Genetic Manipulation Advisory Committee

Annual Report 1998-99

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REPORT FROM THE CHAIR

Emeritus Professor Nancy Millis
AC MBE
GMAC Chair

The work of GMAC, through its Subcommittees, continues to be largely concerned with contained research and development on a small scale. The increase in the numbers of proposals for field trials of live modified crop plants noted last year has continued, with herbicide resistance and insect resistance being the most commonly introduced characteristics. A number of these crops are now approaching general (commercial) release in Australia.

GMAC members and the Secretariat have participated in Commonwealth-State negotiations to provide legislative underpinning to the system for regulation of gene technology in Australia. This process is now being coordinated by the Interim Office of the Gene Technology Regulator in the Department of Health and Aged Care. The GMAC Secretariat will be part of the Interim Office from 1 July 1999.

GMAC is aware of the importance of management on the farm of modified crops once these are commercially available. In 1997, the Standing Committee on Agriculture and Resource Management (SCARM) established a Working Group to develop guidelines for the management of modified crops on the farm; GMAC provided the Secretariat and I chaired the Working Group. The Working Group developed *Good Agricultural Practice Guidelines for the Use of Genetically Modified Plants* which have been endorsed by SCARM. Procedures to implement these Guidelines are currently being considered by SCARM, the Department of Agriculture, Fisheries and Forestry, and the Interim Office of the Gene Technology Regulator.

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 to the institutions conducting the work 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 1998-1999 financial year, GMAC assessed 299 proposals for small scale genetic manipulation work in containment facilities, one proposal for large scale genetic manipulation work in containment facilities, 45 proposals (19 new proposals and 26 extensions to previous proposals) for field trials, one proposal for general release of a genetically modified organism into the environment, and one proposal for an activity with the potential for unintended release of a genetically modified organism.

Increasing numbers of crops are approaching the stage of general (unrestricted) release. GMAC has participated in the development of *Good Agricultural Practice Guidelines for the Use of Genetically Modified Plants* which aim to ensure that genetically modified crops are introduced in a manner that does not pose unacceptable risks to the sustainability of Australian farming systems.

GMAC is also contributing to the development of a new statutory system for the regulation of gene technology in Australia.

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 genetically manipulated organisms to the researchers and institutions undertaking the work. GMAC also provides advice to the responsible Minister and to other government regulatory bodies.

GMAC was formed in 1987 to carry out work previously undertaken by the Recombinant DNA Monitoring Committee (RDMC) and, prior to that, by the Academy of Science Committee on Recombinant DNA. These committees were responsible for formulating and implementing guidelines for experiments involving recombinant DNA techniques (techniques involving combining DNA from different organisms *in vitro*). New techniques that allow the genetic make-up of cells to be changed without using recombinant DNA methods, and that can also result in the production of novel organisms that are unlikely to occur in nature, were subsequently developed. 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, virology, entomology and biosafety engineering are members of the Committee. Besides scientists, the Committee includes members from the wider non-scientific community.

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 Release Subcommittee (formerly 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 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.

Release Subcommittee

The 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 GMAC's scope. It provides advice to relevant Commonwealth, State and local government agencies, as well as to the proponents. The Subcommittee also consults with interested members of the public on deliberate release proposals.

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.

Functions

GMAC is concerned with any operation that results in or uses 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 genetic manipulation 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.

GMAC liaises with Commonwealth, State and Territory, and local government agencies concerned with the regulation of products derived using genetic manipulation techniques, 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.

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's advice and Guidelines. Further details on the operation of IBCs are provided in Chapter 4.

Secretariat

The GMAC Secretariat, within the Department of Industry, Science and Resources, provides secretariat support to GMAC and its various Subcommittees. This support includes coordinating members' assessments and drafting GMAC advice and recommendations to the IBCs. For deliberate release proposals, the Secretariat 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 focus 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 a significant 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. During the year, the Committee received a number of proposals involving novel disabled viral vectors for introducing DNA into mammalian cells.

New techniques are also being introduced for the genetic manipulation of laboratory animals. The mouse is a popular animal model, and researchers are interested in introducing genes into mice and modifying existing mouse genes to enable them to study the mechanism of genes that cause disease (such as cancer) in humans. Molecular systems (such as the Cre-lox recombination system) have been developed that enable genetic changes to be targeted to particular tissues in the mouse or to be switched on only at particular stages during the mouse's development.

