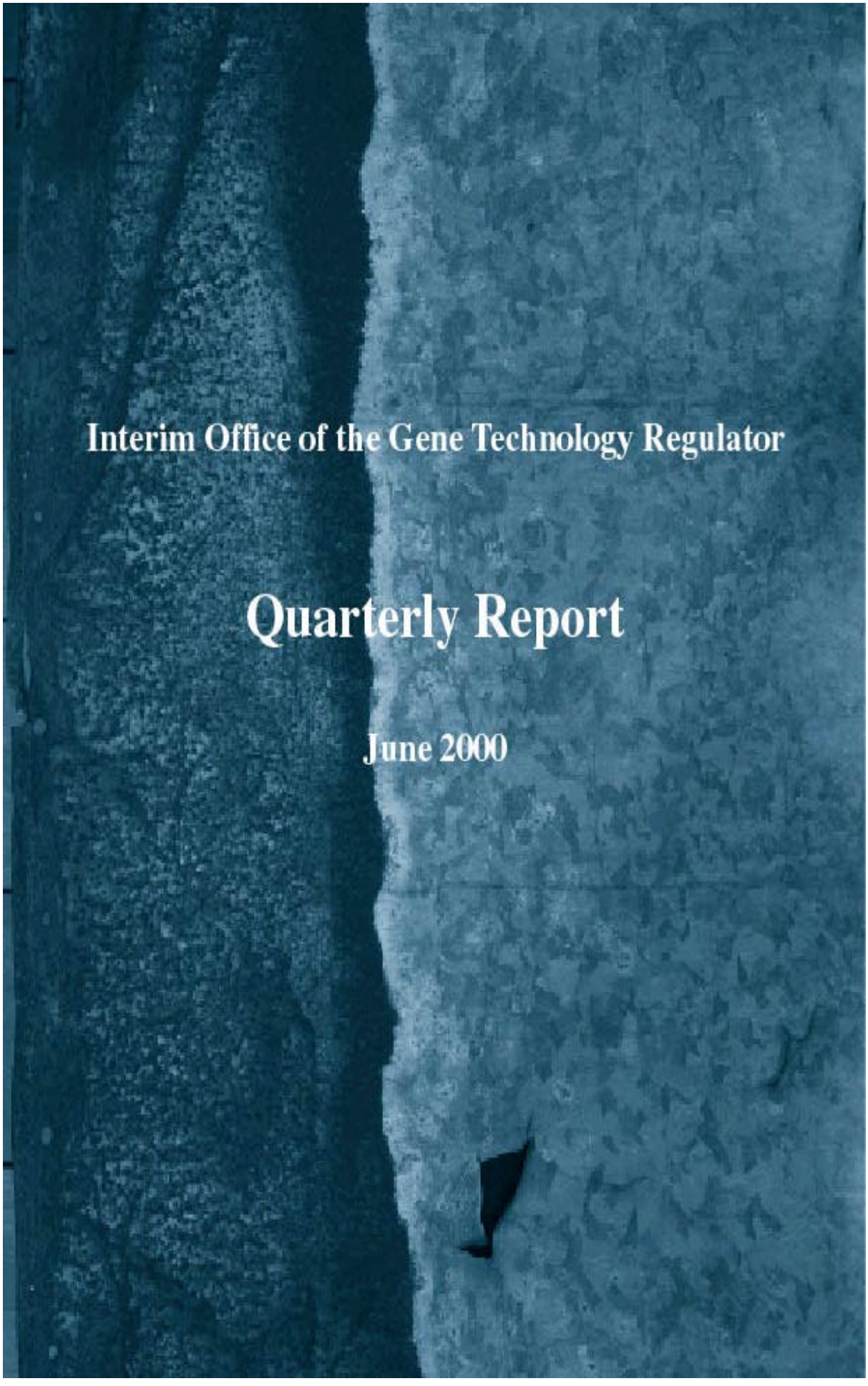
Interim Office of the Gene Technology Regulator
Quarterly Report
June 2000

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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 first quarterly report of the Interim Office of the Gene Technology Regulator (IOGTR).

The purpose of this report is to provide information about the operation of the IOGTR and the independent expert committee, the Genetic Manipulation Advisory Committee (GMAC).

Reporting quarterly is one of a number of initiatives implemented by the IOGTR over the past 12 months to improve the dissemination of information about the Office, and about the GMAC. This report covers both the April-June 2000 quarter and the previous January-March quarter, to provide a comprehensive summary of activities and outcomes for the 2000 calendar year.

Developing a national regulatory system

One of the main achievements of the IOGTR during the reporting period was securing agreement with State and Territory officials to the form and detail of the new national regulatory system for genetically modified organisms (GMOs), including *the Gene Technology Bill 2000*, the *Gene Technology (Consequential Amendments) Bill 2000*, and the *Gene Technology (Licence Charges) Bill 2000*. With the exception of Tasmania, which would prefer to see an explicit 'opt-out' provision included in the *Gene Technology Bill 2000*, there is support for this package of legislation from all States and Territories.

The work of States, Territories and the Commonwealth on this new regulatory system was informed by quality advice from a broad range of organisations and individuals. This included environment and community groups, the research and development sector, industry and people with an interest in ensuring that a rigorous, transparent and accountable regulatory system is introduced in Australia, to:

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

Input from non-government stakeholders was obtained through national consultations, public forums and written submissions. Securing and analysing this advice was a key focus of the IOGTR's effort in the first half of 2000.

Outcomes regarding the development of the *Gene Technology Bill 2000* and related legislation were consistent with the primary function of the IOGTR: to establish a national regulatory framework, including an independent regulator, by 3 January 2001.

Current Voluntary Arrangements

The secondary function of the IOGTR is to oversee and provide strategic advice on the current voluntary/administrative controls over GMOs.

While the GMAC continues to be the main focus of the voluntary system, providing expert biosafety advice on the use of novel genetic manipulation techniques in Australia, the IOGTR has:

- developed a new initiative to ensure independent proactive monitoring of compliance with GMAC recommendations;
- initiated a redesign of the IOGTR and GMAC website to improve the quality and accessibility of information;
- instituted quarterly reporting, with the purpose of providing more comprehensive and timely advice on progress with the development of the new regulatory system, as well as the continued work of the GMAC; and
- contributed to the direction and focus of the recently released *Biotechnology Australia Strategy*.

During the reporting period, the GMAC has:

- provided advice on 52 proposals for high risk contained work with GMOs; and
- provided advice on 22 field trials with GMOs.

The GMAC and the IOGTR have collaborated on assessing one application for the general commercial release of a GMO under the current voluntary system. This assessment has been characterised by a high level of consultation with State and Territory officials, and other stakeholders.

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

Yours sincerely

Terry Slater
National Manager
Therapeutic Goods Administration

10 July 2000

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PREFACE

This is the first quarterly report of the Interim Office of the Gene Technology Regulator (IOGTR).

The main purpose of this report is to provide information about the role and function of the IOGTR, and its operation over the past 6 months, as well as the role and operation of the independent expert committee on the biosafety of genetically modified organisms (GMOs): the Genetic Manipulation Advisory Committee (GMAC).

In May 2000, the IOGTR advised the Minister for Health and Aged Care, Dr Michael Wooldridge MP, that the Office would, in future, report on a quarterly basis in line with the Office's aim of providing interested people with more timely and comprehensive information about current oversight of GMOs. The IOGTR advised the Minister that the first quarterly report would be produced at the end of the second quarter of the calendar year 2000.

This first report records activities undertaken, and outcomes achieved, for the two preceding quarters (January-March 2000, and April-June 2000).

Readers seeking more detailed information on the IOGTR are encouraged to contact the Office:

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Structure of this report

Part 1 – Background

This section provides background information on the role and functions of the IOGTR, and explains the current system of voluntary controls over GMOs in Australia and the role that the GMAC plays within that system.

Part 2 – A National Regulatory Framework

This part provides information on the work of States, Territories and the Commonwealth on the development of a national regulatory framework for GMOs, including consultation with a wide range of non-government stakeholders.

Part 3 – Interim Arrangements

This part reports activities undertaken under the voluntary system of controls over GMOs that will continue to operate in Australia until a new national regulatory framework for gene technology is established. It highlights the work of the GMAC and its subcommittees.

Part 4 – The Quarter Ahead

The section points to activities to be undertaken, and outcomes to be achieved, in the coming quarter (July-September 2000).

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PART 1: BACKGROUND

1.1 The Interim Office of the Gene Technology Regulator (IOGTR)

The IOGTR was established as a branch of the Therapeutic Goods Administration within the Commonwealth Department of Health and Aged Care in May 1999.

The decision to establish the IOGTR followed the 1999 Federal Budget decisions to:

- Establish Biotechnology Australia to coordinate the Commonwealth's non-regulatory activities in biotechnology; and

- Establish a new national regulatory framework, including an independent regulator, by 3 January 2001.

1.2 Functions of the IOGTR

The Health portfolio identified two primary functions for the IOGTR:

- to work with representatives of State and Territory Governments, other Commonwealth agencies, existing regulators, and non-government organisations to develop and implement a new national regulatory system for GMOs (Part 2 refers); and

- pending the establishment of this new system, to provide support and, where necessary, direction, to the current voluntary administrative arrangements for genetically modified organisms (GMOs) (Part 3 refers).

1.3 The IOGTR's staffing and organisational structure

IOGTR maintained an average staffing level of 16 during the reporting period.

In April 2000, IOGTR conducted a review of its structure and agreed a new structure (refer **Attachment 1**) pending the establishment of the permanent Office in January 2001. The Gene Technology Regulator, as the statutory office holder, will make final decisions on the structure, functionality and priorities of the permanent Office.

In May 2000, the IOGTR placed advertisements for a range of positions. This round of recruitment is expected to increase staffing numbers to 33, with a continued emphasis on scientific skills and experience, but also including policy, audit, secretariat and administrative personnel.

1.4 Current administrative system for GMOs and the GMAC's role and function

Australia has a comprehensive system of regulatory controls for most products of gene technology, or genetically modified (GM) products:

- the Australia New Zealand Food Authority (ANZFA) is responsible for food safety, including GM food;
- the Therapeutic Goods Administration (TGA) is responsible for the standard of all Australian medicines, including GM therapeutics;
- the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) controls all agricultural and veterinary chemicals, including any GM chemicals that fall within its mandate;
- the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) covers all industrial chemicals, including any GM chemicals; and
- the Australian Quarantine and Inspection Service (AQIS) is responsible for control of Australia's borders, including the import of GM products.

In respect of controls on live, viable GMOs, Australia relies on a system of voluntary compliance that is underpinned by the work of the GMAC.

The GMAC is a non-statutory advisory committee, which provides expert biosafety advice on the use of novel genetic manipulation techniques in Australia.

The GMAC assesses potential hazards to the community or the environment and recommends appropriate safety and containment procedures for GMOs to researchers and institutions undertaking work on GMOs. The GMAC is concerned with any experiment involving the construction and/or propagation of viroids, viruses, cells or organisms of novel genotype produced by genetic manipulation which are either unlikely to occur in nature, or likely to pose a hazard to public health or the environment.

Under the current voluntary system for GMOs:

- companies, research organisations and other entities dealing with GMOs choose to submit information about a GMO to the GMAC;

- the GMAC assesses the biosafety risks (being risks to the environment and/or risks to human health and safety) associated with that GMO;

- the GMAC provides recommendations to the company, research organisation or other entity about any biosafety risks and how those risks can be managed; and

- the organisation, research organisation or other entity voluntarily implements and complies with those recommendations.

The GMAC has four subcommittees: the Scientific Subcommittee, the Release Subcommittee, the Large Scale Subcommittee, and the Public Liaison Subcommittee.

The GMAC's Terms of Reference are reproduced at **Attachment 2**.

1.5 Need for a new national regulatory system

The GMAC and its predecessors have provided scientific advice regarding any risks posed by the application of gene technology and how such risks should be managed for the past 25 years. Experience with this system indicates that organisations dealing with GMOs have maintained a high level of compliance with the GMAC recommendations.

The major weaknesses of the existing system relate to the fact that, as an administrative system, there is:

- insufficient capacity for independent legally enforceable auditing and monitoring;

- insufficient capacity for the imposition of penalties or other action in the event of a breach; and

- inadequate transparency of decision-making, including in terms of statutory timeframes and obligations.

These problems under the current voluntary system will be addressed and overcome by the implementation of a comprehensive, transparent and accountable regulatory system, involving the enactment of legislation in each State and Territory, and by the Commonwealth.

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PART 2: A NATIONAL REGULATORY FRAMEWORK

2.1 Development of a national regulatory framework for GMOs

On 22 June 2000, the Federal Government introduced three Bills into the House of Representatives:

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

The objective of the gene technology legislation is:

> to protect the health and safety of people and to protect the environment by identifying risks posed by or as a result of gene technology and by managing those risks.

The legislation will accomplish this by regulating certain dealings (or activities) with GMOs.

The Government's objectives in relation to the legislation include:

- ensuring an efficient and cost effective approach to regulating gene technology;
- continuing a science-based approach for risk assessment, but including capacity for formal consideration of broader issues such as ethics;
- avoiding unnecessary duplication between the activities of the new Gene Technology Regulator (GTR) and existing regulators;
- to generally improve the coordination between all regulators involved in the approval of GMOs and products of gene technology;
- creating a more streamlined and certain pathway for industry seeking approval for GMOs and products of gene technology that can be managed safely;
- creating enforceability of the arrangements for managing risk;
- creating greater transparency and accountability; and
- introducing better ability to respond to stakeholder and community views.

The development of this legislation, in concert with States and Territories and with considerable input, support and advice from a range of Commonwealth agencies and non-government stakeholders, represents the major achievement of the IOGTR for the reporting period.

2.2 Key result areas during the reporting period

The following key result areas and milestones relate to the reporting period January 2000 – June 2000.

Key result area 1.

The *Gene Technology Bill 2000* and related legislation agreed by officials from States, Territories and the Commonwealth.

Milestones during reporting period

- Public consultations on the draft *Gene Technology Bill 2000* and the plain-English guide organised and conducted, including public forums in each capital city and three regional centres.
- Scrutiny of 160 written submissions received on the draft Bill.
- Resolution of major outstanding policy matters with a joint State, Territory and Commonwealth position, informed by public consultations and submissions.
- Agreement amongst officials to the *Gene Technology Bill 2000* (with the exception of Tasmania, which sought the inclusion of an explicit opt-out in the Commonwealth legislation).
- Agreement amongst officials to the *Gene Technology (Consequential Amendments) Bill 2000* and the *Gene Technology (Licence Charges) Bill 2000.*
- Agreement amongst all jurisdictions to the Regulation Impact Statements prepared in concert with the Bills.
- Agreement amongst all jurisdictions to the Explanatory Memoranda to the Bills.

Key result area 2.

Gene Technology Bill 2000 and related Bills agreed by the Commonwealth Government and introduced into Federal Parliament.

Milestones achieved during the reporting period

- In concert with Environment Australia, detailed exploration of options for ensuring a legislative basis for rigorous risk assessment of the environmental impacts of GMOs, including possibilities for amending the *Environment Protection and Biodiversity Conservation Act 1999*.

Achieving these outcomes was possible because of the effective partnership between the IOGTR and States and Territories, other Commonwealth agencies and existing regulatory bodies. The IOGTR encouraged a high degree of input and constructive criticism from external stakeholders, including industry, consumer, health and environmental groups, the research and development sector and others within the Australian community.

A summary of the key points in the *Gene Technology Bill 2000* is at **Attachment 3.**

Further commentary on these key result areas and milestones follows.

2.3 Working collaboratively with States and Territories

The IOGTR worked collaboratively with officials from all State and Territory governments to develop the national regulatory framework.

The milestones achieved during the reporting period could not have been accomplished without the genuine commitment and cooperation of officials from all States and Territories.

The State, Territory, Commonwealth partnership works primarily through the Commonwealth/State Consultative Group on Gene Technology (the 'CSCG').

The CSCG is a group of officials representing each State and Territory Government, as well as the Commonwealth Government.

