Genetic Manipulation Advisory Committee

Annual Report 1997-98

ISSN 1038-0825

Cover by Art Graphic Design
Printed by Goanna Print

TABLE OF CONTENTS

REPORT FROM THE CHAIR

Emeritus Professor Nancy Millis
AC MBE
GMAC Chair

This year, as previously, work in contained facilities on a small scale comprises the majority of proposals for genetic manipulation work assessed by GMAC. It is clear, however, that the number of genetically modified plants for general release is increasing. Overseas, the areas planted to modified cotton, canola, maize and soybeans are measured in millions of acres. Most of these plants are tolerant of herbicides, or are resistant to insect attack.

The importation into Australia in December 1996 of modified soybeans for processing alerted GMAC to the need to establish guidelines for appropriate practices to minimise the likelihood of inadvertent escape of genetically modified seed from ships, silos or other bulk containers during their transport to processing factories. Guidelines to provide this advice were published this year. GMAC has also revised its Guidelines for small scale contained work and for the deliberate release of live genetically modified organisms into the environment.

The decision of Cabinet to develop legislation to replace the current non-statutory system of surveillance of genetically modified organisms has led to extensive consultation between the Commonwealth and the States and Territories. GMAC has contributed to the discussions and is aware that the commercial sector will welcome an indication of the form and substance of the legislation, as uncertainty hampers its plans for future developments and exploitation of novel organisms. The general community is equally concerned to learn of progress.

Finally, I should like to record GMAC's appreciation of the cooperation that we receive from institutions in the preparation of their proposals for consideration by the Committee.

Emeritus Professor Nancy Millis AC MBE
Chair
Genetic Manipulation Advisory Committee

EXECUTIVE SUMMARY

GMAC

The Genetic Manipulation Advisory Committee (GMAC) is a non-statutory body responsible for overseeing the development and use of novel genetic manipulation techniques in Australia. GMAC reviews such work and provides advice on the management of potential hazards to the community or the environment. The Committee produces four sets of guidelines: for small scale contained research, large scale contained work, deliberate release of live genetically modified organisms into the environment, and activities with some potential for unintended release of live genetically modified organisms into the environment.

Highlights

During the 1997-1998 financial year, GMAC assessed 358 proposals for small scale genetic manipulation work in containment facilities, two proposals for large scale genetic manipulation work in containment facilities, 35 proposals (17 new proposals and 18 extensions to previous proposals) for field trials, and four proposals for general release of genetically modified organisms into the environment.

During the reporting period, GMAC's Subcommittees revised the *Guidelines for Small Scale Genetic Manipulation Work, Guidelines for Large Scale Genetic Manipulation Work,* and *Guidelines for the Planned Release of Genetically Manipulated Organisms* (now titled *Guidelines for the Deliberate Release of Genetically Manipulated Organisms*). These revisions were necessary as a result of new developments in genetic manipulation techniques and as proposals move towards the stage of general release of genetically manipulated organisms for commercial use.

GMAC also issued a new set of Guidelines, *Guidelines for Activities with the Potential for Unintended Release of Genetically Manipulated Organisms.* These new Guidelines are intended to cover situations, such as importation of bulk quantities of genetically manipulated seed for processing in Australia, where release of a genetically manipulated organism is not the proponent's intention, but where there is some potential for release to occur.

The progression of proposals towards general release has raised new issues for GMAC to consider in its assessment of proposals. Some crops that have been genetically modified for resistance to specific herbicides are now approaching the stage of general release. GMAC has participated with other groups to initiate development of a coordinated national strategy for the deployment of herbicide-resistant transgenic crops in Australian agriculture.

1. COMMITTEE STRUCTURE AND FUNCTION

Introduction

The Genetic Manipulation Advisory Committee (GMAC) is a non-statutory body responsible for overseeing the development and use of novel genetic manipulation techniques in Australia. It assesses whether such work poses potential hazards to the community or the environment and recommends appropriate safety procedures and containment of organisms to the researchers and institutions undertaking the work. GMAC also provides advice to other government regulatory bodies.

GMAC was formed in 1987 to carry out work previously undertaken by the Recombinant DNA Monitoring Committee (RDMC). The RDMC was responsible for formulating and implementing guidelines for experiments involving recombinant DNA techniques (techniques involving combining DNA from different organisms *in vitro*). During the 1980s new techniques were developed which allow the genetic make-up of cells to be changed without using recombinant DNA methods. These new techniques also result in the production of novel organisms that are unlikely to occur in nature. Accordingly, GMAC was established with an expanded scope of review.

The membership of GMAC includes a wide range of expertise in fields that are relevant to risk assessment of genetic manipulation work. Experts in the fields of molecular biology, ecology, plant genetics, microbial genetics, animal genetics, agriculture, virology, entomology and biosafety engineering are members of the Committee. Besides scientists, the Committee includes members from the wider non-scientific community, with backgrounds in the fields of law and journalism.

Membership of GMAC is in Appendix 2 and its Terms of Reference are in Appendix 3. Further details about the history of regulation of genetic manipulation in Australia are given in Appendix 1.

Subcommittees

GMAC's work is largely conducted through its four subcommittees. These are the Scientific Subcommittee, the Large Scale Subcommittee, the Planned Release Subcommittee and the Public Liaison Subcommittee.

Scientific Subcommittee

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

Large Scale Subcommittee

The Large Scale Subcommittee reviews proposals covered by the *Guidelines for Large Scale Genetic Manipulation Work* which, for the most part, involve industrial-scale production. The Subcommittee is also responsible for the inspection and certification of all facilities for work on a large scale, of large work areas and of

laboratories requiring a higher level of containment than the minimum level for genetic manipulation work.

Planned Release Subcommittee

The Planned Release Subcommittee reviews proposals covered by the *Guidelines for the Deliberate Release of Genetically Manipulated Organisms* and *Guidelines for Activities with the Potential for Unintended Release of Genetically Manipulated Organisms*. The Subcommittee assesses the hazards associated with the release into the environment of genetically manipulated live organisms falling within the Guidelines. It provides advice to relevant Commonwealth, State and local government agencies, as well as to the proponents. The Subcommittee also consults with and provides information on deliberate release proposals to interested members of the public.

Public Liaison Subcommittee

The Public Liaison Subcommittee relates the activities of GMAC to the general public, as well as providing general information on other relevant topics, including international regulatory issues.

Functions

GMAC is concerned not only with *in vitro* experiments with recombinant DNA, but with any operation that results in organisms of novel genotype produced by genetic manipulation which fall under its scope of review. GMAC has defined its scope as: *any experiment involving the construction and/or propagation of viroids, viruses, cells or organisms of novel genotype produced by genetic manipulation which are either unlikely to occur in nature, or likely to pose a hazard to public health or to the environment*. An assessment of current risks associated with this area of work is given in Chapter 2.

GMAC issues non-statutory Guidelines for small scale genetic manipulation work in containment facilities, for large scale or industrial genetic manipulation work in containment facilities, and for the release of genetically modified organisms into the environment. The Guidelines specify the procedures to be followed by institutions and researchers intending to undertake genetic manipulation work, and detail the requirements for containment facilities. Proposals for genetic manipulation work are assessed by GMAC on a case-by-case basis. Current activities of GMAC are expanded in Chapter 3.

Any institution which conducts genetic manipulation work is required to set up an Institutional Biosafety Committee (IBC) to supervise work and facilities. GMAC monitors the operations of IBCs and provides them with advice about potential hazards. IBCs supervise day-to-day work within institutions to ensure compliance with GMAC advice and Guidelines. Further details on the operation of IBCs are provided in Chapter 4.

GMAC liaises with Commonwealth, State and Territory, and local government agencies concerned with the regulation of biotechnology products, with representatives of institutions that use genetic manipulation techniques, and with

environmental and consumer organisations. Consultation and liaison activities of GMAC and its Secretariat are summarised in Chapter 3.

Secretariat

The GMAC Secretariat provides secretariat support to GMAC and its various Subcommittees, coordinates members' assessments and drafts GMAC advice and recommendations to the IBCs. For deliberate release proposals, it provides GMAC's advice to those State or Commonwealth agencies which may have a legal jurisdiction over the proposed activities. The Secretariat also undertakes liaison with other State and Commonwealth Departments, with local government and with overseas agencies and provides input to the Minister on matters concerning genetic engineering. It liaises with IBCs, and with members of the general public who inquire about GMAC's activities.

2. CURRENT ASSESSMENT OF RISKS

Small Scale Contained Work

Categories of work

Assessment and management of the risks associated with small scale contained genetic manipulation work focuses on ensuring that the work remains contained within the laboratory. Physical containment of genetically modified organisms is achieved by the use of special procedures and facilities. Biological containment is achieved by the use of particular strains of the organism which have a reduced ability to survive or reproduce in the open environment. GMAC's *Guidelines for Small Scale Genetic Manipulation Work* include a list of approved host/vector systems that provide a high level of biological containment for genetic manipulation work.

The *Guidelines for Small Scale Genetic Manipulation Work* classify small scale contained work into different categories, depending on the level of risk associated with the work. Some types of small scale genetic manipulation work are specified as exempt from the Guidelines because they are of particularly low risk. Small scale contained work that is not exempt from the Guidelines is categorised as Category A (higher risk work), Category B (lower risk work), and Category C (Special Exemptions from the Guidelines).

An example of work that is exempt from the Guidelines because of its low risk is work with approved host/vector systems (those providing biological containment), provided that the DNA being introduced into the host does not present a hazard. Category B includes work with approved host/vector systems where there is some degree of risk associated with the DNA being introduced (for example, DNA encoding pathogenic determinants or oncogenes). Also included in Category B are experiments involving production of transgenic animals or whole plants. Category A includes a number of different types of experiment, including work with microorganisms known to produce toxins, work using pathogenic microorganisms as host or vector, and work involving cloning of complete viral genomes. A full description of the types of work falling within each Category is included in the *Guidelines for Small Scale Genetic Manipulation Work.*

Category B work can proceed after the proposal for the work has been assessed by the local IBC, which subsequently forwards a copy of the proposal to GMAC for information. Category A work has the potential for some risk and requires GMAC assessment and advice to the IBC before the work can begin. Category C proposals are experiments which fall into Categories A or B, but have been granted a 'Special Exemption' after review by GMAC because they do not present any possible risk to occupational or human health or to the environment.

Recent developments

Developments in the techniques used to introduce DNA into cells or organisms continue to take place. In the last few years, there has been increasing use of new types of viral vectors for introducing DNA into mammalian cells, and increasing use

of ‘naked DNA’ vaccines in animals. (Naked DNA is DNA that is not contained within a cell or virus.) GMAC has maintained a close watch on such developments, and this is reflected in the new edition of the *Guidelines for Small Scale Genetic Manipulation Work*.

To take account of the use of viral vectors with the capacity to infect human cells, GMAC has substantially revised the section of the *Guidelines for Small Scale Genetic Manipulation Work* that provides ‘Guidance for work involving genetically manipulated viruses for gene transfer into animal and human cells’. Reflecting discussions that took place in the previous reporting period as well as the current one, work involving injection of naked DNA into animals other than humans was made exempt from the new edition of the *Guidelines for Small Scale Genetic Manipulation Work*; this exemption does not apply if the DNA being used is recombinant and capable of giving rise to infectious agents.

Another exemption has been made for work involving genetic manipulation of animals where only the somatic cells (non-reproductive cells) are being modified. Work with such animals may now take place in standard animal housing facilities.

As foreshadowed in the Annual Report for 1996-97, the *Guidelines for Small Scale Genetic Manipulation Work* have been amended to bring into Category A (the higher risk category) work involving genetic manipulation of certain types of microorganism where the genes introduced could lead to autoimmune disease.

Large Scale Contained Work

Proposals for large scale contained work assessed by the Large Scale Subcommittee during the reporting period have been of low risk, involving use of genetically modified laboratory strains of *Escherichia coli* to produce proteins for therapeutic and veterinary use. Good Industrial Large Scale Practice (GILSP), the minimum level of physical containment for large scale work, was regarded as suitable for the two proposals assessed. GILSP containment is appropriate when the host/vector system used provides biological containment and when the DNA introduced into the host organism does not introduce any particular hazard.

Deliberate Release Work

The proposals for deliberate release of genetically manipulated organisms assessed during the reporting period are described in Chapter 3. All but one of the new proposals and all of the extensions to previous proposals involved modified crop plants. One of the new proposals involved the release of a modified virus. For the other sixteen new proposals assessed, the characteristics introduced into the plants were herbicide resistance (six proposals), resistance to viruses (one proposal), resistance to insect pests (five proposals), resistance to bacterial or fungal pests (three proposals), improved or altered quality characteristics (five proposals) and marker traits (one proposal). Further work was conducted, as extensions to previous proposals, on plants expressing herbicide resistance (eleven extensions), insect resistance (five extensions) and altered quality traits (four extensions).

During the reporting period four proposals were submitted for general release of genetically modified crop plants. The characteristics introduced into the plants were herbicide resistance (three proposals), insect resistance (two proposals) and altered

quality traits (one proposal). However, GMAC's assessment was that these proposals should proceed under the conditions applying to field trials. These conditions include isolation of the genetically modified plants from other plants with which they might be able to cross, procedures after the trial to remove the genetically modified plants from the release site, and post-trial monitoring procedures. The four proposals have therefore been treated as extensions to previous proposals. GMAC's assessment of these proposals is summarised in Chapter 3.

Herbicide-resistant crops

As reported in the Annual Report for 1996-97, the number of proposals for field trials of crop plants modified for resistance to specific herbicides continues to increase. Some of these proposals are approaching the stage of general (commercial) release of the crops to the marketplace. The proponents for this work claim that use of herbicide-resistant crops will increase the weed control options available to farmers by allowing the crops to be sprayed with the particular herbicide after emergence of the crop.

Risks associated with the widespread use of herbicide-resistant crops include the emergence of herbicide-resistant weeds and difficulty in controlling a herbicide-resistant crop that emerges in a subsequent crop of a rotational system. Herbicide-resistant weeds could arise as a result of transfer of the herbicide-resistance gene from the crop plants to weedy relatives, or as a result of increased use of the herbicide leading to a greater selection pressure for the development of resistant weeds.

Because these risks will be compounded as the number of herbicide-resistant crops released increases, GMAC considers that a coordinated national strategy is required for the management of the introduction of herbicide-resistant crops into Australian agricultural systems. The strategy would need to take into account management issues that cross the borders of individual crop industries. As described in Chapter 3, GMAC's Chair is participating in a Working Group established by the Standing Committee on Agriculture and Resource Management to develop a mechanism for management of the development and general release of genetically manipulated crops. In the interim, GMAC is informing proponents that its advice on deliberate release proposals involving herbicide-resistant crops is conditional on the outcomes and requirements of a future national strategy.

