

Interim Office of the Gene Technology Regulator

Quarterly Report

September 2000

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

Dear Minister

I am pleased to present to you the second 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 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 GMAC. This report covers the July–September 2000 quarter.

During the reporting period, the IOGTR:

- developed a detailed submission to the Senate Community Affairs References Committee inquiry into the Gene Technology Bill 2000. The Submission was made on behalf of all States and Territories, excluding Tasmania. This reflects the high degree of agreement amongst jurisdictions to the focus and detail of the national regulatory system for gene technology, as reflected in the Bill;
- coordinated the risk assessment of the application for general (commercial) release of Roundup Ready® cotton and Roundup Ready®/INGARD® cotton, including completing a second round of consultation on the application;
- secured the agreement of all States and Territories to the release of draft Regulations under the Bill for the first round of consultation with non-government stakeholders.

During the reporting period, GMAC has:

- provided advice on 33 proposals for contained work with GMOs; and
- provided advice on 11 field trials with GMOs.

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

Yours sincerely

Terry Slater
National Manager
Therapeutic Goods Administration

November 2000

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PREFACE

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

The main purpose of this report is to provide information about the function of the IOGTR during the period July–September 2000, as well as the activities undertaken by the independent expert committee on the biosafety of genetically modified organisms (GMOs): the Genetic Manipulation Advisory Committee (GMAC).

Tracking commitments made in the first Quarterly Report

Part 4 of the first IOGTR Quarterly Report highlighted six key issues that the IOGTR anticipated addressing during the July–September quarter. A brief summary against those six issues follows:

1. Senate Inquiry: Gene Technology Bill 2000 and related legislation

As flagged in the previous Quarterly Report, the legislation has been the subject of a Senate inquiry conducted by the Senate Community Affairs References Committee. During the July–September quarter, the IOGTR:

- made a detailed submission to the Committee, addressing each of the Committee's terms of reference. A copy of the Submission can be found on the Parliamentary website (www.aph.gov.au) or on the IOGTR's website (www.health.gov.au/tga/genetech.htm);
- appeared before the Committee twice (on 14 and 25 August 2000);
- responded to a number of questions on notice from the Committee and its Secretariat;
- attended the public hearings held in Hobart, Melbourne and Sydney to ensure that the IOGTR was well informed of views being expressed;
- scrutinised the 124 submissions made to the Committee;
- provided a supplementary submission to the Committee, addressing key areas raised in public hearings, submissions and through the questions on notice.

2. Plain guides to the Bill

As foreshadowed in the previous Quarterly Report, a plain-English guide to the legislation was released in July 2000, to assist consideration of the legislation. A copy of the guide is available via the IOGTR website, or by contacting the Office.

3. Regulations under the Gene Technology Bill 2000

As foreshadowed in the IOGTR's first Quarterly Report, draft regulations under the Gene Technology Bill 2000 were released for the first round of public consultations in July. A plain-English explanatory guide was also made available. A copy of both documents is available via the IOGTR website or by contacting the Office.

Because the Senate Committee inquiring into the Gene Technology Bill extended its reporting date from 5 September to 1 November, the timeframe for public consultation on the Regulations has been revised:

- Once the Senate Inquiry is complete, the Regulations will be revised as necessary to respond to any changes made to the Bill by Parliament.
- It is expected that the Regulations will be released for a second round of public consultations in mid-December 2000.
- Face-to-face discussions with key stakeholders will then occur from February 2001.

4. Codes of Practice and Guidelines

Following feedback from the Commonwealth agencies, States and Territories on the draft Regulations, the IOGTR has developed draft guidelines for Certification of Facilities and Accreditation of Organisations.

Commonwealth agencies, States and Territories will consider the guidelines in November, with a view to releasing these documents for public consultation in December, to coincide with the release of the second iteration of the Regulations.

5. Committees

Work on establishing the three statutory committees proposed in the Gene Technology Bill 2000 (the Gene Technology Technical Advisory Committee; the Gene Technology Community Consultative Group; and the Gene Technology Ethics Committee) commenced in the July–September quarter. A paper outlining a process and timeframe for establishing the Committees will be considered by Commonwealth agencies, States and Territories in November, once the final report of the Senate Committee is handed down.

6. Rural consultation

As foreshadowed in the previous IOGTR Quarterly Report, the IOGTR continued to participate in public forums being conducted by Biotechnology Australia, which included community forums in regional Australia.

These forums offered opportunities for members of the public to interact with senior scientists, technical experts and policy and legal advisers from a number of organisations involved in biotechnology. They also offered an opportunity for the IOGTR to provide information on the regulatory system and the status of the draft gene technology Regulations.

States, Territories and the Commonwealth will continue to explore ways to improve the dissemination of information in rural and regional areas, with a view to implementing enhanced arrangements for consultation on key issues in 2001.

Further information

This second quarterly report reflects the IOGTR's commitment to provide interested parties with timely and comprehensive information about the oversight of genetically modified organisms (GMOs) in Australia.

Readers seeking further information on the IOGTR or GMAC are encouraged to contact the Office:

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Structure of this report

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

Part 1 addresses activities undertaken and outcomes achieved in the July–September quarter in relation to the development of the national regulatory framework.

Part 2 outlines work undertaken under the current system of voluntary controls over GMOs, which will continue to operate until the new regulatory system is established.

In addition, **Part 3** points to activities to be undertaken, and outcomes to be achieved, in the coming quarter (October–December 2000).

Information about the roles of the IOGTR and GMAC is set out in the first IOGTR Quarterly Report, which is available on the IOGTR website, or through the Office.

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PART 1: A NATIONAL REGULATORY FRAMEWORK

1.1 Development of a national regulatory framework for GMOs

On 30 August 2000, the House of Representatives passed the three Bills which comprise the Commonwealth's contribution to the national regulatory framework for gene technology:

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

The Bills were introduced into the Senate on 30 August 2000. The Senate Community Affairs References Committee's Inquiry into the Gene Technology Bill 2000 had, at that time, commenced with Terms of Reference for the Inquiry set on 28 June 2000. The original reporting date of 5 September 2000 was extended by the Senate on 31 August 2000 to 10 October 2000, and further extended on 5 October to a reporting date of 1 November 2000.

1.2 Key results during the reporting period

The following key results were achieved in the reporting period (July–September 2000).

Key result 1.

A plain guide to the Gene Technology Bill 2000 and related legislation was released in July 2000, to coincide with the introduction of the legislation into the House of Representatives.

Key result 2.

The *Intergovernmental Agreement on Gene Technology* was agreed by officials from States, Territories and the Commonwealth.

Key result 3.

The Regulations under the Gene Technology Bill 2000 were drafted and agreed by officials from all States, Territories and the Commonwealth and released for the first round of consultation with non-government stakeholders.

Key result 4.

An independent study examining costs associated with the implementation of the national regulatory framework was completed, scrutinised by States, Territories and the Commonwealth and released for the consideration of non-government stakeholders.

Key result 5.

Significant progress was made on the development of the new data system, which will support the regulatory system.

Further commentary on these key result areas follows.

1.3 Working collaboratively with States and Territories

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

The results 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 (CSCG), a group of officials representing each State and Territory Government, as well as the Commonwealth Government. Detail on the form and function of the CSCG is set out in the IOGTR's first Quarterly Report.

During the reporting period, the CSCG met twice: on 4 August 2000 and 11 September 2000.

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

- submission to be made by the IOGTR on behalf of all States and Territories (excluding Tasmania) to the Senate Community Affairs References Committee Inquiry into the Gene Technology Bill 2000;
- possible amendments to the Bill that might arise as a result of that Inquiry;
- appointment of the Gene Technology Regulator (GTR);
- cost recovery policy and the KPMG consultancy;
- draft Regulations and Explanatory Guide;
- new monitoring strategy;
- Information Bulletin No 4 – How outcomes of the first consensus conference on gene technology in the food chain have been addressed;
- draft Guidelines on Certification and draft Guidelines on Accreditation;
- Roundup Ready® cotton risk assessment.

1.4 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. As detailed in Quarterly Report 1, this approach reflects the fact that gene technology is

not a single-portfolio issue and the need to ensure that the new regulatory system has a seamless interface with existing regulatory arrangements.

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 Interdepartmental Committee, or IDC.

During the reporting period, the IDC met once, on 7 September 2000. Issues discussed were primarily those reported under section 1.3.

1.5 The role and contribution of non-government organisations

A high level of input, advice and constructive criticism from non-government stakeholders has characterised the development of the national regulatory framework. The work of the IOGTR on the development of the framework during the reporting period focused heavily on intergovernmental issues, and on the Federal Parliamentary processes, rather than on activities that resulted in the need to consult with non-government stakeholders.

A key focus of consultation with non-government stakeholders was, however, the draft Regulations:

- During August 2000, the IOGTR placed advertisements in a wide range of regional and metropolitan newspapers advising that the draft Regulations were available for the first round of public consultation. Written submissions were sought by 6 October 2000, allowing a period of up to six weeks for consideration of the Regulations and the plain-English explanatory guide.
- The availability of the Regulations and the plain-English guide was also notified through direct mail to approximately 2500 people listed on the IOGTR's mailing list. A copy of both documents was included with the letters.

1.6 Presentations

During the reporting period, presentations made, or key discussions held, by the IOGTR on the national regulatory system included:

- the Meat and Livestock Association of Australia on 6 July 2000;
- AVCARE on 6 July 2000;
- the Wangaratta Branch of the Business and Professional Women's Association on 12 July 2000;

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- the NSW Farmers' Federation Annual Conference on 17 July 2000;
 - the Parliamentary Library on 25 July 2000;
 - the Australian GeneEthics Network, Friends of the Earth and Organic Farmers' Federation on 26 July 2000;
 - the Gene Technology Working Group of the Grains Research and Development Corporation on 26 July 2000;
 - the Executive Committee of the National Health and Medical Research Council (NH&MRC) on 30 August 2000;
 - the Emerald Community Forum on 13 September 2000;
 - the Biotechnology Australia public seminar at Wagga Wagga on 22 September 2000.

The IOGTR also appeared before the Senate Community Affairs References Committee, in the context of the Committee's inquiry into the Gene Technology Bill 2000 on 14 August 2000 and 25 August 2000. A copy of the Hansard of those appearances can be found on the Committee's page at the Parliament House website (www.aph.gov.au). A copy of the IOGTR's submission to the Committee can be found at the parliamentary website or the IOGTR's website.

The IOGTR also attended the public hearings held by the Committee in Hobart, Melbourne and Sydney, to ensure that the IOGTR was able to respond to key issues raised. As a result, and following consideration of written submissions made to the Committee and a range of Questions on Notice put to the IOGTR by the Committee and its Secretariat, the IOGTR made a supplementary submission on 16 October 2000. A copy of this submission can be found at the IOGTR website.

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PART 2: 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 the IOGTR's first Quarterly Report, the Genetic Manipulation Advisory Committee (GMAC) is central to these arrangements, providing advice on environmental and human health risks associated with GMOs.

2.1 Appointments to GMAC: July–September 2000

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

No new appointments were made during the July–September 2000 reporting period.

2.2 GMAC Meetings: July–September 2000

- **GMAC**

The full Committee of GMAC did not meet during the reporting period.

GMAC had intended to meet on 18 August 2000. The main purpose of the meeting would have been to review the draft GMAC Annual Report. While GMAC is not required to table an Annual Report in Parliament, it has traditionally done so at the end of each financial year. However, this year the IOGTR moved to quarterly reporting, covering many of GMAC's key activities. This, combined with the expectation in August 2000 that the new regulatory system would be operational by January 2001, meant that it seemed appropriate to delay drafting the GMAC Annual Report until late 2000. This would ensure that the final GMAC Annual Report would cover both the full 1999-2000 financial year, and also the final months of the interim arrangements, up until the time the legislation took effect. This approach makes unnecessary the production of a second Annual Report from GMAC covering the brief period prior to the introduction of the new regulatory system.

The full meeting of GMAC will be rescheduled in consultation with Committee members.

- **The Scientific Subcommittee (SSC)**

The SSC, chaired by Professor Jim Pittard, met once during the reporting period: on 1 September 2000.

The SSC:

- considered a clinical trial of a vaccine, which will also be considered by the Gene Therapy Research Advisory Panel of the NH&MRC;

-
- considered *ad hoc* scientific matters relating to genetic manipulation work in containment facilities;
 - reviewed 11 proposals, of which 4 were new proposals for field trials, and 7 were extensions to proposals previously assessed by GMAC.

Summaries of the field trials are at **Attachment 2**.

- **The Release Subcommittee (RSC)**

The RSC met twice during the reporting period: on 21 July 2000 and 29 September 2000.

At the meeting of 21 July 2000, members:

- discussed the status of the Roundup Ready® cotton general release proposal and the process for implementation of Crop Management Plans for the crop;
- considered in detail correspondence from a company conducting field trials which proposed changes to GMAC recommendations;
- discussed breaches of GMAC recommendations;
- considered 11 release proposals.