Each jurisdiction is represented by at least one official. The members include:

- the Cabinet Office, New South Wales;
- the Ministry of the Premier and Cabinet, Western Australia;

- the Department of the Premier and Cabinet, Victoria;
- the Department of the Premier and Cabinet and the Department of Primary Industries, Queensland;
- the Department of the Premier and Cabinet, the Crown Solicitor's Office, and the Department of Human Services, South Australia;
- the Department of the Chief Minister and the Department of Primary Industries and Fisheries, Northern Territory;
- the Department of Primary Industries, Water & Environment, Tasmania; and
- the Chief Minister's Department, Australian Capital Territory.

Commonwealth representation on the CSCG includes:

- the IOGTR, which convenes CSCG meetings and provides secretariat support to CSCG;
- Environment Australia;
- Agriculture, Fisheries and Forestry Australia (which represents the Australian Quarantine and Inspection Service);
- the Department of Industry, Science and Resources (Biotechnology Australia);
- The Department of the Prime Minister and Cabinet;
- The Department of Employment, Workplace Relations and Small Business (which represents the National Industrial Chemicals Notification and Assessment Scheme);
- The Office of Regulation Review; and
- the Australian Government Solicitor.

Existing regulators also participate in CSCG meetings:

- The Therapeutic Goods Administration;
- The Australia New Zealand Food Authority; and
- The National Registration Authority.

The CSCG scrutinises all aspects of the legislative framework. The CSCG is responsible for:

- ensuring the new regulatory system is consistent with Government policy across jurisdictions;

- negotiating approaches that best reflect the majority of jurisdictions' policies; and

- the application of policies to the regulatory framework.

During the reporting period, the CSCG met four times and held one teleconference.

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

- outstanding policy issues in relation to the Commonwealth *Gene Technology Bill 2000* including:
    - the possibility of including an explicit 'opt-out' provision in the Commonwealth legislation;
    - liability under the legislation; and
    - the role, functions and membership of the Committees established under the Bill
- the *Gene Technology (Consequential Amendments) Bill 2000* and the *Gene Technology (Licence Charges) Bill 2000* including:
    - ensuring that the consequential amendments legislation provided existing regulators of GM products access to advice on biosafety from the GTR; and
    - ensuring that existing regulators would be required to take the GTR's advice into account when making decisions about GM products
- the Regulation Impact Statements and explanatory materials to accompany the introduction of the gene technology legislation into Federal Parliament;
- early drafts of Model State legislation including:
    - focusing particularly on how the Commonwealth legislation should interface with substantially similar State and Territory legislation to ensure a very high level of national consistency;
- the scope and content of the Inter-governmental Agreement on Gene Technology which will underpin the national regulatory scheme. The draft IGA:
    - describes the main components of the cooperative national scheme;
    - sets out the commitment of all governments to introduce substantially similar legislation in each jurisdiction;
    - sets out the functions and responsibilities of the Gene Technology Ministerial Council;
    - provides for the maintenance of a nationally consistent scheme over time, including provisions for the amendment of the legislation;
    - describes the roles and responsibilities of each of the jurisdictions in the administration and enforcement of the scheme; and
    - provides for the review of the scheme after five years.

- cost recovery:

  - The Commonwealth Government's current policy position is that the new Office of the Gene Technology Regulator will be 100% cost recovered from the organisations regulated by OGTR.
  - In May 2000, following on-going discussion of this matter within CSCG (and as a result of considerable feedback from a range of non-government stakeholders) the Government noted that the IOGTR should undertake further work to inform its policy in this area.
  - The IOGTR conducted a competitive tendering exercise to engage a consultant to cost the functions of new regulations, consider the cost impact on stakeholders and develop models for recovering costs from proponents. A selection panel comprising representatives from Victoria, Queensland and three Commonwealth agencies reviewed tenders submitted by eight companies.
  - As a result of the tendering process, the IOGTR contracted KPMG to undertake the consultancy. KPMG will conduct targeted consultations with all States and Territories, as well as relevant non-government stakeholders over the coming months. KPMG will submit a final report in September 2000. This report will further inform government consideration of the cost recovery policy and approach.

- The data system to support the new regulatory system.

  - In consultation with CSCG, the IOGTR began work to develop a Database Management System to provide the future OGTR with an effective tool for managing its information needs. Detailed specifications for the major components have been established to guide the development of the system in the second half of this year.

2.4 Bringing a whole-of-government approach to the new legislation

The partnership between the IOGTR and Commonwealth agencies and existing national regulatory bodies with an interest in the regulation of GMOs, has also been very important to the development of an appropriate regulatory framework:

- Gene technology is not a single-portfolio issue. GMOs are, or have the potential to be, used in medicine, agriculture, industrial, veterinary and agricultural chemicals and industrial chemicals. The regulation of GMOs is neither a purely' health' issue, nor an 'environmental' issue. It has been important to ensure that the policy underpinning the regulatory system, as well as the detail of the system itself, reflects a whole-of-government approach.

- The new regulatory system must interface seamlessly with existing regulatory arrangements for food (including GM food), therapeutics (including GM therapeutics), agricultural and veterinary chemicals (including the products of gene technology), industrial chemicals and control of Australia's borders.

A close partnership between the IOGTR and Commonwealth agencies and existing regulators has ensured that these issues were 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, or IDC.

The IDC is convened by the IOGTR, which also provides secretariat support to the committee. The IDC comprises representatives from:

- the Department of Health and Aged Care (including the Therapeutic Goods Administration and National Health & Medical Research Council);
- the Department of Prime Minister and Cabinet;
- Environment Australia;
- Agriculture, Fisheries and Forestry Australia, including the Australian Quarantine and Inspection Service;
- the Office of Regulatory Review;
- the Department of Foreign Affairs and Trade;
- the Department of Industry, Science and Resources (Biotechnology Australia);
- the National Registration Authority for Agricultural and Veterinary Chemicals;
- the Australia New Zealand Food Authority;
- the Attorney-General's Department;
- the Australian Government Solicitor;
- the Department of Treasury;
- the Department of Employment, Workplace Relations, and Small Business (National Industrial Chemicals Notification and Assessment Scheme);
- the Australian Customs Service; and
- the Commonwealth Scientific and Industrial Research Organisation.

The IDC has scrutinised all aspects of the legislative framework, and considered the application of Commonwealth Government policy across a range of key issues, within the context of the broader partnership between the Commonwealth and the States and Territories.

During the reporting period, the IDC met four times and held one teleconference. Issues discussed were primarily those reported under section 2.3.

2.5 The role and contribution of non-government organisations

Some of the key non-government stakeholders that provided considerable input, advice and critique of the regulatory system during the reporting period include:

- environmental groups (including the Environment Defenders Office, Australian Conservation Foundation and Friends of the Earth);
- industry groups (including Avcare, the Organic Federation of Australia and the Australian Chamber of Commerce and Industry);
- primary producers (including the Pork Council of Australia, the Australian Cotton CRC, Meat and Livestock Australia and the National Farmers' Federation);
- consumer groups (including the Australian Consumer's Association);
- groups with a particular focus on gene technology (such as the Australian GenEthics Network); and
- a wide range of groups with an interest in research and development (including a number of universities and the Australian Biotechnology Association).

Consultation with these groups continued during the reporting period.

- **National Consultations on the Bill**

In December 1999, the IOGTR released a draft version of the *Gene Technology Bill 2000,* together with a detailed plain English guide.

Written submissions were invited by 10 March 2000.

The Bill and guide were mailed directly to over 1200 stakeholders. A further 1500 stakeholders were advised by mail of the availability of the draft Bill and explanatory guide.

Advertisements notifying availability of the two documents and inviting public comments on the draft Bill were placed in all major metropolitan and regional newspapers in January 2000: a list of newspapers is included at **Attachment 4.**

At the end of the submission period, the IOGTR had received 160 written submissions.

In addition to inviting written submissions, the IOGTR held public forums in each capital city and three regional areas to allow stakeholders the opportunity to discuss the draft legislation with officials from the IOGTR and the CSCG, and to comment on the proposed regulatory approach.

All written submissions were carefully analysed, as were the results of the public consultations, and many proposed changes were incorporated into the final Bill.

Some of the major issues raised by stakeholders included:

- the need to ensure a high degree of transparency, independence and accountability;
- the need for the level of regulation to match the risks involved;
- the need for national consistency to be a cornerstone of the national regulatory framework maintained;
- cost recovery; and
- the desirability of harmonising regulation of GMOs and GM products between existing regulators and the GTR.

- **Presentations**

In addition to the national consultations, the IOGTR made presentations at:

- a cotton 'field day' in Narrabri, NSW, on 17 March 2000;

- the Livestock 2000 Conference and Annual General Meeting of the South Australian Farmers Federation in Adelaide on 22 March 2000. The Conference was entitled *GST, GMOs and good management: your survival kit to the millennium*;

- a public seminar of the National Council of Women ACT Branch on *Gene Technology and Genetically Modified Food* on 6 April 2000;

- the Biotechnology Australia Gene Technology Regional Community Forum in Naracoorte, South Australia on 2 May 2000 and Moama, NSW on 22 June 2000;

- the Agribusiness 2000 conference, hosted by Hunt & Hunt and held in Brisbane on 7 June 2000. The Conference was entitled *GMOs – the facts behind the emotion*;

- the 87th Annual State Conference of the NSW Apiarists Association in June 2000;

- the Dow AgroSciences Conference during the session on regulatory requirements in the Asia Pacific, on 13 June 2000.

The IOGTR also appeared before:

- the House of Representatives Standing Committee on Primary Industries and Regional Services;

- the New South Wales Legislative Council Standing Committee on State Development; and

- the House of Representatives Standing Committee on Legal and Constitutional Affairs.

The presentations provided information on progress with developing the new national regulatory system, the detail of the proposed system, and the operation of the current system of voluntary controls that will continue pending the establishment of the new system.

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PART 3: GMAC AND THE CURRENT VOLUNTARY SYSTEM

Until the new regulatory system takes effect, the current system of voluntary controls over GMOs will remain in place. As set out in Part 1 of this report, the Genetic Manipulation Advisory Committee (GMAC) is central to these arrangements, providing advice on environmental and human health risks associated with GMOs.

3.1 Appointments to the GMAC: January – June 2000

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

The appointment of nine Committee members was due to expire on 31 March 2000. The Minister extended the terms of appointment of these members to 3 January 2001, after which time the new regulatory system is expected to be operational.

A list of current members of the GMAC is at **Attachment 5**.

3.2 GMAC Meetings: January – June 2000

- **The GMAC**

The full GMAC met on 25 May 2000.

The Committee discussed the draft *Gene Technology Bill* 2000 and provided technical expert advice on the development of regulations under the Bill.

Discussions focused on definitions, proposed exemptions, and classes of notifiable low risk dealings.

The next meeting of the GMAC is scheduled for 18 August 2000.

- **The Scientific Subcommittee (SSC)**

The SSC comprises nine members of GMAC and is chaired by Professor Jim Pittard.

The SSC reviews the molecular aspects of all proposals covered by GMAC's Guidelines: small and large scale contained work and release work. Proposals for small scale contained work in laboratories are assessed by the SSC on an ongoing basis.

The SSC met three times during the reporting period: on 28 January 2000, 14 April 2000 and 23 June 2000.

At these meetings the SSC:

- considered minor amendments to the *Guidelines for Small Scale Genetic Manipulation Work;*
- developed improvements to the interface between GMAC and the Gene and Related Therapies Research Advisory Panel (GTRAP) for consideration of gene therapy proposals;
- considered ad hoc scientific matters relating to small scale proposals;
- reviewed 33 proposals for field trials; and
- reviewed one proposal for general release (part 3.9 of this report refers).

Summaries of the field trials are at **Attachment 6**.

- **The Release Subcommittee (RSC)**

The RSC reviews proposals covered by the *Guidelines for the Deliberate Release of Genetically Manipulated Organisms* and *Guidelines for Activities with the Potential for Unintended Release of Genetically Manipulated Organisms*.

The RSC assesses the hazards associated with the release into the environment of live GMOs. It provides advice to relevant Commonwealth, State and local government agencies, as well as to the proponents. The RSC also consults with members of the public on such proposals.

The RSC met twice during the reporting period: on 17 February 2000 and 8 May 2000.

At the 17 February meeting, Dr Keith Gregg, from Murdoch University, attended the meeting to discuss with the RSC the risks and options for his work with rumen bacteria modified to detoxify fluoroacetate (proposal PR-130). Subsequently, the RSC agreed that a future field trial with the modified bacteria could be considered again by the Committee if the results from a transfer experiment using non-modified strains of the rumen bacteria provided a clear indication of the requirements for containment of the bacteria to the field trial site.

The RSC also assessed a proposal for general (commercial) release of glyphosate-tolerant (Roundup Ready®) cotton from Monsanto Australia Ltd at this meeting.

At the meeting of 8 May 2000, the RSC considered the alleged breach of GMAC's recommendations by Aventis CropScience for post-trial monitoring of canola field trials.

A breach reported by Monsanto, whereby canola trash from a field trial site was not disposed of in accordance with the GMAC's recommendations, was also considered by the RSC. The RSC agreed that the incident should have been notified to GMAC sooner. It was agreed that the action taken by Monsanto in response to the breach was appropriate. However, clarification was required on the frequency and procedure for the proposed roadside monitoring for volunteer canola plants. This was built into the risk management plan detailed in the report to the Minister.

Further information of these breaches is at part 3.7 of this Report.

Dr Jim Fortune from the Grains Research and Development Corporation (GRDC) attended the 8 May 2000 meeting of the RSC. Dr Fortune gave a brief presentation on the involvement of GRDC in proposals involving genetically manipulated organisms.

The Subcommittee assessed 22 deliberate release proposals during the reporting period (the difference in the number of proposals considered by the two Subcommittees is because the SSC had one more meeting in the reporting period than the RSC). Summaries of these field trials are at **Attachment 6**.

3.3 New monitoring strategy developed

In keeping with a range of regulatory systems which are underpinned by legislation, the GMAC (and, since May 1999 the IOGTR) has relied on three primary means of identifying non-compliance with GMAC recommendations:

- self-reporting by entities dealing with GMOs as required under GMAC's Guidelines; and
- notification of possible breaches by third parties; and
- data provided by applicants/proponents to the GMAC, which, when scrutinised by the GMAC Secretariat or the GMAC, may highlight non-compliance problems.

During the reporting period, the IOGTR asked the GMAC Secretariat to develop a fourth component to the GMAC's monitoring strategy: a system which would ensure proactive monitoring of compliance with GMAC recommendations.

This new program is to be implemented from July 2000 and will involve spot checks of field trials by IOGTR officials, in the company of independent experts, at key points during the trialing process (for example, when flowering of crops occurs and the possibility of gene transfer is increased). Experience with this monitoring system will be used to inform the monitoring and surveillance activities undertaken by the GTR under the new national regulatory scheme. The monitoring strategy will be available on the IOGTR website from July 2000.

3.4 Protocol for reporting breaches developed

To improve industry and public understanding of the IOGTR's investigative processes, the IOGTR prepared a protocol for reporting breaches. The protocol was prepared in consultation with State and Territory Governments, other Commonwealth agencies and regulatory bodies. In preparing the protocol, the IOGTR considered arrangements under established regulatory systems and decided to base the new protocol on that of the National Registration Authority for Agricultural and Veterinary Chemicals (NRA).

The Breaches Protocol was posted on the IOGTR website in June 2000.

IOGTR anticipates that feedback on the protocol and its use during the third and fourth quarters of the year 2000 will usefully inform arrangements put in place under the new regulatory system. The Breaches Protocol is reproduced at **Attachment 7.**

3.5 New investigation processes implemented

In the past, the GMAC has reported breaches of GMAC recommendations via a summary included in the GMAC Annual Report to the Minister for Health and Aged Care.

In March 2000, IOGTR implemented new arrangements for investigating possible breaches of GMAC recommendations and for reporting on these, which includes providing a detailed report to the Minister.

