the reporting period June – August 2000).

During the September – December 2000 quarter, the CSCG met twice: on 3 November 2000 and 13 December 2000. Some of the key matters dealt with by the CSCG in the reporting period included:

- the Senate Community Affairs References Committee Report on the Gene Technology Bill 2000;
- amendments to the legislation during Senate debate;
- the process for appointing the GTR;
- the process for appointing members to the new committees established under the legislation (the Gene Technology Technical Advisory Committee, the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee);
- cost recovery policy;
- revisions of the draft Regulations and Explanatory Guide;
- the process for developing policy principles;
- the IGA; and
- the development of the Gene Technology Information Management System.

- **Commonwealth Agency Liaison**

The IOGTR also maintains close links with other Commonwealth agencies and existing regulators with an interest in gene technology to ensure that issues raised during consultation are appropriately addressed in the legislation and that the new national regulatory system for GMOs builds on the experience of existing regulators. The partnership between these bodies and the IOGTR primarily operates through an Inter-Departmental Committee (IDC). During the reporting period, the IDC met twice: on 2 November and 12 December 2000. Issues discussed were primarily those reported under section 1.6 above.

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- **Presentations**

The IOGTR is committed to participating in community discussions on gene technology by providing information on the new regulatory system. During the reporting period the IOGTR participated in:

- The Biotechnology Australia regional forum on 10 November 2000 (Tamworth);

- The 2000 Australasian Research Management Conference on 22 November 2000 (Brisbane);

- Four workshops on genetically modified crops staged by the Tasmanian Farmers and Graziers Association on 31 October and 1 November 2000 (held at various regional centres in Tasmania);

- A workshop on Aquaculture and GMOs in conjunction with 'Aquafest Australia' on 9 October 2000 (Hobart);

- A briefing of the incoming National Health & Medical Research Council on 12 October 2000 (Adelaide); and

- The Tasmanian Parliament Select Committee Inquiry on Gene Technology on 20 October 2000 (Hobart).

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. As set out in the IOGTR's first Quarterly Report (for the period April – June 2000), the Genetic Manipulation Advisory Committee (GMAC) is central to the current voluntary 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: October-December 2000

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

No new appointments were made during the October-December 2000 reporting period.

Dr John Manners and Dr Susan Barker resigned from GMAC during the reporting period. Drs Manners and Barker leave GMAC due to work commitments. The IOGTR joins GMAC in thanking Drs Manners and Barker for their contribution to the work of GMAC.

2.2 GMAC Meetings: October-December 2000

- **The Scientific Subcommittee (SSC)**

The SSC, chaired by Professor Jim Pittard, met once during the reporting period on 10 November 2000. The SSC:

- considered *ad hoc* scientific matters relating to genetic manipulation work in containment facilities; and
- reviewed 7 proposals for the release of GMOs into the environment, of which one was a general release proposal, 3 were new proposals for field trials, and 3 were extensions to proposals previously assessed by GMAC.

Summaries of the field trials are at Attachment 1 to this report.

- **The Release Subcommittee (RSC)**

The RSC, chaired by Professor Nancy Millis, met once during the reporting period on 1 December 2000. The RSC:

- considered a presentation made by Dr Bob Hunter from the CSIRO Livestock Division on the safety of INGARD® Cotton seed when used as stock feed;

- subsequently discussed the presentation made by Dr Bob Hunter in relation to the general release application for insect resistant (INGARD) cotton;
- discussed breaches of GMAC recommendations; and
- reviewed the 6 release proposals discussed at Attachment 1 of this Report.

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. Information Bulletin No.2*: Monitoring compliance with GMAC recommendations for the conduct of field trials* outlines the IOGTR's approach to monitoring and it is available on the IOGTR web site. A minimum of 5% of trials are to be inspected each quarter.

In the October-December 2000 quarter, the IOGTR inspected 22 current sites for compliance against GMAC recommendations. Monitoring during the October to December 2000 quarter encompassed 11% of current trials, exceeding the target of 5% monitoring during the quarter.