Summaries of the release proposals are at **Attachment 2**.

At the meeting of 29 September, members:

- considered 4 release proposals;
- considered a presentation made by Dr Phil Salisbury from the University of Melbourne on species which are sexually compatible with canola;
- subsequently discussed the presentation made by Dr Salisbury and other relevant information and agreed that sexually compatible species should include: *Brassica rapa* (including vegetable species), *Brassica juncea* (including condiment, fodder and vegetable species), *Raphanus raphanistrum*, *Hirschfeldia incana*, *Sinapis arvensis*, *Brassica fruticulosa*, *Brassica nigra*, *Brassica tournefortii*, *Diplotaxis muralis*, *Diplotaxis tenuifolia*, *Rapistrum rugosum*, *Brassica alboglabra*, *Brassica chinensis*, *Brassica oleracea*, *Brassica pekinensis*, *Raphanus sativus*, *Sinapis alba*, *Brassica oxyrrhina*, and *Diplotaxis tenuisiliqua*; and that this would be included in a condition of approval of any future field trials of canola;

- discussed new breaches notified to the IOGTR in relation to GMAC recommendations for the conduct of field trials (please refer to Part 2.6 of this report for details);
- discussed and provided feedback to the IOGTR on the audit reports prepared by the IOGTR in respect of Monsanto (final report) and Aventis (draft report) (please refer to Part 2.7 of this report for details); and
- noted the final risk assessment of the proposed general release of glyphosate-tolerant (Roundup Ready®) cotton from Monsanto Australia Ltd (Part 2.8 of this report sets out further detail on this matter).

The Subcommittee assessed 15 deliberate release proposals during the reporting period. (The difference in the number of proposals considered by the SSC and the RSC is because the RSC had one more meeting in the reporting period than the SSC.) Summaries of these field trials are at **Attachment 2**.

2.3 Implementation of new monitoring strategy

In the first IOGTR Quarterly Report, the IOGTR referenced the development of a new monitoring program. This would ensure proactive monitoring of compliance with GMAC recommendations through site inspections carried out by IOGTR and suitably qualified experts.

During the July–September 2000 Quarter, the IOGTR conducted site inspections of approximately 20% of trial sites. The focus of site inspections was on sites currently being used by Aventis CropScience. This is because the site inspections were a useful adjunct to the Audit of Aventis’s mechanisms for ensuring compliance with GMAC recommendations which is set out at Part 2.7 of this report.

In summary, the IOGTR:

- contracted appropriate experts to undertake the site inspections, in the company of officials from the IOGTR. While the IOGTR intends to establish a database of relevant expertise that the IOGTR can draw on for monitoring in the future, this process will take some time. In the interim, the IOGTR will continue to draw on the expertise and advice of GMAC members. In this instance, the IOGTR sought a proposal from Luminus Pty Ltd on the advice of a GMAC member. Luminus is a consultancy company connected with the University of Adelaide. The company had the consultants with appropriate experience (weed/canola experts) and was able to complete the task in the short timeframe required;
- site inspections were conducted from 14 September 2000 to 22 September 2000. This timing was designed to coincide with the period immediately prior to the full flowering of canola crops. The flowering period is a critical monitoring period for detecting non-conformities with GMAC recommendations.

The IOGTR officials were responsible for producing a record of the findings at the sites. Of the 24 sites visited, only three sites presented any concerns. At these three sites, while every effort had been made to implement a 15 m buffer crop of canola around trial crops, the buffers were not considered adequate in some parts. As a result:

- Aventis destroyed one trial crop, prior to flowering, ensuring that there was no possibility of gene flow;
- GMAC agreed that the second site did not require remedial work as it was over 1.9 kilometres from the nearest non-GMO crop of canola;
- Aventis ensured that remedial action was taken at the third site so that plants were either (a) destroyed before flowering or (b) covered with selfing bags (which are insect-proof). This action also ensured that there was minimal potential for gene flow.

The IOGTR considered that the action taken by Aventis was timely, appropriate and conscientious. Further details on the Audit of Aventis are set out in Part 2.7 of this report. The findings and recommendations from the Audit, including in relation to this matter, are due to be released on 17 November 2000.

2.4 Release of information

The Australian Government Solicitor has 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. During the reporting period, however:

- the report of a breach in relation to planned releases PR-63X(4) and PR-85X(2) by Aventis CropScience, as summarised in the previous Quarterly Report of the IOGTR, was provided to the Senate Community Affairs References Committee at the request of the Committee in the context of its inquiry into the Gene Technology Bill 2000. The Committee decided to make the report, excluding the names of individuals referenced in the report, public. The report is therefore available on the Committee's page of the parliamentary website;
- the report on the IOGTR's consideration of allegations about a black market trade in genetically modified seeds was also provided to the Committee. As far as the IOGTR is aware, the Committee did not release this report. A summary of this investigation is at Part 2.5 of this report.

2.5 Investigations completed

The IOGTR, with expert advice from GMAC, completed investigations into three breaches of GMAC recommendations for GMOs during this quarter.

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-87X and PR-83X(4). An investigation into the allegation of possible trade in black market genetically modified seed was also completed.

- **PR-87X was a field trial being conducted by Agriculture Western Australia (AGWEST) for insect-resistant genetically modified INGARD® (Bt) cotton.**

Summary

The IOGTR has investigated AGWEST's compliance with recommendations made by GMAC in relation to field trials of insect-resistant genetically modified cotton.

The IOGTR notes that AGWEST breached one of the GMAC recommendations – that any volunteer cotton plants (those that emerge from seed that falls to the ground during the course of a trial) be removed and destroyed.

The IOGTR, on the basis of advice from GMAC, also concluded that:

- there is no evidence of increased risks to human health resulting from the 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;
- AGWEST took appropriate measures to fix the problem and is undertaking appropriate ongoing monitoring;
- AGWEST has advised the new owner of the property about their obligations to maintain the property according to GMAC requirements.

Notification of the alleged breach

On 31 March 2000, AGWEST notified the GMAC Secretariat by telephone that a breach of GMAC recommendations had occurred at one of its field trial sites near Kununurra, Western Australia.

The breach had occurred in an area of approximately 300 hectares on a property where the owners of the property had gone bankrupt. Subsequently proper maintenance procedures had ceased. The volunteer plants were growing densely at a height of around 20 cm. The plants were badly waterlogged due to high rainfall during the wet season. Volunteer cotton plants up to 1.5 m in height were also growing on internal roads on the property.

The IOGTR asked AGWEST to provide further information in writing about the breach and to indicate how AGWEST proposed to address the breach and ensure that the problem did not occur again.

The investigation

The IOGTR has completed an investigation into the breach.

The IOGTR's actions included:

- undertaking an assessment of the breach and obtaining expert advice on the risks associated with the breach, including advice from GMAC;
- ensuring that AGWEST provided regular updates on progress with clean-up of the property. AGWEST undertook the clean-up by discing (ploughing) of the affected paddocks, discing and grading of the affected roadways, and spot-spraying plants near culverts with herbicide.

The findings

At its 8 May 2000 meeting, the GMAC Release Subcommittee considered the breach and agreed that the actions taken by AGWEST were appropriate and would eliminate any additional risks to the environment. The Subcommittee also agreed that the site would require monitoring for an additional year beyond the original monitoring period specified by GMAC.

The risk management plan

The IOGTR developed a risk management plan that includes:

- requiring AGWEST to notify the new owner of the property about GMAC requirements;
- destruction of the volunteers in accordance with the plan developed by AGWEST and considered by the GMAC Release Subcommittee;
- extension of the period for monitoring for volunteers at the site by a further twelve months. This means that there will be active monitoring of the site until April 2001;
- continued requirements for the reporting of any significant events that occur on the property in future.

The IOGTR will underpin these, and other measures needed, with independent monitoring and surveillance.

- **PR-83X(4) is a field trial being undertaken by Monsanto Australia Limited**

Summary

The IOGTR has investigated compliance by Monsanto Australia Limited with recommendations made by GMAC in relation to field trials of glyphosate-tolerant (Roundup Ready®) cotton.

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 the breach;
- the risks to the environment are low, and can be effectively minimised through the risk management plans developed by IOGTR with GMAC advice; and
- Monsanto 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 21 June 2000, the Regulatory Affairs Manager of Monsanto advised the GMAC Secretary, by telephone, of a breach of GMAC's recommendations for use of the seed harvested from Roundup Ready® cotton plants grown during the 1999-2000 cotton season. Monsanto sent an email report of the breach to the IOGTR on 13 July 2000. The final report was provided by the company on 25 July 2000. In summary:

- In May 2000, 10 modules (containing approximately 57.6 tonnes) of Roundup Ready® cotton seed were ginned at three gins in Queensland without segregation and identity preservation. This constituted between 4.5 and 9.1% of all cotton seed ginned on that day at the designated gins. Queensland Cotton advised Monsanto of the ginning of unsegregated Roundup Ready® cotton seed on 20 June 2000.
- As a result of the lack of segregation and identity preservation, the stockpiled Roundup Ready® cotton seed was mixed with non-Roundup Ready® cotton seed (conventional and INGARD; INGARD cotton has been genetically modified for resistance to insect pests and was approved for general release in New South Wales and Queensland in 1996).
- Given the mixing and stockpiling of the Roundup Ready® cotton and non-Roundup Ready® cotton, there was no possible means to track the exact fate (export, animal feed or crushing) of the Roundup Ready® cotton seed. Sale of whole seed to the domestic market as animal feed is in contravention of GMAC's advice.
- As the Roundup Ready® cotton seed was mixed with non-Roundup Ready® cotton, it was not transported in accordance with the GMAC guidelines. The seed was not packaged and secured; therefore, seed escape was possible.

The investigation

The IOGTR has completed an investigation into the breach.

The IOGTR's actions included:

- undertaking an assessment of the breach and obtaining expert advice on the risks associated with the breach, including advice from GMAC;

-
- conducting an audit of Monsanto Australia Ltd with respect to its processes for the conduct of field trials in accordance with GMAC recommendations.

The findings

On the basis of advice from GMAC, the IOGTR has concluded that there are no risks to the environment or to public health and safety as a result of the breach (sale of seed for animal feed).

The IOGTR was informed in reaching this conclusion in large part by the extensive work that has recently been undertaken by the IOGTR and GMAC in assessing an application by Monsanto for the general release of Roundup Ready® cotton.

GMAC's rationale for concluding that there are no risks to public health and safety or the environment included an assessment of:

- toxicity or allergenicity for humans (including through use of cotton in processed oil for human consumption and stockfeeds);
- risks of weediness;
- transfer of introduced genes to other plants;
- transfer of introduced genes to other organisms (microorganisms and animals).

Risk management plan

The IOGTR considers that the breach posed no risk to environmental or human safety.

However, the breach indicated a failure of Monsanto to maintain full control of the material used in field trials of genetically modified cotton. The IOGTR developed a risk management strategy which involved the IOGTR undertaking a full audit of Monsanto's activities and processes to ensure that such a breach does not occur again. The audit report made recommendations regarding how the processes and operating procedures of Monsanto and its contractors could be improved to ensure that such breaches do not occur again.

An Audit of Monsanto's activities and processes commenced in August 2000 and the audit committee has reported. The report is available on the IOGTR website as *Information Bulletin 7. Report- Audit of Monsanto Australia Ltd: Processes for the conduct of field trials in accordance with GMAC recommendations.*

The IOGTR will require Monsanto to comply with any changes to standard operating procedures (arising from the investigation) to improve the management of field trials and ensure that such a breach does not occur again.

- **Alleged sale of black market genetically modified canola**

Summary

On 24 March 2000, the IOGTR was advised of a possible breach of GMAC recommendations through a reporter from *The Age* newspaper. The allegation that there was a black market in genetically modified canola seed was subsequently published in an article in *The Age* on 25 March 2000.

The alleged breach could not be linked to a particular field trial. IOGTR sought information from the informant who was allegedly offered the GM canola seed. No evidence of a black market in GM canola seed was found.

The IOGTR notes that there are two herbicide-tolerant, conventionally bred varieties of canola that are commercially available (Clearfield and TT canola), and one was released for the first time this season (Clearfield). It is highly possible that these were the seeds being offered for sale.

Notification of alleged breach

The IOGTR was advised of a possible breach of GMAC recommendations through a reporter of *The Age* newspaper on 24 March 2000. The reporter was seeking background information in relation to a story that was subsequently published in *The Age* on 25 March 2000. The report said that a farmer was 'told of a new canola seed with dramatically boosted yields and tolerance to a common herbicide'. With such properties, the new canola seed was assumed by the farmer to be GM canola. The article also claims that two other farmers were offered GM canola seed.

The investigation

The IOGTR sought further information on the alleged breach and consulted GMAC on the possibility that there was a black market operation for GM canola seed.