Each report addresses:

- the alleged breach;
- the dealing with the GMO in question (for example, detail on a particular field trial) and the recommendations proposed by the GMAC for the conduct of the trial;
- an investigation into the allegation (which may include a review of documentation including that held by the company concerned and/or a site visit (or visits) and/or interviews with relevant parties). Documentation may be requested under cover of a statutory declaration;

- a risk assessment of the impact of any identified breaches of GMAC recommendations, including expert advice from the GMAC and/or other relevant experts and/or a review of published data;

- a risk management plan, including any additional monitoring that should be undertaken (either by the proponent or by an independent party) and/or any remedial action required to minimise risks to human health and safety or to the environment.

It should be noted that neither the GMAC nor the IOGTR has legislative underpinning for the conduct of investigations into an entity's voluntary compliance with recommendations made by the GMAC to manage risks associated with GMOs.

Pending the establishment of the new regulatory system, the IOGTR has, therefore, limited capacity to access documents or premises or to investigate matters unless the entity concerned chooses to provide this access.

Similarly, the IOGTR has no legislative capacity to enforce compliance with GMAC recommendations or to enforce compliance with risk management plans.

3.6 Release of information

During the reporting period, the IOGTR consulted extensively with the Australian Government Solicitor on the release of information contained in investigation reports.

The Australian Government Solicitor advised that the IOGTR has limited capacity to release information provided to the Office in confidence, or information that relates to third parties, and that release of this, or other protected information, could result in liability attaching to the Commonwealth. For these reasons, reports of investigations are not released publicly.

The IOGTR has, however, considerably increased the amount of information provided on breaches of GMAC recommendations, in comparison with the level of information provided previously under the voluntary arrangements.

3.7 Investigations completed

The IOGTR, with expert advice from the GMAC, completed investigations into two alleged breaches of GMAC recommendations for GMOs. The IOGTR reported its findings to the Minister for Health and Aged Care in each case.

No breach investigated during the reporting period presented an increased risk to human health and safety, or any increased risk to the environment that could not be effectively managed by the risk management plan developed for the breach.

The breaches were in respect of field trials: **PR-63X(4) and PR-85X(2);** and **PR-77X(2).**

- **PR-63X(4) and PR-85X(2) are field trials being undertaken by Aventis CropScience for herbicide-tolerant hybrid genetically modified canola.**

  Summary: The IOGTR has investigated compliance by Aventis CropScience with recommendations made by the GMAC in relation to field trials of herbicide tolerant hybrid genetically modified canola.

  The IOGTR notes that while Aventis has not fully complied with all GMAC recommendations:

  - there is no evidence of increased risks to human health resulting from any breach;
  - the risks to the environment are low, and can be effectively minimised through the risk management plans developed by the IOGTR with GMAC advice; and
  - Aventis has taken a range of appropriate measures to minimise the potential for future breaches of this type.

  The IOGTR believes that this incident highlights the importance of replacing the current voluntary arrangements with the regulatory system envisaged in the *Gene Technology Bill 2000*.

  Notification of the alleged breach: On 14 March 2000, a private individual notified the IOGTR, in writing, of a possible breach of GMAC recommendations at the site of a field trial of genetically modified (herbicide-tolerant) canola in the Mt Gambier region of South Australia. The IOGTR sought further advice from the individual on 16 March 2000.

  A reporter for *The Age* newspaper (Melbourne) provided further advice about possible breaches connected to the same trials on 24 and 25 March 2000.

  The alleged breaches were identified as relating to two field trials conducted by the company Aventis CropScience. The trials were PR-63X(4) and PR-85X(2).

  In summary, the alleged breaches included claims that:

  - the required isolation areas around trial sites were not being maintained; and
  - proper post-trial monitoring of trial sites for regrowth (i.e. 'volunteer' plants) was not occurring; and
  - waste material from the trials, which contained genetically modified material, had been improperly disposed of (including being stored in an open skip and then 'dumped' at a municipal landfill).

The investigation: The IOGTR has completed a thorough investigation into Aventis' compliance with GMAC recommendations.

The scope of the investigation was much broader than the matters raised by the private individual or *The Age* article, with the IOGTR investigating Aventis' compliance with all GMAC recommendations for all trial sites. While recognising that such an investigation would take additional time and resources, the IOGTR considered it important to establish whether any breach was a 'one-off' problem or the result of a systemic fault in the company's processes.

The IOGTR's investigation included:

- an audit of the company's processes and documents, which were provided under Statutory Declaration by the company, obtaining expert advice from the GMAC; and
- two separate inspections of sites in the Mt Gambier region undertaken by an official from the IOGTR and a co-opted expert in brassica weeds, and a GMAC member.

The findings:
On the basis of expert advice, the IOGTR considers:

1. That the company did not fully comply with GMAC recommendations in respect of:

    - always establishing a 15m buffer zone of non-transgenic canola around plantings at summer trial sites to minimise pollen escape;
    - monitoring of a 50m zone for all sexually compatible species;
    - monitoring for, and removal of, volunteers;
    - compliance with procedures for the transport and disposal of field trash.

2. There were no increased risks to human health as a result of these breaches;

3. The risks to the environment were low. Primarily the risks involved the possibility of transfer of the herbicide-tolerance gene to related weeds or other canola plants. This is unlikely because no commercial canola crops are grown in the area during the summer trial season and there is evidence indicating that hybridisation between canola and brassicaceous weeds is of low frequency and progeny is of low reproductive fitness.

4. Any environmental risk can be further minimised through the risk management plan.

The risk management plan: The IOGTR has developed a risk management plan which will address the small increased risks resulting from the breaches. The plan includes:

- the implementation of a program for monitoring the potential out-crossing of GM canola in relevant areas.;
- expansion of the current monitoring plan to include *Raphanus raphanistrum, Hirschfeldia incana* and *Sinapis arvensis*;
- inspection for volunteers on a monthly basis for three years after the trial.

The IOGTR will underpin these, and other measures needed, with a system of 'spot checks' that will be in addition to the periodic monitoring and surveillance to be undertaken by the IOGTR from July 2000.

- **PR-77X(2) is a field trial being undertaken by Monsanto Australia Ltd in relation to herbicide-tolerant GM canola.**

Summary: The IOGTR has investigated compliance by Monsanto Australia Ltd with recommendations made by the GMAC in relation to field trials of herbicide tolerant genetically modified canola.

The IOGTR notes that while Monsanto has not fully complied with all GMAC recommendations:

- there is no evidence of increased risks to human health resulting from any breach;
- the risks to the environment are low, and can be effectively minimised through the risk management plans developed by IOGTR with the GMAC advice; and
- Monsanto has taken a range of appropriate measures to minimise the potential for future breaches of this type.

Notification of the breach:
On 5 May 2000, the IOGTR was notified of a breach of GMAC recommendations in respect of field trial PR-77X(2) involving Roundup Ready canola. The notification was provided by Monsanto, the company responsible for supervising this field trial.

The breach:

The first breach related to recommendations for the disposal of seed from a GM canola crop. The GMAC had advised that seed should either be stored for use in further field trials or destroyed by incineration or by burial at a municipal landfill under a minimum of one metre of soil. Instead, some of the material remaining after the harvest, which included a small quantity of GM seed, was collected and transported from the site under conditions that constituted a further breach of GMAC guidelines for transport of GMOs.

The investigation:
The breach was investigated by the IOGTR, with expert advice from the GMAC and other appropriately qualified individuals, and the company involved.

The IOGTR actions included:

- undertaking a comprehensive risk assessment of the breach, including an audit of the company's actions to investigate the effect of accidental dispersal of seed;
- obtaining expert advice on risks associated with the breach, including from the GMAC; and
- seeking expert advice on possible risks to public health.

The findings:
The IOGTR found that:

- GMAC recommendations for post-trial procedures and transport had been breached, as had GMAC recommendations for the disposal of seed from the trial;

- the company has taken a range of appropriate measures to minimise the accidental dispersal in transit of seed from the trial sites;

- there are no risks to human health resulting from the breach;

- the risks to the environment are low because a very small quantity of seed was involved. The potential for outcrossing is low since no canola is farmed in the area and the incidence of related weeds is low;

- these risks can be effectively minimised through the risk management plans developed by the IOGTR.

Risk management plan
The IOGTR developed a multifaceted risk management strategy involving activities undertaken by both Monsanto (with independent auditing) and by the IOGTR/GMAC. The strategy includes:

- identifying all areas where seed dispersal is likely to have occurred;

- monitoring areas of possible seed dispersal by the IOGTR and the company involved;
- removal of volunteers;
- monitoring any future canola farming in the area;
- independent auditing of the company's risk management activities;
- future spot inspections.

The IOGTR undertook the first post-breach monitoring inspection during May 2000.

3.8 Breaches of GMAC conditions: current investigations

The IOGTR is currently investigating three possible breaches of GMAC recommendations.

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

3.9 General release applications: January – June 2000

The IOGTR and the GMAC continued to action one application for general release during the reporting period. This application was for glyphosate-tolerant (Roundup Ready®) cotton.

Assessment processes followed the new arrangements for general (commercial) releases in Australia as foreshadowed in the Government's announcement in August 1999. These assessment processes were further enhanced as the detail of the *Gene Technology Bill 2000* was developed, to ensure that the assessment closely mirrored the process for dealing with such applications under the new national regulatory system. Key steps in the assessment are set out in Table 1.

During the reporting period:

- the IOGTR analysed 97 submissions made by interested non-government groups on the general (commercial) release application;

- the GMAC completed its risk assessment in respect of possible human health and environmental concerns;

- the IOGTR continued to liaise with Agriculture, Fisheries and Forestry Australia as the Commonwealth body responsible for developing arrangements to oversee crop management plans for Roundup Ready® canola;

- a draft risk analysis was prepared and released for a second round of public consultations.

The IOGTR projected that a decision on this application, which was submitted to the Office in November 1999, would be made in April 2000.

The deadline was extended to August 2000 because consultation on the development of the draft legislation highlighted the need for the draft risk analysis to be circulated to stakeholders for consideration and comment. The experience with this general release application highlights the need for clearly defined processes and statutory timeframes to be articulated in the new regulatory system.

3.10 Other activities under interim arrangements

- **Freedom of Information (FOI)**

IOGTR processed two FOI requests during the reporting period.

- The first sought access to the locations of GM canola crop trials in Australia planted in 1999; as well as the location of trials planned for 2000. Access was refused on a number of grounds. The applicant requested an internal review of the decision, which also resulted in a decision to refuse access to the requested information on a number of grounds. The applicant has not appealed the internal review decision to the Administrative Appeals Tribunal.

- The second FOI request concerned access to documents relating to an alleged breach of laboratory containment requirements. Specifically, the applicant asked for documents in the possession of the GMAC and the Office of the National Health and Medical Research Council (NH&MRC). The IOGTR provided relevant information to the Departmental decision-maker.

Table 1: General (Commercial) Release Application Assessment Process.

Receipt of application	The IOGTR: • Notifies the Commonwealth Health Minister of receipt of the application; • Prepares newspaper advertisements to notify the public; and • Prepares a summary of the application and a fact sheet.
Call for input into the assessment of the application	The Minister for Health and Aged Care: • Notifies relevant Commonwealth Ministers of receipt of the application and provides a copy of the application and invites comments; and • Writes to State Premiers and Territory Chief Ministers, providing a copy of the application and seeking input into the assessment. The IOGTR: • Places an advertisement in newspapers seeking comments on the application and advising of the availability of (1) summary information (2) a fact sheet and (3) the full application; • Forwards the application to the GMAC for the scientific risk assessment to commence.
Application is subjected to a risk analysis	The IOGTR: • Completes a literature review and provides it to the GMAC; • Analyses submissions made by Commonwealth agencies, State and Territory Governments and non-government stakeholders; • Forwards all comments of a scientific nature to the GMAC. The GMAC • Meets to consider human health and environment risks drawing on the literature review results and comments from submissions; and • Provides risk assessment advice to the IOGTR. The IOGTR • Prepares a draft risk analysis document .
Call for public comment on the risk assessment	The IOGTR: • Provides the draft risk analysis to the Minister for Health and Aged Care, with a recommendation that it be released for further consideration by government and non-government stakeholders; • Places an advertisement in the newspapers calling for public comment on the draft risk analysis. The Minister for Health and Aged Care seeks final advice from relevant Commonwealth Ministers, including the Environment Minister, and from States and Territories.
Decision is made	The IOGTR: • Considers submissions received on the draft risk analysis and provides all comments of a scientific nature to the GMAC for consideration; • On the basis of the GMAC's advice, makes a final recommendation to the Minister for Health and Aged Care. The Minister for Health and Aged Care makes a decision on the application and informs the applicant.
Decision is notified	The IOGTR: • Provides written responses to submissions; • Prepares and releases Public Information Sheet summarising the risk analysis and decision; • If the application is approved, enters into legally binding agreement with the applicant.

- **Website**

During the reporting period, the IOGTR website was restructured and updated with new information on the proposed regulatory system and with new Public Information Sheets on deliberate release proposals.

Throughout the reporting period, the Website was consistently in the top 10 Department of Health and Aged Care websites visited. During the period January to May 2000, the monthly average number of visits to the IOGTR home-page was 2073, and to the GMAC home-page was 1008.

The IOGTR responded to 732 e-mails to the IOGTR website on gene technology related issues.

The IOGTR has received feedback on the difficulties people are having with locating information on the website. During the reporting period, IOGTR tendered for professional expertise to redesign and restructure the website. The website is now undergoing a major redesign to provide easier and quicker access to information. On-line information will also be more comprehensive and more regularly updated. It is expected that the first phase of the redesign will be completed in July 2000.

- **International coordination activities**

The IOGTR is developing a program of international activities to: gather information on gene technology regulation worldwide; contribute effectively in international fora; and participate in the development of whole-of-government positions for biotechnology-related matters.

In the reporting period the IOGTR participated in:

- the 8th session of the OECD Working Group on the Harmonisation of Regulatory Oversight of Biotechnology held in Paris from 23-25 February 2000. The IOGTR also coordinated Australian input into the report prepared by this Working Group, to be considered at the G8 Summit of July 2000. The aim of the report was to provide recommendations on future work programs to harmonise and facilitate the conduct of risk assessments relating to GMOs and GM products internationally;

- a government working group coordinating Australia's involvement in the new Codex Alimentarius ad hoc inter-governmental taskforce on foods derived from biotechnology. The IOGTR's participation was to ensure that Australia's experience in gene technology regulation can assist in harmonising biotechnology-related definitions and risk assessment processes internationally;

- activities stemming from agreement 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 providing input into Australian nominations to expert panels being set up to assist in the Protocol's implementation. The purpose of these activities was to ensure that Australia's experience with gene technology regulation forms part of the technical input into the establishment of an international biosafety Clearing House under the Protocol;

- the OECD conference on the scientific and health aspects of genetically modified foods held in Edinburgh on 28 February – 1 March 2000. A report of the conference has been provided to the G8 for consideration at its July 2000 Summit. The aim of the conference was to undertake a study on the implications of biotechnology internationally, and to scrutinise critically whether the systems in place for the assessment of the risks and benefits and GM foods and crops were considered trustworthy by governments, social interest groups, regulators, scientists and industry. The conference brought together 400 participants from over 40 countries representing governments, industry and civil society organisations.

  The conference concluded that a mechanism should be set up to ensure continuing international dialogue on issues where there was major disagreement; that there was a need for transparency in policy processes; and that there are potential benefits to be gained from gene technology.

The IOGTR also provided:

- briefing on the regulation of GMOs in Australia for the Australian delegation to the OECD 2000 Ministerial Council Meeting. The purpose of the briefing was to provide background on domestic developments in biotechnology, as well as on OECD developments in this field, to facilitate discussion on future OECD work in this area;

- input into the report prepared by the OECD Taskforce of Novel Foods and Feeds, which will also be considered at the G8 Summit. The aim of the report was to provide recommendations for future work programs to harmonise and facilitate the conduct of risk assessments relating to GM foods internationally; and

- briefing on the regulation of GMOs in Australia for members of the European Parliament. The members had requested this information as part of their review of EU legislation controlling GMO releases and was provided to assist the harmonisation of GMO regulation internationally.