Importation of genetically modified bulk seed

A number of genetically manipulated crops have now been granted regulatory approval for commercial use in other countries. One such crop is soybean modified for resistance to the herbicide glyphosate ('Roundup Ready®' soybean) which has been developed by Monsanto. This crop has now been granted 'non-regulated status' by the United States Department of Agriculture, allowing sale of the crop and its products without differentiation from non-transgenic soybeans. The first commercial crops of Roundup Ready® soybean were harvested in late 1996.

Australia imports soybean seed from the USA for processing into vegetable oil and protein meal. As a result of the regulatory decision in the USA, from late 1996 these imported soybean seeds contain a proportion of transgenic seeds.

As more genetically manipulated crops gain non-regulated status overseas, it is likely that other imports into Australia of bulk agricultural commodities will also contain a component that is genetically manipulated. To ensure that any risks to biosafety associated with such imports are assessed, GMAC has produced a new set of Guidelines, *Guidelines for Activities with the Potential for Unintended Release of Genetically Manipulated Organisms.* The new Guidelines will ensure that any risk of spillage of genetically manipulated seed into the environment is appropriately managed.

3. COMMITTEE ACTIVITIES

Meetings

During 1997-1998, GMAC and its Subcommittees met as follows:

GMAC	Scientific Subcommittee	Planned Release Subcommittee	Large Scale and Public Liaison Subcommittees
12 December 1997	1 August 1997	29 August 1997	Did not meet
	30 October 1997	28 November 1997	
	30 January 1998	27 February 1998	
	17 April 1998	15 May 1998	
	26 June 1998		

GMAC

At the GMAC meeting on 12 December 1997, an officer from the Department of Industry, Science and Tourism presented a summary of recent development in progress towards a statutory system for the regulation of gene technology. Establishment of a statutory system to replace the current system was recommended in the report of an inquiry into the regulation of gene technology by the House of Representatives Standing Committee on Industry, Science and Technology (*Genetic Manipulation: The Threat or the Glory?*, 1992). The Commonwealth Government's preferred position on the regulatory system was announced on 30 October 1997, and negotiations with the States and Territories to achieve a uniform national system are in progress.

GMAC agrees that the current voluntary system should be given legislative backing. In its discussion of the issues, GMAC noted the central role of expert scientific assessment in the review of the biosafety aspects of genetic manipulation work. In particular, for contained genetic manipulation work, the technical complexity of proposals is such that only practising scientific experts would have the capacity to assess the safety issues. GMAC members also emphasised the need for flexibility in the regulatory system, the need for timeliness in decision-making, and the important role played by Institutional Biosafety Committees. Concern was expressed that additional steps might be added to the assessment process in the new system with the potential for undue delay in decisions and no significant value added to the scientific assessment.

Scientific Subcommittee

Revision of the *Guidelines for Small Scale Genetic Manipulation Work*

The Scientific Subcommittee completed its revision of the *Guidelines for Small Scale Genetic Manipulation Work* and the new edition of the Guidelines was issued in April 1998. Revision of the Guidelines was necessary to take into account technical developments in the field that may be associated with some risk. On the other hand, increasing experience in some areas has indicated that the associated risks are low, and the degree of surveillance of such work can be reduced.

The major changes in the new edition of the Guidelines were:

- revision of the risk categories of small scale work to include cloning of genes encoding proteins that have the potential to induce autoimmune disease; such proposals now fall within Category A and require GMAC assessment before they can proceed;
- exemption of work involving introduction of naked nucleic acids into animals or plants (unless the nucleic acid sequences are capable of giving rise to infectious recombinant agents);
- exemption of work involving genetic modification of the somatic cells (cells other than reproductive cells) of animals;
- revision of the precautions for work involving use of genetically manipulated viruses as vectors for gene transfer into animal and human cells;
- addition of new host/vector systems to the list of 'approved' systems (those that provide substantial biological containment);
- addition of requirements for handling of genetically manipulated fish and other aquatic organisms.

Minor changes were made to the specifications for physical containment facilities. Amendments were also made to the Guidelines to improve the clarity of instructions to institutions in classifying their work into the risk categories and in submitting proposals.

Assessment of proposals

The Scientific Subcommittee reviewed the biosafety aspects of small scale, large scale and deliberate release proposals at its meetings during the year. In addition, matters concerning the application of the *Guidelines for Small Scale Genetic Manipulation Work* and *ad hoc* scientific matters were also considered. The Scientific Subcommittee uses a proactive approach in its consideration of potential risks associated with new genetic manipulation techniques. At meetings during the year, members of the Subcommittee raised specific items and new techniques for discussion. These included new methods to produce recombinant viruses, production of 'knock-in' mice (mice into which a modified copy of one of their genes has been introduced), development of transgenic animals for production of organs for transplantation into humans (xenotransplantation), and development of new sterility systems in transgenic plants.

Proposals for small scale genetic manipulation work are routinely handled by the Chair of the Scientific Subcommittee and the Secretariat, following consultation with the other members of the Subcommittee. Small scale proposals that raise new or complex biosafety issues are further discussed at meetings of the Subcommittee. Advice on proposals falling into Categories A and C of the *Guidelines for Small Scale Genetic Manipulation Work* was usually sent to IBCs about seven weeks after receipt of the proposals.

During the reporting period, 358 small scale proposals were received. Of these, 74 (20.7%) proposals were Category A (proposals for GMAC advice), 271 (75.7%) were Category B (proposals for GMAC notification), and 6 (1.7%) were Category C (proposals for Special Exemption). The remaining 7 proposals (1.9%) were exempt from the Guidelines under the general exemption categories (submission of these proposals to GMAC is not required). The number of small scale proposals submitted to GMAC has increased since the previous reporting period.

Of non-exempt small scale proposals received during the reporting period, 93.6% were carried out under PC2 physical containment, and the remainder under PC3 physical containment. PC2 is the lowest level of physical containment required for genetic manipulation work (unless the work is exempt from the GMAC Guidelines).

Proposals for large scale genetic manipulation work in containment facilities are assessed by the Scientific Subcommittee before being forwarded to the Large Scale Subcommittee. The two large scale proposals assessed during the reporting period were of low risk.

Proposals for the deliberate release of genetically modified organisms into the environment, either in field trials or for general (unrestricted) release are also assessed by the Scientific Subcommittee before their assessment by the Planned Release Subcommittee. As the number of deliberate release proposals submitted to GMAC increases, an increasing proportion of the Scientific Subcommittee's time at meetings is devoted to consideration of these proposals. The Scientific Subcommittee considers potential risks associated with the genetic modification and novel traits of the organism to be released, as well as identifying areas where further information or clarification from the proponent is required. In assessing deliberate release proposals, the Scientific Subcommittee also considers the likely nature of future work that may develop from a particular proposal so that proponents can be alerted to the issues that may need to be addressed at later stages. The Subcommittee's assessment of proposals, together with responses from proponents to requests for further information, is forwarded to the Planned Release Subcommittee, which considers broader environmental issues.

Large Scale Subcommittee

Assessment of proposals

The Large Scale Subcommittee did not meet during the reporting period. The Subcommittee assessed out-of-session two proposals for large scale contained work. The proposals involved production of recombinant canine somatotropin and a cytokine in laboratory strains of *Escherichia coli*. Both proposals were assessed as requiring Good Industrial Large Scale Practice (GILSP) containment, the lowest level of physical containment for large scale genetic manipulation work.

Inspections

The following facilities were inspected and/or certified by GMAC's biocontainment engineer Mr David Martin:

- PC3 laboratory, Royal Perth Hospital, Perth (certified July 1997);
- PC2 large work area, Institute of Medical and Veterinary Science, Adelaide (inspected July 1997 by Associate Professor Langridge);
- PC3 laboratory, University of Melbourne (certified September 1997);
- PC3 laboratory and small animal room, Menzies School of Health Research, Darwin (inspected October 1997);
- PC2 large scale animal facility, CSIRO Australian Animal Health Laboratory, Werribee (inspected October 1997);
- PC2 large work area, St Vincent's Hospital (Garvan Institute), Sydney (inspected December 1997);
- PC3 laboratory, James Cook University, Townsville (inspected February 1998);
- PC3 animal facilities and laboratories, Royal Brisbane Hospital (Herston Medical Research Centre), Herston (inspected February 1998);
- PC3 laboratory, Macfarlane Burnet Centre for Medical Research, Fairfield (inspected April 1998).

Planned Release Subcommittee

Revision of the *Guidelines for the Planned Release of Genetically Manipulated Organisms*

The Planned Release Subcommittee completed its revision of the *Guidelines for the Planned Release of Genetically Manipulated Organisms* and issued the new edition, now titled *Guidelines for the Deliberate Release of Genetically Manipulated Organisms*, in April 1998. The major reason for the revision was to provide clearer procedures and an appropriate format for submission of proposals for general release of genetically modified organisms. Deliberate release proposals that precede general release proposals have been designated by GMAC as 'field trials'. These releases include procedures for minimising the likelihood of persistence of the organism in the environment or dissemination of the organism or its genetic material into the environment beyond the release site. In contrast, 'general release', which includes commercial release, refers to releases which have no provisions in place for limiting the potential for dissemination or persistence of the organism in the environment. GMAC expects to receive increasing numbers of general release proposals, particularly for genetically manipulated crop varieties, in the next few years.

In the new edition of the Guidelines, different sets of questions are posed for proponents of field trials and general releases. For field trials, proponents are required to describe the experimental protocol for the trial, the nature of the trial site, and the monitoring procedures to be used during and after the trial. These issues are not relevant for general releases, since the safety of the modified organism for release will have been established in previous studies.

Another change to the Guidelines requires the submission of a second report to GMAC after the completion of the post-trial monitoring period for each field trial; this report is in addition to the report of the trial that must be forwarded to GMAC when the experimental stage of the trial is complete.

Guidelines for Activities with the Potential for Unintended Release of Genetically Manipulated Organisms

As a result of the increasing commercial use of genetically manipulated crops in other countries, Australia is increasingly likely to import the products of such crops for processing. As described in Chapter 2, the first such genetically modified agricultural commodity to be imported into Australia for commercial processing was soybean seed modified for resistance to the herbicide Roundup®.

In recognition of this new type of activity involving genetically modified organisms, GMAC's Planned Release Subcommittee has produced a new set of Guidelines, *Guidelines for Activities with the Potential for Unintended Release of Genetically Manipulated Organisms*. These Guidelines are intended to capture activities, such as the importation of genetically modified seed for processing, where there is no intention to grow the modified organism in Australia but there is some potential for unintentional release of the organism into the Australian environment (for example, by spillage of seed during transport).

The new Guidelines will also be applicable to other situations where there is no intention for release of a genetically manipulated organism into the environment, but where there is some potential for release to occur. For example, vaccination of human patients with a live microorganism could be such a case.

The new Guidelines were issued in April 1998.

Herbicide-resistant crops

The need for a policy for management of the use of herbicide-resistant crops in Australian agriculture was discussed by the Planned Release Subcommittee at its meetings during the year. GMAC has now received proposals for general release of herbicide-resistant crops (see below). GMAC has advised the proponents for these proposals that it considers that general release of herbicide-resistant crops should not proceed until a coordinated national strategy is in place for the management of such crops. Professor Millis, GMAC's Chair, chaired a working group established by the Standing Committee on Agriculture and Resource Management to prepare good agricultural practices for genetically modified crops and pastures. Management practices for crops modified for resistance to herbicides and for resistance to pests and diseases are addressed in the document (see page 32).

Assessment of proposals

During 1997-98, seventeen new deliberate release proposals, four general release proposals and eighteen extensions to previous proposals were received and assessed.

New proposals

PR-81 (CSIRO Plant Industry - The planned release of INGARD® cotton expressing glyphosate tolerance and CryIIA)

Proposal PR-81 was received in the previous reporting period. It involved a field trial of cotton plants genetically modified for tolerance to the herbicide glyphosate (Roundup®) as well as for resistance to insect pests. A total of approximately 1500 plants in an area under 0.02 hectares was to be planted at the Australian Cotton Research Institute in Myall Vale, NSW.

Successful out-crossing of cotton with wild *Gossypium* species is regarded as unlikely because of genome incompatibility, and no native *Gossypium* species are regarded as weeds in Australia. GMAC's view was that the major biosafety concern with the proposal related to the general issues associated with deployment of herbicide-resistant crops in Australian farming systems. This was not regarded as being a problem for the current proposal because the use of glyphosate in the trial would be no greater than the current level of use on non-transgenic cotton.

GMAC also noted that the use of cotton modified to contain the Bt insecticidal protein on a large scale has the potential to lead to development of resistance to the Bt toxin in insect pests. The use of more than one insect-resistance gene in a single plant, as in this proposal, is one of the strategies that could delay the development of insect resistance. GMAC concluded that the proposal would not propose a significant risk to the environment or the community.

PR-82 (CSIRO Plant Industry - The planned release of transgenic cotton expressing tolerance to the herbicide Basta®)

This proposal, received in the previous reporting period, was for a field trial involving the seed increase and performance evaluation of two lines of cotton that have been genetically modified for tolerance to the herbicide glufosinate (Basta®). The trial involved growing approximately 400 plants in an area under 0.04 hectares at the Australian Cotton Research Institute in Myall Vale, NSW.

GMAC advised that the deliberate release would not pose a significant risk to the community or the environment. The major biosafety concern with the proposal related to the general issues associated with the deployment of herbicide-resistant crops. This was not expected to be a problem for this proposal because the use of Basta® was to be confined to a very small area. As in its assessment of other proposals involving transgenic cotton, GMAC noted that successful out-crossing of cotton with wild related species is unlikely because of genome incompatibility, and that none of these native species are regarded as weeds in Australia.

PR-83 (Deltapine Australia Pty Ltd - Roundup Ready® (RR) and INGARD® (Bt)/Roundup Ready® (RR) seed increase 1997-1998)

The aim of proposal PR-83, received in the previous reporting period, was to increase seed supplies of cotton lines modified for tolerance to the herbicide glyphosate (Roundup®). Some of the plants also contained a gene (Bt) conferring resistance to

insect pests. The proposal involved planting 80 hectares of transgenic cotton over several sites in NSW and Queensland.

GMAC's assessment of the risks associated with the proposal, with regard to both the herbicide-resistance gene and the insect-resistance gene, was similar to its assessment for PR-81 (see above).

GMAC concluded that the trial would not pose a significant risk to the environment or community, with the added precaution that a tarpaulin be used to cover the harvested seed cotton during transport by road to minimise seed escape.

PR-84 (Florigene Ltd - Planned release of carnation modified for resistance to fungal pathogens)

This proposal was received in the last reporting period and involved a glasshouse trial of carnations modified for resistance to fungal attack. The trial involved the planting of modified carnations in greenhouses in three locations in metropolitan Melbourne.