During the reporting period, the first proposal for a clinical trial of a genetically modified vaccine for use in humans was received and assessed. The proposal involved a clinical trial of a genetically modified fowlpox virus as a vaccine for HIV-AIDS in humans. While the proposal was assessed by GMAC as of no significant risk to the community, it raised questions regarding the most appropriate procedures for assessment of human vaccine proposals in the future. It is likely that the number of proposals for clinical trials of human vaccines containing live genetically manipulated organisms will increase. GMAC's view of the most appropriate mechanisms for handling and assessment of such proposals is discussed in further detail below (page 15).

Large Scale Contained Work

As for small scale contained work, risk assessment and risk management for large scale contained work emphasise the containment of the work within certified containment facilities. Large scale contained work raises a number of additional issues associated with the design of the facility and of the equipment used for growing, harvesting and processing cultures of genetically manipulated cells.

The only proposal for large scale contained work assessed by the Large Scale Subcommittee during the reporting period was of low risk, involving use of genetically modified Chinese hamster ovary (CHO) cells to produce antibodies for therapeutic use. Good Industrial Large Scale Practice (GILSP), the minimum level of physical containment for large scale work, was regarded as suitable for the proposal. This containment level is similar to that used for the manufacture of vaccines. 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 of the new proposals and all but one of the extensions to previous proposals involved modified crop plants. One of the extensions to a previous proposal involved the release of a modified virus. For the nineteen new proposals assessed, the characteristics introduced into the plants were herbicide resistance (five 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 (four proposals) and marker traits (four proposals). Further work was conducted, as extensions to previous proposals, on plants expressing herbicide resistance (fourteen extensions), virus resistance (three extensions), insect resistance (seven extensions), fungal resistance (one extension) and altered quality traits (six extensions).

During the reporting period, one proposal was submitted for general release of a genetically modified crop plant. The characteristic introduced into the plant was herbicide resistance. GMAC's assessment of the proposal is summarised in Chapter 3.

Herbicide-resistant crops

As reported in GMAC's previous Annual Report, 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 (unrestricted) release of the crops to the marketplace; as noted above, one such general release proposal was assessed during the reporting period. The proponents for release of herbicide-resistant crops claim that use of the 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 without damaging the crop itself.

Risks associated with the widespread use of herbicide-resistant crops include the emergence of herbicide-resistant weeds and difficulty in controlling 'volunteer' plants of a herbicide-resistant crop that emerge 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 participated in a Working Group established by the Standing Committee on Agriculture and Resource Management to develop guidelines for management of the development and general release of genetically manipulated crops.

Scale of release proposals

As several proposals reach the stage of general release of crop plants for commercial use, the scale and number of sites for field trials of these crops is increasing. Until general release is granted, GMAC requires that releases are conducted under the same types of conditions that apply to field trials, including isolation of the crop from related plants and monitoring of the release sites after harvest of the crop. As the scale and number of sites for certain proposals increases, greater attention must be paid by proponents to ensuring that isolation and monitoring conditions are enforced.

'Unintended' release work

Importation of genetically modified bulk seed

A number of genetically manipulated crops have now been granted regulatory approval for commercial use in other countries. As a result, seeds imported into Australia for processing may contain a proportion of seed that is genetically manipulated. To ensure that any risks to biosafety associated with such imports are assessed, GMAC in the previous reporting

period produced a set of Guidelines, *Guidelines for Activities with the Potential for Unintended Release of Genetically Manipulated Organisms.*

To date, GMAC has received only one application for importation of genetically modified seed under the new Guidelines; this application, assessed by GMAC in 1996, was for importation of soybean seeds modified for resistance to the herbicide glyphosate ('Roundup Ready®' soybean). No applications were received in the current reporting period.