In addition to the current trial sites, 13 past trial sites under active post-trial monitoring by an organisation were also inspected by the IOGTR.

Inspections spanned seven planned release proposals (PRs:77X(2), 77X(3), 102X, 105,113,131,139) covering 5 different types of crops (canola, wheat, barley, peas and cotton).

In summary, the IOGTR:

1. contracted appropriate experts to undertake the site inspections, in the company of officials from the IOGTR.

   The IOGTR will establish a database of relevant experts that the IOGTR can draw on for monitoring in the future. Pending this, the IOGTR will continue to draw on the expertise and advice of GMAC members. In this instance, the IOGTR sought a proposal from Luminus Pty Ltd on the advice of a GMAC member. Luminus is a consultancy company connected with the University of Adelaide. The company had the consultants with appropriate experience (weed/crop production experts) and was able to complete the task in the short timeframe required; and

2. conducted site inspections from 15 to 29 November 2000.

   The timing of inspections was designed to coincide with the period immediately prior to harvesting of the crops, particularly canola, which are

currently under trial. This period provides an ideal opportunity to check compliance with a number of GMAC recommendations.

Four of the 35 randomly inspected sites for this quarter required some level of remedial action to ensure compliance with GMAC conditions. However, the non-compliance observed at the sites represented negligible risks to human health or the environment because appropriate remedial action was taken.

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

(1) PR113

Summary of the trial PR113

PR113 was a trial of transgenic peas conducted in Western Australia during 1999. The trials were conducted to field test genetic modifications to peas confer tolerance to the herbicide glufosinate ammonium (Basta), or confer resistance to attack by pea weevil. The trials had been completed at the time of the routine inspection by the IOGTR monitoring team, but the sites were still subject to GMAC recommendations for post trial monitoring and management.

Conduct of the inspection

A total of 13 pea trial sites were inspected by the IOGTR to ascertain compliance to GMAC recommendations. The purpose of GMAC's recommendations for the post trial management of trial sites is to minimise dissemination of the GMO and its genetic material, minimise the persistence of the GMO in the environment, and ensure the full control of the GMO is maintained.

Findings

Three of 13 previous trial sites inspected had been oversown with conventional peas. As GMAC recommendations are that volunteer GM peas be controlled, there was a concern that it would be difficult to detect and control the volunteer GM peas amongst conventional peas. However, the transgenic peas were a different variety to the commercial peas and can be detected on the small sites by their flowering colour (white instead of purple) and growth habit (erect rather than low growing).

Remedial Action

Whilst there are differences between the 2 types of peas, the trial site manager took the precaution of isolating and arranging the destruction of the conventional peas harvested from the past trial sites. GMAC noted the differences in these 2 types of peas but has taken the precaution of recommending that in future peas not be grown on past pea sites for 2 years. GMAC has advised that following the remedial action taken by the site manager, the risks of the GMO impacting on the environment and public health and safety are negligible.

(2) PR77X(3)

Summary of the trial PR77X(3)

PR77X(3) is a current field trial for transgenic canola expressing tolerance to the herbicide glyphosate (Roundup Ready® canola).

Conduct of the inspection

As discussed above, the inspections were timed to ensure compliance with GMAC recommendations for the management of current sites prior to the period of seed generation. This was done to enable potential site management problems to be identified and risks to the environment and health and public safety avoided. The inspection included the monitoring of a 50 m zone around the site for evidence of brassicaceous weeds (weedy relatives of canola).

Findings

AT PR77X(3), 1 of the 13 Monsanto canola trials sites inspected required remedial action. A small number of wild radish plants (approximately 6), which is a weedy relative of canola, had been found within the 50m exclusion zone. One GMAC recommendation is that related weeds be removed from around the site to remove the potential for outcrossing from the transgenic plants to related plants. The weeds observed may have been missed during herbicide applications applied to the area prior to flowering. A number of the plants had reached early seed development and the trial manager destroyed the plants before seeds became viable.