As in its assessment of previous proposals involving genetically modified carnations, GMAC accepted that the probability of gene dispersal from the cultivated carnation is very low. The carnation is a domesticated, cultivated species which produces little or no pollen. During commercial production of cut-flower crops, setting of seed does not occur and, although carnation is vegetatively propagated (by cuttings), it does not spread vegetatively under natural conditions. GMAC requested that the mother plants be killed, using herbicide, before their disposal. GMAC concluded that the trial would not propose a significant risk to the community or the environment.

*PR-85 (AgrEvo Pty Ltd - Small and large scale seed increase of a genetically modified canola (*Brassica rapa*) with a new hybridisation system)*

Under previous deliberate release proposals, AgrEvo carried out field trials of canola plants (*Brassica napus*) modified to provide a new genetic system for making hybrid varieties and for tolerance to the herbicide glufosinate ammonium (Basta® or Liberty®). In this proposal, received in the last reporting period, the same genetic modifications were introduced into canola of the species *Brassica rapa*. The trial involved a total of 450 hectares over several sites in Victoria, Tasmania and South Australia.

GMAC considered that the major risk associated with the large-scale use of the modified plants was the potential for development of herbicide-resistant weeds. Several members of the *Brassica* species are considered to be weeds in Australia and there are reports of cross-pollination between *B. rapa* and other *Brassica* species. There is also potential for canola itself to act as a weed in subsequent crops. Although GMAC recognised that any future unrestricted release of glufosinate ammonium-resistant canola would have the potential to lead to development of resistance to the herbicide in weeds, GMAC considered that this would be agronomically manageable. However, the proponent was advised that the general release of herbicide-resistant crops should only take place in the context of a national coordinated strategy for the deployment of such crops.

PR-86 (CSIRO Entomology - Dispersal ecology of a genetically marked Helicoverpa armigera *singly-enveloped nucleopolyhedrovirus (HaSNPV) in the cotton agro-ecosystem)*

Nucleopolyhedroviruses are insect-specific viruses that have potential as biological insecticides because of their infectivity and pathogenicity to insects. In future, they may be genetically modified by insertion of a toxin gene into the viral genetic material to enable the viruses to kill insect pests more rapidly. Proposal PR-86 was a precursor to this approach. This proposal involved trialling a genetically 'marked' insect-specific nucleopolyhedrovirus to establish the most practical designs for conducting future trials. A maximum of 130 square metres of cotton within a field in Myall Vale, NSW, would be treated with the genetically marked virus.

The parent isolate of the virus (HaSNPV) is already present in the Australian environment. There is no evidence that these types of viruses can cause disease or adverse effects in any vertebrate or plant species. Furthermore, the genetic modifications introduced into the viral genome were 'silent' changes which were not expected to have any significant effect on the phenotype of the virus. GMAC noted that some dispersal of virus from the trial site was possible; however, GMAC's assessment was that dispersal of the marked virus from the release site would not constitute a biosafety hazard. GMAC also considered the possibility that the modified genetic sequences could be transferred to other viruses, but this would not be expected to provide any advantage to the other viruses since the genetic modifications have no phenotypic effects. GMAC concluded that the proposal was of very low risk.

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

The aim of proposal PR-87 was to field trial cotton plants genetically modified for resistance to insect pests under the conditions at Kununurra and Broome, Western Australia. The modified cotton plants contained a gene (Bt) which codes for an insecticidal protein that is toxic to caterpillar pests of cotton. The trial involved the planting of a total of 40 million plants over 390 hectares.

GMAC's view was that the major concern with the proposal related to the potential for emergence of resistance to the Bt toxin in insect pests as a result of large scale release of Bt transgenic cotton. The risk of development of resistance associated with the current trial was minimal as a result of the diversity of alternative crops for insect pests in the trial area. GMAC advised the proponents that it was still reviewing data relevant to the potential for a low rate of successful crossing between cotton and related native species in northern Western Australia and the potential for cotton itself to establish as an environmental weed in that region. The trial was considered to pose no significant risk to the environment or to the community.

PR-88 (CSIRO Plant Industry - Field evaluation of barley yellow dwarf virus-resistant Schooner barley)

The aim of this proposal was to evaluate the resistance of three types of genetically modified barley to barley yellow dwarf virus (BYDV) infection in the field. The trial

involved the planting of 780 plants in two plots of approximately 10 square metres in Hall, ACT.

In its assessment of previous proposals involving plants modified for resistance to viruses by insertion of viral genes, GMAC has considered the possibility of recombination between the introduced viral genes and a different virus infecting the plants, potentially giving rise to a new recombinant virus. GMAC's view was that the use of the transgenic plants would not necessarily introduce any new risks above those that exist during natural viral infection of plants.

Barley is predominantly self-pollinating and cultivated varieties of barley do not have weedy characteristics. Two species of barley grass are weeds in Australia and were present in patches at the trial site, but were prevented from flowering during the trial. As well, hybrids between cultivated barley and barley grasses are sterile. GMAC also 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.

PR-89 (CSIRO Plant Industry - Agronomic and varietal assessment in Northern Australia of transgenic cotton expressing the CryIA(c) and combinations of CryIA(c) and CryIIA delta-endotoxins from Bacillus thuringiensis*)*

The aim of this trial was to begin to evaluate the potential for a cotton industry in northern Australia based on cotton genetically modified for resistance to insect pests. The cotton plants contained either or both of the CryIA(c) and CryIIA genes from the bacterium *Bacillus thuringiensis* (Bt). The trial involved approximately 2.4 million plants over a total area of 64 hectares at several sites in Western Australia and the Northern Territory.

GMAC considered that the proposal would not present any significant risks to the environment or the community. However, before the general release of insect-resistant cotton could be extended to northern Australia, GMAC advised that further data would be required on the potential for transfer of the insect-resistance genes into species related to cotton, particularly those occurring specifically in northern Western Australia. In addition, data on the incidence and persistence of naturalised (feral) cotton in northern Australia, and the consequences of transfer of the insect-resistance genes to these cotton plants, would need to be considered. As in its assessment of previous proposals involving the release of insect-resistant cotton, GMAC noted the need for resistance management strategies to delay the emergence of insect pests with resistance to the Bt toxin.

PR-90 (AgrEvo Pty Ltd - Development of herbicide tolerant hybrid Brassica juncea*)*

The Indian mustard plant (*Brassica juncea*) is closely related to commercially grown canola (*Brassica napus*). Features of non-canola quality *B. juncea* lines, such as greater tolerance to heat and drought and early maturity, are desirable in canola quality breeding. The aim of this release was to trial in the field a new system for making hybrids in suitably modified Indian mustard plants. The hybridisation system comprises two genetically modified mustard lines; a male sterile line and a fertility restorer line. The mustard lines also contain a gene for resistance to the herbicide

glufosinate ammonium. The trial involved an area of approximately 11 hectares in Wagga Wagga, NSW.

GMAC's major concern relating to the development of herbicide-resistant crops is the potential for emergence of herbicide-resistant weeds. GMAC noted that *Brassica juncea* itself is identified as a weed species in Australia. There is also some potential for gene transfer from the transgenic plants to other related weedy species, and for selection of herbicide-resistant weeds in the crop as a result of increased use of the herbicide. GMAC's assessment was that any future unrestricted release of glufosinate ammonium-resistant *B. juncea* would be likely to lead to development of glufosinate ammonium resistance in weeds in the long term and should only occur in the context of a national strategy for use of herbicide-resistant crops.

*PR-91 (Tasmanian Department of Primary Industry and Fisheries - Planned release of GMO oilseed poppy (*Papaver somniferum*))*

Oilseed poppy (*Papaver somniferum*) is grown commercially for the production of alkaloids for the pharmaceutical market. The proponent's ultimate aim is to modify the pathway of alkaloid production in oilseed poppy plants to cause increased alkaloid output. As a precursor to this work, the poppy plants trialled under this proposal had been modified by insertion of marker genes that enable the plants to be distinguished from unmodified plants. The trial involved 500 plants in Sassafras, Tasmania.

Several members of the *Papaver* genus are weed species in Tasmania. The proponent claimed that there were no known reports of natural cross-pollination between *P. somniferum* and any of the species present in Tasmania except for one weed species which is relatively rare in the regions for growing oilseed poppy. GMAC noted that the data to be collected on pollen movement and crossing with wild species would provide an important basis for future work. While GMAC's view was that the current proposal did not pose any significant biosafety risks, GMAC advised the proponent that new issues would be raised by future proposals involving poppy plants with modified alkaloid pathways. For example, information on whether the species with which *P. somniferum* can cross also possess these alkaloid pathways would be relevant.

PR-92 (CSIRO Plant Industry - Field evaluation of genetically engineered barley)

The aim of this release was to assess the field performance of two lines of barley genetically modified for malting quality characteristics. The first line of modified barley contained an additional copy of a barley gene encoding the starch-degrading enzyme, α-amylase, and the second line contained a gene encoding a hybrid bacterial heat-stable enzyme, β-glucanase. The trial involved 400 plants in an area of 33 square metres at Ginninderra Experiment Station in Hall, ACT.

Barley is predominantly self-pollinating and cultivated varieties of barley do not have weedy characteristics. Two species of barley grass are weeds in Australia and were present in patches at the trial site, but were prevented from flowering during the trial. As well, hybrids between cultivated barley and barley grasses are sterile. Some of the barley plants trialled in this proposal contained a marker gene for resistance to the herbicide glufosinate (Basta®). However, the development of herbicide-resistant

barley was not an aim of the release and the herbicide would not be used in the trial. GMAC also 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.

PR-93 (AgrEvo Pty Ltd - Development of fungal disease resistant canola cultivars)

The canola lines (*Brassica napus*) that were released in this trial were genetically modified for tolerance to fungal diseases such as blackleg and Sclerotinia. In addition, some of the plants were also modified for resistance to the herbicide glufosinate-ammonium. The release involved a total area of 20 hectares over four sites in NSW, Victoria and Tasmania.

As in its assessment of a previous proposal for a field trial of canola plants modified for resistance to fungal diseases, GMAC advised that further information would be required before the proponents proceeded to general release of the canola plants. In particular, information would be required on whether the fungal-resistance genes could confer a fitness advantage on related species into which the genes might transfer, increasing the potential for these species to become weeds in cultivated, disturbed or natural environments. With regard to the use of a herbicide-resistance gene in some of the canola plants, GMAC considered that some potential for successful crossing of *B. napus* with weedy relatives existed. GMAC's conclusion was that any future unrestricted release of glufosinate-ammonium-resistant canola would be likely to lead to development of glufosinate-ammonium resistance in weeds in the long term and that such a release should only take place in the context of a national coordinated strategy for the deployment of herbicide-resistant crops.

PR-94 (CSIRO Plant Industry - Winter seed increase of INGARD® cotton expressing glyphosate tolerance)

CSIRO Plant Industry submitted a proposal for a field trial of cotton plants that were genetically modified for tolerance to the herbicide glyphosate (Roundup®) as well as for resistance to insect pests. Both the herbicide-resistance and the insect-resistance genes have been the subject of previous deliberate release proposals involving cotton. The trial involved 400 000 plants in a total area of 4 hectares in Kununurra, Western Australia.

GMAC's assessment of the risks associated with this proposal was similar to its assessment for previous similar proposals. Biosafety issues raised in GMAC's advice related to the potential for out-crossing of cotton with native species in northern Western Australia, the need for management strategies to delay insect resistance to the Bt toxin, and the need for management of herbicide-resistant crops.

PR-95 (University of Queensland - Field test of pineapple plants modified to control flowering and ripening)

The University of Queensland, in conjunction with Golden Circle Ltd and the Queensland Department of Primary Industries, submitted a proposal for a field trial of genetically modified pineapple (*Ananas comosus*) plants. The plants were modified to

allow improved control over their flowering and fruit ripening characteristics by the introduction of one of two genes coding for enzymes that already occur in pineapple. The trial involved the planting of 2200 plants in an area of 0.1 hectares in Cleveland, Queensland.

GMAC's view was that dispersal of the modified pineapple plants or their genetic material beyond the trial site was very unlikely and would, in any case, be unlikely to have adverse consequences. In addition to the isolation of the trial site from commercial pineapple plantations, fertility in commercially grown cultivars of pineapple is very low. *Ananas comosus* will readily hybridise with other species within the *Ananas* genus, but no members of this genus are considered to be weeds in Australia. Although the modified plants contained a marker gene for resistance to the herbicide chlorsulfuron, the herbicide was not intended for use during the field trial. Chlorsulfuron is not used in commercial pineapple plantations and is not registered for use on pineapple crops. GMAC reminded the proponent that consultation with the Australia New Zealand Food Authority would be necessary before the fruit from the plants could be made available for human consumption.

*PR-96 (CSIRO Plant Industry - Field evaluation of transgenic lines of field pea (*Pisum sativum *L.) for resistance to Ascochyta blight*

The aim of this trial was to field-test the levels of resistance of two lines of field pea plants modified for resistance to the fungal disease Ascochyta blight. Ultimately, field peas carrying modified versions of the fungal-resistance genes may be used in cropping situations in Australia and overseas. The field trial was located in Medina, Western Australia, where up to 200 field pea plants were to be planted.

In its assessment of previous proposals involving genetically modified field peas, GMAC has noted that the likelihood of the modified plants hybridising with surrounding plants is low. The proponent presented further evidence in this proposal to support the lack of out-crossing of field peas under Australian conditions. GMAC reminded the proponent that consultation with the Australia New Zealand Food Authority, for use of the peas as a human food, and relevant State agencies, for use of the peas in stockfeed, would be required before ultimate general release of the genetically modified pea plants. GMAC also advised that further data would be required on possible effects of the genetic modification on soil microbiology (particularly the soil surrounding the roots of the plants) before a general release was considered. The modified peas also contained a gene for resistance to the herbicide Basta® as a selectable marker. Basta® is currently not registered for use on peas. GMAC reminded the proponent of its policy that ultimate general release of herbicide-resistant crops should only take place in the context of a national strategy for the deployment of such crops.

PR-97 (CSIRO Plant Industry - Genetically enhanced subterranean clover expressing sunflower seed albumin)

The clover plants released in this trial were modified to contain a protein, sunflower seed albumin, that is rich in sulfur-containing amino acids and is resistant to breakdown in the rumen of sheep. Wool growth in sheep is limited by the supply of

sulfur-containing amino acids available in the diet. This proposal was a continuation of field trials carried out under previous deliberate release proposals except that the lines of clover used in this proposal expressed sunflower seed albumin at higher levels. As well, the herbicide-resistance gene used as a marker in the previous proposals had been replaced with an antibiotic-resistance gene. The trial involved the planting of 9000 clover plants in an area of 100 square metres at Medina, Western Australia.