Vaccine trials

In consultation with the Gene Therapy Research Advisory Panel (GTRAP) of the National Health and Medical Research Council, GMAC has given extensive consideration to the most appropriate procedure for assessment of proposals involving clinical trials in humans of vaccines that contain live genetically manipulated organisms. The conclusion is that, where there is any potential for dissemination of the vaccine organism from the vaccinated subjects, but where such dissemination is not an aim of the clinical trial, the *Guidelines for the Potential for Unintended Release of Genetically Manipulated Organisms* should apply. It should be noted that these Guidelines only relate to the aspects of the trial that are relevant to GMAC; other aspects, including the clinical trial protocol, and the safety and efficacy of the vaccine for the subjects who are vaccinated, are the responsibility of GTRAP. Thus all proposals involving genetically manipulated living microorganisms to be used as vaccines in humans will be reviewed by both GMAC and GTRAP.

One proposal for a clinical trial of a live vaccine was received and assessed during the reporting period (see Chapter 3). GMAC considered that the proposed trial posed no significant risk to the community and the environment.

3. COMMITTEE ACTIVITIES

Meetings

During 1998-1999, GMAC and its Subcommittees met as follows:

GMAC	Scientific Subcommittee	Release Subcommittee	Large Scale Subcommittee
16 October 1998	4 September 1998	11 August 1998	16 April 1999
	17 November 1998	16 October 1998	
	29 January 1999	11 December 1998	
	16 April 1999	19 February 1999	
	25 June 1999	21 May 1999	

GMAC

At the GMAC meeting on 16 October 1998, Dr Mikael Hirsch, on secondment from CSIRO to the Department of Industry, Science and Resources, presented a summary of recent developments in progress towards a statutory system for the regulation of gene technology, particularly work underway to develop operational options for the new scheme. Establishment of a statutory system to replace the current system was initially 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 progressing. The Government announced in the May 1999 Budget that responsibility for GMAC and for development of the new regulatory system would be transferred from the Minister for Industry, Science and Resources to the Minister for Health and Aged Care.

GMAC has agreed that the current voluntary system should be given legislative backing. In its discussion of the issues with Dr Hirsch, GMAC expressed concern that the regulatory scheme should not impose too great a burden on small companies and research organisations, particularly in the research phase.

Another item for discussion at the GMAC meeting was the role of the Public Liaison Subcommittee. GMAC noted that a number of other agencies were developing information programs for gene technology, and this was not seen as a necessary or appropriate role for GMAC. GMAC's public liaison activities will, however, continue through the GMAC newsletter produced by the GMAC Secretariat, seminars for members of IBCs, and the activities of individual GMAC members in communicating with interested organisations and individuals.

Scientific Subcommittee

Activities at meetings

The Scientific Subcommittee reviewed the biosafety aspects of small scale, large scale, deliberate release and unintended 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. At meetings during the year, members of the Subcommittee raised specific items and new techniques for discussion. These included the potential risks associated with plants modified for virus resistance by insertion of viral genes (see below), the procedures for assessment of human vaccine proposals, the 'Cre-lox' recombination system for site-specific excision of selected genes, and the containment requirements for work with transgenic laboratory mice.

At its meeting on 4 September 1998, the Scientific Subcommittee gave consideration to the potential risks associated with plants modified for virus resistance by insertion of viral genes. Two invited experts, Professor Bob Symons from the Waite Institute at the University of Adelaide, and Dr Mark Gibbs from the Australian National University, attended the meeting to discuss this issue with the Subcommittee. There was a detailed discussion of the possible differences between transgenic plants expressing viral genes and non-transgenic plants suffering mixed infections with different viruses. In particular, the possibility of recombination events, the possible synergistic effects of some viral proteins on the dissemination of other viruses within the plant, and the advantages, where possible, of using partial viral genes in the transgene construct, were discussed. Although the Subcommittee was not persuaded to modify any of its recommendations on projects involving virus-resistant plants, it agreed to continue a watching brief on new developments in this area of research.

Assessment of proposals

Small scale contained work

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, 299 small scale proposals were received. Of these, 75 (25.1%) proposals were Category A (proposals for GMAC advice), 217 (72.6%) were Category B (proposals for GMAC notification), and 4 (1.3%) were Category C (proposals for Special Exemption). The remaining 3 proposals (1.0%) were exempt from the Guidelines under the general exemption categories (submission of these proposals to GMAC is not required).

Of non-exempt small scale proposals received during the reporting period, 94.9% were carried out under PC2 physical containment, the lowest level of physical containment required for genetic manipulation work (unless the work is exempt from the GMAC Guidelines). The remainder of proposals were carried out under PC3 physical containment, a higher containment level.