Remedial Action

As remedial action was taken, to remove the related weeds from the exclusion zone, the risks to the environment and human health and safety are considered negligible.

Further background on the individual PR proposals can be found on the IOGTR website.

2.4 Investigations completed

The IOGTR, with expert advice from GMAC, completed one investigation into an alleged breach of GMAC recommendations for GMOs during this quarter. The breach was in respect of field trial PR74. Two further alleged breaches are still being investigated.

The breach investigated during the reporting period did not present an increased risk to human health and safety, or any increased risk to the environment that could not be effectively managed through a risk management plan.

2.5 Breaches of GMAC conditions

- **Discovery of volunteer lupins on past trial sites**

Notification of alleged breach

On 28 September 2000 the Centre for Legumes in Mediterranean Agriculture (CLIMA), who are responsible for the trials in question, informed the IOGTR that lupin volunteers, which had reached or passed flowering, had been discovered at two sites in Western Australia, near the districts of Mingenew and Quairading.

GMAC recommendations for the lupin trial site

This potential breach relates to the planned release PR74 submitted to GMAC in 1997 for herbicide resistant lupin trials to be run in 1997 and 1998. The lupins have been the subject of a number of field trials by CLIMA which is now operating as a centre within the Faculty of Agriculture, University of Western Australia.

GMAC recommendations require post trial monitoring of the sites for two years. During this time volunteer lupins are to be destroyed before flowering. Monitoring and removal of volunteers at the two sites in Western Australia did not meet this requirement.

The investigation

The original project manager for the sites resigned in July 1999. The trial sites were under interim management from July 1999 until July 2000. A new project

manager was appointed in July 2000 to oversee the various past trial sites. This project manager was also a GMAC member at the time.

The project manager wrote to the IOGTR on 28 September 2000 detailing a breach of conditions that had been found and the risk management actions being employed.

The IOGTR wrote to the project supervisor after initial investigations and discussions with GMAC to indicate that GMAC had agreed with the risk management actions being undertaken. It should be noted that the project manager was not present at any GMAC meetings that discussed the breach. In addition, an IOGTR staff member inspected the Quairading site during the investigation. The inspection found several lupin volunteers that were removed and subsequently destroyed.

The findings

A breach of GMAC recommendations was found during the investigation. The breach relates to the failure to remove lupin volunteers before flowering. GMAC discussed the potential breach and agreed with the proposed management actions being undertaken by CLIMA. It was considered that the breach presented negligible risks to human health and the environment. GMAC has previously indicated in its advice for PR74 that lupins show only a low level of cross-pollination within the species and that hybridisation with other species does not occur. This significantly minimises environmental risks.

Risk management plan

The risk management actions proposed by the University of Western Australia and agreed to by GMAC for the sites are as follows:

For the Mingenew site:
- The volunteer lupins are to be removed and this is a continuous process as new volunteers are discovered.
- The lupin agronomy trial buffer be slashed out in case pollination occurred.
- Mature lupins from the agronomy trial harvested and destroyed by deep burial in case pollination occurred.

For the Quairading site, the volunteer lupins are to be removed and this is a continuous process as new volunteers are discovered.

Future management actions at the Mingenew and Quairading sites include:
- Property manager/farmer to be made fully aware of the monitoring requirements;
- Sites to be planted to cereal or pasture;

- Monitoring should continue until no volunteers are detected for two consecutive years;
- Sites to be inspected by the trial manager in August before flowering occurs; and
- Sites to be re-inspected by the trial manager in October for additional late emergence of volunteers.

2.6 Audits completed

The audit of Aventis CropScience was finalised during this quarter with the full report being publicly released on 17 November 2000.

- **Audit activities of Aventis Cropscience Pty Ltd: Conduct of field trials in accordance with GMAC recommendations**

The Reason for the Audit

As reported in the July – September 2000 Quarterly Report, alleged breaches by Aventis were identified as relating to PR-63X(4) and PR-85X(2) field trials that were being conducted in the Mt Gambier region of South Australia.