The IOGTR wrote on two occasions to the farmer mentioned in *The Age* article seeking further information to investigate the allegations. No information was received from the farmer.

The allegation was discussed at a meeting of the GMAC Release Subcommittee on 8 May 2000. GMAC indicated that there were two varieties of non-transgenic herbicide tolerant canola available commercially. One of these, triazine tolerant canola, has been grown widely throughout Australia. The second, 'Clearfield Canola', was being offered commercially for the first time this season. GMAC members suggested that it may have been a variety of non-GM canola seed that had been offered for sale.

The findings

As no information was provided to substantiate the allegations, no further investigation of this allegation could be made.

2.6 Breaches of GMAC conditions: current investigations

The IOGTR is currently investigating two 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 GMAC and other relevant sources) believes presents a serious risk to human health or the environment. All such breaches will be notified immediately, pending the outcome of any investigation.

2.7 Audit activities

- **Audit of Monsanto Australia Ltd: Processes for the conduct of field trials in accordance with GMAC recommendations**

The Reason for the Audit

A breach of GMAC conditions led to the recommendation that an audit be undertaken on the field trials of Roundup Ready® cotton conducted by Monsanto during the 1999/2000 season. The breach relates to the trial proposal PR-83X(4). As described in Part 2.5 of this report, Monsanto failed to ensure that seed harvested from the trial was used in accordance with the GMAC recommendation that whole seed from Roundup Ready® cotton plants not enter commercial use in Australia. GMAC has carefully considered the breach and advised that there are no risks to the environment or to human health and safety resulting from this breach.

However, the breach indicated a failure of Monsanto to maintain full control of the material used in field trials of genetically modified cotton. Although this failure did not result in any increased risks, this would not necessarily be the

case if the same failure were to occur for other genetically modified crops. A thorough audit of Monsanto's processes for managing field trials to limit the possibility of such an incident occurring in the future was therefore warranted.

Scope of the Audit

The Audit Committee investigated Monsanto's internal processes for ensuring compliance with the GMAC recommendations. This included a review of Monsanto's Standard Operating Procedures (SOPs) with reference to the breach of the GMAC recommendations in respect of the field trial of Roundup Ready® cotton (PR-83X(4)).

The objective of the Audit was to identify any deficiencies in processes employed by Monsanto Australia Ltd to control field trials in accordance with recommendations made by GMAC. If any deficiencies were identified, then the Audit Committee was to identify enhancements or improvements to overcome these deficiencies.

Results of the Audit

The Audit Committee made the following recommendations:

- That Monsanto's SOP for monitoring and compliance be expanded to clearly indicate the scope, parameters and frequency of monitoring. Large scale field trials may require their own SOPs and these may need to be specific to a particular crop. This is because processing of plants or seeds may be different for each crop; for example, canola does not have an additional step of ginning that applies to cotton.
- That Monsanto establish a procedure to ensure that cotton gins will process GM cotton seed in such a way that results in segregation of the GM seed. However, this is no longer applicable to Roundup Ready® cotton as the general release application has since been approved.
- That Monsanto improve communication processes between all participants in a GM crop trial to ensure effective and efficient dissemination of the GMAC requirements and other relevant information. This should be incorporated into appropriate SOPs.
- That Monsanto implement the revised procedures in respect of large-scale field trials of GMOs.

A full report of the audit findings and recommendations is available in *Information Bulletin 7. Report- Audit of Monsanto Australia Ltd: Processes for the conduct of field trials in accordance with GMAC recommendations.*

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

The Reason for the Audit

In March 2000, alleged breaches by Aventis were identified as relating to PR-63X(4) and PR-85X(2) field trials that were being conducted in the Mt Gambier region of South Australia. The IOGTR found that Aventis had not complied with some aspects of conducting these field trials.

There were no increased risks to human health as a result of these breaches. The risks to the environment were low. The potential environmental risk was minimised further through the risk management plan proposed by IOGTR/GMAC and implemented by Aventis. This breach was reported in detail in the June Quarterly Report.

A 'spot check' conducted by IOGTR staff on 27 July 2000 raised further issues of concern with Aventis's post trial monitoring.

The cumulative effect of the breaches, and the issues raised as a result of the spot check, indicated a possible weakness in Aventis's processes. In the context of the current system, the IOGTR needs to satisfy itself that Aventis has the ability to maintain full control of field trials of genetically modified canola.

Scope of the Audit

The Audit Committee investigated Aventis's internal processes for ensuring compliance with GMAC recommendations. This included a review of Aventis's SOPs and site visits to all current field trial locations.

The objectives of the Audit were to identify whether there are any deficiencies in processes employed by Aventis to control field trials in accordance with recommendations made by GMAC. If any deficiencies are identified, the Audit Committee is to consider options for improving Aventis's system of operation.

Results of the Audit

The Audit committee is due to hand down its findings to the Head of the IOGTR at the end of October 2000. It is anticipated that the report on the findings and recommendations will be made publicly available on 17 November 2000.

2.8 General release applications: July–September 2000

- **Assessments completed/approvals granted**

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

- **New general release applications**

One new application for general release approval was received during the reporting period. This application was made by Monsanto Australia Ltd and relates to the GMO: INGARD® cotton.

INGARD® cotton has been approved for general release in Australia since 1996. Under the conditions of the original approval, Monsanto Australia Ltd is required to seek reapproval for the release within 5 years.

The application was made to the IOGTR on 5 September 2000. The key steps in the assessment process are set out at Table 1 at the end of this Section of the report. To date, the IOGTR has:

- advertised receipt of the application in *The Australian* newspaper, in regional newspapers in the cotton-growing areas of New South Wales and Queensland, and in the Commonwealth *Government Notices Gazette*;
- notified the Minister of receipt of the application and asked that the Minister formally notify the Premier of each State, and the Chief Ministers of the Territories;
- provided a full copy of the application to Environment Australia;
- notified receipt of the application to the GMAC mailing list;
- produced a Public Information Sheet and Information Bulletin on the proposed general release and the process for its consideration;
- commenced a literature review to support the risk assessment of the application; and
- forwarded the application to GMAC for assessment.

2.9 Other activities under interim arrangements

- **Freedom of Information (FOI)**

No FOI requests were received during the reporting period.

- **Information Bulletins**

The IOGTR added a number of Information Bulletins to the series begun in the second quarter of 2000. These were made available on the IOGTR website, and through direct mailouts, during the July–September quarter:

Information Bulletin No 2: Monitoring Compliance with GMAC recommendations for the conduct of field trials;

Information Bulletin No 3: The Audit of Monsanto Australia Ltd processes for the conduct of field trials in accordance with GMAC recommendations;

Information Bulletin No 4: How the outcomes of the First Consensus Conference on Gene Technology in the Food Chain are being addressed;

Information Bulletin No 5: The audit of Aventis CropScience Pty Ltd's conduct of field trials in accordance with GMAC recommendations;

Information Bulletin No 6: Questions and Answers on the commercial release of Roundup Ready® cotton/Roundup Ready® INGARD cotton.

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

Receipt of application	<p>The IOGTR:</p> <ul style="list-style-type: none"> • 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	<p>The Minister for Health and Aged Care:</p> <ul style="list-style-type: none"> • 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. <p>The IOGTR:</p> <ul style="list-style-type: none"> • 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	<p>The IOGTR:</p> <ul style="list-style-type: none"> • 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. <p>The GMAC</p> <ul style="list-style-type: none"> • 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. <p>The IOGTR</p> <ul style="list-style-type: none"> • Prepares a draft risk analysis document .
Call for public comment on the risk assessment	<p>The IOGTR:</p> <ul style="list-style-type: none"> • 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. <p>The Minister for Health and Aged Care seeks final advice from relevant Commonwealth Ministers, including the Environment Minister, and from States and Territories.</p>
Decision is made	<p>The IOGTR:</p> <ul style="list-style-type: none"> • 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. <p>The Minister for Health and Aged Care makes a decision on the application and informs the applicant.</p>
Decision is notified	<p>The IOGTR:</p> <ul style="list-style-type: none"> • 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 updated with:

- new information on the proposed regulatory system including the Explanatory Guide to the Bill, the draft Regulations and the Explanatory Guide for the Regulations;
- information on new deliberate release proposals;
- the Roundup Ready® cotton risk assessment document;
- the submission to the Senate Community Affairs References Committee Inquiry into the Gene Technology Bill 2000;
- Information Bulletins 2–6;
- the first Quarterly Report of the IOGTR; and
- a Media Release: 'Gene technology regulations will be amongst the best in the world'.

Throughout the reporting period, the Website was consistently in the top 10 Department of Health and Aged Care websites visited, with approximately 8 300 visits recorded to the IOGTR home-page during the reporting period. This brings the total number of home-page hits since recording began in March 2000 to 14 700.

During the reporting period, the IOGTR also responded to 134 emails to the IOGTR website on gene technology related issues – this brings the total number of emails responded to since the beginning of the year to 883.

As foreshadowed in the first IOGTR Quarterly Report, the IOGTR has been undergoing a major redesign to provide easier and quicker access to information. On-line information will also be more comprehensive and more regularly updated.

As foreshadowed in the previous Quarterly Report, the first phase of the redesign was completed during the reporting period July–September 2000. The redesigned website will now be tested with States and Territories, to iron out any operating problems before it goes live during the next reporting period.

- **International coordination activities**

The IOGTR has continued to develop a program of international activities.

Significant progress was made during the quarter on gathering information on gene technology regulation worldwide. This enabled the IOGTR to provide comprehensive and detailed information to the Senate Community Affairs References Committee Inquiry into the Gene Technology Bill 2000. A table summarising gene technology regulation worldwide is at **Attachment 1**.

Also during the reporting period the IOGTR participated in:

- a government working group coordinating Australia's involvement in the new Codex Alimentarius ad hoc intergovernmental taskforce on food derived from biotechnology. The IOGTR's participation in this working group is to ensure that Australia's experience in gene technology assists in harmonising biotechnology-related definitions and risk assessment processes internationally; and
- activities stemming from agreement of the Biosafety Protocol in Montreal on 28 January 2000, including analysis of the potential impact of the Protocol on Australia's proposed domestic legislation and public consultation processes.

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

- Swedish Parliamentary Committee on Civil Law;
- Government officials from the United States of America;
- Government official from Japan.

The IOGTR provided regular information on the proposed new regulatory system for GMOs to government officials in New Zealand as well as receiving information on the New Zealand Royal Commission into gene technology. The IOGTR also provided information and received briefing from the Japan-based outposted officer from Agriculture, Fisheries and Forestry Australia.

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

- **CSIRO risk assessment project**

CSIRO is currently developing an ecological risk assessment group which will work in two key research areas. These are 1) the development of robust risk assessment frameworks for GMOs that consider effects on a large scale and over extended time-frames, and 2) case studies of specific GMOs and GMO 'surrogates' in the field, to examine the possible consequences of GMO introductions (including indirect and long-term impacts). The program will involve a multi-disciplinary approach. It is intended that the information produced by the GMO case studies will feed back into the first component of the program, by providing data that can be used to test and refine the risk assessment framework. The data generated by the program will also feed into the regulatory system for GMOs. For this reason, CSIRO is developing partnerships with a range of government agencies, including GMAC and the IOGTR, to ensure that the studies are relevant to the needs of these agencies.

- **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.

During the reporting period the IOGTR has continued to act as a coordinating point to provide input from the Health Portfolio to Biotechnology Australia activities. This includes attending BA regional Forums to describe the proposed legislation for gene technology.

• **Consultants**

The IOGTR established one new contract for services during the reporting period, with McNiece Communications Pty Ltd, to provide a media officer on a short-term basis pending permanent recruitment.

During the reporting period, KPMG completed its work on costing the functions of new regulations, considering the cost impact on stakeholders and developing models for recovering costs from proponents.

The final report from KPMG was provided on 5 October 2000. A copy is available on the IOGTR's website at www.health.gov.au/tga/genetech.htm.

Also during the reporting period, the work contracted by the IOGTR from Swell Designs was completed. Swell Designs was to provide advice on the style and design of the web pages and create a visual identity for the IOGTR which can translate readily into an identity for the (permanent) Office following the passage of legislation. Given the expectation that the new national regulatory system would be operational early in the New Year, the IOGTR decided to hold the implementation of a visual identify, pending the appointment of the GTR. The new website is expected to go live in November 2000.

During the reporting period, the IOGTR 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 GMAC's general business.

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PART 3: THE QUARTER AHEAD

During the forthcoming quarter (October to December 2000) the IOGTR anticipates that:

- Responses to all submissions received during the first round of consultations on the Regulations will be finalised. Further drafting instructions for the Regulations will be developed in consultation with States and Territories, and a further iteration of the Regulations will be prepared;
- The second round of consultations on the Regulations will commence;
- Draft guidelines for Certification and Accreditation will be released for consultation;
- The receipt of the inquiry into the Gene Technology Bill 2000, by the Senate Community Affairs References Committee will be scrutinised and debate on the Bill will commence in the Senate;
- Progress will be made to establish the 3 Statutory Committees made under the Bill;
- Monitoring and surveillance activities will continue.