GMAC's assessment was that the proposed field trial would not present any significant risks to the environment or the community. GMAC has previously agreed that the risk of escape of the introduced genes by out-crossing of the subterranean clover with other plants of the same or different species is low. The very low rate of out-crossing was confirmed in studies conducted under previous field trials of transgenic subterranean clover.

Extensions to previous proposals

PR-36X(3) (CSIRO Division of Plant Industry - The planned release of transgenic cotton expressing the CryIA(c) and CryIIA delta-endotoxins from Bacillus thuringiensis - *breeding plots and preliminary multi-site evaluation and seed increase)*

The aim of this extension to the original proposal was to examine the field performance of cotton plants, genetically modified for resistance to insect pests, in controlling caterpillar pests of cotton over a variety of sites and environments. The trial took place over 16 sites comprising a total area of under 40 hectares in the cotton growing areas of northern NSW and Queensland.

PR-47X(3) (Deltapine Australia Pty Ltd - Winter nursery seed increase of Bt transgenic cotton plants, 1998)

This extension involved the increase of seed stocks of cotton genetically manipulated for resistance to insect pests. The cotton was grown over 10 hectares in Kununurra, Western Australia.

PR-49X(2) (CSIRO Plant Industry - Production of genetically engineered lupin seeds expressing sunflower seed albumin)

The lupins in this trial were genetically modified for increased content of methionine (a nutritionally essential amino acid), and hence improved nutritive value, in their seed. It is expected that sheep fed on the high-methionine lupins will produce more wool than sheep fed the unmodified variety. Approximately 800 000 lupin plants in an area of 2 hectares were grown for seed increase in Wongan Hills, Western Australia.

PR-51X(2) (Deltapine Australia Pty Ltd - Bt agronomic selection and yield trials 1997-1998)

The aim of this extension was to continue the agronomic evaluation of new breeding lines of cotton that had been modified for resistance to insect pests. Various trials of up to 4 hectares in size were planted at up to ten sites in the major cotton-producing regions of NSW and Queensland, as well as 10 hectares at Goondiwindi in the Macintyre Valley.

PR-51X(3) (Deltapine Australia Pty Ltd - Bt agronomic selection and yield trials 1998-1999)

This extension continued the evaluation of cotton modified for resistance to insect pests undertaken under previous proposals. A total of 28 hectares of cotton was planted over eleven sites in Queensland and NSW.

PR-52X(2) (Deltapine Australia Pty Ltd - Progeny selection and screening of Roundup Ready® (RR) transgenic cotton plants 1997-1998)

The aim of this extension was to continue the agronomic evaluation and yield testing of cotton lines which had been modified for tolerance to the herbicide glyphosate (Roundup®). Trials of up to 4 hectares in size were planted at 10 sites in the major cotton-producing regions of NSW and Queensland. As well, a total of 10 hectares was planted at Goondiwindi in the Macintyre Valley.

PR-52X(3) (Deltapine Australia Pty Ltd - Progeny selection and screening of Roundup Ready® (RR) transgenic cotton plants 1998-1999)

This extension continued the evaluation of cotton modified for tolerance to the herbicide glyphosate (Roundup®) undertaken under previous proposals. A total of eleven sites of 50 hectares and one site of 62 hectares were planted in the cotton growing regions of NSW and Queensland.

PR-54X(2) (CSIRO Plant Industry - Proposal for the planned release of genetically engineered cotton plants with tolerance to spray drift damage caused by the herbicide 2,4-D)

This extension continued the examination of field performance of cotton plants modified for resistance to the herbicide 2,4-D. A total of approximately 50 000 plants in an area under 0.4 hectares were trialled in Myall Vale and Premer, NSW.

PR-55X(2) (CSIRO Plant Industry - The planned release of transgenic cotton expressing tolerance to the herbicide glyphosate)

This extension continued the examination of field performance of cotton plants modified for tolerance to the herbicide glyphosate (Roundup®). As well, some integrated weed management options using the transgenic plants were examined. Approximately 5.5 million plants, in an area under 55 hectares, were planted on six commercial cotton farms in NSW and Queensland, as well as at the Australian Cotton Research Institute in Myall Vale, NSW.

*PR-59X (CSIRO Plant Industry - Field evaluation of a transgenic line of field pea (*Pisum sativum *L.) with enhanced grain sulfur levels)*

Under proposal PR-59, CSIRO Plant Industry evaluated the field performance of peas which had been modified for improved nutritional quality by raising the level of sulfur-containing amino acids in the pea seeds. This extension aimed to continue the evaluation of the modified peas in the field as well as using the seed produced in animal feeding trials. Approximately 4500 plants in an area of 150 square metres were planted at the Agricultural Research Institute in Wagga Wagga, NSW.

PR-60X(2) (Monsanto Australia Ltd - A planned release of Brassica napus*, variety laurate canola)*

Under this extension a total of approximately 12 hectares of canola, genetically modified to have an altered fatty acid composition in the seed, was planted over several sites in South Australia and NSW. The aim of the extension was threefold: (i) to continue the evaluation of the agronomic performance of the modified canola; (ii) to assess compositional quality of the canola grown under commercial conditions; and (iii) to screen the canola for resistance to blackleg disease.

PR-62X(2) (AgrEvo Pty Ltd - Development of glufosinate ammonium tolerant canola cultivars)

The aim of this extension was to allow nursery, small scale and large scale seed production from lines of canola *(Brassica napus*) that had been genetically modified for tolerance to the herbicide glufosinate ammonium. The trial comprised approximately 0.3 hectares of modified canola grown over five sites on privately owned properties extending from southern Victoria to northern Tasmania and South Australia.

PR-62X(3) (AgrEvo Pty Ltd - Development of glufosinate ammonium tolerant canola cultivars)

This extension aimed to complete the breeding trials initiated under the original proposal. These involved screening genetically modified canola lines in the field for a range of traits, and generating field data for the purposes of registration (with the National Registration Authority for Agricultural and Veterinary Chemicals) of glufosinate ammonium for selective use in canola. The canola lines were genetically modified for tolerance to the herbicide glufosinate ammonium. The trial involved a total of approximately 12 hectares of modified canola grown over several sites at Toowoomba and Gatton in Queensland, and Guyra in NSW.

*PR-63X(2) (AgrEvo Pty Ltd - Small and large scale parent and hybrid seed increase of a genetically modified canola (*Brassica napus*) with a new hybridisation system)*

The aim of this extension was to allow nursery, small scale and large scale seed production from lines of canola (*Brassica napus*) that had been genetically modified

to provide a new system for making hybrid varieties. The canola plants were also modified for tolerance to the herbicide glufosinate ammonium. The trial involved the planting of 136 hectares of canola over 30-40 sites on privately owned properties extending from southern Victoria to northern Tasmania and South Australia.

PR-69X (CSIRO Plant Industry - The planned release of transgenic cotton expressing tolerance to the herbicide bromoxynil)

This extension continued the examination of the fate of the herbicide bromoxynil applied to cotton plants modified for resistance to this herbicide, and began studies of integrated weed management strategies. For this proposal, 50 000 modified cotton plants were planted in an area under one hectare at the Australian Cotton Research Institute at Myall Vale, NSW.

PR-71X (Deltapine Australia Pty Ltd - Winter nursery seed increase of Roundup Ready® transgenic cotton plants, 1998)

This extension involved carrying out similar trials to those undertaken in the original proposal to increase seed stocks of cotton modified for tolerance to the herbicide glyphosate (Roundup®). The proposal involved the planting of 5 hectares of modified cotton at Kununurra in Western Australia.

PR-77X (Monsanto Australia Ltd - Planned release of transgenic canola expressing tolerance to the herbicide glyphosate)

Under this extension, canola lines imported from Canada and modified for tolerance to the herbicide glyphosate (Roundup®) were assessed for adaptation to the Australian environment and tolerance to blackleg disease. As well, studies to measure residues of the herbicide and its metabolites in the plant and in unprocessed commodities derived from canola were continued. In this trial, approximately 2 700 000 plants were grown over a total of 15 hectares at sites in Millicent in South Australia, Wagga Wagga and Guyra in NSW, Gatton in Queensland, and Horsham and Lake Bolac in Victoria.

PR-83X (Deltapine Australia Pty Ltd - Roundup Ready® (RR) and INGARD® (Bt)/Roundup Ready® (RR) seed increase 1998-1999)

The aim of this extension was to continue the agronomic evaluation and seed increase of several lines of cotton which had been modified for tolerance to the herbicide glyphosate (Roundup®), as well as lines expressing the Roundup®-tolerance gene in combination with a gene conferring resistance to insect attack. Eleven sites of 46 hectares were planted in cotton-growing regions of Queensland and NSW. In addition, 52 hectares were also planted at Goondiwindi in the Macintyre Valley.

General release proposals

GR-4 (Monsanto Australia Ltd - Evaluation of Roundup Ready® cotton grown under commercial use conditions)

This proposal was submitted as a general release for cotton modified for tolerance to the herbicide glyphosate (Roundup®). Some of the cotton lines also contained a gene conferring resistance to insect pests.

GMAC's major concern related to the potential for emergence of herbicide-resistant weeds. GMAC considered that it would be premature for an unrestricted release of a herbicide-resistant crop to take place until a national strategy for the deployment of herbicide-resistant crops was in place. GMAC also advised the proponent that, before general release of Roundup Ready® cotton, data would be required on the incidence of naturalised (feral) cotton as a weed in non-agricultural areas and details of methods used to control such plants, together with a management plan for control of herbicide-resistant feral cotton that might arise following general release.

GMAC therefore advised that this release should take place under 'planned release' conditions, observing similar requirements to those that have applied to previous field trials. This proposal was renumbered as PR-83X(2).

GR-5 (AgrEvo Pty Ltd - Release of glufosinate ammonium tolerant hybrid and open-pollinated canola cultivars)

A new system, trademarked as SeedLink, has been developed which allows the production of pure hybrid seed. The SeedLink system ensures that plants cross-pollinate rather than self-pollinate. To ensure that canola (*Brassica napus)* plants cross-pollinate, a bacterial gene conferring male-sterility has been introduced into the plants. A second line of canola contains a bacterial gene that restores fertility, so that the hybrid formed when the two lines cross is fertile. A gene for resistance to the herbicide glufosinate ammonium has also been transferred into the canola plants.

GMAC's major concern with this proposal for general release of the transgenic canola related to the potential for emergence of herbicide-resistant weeds. There is some potential for gene transfer from the transgenic plants to other related weedy species, and for selection of herbicide-resistant weeds in the crop as a result of increased use of the herbicide. GMAC's assessment was that any unrestricted release of glufosinate ammonium-resistant canola would be likely to lead to development of glufosinate ammonium resistance in weeds in the long term. GMAC considered that it would be premature for an unrestricted release of a herbicide-resistant crop to take place until a national strategy for the deployment of such crops is in place.

GMAC therefore advised that this proposal should take place under 'planned release' conditions, observing the requirements that have applied to previous field trials of canola. This proposal was renumbered as PR-63X(3).

GR-6 (CSIRO Plant Industry - Field evaluation of transgenic lines of peas with resistance to pea weevil)

CSIRO Plant Industry has developed field peas that are resistant to attack by the pea weevil (*Bruchus pisorum*). Pea weevil is one of two major insect pests of peas that cause major losses in pea production in Australia.

In its assessment of the proposal, GMAC gave detailed consideration to the question of whether the release should be assessed as a field trial or as a general release. GMAC's conclusion was that further information in a number of areas was required before general release of the transgenic peas. The possibility of anti-nutritional effects of the introduced gene will be examined further by the proponents in chicken-feeding trials, which will use the seed generated in the current proposal. GMAC also advised that an integrated pest management strategy, including an assessment of possible effects of the pest-resistance gene on insect ecology, would be required before general release.

GMAC therefore advised that this proposal should take place under 'planned release' conditions, observing the requirements that have applied to previous field trials of field peas. This proposal was renumbered as PR-80X.

GR-7 (CSIRO Plant Industry - Field evaluation of bromoxynil-tolerant subterranean clover)

Subterranean clover has a moderate level of natural tolerance to the herbicide bromoxynil and there is extensive use of bromoxynil for the control of broad-leafed weeds in subterranean clover-based pastures. CSIRO Plant Industry has developed subterranean clover plants with an increased tolerance to the herbicide bromoxynil. This modification would enable farmers to use the herbicide at an earlier stage in the growing season when lower rates of herbicide are sufficient to kill the broad-leafed weeds.

As in its assessment of proposal GR-6, GMAC's conclusion was that further information was required before general release of the transgenic subterranean clover. For example, an information package would be required detailing an integrated weed management strategy for use of the transgenic plants. In addition, GMAC considered that it would be premature for an unrestricted release of a herbicide-resistant crop to take place until a national strategy for the deployment of such crops was in place.

GMAC therefore advised that this proposal should take place under 'planned release' conditions, observing the requirements that have applied to previous field trials of subterranean clover. This proposal was renumbered as PR-58X(2).

Other proposals received

Six new proposals and ten extensions to previous proposals were received late in the reporting period and will be assessed in the next reporting period. These proposals were:

- PR-98 (Deltapine Australia Ltd - Queensland cotton: Flinders River cotton project 1998-99)

- PR-99 (CSIRO Plant Industry - Field evaluation of transgenic cotton for enhanced tolerance to waterlogging)
- PR-100 (CSIRO Plant Industry - Evaluation of subclover stunt virus promoters under field conditions)
- PR-101 (CSIRO Plant Industry - Genetic engineering of Verticillium wilt tolerance of cotton)
- PR-102 (CSIRO Plant Industry - Transgenic wheats with modified grain qualities)
- PR-103 (CSIRO Plant Industry - Field trial of transgenic poppy, *Papaver somniferum*)
- PR-36X(4) (CSIRO Plant Industry - The planned release of transgenic cotton expressing the CryIA(c) and CryIIA delta-endotoxins from *Bacillus thuringiensis*: Breeding plots and preliminary multi-site evaluation and seed increase)
- PR-36X(5) (Cotton Seed Distributors Ltd - The field testing of cotton expressing CryIIA and CryIA(c) (INGARD®))
- PR-54X(3) (CSIRO Plant Industry - Proposal for the planned release of genetically engineered cotton plants with tolerance to spray drift damage caused by the herbicide 2,4-D)
- PR-55X(3) (CSIRO Plant Industry - The planned release of transgenic cotton expressing tolerance to the herbicide glyphosate)
- PR-55X(4) (Cotton Seed Distributors Ltd - The seed increase of transgenic cotton expressing tolerance to the herbicide glyphosate)
- PR-62X(4) (AgrEvo Pty Ltd - Development of glufosinate ammonium tolerant canola cultivars)
- PR-69X(2) (CSIRO Plant Industry - The planned release of transgenic cotton expressing tolerance to the herbicide bromoxynil)
- PR-82X (CSIRO Plant Industry - The planned release of transgenic cotton expressing tolerance to the herbicide Basta®)
- PR-85X (AgrEvo Pty Ltd - Small and large scale seed increase of a genetically modified canola (*Brassica rapa*) with a new hybridisation system)
- PR-94X (Cotton Seed Distributors Ltd - The seed increase of INGARD® cotton expressing glyphosate tolerance)

Public Liaison Subcommittee

The Public Liaison Subcommittee did not meet during this reporting period.