The IOGTR found that Aventis had not complied with some aspects of conducting these field trials. There were no increased risks to human health as a result of these breaches. The risks to the environment were low. The potential environmental risk was minimised further through the application of the risk management plan for the trials. A 'spot check' conducted by IOGTR staff on 27 July 2000 raised further issues of concern with Aventis post trial monitoring.

In September Quarterly Report, the IOGTR reported that the cumulative effect of the breaches, and the issues raised as a result of the spot check, indicated a possible weakness in Aventis processes. In the context of the current voluntary system, the IOGTR needs to satisfy itself that Aventis has the ability to maintain full control of field trials of genetically modified canola. An audit of Aventis processes was instigated to give greater certainty in the control of field trials.

Scope of the Audit

As reported in September, the Audit Committee investigated Aventis internal processes for ensuring compliance with GMAC recommendations. This included a review of Aventis Standard Operating Procedures (SOPs) and site visits to all current field trial locations. The objectives of the Audit were to identify whether there are any deficiencies in processes employed by Aventis to control field trials in accordance with recommendations made by GMAC. Where any deficiencies

were identified, the Audit Committee was to consider options for improving Aventis's system of operation.

Results of the Audit

The Audit Committee reported to the Head of the IOGTR on 31 October 2000. The recommendations from the audit are designed to improve Aventis system of operation to ensure the company maintains control of field trials.

Generally, the committee found that Aventis had made efforts to comply with GMAC requirements. Aventis had also begun recruiting a third party auditor to advise them on how to improve their consistency in meeting GMAC requirements. The Audit Committee found this to be an important step by Aventis to show that they are serious about meeting the requirements.

However, the Audit Committee did have some concerns with Aventis approach to aspects of communication and their implementation of GMAC recommendations. The major issues from the report are set out below.

The Audit Committee was concerned that a number of essential activities were not written into the SOPs such as:
- No procedure for dealing with waste at trial sites;
- A limited coverage of weeds compared to that required by GMAC in their site monitoring procedures;
- No procedure for dealing with non-compliance issues that were reported by their own staff; and
- No procedure for monitoring past trial sites.

Whilst field staff appeared to be acting appropriately in most cases without the SOPs, actions were taken on an informal basis and in an *ad hoc* manner by field staff as issues arose.

On-site field inspections found that Aventis had, at the majority of its sites, been in compliance with GMAC recommendations. However, 3 of the 24 sites inspected had inadequate buffer crops and action was taken as soon as possible to manage the risks associated with this. Aventis had sown the buffer crops as required but the planning and agricultural practices employed, as well as environmental circumstances, led to poor establishment of the crops. Aventis indicated that GMAC recommendations for the trial came in late June which made it difficult to establish the buffer crops on these sites.

Timeliness and flow of communication between field staff, Aventis head office and GMAC appeared to be an issue. The timing of advice from GMAC affected Aventis' ability to meet the recommendations. The informal procedures relating

to the practical implementation of GMAC recommendations used by the field staff were not necessarily conveyed to Aventis head office or back to IOGTR/GMAC.

A range of recommendations have been put forward by the Audit Committee to remedy these issues.

The full report from the Audit Committee is available on the IOGTR Website at: http://www.health.gov.au/tga/gene/genetech/bulletin5.htm

2.7 General release applications: October – December 2000

Assessments completed/approvals granted

The Minister for Health approved one general release during the reporting period. This application was for herbicide-resistant (Roundup Ready) cotton.

As the risk assessment of this application provided to the Minister by the IOGTR and GMAC did not identify any significant risks to the health and safety of people or the environment, the general release was approved. The risk assessment is available on the IOGTR website at (http://www.health.gov.au/tga/gene/genetech/riskcotn.htm).

New general release applications

No new general release applications were received in this quarter.