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ATTACHMENT 1

**COMPARISON OF REGULATION IN RELATION TO THE APPROVAL PROCESS FOR THE INTENTIONAL RELEASE
OF GENETICALLY MODIFIED PLANTS INTO THE ENVIRONMENT**

	United States	Canada	New Zealand	EU	United Kingdom
Relevant legislation	Federal Plant Pest Act and Federal Insecticide, Fungicide and Rodenticide Act	Canadian Environmental Protection Act	The Hazardous Substances and New Organisms Act	Council Directive 90/220/EEC	Environment Protection Act 1990 Part VI, the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (SI 1992/3280) and the Genetically Modified Organisms (Deliberate Release) Regulations 1995 (SI 1995/304).
Relevant Regulatory authority	The US Department of Agriculture Animal and Plant Health Inspection Service (for plant pests, plants and veterinary biologics) The U.S. Environmental Protection Agency (for microbial/plant pesticides, new uses of existing pesticides and novel micro-organisms).	Environment Canada	Environmental Risk Management Authority (ERMA)	The Council of the European Communities Member states must designate a competent authority responsible for carrying out the requirements of the Directive.	The Department of the Environment, Transport and Regions (DETR)

Coverage	Field testing, moving, importing and commercial release of organisms and products altered or produced through genetic engineering which are plant pests or may become plant pests	Manufacture or import of new substances (i.e. that are not on the list of Domestic Substances). Substances include living organisms that are an animate product of biotechnology.	Importation, development, field testing and release of new organisms. All GMOs are considered to be new organisms.	The deliberate release of GM micro-organisms into the environment	The culturing storage, use, transport, destruction, disposal, release (field trials for research purposes and commercial releases) into the environment or marketing of GMOs.
Assessment process	<p>Developer submits data to the USDA Animal and Plant Health Inspection Service</p> <p>Data must demonstrate that the plant is safe to release and is not itself a plant pest or potential noxious weed.</p> <p>The USDA conducts an assessment in accordance with the National Environmental Protection Act.</p> <p>If the GMO is also a plant pesticide then EPA approval is</p>	<p>The Minister must be notified if someone wishes to manufacture or import a new substance that is not on the Domestic Substances List (if it is on the list no approval is necessary).</p> <p>Information relevant to the assessment must be provided to the Minister.</p> <p>Assessment is undertaken by Environment Canada who may utilise external advice</p>	<p>Any person importing or releasing a 'new organism' into the environment must apply to the ERMA for approval.</p> <p>The organism is assessed according to whether it is likely to cause:</p> <ul style="list-style-type: none"> - any significant displacement of any native species within its natural habitat; - any significant deterioration of natural habitats; - any significant adverse effects on New Zealand's inherent genetic diversity; and 	<p>A person must submit notification about the proposed release including all of the information required by the Directive and an evaluation of the impacts.</p> <p>The competent authority must examine the application for compliance with the directive and evaluate the risks posed by the release – this must be a science based consideration.</p> <p>The competent authority may</p>	<p>Application must be made to the Department of the Environment.</p> <p>Application must include a risk assessment prepared by the applicant.</p> <p>The Advisory Committee on Releases to the Environment (ACRE) carries out an assessment of the application and advises on the risks posed to human health and the environment, whether a consent should be granted and whether any risk management of the release should be required as a condition of consent.</p>

	<p>also required under the Federal Insecticide, Fungicide and Rodenticide Act as pesticide is broadly defined to include plants modified by biotechnology to resist disease.</p> <p>The EPA may also treat micro-organisms as subject to the Toxic Substances Control Act</p>		<ul style="list-style-type: none"> - disease, become parasitic or become a vector for human, animal or plant disease. <p>The positive effects of the organism must outweigh the adverse effects of the organism and any inseparable organism.</p>	<p>consult on any aspect of the proposed deliberate release.</p>	
Approvals	<p>A “determination of non-regulated” status is issued by APHIS if the crop is not a plant pest allowing the crop to be released without restriction. EPA would also issue approval.</p>	<p>Minister decides whether the substance is toxic or capable of becoming toxic.</p> <p>If the organism is not toxic or capable of becoming toxic, the Minister can place the organism on the Domestic Substance Register but cannot impose any conditions.</p> <p>If the organism is toxic or capable of becoming toxic, the Minister can permit its manufacture or importation subject to conditions or can prohibit its import or manufacture.</p>	<p>Approval for release can only be granted without conditions.</p>	<p>Consent to release may be granted with conditions</p> <p>The competent authority must send to the commission the results of the decision and the Commission must forward summaries to other Member States.</p>	<p>Release may only take place with the consent of the Secretary of State for the Environment and the Minister of Agriculture, Fisheries and Food.</p> <p>Consent may be subject to risk management conditions.</p>

Enforcement	Once permission for the cultivation of their transgenic crops has been granted, progress is monitored. The system does not rely on significant enforcement powers as the regulatory system is based on 'permits, testing and tolerance setting'.	<p>The Minister can appoint enforcement officers to investigate alleged offences against the Act.</p> <p>The enforcement officers have broad powers including to search, seize etc.</p>	Considerable powers of enforcement and inspection including search and seizure powers.	Member states shall ensure that the competent authority organises inspections and other control measures as appropriate to ensure compliance with the Directive.	Specialist inspectors may be appointed on behalf of DETR.
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DELIBERATE RELEASE PROPOSALS (FIELD TRIALS)**PR-137: Field test of pineapple plants modified for blackheart resistance**

Organisation	Queensland Department of Primary Industries GPO Box 46 Brisbane QLD 4001
Contact person	Dr Michael K Smith telephone: (07) 5441 2211, facsimile: (07) 5441 2235
Organism	Pineapple (<i>Ananas comosus</i>)
Location	Two locations in south-east Queensland
Scale	Up to 735 plants in an area of 0.12 hectares
Expected date of release	October 2000 – 2004

Brief summary of the aim and nature of the deliberate release

Blackheart is a discolouration of the tissue of pineapple fruit. In Australia, blackheart occurs in the field in winter-grown crops, causing heavy losses to industries due to downgrading of fruit quality, immature harvest of fruits and reduced winter production. The tissue discolouration in blackheart is a consequence of the expression of the enzyme polyphenol oxidase (PPO) in response to chilling. The aim of this trial is to assess the commercial utility of pineapples genetically modified to control blackheart. The modified pineapple plants contain additional copies of the pineapple PPO genes.

The trial will involve testing of modified pineapple lines for agronomic performance, activity of gene control elements (promoters) and resistance to blackheart.

Organism

The parent organism is pineapple (*Ananas comosus* (L.) Merrill), cultivar Smooth Cayenne. Pineapple has a long history of cultivation and safe use. Smooth Cayenne pineapple originated in Central or South America and was introduced into Australia in 1858. Smooth Cayenne is the major pineapple cultivar grown in Australia and elsewhere in the world and is used for canning.

Genetic modification and its effect

Some of the modified pineapple lines contain additional copies of the pineapple polyphenol oxidase (PPO) genes either in sense (correct) or anti-sense (opposite) direction. The addition of extra copies of the PPO gene is intended to reduce expression of the PPO enzyme, which is believed to be responsible for the tissue discolouration in blackheart. The modified pineapple lines also contain a selectable marker gene which confers resistance to the antibiotic kanamycin and related antibiotics. The marker gene enables identification and selection of the modified plants in the laboratory.

Some of the pineapple plants contain, instead of the extra PPO gene, another marker gene. This gene encodes the enzyme β -glucuronidase linked to various promoter sequences. Promoters are genetic 'switches' which, when coupled with a gene of interest, cause that gene to be expressed at high levels in particular tissues of a plant. The aim of this part of the trial is to assess the activity of different promoters in the plants under field conditions.

Vector

The DNA was introduced into the pineapple plants on a plasmid either by one of two methods. In some plants, the DNA was coated onto very small particles of metal which are 'shot' into the plant tissue. In other plants, the DNA was carried into the plants cells by the vector *Agrobacterium tumefaciens* (a bacterium). The vector is 'disarmed' since it lacks the genes which encode the tumorigenic functions of *A. tumefaciens*. This type of vector has been used frequently in Australia and overseas for introducing new genes into plants without causing any biosafety problems.

Procedures for release

For the current trial, up to 490 transgenic pineapple plants will be grown on 0.08 hectares at a site in south-east Queensland. Also at this site, 70 non-transgenic control plants will be planted as well as 180 conventionally propagated plants in guard rows surrounding the site. This site is located at a considerable distance (more than 30 km) from commercial pineapple crops.

An area of 0.04 hectares at a second site in south-east Queensland will be planted with 245 modified pineapple plants, 35 non-modified control plants and 186 guard plants. The site is located close to commercial pineapple crops.

At both sites, the flowers on the transgenic plants will be bagged to prevent pollen spread by insects.

It is common practice in the pineapple industry to produce two fruit crops from a single plant (the second crop being known as a 'ratoon'). In this trial, both fruit crops will be produced and tested. This will mean that the pineapple plants will be in the field for 4-five years.

Procedures following release

Fruit from the initial crop and the ratoon crop will be harvested and subjected to destructive analysis. All unused material will be destroyed by autoclaving or deep burial. All vegetative material resulting from the process of production of the ratoon crop will be disposed of by deep burial. The vegetative material remaining at the completion of the full cropping cycle will also be disposed of by deep burial.

GMAC advised that the trial sites should be monitored for 'volunteer' pineapple plants for a period of one year after the trial, with any such plants being removed and destroyed.

Transport

Pineapples clones will initially be grown in a PC2 glasshouse. GMAC advised the proponent that the requirements in GMAC's Guidelines should be observed for transport of the plants to the trial sites.

Summary of risk assessment and GMAC's recommendations

Smooth Cayenne pineapple is not a competitive coloniser of natural ecosystems, as evidenced by the absence of Smooth Cayenne in a natural state in Australia.

GMAC noted that transmission of the introduced genes to other pineapples in commercial production is unlikely. In addition to the isolation of the trial site from commercial pineapple plantations, fertility in commercially grown cultivars of pineapple is very low and pineapple

plants rarely produce seed. Pineapple flowers are normally self-sterile so that pollen transmission within the plants still does not result in seed production. Consequently, gene transfer through pollination is very unlikely.

Commercial propagation of pineapple is not through seeds but by the use of vegetative shoots. If pollination of other pineapple plants by the transgenic plants should occur, the seed would therefore not be used for propagating further plants. Although the pineapple plant reproduces vegetatively, the proponent claims that this is not a likely avenue of dispersal. Vegetative shoots are not easily removed from the plant and pineapple plants are not capable of producing underground shoots.

Ananas comosus can hybridise with other species within the *Ananas* genus and with related bromeliads outside the *Ananas* genus. These other species include *A. ananassoides* and *A. bracteatus*, which occur as ornamental plants in gardens and nurseries. However, no members of the genus *Ananas* are considered to be weeds in Australia. Some sexually compatible relatives may exist in very low numbers near the trial sites, in domestic gardens or commercial nurseries.

Bagging of the flowers on the transgenic plants will minimise the potential for pollen transfer from the transgenic plants to other plants.

Conclusion

GMAC concluded that the field trial would present no significant risk to the environment or the community. Dispersal of the transgenic plants or their genetic material in the environment is very unlikely, as a result of the biology of pineapple and the procedures to be used during the trial.

Other agencies advised by GMAC

Australia New Zealand Food Authority
Queensland Department of Primary Industries
Queensland Department of Environment & Heritage
Redlands Shire Council
Maroochy Shire Council

Date of GMAC advice

22 August 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.

Brief summary of deliberate release proposal in lay terms

PR-137: Field test of pineapple plants modified for blackheart resistance

Blackheart in pineapples is a discolouration of the tissue of the pineapple fruit. In Australia, blackheart occurs in the field in winter-grown crops, causing heavy losses to industries. The aim of this trial is to study the pineapples that have been genetically modified to control blackheart. The trial will involve testing of modified pineapple lines for agronomic performance, activity of gene control elements (promoters) and resistance to blackheart.

The modified pineapple lines contain additional copies of a gene that is already present in pineapples. This gene produces an enzyme called polyphenol oxidase (PPO) which is believed to be responsible for the tissue discolouration in blackheart. The addition of extra copies of the PPO gene is intended to reduce the level of the PPO enzyme in the plants.

The trial will also include a study of the activity of different promoters. Promoters are genetic 'switches' which, when coupled with a gene of interest, cause that gene to be 'turned on'. The pineapple plants to be used in this study contain different promoters linked to marker genes. The genetically modified pineapple lines also contain selectable marker genes, which enable the modified plants to be identified in the laboratory.