GMAC Membership

Dr Stephen Goodwin and Dr Eric Haan completed their terms of appointment during the reporting period. Professor Staffan Kjelleberg and Dr Robyn van Heeswijck were not available to accept reappointment to the Committee when their terms of appointment expired.

The Minister for Industry, Science and Tourism, the Hon John Moore MP, appointed three new members to GMAC for a two-year term in early 1998. Dr Susan Barker, a lecturer in plant science at the University of Western Australia, has expertise in plant molecular biology and genetics. Dr John Manners, Senior Research Scientist at CSIRO Tropical Agriculture, is an expert in plant molecular biology and molecular plant-microbe interactions. Associate Professor Richard Roush is the Director of the Cooperative Research Centre for Weed Management Systems. His major research interest is the genetics and management of insect and weed resistance to insecticides and herbicides, and also the biological control of weeds.

Minister Moore also reappointed several members for a further period of two years. The members who accepted reappointment were Dr Annabelle Bennett, Professor Ashley Dunn, Associate Professor Peter Langridge, Professor Nancy Millis, Dr John Oakeshott, Dr Ian Parsonson and Professor Jim Pittard.

Consultation

Other Government Agencies

The Secretariat continued its liaison with relevant Commonwealth Government agencies, including the National Registration Authority for Agricultural and Veterinary Chemicals, the Australia New Zealand Food Authority and the Australian Quarantine and Inspection Service. Consultation on deliberate release proposals also took place with State, Territory and local government agencies.

SCARM Working Group

GMAC's Chair, Professor Millis, chaired a Working Group established by the Standing Committee on Agriculture and Resource Management (SCARM) to prepare guidelines for the sustainable development and use of genetically modified crops and pastures in Australian agriculture. The Working Group also included representatives from CSIRO, the National Farmers' Federation, SCARM, the Grains Research and Development Corporation and the Department of Primary Industries and Energy. The Working Group met three times during the reporting period.

As a result of these discussions, a document was drafted ('Points to be considered in developing genetically modified crops and pastures for Australian agriculture') that was circulated for comment to a wide audience in April 1998. The document set out a suggested set of procedures to be followed by organisations developing genetically modified crops or pastures for general release in Australia. The major aims of these procedures were to guide plant breeders and biotechnologists in the most appropriate genes to incorporate into agricultural plants, and to provide a mechanism to educate farmers and their consultants in best practices in the use of these genetically modified plants.

International negotiations

GMAC's Secretary, Dr Faragher, participated in an Interdepartmental Committee Subgroup on biosafety, chaired by the Department of Foreign Affairs and Trade. The Subgroup provides the focus for discussions on the development of an international protocol on biosafety under the Convention on Biological Diversity. The emphasis of the protocol is the safe transboundary movement of genetically modified organisms.

Conference Attendance

Members of GMAC and the Secretariat attended a number of scientific conferences. GMAC's Chair, Professor Millis, attended an ASEAN Workshop on 'Regulations for agricultural products derived from biotechnology' in Singapore in April 1998. She presented a paper on Australia's experience with the regulation of biotechnology and chaired a session on international perspectives.

Professor Millis also addressed a range of audiences on topics related to GMAC's work, in addition to presenting papers at conferences and seminars.

Non-Government Agencies

GMAC received submissions on deliberate release proposals from a number of non-government organisations and individuals.

During the year, the Secretariat and the Chair met with representatives from industry and from regulatory agencies in other countries to discuss the GMAC system.

IBC Liaison

Members of several IBCs visited the GMAC Secretariat for general discussions during the reporting period.

A half-day seminar for members of IBCs in New South Wales was held in Sydney on 25 March 1998. The aims of the seminar were to remind the IBCs of their roles and responsibilities, to inform them of new developments and changes to the Guidelines, and to provide an opportunity for IBC members to comment on the operation of the regulatory system. Speakers at the seminar were Professor Millis (GMAC's Chair), Professor Pittard (Chair of the Scientific Subcommittee) and Dr Faragher (GMAC's Secretary). The seminar was attended by members from most of the IBCs operating in New South Wales. Attendees provided positive feedback on the seminar to GMAC and the Secretariat. It is intended that similar seminars will be arranged for the IBCs in other States.

Publications

GMAC issues four sets of Guidelines covering the development and use of genetically modified organisms. In April 1998, GMAC issued revised editions of its *Guidelines for Small Scale Genetic Manipulation Work, Guidelines for the Deliberate Release of Genetically Manipulated Organisms* and *Guidelines for Activities with the Potential for Unintended Release of Genetically Manipulated Organisms.*

Public Information Sheets are issued on deliberate release proposals received and assessed by GMAC. GMAC also publishes a booklet on safety practices for the use of

research workers and general information on genetic manipulation for use by students. The GMAC newsletter was not issued during the reporting period. An Annual Report for the period 1996-97 was produced.

GMAC's publications are listed in Appendix 9.

GMAC also maintains a home page on the World Wide Web. Most of GMAC's publications can be accessed from the home page at:

http://www.dist.gov.au/science/gmac/gmachome.htm

4. OPERATION OF INSTITUTIONAL BIOSAFETY COMMITTEES

Overview

Any institution or organisation that conducts genetic manipulation work falling under the scope of the GMAC Guidelines, including work with imported genetically modified organisms, or release of genetically modified organisms into the environment or for sale, is expected to abide by the relevant GMAC Guidelines. It is required to set up an IBC or place its work under the supervision of an existing IBC, provide the resources and facilities necessary for safe work, and ensure that workers are adequately trained and supervised.

IBCs monitor day-to-day work in the institutions carrying out genetic manipulation work and ensure that the GMAC Guidelines and GMAC's advice on specific projects are observed. They assess and review all proposals involving the use of genetic manipulation techniques and, where required by the GMAC Guidelines, submit them to GMAC for assessment. Proposals for small scale work falling within the low-risk Category B of the *Guidelines for Small Scale Genetic Manipulation Work*, and proposals that are exempt from the GMAC Guidelines, can be approved by the IBC without GMAC advice. All other small scale proposals, as well as proposals for large scale work and deliberate release work, require GMAC advice to the IBC before the work can commence. (IBCs submitting proposals to GMAC may classify parts of them as 'Commercial-in-Confidence'. Such information is made available only to GMAC members and the Secretariat, who are required to maintain confidentiality.)

As well as reviewing and approving proposals, IBCs certify PC2 physical containment facilities (including laboratories, animal houses and glasshouses). They regularly inspect all containment facilities to ensure that the facilities continue to meet GMAC's requirements, that laboratory workers have sufficient training, and that the workers comply with the Guidelines and with GMAC advice. IBCs maintain a register of work, personnel involved and containment facilities. They are also required to provide an annual report to GMAC.

IBCs are of crucial importance in the overall advisory system. Surveillance by IBCs has the advantage of decentralised administration based upon local knowledge and resources, and places responsibility and costs for monitoring on the institution that employs the scientists. Readers are referred to the GMAC *Guidelines for Small Scale Genetic Manipulation Work*, April 1998, for a complete description of the roles and responsibilities of IBCs.

There are 85 IBCs operating in Australia. A list of IBCs, their Chairs and the number of current proposals supervised by each IBC appears in Appendix 4.

Changes in IBCs

Several new IBCs registered with GMAC during the reporting period. These were:

- University of Southern Queensland;

- Cotton Seed Distributors;
- Monsanto Australia Limited;
- Queensland Health; and
- ForBio Research.

There were a number of other changes to IBCs during the reporting period:

- the IBC of CSIRO Tropical Crops and Pastures amalgamated with the IBC of CSIRO Tropical Animal Production to form the CSIRO Tropical Agriculture IBC;
- the IBC of Unifoods Pty Ltd disbanded;
- the IBC of Seedex Pty Ltd disbanded; and
- the IBC of Cyanamid Websters Pty Ltd disbanded.

Observance of the Guidelines

GMAC reports to the Minister any breaches of the Guidelines which directly compromised safety, where supervision of the work was unsatisfactory, or when an accident involving genetic manipulation occurred which might jeopardise the health of workers.

During the reporting period, the IBCs of the University of Western Australia and BresaGen notified GMAC of breaches of GMAC guidelines involving their institutions.

Two incidents of unauthorised release of transgenic lupins modified for herbicide resistance occurred at a Western Australian Research Station. The first incident was regarded by GMAC as a serious breach of the Guidelines. Planting of transgenic lupins was carried out intentionally, before receipt of GMAC advice on the proposal and without the approval of the IBC. The proponent was informed that such unapproved releases must not occur in the future. However, since the conditions used for the work were in accordance with subsequent GMAC advice, destruction of the crop was not required by GMAC.

Poor communication between collaborating researchers resulted in the second incident, in which a transgenic lupin crop was inadvertently planted. The crop was destroyed as soon as the error was realised, and the surrounding area sprayed with herbicide. The IBC advised that appropriate monitoring of the crop site for volunteer plants would be undertaken, in accordance with GMAC's advice for deliberate releases of transgenic lupins. A series of procedural reforms have been initiated to ensure that similar breaches do not occur again.

BresaGen reported the unauthorised removal of a transgenic piglet from facilities overseen by the BresaGen IBC. The piglet was transported to St Vincent's Hospital in Melbourne, where it was euthanased, and the carcass was incinerated. Although appropriate containment was used, the incident occurred without the approval or knowledge of the IBCs of BresaGen or St Vincent's Hospital. St Vincent's Hospital staff are now fully aware that appropriate IBC approval must be obtained for this type of work in future. The BresaGen IBC has requested a report on the incident with recommendations for procedural changes to ensure that incidents of this type are not repeated.

Report received on a previous incident

During the previous reporting period, GMAC was informed by the IBCs of the University of Queensland and the Queensland Department of Primary Industries of a breach of the GMAC Guidelines involving these institutions. The incident involved genetic manipulation of a plant pathogen (*Fusarium oxysporum*) without notification to the relevant IBCs, and use of the genetically manipulated organism to inoculate bananas in a non-certified glasshouse. The genetic modification involved insertion of a 'marker gene' (encoding β-glucuronidase). The work also contravened the conditions of a quarantine entry permit.

The Queensland Department of Primary Industries, the University of Queensland and the Australian Quarantine and Inspection Service carried out an investigation of the incident. As a result of this inquiry, the University of Queensland has accepted a series of recommendations that are designed to ensure that breaches of GMAC Guidelines and quarantine regulations do not occur in the future. The nature of the genetic modification of the *Fusarium* strain was such that the modification did not present risks to human health or the environment.

Database records

GMAC maintains a record of IBC membership, certified containment laboratories and proposals (both current and non-current) on a database. A computer print-out of the details for each institution conducting genetic manipulation work is sent to the IBC every year for amendment. The completed return of the amended print-out by the IBC fulfils the IBC annual reporting requirements under the GMAC guidelines.

5. ADMINISTRATION

Finance

GMAC is funded by appropriation; it receives no funding from other sources, nor does it have a granting function. No revenue is generated.

The total appropriation for running costs (nearest thousand dollars) for 1997-98 was $437 000. The actual expenditure outcome for the year was $215 000 (salaries) and $222 000 (administrative expenses).

Members are paid according to Remuneration Tribunal Determination 16 of 1997.

Staffing

At 30 June, the Secretariat had four full-time staff members: two scientists and two administrative staff members. The Secretariat is located in the Department of Industry, Science and Tourism. Details of the Secretariat are provided in Appendix 8.

Auditor-General's Reviews

There have been no Auditor-General's reports affecting GMAC in the reporting period.

Freedom of Information Act 1982 (FOI)

One request was made under FOI in the previous reporting period. It was still being processed at the end of this reporting period.

APPENDIX 1. HISTORY

Historical background

Recombinant DNA technology is generally recognised as a very powerful research tool. In the early 1970s, when the technology was being developed, some scientists became concerned that it might be possible to create hazardous microorganisms using recombinant DNA techniques. The scientists themselves called for an investigation of the safety of the technique. Molecular biologists from around the world, including two from Australia, met for this purpose at Asilomar in California in 1975. The outcome of the Asilomar meeting was that scientists decided to continue recombinant DNA research using precautions to contain any possible hazards.

In response to this conclusion, the Australian Academy of Science set up a Committee on Recombinant DNA (ASCORD) which drew up the first Australian guidelines for these techniques in 1975. In October 1981 the Recombinant DNA Monitoring Committee (RDMC) was established in the Department of Science by the Australian Government. This committee produced three sets of guidelines: for small scale contained work (volumes less than 10 litres), large scale contained work (volumes greater than 10 litres, usually industrial) and for planned releases of live organisms to the environment.

In 1986, the RDMC presented a report, *Monitoring Recombinant DNA Technology: A Five Year Review*, to the then Minister for Industry, Technology and Commerce. This report addressed the need for continued monitoring. It concluded that, since there were some areas in which possible hazards could be seen and novel systems were constantly being introduced, the technology should continue to be monitored to ensure that appropriate safety standards and practices were adopted. The review also concluded that the non-statutory monitoring system had been effective and was likely to remain so for at least the next five years.

In September 1987, the establishment of the Genetic Manipulation Advisory Committee was announced by the then Minister for Industry, Technology and Commerce to replace the RDMC, with somewhat wider terms of reference. Responsibility for GMAC was transferred to the Minister for Administrative Services in July 1988. In August 1988, members were appointed to GMAC by the then Minister for Administrative Services and the first GMAC meeting took place in Canberra in December 1988.

On 12 June 1990, the then Minister for Industry, Technology and Commerce wrote to the House of Representatives Standing Committee on Industry, Science and Technology proposing an inquiry into the issues arising from, and the regulation of, genetically modified organisms. The Committee's report, *Genetic Manipulation: the Threat or the Glory?*, was tabled in February 1992. The Government accepted the broad thrust of the Committee's report, which was to give legal force to guidelines and procedures for contained research work, and to establish an effective legal framework for the assessment of all proposals for the release of GMOs into the environment. It was agreed that the existing Genetic Manipulation Advisory Committee would continue to administer the guidelines until new arrangements (i.e.

legislation) were implemented. GMAC's response to the Report's recommendations is included in the GMAC 1991-92 Annual Report.

GMAC's Terms of Reference directed it to provide to the Minister, no later than December 1992, a report reviewing the risk levels associated with innovative genetic manipulation techniques and commenting on the need for GMAC's specialised role to continue. GMAC's report to the Minister on risk levels was included as Attachment 1 in its Annual Report for 1992-93.