2.8 Other activities under the interim arrangements

Freedom of Information (FOI)

No FOI requests were received during the reporting period.

Information Bulletins

The IOGTR added two Information Bulletins to the series begun in the April - June quarter of 2000. These were made available on the IOGTR Website, and through direct mailouts, during the October– December quarter:

Information Bulletin No 7: The Audit of Monsanto Australia Ltd processes for the conduct of field trials in accordance with GMAC recommendations;

Information Bulletin No 8: Assessment process for approval to continue the commercial release of INGARD® cotton.

Website

During the reporting period, the IOGTR Website was updated with:

- Information Bulletins 7 - 8;

- the second Quarterly Report of the IOGTR (September 2000);

- Invitation to make a submission on the second draft of the Commonwealth Gene Technology Regulations 2000; and

- GR-10: Application for commercialisation of insect-resistant (INGARD®) cotton.

Throughout the reporting period, the Website was consistently in the top 10 Department of Health and Aged Care Websites visited, with approximately 9,450 visits recorded to the IOGTR home page during the reporting period. This brings the total number of home-page hits since recording began in March 2000 to 24,150.

During the reporting period, the IOGTR also responded to 58 emails to the IOGTR Website on gene technology related issues – this brings the total number of emails responded to since the beginning of the year to 581.

International coordination activities

During the September – December 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 participation in this working group is to ensure that Australia's experience in gene technology assists in harmonising biotechnology-related definitions and risk assessment processes internationally); and

- 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 advising on the proposed regulatory system to the Parliament of Australia Joint Standing Committee on Treaties.

An officer from the IOGTR was part of the Australian delegation to the first meeting of the Inter-Governmental Committee for the Cartagena Protocol held in Montpellier, France from 11-15 December 2000.

The meeting was tasked with progressing several items under the protocol, including a Biosafety Clearing House, information sharing parameters, compliance procedures under the protocol, and documentation requirements.

The IOGTR also provided briefing on the proposed new regulatory system for GMOs to:

- Government officials from China; and

- Government officials from Taiwan.

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.

A Joint Policy Reference Group (JPRG) consisting of representatives from CSIRO, Environment Australia and IOGTR was established to enhance collaboration and coordination between the agencies. The JPRG met on 15 December 2000 to consider the terms of reference, membership and operational issues.

JPRG members will meet in 2001 to finalise the list of research projects to be funded by this program.

b) Biotechnology Australia (BA) coordination activities

As reported in previous quarters, Biotechnology Australia (BA) is the Commonwealth Government's coordinating agency for the whole-of-government approach to biotechnology and related issues.

The agency consists of five portfolios with an interest in biotechnology: 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 reporting period (October – December 2000) the IOGTR has continued to act as a coordinating point to provide input from the Health Portfolio to Biotechnology Australia activities. This includes attending BA regional forums to describe the proposed legislation for gene technology.

Consultants

During the reporting period, the IOGTR managed 4 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;
- McNiece Communications Pty Ltd providing continued communications support and advice to the IOGTR; and
- Mr Bill Harris, regarding an inquiry into a complaint made by an individual about the conduct of GMAC's general business.

PART 3: THE QUARTER AHEAD

During the forthcoming quarter (January to March 2001) the IOGTR will undertake the following activities:

- A second round of consultations on the Regulations to be made under the Act. This will include meetings with every IBC, all persons or organisations who made submissions, as well as key environment, health and industry groups in each State and Territory complemented by a general invitation to the public to provide written comments on the revised draft Regulations.

- An analysis of all submissions received during the second round of consultations on the Regulations will be finalised. Further drafting instructions for the Regulations will be developed in consultation with States and Territories, with a view to finalising the Regulations in time for the commencement of the *Gene Technology Act 2000* in June 2001.

- Work to recruit the Gene Technology Regulator.

- Work to establish 3 new committees will continue including a call for nominations from a range of key stakeholder groups early in 2001.

- Monitoring and surveillance activities will continue.