The IOGTR undertook research into gene technology regulation in several other countries, kept a watching brief on international developments, and made contact with relevant officials in foreign missions in Australia.

- **Improved dissemination of information**

Feedback from public forums, presentations, written submissions, E-mails and other correspondence indicated that there was a high level of interest in public access to information on the development of the new regulatory system, as well activities undertaken under the current voluntary arrangements.

In the period January – June 2000, the IOGTR worked with State and Territory government officials, non-government organisations and the general public to develop mechanisms for the timely dissemination of useful information on gene technology.

A document identifying new measures for the improved dissemination of information was posted on the website in June 2000.

- **Collaboration in other regulatory related activities**

  - **ANZFA GM food activities**

    The IOGTR participated in the Inter-governmental Taskforce on Genetically Modified Food Labelling which identified options for approaches to labelling and provided advice to the Australia New Zealand Food Standards Council (ANZFSC), the Ministerial body responsible for food.

    The IOGTR continues to monitor the food labelling regime for GM foods and other food-related issues to ensure that decisions are compatible with the operation of the gene technology legislation.

  - **Biotechnology Australia (BA) coordination activities**

    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. The IOGTR maintains a continuing dialogue with BA on a number of biotechnology issues and provides a Department of Health and Aged Care perspective on several BA activities including:

    - public awareness: attendance at regular meetings on the development of a general biotechnology awareness strategy; IOGTR representation at public forums in metropolitan and rural areas to present information on the regulation of gene technology;

- intellectual property: the IOGTR is keeping a watching brief on this issue through BA working groups and monitoring events that may impact on the regulation of gene technology; and

- national Biotechnology Strategy: the IOGTR provided input on specific areas of the strategy relevant to the Department of Health and Aged Care. The IOGTR also provided input through attendance at regular Strategy meetings to ensure that a rigorous regulatory system is a key element of the Strategy.

The IOGTR is working with other Department of Health and Aged Care officials to develop a Human Health and Biotechnology Strategy that complements and enhances the National Biotechnology Strategy. The Human Health and Biotechnology Strategy will examine and respond to specific issues of interest to the Health portfolio. This strategy will be completed in the fourth quarter of 2000.

- **Consultants**

IOGTR let two new consultancies during the reporting period: with KPMG; and with Swell Designs.

- **KPMG**

The IOGTR contracted KPMG to: cost the functions of new regulations; consider the cost impact on stakeholders; and develop models for recovering costs from proponents.

The consultancy will run from June until September 2000 when a final report will be provided to government for further consideration of the cost recovery issue.

The individuals and organisations that were approached for the consultancy were from the Department of Health and Aged Care panel of providers for contracting and consulting services in accounting, financial management, audit, risk management and ethics. This panel of twelve organisations was compiled as a result of advertisements in the press. Eight proposals for the consultancy were received and three were shortlisted for interviews. KPMG was the successful consultant.

- **Swell Design**

As part of a project to redevelop the IOGTR and the GMAC web pages and create an identity for the office, Swell Design was engaged to provide advice on the style and design of the web pages. Swell Design will also create a visual identity for the IOGTR which can translate readily into an identity for the (permanent) Office following the passage of legislation.

The IOGTR also continued to oversee two existing contracts with: Matthews Pegg Consulting (MPC) for legal policy advice; and with Mr Bill Harris regarding an inquiry into a complaint made by an individual about the conduct of the GMAC's general business.

- **Matthews Pegg Consulting**

Matthews Pegg Consulting (MPC) was engaged in October 1999, following a competitive tending process to assist the IOGTR with legal policy support for the development of the legislative framework including in relation to:

- developing parameters for the legislative scheme;
- the detail of Commonwealth legislation and developing regulations under the *Gene Technology Bill 2000*;
- the interface between Commonwealth legislation and complimentary State and Territory legislation; and
- establishing the permanent Office of the Gene Technology Regulator.

Throughout the reporting period, MPC has been monitored to ensure that progress against the project's objectives has been met. The IOGTR, the CSCG and the IDC have been impressed with the quality of the work undertaken by MPC.

- **Mr Bill Harris**

Mr Bill Harris was engaged in October 1999 to inquire into, and report on, matters raised in correspondence from an individual concerned about GMAC processes. The report from Mr Harris would be used by the Department of Health and Aged Care to inform the Commonwealth's response to the individual.

Mr Harris is now close to concluding his consideration of relevant matters. The Department will report to the Minister for Health and Aged Care on the basis of advice from Mr Harris.

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PART 4: THE QUARTER AHEAD

- **Senate Inquiry: *Gene Technology Bill 2000* and related legislation**

  The legislation will be the subject of a Senate inquiry, to be conducted by the Senate Community Affairs References Committee.

  Submissions to the Committee are due in the first week of August 2000.

  Further information on the current debate on the gene technology legislation can be found on the parliament house webpage at www.aph.gov.au.

- **Plain guides to the Bill**

  During consultations on the *Gene Technology Bill 2000*, stakeholders indicated that it was difficult to understand how the legislation would work by simply looking at the draft Bill.

  A plain-English guide to the legislation will be released in July 2000, to assist consideration of the legislation.

- **Regulations under the *Gene Technology Bill 2000***

  Draft regulations under the *Gene Technology Bill 2000* will be released for public consultation in August.

  The consultation period will be throughout August and September and October, and will involve public fora and the opportunity to make written submissions.

  Details of the consultations will be advertised in the press in each State and Territory and notified on the IOGTR website.

- **Codes of Practice and Guidelines**

  Following feedback on the draft Regulations, the IOGTR will commence drafting the procedural and technical guidelines.

  The guidelines will include more detailed information about issues such as:

  - application requirements for licences;
  - the risk assessment process to be undertaken by the GTR;
  - requirements for certification of facilities to certain containment levels; and

- requirements for accreditation of organisations including detail about how Institutional Biosafety Committees (IBCs) should be constituted and their role under the gene technology legislation.

The IOGTR will undertake extensive public consultation on early drafts of each of the guidelines developed.

- **Committees**

The *Gene Technology Bill 2000* proposes that three statutory committees be established: the Gene Technology Technical Advisory Committee (GTTAC); the Gene Technology Community Consultative Group (GTCCG); and the Gene Technology Ethics Committee (GTEC).

Initial work on establishing these committees will commence in the next quarter, to the extent possible prior to the completion of the Senate inquiry into the legislation.

- **Rural consultation**

The IOGTR will continue to participate in public forums being conducted by Biotechnology Australia.

In the next quarter, Biotechnology Australia will conduct community forums in regional Australia.

These forums will be conducted in all States and throughout regional and rural Australia and will offer opportunities for members of the public to interact with senior scientists, technical experts and policy and legal advisers from a number of organisations involved biotechnology. It also offers an opportunity for the IOGTR to provide information on the regulatory system and the status of the draft gene technology regulations.

The IOGTR has also sought advice from States and Territories, through the CSCG, on ways to improve the dissemination of information in rural and regional areas. This information will be used to better target these areas and obtain input from them on the development of the national regulatory framework for GMOs.

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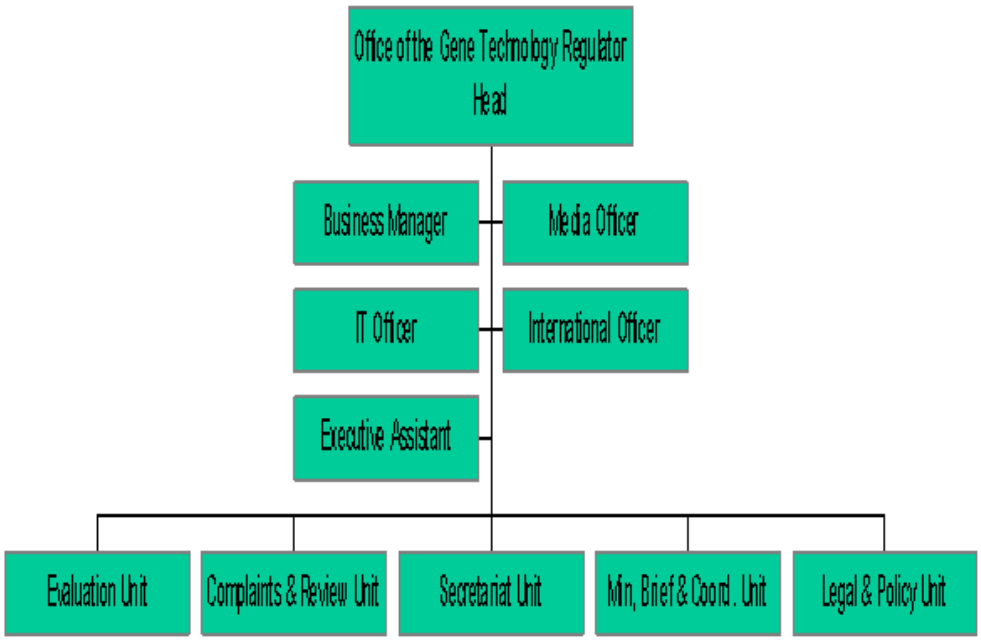
ATTACHMENT 1

STRUCTURE OF THE IOGTR



ATTACHMENT 2

TERMS OF REFERENCE
GENETIC MANIPULATION ADVISORY COMMITTEE

Objectives

The Committee's objectives are:

- to oversee the development and use of innovative genetic manipulation techniques in Australia so that any biosafety risk factors associated with the novel genetics of manipulated organisms are identified and can be managed; and
- to advise the Minister about matters affecting the regulation of innovative genetic manipulation technology.

Scope

Innovative genetic manipulation techniques shall include those techniques which can transfer genetic material between species which may not normally exchange genetic material in natural circumstances and non-traditional techniques capable of modifying the genetic material of organisms.
The risk factors shall include those which are associated with the altered genetic capabilities of the manipulated organism and which may give rise to safety concerns in public health, occupational health and safety, agricultural production or about the quality of the environment.

Functions

The Committee shall undertake the following functions in accord with the Minister's directions:

1. maintain an overview of the biosafety factors associated with these techniques;
2. identify and keep under review classes of work which have undefined risk levels;
3. alert Australian regulatory authorities, whether Commonwealth or State-based, to the existence of novel risk factors;
4. provide specialist technical advice on specific biosafety matters to organisations using these techniques and to regulatory agencies;
5. prepare, or as appropriate assist with the preparation of, codes, standards or guidelines for the assessment and management of biosafety risk factors; whether for the Committee's own overseeing activities or to assist regulatory agencies;
6. participate in public discussions about the biosafety of these techniques;
7. liaise with agencies overseas to ensure that, as far as practicable, Australian guidelines and regulations are in harmony with international practice.

Responsibilities and Powers

In pursuing the functions the Committee shall:

1. provide the Minister annually:
   - a review of the risks associated with genetic manipulation technology; and
   - a report on the activities of GMAC;

2. provide advice on matters referred to it by the Minister from time to time;

3. whenever practicable, work through established regulatory agencies in preference to establishing its own regulatory regimes;

4. consult with interested organisations and individuals especially during the drafting of code, standard or guideline documents;

5. institute procedures to protect commercially sensitive information submitted as part of any risk assessment review;

6. immediately advise the most appropriate Commonwealth or State agency should the Committee become aware of any project or activity in which biosafety is known, or thought likely, to be seriously compromised;

7. provide advice on the release of genetically modified organisms into the environment; and make available detailed statements of reasons for the assessment made including health, safety, environmental and any broader social issues taken into account.

ATTACHMENT 3

SUMMARY OF KEY PROVISIONS IN THE *GENE TECHNOLOGY BILL 2000*

The Bill creates the office of the Gene Technology Regulator (GTR) who is:

- a statutory office holder with significant independence akin to the Tax Commissioner and Commonwealth Ombudsman;
- Is appointed by the Governor-General with the agreement of the majority of Australian jurisdictions.

Functions of the GTR include:

- Administering the legislation – regulate GMOs;
- Providing advice to the public, industry and government regarding the regulation of GMOs;
- Providing risk assessment advice to other regulatory agencies and promote harmonisation or risk assessments for GMOs and GM products;
- Developing guidelines and standards;
- Undertaking research on risk management and GMOs;
- Maintaining links with international organisations.

The Prohibition

- The *Gene Technology Bill 2000* prohibits all dealings with GMOs unless the dealing is:
  - exempt (assessed low risk contained work);
  - a notifiable low risk dealing;
  - a licensed dealing; or
  - a registered dealing.

- Dealing with a GMO other than in a manner allowed by the legislation is an offence punishable by up to $220,000 for an individual and $1.1 million for a body corporate.

The Bill establishes a system for the GTR to assess dealings with GMO's ranging from contained work to general releases of GMOs into the environment:

- **Contained work (eg. dealing with low risk GMOs in a laboratory)**
  - The GTR must undertake any consultation necessary (ie. with States and Territories, expert committees, Commonwealth agencies, local government); and
  - prepare a risk assessment and a risk management plan;
  - notify the approval of the dealing (for example, on the database and in the annual report).

- **Intentional Release into the Environment**

- Where the GTR believes that a dealing may pose significant risk to health and safety of people or the environment, the GTR must publish a notice in the Gazette, and relevant newspapers, enter a notice on the GTR's website and generally make relevant people aware that the application has been received, is available on request and invite submissions;
- The GTR must prepare a draft risk assessment and a draft risk management plan, taking into account any submissions received, as well as advice from the GTR's expert technical committee;
- Release the draft risk assessment and risk management plan for a second round of public consideration and invite submissions;
- Make a final decision and notify the public.

The Bill establishes three Committees to assist the GTR and provide advice to the Ministerial Council

The Gene Technology Technical Advisory Committee (GTTAC) *to provide scientific and technical advice, including on individual applications.*

The Gene Technology Ethics Committee (GTEC) to develop ethics guidelines and prohibitive directives.

The Gene Technology Community Consultative Group (GTCCG) to provide advice on matters of general concern in relation to GMOs and the need for policy, technical or procedural guidelines and codes of practice in relation to GMOs and GM products.

Record of GMOs and GM Product Dealings

The *Record of GMOs and GM Product Dealings* provides for a centralised publicly available database of all GMOs and GM products approved in Australia, including those approved by the other regulators such as TGA, NRA, NICNAS, ANZFA and AQIS.

Interface with Other Regulators

The regulatory framework established by the *Gene Technology Bill 2000* is to operate concurrently with other Commonwealth and State regulatory schemes relevant to GMOs and GM products including:

- The Australia New Zealand Food Authority for food;
- The Therapeutic Goods Administration for therapeutic goods;
- The National Registration Authority for agricultural and veterinary chemicals;
- Australian Quarantine and Inspection Service; and
- The National Industrial Chemicals Notification and Assessment Scheme for industrial chemicals.