In 1994, a Gene Therapy Committee was established by the National Health and Medical Research Council to assess proposals for human gene therapy. Gene therapy proposals are submitted directly to this committee (now called the Gene Therapy Research Advisory Panel), rather than to GMAC. Liaison between GMAC and the Gene Therapy Committee is maintained by cross-membership between the Committees; two members of GMAC's Scientific Subcommittee are members of the Gene Therapy Committee.

During 1993-94 GMAC increased the information it makes available on planned release proposals via its Public Information Sheets. The Public Information Sheets now contain greater details of planned release proposals as well as a summary of GMAC's safety assessment and reasons for its decisions on releases.

On 11 March 1996, responsibility for GMAC was transferred from Administrative Services in the Finance portfolio to the Industry, Science and Tourism portfolio. The Minister responsible for GMAC is the Hon John Moore MP, Minister for Industry, Science and Tourism.

Nature of the advisory system

GMAC's mandate is to review proposals for genetic manipulation work in Australia falling under its Terms of Reference, so that any risks associated with the novel genetics of the resulting organisms are identified and managed. GMAC is also to advise the responsible Minister about matters affecting the regulation of this technology. (See Appendix 2 for GMAC's Terms of Reference.)

Although GMAC's recommendations are advisory, sanctions exist for non-compliance. These include the withdrawal of government funding for research and development and the possible withdrawal of any tax concessions. In the case of commercial operations, unfavourable publicity would result from public disclosure by the Minister of non-compliance with the Guidelines. The provisions of common law and occupational health and safety legislation apply to work with genetic manipulation techniques as they do to other work.

The regulation of releases of genetically modified organisms to the marketplace or the environment requires cooperation between Commonwealth and State agencies. GMAC's role is to assess proposals and provide technical advice to investigators and to the authorities which administer legislation relevant to the use of the organism. Statutory responsibility for regulation of the products of genetic manipulation technologies at present rests with State and Commonwealth Government agencies, depending on the end use proposed for the product. These agencies include the National Registration Authority for Agricultural and Veterinary Chemicals, the National Food Authority and the Therapeutic Goods Administration. Where there is

uncertainty in specific cases, relevant authorities which may have an interest (e.g. State Department of Agriculture for an agricultural product) would be consulted.

The key elements of the advisory system are the Committee's Guidelines and the supervisory responsibility undertaken by local IBCs at the institutions where work is performed. The Committee administers three sets of Guidelines for small scale, large scale and deliberate release work. The Guidelines specify the roles of the various players in the system, physical standards for containment, and proper procedures, supervisory practices and record keeping.

On 30 October 1997, the Commonwealth Government announced that it had decided to introduce a national regulatory framework for genetic manipulation work ('gene technology') to provide statutory backing to the current system. The Government's proposed regulatory package includes introduction of new legislation to provide some statutory control of gene technology research and to provide statutory coverage of general releases of genetically modified organisms that are not covered by existing bodies. The existing legislation of other product regulatory bodies would be retained.

APPENDIX 2. GMAC MEMBERSHIP

Emeritus Professor Nancy Millis AC MBE MAgSc, PhD, FTSE, DSc (Chair)	Department of Microbiology, University of Melbourne
Dr Susan Barker BSc, PhD	Lecturer, Department of Plant Sciences, University of Western Australia
Dr Annabelle Bennett SC BSc, PhD, LLB	Barrister at Law
Professor Angela Delves BAppBiol, PhD	Pro-Vice Chancellor, Southern Cross University
Professor Ashley Dunn MPhil, PhD	Head, Molecular Biology Program, Ludwig Institute for Cancer Research
Professor Peter Hudson BSc, PhD	Program Leader for Protein Engineering, CSIRO Division of Biomolecular Engineering
Professor Byron Lamont BScAgric, PhD, DSc	Personal Chair in Plant Ecology, Curtin University
Associate Professor Peter Langridge BSc, PhD	Research Leader, ARC for Basic and Applied Plant Molecular Biology, Waite Agricultural Research Institute
Dr John Manners BSc, PhD, DIC	Senior Research Scientist, CSIRO Division of Tropical Agriculture
Mr David Martin Diploma of Mechanical Engineering	Retired Biocontainment Engineer, Australian Animal Health Laboratory, CSIRO
Dr John Oakeshott BSc, PhD	Head of Molecular Biology, CSIRO Division of Entomology
Dr Ian Parsonson MA, BVSc, PhD, MACVSc	Retired Assistant Chief, Australian Animal Health Laboratory, CSIRO
Professor Jim Pittard BSc, MSc, PhD, DSc, FAA	Head, Department of Microbiology, University of Melbourne
Associate Professor Richard Roush BSc, PhD	Director, CRC for Weed Management Systems, Waite Agricultural Research Institute

Associate Professor Loane Skene LLB, LLM	Senior Lecturer, Department of Law, University of Melbourne
Dr Jan Tennent BSc (Hons), PhD	Project Leader, CSIRO Division of Animal Health, CRC for Vaccine Technology Unit
Ms Sally White BA (Hons), MA	Freelance journalist, Melbourne
Mr John Whitelaw BAgSc	Environment Australia

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

Members of GMAC are appointed by the Minister for Industry, Science and Tourism. The level of remuneration is determined by the Remuneration Tribunal.

Four GMAC members completed their terms of appointment during the year: Dr Stephen Goodwin, Dr Eric Haan, Professor Staffan Kjelleberg and Dr Robyn van Heeswijck. Seven other members - Dr Annabelle Bennett, Professor Ashley Dunn, Associate Professor Peter Langridge, Professor Nancy Millis, Dr John Oakeshott, Dr Ian Parsonson and Professor Jim Pittard - were re-appointed by the Minister for a further term of two years.

Three new members were appointed to the Committee: Dr Susan Barker, Dr John Manners and Associate Professor Richard Roush.

Members of Subcommittees

Scientific Subcommittee

Professor Pittard (Chair)	Associate Professor Langridge
Dr Barker	Dr Oakeshott
Professor Dunn	Dr Parsonson
Professor Hudson	Dr Tennent

Large Scale Subcommittee

Professor Millis (Chair)
Professor Hudson
Mr Martin

Consultants to the Large Scale Subcommittee: Mr Norman Ackland, retired manager of CSL Limited, Parkville, Victoria; Mr Geoffrey Connellan, Senior Lecturer in Plant Science and Engineering at Victoria College of Agriculture and Horticulture, Burnley, Victoria.

Planned Release Subcommittee

Professor Millis (Chair)
Dr Bennett
Professor Delves
Professor Lamont
Associate Professor Langridge
Dr Manners
Dr Parsonson
Professor Pittard
Associate Professor Roush
Associate Professor Skene
Ms White
Mr Whitelaw

Public Liaison Subcommittee

Dr Bennett (Chair)
Professor Delves
Professor Millis
Associate Professor Skene
Ms White

APPENDIX 3. TERMS OF REFERENCE

Objectives

The Committee's objectives are:

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

Scope

Innovative genetic manipulation techniques shall include those techniques which can transfer genetic material between species which may not normally exchange genetic material in natural circumstances and non-traditional techniques capable of modifying the genetic material of organisms.

The risk factors shall include those which are associated with the altered genetic capabilities of the manipulated organism and which may give rise to safety concerns in public health, occupational health and safety, agricultural production or about the quality of the environment.

Functions

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

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

Responsibilities and Powers

In pursuing the functions the Committee shall:

1. provide the Minister annually:

- a review of the risks associated with genetic manipulation technology; and
- a report on the activities of GMAC;

2. provide advice on matters referred to it by the Minister from time to time;
3. whenever practicable, work through established regulatory agencies in preference to establishing its own regulatory regimes;
4. consult with interested organisations and individuals especially during the drafting of code, standard or guideline documents;
5. institute procedures to protect commercially sensitive information submitted as part of any risk assessment review;
6. immediately advise the most appropriate Commonwealth or State agency should the Committee become aware of any project or activity in which biosafety is known, or thought likely, to be seriously compromised;
7. provide advice on the planned release of genetically modified organisms into the environment; and make available detailed statements of reasons for the assessment made including health, safety, environmental and any broader social issues taken into account.

APPENDIX 4. IBC CHAIRS AND CURRENT PROJECTS

The following table lists the Chair and the number of current proposals (small scale contained work - SS, large scale contained work - LS, deliberate release proposals (including general releases and extensions to deliberate release proposals) - PR) for each IBC, as at 30 June 1998. These IBCs represent the main institutions registered with GMAC. Some committees may in turn supervise other institutions.

		Current projects		
Institution	**IBC Chair**	**SS**	**LS**	**PR**
Australian Capital Territory				
Australian National University	Prof P Board	55	0	1
CSIRO Entomology	Dr P Christian	24	0	1
CSIRO Plant Industry	Dr A Richardson	34	0	4
CSIRO Wildlife and Ecology	Dr K Williams	23	0	0
New South Wales				
Applied Horticultural Research Pty Ltd	Dr G Rogers	0	0	0
Australian Red Cross Blood Service - NSW	Prof Y Cossart	3	0	0
Biotech Australia Pty Ltd	Dr D Irving	24	5	0
Charles Sturt University, Riverina	Dr G McKenzie	3	0	0
Children's Medical Research Institute/Royal Alexandra Hospital for Children	Prof P Rowe	18	0	0
Cotton Seed Distributors	Mr G Windeatt	0	0	3
CSIRO Animal Production	Dr I Franklin	21	0	0
CSIRO Molecular Science - Sydney Lab	Dr P Molloy	13	0	0
Johnson & Johnson Research	Dr W Gerlach	6	0	0
Macquarie University	A/Prof J Whalley	17	0	0
NSW Agriculture, Elizabeth Macarthur Agricultural Institute	Dr P Kirkland	15	0	0
Royal North Shore Hospital and University of Technology	Dr R Pritchard	23	0	0
Royal Prince Alfred Hospital	Prof J Seale	28	0	0
Southern Cross University	Prof A Delves	4	0	0
St Vincent's Hospital	Prof J Eisman	22	0	0
University of New England	Dr B Cheetham	4	0	0
University of New South Wales	Prof A Lee	65	0	0
University of Newcastle	A/Prof R Rose	32	0	0
University of Sydney	Dr A Weiss	54	0	0
University of Western Sydney, Hawkesbury	A/Prof J Bavor	2	0	0

University of Western Sydney, Macarthur	Dr M Campbell	1	0	0
University of Western Sydney, Nepean	A/Prof E Deane	0	0	0
University of Wollongong	A/Prof R Lilley	9	0	0
Westmead Hospital	Dr P O'Connell	29	0	0
Northern Territory				
Menzies School of Health Research	Dr D Kemp	40	0	0
Queensland				
Australian Institute of Marine Science	Dr R Reichelt	0	0	0
Bureau of Sugar Experiment Stations	Dr C Ryan	11	0	1
CSIRO Tropical Agriculture	Dr I East	33	0	1
Deltapine Australia Pty Ltd	Mr K Flower	1	0	6
ForBio Research	Ms B Morris	14	0	0
Griffith University	Mr J Urquhart	6	0	0
James Cook University	Dr G Burgess	4	0	0
Pacific Seeds Pty Ltd	Dr B Hare	0	0	0
Progen Industries	Mr J Grew	0	0	0
Queensland Department of Primary Industries	Dr P Young	33	0	1
Queensland Health	Mr L Smythe	3	0	0
Queensland Institute of Medical Research	Dr G Lawrence	82	0	0
Queensland University of Technology	A/Prof P Timms	27	0	0
Royal Brisbane, Royal Children's and Royal Women's Hospitals	Dr J Rowell	20	0	0
University of Southern Queensland	Dr T Mukkur	2	0	0
University of Queensland	Prof M McManus	137	0	4
South Australia				
BresaGen Ltd	Dr R Clay	2	8	1
CSIRO Plant Industry, Horticulture Research Unit	Dr J Jackson	5	0	0
CSIRO Land and Water	Mr P Lee	4	0	0
Flinders University/Flinders Medical Centre	Dr J Oliver	46	0	0
GroPep Pty Ltd	Dr F Ballard	3	0	0
Institute of Medical and Veterinary Science	Dr Z Rudzki	45	0	0
North West Adelaide Health Service (Queen Elizabeth Hospital)	Prof D Grove	14	0	0
University of Adelaide	Prof R Milbourne	61	1	0
University of South Australia	Dr W Woods	4	0	0
Women's and Children's Hospital	Dr W Carey	9	0	0

Tasmania				
Department of Primary Industry and Fisheries	Mr D Munro	3	0	1
University of Tasmania	Prof H Muller	4	0	0
Victoria				
AgrEvo Pty Ltd	Mr R Harris	0	0	6
AMRAD Burnley	Dr L Ward	9	0	0
Austin Repatriation Medical Centre	Dr C White	23	0	0
Australian Animal Health Laboratory, CSIRO	Dr G Abraham	29	0	0
CSIRO Molecular Science - Parkville Lab	Dr D Hewish	7	0	0
CSL Limited	Mr K J Healy	6	3	0
Deakin University	Prof P Hamilton	0	0	0
Florigene Pty Ltd	Prof L Stubbs	13	0	5
La Trobe University	Dr J Jenkin	31	0	1
Ludwig Institute for Cancer Research	Dr M Hibbs	51	0	0
Monash University	A/Prof V Krishnapillai	130	0	0
Monsanto Australia Limited	Dr W Blowes	5	0	0
Peter MacCallum Cancer Institute	Dr J Radley	25	0	0
RMIT University	Dr B Davey	Did not report		
Royal Children's Hospital	Mr A B Holt	21	0	0
Royal Melbourne Hospital Research Foundation	Prof A Dunn	75	0	0
Southern Cross Biotech	Mr D Hughes	0	1	0
St Vincent's Hospital	Dr M Gillespie	13	0	0
University of Melbourne	Prof M Hynes	69	0	0
Victoria University of Technology	Prof R Fairclough	0	0	0
Victorian Department of Agriculture	Dr R Condron	16	0	0
Walter & Eliza Hall Institute of Medical Research	Dr A Cowman	25	0	0
Western Australia				
Agriculture Western Australia	Dr T Ellis	0	0	1
Curtin University of Technology	A/Prof J Warmington	8	0	0
Murdoch University	Dr P O'Brien	21	0	0
Princess Margaret Children's Medical Research Foundation	Prof W Thomas	15	0	0
Royal Perth Hospital	Dr P Cannell	2	0	0
University of Western Australia	Prof G Yeoh	82	0	3

Total number of IBCs	85
Total number of current projects	
Small scale	1818
Large scale	18
Deliberate release	40

APPENDIX 5. SMALL SCALE PROPOSAL DETAILS 1981 - 30 JUNE 1998

Year	Number of proposals				
	Containment Level*			Exemptions (including special exemptions)	Total
	PC2	PC3	PC4		
1981-1983	198	24	0	5	227
1984	204	7	0	0	211
1985	182	4	0	1	187
1986	199	9	0	11	219
1987	225	11	0	7	243
1988	238	6	0	5	249
1989	305	9	0	9	323
1990	277	5	0	5	287
1991	336	5	0	11	352
1992	352	14	0	12	378
1993	356	8	0	10	374
1994	334	8	0	6	348
1995	312	14	0	11	337
1996	341	5	0	11	357
1997**	145	6	0	1	152
1997/98***	323	22	0	13	358
Total	**4327**	**157**	**0**	**118**	**4602**

* PC2, PC3 and PC4 refer to levels of physical containment under which the proposals may be conducted. PC2 is the lowest level of containment required for genetic manipulation work. Depending on facility availability, levels of containment that are higher than necessary are sometimes used for project work. See GMAC's *Guidelines for Small Scale Genetic Manipulation Work*, April 1998, for the requirements of these containment levels.