- Preparations for GTIMS to go live in June 2001 will continue, including consultation with and training for, key users (such as IBCs) within the next quarter.

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-142: Evaluation of transgenes in grapevine No. 2

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 expression of the introduced genes and to study the field performance of transgenic grapevine plants. Four types of genetic modifications are involved:
1. to produce low browning raisins;
2. to modify flower and fruit characters;
3. to alter berry colour; and
4. to insert a marker gene, for monitoring gene flow.

Brief description of the nature and effect of the genetic modification: The first 3 groups of transgenic plants contain extra copies of genes derived from grapevine:

1. sense or antisense copies of a gene for an enzyme, polyphenol oxidase (PPO) involved in the browning process;
2. a transcription regulator gene for regulating flower and fruit development; and
3. a gene for an enzyme from the pathway that determines berry colour.

The fourth group of plants contains a gene for green fluorescent protein (GFP) from jellyfish (*Aequorea victoria*). Pollen and seeds containing the GFP gene are easily identified, and these plants will be used to study pollen flow in the field.

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: Approximately 0.2 hectare at the Merbein Laboratory, Merbein, Victoria.

Further information: The institution's contact officers for this proposal are Dr Mark Thomas and Dr Nigel Scott, ph (08) 8303 8600, fax (08) 8303 8601.

PR-143: Winter nursery seed increase of Roundup Ready® (RR), INGARD® (Bt)/ Roundup Ready® (RR) and INGARD® (Bt)/CryX/Roundup Ready® (RR) transgenic cotton plants

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

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

Purpose of the release: The aim of the trial is to increase seed for both new and advanced breeding lines of modified cotton. The cotton has been modified for tolerance to the herbicide glyphosate (Roundup®), with some lines also expressing genes conferring resistance to insect attack. The seed derived from this release will be used in the following summer to conduct multi-site yield and fibre trials and further seed increase. It is expected that use of the herbicide-tolerant cotton will permit more effective control of weeds in cotton crops, while the insect-resistant trait has the potential to reduce the amount of insecticide applied to cotton crops.

Brief description of the nature and effect of the genetic modification: The cotton plants have been modified to contain the 5-enolpyruvyl shikimate-3-phosphate synthase (EPSPS) gene from *Agrobacterium*. This gene confers tolerance to the herbicide glyphosate, the active ingredient of Roundup®. Some cotton lines will also contain genes encoding CrylA(c) and/or CryX insecticidal proteins from the bacterium *Bacillus thuringiensis*, which confer tolerance to the major insect pests of cotton.

All the plants will also 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. A gene for resistance to the antibiotics spectinomycin and streptomycin is also transferred to the plants. This gene is not expressed in the plants.

Location and size of trial: A total of 5 hectares in the Ord river irrigation area, Kunnunurra of Western Australia.

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

PR-144: Field performance and integrated pest management studies on transgenic cotton expressing the CryIA(c) and / or CryX delta-endotoxin from *Bacillus thuringiensis*, in the Kimberley region of Western Australia

Organisation proposing release: Agriculture Western Australia &
Western Agricultural Industries Pty Ltd
Locked Bag 4
Bentley Delivery Centre WA 6983

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

Purpose of the release: The aim of this trial is to assess the field efficacy and agronomic performance of cotton modified for resistance to insect pests in the conditions at Kununurra and Broome. A major aim is the development of an integrated pest management (IPM) system for transgenic cotton. The use of insect-resistant cotton plants has the potential to reduce the use of chemical pesticides on cotton crops.

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

In addition to the insecticidal gene, the plants contain a selectable marker gene that confers resistance to the antibiotics kanamycin and neomycin.

Location and size of trial: 50 million plants will be grown in an area of 500 hectares in the Ord River Irrigation Area, Kununurra, Western Australia, and 1.8 million plants in 20 hectares near Broome, Western Australia.

Further information: The institution's contact officer for this proposal is Mr Geoff Strickland, ph (08) 9368 3756, fax (08) 9368 3223.