In the current trial, up to 735 modified pineapple plants will be planted in an area of 0.12 hectares in two locations in south-east Queensland.

GMAC assessed this proposal as being of no significant risk to the environment or the community. Pineapple plants have a number of characteristics which mean that the transfer of genes from the modified plants to other plants is very unlikely. As well, the researchers will cover the flowers on the plants with bags to prevent insects carrying pollen from the plants.

PR-138: Evaluation of subclover stunt virus promoters in cotton plants under field conditions

Organisation	CSIRO Plant Industry GPO Box 1600 Canberra ACT 2601
Contact person	Dr Danny Llewellyn telephone: (02) 6246 5470 Dr Greg Constable telephone: (02) 6799 1522
Organism	Cotton (<i>Gossypium hirsutum</i>)
Location	Australian Cotton Research Institute, Myall Vale, NSW
Scale	Approximately 6000 transgenic plants in an area under 0.1 hectare
Expected date of release	October 2000 - April 2001

Brief summary of the aim and nature of the planned release

Many of the genes, such as insect-resistance and herbicide-resistance genes, that have been used in field trials of genetically manipulated cotton in the past have used a promoter from a virus that infects cauliflowers, the cauliflower mosaic virus. Promoters, when coupled to a gene of interest, cause that gene to be expressed at high levels in particular tissues of a plant. Transgenic cotton plants expressing insecticidal genes from *Bacillus thuringiensis* (Bt) driven by the cauliflower mosaic virus promoter have experienced variable performance in the field and a decline in efficacy towards the end of the season.

In glasshouse tests, two new promoters isolated from a virus that infects subterranean clover plants seem to work as well as the cauliflower mosaic virus promoter. This trial aims to test the performance of the new promoters under field conditions.

Organism

The parent organism is cultivated cotton (*Gossypium hirsutum*). Cotton, which is exotic to Australia, is grown as an agricultural crop in northern NSW and south-eastern and central Queensland.

Genetic modification and its effect

The transgenic cotton plants contain one of two promoters from the subterranean clover stunt virus (from virus segments 4 and 7) coupled to two 'marker' genes. The first marker gene is neomycin phosphotransferase from the bacterium *Escherichia coli*. This gene confers resistance to the antibiotics kanamycin and neomycin, allowing selection of the transgenic plants from non-transgenic plants in tissue culture. The second gene encodes an enzyme, β -glucuronidase, from the bacterium *Escherichia coli* which enables the visual identification of plant tissues where the promoter is effecting the expression of this gene.

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

Vector

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

Procedures for release

The trial site is at the Australian Cotton Research Institute in Myall Vale, NSW. About 6000 transgenic cotton plants will be planted in an area under 0.1 hectare. Small plots of other transgenic herbicide-tolerant cotton will be adjacent to the trial plot, but separated from the plants in this trial by at least 50 m of conventional cotton. The site contains other experimental plots of cotton and commercial cotton fields are nearby.

The transgenic plants will be surrounded by a 20 m buffer of conventional cotton that will in turn be embedded within a much bigger plot of commercial cotton. The trial plot will be isolated by at least 50 m from any cotton breeding material. The general features of planting and agronomic management will be the same as for a conventional cotton crop. Irrigation and spraying for insect pests will be as dictated by normal management practice.

Procedures following release

At the end of the trial, the transgenic plants will be harvested and removed by hand and incinerated. The lint and any excess seed will be destroyed. Some transgenic seed will be retained for other trials. The surrounding commercial crop will be harvested and the buffer rows will be ploughed in without harvesting. Seed from the buffer rows will be destroyed. The rest of the field will be harvested, slashed and crop residues incorporated. The field will then be sown with wheat, which normally suppresses the growth of any volunteer cotton plants. Any volunteer cotton plants that emerge will be removed by hand and destroyed. After harvest of the wheat, the field will be cultivated and allowed to remain fallow until planted back to cotton nine months later.

Transport

GMAC advised the proponent that the requirements in GMAC's *Guidelines for the Deliberate Release of Genetically Manipulated Organisms* should be observed for transport of the seed to the trial site.

Summary of risk assessment and GMAC's recommendations

Cotton is largely self-pollinated and cross-pollination is rare. When it occurs it is mediated by insects, usually honeybees. Vegetative propagation of cotton does not occur in the field, and cotton seeds do not have long-term survival in soils.

No *Gossypium* species are recognised as weeds in Australia.

There are two wild Australian species of *Gossypium* (*G. sturtianum* and *G. australe*) whose distribution overlaps that of cultivated cotton. *Gossypium sturtianum* has been recorded in isolated populations about 50 km from the trial site. However, gene transfer to wild species is unlikely due to genome incompatibility, the relatively isolated distribution of Australian native *Gossypium* species and different breeding systems. Hybrids resulting from artificial crosses between cotton and wild Australian species are generally sterile, unstable and of poor fitness, and are difficult to maintain, even under glasshouse conditions.

GMAC considered that the proposal was of low risk. The introduced genes would not be expected to confer a competitive advantage on the transgenic cotton. The procedures to be

used during the trial were considered appropriate to minimise the potential for dispersal of the transgenic plants or the transgenes beyond the trial site.

Conclusion

GMAC considered that the proposal would not present any significant risks to the environment or the community.

Other agencies advised by GMAC

National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority
NSW Department of Agriculture
NSW Department of Land and Water Conservation
NSW Environment Protection Authority
Narrabri Council

Date of GMAC advice

18 August 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.

Brief summary of deliberate release proposal in lay terms

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

CSIRO Plant Industry intends to study lines of genetically modified cotton plants containing two new promoters. Promoters are genetic 'switches' which, when coupled to a gene of interest, cause that gene to be 'turned on'. Many of the genes, such as insect-resistance and herbicide-resistance genes, that have been used in field trials of genetically modified plants in the past have used a promoter from a virus that infects cauliflowers, the cauliflower mosaic virus. The promoters to be studied in this trial have been isolated from a virus that infects subterranean clover plants. In glasshouse tests, the new promoters seem to work as well as the cauliflower mosaic virus promoter. This trial aims to test the performance of the new promoters under field conditions.

Most of the modified cotton plants to be trialled contain the new promoters attached to a marker gene. The marker gene encodes an enzyme, β -glucuronidase, from the bacterium *Escherichia coli*. This marker gene allows the plants expressing the gene to be easily identified. The plants also contain another marker gene, which confers resistance to the antibiotics kanamycin and neomycin.

A small number of the modified cotton plants to be trialled will contain the same promoters attached to a gene that produces a protein that is toxic to caterpillar pests of cotton. As well, these plants contain a marker gene that makes the plants tolerant to the herbicide Basta.

In the current trial, the modified cotton will be planted on an area of 0.1 hectare at the Australian Cotton Research Institute, Myall Vale, NSW. The seed harvested from the plants that are not required for later trials will be destroyed.

GMAC considered that the proposal would not present any significant risks to the environment or the community. It is very unlikely that the modified cotton plants could spread their genes into other plants.

PR-139: Field evaluation of introgressed, genetically engineered barley

Organisation	CSIRO Plant Industry GPO Box 1600 Canberra ACT 2601
Contact person	Dr Jake Jacobsen telephone (02) 6246 5464; facsimile (02) 6246 5000
Organism	Barley (<i>Hordeum vulgare</i>)
Location	Ginninderra Experiment Station, Hall, ACT
Scale	Up to 2940 transgenic plants in an area of approximately 160 square metres
Expected date of release	August 2000 – January 2001

Brief summary of the aim and nature of the planned release

The aim of the release is to assess the field performance and malting quality of seven lines of barley genetically modified for improved malting and brewing performance. Similar lines have been trialled previously in Australia (under proposal PR-92). The transgenic varieties of barley to be tested in the current trial have been backcrossed for several generations into a new Australian barley cultivar.

Organism

The parent organism is barley (*Hordeum vulgare*), cultivar Golden Promise, which is an old English malting cultivar grown in England and Scotland but not grown commercially in Australia. The transgenic plants have been introgressed by several generations of backcrossing into a new Australian malting cultivar, Sloop. Barley evolved in the fertile crescent in the Middle East. It originates in zones of moderate to low rainfall and its range extends from the Mediterranean region, Asia Minor through to Pakistan and the Himalayas. The wild progenitor of cultivated barley does not occur in Australia.

Genetic modification and its effect

The transgenic barley lines contain extra copies of genes for enzymes involved in starch breakdown. The modifications are aimed at increasing the ability of the barley grain to degrade its own starch during malting and brewing. Six of the transgenic lines contain extra copies of either one or both of two genes for different forms of the enzyme α -amylase. The remaining transgenic barley line contains a gene for another enzyme involved in starch breakdown, α -glucosidase. The introduced genes are from barley and function in the plant in the same way as the native genes.

A selectable marker gene, conferring resistance to an antibiotic, that was originally present has been removed from the barley lines to be used in this proposal.

Vector

The DNA was introduced into barley 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 and overseas for introducing new genes into plants without causing any biosafety problems.

Procedures for release

The trial will be conducted at the Ginninderra Experiment Station at Hall in the ACT. The trial involves a total of 2940 transgenic plants in an area of approximately 160 square metres. The trial will comprise 420 plants of each transgenic line and the same number of non-transgenic sibling 'control' plants. In addition, 840 plants of each of the parental cultivars Sloop and Golden Promise will be grown as further controls. The trial plot will be surrounded by two rows of Sloop plants acting as a buffer and to reduce edge effects. The control barley plants will be used for comparison of grain yield, plant morphology and malting characteristics.

The trial plot will be surrounded on all sides and overhead with nylon mesh to exclude rabbits and birds.

The seed will be sown by hand. A 20 m wide buffer of peas will be grown around the plot to discourage growth of volunteer barley or barley grass. Volunteer barley or barley grass plants within the buffer zone will either be eliminated (removed by hand or treated with herbicide) or prevented from flowering.

No commercial crops of barley are grown within 30 km of the trial site. A small experimental plot of barley will be grown on the farm, but at a distance of at least 500 metres.

Procedures following release

After the trial, the plots will be harvested by hand to reduce the opportunity for accidental spillage of seed and threshed on site. Threshing machinery will be cleaned on site. The harvested seed will be retained for laboratory analysis; Any residual plant material will be cultivated or incinerated. The pea plants forming the buffer will be slashed and the area cultivated.

Any remaining barley seed at the site will be encouraged to germinate by irrigation of the plot following harvest, and then sprayed with a non-selective herbicide such as glyphosate, 6 to 10 weeks later. The plot will be monitored for two years after completion of the trial and any volunteer barley plants will be destroyed before flowering.

Transport

The seed will be transported in sealed containers from the laboratory in Canberra to the release site in accordance with GMAC guidelines. Harvested seed will be transported back to the laboratory according to GMAC guidelines.

Summary of risk assessment and GMAC's recommendations

Barley is predominantly self-pollinating; however, pollen is shed from the floret and can be transferred to other plants by wind. There is no evidence to suggest that barley pollen is spread by insects. The barley flower lacks nectar and is not attractive to insect pollinators. Cultivated varieties of barley do not have weedy characteristics.

Hordeum spontaneum is a weedy progenitor of cultivated barley but it does not occur naturally in Australia. *Hordeum bulbosum* does occur in Australia and was once grown at Ginninderra, but it has not been sighted for some time. *Hordeum marinum* and *Hordeum murinum* (barley grasses) are weeds in Australia and are present in patches at the site, but will be eliminated or prevented from flowering for a zone of 20 m surrounding the trial site, for the duration of the trial. Hybrids between cultivated barley and barley grasses are sterile.

GMAC concluded that the isolation procedures to be used during the trial were sufficient to minimise the potential for out-crossing of plants in the trial plot to other barley plants or barley grass plants nearby.

Barley does not propagate vegetatively in the field. Barley seeds are sufficiently large that the potential for dispersal of seed from the trial site by wind or water is negligible. Dispersal by rodents and birds is a remote possibility, but the use of a nylon mesh around the site will reduce the likelihood of this occurring. The seeds can remain dormant for periods of up to six months; however, under field conditions, any seeds remaining on the soil surface would germinate readily given a moist soil. Volunteer plants from the trial will be controlled by irrigation and herbicide application.

GMAC advised the proponent that, before the barley could be made available for human consumption, consultation with the Australia New Zealand Food Authority would be required.

Conclusion

GMAC's assessment was that the proposed field trial would not pose any significant risks to the environment or the community.

Other agencies advised by GMAC

Australia New Zealand Food Authority
ACT Department of Urban Services

Date of GMAC advice

18 August 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.

Brief summary of deliberate release proposal in lay terms

PR-139: Field evaluation of introgressed, genetically engineered barley

In this proposal, CSIRO Plant Industry intends to assess the growth of genetically modified barley plants in the field. The barley has been modified by adding extra copies of the barley's own genes for enzymes involved in starch breakdown. The researchers also aim to test whether this modification increases the ability of barley to break down starch and improves its performance in malting and brewing.