ATTACHMENT 4

LIST OF NEWSPAPERS USED TO NOTIFY AVAILABILITY OF THE DRAFT *GENE TECHNOLOGY BILL 2000* FOR CONSULTATIONS

Canberra Times	Dalby Herald
Burnie Advocate	Emerald
Hobart Mercury	Gatton
Launceston Examiner	Mackay Daily Mercury
Tasmanian Country	Mt Isa North West Star
Melbourne Age	Queensland Country Life
Horsham/Wimmera Mail Times	Stanthorpe Bor. Post
Portland Observer	Perth West Australian
Shepparton News	Albany Advertiser
The Weekly Times	Broome Advertiser
Mt Gambier Border	Central Midlands Advocate
Naracoorte Herald	Geraldton Guardian
Cootamundra Herald	Kimberley Echo
Glenn Innes Examiner	Merredin Wheatbelt Mercury
Griffith Area News	The Countryman
Gunnedah Namoi Valley	Syndney Morning Herald
Moree Champion	Newcastle Herald
Murrumbidgee Irrigation	Albury border Mail
Narrabri North West Courier	Orange Central West Daily
Broken Hill Barrier	Tamworth North Daily
The Land	Wagga Daily Advertiser
The Weekend Australian	Bourke Western Herald
Whyalla News	Cootamundra Herald
Stock Journal	Glenn Innes Examiner
Adelaide Advertiser	Griffith Area News
Ballarat Courier	Gunnedah Namoi Valley
Bendigo Advertiser	Moree Champion
Geelong Advertiser	Murrumbidgee Irrigation
Sunraysia Daily	Narrabri North West Courier
Warrnambool Standard	Broken Hill Barrier
Northern Territory News Net	The Land
Centralian Advocate	Newcastle Herald
Katherine Times	Albury border Mail
Brisbane Courier Mail	Orange Central West Daily
Bundaberg News mail	Tamworth North Daily
Gympie Times	Wagga Daily Advertiser
Toowoomba Chronicle	Bourke Western Herald
Townsville Bulletin	Cairns Post
Atherton Tablelander	

ATTACHMENT 5

GMAC MEMBERSHIP

Emeritus Professor Nancy Millis AC MBE MAgSc, PhD, FTSE, DSc (Chair)	Department of Microbiology, University of Melbourne
Dr Susan Barker BSc, PhD	Lecturer, Department of Plant Sciences, University of Western Australia
Dr Gerald Both BSc (Hons), PhD	Chief Research Scientist, CSIRO Molecular Science
Professor James Dale BscAgr (Hons), PhD	Head, School of Life Sciences, Queensland University of Technology
Professor Angela Delves BAppBiol, PhD	Pro-Vice Chancellor, Southern Cross University
Professor Ashley Dunn MPhil, PhD, FAA	Head, Molecular Biology Program, Ludwig Institute for Cancer Research
Dr John Fleming BA, TLL (Hons), PhD	Director, Southern Cross Bioethics Institute
Ms Judith Jones BSc, LLB	Lecturer, Faculty of Law, Australian National University
Professor Peter Langridge BSc, PhD	Research Leader, ARC for Basic and Applied Plant Molecular Biology, Waite Agricultural Research Institute
Dr John Manners BSc, PhD, DIC	Senior Research Scientist, CSIRO Tropical Agriculture
Mr David Martin Diploma of Mechanical Engineering	Retired Biocontainment Engineer, Australian Animal Health Laboratory, CSIRO
Dr John Oakeshott BSc, PhD	Head of Molecular Biology, CSIRO Entomology
Dr Dane Panetta BA, PhD	Principal Scientist/Professional Leader Queensland Department of Natural Resources
Dr Ian Parsonson MA, BVSc, PhD, MACVSc	Retired Assistant Chief, Australian Animal Health Laboratory, CSIRO
Professor Jim Pittard BSc, MSc, PhD, DSc, FAA	Head, Department of Microbiology, University of Melbourne
Associate Professor Richard Roush BSc, PhD	Director, CRC for Weed Management Systems, Waite Agricultural Research Institute
Dr Jan Tennent BSc, PhD	Unit Leader, CSIRO Division of Animal Health, CRC for Vaccine Technology Unit
Associate Professor Duncan Veal PhD	Associate Professor, Department of Biological Sciences, Macquarie University
Mr John Whitelaw BagSc	Environment Australia

The affiliations of GMAC members are included for identification purposes only. Members are appointed as individuals, not as representatives of particular organisations.

ATTACHMENT 6

DELIBERATE RELEASE PROPOSALS (FIELD TRIALS)

NEW PROPOSALS:

PR-132: Development of photoperiod insensitive canola cultivars (*Brassica napus*)

Organisation	Aventis CropScience Pty Ltd (formerly AgrEvo Pty Ltd) 391-393 Tooronga Road East Hawthorn VIC 3123
Contact person	Mr Peter Whitehouse telephone: (03) 9248 6837, facsimile: (03) 9248 6800
Organism	Canola (*Brassica napus*)
Location	Sites will be chosen from the following shires: Wagga Wagga and Coolamon (NSW); Glenelg, Horsham, Moyne, Northern Grampians, Southern Grampians and West Wimmera (Victoria); Gatton, Inglewood, Jondaryan, Laidley, Milmerran, Rosalie and Waggamba (Queensland); and Burnie, Central Coast, Devonport, Kentish and Latrobe (Tasmania).
Scale	Initially four sites of 1 hectare each, increasing to six sites of 1 hectare each in 2001-2002
Expected date of release	May 2000-2002 and September 2000-2002

Brief summary of the aim and nature of the deliberate release

The trial is part of a research program evaluating different strategies for obtaining varieties of canola whose flowering times are not dependent on day-length. Overseas lines of canola are typically not suited to Australian growing conditions because they are adapted for growing in spring, when the days are long, whereas the Australian canola season begins in autumn/winter. The development of canola that is insensitive to day-length for flowering ('photoperiod insensitive') would also allow crossing of lines that normally flower at different times, thus providing access to new hybrid varieties. The current trial will involve evaluation of modified plants in the field and a comparison with unmodified canola plants.

Organism

The parent organism is *Brassica napus oleifera*. *Brassica napus* originated in the Mediterranean area and is a significant oilseed crop in large areas worldwide. It is widely used in Europe, China, North America and Australia. Canola is an established crop in the medium and high rainfall areas of southern Australia, and is grown on a large scale in New South Wales, Victoria, South Australia and Western Australia.

Genetic modification and its effect

The canola lines to be released have been genetically modified for photoperiod insensitivity using one of three different genes involved in flower development from *Arabidopsis thaliana* (mustard weed). It is hoped that this gene will cause the late-flowering lines to commence flowering earlier.

Vector

The DNA was introduced into canola on a plasmid carried by the vector *Agrobacterium tumefaciens* (a bacterium). The vector is 'disarmed' since it lacks the genes that encode the tumorigenic functions of *A. tumefaciens*. This type of vector has been used frequently in Australia without causing any biosafety problems.

Procedures for release

The release will involve up to four 1-hectare sites in 2000 and up to six sites 1-hectare sites in both 2001 and 2002. The sites will be chosen from those listed above, in the canola-growing regions of New South Wales, Queensland, Victoria and Tasmania. Winter trials will be carried out in New South Wales, Queensland and Victoria, and summer trials in Victoria and Tasmania.

The trial plots will be planted with a small plot seeder or by hand. Seeders, windrowers and headers will be cleaned using compressed air on the trial site to minimise seed escape. The trial sites will be separated by 400 metres from other *Brassica* crops and the trial sites will be surrounded by a 15-metre buffer of non-transgenic canola or a non-*Brassica* crop of similar flowering timing. A 50-metre zone around the site will be monitored for sexually compatible species one month before planting, and from a week before the crop begins to flower until the crop stops flowering. Any sexually compatible plants found in this area will be removed.

Procedures following release

The seed harvested from the trials will be returned to Aventis CropScience in Canada and/or Belgium or stored by Aventis CropScience for use in subsequent trials. Harvested seed that is not required will be destroyed. Suitable techniques will be used to manage the canola trash remaining on the site after harvest including light cultivation followed by the application of a suitable herbicide, burning of trash or application of herbicide to emerging canola.

The trial site and surrounding area will be monitored for three years following harvest and any volunteer canola plants or related weedy species that emerge will be eliminated by herbicide treatment or cultivation. In the following season, the trial site may be seeded to pasture or cereal crops in which all *Brassica* and related species will be readily observed and eliminated by herbicides as required. No canola crops will be planted on the trial site for three years following the trial.

Transport

Seed for the release will be imported from Belgium. All seed harvested from the trial will be transported according to GMAC's Guidelines and seed movements will be monitored. Harvested seed will be cleaned in areas of suitable isolation and hygiene before being sent to North America or Belgium for further evaluation.

Summary of risk assessment and GMAC's recommendations

Canola is a self-compatible plant but cross-pollination is also possible. Canola reproduces by wind and insect pollination and there is potential for the pollen to disperse about a metre through plants brushing together in the wind. Canola has nectar that attracts a range of nectar-feeding and pollen-collecting insects, the most important of which is the honey bee (*Apis mellifera*). Bees can transfer pollen but rarely more than 50 metres. Canola cannot reproduce vegetatively.

Several members of the *Brassica* genus are weeds in Australia. There are reports of cross-pollination between *B. napus* and some of these species. The sites will be monitored for the presence of sexually compatible species (*B. napus*, *B. rapa*, *B. juncea* and *Raphanus raphanistrum*) and these will be removed. The hybrids which can form between *B. napus* and other *Brassica* species or members of other genera are generally either sterile or of low fertility.

The normal means of reproduction of *Brassica napus* is through seed. Seed can disperse short distances if ripe fruiting structures shatter and canola seed can persist dormant in soil for some years. However, if the seed drops to the ground it germinates under moist conditions and does not constitute a long-term survival structure; buried seed loses viability rapidly. Although *B. napus* seed has some capacity for dormancy, the proponents claim that normal rotational practice and weed control techniques will ensure that volunteer canola plants after the trial will not be a problem.

GMAC considered that the isolation and monitoring procedures to be used for this trial were sufficient to minimise the potential for spread or persistence of the modified plants or their genes.

Conclusion

GMAC concluded that the current field trial would not present any significant risk to the environment or the community.

Other agencies advised by GMAC

National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority
Australian Quarantine and Inspection Service
NSW Environment Protection Authority
NSW Department of Land and Water Conservation
NSW Department of Agriculture
Tasmanian Department of Primary Industry, Water and Environment
Victorian Department of Natural Resources and the Environment
Victorian Environment Protection Authority
Queensland Environmental Protection Agency
Queensland Department of Natural Resources
Queensland Department of Primary Industries
Coolamon Shire Council
Wagga Wagga City Council
Glenelg Shire Council
Horsham Rural City Council
Moyne Shire Council
North Grampians Shire Council
South Grampians Shire Council
West Wimmera Shire Council
Burnie City Council
Central Coast Council
Gatton Shire Council
Laidley Shire Council
Inglewood Shire Council
Jondaryan Shire Council
Milmerran Shire Council
Rosalie Shire Council
Waggamba Shire Council

Other agencies to be consulted as at 1 June 2000

Devonport City Council
Kentish Council
Latrobe Council

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a deliberate release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

PR-133: Development of fungal disease resistant canola cultivars

Organisation	Aventis CropScience Pty Ltd (formerly AgrEvo Pty Ltd) 391-393 Tooronga Road East Hawthorn VIC 3123
Contact person	Mr Peter Whitehouse telephone: (03) 9248 6837, facsimile: (03) 9248 6800
Organism	Canola (*Brassica napus*)
Location	Sites will be chosen from the following locations: Wagga Wagga and Coolamon (NSW); Horsham, West Wimmera, Southern Grampians, Northern Grampians, Glenelg and Moyne (Victoria); and Burnie, Central Coast, Devonport, Kentish and Latrobe (Tasmania).
Scale	Initially four sites of 1 hectare each, increasing to six sites of 1 hectare each in 2001-2002
Expected date of release	May 2000–2002 and September 2000–2002

Brief summary of the aim and nature of the deliberate release

The canola lines to be released in this trial have been genetically modified for tolerance to fungal diseases such as Blackleg and Sclerotinia. Development of fungal disease resistance would greatly assist canola growers in managing major fungal diseases in canola crops.

The trial will be used to increase seed as part of a global research program evaluating different strategies for obtaining fungal disease resistance in canola. The modified canola will be tested in areas where there is natural infestation with fungal diseases and the level of fungal resistance will be determined.

Organism

The parent organism is *Brassica napus oleifera*. *Brassica napus* originated in the Mediterranean area and is a significant oilseed crop in large areas worldwide. It is widely grown in Europe, China, North America and Australia. Canola is an established crop in the medium and high rainfall areas of southern Australia, and is grown on a large scale in New South Wales, Victoria, South Australia and Western Australia.

Genetic modification and its effect

The canola lines to be released have been genetically modified for resistance to fungal diseases using one of four different genes from plant sources or the bacterium *Bacillus amyloliquefaciens*.

Vector

The DNA was introduced into canola on a plasmid carried by the vector *Agrobacterium tumefaciens* (a bacterium). The vector is 'disarmed' since it lacks the genes that encode the tumorigenic functions of *A. tumefaciens*. This type of vector has been used frequently in Australia without causing any biosafety problems.

Procedures for release

The release will involve up to four 1-hectare sites in 2000 and up to six sites 1-hectare sites in both 2001 and 2002. The sites will be chosen from those listed above, in the canola-growing regions of New South Wales, Queensland, Victoria and Tasmania. Winter trials will be carried out in New South Wales, Queensland and Victoria, and summer trials in Victoria and Tasmania.

Visual observations of emergence and crop vigour will be noted during the trial. The plants will not be treated with fungicides, in order to provide clear readings of the level of introduced fungal tolerance.

The trial plots will be planted with a small plot seeder or by hand. Seeders, windrowers and headers will be cleaned using compressed air on the trial site to minimise seed escape. The trial sites will be separated by 400 metres from other *Brassica* crops. Cages (tents) may be used around the plants to ensure seed purity. If cages are not used, the sites will be surrounded by a 15-metre buffer of non-transgenic canola**.** A 50-metre zone around the sites will be monitored for sexually compatible species one month before planting, and from a week before the crop begins to flower until the crop stops flowering. Any sexually compatible plants found in this area will be removed.

Procedures following release

The seed harvested from the trials will be returned to Aventis CropScience in North America and/or Belgium or stored by Aventis CropScience for use in subsequent trials. Harvested seed that is not required will be destroyed. Suitable techniques will be used to manage the canola trash remaining on the site after harvest including light cultivation followed by the application of a suitable herbicide, burning of trash or application of herbicide to emerging canola.

The trial sites and surrounding areas will be monitored for three years following harvest and any volunteer canola plants or related weedy species that emerge will be killed by herbicide application or cultivation. In the following season, the trial sites may be seeded to pasture or cereal crops in which all *Brassica* and related species will be readily observed and eliminated by herbicide as required. No canola crops will be planted on the trial sites for three years following the trial.

Transport

Seed for the release will be imported from Belgium. All seed harvested from the trial will be transported according to GMAC's Guidelines and seed movements will be monitored. Harvested seed will be cleaned in areas of suitable isolation and hygiene before being sent to North America or Belgium for further evaluation.

Summary of risk assessment and GMAC's recommendations

Canola is a self-compatible plant but cross-pollination is also possible. Canola reproduces by wind and insect pollination and there is potential for the pollen to disperse about a metre through plants brushing together in the wind. Canola has nectar that attracts a range of nectar-feeding and pollen-collecting insects, the most important of which is the honey bee (*Apis mellifera*). Bees can transfer pollen but rarely more than 50 metres. Canola cannot reproduce vegetatively.

Several members of the *Brassica* genus are weeds in Australia. There are reports of cross-pollination between *B. napus* and some of these species. The sites will be monitored for the presence of sexually compatible species (*B. napus*, *B. rapa*, *B. juncea* and *Raphanus raphanistrum*) and these will be removed. The hybrids which can form between *B. napus* and other *Brassica* species or members of other genera are generally either sterile or of low fertility.

The normal means of reproduction of *Brassica napus* is through seed. Seed can disperse short distances if ripe fruiting structures shatter and canola seed can persist dormant in soil for some years. However, if the seed drops to the ground it germinates under moist conditions and does not constitute a long-term survival structure; buried seed loses viability rapidly. Although *B. napus* seed has some capacity for dormancy, the proponents claim that normal rotational practice and weed control techniques will ensure that volunteer canola plants after the trial will not be a problem.

As in its assessment of previous proposals for field trials of canola plants modified for resistance to fungal diseases, GMAC noted that little information is currently available on the mechanism of action of the gene introduced to confer resistance to fungal disease. GMAC advised that further details on this issue would be required before the proponents proceeded to general release of the canola plants. In particular, information would be required on whether the fungal-resistance genes could confer a fitness advantage on related species into which the genes might transfer, increasing the potential for these species to become weeds in cultivated, disturbed or natural environments.

GMAC also noted that further data would be required before general release on any effects of the fungal-resistance trait on non-target fungi in the root system of the plant.

GMAC considered that the isolation and monitoring procedures to be used for this trial were sufficient to minimise the potential for spread or persistence of the modified plants or their genes.

Conclusion

GMAC concluded that the current field trial would not present any significant risk to the environment or the community.