** To June 1997

*** From July 1997 to June 1998

APPENDIX 6. LARGE SCALE PROPOSAL DETAILS 1981 - 30 JUNE 1998

Of the 36 large scale proposals assessed between 1981 and 30 June 1998, 14 have been carried out at the GILSP level of containment and 22 assessed as requiring physical containment level PC2-LS.

The organisations carrying out, or who have carried out, large scale work are:

Cyanamid Websters (previously Arthur Webster) Pty Ltd, NSW
Biotech Australia, NSW
BresaGen (previously Bresatec) Pty Ltd, SA
Bunge Australia Pty Ltd, NSW
CSIRO Molecular Science, NSW
(previously CSIRO Division of Biotechnology)
CSL Ltd, Victoria
University of Adelaide, SA

APPENDIX 7. DELIBERATE RELEASE PROPOSAL DETAILS 1981 -30 JUNE 1998

Public Information Sheets on each of the releases for which the assessment has been completed, except for exempt proposals and some proposals which did not proceed, are available from the GMAC Secretariat.

Institution	Deliberate release proposal	
WA Department of Agriculture	PR-1	Field trial of a live *Salmonella* vaccine to prevent death during live sheep export
Australian National University	PR-2	To test a recombinant *Rhizobium* strain marked with the transposon Tn5 LacZ in a controlled field release experiment
Queensland Department of Primary Industries	PR-3	Inoculation of cattle with a thymidine kinase negative, deletion mutant, infectious bovine rhinotracheitis vaccine virus
Victorian Department of Agriculture	PR-4	Preliminary proposal towards the release of live *Salmonella typhimurium* vaccine strain DD30 for use in sheep (did not proceed)
Bio-care Technology Pty Ltd	PR-5	National clearance and registration of *Agrobacterium radiobacter* K1026 for the control of Crown Gall disease
CSIRO Division of Biotechnology (now CSIRO Molecular Science)	PR-6	Commercial evaluation of melibiose utilising baker's yeast
University of Melbourne	PR-7	(Considered as large scale proposal)
CSIRO Division of Soils	PR-8	Field release of a live genetically engineered strain of *Pseudomonas* for the purpose of testing a microbial tracking system
Australian National University	PR-9	Controlled field release experiment of a *Rhizobium* strain containing a Sym plasmid marked with the transposon Tn5
University of Newcastle	PR-10	Phase I study of vaccinia interleukin 2 (IL-2) recombinants in patients with stage III melanoma (referred to the NHMRC Gene Therapy Committee)
University of Melbourne	PR-11	Construction of lactic acid bacteria with improved technological properties (exempt from GMAC Guidelines)
CSIRO Division of Plant Industry	PR-12	Synthetic resistance genes to potato leafroll virus
Bresatec Ltd (now BresaGen Ltd)	PR-13	Planned release of transgenic pigs (did not proceed)
Pacific Seeds Pty Ltd	PR-14	Field evaluation of canola protoplast fusion breeding lines
Unifoods Pty Ltd	PR-15	Planned release of genetically modified tomatoes in

		Australia 1992
CSIRO Division of Plant Industry	PR-16	Synthetic resistance genes to potato leafroll virus (stage 2)
CSIRO Division of Plant Industry	PR-16X	Proposal for the planned release of four lines of genetically engineered potatoes for seed tuber production
Deltapine Australia Pty Ltd	PR-17	Bt cotton seed increase
Calgene Pacific Pty Ltd (now Florigene Pty Ltd)	PR-18	Application for permission to field trial transgenic potato
Calgene Pacific Pty Ltd (now Florigene Pty Ltd)	PR-19	Proposal for planned release of transgenic carnation for trialling under commercial glasshouse production conditions
CSIRO Division of Plant Industry	PR-20	Genetic engineering of cotton for resistance to insect pests
CSIRO Division of Plant Industry	PR-20X	Proposal for the planned release of genetically engineered cotton plants expressing insecticidal protein genes from *Bacillus thuringiensis*
Calgene Pacific Pty Ltd (now Florigene Pty Ltd)	PR-21	Application for planned release of transgenic rose containing reporter gene, antibiotic resistance gene, chlorsulfuron resistance gene and phytohormone over-production genes (did not proceed)
RMIT University	PR-22	Use of an Aro$^-$ *S. typhimurium* as a vaccine in poultry
RMIT University	PR-22X	Use of an Aro$^-$ *S. typhimurium* as a vaccine in poultry
University of Queensland	PR-23	Evaluation of transgenic sugarcane
University of Queensland	PR-23X	Evaluation of transgenic sugarcane
Queensland Department of Primary Industries	PR-24	Contained field growth of grafted apple stock transformed for kanamycin resistance
Queensland Department of Primary Industries	PR-24	Contained field growth of grafted apple stock transformed for kanamycin resistance
Calgene Pacific Pty Ltd (now Florigene Pty Ltd)	PR-25	Glasshouse trialling of transgenic chrysanthemum under non-PH1 conditions
Unifoods Pty Ltd	PR-26	Planned release of genetically modified tomatoes in Australia – 1993
Queensland Department of Primary Industries	PR-27	Non-chemical control of bacterial wilt (*Pseudomonas solanacearum*) in north Queensland
Calgene Pacific Pty Ltd (now Florigene Pty Ltd)	PR-28	Planned release proposal for trialling carnation with modified flower colour under non-contained glasshouse conditions

Calgene Pacific Pty Ltd (now Florigene Pty Ltd)	PR-29	Proposal for planned release of transgenic carnation modified for enhanced cutflower vase life
Calgene Pacific Pty Ltd (now Florigene Pty Ltd)	PR-28/29X	Proposal for extension of PR-28 and PR-29 to an igloo trialling area
Calgene Pacific Pty Ltd (now Florigene Pty Ltd)	PR-30	Planned release of sense suppressed, petal colour modified, transgenic hybrid tea rose containing kanamycin resistance gene, reporter gene and chalcone synthase gene
Deltapine Australia Pty Ltd	PR-31	Seed increase of Bt transgenic cotton plants, 1994
Deltapine Australia Pty Ltd	PR-32	Seed increase and efficacy screening of Roundup™ tolerant (RT) transgenic cotton plants
Deltapine Australia Pty Ltd	PR-33	Efficacy evaluation and agronomic selection of Bt transgenic cotton plants, 1994-95
Deltapine Australia Pty Ltd	PR-34	Bt replicated yield and fibre tests 1994-95, Bt vs non-Bt yield test 1994-95
Florigene Pty Ltd	PR-35	Planned release of transgenic tea rose (*Rosa* X *hybrida*) containing kanamycin or chlorsulfuron resistance gene and 'blue' gene (flavonoid 3'5' hydroxylase)
CSIRO Division of Plant Industry	PR-36	Planned release of transgenic cotton expressing the CryIA(c) or CryIIA delta-endotoxins from *Bacillus thuringiensis*
CSIRO Division of Plant Industry	PR-36X	Planned release of transgenic cotton expressing the CryIA(c) and CryIIA delta-endotoxins from *Bacillus thuringiensis* - breeding plots
CSIRO Division of Plant Industry	PR-36X(2)	Planned release of transgenic cotton expressing the CryIA(c) and CryIIA delta-endotoxins from *Bacillus thuringiensis* - breeding plots
CSIRO Division of Plant Industry	PR-36X(3)	The planned release of transgenic cotton expressing the CryIA(c) and CryIIA delta-endotoxins from *Bacillus thuringiensis* - breeding plots and preliminary multi-site evaluation and seed increase*
CSIRO Division of Plant Industry	PR-37	Field testing of genetically engineered subterranean clover
CSIRO Division of Plant Industry	PR-37X	Field testing of genetically engineered subterranean clover
CSIRO Division of Plant Industry	PR-38	Assessment of environment impact and resistance management options for genetically engineered cotton plants expressing insecticidal protein genes from *Bacillus thuringiensis*
CSIRO Division of Plant Industry	PR-38X	Assessment of environment impact and resistance management options for genetically engineered cotton plants expressing insecticidal protein genes from *Bacillus thuringiensis*
CSIRO Division of Plant Industry	PR-39	Multiple site evaluation of virus resistant potatoes

CSIRO Division of Plant Industry	PR-39X	Multiple site evaluation of virus resistant potatoes
University of Western Australia	PR-40	Release of herbicide resistant lupins (*Lupinus angustifolius*)
Queensland Department of Primary Industries	PR-41	Small scale planned release of modified bovine herpesvirus 1 for intranasal vaccination of cattle
CSIRO Division of Horticulture	PR-42	Field evaluation of low browning potatoes
CSIRO Division of Horticulture	PR-42X	Field evaluation of low browning potatoes
CSIRO Division of Plant Industry	PR-43	Use of transgenic plants to monitor the frequency of Bt resistance in field populations of *Helicoverpa armigera*
CSIRO Division of Plant Industry	PR-43X	Use of transgenic plants to monitor the frequency of Bt resistance in field populations of *Helicoverpa armigera*
CSIRO Division of Plant Industry	PR-44	Winter seed increase of transgenic cotton expressing the CryIA(c) delta-endotoxin from *Bacillus thuringiensis*
CSIRO Division of Plant Industry	PR-44X	Winter seed increase and preliminary northern assessment of transgenic cotton expressing the CryIA(c) delta-endotoxin from *Bacillus thuringiensis*
CSIRO Division of Plant Industry	PR-44X(2)	Winter seed increase and preliminary northern assessment of transgenic cotton expressing the CryIA(c) delta-endotoxin from *Bacillus thuringiensis*
University of New England	PR-45	Genetic manipulation of rumen bacteria for detoxification of the plant poison fluoroacetate (GMAC advised that this proposal should not proceed)
Murdoch University	PR-46	Glasshouse and field analysis of transgenic tobacco plants for resistance to Australian cucumber mosaic virus strains from lupins (proposal withdrawn)
Deltapine Australia Pty Ltd	PR-47	Seed increase of Bt transgenic cotton plants, 1995
Deltapine Australia Pty Ltd	PR-47X	Seed increase of Bt transgenic cotton plants, 1996
Deltapine Australia Pty Ltd	PR-47X(2)	Winter nursery seed increase of Bt transgenic cotton plants 1997
Deltapine Australia Pty Ltd	PR-47X(3)	Winter nursery seed increase of Bt transgenic cotton plants 1998*
Arthur Webster Pty Ltd (now Cyanamid Webster Pty Ltd)	PR-48	Site evaluation of a fowlpox virus vaccine expressing the glycoprotein B of Marek's disease virus
CSIRO Division of Plant Industry	PR-49	Production of genetically engineered lupin seeds expressing sunflower seed albumin
CSIRO Division of Plant Industry	PR-49X	Production of genetically engineered lupin seeds expressing sunflower seed albumin
CSIRO Division of Plant Industry	PR-49X(2)	Production of genetically engineered lupin seeds expressing sunflower seed albumin*

Deltapine Australia Pty Ltd	PR-50	Bt seed increase 1995-96
Deltapine Australia Pty Ltd	PR-50X	INGARD® (Bt) seed increase 1996-97
Deltapine Australia Pty Ltd	PR-51	Bt agronomic selection and yield trials 1995-96
Deltapine Australia Pty Ltd	PR-51X	Bt agronomic selection and yield trials 1996-97
Deltapine Australia Pty Ltd	PR-51X(2)	Bt agronomic selection and yield trials 1997-98*
Deltapine Australia Pty Ltd	PR-51X(3)	Bt agronomic selection and yield trials 1998-99*
Deltapine Australia Pty Ltd	PR-52	Progeny selection and screening of glyphosate tolerant (RT) transgenic cotton plants 1995-96
Deltapine Australia Pty Ltd	PR-52X	Progeny selection and screening of Roundup Ready® (RR) transgenic cotton plants 1996-97
Deltapine Australia Pty Ltd	PR-52X(2)	Progeny selection and screening of Roundup Ready® (RR) transgenic cotton plants 1997-98*
Deltapine Australia Pty Ltd	PR-52X(3)	Progeny selection and screening of Roundup Ready® (RR) transgenic cotton plants 1998-99*
Australian National University	PR-53	Behaviour in soil of bioluminescent *Pseudomonas* biological control bacteria tagged with luciferase or *lux* genes
CSIRO Division of Plant Industry	PR-54	Proposal for the planned release of genetically engineered cotton plants with tolerance to spray drift damage caused by the herbicide 2,4-D
CSIRO Division of Plant Industry	PR-54X	Proposal for the planned release of genetically engineered cotton plants with tolerance to spray drift damage caused by the herbicide 2,4-D 1996
CSIRO Division of Plant Industry	PR-54X(2)	Proposal for the planned release of genetically engineered cotton plants with tolerance to spray drift damage caused by the herbicide 2,4-D*
CSIRO Division of Plant Industry	PR-55	The planned release of transgenic cotton expressing tolerance to the herbicide glyphosate
CSIRO Division of Plant Industry	PR-55X	The planned release of transgenic cotton expressing tolerance to the herbicide glyphosate
CSIRO Division of Plant Industry	PR-55X(2)	The planned release of transgenic cotton expressing tolerance to the herbicide glyphosate*
CSIRO Division of Plant Industry	PR-56	Multi-site evaluation and seed increase of transgenic cotton expressing the CryIA(c) delta-endotoxin from *Bacillus thuringiensis*
Victorian Department of Agriculture	PR-57	Agronomic assessment of four potato cultivars transformed with anti-viral genes (proposal did not proceed)