An area of approximately 160 square metres will be planted to the modified barley at the Ginninderra Experiment Station at Hall in the ACT. The seed that is harvested will be tested for malting quality.

GMAC's view of this proposal was that it would not pose any significant risks to the environment or the community. Barley does not have the properties of a weed and the trial will be carried out under conditions to limit any spread of genetic material from the site.

If the plants were in future to be released commercially, the Australia New Zealand Food Authority would assess the safety for human consumption of the barley and beer produced from it.

**PR-140: Agronomic selection and seed increase of Roundup Ready (RR),
Ingard (Bt)/Roundup Ready (RR) and CryX/Ingard (Bt)/Roundup Ready
(RR) cotton plants, 2000 - 2001**

Organisation	Deltapine Australia Pty Ltd PO Box 196 Narrabri NSW 2390
Contact person	Dr Richard Leske telephone: (07) 4671 3136
Organism	Cotton (<i>Gossypium hirsutum</i>)
Location	Emerald Irrigation Area, Theodore/Biloela Irrigation Area, Darling Downs, MacIntyre Valley, St George Irrigation Area, Gwydir Valley, Namoi Valley, Liverpool Plains, Macquarie Valley, Bourke Irrigation Area, Lake Tandou, and Lachlan Valley (all in the cotton-growing regions of New South Wales and Queensland)
Scale	Up to 712 hectares, consisting of breeding nurseries (24 hectares), seed increase (400 hectares) and other trial sites (288 hectares)
Expected date of release	September 2000 – June 2001

Brief summary of the aim and nature of the deliberate release

The aim of the release is the agronomic evaluation and seed increase of several lines of cotton which have been modified for tolerance to the herbicide glyphosate (Roundup®), as well as lines expressing the Roundup®-tolerance gene in combination with one or two genes conferring resistance to insect attack. Similar plants have been used in previous field trials. The current trial will include agronomic evaluation and selection of new breeding lines, multi-site yield and fibre trials on new crossbred selections, and seed increase of newly selected lines.

The cotton plants in this trial are derived from backcrossing donor parent cotton lines, which contain the introduced genes, with elite cotton varieties using traditional plant breeding methods. The long-term goal of the work is to develop new commercial cotton cultivars which are resistant to Roundup® and/or insect damage. It is intended that use of the herbicide-tolerant cotton will permit more effective control of weeds in cotton crops, while the insect-resistance trait has the potential to reduce the amount of insecticide applied to cotton crops.

Organism

The parent organism is cultivated cotton (*Gossypium hirsutum*). Cotton, which is exotic to Australia, is grown as an agricultural crop in northern NSW and south-eastern and central Queensland.

Genetic modification and its effect

The cotton plants have been modified to contain the 5-enolpyruvyl shikimate-3-phosphate synthase (EPSPS) gene from *Agrobacterium*. This gene confers tolerance to the herbicide

glyphosate, the active ingredient of Roundup®. Some cotton lines will contain the CryIA(c) gene from the bacterium *Bacillus thuringiensis* (Bt) in addition to the EPSPS gene, while some other lines will contain the EPSPS gene, the CryIA(c) gene and the CryX gene from *Bacillus thuringiensis*. The CryIA(c) and CryX genes both encode for insecticidal proteins which confer tolerance to the major insect pests of cotton. In addition, all the plants contain a selectable marker gene that confers resistance to the antibiotics kanamycin and neomycin.

Vector

The CryIA(c) and EPSPS genes were introduced into the cotton plant cells 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 and overseas for introducing new genes into plants without causing any biosafety problems. Particle bombardment of cotton tissue was used to insert the CryX gene into cotton cells. Conventional plant breeding and selection was used to transfer the EPSPS, CryIA(c) and CryX genes into superior Deltapine cotton varieties.

Procedures for release

A total of 712 hectares will be planted to the modified cotton. This area will consist of: (1) research and breeding nurseries totalling 24 hectares at three different Deltapine Research Stations in NSW and Queensland; (2) multi-site yield and fibre trials in 12 commercial cotton-growing regions of NSW and Queensland totalling 288 hectares; and (3) seed increase sites at 10 locations of 40 hectares each. The plants containing all three genes will only be planted at the research and breeding nursery locations.

The transgenic plants will be separated by a minimum of 50 m from breeding lines and seed increase fields of non-transgenic or other transgenic cotton. This separation could be bare ground, another crop or a commercial cotton crop where the seed is crushed.

The release of cotton containing the Bt genes will include adherence to the insect resistance management plan already operating for INGARD cotton (which was approved for commercial release in NSW and Queensland in 1996). This management plan is designed to reduce the potential for insects developing resistance to the insecticidal proteins.

Procedures following release

After the small plot trials, the unwanted seed will be dumped into a commercial cotton module. Seed from individual progeny selections required for future breeding will be saved. Delinted and treated seed will be stored for future commercial sale and all the cotton lint from this release will be sold. The remaining plant material will be controlled in the field according to the INGARD® insect management plan.

The trial sites will be monitored after harvest for 6 months and any volunteer cotton plants will be destroyed. The sites will then be either fallowed for a further period, planted to an alternative crop, planted back to cotton where the crop will be grown for lint production and all the seed will be crushed after ginning.

Transport

GMAC advised the proponent that the requirements in GMAC's *Guidelines for the Deliberate Release of Genetically Manipulated Organisms* should be observed for transport of the seed to and from the trial site.

Summary of risk assessment and GMAC's recommendations

As in its assessment of previous proposals involving cotton, GMAC's view was that the risk of transfer of the introduced genes from the transgenic plants to other cotton plants or other

species related to cotton is low. Cotton is largely self-pollinated and cross-pollination is rare. When cross-pollination occurs it is mediated by insects, usually honeybees. Gene transfer to wild *Gossypium* species is unlikely due to genome incompatibility, the relatively isolated distribution of Australian native *Gossypium* species and different breeding systems. Hybrids resulting from artificial crosses between cotton and wild Australian species are generally sterile, unstable and of poor fitness, and are difficult to maintain, even under glasshouse conditions.

No *Gossypium* species are recognised as weeds in Australia. However, there are two wild Australian species of *Gossypium* (*G. sturtianum* and *G. australe*) whose distribution overlaps that of cultivated cotton. The native *Gossypium* species are not known to occur on the black clay soils traditionally found in cotton-growing areas.

Vegetative propagation of cotton does not occur in the field, and cotton seeds do not have long-term survival in soils.

A risk associated with the release of herbicide-resistant plants is the possible development of herbicide resistance in weeds. GMAC considers that the ultimate general release of herbicide-resistant crops should only take place in the context of a national coordinated strategy for the development of such crops. The national strategy will require that integrated management practices are developed to minimise the likelihood of emergence of herbicide-resistant weeds. Development of the strategy is the responsibility of the Standing Committee on Agriculture and Resource Management.

Conclusion

GMAC's assessment was that the proposed field trial would not pose any significant risks to the environment or the community.

Other agencies advised by GMAC

National Registration Authority for Agricultural and Veterinary Chemicals

Australia New Zealand Food Authority

NSW Department of Agriculture

NSW Department of Land and Water Conservation

NSW Environment Protection Authority

Queensland Department of Environment

Queensland Department of Primary Industries

Emerald Shire Council

Banana Shire Council

Wambo Shire Council

Jondaryan Shire Council

Pittsworth Shire Council

Millmerran Shire Council

Waggamba Shire Council

Narromine Shire Council

Moree Plains Shire Council

Balonne Shire Council

Walgett Shire Council

Narrabri Shire Council

Gunnedah Shire Council

Quirindi Shire Council

Warren Shire Council

Brewarrina Shire Council

Bourke Shire Council

Central Darling Shire Council
Carrathool Shire Council

Date of GMAC advice

18 August 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.

Brief summary of deliberate release proposal in lay terms

PR-140: Agronomic selection and seed increase of Roundup Ready (RR), Ingard (Bt)/Roundup Ready (RR) and CryX/Ingard (Bt)/ Roundup Ready (RR) cotton plants 2000 – 2001

Cotton plants have been developed that are resistant to attack by caterpillars. Large amounts of chemical pesticides are currently used on cotton crops to control caterpillar pests. The insect-resistant cotton crop should be more environmentally friendly because it will require less spraying with chemical pesticides. The cotton plants have been modified by introducing two insect-resistance genes from a bacterium. These genes produce proteins that are toxic only to caterpillars.

Cotton plants have also been produced that are resistant to a herbicide, glyphosate (Roundup®). Glyphosate is a very useful herbicide for controlling weeds but it cannot be used on unmodified cotton crops after emergence of the cotton plants because it would kill the plants. The use of glyphosate-resistant cotton plants will allow farmers to use Roundup® on their cotton crops after the crop has emerged. This is expected to lead to more effective control of weeds, and may also reduce the use of other herbicides. The gene that provides resistance to glyphosate has been transferred from a soil bacterium.

Both the insect-resistance genes and the glyphosate-resistance gene have now been introduced into the same lines of cotton plants. In this proposal, Deltapine Australia Pty Ltd intends to continue to assess the field performance of the modified cotton plants. Supplies of the seed from the modified cotton plants will also be increased. The long-term goal of this work is to develop commercial cotton varieties that are resistant to both glyphosate and to insect damage.

In the current trial, an area of 712 hectares will be planted to the modified cotton in the cotton-growing regions of NSW and Queensland. The seed harvested from the plants will be stored for use in later trials or until approved for commercialisation.

GMAC considered that the proposal would not present any significant risks to the environment or the community. It is very unlikely that the modified cotton plants could spread their genes into other plants.

Extension to PR-51X(4): Bt agronomic selection and yield trials 1998-1999

PR-51X(5): Agronomic yield trials, progeny row selection and seed increase of Bt cotton plants 2000 - 2001

Organisation	Deltapine Australia Pty Ltd PO Box 196 Narrabri NSW 2390
Contact person	Richard Leske telephone: (07) 4671 3136
Organism	Cotton (<i>Gossypium hirsutum</i>)
Location	Emerald Irrigation Region, Theodore/Biloela Irrigation Area, Darling Downs, St George Irrigation Area, Gwydir Valley, Namoi Valley, Liverpool Plains, Macquarie Valley, Bourke Irrigation Area, Lachlan Valley, Lake Tandou, and MacIntyre Valley (all in the cotton-growing areas of Queensland and New South Wales).
Scale	A total of 56 hectares
Expected date of release	September 2000 - June 2001

A further extension to the original proposal has been received. The aim of this extension is to continue the agronomic evaluation of new breeding lines of cotton that have been modified for resistance to insect pests. In addition, multi-site evaluation of yield and fibre characteristics of some lines will be continued. The trials will also be used for preliminary seed increase of some new crossbred lines. The use of insect-resistant cotton plants has the potential to reduce the use of chemical pesticides on cotton crops.

Parent cotton lines have been modified by the introduction of the CryIA(c) gene together with the CryX gene, both from the bacterium *Bacillus thuringiensis* (Bt). These genes produce proteins that are toxic to certain caterpillars, including the major caterpillar pests that attack cotton. Plants expressing the insecticidal proteins should require fewer applications of chemical pesticides during their cropping. 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 modified cotton plants in this trial are derived from backcrossing the donor parent cotton lines which contain the introduced genes with elite cotton varieties using traditional plant breeding methods.

A total of 56 hectares of the modified cotton will be planted over 25 sites in the cotton-growing regions of NSW and Queensland. Procedures for management of the trial and treatment of the sites after the trial will be similar to those used for previous proposals. Seed will be collected and stored for subsequent trials.

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 Department of Land and Water Conservation
NSW Department of Agriculture
NSW Environment Protection Authority
Qld Department of Environment and Heritage
Qld Department of Primary Industries
Emerald Shire Council
Banana Shire Council
Wambo Shire Council
Jondaryan Shire Council
Pittsworth Shire Council
Millmerran Shire Council
Waggamba Shire Council
Balonne Shire Council
Gunnedah Shire Council
Quirindi Shire Council
Narromine Shire Council
Central Darling Shire Council
Moree Plains Shire Council
Walgett Shire Council
Narrabri Shire Council
Bourke Shire Council
Brewarrina Shire Council
Warren Shire Council
Carrathool Shire Council

Date of GMAC advice

18 August 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.

Brief summary of deliberate release proposal in lay terms

PR-51X(5): Agronomic yield trials, progeny row selection and seed increase of Bt cotton plants 2000 – 2001

In this proposal, Deltapine Australia Pty Ltd intends to study the field performance of genetically modified cotton plants. As well, new breeding lines will be selected and supplies of the seed from the plants will be increased. The cotton plants have been made resistant to attack by caterpillars. Large amounts of chemical pesticides are currently used on cotton crops to control caterpillar pests. The new insect-resistant cotton varieties should be more environmentally friendly because they will require less spraying with the chemical pesticides.