PR-105X(2): Field evaluation of a transgenic line of field pea (*Pisum sativum* L.) with resistance to pea weevil (*Bruchus pisorum*)

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

Organism to be released: Field pea (*Pisum sativum* L.)

Purpose of the extension to the release: The peas have been genetically modified with the aim of conferring resistance to pea weevil attack. Pea weevil is a major insect pest of peas that is responsible for great losses in pea production in Australia. The aim of this extension is to produce commercial quantities of seed for further evaluation prior to general release.

Brief description of the nature and effect of the genetic modification: The peas contain a gene that confers resistance to attack by the pea weevil (*Bruchus pisorum*). The gene codes for a protein (an α-amylase inhibitor) found in the seeds of the common bean (*Phaseolus vulgaris*). In addition, the peas also contain a selectable marker gene that confers resistance to the antibiotics kanamycin and neomycin.

Location and size of trial: Approximately 10 million seeds will be sown on 10 hectares in December 2000 in the Naracoorte/Lucindale Shire of South Australia; and 500 million plants will be sown on 100 hectares in the winter of 2001, on a site to be determined.

Further information: The institution's contact officer for this proposal is Dr TJ Higgins, ph (02) 6246 5063, fax (02) 6246 5000.

PR-112X(2): Winter nursery seed increase of INGARD® (Bt) and INGARD® /CryX transgenic cotton plants, 2001

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

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

Purpose of extension to the release: The aim of this extension is to increase seed stocks of cotton modified for resistance to insect pests for future trials. The use of insect-resistant cotton plants has the potential to reduce the use of chemical pesticides on cotton crops.

Brief description of the nature and effect of the genetic modification: The genes introduced into the cotton plants are the CryIA(c) and CryX genes from the bacterium *Bacillus thuringiensis*. These genes produce proteins that are toxic to certain insects, including the major caterpillar pests that attack cotton. The plants to be trialled contain either the CryIA(c) gene or both the CryIA(c) and CryX genes. The presence of more than one insecticidal gene in a single plant may give better insect control and reduce the potential for the pest insects to become resistant to the proteins.

In addition to the insecticidal genes, the plants contain a selectable marker gene that confers resistance to the antibiotics kanamycin and neomycin.

Location and size of trial: A total of 5 hectares will be grown in the Ord River Irrigation Area, Kununurra (WA), and Katherine (NT).

Further information: The institution's contact officer for this proposal is G F Smart, ph and fax (02) 6793 1114.

PR-131X(2): Agronomic assessments and seed increase in northern Australia of transgenic cotton expressing the CryIA(c) or CryIA(c) and Cry2A(b) genes from *Bacillus thuringiensis*

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

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

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

Brief description of the nature and effect of the genetic modification: The genes introduced into the cotton plants are the CryIA(c) and/or Cry2A(b) (previously called CryX) genes from the bacterium *Bacillus thuringiensis.* The Cry genes produce proteins that are toxic to certain insects, including the major caterpillar pests that attack cotton. INGARD® cotton, which has been released commercially, contains only a single insecticidal gene, CryIA(c). The presence of more than one insecticidal gene in a single plant may give better insect control and reduce the potential for the insect pests to become resistant to the toxins. Some of the plants also contain the 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene from the soil bacterium *Agrobacterium*. The EPSPS gene produces a protein which confers tolerance to the herbicide glyphosate, the active ingredient of Roundup®. RoundupReady® cotton has been released commercially.

The plants also contain a selectable marker gene conferring resistance to the antibiotics kanamycin and neomycin. Plants with the Cry2A (b) gene also contain a marker gene coding for the enzyme β-glucuronidase, which enables visual identification of plant tissues in which this gene is being expressed.

Location and size of trial: A maximum of 56 hectares (approximately 5,600,000 modified cotton plants) at Kununurra (WA) and Katherine, Darwin, Douglas-Daly, Adelaide River, Larrimah and Mataranka (NT).

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