CSIRO Division of Plant Industry	PR-58	A field trial to test the effectiveness of a bromoxynil-resistance gene in subterranean clover under field conditions
CSIRO Division of Plant Industry	PR-58X	Field release of bromoxynil-tolerant subterranean clover
CSIRO Division of Plant Industry	PR-58X(2) (Originally GR-7)	Field release of bromoxynil-tolerant subterranean clover*
CSIRO Division of Plant Industry	PR-59	Field evaluation of a transgenic line of field pea (*Pisum sativum* L.) for enhanced grain sulfur levels
CSIRO Division of Plant Industry	PR-59X	Field evaluation of a transgenic line of field pea (*Pisum sativum* L.) for enhanced grain sulfur levels*
Seedex Pty Ltd	PR-60	Field evaluation of a genetically modified canola (*Brassica napus*) for agronomic performance
Seedex Pty Ltd	PR-60X	Planned release of *Brassica napus*, variety laurate canola
Monsanto Australia Pty Ltd	PR-60X(2)	Planned release of *Brassica napus*, variety laurate canola*
CSIRO Division of Plant Industry	PR-61	Field evaluation of a transgenic line of field pea (*Pisum sativum* L.) for resistance to pea weevil (*Bruchus pisorum*)
Hoechst Schering AgrEvo Pty Ltd	PR-62	Development of glufosinate ammonium tolerant canola cultivars
Hoechst Schering AgrEvo Pty Ltd	PR-62X	Development of glufosinate ammonium tolerant canola cultivars
Hoechst Schering AgrEvo Pty Ltd	PR-62X(2)	Development of glufosinate ammonium tolerant canola cultivars*
AgrEvo Pty Ltd	PR-62X(3)	Development of glufosinate ammonium tolerant canola cultivars*
Seedex Pty Ltd	PR-63	Field evaluation of a genetically modified canola (*Brassica napus*) with a new hybridisation system
Hoechst Schering AgrEvo Pty Ltd	PR-63X	Field evaluation of a genetically modified canola (*Brassica napus*) with a new hybridisation system
Hoechst Schering AgrEvo Pty Ltd	PR-63X(2)	Small and large scale parent and hybrid seed increase of a genetically modified canola (*Brassica napus*) with a new hybridisation system*
AgrEvo Pty Ltd	PR-63X(3) (Originally GR-5)	Release of glufosinate ammonium tolerant hybrid and open-pollinated canola cultivars*
La Trobe University	PR-64	Evaluation of transgenic white clover for field resistance to alfalfa mosaic virus
CSIRO Division of Plant Industry	PR-65	Evaluation of the potential for gene flow from transgenic wheat, using a herbicide-resistance marker gene
CSIRO Division of Plant Industry	PR-66	Evaluation of the performance of transgenic wheat with altered starch composition under field conditions
CSIRO Division of Plant Industry	PR-67	The evaluation of transgenic white clover for field resistance to alfalfa mosaic virus (AMV)

University of Queensland	PR-68	Field trial of sugarcane modified for resistance to leaf scald disease
CSIRO Division of Plant Industry	PR-69	The planned release of transgenic cotton expressing tolerance to the herbicide bromoxynil
CSIRO Division of Plant Industry	PR-69X	The planned release of transgenic cotton expressing tolerance to the herbicide bromoxynil*
Applied Horticultural Research Pty Ltd	PR-70	Field evaluation of tomatoes expressing the CryIA(c) delta endotoxin gene from *Bacillus thuringiensis*
Deltapine Australia Pty Ltd	PR-71	Winter nursery seed increase of Roundup Ready® (RR) transgenic cotton plants 1997
Deltapine Australia Pty Ltd	PR-71X	Winter nursery seed increase of Roundup Ready® (RR) transgenic cotton plants 1998*
Bureau of Sugar Experiment Stations	PR-72	Field test of sugarcane modified for resistance to sugarcane mosaic virus
CSIRO Division of Tropical Agriculture	PR-73	Field maintenance and propagation of sugarcane modified for sucrose metabolism and juice colour
University of Western Australia	PR-74	Release of herbicide resistant lupins (*Lupinus angustifolius*)
University of Western Australia	PR-75	Development of herbicide and virus resistant lupins (*Lupinus luteus*)
University of Western Australia	PR-76	Development of herbicide and virus resistant lupins (*Lupinus angustifolius*)
Seedex Pty Ltd	PR-77	Planned release of transgenic canola expressing tolerance to the herbicide glyphosate (Roundup Ready® canola)
Monsanto Pty Ltd	PR-77X	Planned release of transgenic canola expressing tolerance to the herbicide glyphosate*
CSIRO Division of Plant Industry	PR-78	Assessment of potatoes resistant to potato leafroll virus (PLRV) and potato virus Y (PVY)
Hoechst Schering AgrEvo Pty Ltd	PR-79	Development of fungal disease resistant canola cultivars
CSIRO Division of Plant Industry	PR-80	Field evaluation of transgenic field peas (*Pisum sativum*) with resistance to pea weevil
CSIRO Division of Plant Industry	PR-80X (Originally GR-6)	Field evaluation of transgenic field peas (*Pisum sativum*) with resistance to pea weevil*
CSIRO Division of Plant Industry	PR-81	The planned release of INGARD® cotton expressing glyphosate tolerance and CryIIA*
CSIRO Division of Plant Industry	PR-82	The planned release of transgenic cotton expressing tolerance to the herbicide Basta®*
Deltapine Australia Pty Ltd	PR-83	Roundup Ready® (RR) and INGARD® (Bt)/Roundup Ready® (RR) seed increase 1997-1998*
Deltapine Australia Pty Ltd	PR-83X	Roundup Ready® (RR) and INGARD® (Bt)/Roundup Ready® (RR) seed increase 1998-1999*
Monsanto Australia Ltd	PR-83X(2) (Originally GR-4)	Evaluation of Roundup Ready® cotton grown under commercial use conditions*

Florigene Ltd	PR-84	Planned release of carnation modified for resistance to fungal pathogens*
AgrEvo Pty Ltd	PR-85	Small and large scale seed increase of a genetically modified canola (*Brassica rapa*) with a new hybridisation system*
CSIRO Division of Entomology	PR-86	Dispersal ecology of a genetically marked *Helicoverpa armigera* singly-enveloped nucleopolyhedrovirus (HaSNPV) in the cotton agro-ecosystem*
Agriculture Western Australia	PR-87	Field performance and integrated pest management studies on transgenic cotton expressing the CryIA(c) delta-endotoxin from *Bacillus thuringiensis*, in the Kimberley region of Western Australia*
CSIRO Division of Plant Industry	PR-88	Field evaluation of barley yellow dwarf virus-resistant Schooner barley*
CSIRO Division of Plant Industry	PR-89	Agronomic and varietal assessment in Northern Australia of transgenic cotton expressing the CryIA(c) and combinations of CryIA(c) and CryIIA delta-endotoxins from *Bacillus thuringiensis**
AgrEvo Pty Ltd	PR-90	Herbicide tolerant hybrid *Brassica juncea**
Tasmanian Department of Primary Industry and Fisheries	PR-91	Planned release of GMO oilseed poppy (*Papaver somniferum*)*
CSIRO Division of Plant Industry	PR-92	Field evaluation of genetically engineered barley*
AgrEvo Pty Ltd	PR-93	Development of fungal disease resistant canola cultivars*
CSIRO Division of Plant Industry	PR-94	Winter seed increase of INGARD cotton expressing glyphosate tolerance*
University of Queensland	PR-95	Field test of pineapple plants modified to control flowering and ripening*
CSIRO Division of Plant Industry	PR-96	Field evaluation of transgenic lines of field pea (*Pisum sativum* L.) for resistance to Ascochyta blight*
CSIRO Division of Plant Industry	PR-97	Genetically enhanced subterranean clover expressing sunflower seed albumin*
Florigene Pty Ltd	GR-1	Commercialisation of carnation genetically engineered for improved vase life
Florigene Pty Ltd	GR-2	Commercialisation of violet carnation developed using genetic engineering
Monsanto Australia Ltd	GR-3	Application for commercialisation of insect-resistant cotton

* Assessed by GMAC in this reporting period (1997-98).

The table on the following pages shows the location of deliberate release proposals in Australia.

Locations of Deliberate Releases of Genetically Manipulated Organisms in Australia (assessed to 30 June 1998)

Tasmania

Region	Organism
Burnie	Potato
Cambridge	Canola
Devonport	Canola
Sassafras	Poppy

Victoria

Region	Organism
Aspley	Canola
Bendigo	Canola
Boort	Tomato
Corop	Tomato
Dennington	Canola
Gnarwarre	Canola
Hamilton	Clover
Hawkesdale	Canola
Heywood	Canola
Horsham	Canola, field pea
Lake Bolac	Canola
Melbourne	Carnation, *Salmonella*, potato, rose
Mooroopna	*Salmonella*
Numurkah	Canola
Portland	Canola
St Arnaud	Canola
Tatura	Tomato
Toolangi	Potato

Northern Territory

Region	Organism
Douglas-Daly	Cotton
Katherine	Cotton

ACT

Region	Organism
Canberra	Clover, *Rhizobium*, *Pseudomonas*
Hall	Wheat, barley

New South Wales

Region	Organism
Bellata	Cotton
Boggabilla	Cotton
Boggabri	Cotton
Bourke	Cotton
Bourke Irrigation Area	Cotton
Breeza	Cotton
Camden	Potato
Collarenabri	Cotton
Cootamundra	Canola
Crookwell	Potato
Euberta	Canola
Glen Innes	Canola
Gosford	Potato
Guyra	Canola
Gwydir Valley	Cotton
Lake Tandou	Cotton
Liverpool Plains	Cotton
Macintyre Valley	Cotton
Macquarie Valley	Cotton
Menindee Lakes	Cotton
Moree	Cotton
Murrumbidgee Irrigation Area	Cotton
Myall Vale	Cotton, *Helicoverpa armigera* singly-enveloped nucleopolyhedro-virus
Namoi Valley	Cotton
Narrabri	Cotton, tobacco
Narromine	Canola
Premer	Cotton
Severn	Canola
Sydney	Baker's yeast, *Salmonella*
Tambar Springs	Cotton
Tamworth	Fowlpox virus
Temora	Canola
Wagga Wagga	Canola, clover, field pea, Indian mustard
Warren	Cotton
Wee Waa	Cotton
Whitton	Canola

South Australia

Region	Organism
Avenue Range	Canola
Beachport	Canola
Carpenters Rock	Canola
Glencoe	Canola
Kalangadoo	Canola
Kingston SE	Canola
Kybybolite	Canola
Lenswood	Potato
Millicent	Canola
Mt Burr	Canola
Mt Gambier	Canola
Penola	Canola
Roseworthy	*Pseudomonas*
Struan	Canola
Tantanoola	Canola
Turrettfield	Field pea
Yahl	Canola

Western Australia

Region	Organism
Badgingarra	Lupin, canola
Boxwood Hills	Lupin
Broome	Cotton
Fremantle	*Salmonella*
Geraldton	Lupin
Katanning	Field pea
Kununurra	Cotton
Medina	Field pea, clover
Meredin	Canola
Mt Barker	Lupin
Mullewa	Lupin
Newdegate	Lupin
Ord River	Cotton
Perth	Lupin
Shenton Park	Lupin
Subiaco	Lupin
Wagin	Canola
Wongan Hills	Lupin, canola

Queensland

Region	Organism
Applethorpe	Apple
Atherton	Potato
Ayr	Tomato, sugarcane
Brisbane	Bovine herpes virus 1, sugarcane
Brookstead	Cotton
Bundaberg	Sugarcane, tomato
Cleveland	Pineapple
Clifton	Canola
Dalby	Cotton
Darling Downs	Cotton
Emerald Irrigation Area	Cotton
Gatton	Potato, canola, tomato
Jandowae	Cotton
Mareeba	*Pseudomonas*
Meringa	Sugarcane
St George Irrigation Area	Cotton
Theodore/ Biloela Irrigation Area	Cotton
Toowoomba	Canola
Townsville	Sugarcane

Australia-wide (General release)

Organism	Modification
Agrobacterium	No Gall pesticide
Carnation	Improved vase life and altered flower colour
Cotton	Insect-resistant (restricted to parts of Queensland and NSW)

APPENDIX 8. GMAC SECRETARIAT

The GMAC Secretariat is provided by the Department of Industry, Science and Tourism (Science and Technology Division).

The Secretariat is located at:

20 Allara Street
CANBERRA ACT 2601

The postal address for GMAC and the Secretariat is:

Genetic Manipulation Advisory Committee
GPO Box 2183
CANBERRA ACT 2601

Telephone: (02) 6213 6490
Facsimile: (02) 6213 6462

The staff of the Secretariat at 30 June 1998 were:

Dr Andina Faragher (Secretary)
Ms Catherine Brady
Ms Marika Mueller
Mr Tom Glynn

APPENDIX 9. PUBLICATIONS AVAILABLE

GMAC News
Published February 1991, August 1991, March 1992, August 1992, March 1993, September 1993, May 1994, November 1994, April 1995, September 1995, January 1996, July 1996, January 1997

Guidelines for Small Scale Genetic Manipulation Work
Published April 1998

Guidelines for Large Scale Genetic Manipulation Work
Published December 1994

Guidelines for the Deliberate Release of Genetically Manipulated Organisms
Published April 1998

Guidelines for Activities with the Potential for Unintended Release of Genetically Manipulated Organisms
Published April 1998

Deliberate Release Proposals - Public Information Sheets
Updated regularly

Annual Reports of Committee operations

Monitoring Recombinant DNA Technology: A Five Year Review
Published 1986

A Review of the Risk Levels Associated with Innovative Genetic Manipulation Techniques
December 1992: Published with the GMAC Annual Report 1992-93

Biotechnology Information Series, Iowa State University Extension
Reprinted with permission, March 1995

Safety Practices in PC2 Laboratories
Published 1995

APPENDIX 10. DETAILS OF AGENCY

Agency details are as follows:

- GMAC was created in September 1987.
- The Committee currently has 18 part-time members.
- Members are appointed by the relevant Minister (currently the Minister for Industry, Science and Tourism) for a term determined by the Minister.
- GMAC has no *ex officio* members.
- Members are paid in accordance with Remuneration Tribunal Determination 16 of 1997.
- GMAC produces an Annual Report.
- There is no review pending.
- Secretariat support to the Committee is provided by the Department of Industry, Science and Tourism.

GMAC was formerly the Recombinant DNA Monitoring Committee (RDMC), within the Industry, Technology and Commerce portfolio, from 1981 until 1987. From 1988 to March 1996, GMAC was within the Administrative Services portfolio.

APPENDIX 11. ACRONYMS

ASCORD	Australian Academy of Science Committee on Recombinant DNA
Bt	*Bacillus thuringiensis*
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DNA	Deoxyribonucleic acid
FOI	Freedom of Information
GILSP	Good Industrial Large Scale Practice
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically Manipulated Organism
IBC	Institutional Biosafety Committee
NHMRC	National Health and Medical Research Council
RDMC	Recombinant DNA Monitoring Committee
SCARM	Standing Committee on Agriculture and Resource Management

INDEX