Two genes from a bacterium have been inserted into the cotton plants to make them resistant to the caterpillar pests. These genes produce proteins that are toxic to certain insects, including caterpillars. The proteins are not harmful to humans or other animals.

In the current trial, an area of 56 hectares will be planted to the modified cotton in the cotton-growing regions of New South Wales and Queensland. The seed supplies from this proposal will be used for later assessment of the modified cotton in the field.

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.

Extension to PR-55X(5): The release of transgenic cotton expressing tolerance to the herbicide glyphosate

PR-55X(6): The release of transgenic cotton expressing tolerance to the herbicide glyphosate

Organisation	CSIRO Plant Industry GPO Box 1600 Canberra ACT 2601
Contact person	Dr Danny Llewellyn telephone: (02) 6246 5470 Dr Greg Constable telephone: (02) 6799 1522 Mr Graham Charles telephone: (02) 6799 1524
Organism	Cotton (<i>Gossypium hirsutum</i>)
Location	Up to 16 sites at Myall Vale, Warren, Bourke, Breeza, Wee Waa, Moree, Merah North, Collarenebri, Boggabilla and Hillston (NSW); and St. George, Biloela, Theodore, Dalby, Emerald and Brookstead (Qld)
Scale	Approximately 550 000 plants in an area under 5.5 hectares
Expected date of release	October 2000 - April 2001

A further extension to the original proposal has been received. The aim of this extension is to examine the field performance of cotton plants, modified for resistance to the herbicide glyphosate (Roundup[®]), when sprayed with the herbicide. As well, some integrated weed management options using transgenic Roundup[®]-tolerant cotton plants will be examined. The trial will also continue the selection of more advanced transgenic breeding material as part of an ongoing program to produce commercially useful cotton cultivars with tolerance to Roundup[®]. It is intended that use of Roundup[®]-tolerant cotton plants will allow more effective weed control in cotton crops by allowing the crop to be sprayed with Roundup[®] to kill problem weeds without damaging the crop itself.

The cotton plants have been modified to contain a 5-enolpyruvyl shikimate-3-phosphate synthase (EPSPS) gene derived from a soil bacterium. This gene confers tolerance to the herbicide glyphosate, the active ingredient of Roundup[®].

Approximately 550 000 transgenic plants in a total area of less than 5.5 hectares will be released at up to 16 sites on commercial cotton farms in New South Wales and Queensland as well as at the Australian Cotton Research Institute in Myall Vale, NSW. Procedures for management of the trial and treatment of the sites after the trial will be similar to those used for previous proposals.

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 Department of Agriculture
NSW Department of Land and Water Conservation
NSW Environment Protection Authority
Queensland Department of Environment and Heritage
Queensland Department of Primary Industries
Narrabri Council
Moree Plains Council
Warren Council
Shire of Wambo
Shire of Banana
Shire of Milmerran
Balonne Shire Council
Gunnedah Shire Council
Carrathool Shire Council
Bourke Shire Council
Emerald Shire Council
Pittsworth Shire Council

Date of GMAC advice

18 August 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.

Brief summary of deliberate release proposal in lay terms

PR-55X(6): The release of transgenic cotton expressing tolerance to the herbicide glyphosate

Cotton plants have been produced that are resistant to a herbicide, Roundup[®]. Roundup[®] is a very useful herbicide for controlling weeds but it cannot be used on unmodified cotton crops after emergence of the cotton plants because it would kill the plants. The use of Roundup[®]-resistant ('Roundup Ready[®]') cotton plants will allow farmers to use Roundup[®] on their cotton crops after the crop has emerged. This is expected to lead to more effective control of weeds, and may also reduce the use of other herbicides. The gene that provides resistance to Roundup[®] has been transferred from a harmless soil bacterium.

In this proposal, researchers from CSIRO Plant Industry will study the field performance of the modified cotton when it is sprayed with Roundup[®] and investigate options for weed management. They will also continue to select new lines of the modified cotton. An area of 5.5 hectares will be planted to the modified cotton in NSW and Queensland. The seed harvested from the plants will be stored for later use or crushed for use as animal feed.

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.

Extension to PR-69X(3): The planned release of transgenic cotton expressing tolerance to the herbicide bromoxynil

PR-69X(4): Release of transgenic cotton expressing tolerance to the herbicide bromoxynil – Weed management studies

Organisation	CSIRO Plant Industry GPO Box 1600 Canberra ACT 2601
Contact person	Dr Danny Llewellyn telephone: (02) 6246 5470 Dr Greg Constable telephone: (02) 6799 1522 Mr Graham Charles telephone: (02) 6799 1524
Organism	Cotton (<i>Gossypium hirsutum</i>)
Location	Australian Cotton Research Institute, Myall Vale, NSW
Scale	Approximately 80 000 plants in an area of 0.8 hectares
Expected date of release	October 2000 - April 2001

A further extension to the original proposal has been received. The aim of the extension is to continue integrated weed management studies with cotton that has been modified for tolerance to the herbicide bromoxynil. It is intended that use of the bromoxynil-tolerant cotton plants will allow more effective weed control in cotton crops by allowing spraying of the crop with bromoxynil to kill broadleaf weeds without impacting on yield and damaging the crop itself. Bromoxynil is rapidly degraded in the soil, making it an environmentally acceptable option for weed control.

The herbicide-resistance gene introduced into the transgenic plants is a nitrilase gene from a soil bacterium (*Klebsiella*) that normally degrades bromoxynil in soil. When over-expressed in the plant, this enzyme breaks down the herbicide before it can cause any damage to the plant.

Approximately 80 000 transgenic cotton plants will be planted at the Australian Cotton Research Institute at Myall Vale (near Narrabri), NSW. A number of small plots totalling approximately 0.8 hectares will be planted.

Procedures for management of the trial and treatment of the site after the trial will be similar to those used for previous proposals. Seed from the transgenic plants will be retained for subsequent trials.

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 Department of Agriculture
NSW Department of Land and Water Conservation
NSW Environment Protection Authority
Narrabri Council

Date of GMAC advice

18 August 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.

Brief summary of deliberate release proposal in lay terms**PR-69X(4): Release of transgenic cotton expressing tolerance to the herbicide bromoxynil**

Cotton plants have been produced that are resistant to a herbicide, bromoxynil. Bromoxynil is a very useful herbicide for controlling weeds but it cannot be used on unmodified cotton crops after emergence of the cotton plants because it would kill the plants. The use of bromoxynil-resistant cotton plants will allow farmers to use bromoxynil on their cotton crops after the crop has emerged. This is expected to lead to more effective control of weeds, and may also reduce the use of other herbicides that are less friendly to the environment. The gene that provides resistance to bromoxynil has been transferred from a bacterium that normally breaks down bromoxynil in soil.

In this proposal, researchers from CSIRO Plant Industry will study the use of the modified cotton and the options for weed management to find out how the cotton would fit in with weed control practices in cotton. An area of 0.8 hectares will be planted to the modified cotton at the Australian Cotton Research Institute near Narrabri in NSW. Procedures for management of the trial and treatment of the site after the trial will be the same as for previous proposals. The seed harvested from the plants will be stored for use in later field trials.

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.

Extension to PR-99X: Field evaluation of transgenic cotton for enhanced tolerance to waterlogging

PR-99X(2): Field evaluation of transgenic cotton for enhanced tolerance to waterlogging

Organisation	CSIRO Plant Industry GPO Box 1600 Canberra ACT 2601
Contact person	Dr Marc Ellis telephone: (02) 6246 5306 Dr Greg Constable telephone: (02) 6799 1522 Dr Ian Rochester telephone: (02) 6799 1574
Organism	Cotton (<i>Gossypium hirsutum</i>)
Location	Australian Cotton Research Institute, Myall Vale, NSW
Scale	Approximately 40 000 plants in an area under 0.5 hectares
Expected date of release	October 2000 - April 2001

A further extension to the original proposal has been received. The purpose of the extension is to continue the field assessment of cotton lines with enhanced tolerance to waterlogging. Because of the heavy clay soils on which cotton is grown in Australia, and the sensitivity of cultivated cotton to waterlogging, losses in production are common when rain follows a scheduled irrigation. The trial will examine the physiological and agronomic characteristics of cotton plants modified to over-produce two plant enzymes that are normally involved in helping plants survive long periods of waterlogging.

The transgenic cotton plants contain an extra copy of either or both of the following genes: the alcohol dehydrogenase gene (Adh) from cotton or a pyruvate decarboxylase gene (Pdc) from rice. The extra copy of these genes results in a higher level of expression of these two enzymes in the cotton plants. For comparison, transgenic cotton plants are also being trialled which contain the Adh gene in the opposite or 'antisense' orientation. This results in plants that have lower levels of the alcohol dehydrogenase enzyme than normal.

A total of approximately 40 000 plants of the transgenic cotton will be grown in an area under 0.5 hectares at Australian Cotton Research Institute near Narrabri in NSW. Procedures for management of the trial site and treatment of the site 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

Australia New Zealand Food Authority
NSW Department of Agriculture

NSW Department of Land and Water Conservation
NSW Environment Protection Authority
Narrabri Council

Date of GMAC advice

18 August 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.

Brief summary of deliberate release proposal in lay terms

PR-99X(2): Field evaluation of transgenic cotton for enhanced tolerance to waterlogging

Because cotton is grown in heavy clay soils in Australia, losses in cotton production due to waterlogging are common when rain follows irrigation of the crop. This trial continues work by CSIRO Plant Industry to develop cotton plants that are more tolerant to waterlogging.

The trial will study the effect of increasing the level in cotton of two enzymes that are normally involved in helping plants survive waterlogging. The modified cotton contains extra copies of genes that produce these enzymes, from cotton or rice. The enzymes help the plant generate energy in the absence of oxygen, thereby allowing the plant to survive until the water recedes.

A total of approximately 40 000 plants of the transgenic cotton will be grown in an area under 0.5 hectares at Australian Cotton Research Institute near Narrabri in NSW. Procedures for management of the trial site and treatment of the site 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.

Extension to PR-118: Regulatory trials for efficacy, crop safety and environmental impact with CryIA(c)/CryX and CryX, 1999 – 2000.

PR-118X: Regulatory trials for efficacy, crop safety and environmental impact with CryIA(c)/CryX and CryX cotton plants, 2000 - 2001

Organisation	Deltapine Australia Pty Ltd PO Box 196 Narrabri NSW 2390
Contact person	Stewart Addison telephone: (02) 6742 4251
Organism	Cotton (<i>Gossypium hirsutum</i>)
Location	Darling Downs, MacIntyre Valley, Gwydir Valley, Namoi Valley, Macquarie Valley, Liverpool Plains, Bourke, Hillston, St. George, Upper Namoi Valley, Richmond and Emerald (in New South Wales and Queensland)
Scale	Up to 40 hectares in total on 12 sites
Expected date of release	September 2000 - June 2001

The aim of this extension to the original proposal is to assess in the field lines of cotton plants that have been modified for resistance to insect pests. Specifically, assessments will be made of the insecticidal efficacy of the plants, the impact of the introduced genes on non-target insects occurring in cotton crops, and the agronomic performance of the plants. The long-term goal of the work is to develop commercial cotton cultivars that are resistant to insect damage. The insect-resistant cotton should reduce the need for use of chemical pesticides on the crop.

The genes introduced into the cotton plants are the CryIA(c) and CryX genes from the bacterium *Bacillus thuringiensis*. These genes encode proteins which are toxic to the major caterpillar pests of cotton in Australia (including two *Helicoverpa* species) but are not toxic to other animals and humans. Cotton containing the CryIA(c) gene is currently registered for commercial use in Australia. The use of a second insecticidal gene, CryX, is expected to enhance the plants' insecticidal activity and delay the development of resistance in the target pests.

A total of up to 40 hectares of transgenic cotton spread over 12 sites will be grown in cotton-producing regions of NSW and Queensland. Procedures for management of the trial and treatment of the sites after the trial will be similar to those used for previous proposals.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC considered that the proposal would not present any significant risks to the environment or the community.

Other agencies advised by GMAC

National Registration Authority for Agricultural & Veterinary Chemicals
Australia New Zealand Food Authority
Queensland Department of Environment and Heritage
Queensland Department of Primary Industries
NSW Department of Agriculture

NSW Department of Land and Water Conservation
NSW Environment Protection Authority
Gunnedah Shire Council
Moree Plains Shire Council
Narrabri Shire Council
Warren Shire Council
Wambo Shire Council
Waggamba Shire Council
Pittsworth Shire Council
Jondaryan Shire Council
Milmerran Shire Council
Walgett Shire Council
Quirindi Shire Council
Narromine Shire Council

Date of GMAC advice

18 August 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.

Brief summary of deliberate release proposal in lay terms**PR-118X: Regulatory trials for efficacy, crop safety and environmental impact with CryIA(c)/CryX and CryX cotton plants, 2000 - 2001**

In this proposal, Deltapine Australia Pty Ltd will study the field performance of genetically modified cotton plants. The cotton plants have been made resistant to attack by caterpillars. Large amounts of chemical pesticides are currently used on cotton crops to control caterpillar pests. The new insect-resistant cotton crop should be more environmentally friendly because it will require less spraying with the chemical pesticides.