Large scale contained work

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 large scale proposal assessed during the reporting period was of low risk.

Deliberate release work

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 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 Release Subcommittee, which considers broader environmental issues.

'Unintended' release work

The Scientific Subcommittee assessed a proposal for a clinical trial of a vaccine against HIV-AIDS during the reporting period. The vaccine consisted of a fowlpox virus modified to carry genes from HIV as well as a human gene for an immune system protein. The Subcommittee's assessment was that the proposed trial was of no significant risk to the community or the environment. The fowlpox virus used as the vaccine vector is capable of replication only in avian (bird) cells and dissemination of the vaccine organism from the vaccinated patients was not expected. The strain of fowlpox virus used was the vaccine strain that is already used in the poultry industry.

Following consultation with GMAC, the proponent for the trial had been advised to submit the proposal in the format described in the *Guidelines for Activities with the Potential for Unintended Release of Genetically Manipulated Organisms*. This was because there was some potential for the vaccine organism to be disseminated from the vaccinated patients, even though this was not intended or expected.

During its assessment of the proposal, the Scientific Subcommittee gave consideration to the appropriate procedures for handling this proposal and future proposals for trials of human vaccines. It was agreed that the Release Subcommittee was not an appropriate forum for consideration of vaccine proposals, since the expertise of the Release Subcommittee was not designed for the issues raised by such proposals. It was also suggested that the usual public consultation procedures applying to deliberate release proposals were not appropriate; this is because of the need to protect the privacy of the subjects and the possibility that advertising of vaccine trials could raise unwarranted hopes in people suffering from the specific disease.

While GMAC will assess the safety aspects associated with the potential for spread of the vaccine organism from patients, the Gene Therapy Research Advisory Panel (GTRAP) of the National Health and Medical Research Council will also need to examine proposals for vaccine trials. GTRAP's interest will be in the aspects of the proposal relating to the clinical trial protocol and the safety to vaccinated patients.

The Scientific Subcommittee intends to formulate a set of relevant questions, extracted from the *Guidelines for Activities with the Potential for Unintended Release of Genetically Manipulated Organisms*, for proponents of vaccine trials. GMAC will consult with GTRAP about the possibility of combining the information requirements of GMAC and GTRAP in a single proposal. The *Guidelines for the Deliberate Release of Genetically Manipulated Organisms* will also require consequential amendment.

Large Scale Subcommittee

Assessment of proposals

The Large Scale Subcommittee met once during the reporting period and discussed recent inspections of containment facilities undertaken by members of the Subcommittee and a proposed revision of the Australia/New Zealand Standard 2243.3: *Safety in Laboratories: Microbiology*. The Subcommittee assessed out-of-session one proposal for large scale contained work. The proposal involved production of a recombinant human antibody in Chinese hamster ovary (CHO) cells. It was 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 the Large Scale Subcommittee:

- PC2 large work area, Institute of Medical and Veterinary Science, Adelaide (certified August 1998)
- PC2 large scale animal facility, CSIRO Australian Animal Health Laboratory, Werribee (certified September 1998)
- PC3 laboratory, Queensland Department of Primary Industries Animal Research Institute, Yeerongpilly (certified September 1998)
- PC3 laboratories and small animal room, Menzies School of Health Research, Darwin (certified September 1998)
- PC3 laboratories, Prince of Wales Hospital, Randwick (inspected October 1998)
- PC3 laboratory, James Cook University, Townsville (certified March 1999)
- PC3 animal rooms, Herston Medical Research Centre, Brisbane (certified April 1999)
- PC2 large scale laboratory, CSL Limited, Parkville (certified April 1999)
- PC2 large work area, Johnson & Johnson Research, Australian Technology Park, Sydney (certified May 1999)
- PC2 large work area, CSIRO Wildlife and Ecology, Gungahlin (certified June 1999)

- PC3 laboratory and animal room, Berrimah Veterinary Laboratories, Darwin (inspected June 1999).