Other agencies advised by GMAC

National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority
Australian Quarantine and Inspection Service
NSW Environment Protection Authority
NSW Department of Land and Water Conservation
NSW Department of Agriculture
Victorian Department of Natural Resources and the Environment
Victorian Environment Protection Authority
Tasmanian Department of Primary Industry, Water and Environment
Coolamon Shire Council
Wagga Wagga City Council
Glenelg Shire Council
Horsham Rural City Council
Moyne Shire Council
North Grampians Shire Council
South Grampians Shire Council
West Wimmera Shire Council
Burnie City Council
Central Coast Council

Other agencies to be consulted as at 1 June 2000

Devonport City Council

Kentish Council
Latrobe Council

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a deliberate release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

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

PR-134: Field evaluation of a transgenic line of field pea (*Pisum sativum* L.) for resistance to Ascochyta blight

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

Agriculture Western Australia
3 Baron-Hay Court
South Perth WA 6151

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

Purpose of the release: The aim of the trial is to determine if a new variety of transgenic field pea offers any resistance to attack from the fungal disease Ascochyta blight (also known as 'black spot').

Brief description of the nature and effect of the genetic modification: The leaves of the transgenic peas contain a protein (osmotin) normally found in the flowers of tobacco. This protein has been shown to prevent the growth of some fungi when produced in the leaves of plants.

The genetically modified field peas also contain selectable marker genes encoding resistance to the herbicide glufosinate ammonium (Basta®) and the antibiotic ampicillin.

Location and size of trial: Up to 100 plants at the Agricultural Research Station in Medina, Western Australia.

Further information: The institution's contact officers for this proposal are
Dr TJ Higgins, telephone (02) 6246 5063, facsimile (02) 6246 5000; and
Dr Tanveer Khan, telephone (08) 9368 3602, facsimile (08) 9474 2840.

PR-135: Field evaluation of transgenic lines of field pea (*Pisum sativum* L.) with enhanced grain protein levels

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

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

Purpose of the release: Two pea cultivars have been modified for improved nutritional quality by introducing a protein that is unusually rich in sulfur-containing amino acids. The peas have been shown to have significantly higher total levels of seed protein. The aim of this trial is to determine if the high protein levels are found in field-grown peas.

Brief description of the nature and effect of the genetic modification: A gene coding for a sulfur-rich seed protein found in sunflower (*Helianthus annuus*) has been introduced into two commercial pea cultivars to improve nutritional quality. In addition, the peas also express a gene from the bacterium *Streptomyces hygroscopicus* that confers resistance to the herbicide glufosinate ammonium (Basta®) and a gene from the bacterium *Escherichia coli* encoding the screenable marker β-glucuronidase (GUS).

Location and size of trial: Up to 100 transgenic plants are to be grown on the CSIRO Black Mountain campus, Canberra, ACT.

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

PR-136: Field maintenance and propagation of sugarcane modified for sucrose metabolism and juice colour

Organisation proposing release: CSIRO Tropical Agriculture
306 Carmody Road
St Lucia QLD 4067

Organism to be released: Sugarcane (*Saccharum* species)

Purpose of the release: The plants will be grown to obtain mature cane for harvest and propagation increase. This will provide bulk stalk samples for juice extraction for laboratory evaluation of sucrose, juice colour and crystal colour. These evaluations, if successful, will lead to yield and agronomic assessment of selected transgenic lines.

Brief description of the nature and effect of the genetic modification: Two different lines of genetically modified sugarcane will be grown. One variety has been modified by the introduction of copies of sections of the sugarcane invertase gene. Invertase is a key enzyme in sugar production. The modification is designed to block the activity of the invertase gene and increase the sugar content of the plants.

In the second line, copies of sections of the sugarcane polyphenol oxidase (PPO) gene have been introduced. PPO is an enzyme responsible for the browning of juice and crystals from sugarcane. The aim of the modification is to block the action of the PPO gene so that the sugar has lower colour and higher quality. These plants also contain a gene for a green fluorescent protein from jellyfish. This acts as a marker to distinguish genetically modified from unmodified plants.

In addition, both lines of sugarcane express the marker gene *aphA*, which confers resistance to the antibiotic geneticin, and is used to select genetically modified plants in the laboratory.

Location and size of trial: Up to 0.1 hectares at a CSIRO site at Townsville, 0.3 hectares at Brisbane, and either 0.26 hectares at Ayr or 0.4 hectares near Halifax, Queensland.

Further information: The institution's contact officer for this proposal is
Dr Christopher Grof, telephone (07) 3214 2232, facsimile (07) 3214 2848.

EXTENSIONS TO PREVIOUS PROPOSALS:

Extension to PR-79X:

PR-79X(2): Development of fungal disease resistant canola cultivars (*Brassica napus*)

Organisation	Aventis CropScience Pty Ltd (formerly AgrEvo Pty Ltd) 391-393 Tooronga Road East Hawthorn VIC 3123
Contact person	Mr Peter Whitehouse telephone: (03) 9248 6837, facsimile: (03) 9248 6800
Organism	Canola (*Brassica napus*)
Location	Sites will be chosen from the following locations: Wagga Wagga and Coolamon (NSW); Burnie, Central Coast, Devonport, Kentish, Latrobe (Tasmania); and Horsham, West Wimmera, Southern Grampians, Northern Grampians, Glenelg and Moyne (Victoria)
Scale	Three sites of 1 hectare each
Expected date of release	May and September 2000

The aim of this extension to the original proposal is to continue the evaluation of strategies for obtaining fungal disease tolerance in *Brassica napus* (canola). Control of fungal diseases such as Blackleg (*Leptosphaeria maculans*) is of major importance in Australia. The modified canola plants will be tested in an area where there is natural infestation with fungal diseases and the level of fungal disease resistance will be determined.

The canola plants have been genetically modified for tolerance to fungal diseases by introduction of a gene coding for the enzyme peroxidase from the tropical legume *Stylosanthes humilis*. The peroxidase enzyme enhances plant cell wall cross-linking, and this aids tolerance to diseases such as Blackleg. A selectable 'marker' gene from the bacterium *Escherichia coli* conferring resistance to the antibiotics kanamycin and neomycin was also transferred to the plants.

The trial will take place on three plots of 1 hectare each at sites chosen from the list above. Procedures for management of the trial and treatment of the sites after the trial will be the same as for the previous proposal.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC concluded that the risks to the community or the environment were low.

Other agencies advised by GMAC
National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority
NSW Environment Protection Authority
NSW Department of Land and Water Conservation
NSW Department of Agriculture
Victorian Department of Natural Resources and the Environment
Victorian Environment Protection Authority
Tasmanian Department of Primary Industry, Water and Environment
Coolamon Shire Council

Wagga Wagga City Council
Glenelg Shire Council
Horsham Rural City Council
Moyne Shire Council
North Grampians Shire Council
South Grampians Shire Council
West Wimmera Shire Council
Burnie City Council
Central Coast Council

Other agencies to be consulted as at 1 June 2000

Devonport City Council
Kentish Council
Latrobe Council

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a deliberate release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

Extension to PR-85X(2):

PR-85X(3): Small and large scale seed increase of a genetically modified canola (*Brassica rapa*) with a new hybridisation system

Organisation	Aventis CropScience Pty Ltd (formerly AgrEvo Pty Ltd) 391-393 Tooronga Road East Hawthorn VIC 3123
Contact person	Mr Peter Whitehouse telephone: (03) 9248 6837, facsimile: (03) 9248 6800
Organism	Canola (*Brassica rapa*)
Location	Sites will be chosen from the following locations: Wagga Wagga and Coolamon (NSW); Horsham, West Wimmera, Southern Grampians, Northern Grampians and Glenelg (Victoria); Burnie, Central Coast, Kentish, Meander Valley, Central Highlands, New Norfolk, Huon Valley, Devonport, Latrobe, West Tamar, George Town, Dorset, Launceston, Northern Midlands, Break O'Day, Southern Highlands, Spring Bay, Brighton, Glenorchy, Sorell, Tasman, Clarence, Hobart, Kingborough (Tasmania); and Grant, Wattle Range, Robe, Mount Gambier, Lucindale and Naracoorte (South Australia).
Scale	A total of 121 hectares at 15 sites of 1-10 hectares
Expected date of release	May 2000 (NSW, Vic) and September 2000 (Vic, SA, Tas).

A further extension to the original proposal has been received. The aim of the extension is to increase seed stocks and conduct breeding trials of genetically modified canola (*Brassica rapa*) for use in the Canadian breeding program by Aventis Canada and licensed commercial partners. The work in Australia allows 'contra-season' production of the canola. Part of the trial aims to investigate the level of tolerance of the transgenic canola to Blackleg, a fungal disease.

The canola plants have been modified to provide a new genetic system for making hybrid varieties (which produce higher yields than standard varieties) and for tolerance to the herbicide glufosinate-ammonium (Liberty®). Some lines contain only the herbicide-tolerance gene. The presence of 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, some of which are not currently well controlled with existing herbicides.

The herbicide-tolerance gene introduced into the canola plants is the phosphinothricin acetyl transferase gene from the bacteria *Streptomyces viridichromogenes* or *Streptomyces hygroscopicus*. The enzyme encoded by this gene chemically modifies the herbicide glufosinate-ammonium and renders it inactive, thereby conferring tolerance to the herbicide.

The herbicide-tolerance gene also acts as a selectable marker gene that allows the researchers to distinguish the modified plants from plants that have not been modified.

The hybridisation system involves ensuring that the plants cross-pollinate rather than self-pollinate. The 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*. Crossing of the male sterile line with the fertility restorer line results in hybrids that are fertile.

The trial will take place at 15 sites of 1 to 10 hectares each at locations chosen from the list above. Procedures for management of the trial and treatment of the sites after the trial will be the same as for the previous proposal.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC concluded that the risks to the community or the environment were low.

Other agencies advised by GMAC
National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority
NSW Environment Protection Authority
NSW Department of Land and Water Conservation
NSW Department of Agriculture
Tasmanian Department of Primary Industry, Water and Environment
Victorian Department of Natural Resources and the Environment
Victorian Environment Protection Authority
South Australian Department of Primary Industries and Resources
South Australian Department for Environment, Heritage and Aboriginal Affairs
South Australian Environment Protection Agency

New South Wales Local Councils
Coolamon Shire Council
Wagga Wagga City Council

Tasmanian Local Councils
Break O'Day Council
Brighton Council
Burnie City Council
Central Coast Council
Central Highlands Council
Clarence City Council
Devonport City Council
Dorset Council
George Town Council
Glamorgan/Spring Bay Council
Glenorchy Council
Hobart City Council
Huon Valley Council
Kentish Council
Kingborough Council
Launceston City Council
Latrobe Council
Meander Valley Council
New Norfolk Council

Northern Midlands Council
Sorell Council
Southern Midlands Council
Tasman Council
West Tamar Council

Victorian Local Councils
Glenelg Shire Council
Horsham Rural City Council
Northern Grampians Shire Council
Southern Grampians Shire Council
West Wimmera Shire council

South Australian Local Councils
Grant District Council
Lucindale District Council
Mount Barker District Council
City of Mount Gambier
Naracoorte District Council
Robe District Council
Wattle Range Council

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a deliberate release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

Extension to PR-87X:

PR-87X(2): Field performance and integrated pest management studies on transgenic cotton expressing the CryIA(c) delta-endotoxin from *Bacillus thuringiensis*, in the Kimberley region of Western Australia

Organisation	Agriculture Western Australia 3 Baron-Hay Court South Perth WA 6151
Contact person	Mr Geoff Strickland telephone: (08) 9368 3756; facsimile: (08) 9368 3223
Organism	Cotton (*Gossypium hirsutum*)
Location	Kununurra, Western Australia
Scale	34.6 million plants in an area of 350 hectares at Kununurra
Expected date of release	April – October 2000

The aim of this additional extension to the original proposal is to assess the field efficacy and agronomic performance of cotton modified for resistance to insect pests in the conditions at Kununurra. A major aim is the development of an integrated pest management (IPM) system for transgenic cotton in the Kimberley region, as a precursor to the eventual re-introduction of cotton as a commercial crop in the Kimberley. The use of insect-resistant crops has the potential to reduce the use of chemical pesticides on cotton crops.

The insecticidal gene introduced into the cotton plants is the CryIA(c) gene from the bacterium *Bacillus thuringiensis*. This gene produces a protein that is toxic to certain caterpillars, including the major caterpillar pests that attack cotton. In addition, the plants contain a selectable 'marker' gene from a bacterium that confers resistance to the antibiotics kanamycin and neomycin. Another bacterial gene, encoding resistance to the antibiotics spectinomycin and streptomycin, is also present in the transgenic plants, but is not expressed in the plants.

The Kununurra trials will be located on properties within the Ord River Irrigation Area of Western Australia. Four IPM strategies will be evaluated with plot sizes of approximately 20 to 30 hectares (a total area of approximately 350 hectares). Procedures for management of the trial sites and treatment of the sites after the trial will be the same as for the previous proposal.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC concluded that the risks to the community or the environment were very low.

Other agencies advised by GMAC

National Registration Authority for Agricultural & Veterinary Chemicals
Australia New Zealand Food Authority
Western Australian Department of Agriculture
Western Australian Environmental Protection Authority
Western Australian Department of Conservation and Land Management
Western Australian Department of Environmental Protection
Shire of Wyndham-East Kimberley

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a planned release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

Extension to PR-90X: Development of herbicide tolerant hybrid *Brassica juncea*

PR-90X(2): Development of herbicide tolerant *Brassica juncea*

Organisation	Aventis CropScience Pty Ltd (formerly AgrEvo Pty Ltd) 391-393 Tooronga Road East Hawthorn VIC 3123
Contact person	Mr Peter Whitehouse telephone: (03) 9248 6837, facsimile: (03) 9248 6800
Organism	Indian mustard (*Brassica juncea*)
Location	Ten sites in the canola-growing regions of South Australia, Victoria, Queensland, Tasmania and NSW (to be advised)
Scale	A total area of 10 hectares (1 hectare per site)
Expected date of release	May (NSW, Vic, Qld) and September (SA, Vic, Tas) 2000

The Indian mustard plant (*Brassica juncea*) is closely related to commercially grown canola (*Brassica napus*), and modern plant breeding would suggest that a canola-quality *B. juncea* would be interchangeable with *B. napus* for processing. Features of non-canola quality *B. 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. Although standard varieties yield well, considerably higher yields can be obtained from hybrid varieties. The modified plants to be trialed have also been made resistant to the herbicide glufosinate-ammonium.

The hybridisation system involves ensuring that the plants cross-pollinate rather than self-pollinate. The 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*. Crossing of the male sterile line with the fertility restorer line results in hybrids that are fertile.

The lines containing the new hybridisation system also contain the *bar* gene from the bacterium *Streptomyces hygroscopicus*. This gene encodes the enzyme phosphinothricin acetyltransferase that chemically modifies the herbicide glufosinate-ammonium and renders it inactive. Plants expressing the *bar* gene are therefore resistant to the herbicide. Some of the plants also contain a selectable 'marker' gene conferring resistance to the antibiotics kanamycin and neomycin, from the bacterium *Escherichia coli*.

Trial sites of one hectare each will be planted at ten sites in the canola-growing regions of New South Wales, Victoria, Tasmania, South Australia and Queensland. Glufosinate-ammonium will be applied to assist weed control in the crop and as a selection tool. Procedures for management of the trial and treatment of the sites after the trial will be the same as for the previous proposal.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC concluded that the risks to the community or the environment were very low.