Two genes from a bacterium have been inserted into the cotton plants to make them resistant to the caterpillar pests. These genes produce proteins that are toxic to certain insects, including caterpillars. The proteins are not harmful to humans or other animals.

In the current trial, an area of up to 40 hectares will be planted to the modified cotton in the cotton-producing areas of NSW and Queensland. The cotton will be tested to see whether it is resistant to insect pests, and whether the toxin-producing genes have any effect on non-target insects. As well, the overall performance of the plants in the field will be studied.

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.

Extension to PR-123: Preliminary field evaluation of transgenic cotton expressing the CryIA(c) and CryX delta-endotoxins from *Bacillus thuringiensis*.

PR-123X: Preliminary field evaluation of transgenic cotton expressing the CryIA(c) and CryX delta-endotoxins from *Bacillus thuringiensis*

Organisation	CSIRO Plant Industry GPO Box 1600 Canberra ACT 2601
Contact person	Dr Danny Llewellyn telephone: (03) 9246 5470 Dr Gary Fitt telephone: (02) 6799 1514 Dr Greg Constable telephone: (02) 6799 1522
Organism	Cotton (<i>Gossypium hirsutum</i>)
Location	Warren, Bogabilla, Bourke, Moree, Breeza, Myall Vale and Narrabri (NSW); and Biloela (Qld).
Scale	Approximately 1.5 million plants in total area of 15 hectares, spread over up to seven sites
Expected date of release	October 2000 - April 2001

The purpose of this extension to the original proposal is to continue to examine the field performance of transgenic cotton expressing two insecticidal genes over a variety of sites and environments. Selection of breeding material and seed increase will also be conducted. The use of insect-resistant cotton plants has the potential to reduce the use of chemical pesticides on cotton crops.

The modified cotton plants contain either the CryX gene, or the CryX gene in combination with the CryIA(c) gene, from the bacterium *Bacillus thuringiensis*. These genes encode proteins which are toxic to the major caterpillar pests of cotton in Australia (including two *Helicoverpa* species) but are not toxic to other animals and humans. Cotton containing the CryIA(c) gene is currently registered for commercial use in Australia. The use of a second insecticidal gene, CryX, is expected to enhance the plants' insecticidal activity and delay the development of resistance in the target pests.

A total of 1.5 million modified cotton plants will be grown in an area of 15 hectares spread over seven sites at the Australian Cotton Research Institute and Plant Breeding Institutes at Narrabri, private farms in NSW and at the Biloela Research Station in Queensland. Procedures for management of the trial and treatment of the sites after the trial will be similar to those used for previous proposals.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC considered that the proposal would not present any significant risks to the environment or the community.

Other agencies advised by GMAC

National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority

NSW Department of Agriculture
NSW Department of Land and Water Conservation
NSW Environment Protection Authority
Qld Department of Environment & Heritage
Qld Department of Primary Industries
Narrabri Council
Warren Council
Bourke Shire Council
Moree Plains Shire Council
Gunnedah Shire Council
Banana Shire Council

Date of GMAC advice

18 August 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.

Brief summary of deliberate release proposal in lay terms

PR-123X: Preliminary field evaluation of transgenic cotton expressing the CryIA(c) and CryX delta-endotoxins from *Bacillus thuringiensis*

In this proposal, researchers from CSIRO Plant Industry will study the field performance of genetically modified cotton plants in a variety of sites and environments. The cotton plants have been made resistant to attack by caterpillars. Large amounts of chemical pesticides are currently used on cotton crops to control caterpillar pests. The new insect-resistant cotton crop should be more environmentally friendly because it will require less spraying with the chemical pesticides. The seed supplies from this trial will be used for later assessment of the modified cotton in the field.

Two genes from a bacterium have been inserted into the cotton plants to make them resistant to the caterpillar pests. These genes produce proteins that are toxic to certain insects, including caterpillars. The proteins are not toxic to humans or other animals. The use of two different insecticidal genes in a single plant will reduce the potential for the insects to become tolerant to the insecticidal proteins.

In the current trial, a total of 15 hectares will be planted with modified cotton in New South Wales and Queensland. Procedures for management of the trial and treatment of the sites after the trial will be similar to those used for previous proposals.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC considered that the proposal would not present any significant risks to the environment or the community.

Extension to PR-124: Release of transgenic cotton expressing tolerance to the herbicide Basta®

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

Organisation	CSIRO Plant Industry GPO Box 1600 Canberra ACT 2601
Contact person	Dr Danny Llewellyn telephone: (03) 9246 5470 Dr Greg Constable telephone: (02) 6799 1522
Organism	Cotton (<i>Gossypium hirsutum</i>)
Location	Myall Vale, NSW.
Scale	Approximately 40 000 plants in an area of less than 0.4 hectares.
Expected date of release	October 2000 - April 2001

The aim of this extension to the original proposal is to continue the field evaluation and breeding of new lines of cotton that have been modified for tolerance to the herbicide glufosinate ammonium (phosphinothricin, Basta®). This will involve looking at efficacy in the field, increasing seed for subsequent trials, and carrying out crosses to elite breeding material. It is expected that use of glufosinate ammonium-tolerant cotton plants will allow more effective weed control in cotton crops by allowing the crop to be sprayed with glufosinate ammonium to kill problem weeds without damaging the crop itself. As well, continuation of weed management studies will allow evaluation of how this herbicide and herbicide-tolerant cotton will fit into the cotton production system in Australia.

The plants contain one of two genes (*bar* or *pat*) conferring tolerance to glufosinate ammonium, the active ingredient of the herbicide Basta®. Both genes encode the enzyme phosphinothricin acetyltransferase, which acts to detoxify glufosinate ammonium. The two genes have been isolated from two different species of the soil bacterium *Streptomyces*: *Streptomyces hygroscopicus* (the *bar* gene) and *Streptomyces viridichromogenes* (the *pat* gene).

Up to 40 000 modified cotton plants will be planted in an area of approximately 0.4 hectares in two fields, at the Australian Cotton Research Institute near Narrabri. Procedures for management of the trial and treatment of the sites after the trial will be similar to those used for previous proposals.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC considered that the proposal would not present any significant risks to the environment or the community.

Other agencies advised by GMAC

National Registration Authority for Agricultural and Veterinary Chemicals
Australia New Zealand Food Authority
NSW Department of Agriculture
NSW Department of Land and Water Conservation

NSW Environment Protection Authority
Narrabri Council

Date of GMAC advice

18 August 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.

Brief summary of deliberate release proposal in lay terms**PR-124X: Release of transgenic cotton expressing tolerance to the herbicide Basta®**

CSIRO Plant Industry intends to study new lines of genetically modified cotton plants in the field. The plants have been modified to make them resistant to the herbicide Basta®. Basta® is a very useful herbicide for controlling weeds but it cannot be used on unmodified cotton crops after emergence of the cotton plants because it would kill the plants. The use of Basta®-resistant cotton plants will allow farmers to use Basta® on their cotton crops after the crop has emerged. This is expected to lead to more effective control of weeds, and may also reduce the use of other herbicides that are less friendly to the environment. The genes that provide resistance to Basta® have been transferred from soil bacteria.

In the current trial, an area of under 0.4 hectares will be planted with modified cotton at the Australian Cotton Research Institute near Narrabri in New South Wales. Procedures for management of the trial and treatment of the sites after the trial will be similar to those used for previous proposals.

GMAC's assessment of the risks associated with this extension was the same as its assessment of the risks of the original proposal. GMAC considered that the proposal would not present any significant risks to the environment or the community.

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

PR-141: Field performance and Integrated Pest Management studies on transgenic cotton expressing the CryIA(c) delta-endotoxin from *Bacillus thuringiensis*, in the Richmond region of northern Queensland.

Organisation proposing release: Queensland Department of Primary Industries
GPO Box 46
Brisbane QLD 4001

Organism to be released: Cultivated cotton (*Gossypium hirsutum*)

Purpose of the release: The use of insect-resistant cotton has the potential to reduce the use of chemical pesticides on cotton crops. The aim of the release is to study the potential for introduction of insect-resistant cotton as a commercial crop in northern Queensland. It will include studies of the variability in performance of different varieties of INGARD[®] (insect-resistant) cotton and the effectiveness of Integrated Pest Management (IPM) systems in the Richmond region of Queensland. INGARD[®] cotton has been released commercially in the cotton-growing regions of northern New South Wales and southern and central Queensland.

Brief description of the nature and effect of the genetic modification: Two additional genes are expressed in the modified cotton plants. One encodes the delta endotoxin gene CryIA(c) from the bacterium *Bacillus thuringiensis* (Bt). The toxin produced in the INGARD cotton is specific to lepidopteran (caterpillar) larvae, including two *Helicoverpa* species which are major pests of cotton.

The other gene is a 'marker' gene from the bacterium *Escherichia coli* that allows identification of the transgenic plants. This gene encodes neomycin phosphotransferase which confers resistance to the antibiotics kanamycin and neomycin.

Location and size of trial: A block of 500 hectares of modified plants in the Richmond region of Queensland.

Further information: The institution's contact officer for this proposal is Dr Ian Titmarsh, telephone (07) 4983 7409; facsimile: (07) 4983 7459.

**PR-129X: Planned release of genetically manipulated organism
(*P. somniferum*) oilseed poppy**

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

Supervising Biosafety Committee: Tasmanian Department of Primary Industries,
Water and Environment

Organism to be released: Poppy (*Papaver somniferum*)

Purpose of extension to the release: Oilseed poppy is cultivated for the production of morphine, codeine and thebaine for the pharmaceutical market. The proponent has modified the poppy plants by the insertion of a gene from the alkaloid synthesis pathway to cause increased alkaloid production. The aim of this extension is to evaluate whether the modification has had any effect on alkaloid production by the plant. The modified plants will be evaluated for potential commercial use, if a desirable effect on the production of alkaloid is observed.

Brief description of the nature and effect of the genetic modification: The modified poppy plants contain a gene for a poppy alkaloid pathway enzyme and a selectable marker gene conferring resistance to the antibiotic hygromycin.

Location and size of trial: 500 plants (in an area of 5m²) in a bee-proof cage will be grown at Sassafras, Tasmania.

Further information: The institution's contact officer for this proposal is Dr M J Doyle, telephone (03) 6426 1078, facsimile (03) 6426 2300.

PR-130X: The use of genetically modified rumen bacteria to protect livestock against fluoroacetate poisoning

Organisation proposing release: Murdoch University
Murdoch WA 6150

Organism to be released: *Butyrivibrio fibrisolvens* and *Bacteroides* sp. (rumen bacteria)

Purpose of the extension to the release: The ultimate aim of this project is to provide domestic ruminant animals with an increased tolerance to a poison, monofluoroacetate, that occurs naturally in some native plants. Annual losses of livestock due to monofluoroacetate poisoning are economically significant. This extension aims to assess the degree of protection against fluoroacetate poisoning that genetically modified rumen (forestomach) bacteria can provide to three ruminant species (cattle, sheep and goats) under field conditions. Another aim is to measure colonisation of ruminants by the modified bacteria under field conditions. The trial will also examine the spread of the modified bacteria between animals. Finally, the effect of the modified bacteria on the browsing behaviour of the animals in response to novel feeds that contain fluoroacetate will be examined.

Brief description of the nature and effect of the genetic modification: The trial will involve seven strains of the rumen bacterium *Butyrivibrio fibrisolvens* and two ruminal strains of *Bacteroides*, which have been modified by the insertion of a gene encoding fluoroacetate dehalogenase. The fluoroacetate dehalogenase gene is derived from a soil bacterium (*Moraxella* species) and codes for an enzyme which detoxifies the natural plant poison monofluoroacetate.

Selectable marker genes, conferring resistance to antibiotics (erythromycin, clindamycin and ampicillin), have also been transferred to the rumen bacteria.

Location and size of trial: The test area at Murdoch in Western Australia will total 5850 square metres and will be surrounded by double fencing. The inner area of 225 square metres will contain cattle and an adjoining area of 45 square metres will be for sheep and goats. Ten adult cattle, five adult sheep and five adult goats will be inoculated with the genetically modified rumen bacteria.

Further information: The institution's contact officer for this proposal is Dr Keith Gregg, telephone (08) 9360 2122, facsimile (08) 9360 6303.

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

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

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

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

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

Location and size of trial: A maximum of 400 hectares (approximately, 10,000,000 modified cotton plants) at Emerald (Qld), Cunnamulla (Qld) and Wee Waa (NSW).

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