Release Subcommittee

Activities at meetings

A mechanism for ensuring appropriate management of the use of herbicide-resistant crops in Australian agriculture was discussed extensively by the Release Subcommittee at its meetings during the year. During this and the previous reporting period, GMAC has received several proposals for general release of herbicide-resistant crops. The proponents for these proposals have been advised that general release of herbicide-resistant crops should not proceed until a coordinated national strategy is in place for the management of such crops. (The proposals have therefore not proceeded as general releases; they were assessed by GMAC as requiring the same conditions for isolation and monitoring that apply to field trials.) Professor Millis, GMAC's Chair, has 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. The *Good Agricultural Practice Guidelines for the Use of Genetically Modified Plants* developed by the Working Group put in place a procedure to ensure that proponents develop management practices for crops modified for resistance to herbicides and for resistance to pests and diseases (see page 11).

At the meeting of the Release Subcommittee on 11 August 1998, representatives from Avcare gave a presentation on Avcare's proposal for a strategy for herbicide-resistant crops in Australia. Avcare is an organisation that represents companies involved in agrichemical sales in Australia, including the major global companies developing agricultural applications of biotechnology. Since the meeting, Avcare and the Cooperative Research Centre for Weed Management Systems have developed general guidelines for the integration of herbicide-resistant crops into Australian cropping systems that are consistent with the recommendations in the *Good Agricultural Practice Guidelines*.

The Release Subcommittee meeting on 21 May 1999 included a discussion with the proponents for a proposal for release of a genetically modified insect virus (baculovirus). The proponents, from CSIRO Entomology, have already conducted field trials (proposals PR-86 and PR-86X) of a baculovirus that has been genetically 'marked' so that it can be distinguished from the wild-type virus. Their eventual aim is to develop a virus that can be used as a biological control agent for caterpillar pests of crops. The proponents, together with representatives from the IBC, attended the Release Subcommittee meeting to seek GMAC's advice on the risks associated with a potential future trial of a baculovirus expressing a scorpion toxin. Dr Ken Winkel, from the Australian Venom Research Unit, Department of Pharmacology, University of Melbourne, was also present as a co-opted expert. A detailed consideration was given to the possible consequences of such a trial, including the difficulty in containing the virus within the trial area and the potential for unintended effects on non-target insects. As a result of the discussion, the proponents and the IBC are reviewing their approach to this work.

The Release Subcommittee also gave consideration to the Public Information Sheets on release proposals at its meetings during the year. As a result of comments received from members of the public about the level of technical detail in the Public Information Sheets, the Subcommittee has decided to include an additional page that provides a brief summary of the proposal in non-technical language.

Assessment of proposals

During 1998-99, 19 new deliberate release proposals, 26 extensions to previous proposals, one general release proposal, and one proposal with the potential for unintended release of a genetically manipulated organism, were received and assessed.

New proposals

PR-98 (Deltapine Australia Pty Ltd – Queensland cotton: Flinders River cotton project 1998-1999)

Proposal PR-98 was received in the previous reporting period. It involved a field trial of cotton plants genetically modified for resistance to insect pests. A total of approximately 3 hectares was to be planted in the Flinders River region of Queensland.

Successful out-crossing of cotton with related wild species is regarded as unlikely because of genome incompatibility, and no related native species are regarded as weeds in Australia. GMAC noted that the use of cotton modified to contain the insecticidal (Bt) protein on a large scale has the potential to lead to development of resistance to the Bt toxin in insect pests. Development of resistance was not an issue for this small scale trial, and resistance management studies are continuing as part of other trials. GMAC concluded that the proposal would not pose a significant risk to the environment or the community.

PR-99 (CSIRO Plant Industry – Field evaluation of transgenic cotton for enhanced tolerance to water logging)

This proposal, received in the previous reporting period, was for a field trial involving the evaluation of two lines of cotton that have been genetically modified for tolerance to waterlogging. The trial involved growing approximately 40 000 plants in an area under 0.5 hectare 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 transgenic plants being released might be more tolerant to waterlogging and therefore might have a selective advantage over conventional cotton in agricultural situations where waterlogging is prevalent. However, it is unlikely that waterlogging tolerance would give the transgenic plants any greater capacity for invasiveness or weediness.

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-100 (CSIRO Plant Industry – Evaluation of subclover stunt virus promoters under field conditions)

The aim of proposal PR-100, received in the previous reporting period, was to trial cotton plants containing two new promoters isolated from a virus that infects subterranean clover plants. Promoters are genetic 'switches' which, when coupled to a gene of interest, cause that gene to be expressed in particular tissues of a plant. In this proposal, the new promoters were coupled to 'marker' genes that enable identification of the plants.