Other agencies advised by GMAC
National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority
NSW Environment Protection Authority
NSW Department of Land and Water Conservation
NSW Department of Agriculture
Tasmanian Department of Primary Industry, Water and Environment
Victorian Department of Natural Resources and the Environment
Victorian Environment Protection Authority
South Australian Department for Environment, Heritage and Aboriginal Affairs
South Australian Environment Protection Agency
Queensland Department of Natural Resources
Queensland Department of Primary Industries

New South Wales Local Councils
Barraba Shire Council
Bland Shire Council
Coolamon Shire Council
Dubbo City Council
Forbes Shire Council
Moree Plains Shire Council
Murrumbidgee Shire Council
Narrabri Shire Council
Narrandera Shire Council
Narromine Shire Council
Temora Shire Council
Wagga Wagga City Council
Weddin Shire Council

Tasmanian Local Councils
Break O'Day Council
Brighton Council
Burnie City Council
Central Coast Council
Central Highlands Council
Clarence City Council
Devonport City Council
Dorset Council
George Town Council
Glamorgan/Spring Bay Council
Glenorchy Council
Hobart City Council
Huon Valley Council
Kentish Council
Kingborough Council
Launceston City Council
Latrobe Council
Meander Valley Council
New Norfolk Council
Northern Midlands Council

Sorell Council
Southern Midlands Council
Tasman Council
West Tamar Council

Victorian Local Councils
Glenelg Shire Council
Hindmarsh Shire Council
Horsham Rural City Council
Northern Grampians Shire Council
Southern Grampians Shire Council
West Wimmera Shire council
Yarriambiack Shire Council

South Australian Local Councils
Grant District Council
Lucindale District Council
Mount Barker District Council
City of Mount Gambier
Naracoorte Lucindale District Council
Robe District Council
Wattle Range Council

Queensland Local Councils
Gatton Shire Council
Laidley Shire Council
Inglewood Shire Council
Jondaryan Shire Council
Milmerran Shire Council
Rosalie Shire Council
Waggamba Shire Council

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a deliberate release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

Extension to PR-93X:

PR-93X(2): Development of fungal disease resistant canola cultivars

Organisation	Aventis CropScience Pty Ltd (formerly AgrEvo Pty Ltd) 391-393 Tooronga Road East Hawthorn VIC 3123
Contact person	Mr Peter Whitehouse telephone: (03) 9248 6837, facsimile: (03) 9248 6800
Organism	Canola (*Brassica napus*)
Location	Sites will be chosen from the following locations: Wagga Wagga and Coolamon (NSW); Horsham, West Wimmera, Southern Grampians, Northern Grampians, Glenelg and Moyne (Victoria); and Burnie, Central Coast, Devonport, Kentish and Latrobe (Tasmania).
Scale	Initially three sites of 1 hectare each, increasing to six sites of 1 hectare each in 2001-2002
Expected date of release	May 2000, 2001, 2002 (NSW, Vic) and September 2000, 2001, 2002 (Vic, Tas)

The aim of this trial is to continue evaluation of strategies for obtaining fungal disease tolerance in canola. Development of fungal disease resistance would assist canola growers in managing major fungal diseases such as Blackleg and Sclerotinia in canola crops. In addition, the modified plants have also been made resistant to the herbicide glufosinate-ammonium. This herbicide could be used in canola crops to control weeds that are not currently well controlled with other herbicides.

A line of transgenic canola for which the seed was not available for planting under the original proposal will be tested under this extension in areas where natural fungal disease infestation is high. The level of introduced fungal tolerance will be determined.

The canola line to be released has been genetically modified for tolerance to fungal diseases using one or two genes from tobacco (*Nicotiana tabacum*). The genes from tobacco have antimicrobial activity and are induced upon infection of the plants by various disease-causing organisms. The *bar* gene from the soil bacterium *Streptomyces hygroscopicus*, which confers resistance to the herbicide glufosinate-ammonium, was also transferred to the plants.

The release will be conducted on plots of up to 1 hectare at sites selected from the areas listed above. Three sites will be used in 2000 and up to six sites in both 2001 and 2002. Procedures for management of the trial and treatment of the sites after completion of the trial will be the same as for the previous proposal.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC concluded that the risks to the community or the environment were very low.

Other agencies advised by GMAC
National Registration Authority for Agricultural and Veterinary Chemicals

Australia New Zealand Food Authority
NSW Environment Protection Authority
NSW Department of Land and Water Conservation
NSW Department of Agriculture
Victorian Department of Natural Resources and the Environment
Victorian Environment Protection Authority
Tasmanian Department of Primary Industry, Water and Environment
Coolamon Shire Council
Wagga Wagga City Council
Glenelg Shire Council
Horsham Rural City Council
Moyne Shire Council
North Grampians Shire Council
South Grampians Shire Council
West Wimmera Shire Council
Burnie City Council
Central Coast Council

Other agencies to be consulted as at 1 June 2000

Devonport City Council
Kentish Council
Latrobe Council

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a planned release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

Extension to PR-109:

PR-109X: Winter nursery seed increase of Roundup Ready® and Ingard® (Bt)/Roundup Ready® (RR) cotton plants, 2000

Organisation	Deltapine Australia Pty Ltd PO Box 196 Narrabri NSW 2390
Contact person	G F Smart telephone: (02) 6792 5233, facsimile: (02) 6792 5235
Organism	Cotton (*Gossypium hirsutum*)
Location	Ord River Irrigation Area, Kununurra, Western Australia
Scale	8 hectares
Expected date of release	April 2000 - October 2000

Deltapine has previously conducted field trials for seed increase of Roundup® Ready (RR) (PR-71) and Roundup Ready®/Bt cotton (PR-109). This extension application combines the field trials for each type of cotton. The proposal aims to increase seed supplies of several lines of cotton which express the Roundup®-tolerance gene with or without a gene conferring resistance to insect attack. The long-term goal of the work is to develop commercial cotton cultivars that are resistant to Roundup® and to insect damage.

Glyphosate is a broad-spectrum herbicide that has no residual soil activity and very low mammalian toxicity. The development of glyphosate-tolerant cotton plants would allow glyphosate to be used on both pre-emergent and post-emergent cotton to control broadleaf and grass weeds. The insecticidal gene used in the transgenic plants produces a protein that is toxic to the major caterpillar pests of cotton in Australia, but is not toxic to other animals, including humans. The insect-resistance gene should provide effective control of insects and therefore reduce the need for use of chemical pesticides on the crop.

The herbicide-resistance gene in the transgenic plants encodes the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) from a soil bacterium (*Agrobacterium*). This enzyme is already present in cotton plants and is the target enzyme for the herbicidal action of glyphosate, the active ingredient of Roundup®. The genetically modified plants are able to produce the enzyme in sufficient amounts to overcome the herbicidal action of glyphosate.

Some of the modified cotton plants also contain the CryIA(c) delta-endotoxin gene from the bacterium *Bacillus thuringiensis* (Bt). The protein resulting from expression of this gene is toxic to the major caterpillar pests of cotton.

The plants contain a ‘marker’ gene, from a bacterium, which encodes resistance to the antibiotics kanamycin and neomycin. Another bacterial gene, encoding resistance to the antibiotics streptomycin and spectinomycin, is also present in the transgenic plants, but is not expressed in the plants.

A maximum of 8 hectares of transgenic cotton will be grown at Kununurra in the Ord River Irrigation Area of Western Australia. Procedures for management of the trial and treatment of the site after completion of the trial will be the same as for the previous proposal.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC concluded that the risks to the community or the environment were very low.

Other agencies advised by GMAC

National Registration Authority for Agricultural & Veterinary Chemicals
Australia New Zealand Food Authority
Western Australian Department of Agriculture
Western Australian Environmental Protection Authority
Western Australian Department of Conservation and Land Management
Shire of Wyndham-East Kimberley

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a planned release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

Extension to PR-110:

PR-110X: Development of fungal disease resistant canola cultivars (*Brassica napus*)

Organisation	Aventis CropScience Pty Ltd (formerly AgrEvo Pty Ltd) 391-393 Tooronga Road East Hawthorn VIC 3123
Contact person	Mr Peter Whitehouse telephone: (03) 9248 6837, facsimile: (03) 9248 6800
Organism	Canola (*Brassica napus*)
Location	Sites will be chosen from the following locations: Wagga Wagga and Coolamon (NSW); Burnie, Central Coast, Devonport, Kentish and Latrobe (Tasmania); and Horsham, West Wimmera, Southern Grampians, Northern Grampians, Glenelg and Moyne (Victoria).
Scale	Initially three sites of 1 hectare each, increasing to six sites of 1 hectare each in 2001-2002
Expected date of release	May 2000, 2001, 2002 (NSW, Vic) and September 2000, 2001, 2002 (Vic, Tas)

This trial is an extension of a research program evaluating different strategies for obtaining tolerance to fungal diseases in canola. Two genetically modified canola lines will be compared for their fungal disease tolerance in areas where there is natural infestation with the fungi that cause disease (especially Blackleg and Sclerotinia). Development of fungal disease resistance would assist canola growers in managing fungal diseases in canola crops.

The canola lines to be released have been genetically modified for tolerance to fungal diseases using genes derived from barley and *Aspergillus giganteus* (a fungus).

The canola lines have also been modified for resistance to the herbicide glufosinate-ammonium by inserting a gene from the bacterium *Streptomyces hygroscopicus.* The gene encodes the enzyme phosphinothricin acetyltransferase that chemically modifies the herbicide and renders it inactive. The use of the herbicide-resistance gene would allow glufosinate-ammonium to be used in canola crops to control weeds that are not currently well controlled with other herbicides.

The release will be conducted on plots of up to 1 hectare at sites selected from the areas listed above. Three sites will be used in 2000 and up to six sites in both 2001 and 2002. Procedures for management of the trial and treatment of the sites after completion of the trial will be the same as for the previous proposal.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC concluded that the risks to the community or the environment were very low.

Other agencies advised by GMAC
National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority
NSW Environment Protection Authority
NSW Department of Land and Water Conservation
NSW Department of Agriculture
Victorian Department of Natural Resources and the Environment
Victorian Environment Protection Authority
Tasmanian Department of Primary Industry, Water and Environment
Coolamon Shire Council
Wagga Wagga City Council
Glenelg Shire Council
Horsham Rural City Council
Moyne Shire Council
North Grampians Shire Council
South Grampians Shire Council
West Wimmera Shire Council
Burnie City Council
Central Coast Council
Other agencies to be consulted as at 1 June 2000
Devonport City Council
Kentish Council
Latrobe Council

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a deliberate release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

Extension to PR-111:

PR-111X: Development of photoperiod insensitive canola cultivars

Organisation	Aventis CropScience Pty Ltd (formerly AgrEvo Pty Ltd) 391-393 Tooronga Road East Hawthorn VIC 3123
Contact person	Mr Peter Whitehouse telephone: (03) 9248 6837, facsimile: (03) 9248 6800
Organism	Canola (*Brassica napus*)
Location	Sites will be chosen from the following locations: Wagga Wagga and Coolamon (NSW); Gatton, Laidley, Jondaryan, Rosalie, Waggamba, Inglewood and Milmerran (Queensland); Horsham, West Wimmera, Southern Grampians, Northern Grampians, Glenelg and Moyne (Victoria); and Burnie, Central Coast, Devonport, Kentish and Latrobe (Tasmania)
Scale	Initially four sites of 1 hectare each, increasing to six sites of 1 hectare each in 2001-2002
Expected date of release	May 2000, 2001, 2002 (NSW, Vic, Qld) and September 2000, 2001, 2002 (Vic, Tas)

This trial is an extension of a research program evaluating different strategies for obtaining varieties of canola with flowering times that are not dependent on day-length. No trials were conducted in 1999 under the original proposal (PR-111) due to unavailability of seeds. Overseas lines of canola are typically not suited to Australian growing conditions because they are adapted for growing in spring, when the days are long, whereas the Australian canola season begins in autumn/winter. The development of canola that is insensitive to day-length for flowering ('photoperiod insensitive') would allow crossing of lines that normally flower at different times, thus providing access to new hybrid varieties. The current trial will involve evaluation of the modified plants in the field and a comparison with unmodified canola plants.

The canola lines to be released have been genetically modified for photoperiod insensitivity using a gene involved in flower development derived from rice. It is possible that this gene will cause the late-flowering lines to commence flowering earlier.

The lines to be trialled have also been modified by insertion of a gene conferring resistance to the herbicide glufosinate-ammonium from the bacterium *Streptomyces hygroscopicus*. This gene encodes the enzyme phosphinothricin acetyltransferase that chemically modifies the herbicide and renders it inactive. Herbicide tolerance is expected to benefit growers by increasing their options for managing weeds in canola crops.

The release will be conducted on plots of up to 1 hectare at sites selected from the areas listed above. Four sites will be used in 2000 and up to six sites in 2001 and 2002. Procedures for management of the trial and treatment of the sites after completion of the trial will be the same as for the previous proposal.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC concluded that the risks to the community or the environment were very low.

Other agencies advised by GMAC

National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority
NSW Environment Protection Authority
NSW Department of Land and Water Conservation
NSW Department of Agriculture
Victorian Department of Natural Resources and the Environment
Victorian Environment Protection Authority
Queensland Department of Natural Resources
Queensland Department of Primary Industries
Coolamon Shire Council
Wagga Wagga City Council
Glenelg Shire Council
Horsham Rural City Council
Moyne Shire Council
North Grampians Shire Council
South Grampians Shire Council
West Wimmera Shire Council
Burnie City Council
Central Coast Council
Gatton Shire Council
Laidley Shire Council
Inglewood Shire Council
Jondaryan Shire Council
Milmerran Shire Council
Rosalie Shire Council
Waggamba Shire Council

Other agencies to be consulted as at 1 June 2000

Devonport City Council
Kentish Council
Latrobe Council

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a deliberate release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

Extension to PR-112:

PR-112X: Winter nursery seed increase of INGARD® (Bt) and INGARDâ (Bt)/CryXcotton plants, 2000

Organisation	Deltapine Australia Pty Ltd PO Box 196 Narrabri NSW 2390
Contact person	Richard Leske telephone: (07) 4671 3136
Organism	Cotton (*Gossypium hirsutum*)
Location	Ord River Irrigation Area, Kununurra and Broome, Western Australia
Scale	A total of 5.1 hectares
Expected date of release	April - October 2000

The aim of this extension is to further increase seed stocks of cotton modified for resistance to insect pests for use in future trials. The presence of the insecticidal genes in the plants has the potential to reduce the amount of insecticide used on cotton crops. Insect-resistant (Bt) cotton has been the subject of previous deliberate release proposals, and insect-resistant INGARD® cotton was approved for limited general release in parts of eastern Australia in 1996. 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.

The genes introduced into the cotton plants are the CryIA(c) and CryX genes from the bacterium *Bacillus thuringiensis* (Bt). The plants to be trialled contain either the CryIA(c) gene alone or both the CryIA(c) and CryX genes in combination. The proteins resulting from expression of these genes are toxic to the major caterpillar pests of cotton but are not toxic to other animals, including humans.

The plants also contain a selectable 'marker' gene from a bacterium which confers resistance to the antibiotics kanamycin and neomycin. A second bacterial marker gene, coding for the enzyme β-glucuronidase, was also transferred and allows visual identification of plant tissues where this gene is being expressed. Another bacterial gene, encoding resistance to the antibiotics streptomycin and spectinomycin, is also present in the transgenic plants, but is not expressed in the plants.

A total area of 5.1 hectares will be planted to the modified cotton at Kununurra in the Ord River Irrigation Area and Broome in Western Australia. Procedures for management of the trial and treatment of the site after completion of the trial will be the same as for the previous proposal.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC concluded that the risks to the community or the environment were very low.

Other agencies advised by GMAC

National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority
Western Australian Department of Environmental Protection

Western Australian Department of Conservation and Land Management
Western Australian Department of Agriculture
Western Australian Environmental Protection Authority
Shire of Wyndham-East Kimberley
Shire of Broome

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a planned release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

Extension to PR-119:

PR-119X: Development of fungal disease resistant canola cultivars

Organisation	Aventis CropScience Pty Ltd (formerly AgrEvo Pty Ltd) 391-393 Tooronga Road East Hawthorn VIC 3123
Contact person	Mr Peter Whitehouse telephone: (03) 9248 6837, facsimile: (03) 9248 6800
Organism	Canola (*Brassica napus*)
Location	Sites will be chosen from the following locations: Wagga and Coolamon (NSW); Horsham, West Wimmera, Southern Grampians, Northern Grampians, Glenelg and Moyne (Victoria); and Burnie, Central Coast, Devonport, Kentish and Latrobe (Tasmania).
Scale	Initially, three sites of up to 1 hectare each, increasing to six sites of 1 hectare each in 2001–2002.
Expected date of release	May 2000, 2001, 2002 (NSW, Vic) and September 2000, 2001, 2002 (Vic, Tas)

The canola lines to be released in this trial have been genetically modified for tolerance to fungal diseases such as Blackleg and Sclerotinia. Development of fungal disease resistance would greatly assist canola growers in managing major fungal diseases in canola crops.