The proposal involved planting 400 transgenic cotton plants in an area under 0.01 hectare at the Australian Cotton Research Institute in Myall Vale, NSW.

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

PR-101 (CSIRO Plant Industry – Genetic engineering of Verticillium *wilt tolerance of cotton)*

This proposal was received in the previous reporting period and involved a trial to assess the field performance of transgenic cotton plants modified for resistance to fungal attack. The trial involved the planting of 3600 modified cotton plants at the Australian Cotton Research Institute in Myall Vale, NSW, and at Brookstead in Queensland.

If the plants being released are more tolerant of fungal wilt disease, they might have a selective advantage in agricultural situations where such diseases are present, as occurs in intensive cultivation. Under natural conditions they would have no specific advantage.

GMAC concluded that the trial would not pose a significant risk to the community or the environment.

PR-102 (CSIRO Plant Industry – Transgenic wheats with modified grain qualities)

This proposal, received in the previous reporting period, was for a field trial of wheat modified to over-produce a glutenin protein in the wheat grain. The proponents wished to determine the quality characteristics, such as dough strength, of flour produced from the modified grain. The transgenic wheat also contained a marker gene conferring resistance to the herbicide Basta® (glufosinate-ammonium). The trial involved 1500 wheat plants in an area of 400 square metres at the Ginninderra Experiment Station in the ACT.

The modified wheat plants would have a competitive advantage only in the presence of phosphinothricin-based herbicides such as Basta®. Basta® is not registered for use on cereals in Australia and the herbicide-resistance gene was introduced into the wheat plants only as a selectable marker.

GMAC advised that it would have serious concerns about the use of the Basta®-resistance gene in wheat intended for commercial release, and any such proposal would be unlikely to be permitted to proceed. This concern relates to potential difficulties with the control of volunteer wheat plants in canola crops used in a rotation.

GMAC's assessment was that the proposal was of low risk. There was little potential for spread of the transgenic plants or their genetic material beyond the trial site.

PR-103 (CSIRO Plant Industry – Field trial of transgenic poppy, Papaver somniferum*)*

Proposal PR-103 was received in the previous reporting period. Oilseed poppy (*Papaver somniferum*) is grown commercially in Tasmania 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. The purpose of this release was to assess the potential for gene flow from genetically modified poppy plants to unmodified poppy plants and related species. The poppy plants trialled under this proposal had been modified by insertion of a marker gene conferring resistance to the herbicide Basta® (glufosinate-ammonium). The trial involved 124 plants at Egmont, Tasmania.

The cultivation of poppies in Tasmania is strictly controlled by the Poppy Advisory and Control Board. Poppies have not become established as a weed in natural areas of Tasmania. Although several members of the *Papaver* genus are weed species in Tasmania, these species do not occur near the release area and, in any case, are unlikely to hybridise with poppies under natural conditions. GMAC noted that the data to be collected during the trial on pollen movement and crossing with wild species would provide an important basis for future work.

The transgenic poppy plants would have a competitive advantage only in the presence of the herbicide Basta®. This herbicide is currently not used on poppy plants and the trial did not involve use of Basta® on the modified plants.

GMAC concluded that the likelihood of dispersal of the transgenic plants or their genetic material from the trial site was very low. While GMAC's view was that the current proposal did not pose significant risks to biosafety, the proponent was advised that new issues would be raised by any future proposals involving poppy plants with modified alkaloid pathways.

PR-104 (CSIRO Plant Industry Horticulture Unit – Evaluation of transgenes in grapevine)

The aim of this release was to evaluate the field performance of transgenic grapevines and to determine the effect on fruit quality of modifying the levels of the enzyme polyphenol oxidase (PPO). This enzyme is involved in fruit browning. The eventual aim is to produce plants with reduced PPO levels, for use in the dried fruit industry for production of low browning sultana raisins. The trial involved the planting of a total of 109 plants in an area of 0.1 hectare.

The natural role of PPO in plants has not been determined. One possibility is that the enzyme might have a role in deterring insects that feed on the plants. GMAC noted that the susceptibility of the transgenic plants to pests would be one of the characteristics evaluated during the trial.