The trial will be used to increase seed as part of a global research program evaluating different strategies for obtaining fungal disease resistance in canola. The modified canola will be tested for the level of fungal resistance in areas where there is natural infestation with fungal diseases.

The canola lines have been genetically modified for resistance to fungal diseases using a gene from a legume. A selectable 'marker' gene conferring resistance to the antibiotics kanamycin and neomycin was also transferred to the transgenic plants.

The release will be conducted on plots of up to 1 hectare at sites selected from the areas listed above. Three sites will be used in 2000 and up to six sites in both 2001 and 2002. Procedures for management of the trial and treatment of the sites after completion of the trial will be the same as for the previous proposal.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC concluded that the risks to the community or the environment were very low.

Other agencies advised by GMAC
National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority
NSW Environment Protection Authority
NSW Department of Land and Water Conservation

NSW Department of Agriculture
Victorian Department of Natural Resources and the Environment
Victorian Environment Protection Authority
Tasmanian Department of Primary Industry, Water and Environment
Coolamon Shire Council
Wagga Wagga City Council
Glenelg Shire Council
Horsham Rural City Council
Moyne Shire Council
North Grampians Shire Council
South Grampians Shire Council
West Wimmera Shire Council
Burnie City Council
Central Coast Council

Other agencies to be consulted as at 1 June 2000

Devonport City Council
Kentish Council
Latrobe Council

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a deliberate release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

Extension to PR-120:

PR-120X: Development of methods to reduce glucosinolate content in canola cultivars

Organisation	Aventis CropScience Pty Ltd (formerly AgrEvo Pty Ltd) 391-393 Tooronga Road East Hawthorn VIC 3123
Contact person	Mr Peter Whitehouse telephone: (03) 9248 6837, facsimile: (03) 9248 6800
Organism	Canola (*Brassica napus*)
Location	Sites will be chosen from the following locations: Wagga Wagga and Coolamon (NSW); Horsham, West Wimmera, Southern Grampians, Northern Grampians, Glenelg and Moyne (Victoria); and Burnie, Central Coast, Devonport, Kentish and Latrobe (Tasmania).
Scale	Initially three sites of 1 hectare each increasing to six sites of 1 hectare each in 2001-2002
Expected date of release	May 2000, 2001, 2002 (NSW, Vic) and September 2000, 2001, 2002 (Vic, Tas)

The canola lines to be released in this trial have been genetically modified with the aim of reducing the content of anti-nutritional factors (glucosinolates) in the canola while maintaining high crop yields. Anti-nutritional factors in canola can limit the use of canola meal as a feed source. Eventually, the new genetically modified canola varieties may provide an alternative source of high quality protein for use as a stockfeed supplement.

The trial will be used to increase seed as part of a global research program evaluating different strategies for reducing anti-nutritional content in canola. The work to be conducted under the current proposal will test two constructs. No plantings were conducted under the original proposal PR-120 due to unavailability of seeds.

The canola lines to be released have been genetically modified using a gene from a *Brassica* species.

The release will be conducted on plots of up to 1 hectare at sites selected from the areas listed above. Three sites will be used in 2000 and up to six sites in both 2001 and 2002. Procedures for management of the trial and treatment of the sites after completion of the trial will be the same as for the previous proposal.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC concluded that the risks to the community or the environment were very low.

Other agencies advised by GMAC
National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority
NSW Environment Protection Authority
NSW Department of Land and Water Conservation

NSW Department of Agriculture
Victorian Department of Natural Resources and the Environment
Victorian Environment Protection Authority
Tasmanian Department of Primary Industry, Water and Environment
Coolamon Shire Council
Wagga Wagga City Council
Glenelg Shire Council
Horsham Rural City Council
Moyne Shire Council
North Grampians Shire Council
South Grampians Shire Council
West Wimmera Shire Council
Burnie City Council
Central Coast Council

Other agencies to be consulted as at 1 June 2000

Devonport City Council
Kentish Council
Latrobe Council

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a deliberate release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

Extension to PR-121:

PR-121X: Development of dwarfed canola cultivars

Organisation	Aventis CropScience Pty Ltd (formerly AgrEvo Pty Ltd) 391-393 Tooronga Road East Hawthorn VIC 3123
Contact person	Mr Peter Whitehouse telephone: (03) 9248 6837, facsimile: (03) 9248 6800
Organism	Canola (*Brassica napus*)
Location	Sites will be chosen from the following locations: Wagga Wagga and Coolamon (NSW); Horsham, West Wimmera, Southern Grampians, Northern Grampians, Glenelg and Moyne (Victoria); and Burnie, Central Coast, Devonport, Kentish and Latrobe (Tasmania).
Scale	Initially three sites of 1 hectare each, increasing to six sites of 1 hectare each in 2001-2002
Expected date of release	May 2000, 2001, 2002 (NSW, Vic) and September 2000, 2001, 2002 (Vic, Tas)

The canola lines to be released in this trial have been genetically modified to be dwarfed, with the aim of increasing yield. For example, the use of dwarfed canola plants might reduce wind damage or lead to more efficient nutrient uptake and seed production.

The trial will be used to increase seed as part of a global research program evaluating different strategies for modifying plant architecture in canola. The work to be conducted under the current proposal will test four constructs. No plantings were conducted under the original proposal PR-121 due to unavailability of seeds.

The canola lines to be released have been genetically modified using a gene from another plant.

The release will be conducted on plots of up to 1 hectare at sites selected from the areas listed above. Three sites will be used in 2000 and up to six sites in both 2001 and 2002. Procedures for management of the trial and treatment of the sites after completion of the trial will be the same as for the previous proposal.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC concluded that the risks to the community or the environment were very low.

Other agencies advised by GMAC
National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority
NSW Environment Protection Authority
NSW Department of Land and Water Conservation
NSW Department of Agriculture
Victorian Department of Natural Resources and the Environment
Victorian Environment Protection Authority

Tasmanian Department of Primary Industry, Water and Environment
Coolamon Shire Council
Wagga Wagga City Council
Glenelg Shire Council
Horsham Rural City Council
Moyne Shire Council
North Grampians Shire Council
South Grampians Shire Council
West Wimmera Shire Council
Burnie City Council
Central Coast Council

Other agencies to be consulted as at 1 June 2000

Devonport City Council
Kentish Council
Latrobe Council

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a deliberate release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

Extension to PR-122:

PR-122X: Development of canola cultivars (*Brassica napus*) with reduced pod-shatter

Organisation	Aventis CropScience Pty Ltd (formerly AgrEvo Pty Ltd) 391-393 Tooronga Road East Hawthorn VIC 3123
Contact person	Mr Peter Whitehouse telephone: (03) 9248 6837, facsimile: (03) 9248 6800
Organism	Canola (*Brassica napus*)
Location	Sites will be chosen from the following locations: Wagga Wagga and Coolamon (NSW); Horsham, West Wimmera, Southern Grampians, Northern Grampians, Glenelg and Moyne (Victoria); and Burnie, Central Coast, Devonport, Kentish and Latrobe (Tasmania).
Scale	Initially three sites of 1 hectare each, increasing to six sites of 1 hectare each in 2001-2002
Expected date of release	May 2000, 2001, 2002 (NSW, Vic) and September 2000, 2001, 2002 (Vic, Tas)

The canola lines to be released in this trial have been genetically modified with the aim of reducing yield loss through pod-shattering in canola crops. Decreased pod-shattering can allow a longer delay between seed maturity and harvesting because seed loss from over-mature pods is reduced. As a result, higher yields should be possible.

The trial will be used to increase seed as part of a global research program evaluating different strategies for preventing yield loss in canola. The work to be conducted under the current proposal will test six new lines of transgenic canola containing genes from plant and bacterial sources. No plantings were conducted under the original proposal PR-122 due to unavailability of seeds.

The release will be conducted on plots of up to 1 hectare at sites selected from the areas listed above. Three sites will be used in 2000 and up to six sites in both 2001 and 2002. Procedures for management of the trial and treatment of the sites after completion of the trial will be the same as for the previous proposal.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC concluded that the risks to the community or the environment were very low.

Other agencies advised by GMAC
National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority
NSW Environment Protection Authority
NSW Department of Land and Water Conservation
NSW Department of Agriculture

Victorian Department of Natural Resources and the Environment
Victorian Environment Protection Authority
Tasmanian Department of Primary Industry, Water and Environment
Coolamon Shire Council
Wagga Wagga City Council
Glenelg Shire Council
Horsham Rural City Council
Moyne Shire Council
North Grampians Shire Council
South Grampians Shire Council
West Wimmera Shire Council
Burnie City Council
Central Coast Council

Other agencies to be consulted as at 1 June 2000

Devonport City Council
Kentish Council
Latrobe Council

Date of GMAC advice

21 March 2000

In offering advice to the proponent in respect of a deliberate release proposal, GMAC critically evaluates, among other data, information provided by the proponent. It is the proponent's responsibility to provide GMAC with complete answers to questions and ongoing data, as well as any information that changes or elaborates any information previously given.

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

PR-63X(5): Release of glufosinate-ammonium tolerant hybrid and open-pollinated canola cultivars

Organisation proposing release: AgrEvo Pty Ltd
1731 Malvern Road
Glen Iris VIC 3146

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 AgrEvo 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 1200 hectares will be grown across numerous sites in the canola-growing regions of Western Australia, South Australia, Victoria, Queensland, NSW and Tasmania.

Further information: The institution's contact officer for this proposal is Mr Peter Whitehouse, telephone (03) 9248 6666, facsimile (03) 9248 6650.

PR-77X(3): Backcrossing Canadian Roundup® Ready canola varieties into Australian canola varieties, seed production and evaluation of the Roundup® Ready canola system

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 which emerge following crop planting. In addition, options for weed management in glyphosate-tolerant canola will be examined during the trial. Seed production is 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 which produce proteins known as EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) and GOX (glyphosate oxidoreductase). These proteins are found naturally in common soil microorganisms, and together they confer tolerance to glyphosate, the active ingredient of the herbicide Roundup®.

Location and size of trial: A total area of approximately 1000 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-102X: Transgenic wheats with modified grain qualities

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

Organism to be released: Wheat (*Triticum aestivum*)

Purpose of the extension to the release: The aim of the extension is to continue assessment of the field performance of wheat modified to over-produce a wheat glutenin protein in the wheat grain and to determine the quality characteristics of the flour produced from this grain.

Brief description of the nature and effect of the genetic modification: The transgenic wheat contains an extra copy of the wheat glutenin gene. This modification results in an over-production of glutenin in the wheat grain. It is anticipated that the excess production of glutenin will alter quality traits such as the strength of the dough prepared from the flour. The wheat plants also contain a selectable marker gene conferring resistance to the herbicide glufosinate ammonium (Basta®).

Location and size of trial: Approximately 1500 plants at the Ginninderra Experiment Station, Hall, ACT.

Further information: The institution's contact officers for this proposal are Dr R Appels and Dr F Bekes, telephone (02) 6246 5495.

PR-105X: 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 trial will continue assessment of the field performance of the peas.

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 35 000 seeds will be sown on 1 hectare at the Agricultural Research Institute, Wagga Wagga, NSW.

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

ATTACHMENT 7

BREACH PROTOCOL

The IOGTR is a branch within the Commonwealth Department of Health and Aged Care. It has been established to work with States and Territories to develop and implement a new regulatory system for GMOs in Australia. The new regulatory system is to be operational by 3 January 2001.

The Genetic Manipulation Advisory Committee (GMAC) is the IOGTR's independent expert scientific advisory body on GMOs. GMAC is an administrative system with no legislative basis.

Until the new regulatory system is in place, researchers (such as those in CSIRO) and industry, voluntarily comply with requirements of the GMAC. This includes conditions that GMAC may recommend to limit and manage any risks to the environment or to human health posed by, or as a result of, gene technology.

While GMAC does not have the regulatory force of a system underpinned by legislation, GMAC and the IOGTR are keen to encourage compliance with GMAC conditions in a productive and positive manner.

This Breaches Protocol is intended to promote this goal.

This Breaches Protocol is based on the National Registration Authority's reporting on unregistered or non-compliant agricultural or veterinary chemicals.

Where are GMAC recommendations notified?
From June 2000, any person interested in recommendations applied to any GMO to be released into the Australian environment, including for the purposes of field trials, can access these recommendations by:

- Looking them up on the GMAC or IOGTR websites:
  - http://www.health.gov.au/tga/gene/gmac/gmachome.htm
  - http://www.health.gov.au/tga/genetech.htm
- Reading the Commonwealth Gazette;
- Writing to the IOGTR and asking to be put on the database to receive this information routinely
- Reading the IOGTR's quarterly reports (the first of which will be available in June 2000).

How to report breaches of GMAC recommendations and what to expect
The IOGTR welcomes reports from industry and the public about possible breaches of GMAC recommendations.

The IOGTR is establishing, from June 2000, a new Compliance Program which aims to monitor GMOs to ensure compliance with GMAC recommendations.

All reports are useful
The IOGTR considers the information supplied by industry and the public to be a vital component of our Compliance Program.

The way the information will be used will vary, depending on a number of factors. For example, not all reports result in a comprehensive investigation, or immediate compliance action. However, they are used to help focus the IOGTR's ongoing compliance activities.

How the reports will be handled
The IOGTR prefers to acknowledge all reports in writing.

IOGTR staff will undertake a preliminary check on the validity of the information before a decision is made on the appropriate action to be taken. Any compliance actions taken will be consistent with GMAC's Terms of Reference (this is important to note, as GMAC has a limited mandate, which focuses on managing risks to the environment and risks to human health).

Any follow-up action will depend on several key factors including:

- The potential significance of the non-compliance in terms of the GMAC system and its administrative obligations for human health and the environment;
- Any history of the matter (for example, previous non compliance with GMAC recommendations);
- The completeness of the information provided;
- The resources required and available to pursue the matter.

Possible outcomes
Depending on the type and quality of the information received, and the outcome of the IOGTR's preliminary assessment of it, the IOGTR may:

- Add the information to our compliance database;
- Write to the potential offender explaining his/her obligations under GMAC recommendations;
- Initiate a full investigation into the alleged breach; and/or
- Require sampling and analysis depending on the risk posed by the particular action.

Investigations can take time
In many cases, it will be possible to achieve a fairly quick resolution to problems of non-compliance with GMAC recommendations when these are reported to the IOGTR. Some investigations will, however, take time to complete, depending on, for example, the relative priority of the matter upon a consideration of risk to public health or risk to the environment. In all cases, the IOGTR works to ensure that all reports are actively considered within two weeks of notification of the alleged breach.

Feedback on your complaint
The reports provided to the IOGTR on possible breaches of GMAC recommendations are extremely valuable. Unfortunately, the nature of IOGTR's investigations and compliance work means that detailed feedback is not always possible, especially while an investigation is in progress. This is because:

- The IOGTR may be dealing with information that is protected by legislation (for example the Privacy Act 1988) or which may be commercial-in-confidence.
- The information may unfairly damage the reputation of a company or individual under investigation if the allegation is not subsequently proved; and

- The information may unfairly damage the reputation of a third party who has not, themselves, breached GMAC recommendations.

Reporting breaches
In all cases where a breach of GMAC recommendations is demonstrated, the IOGTR will report this breach in quarterly reports to be produced from June 2000. Serious breaches of recommendations will be notified in the print media as well as in quarterly reports. Should a very serious breach occur, the IOGTR will utilise additional media to inform the Australian community.

This reporting of breaches applies to all demonstrated breaches, whether notified by a company, a member of the public, or those identified through other mechanisms within our Compliance Program.