GMAC's conclusion was that the introduced genes would not pose any significant risks, and that the likelihood of dispersal of the transgenic grapevines or their genetic material was very low. The plants to be trialled were sultana varieties, which produce seedless (sterile) fruit. However, GMAC suggested that data on the extent of pollen dispersal would be useful for subsequent proposals and that monitoring of pollen transfer should be included as one of the aims of the field trial.

*PR-105 (CSIRO Plant Industry – Field evaluation of transgenic lines of field peas (*Pisum sativum *L.) with resistance to pea weevil (*Bruchus pisorum*))*

This proposal aimed to evaluate the performance of field peas that are resistant to attack by the pea weevil (*Bruchus pisorum*) through expression of an α-amylase inhibitor protein from the common bean. Pea weevil is one of two major insect pests of peas that cause major losses in production in Australia. The field trial was located in Wagga Wagga, NSW, and Canberra, ACT, in a total area of 0.2 hectare.

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 noted that pea weevils with resistance to the inhibitor protein could emerge with widespread use of the transgenic plants. The proponent intends to develop an integrated pest management strategy, which will delay the development of resistance, prior to general release of the peas. An information package to be provided to growers will be developed as part of this strategy.

GMAC's assessment was that this proposal raised no new biosafety issues that had not previously been considered in assessment of similar proposals. The proposal was regarded as posing no significant risk to the environment or the community.

PR-106 (University of Adelaide – Evaluation of the performance of transgenic barley under field conditions)

The aim of this proposal was to test the field performance of genetically modified barley containing two 'marker' genes. Future releases may involve barley modified for quality traits. The trial was carried out at the Charlick Experimental Station, Strathalbyn, South Australia, with 1500 transgenic plants in an area of 2500 square metres.

GMAC concluded that the proposal posed negligible risk to the environment or the community. The procedures to be used during the trial, including isolation of the transgenic plants from other barley crops, were appropriate to minimise the potential for dispersal of the transgenic plants or their genetic material beyond the trial site. Cultivated barley does not have weedy properties and wild relatives to which the introduced genes could transfer were not present at the trial site. However, GMAC considered that data on the extent of pollen movement from the transgenic barley would be of value for subsequent release proposals. The proponent was therefore advised to monitor gene transfer from the transgenic plants as part of the trial.

PR-107 (University of Adelaide – Evaluation of the performance of transgenic wheat under field conditions)

This proposal was similar to PR-106, but involved wheat instead of barley modified to express marker genes. The trial was carried out at the Charlick Experimental Station, Strathalbyn, South Australia, with up to 600 transgenic plants in an area of 400 square metres.

GMAC's assessment was that the procedures to be used during the trial were appropriate to minimise the potential for dispersal of the transgenic plants or their genetic material

beyond the trial site. Wheat does not have weedy characteristics, and wild species related to wheat that are potentially weedy do not occur in Australia.

GMAC concluded that the proposal posed negligible risk to the environment or the community.

PR-108 (Queensland Department of Primary Industries – Field assessment of transgenic papaya for virus resistance)

In this proposal, transgenic papaya plants modified for resistance to infection by papaya ringspot virus were assessed in the field. Papaya ringspot virus is the most damaging pathogen affecting papaya worldwide and is a threat to the Queensland papaya industry. One hundred transgenic papaya plants were trialled in an area of 1500 square metres at Bridgeman Downs, Queensland.

The proponent noted that there is potential for the following three events to occur in plants modified to contain a viral coat protein gene: recombination may occur between the viral coat protein gene in the transgenic plants and another virus that may infect the plants; the viral coat protein may 'transcapsidate' the genetic material of another virus that infects the transgenic plants; and the viral coat protein gene may act to complement the activities of other viruses. However, no viruses other than papaya ringspot virus have been reported in Australian papaya. GMAC's assessment was that these risks are already present under natural conditions of viral infection of plants.

GMAC's assessment was that the proposal would not pose significant risks. Additional precautions were recommended by GMAC to minimise the potential for the introduced genes to be dispersed to papaya plants being grown for domestic use near the trial site. The proponent undertook to wrap the male (pollen-producing) flowers in netting, to prevent access of pollinating insects.

PR-109 (Deltapine Australia Pty Ltd – Winter nursery seed increase of INGARD® (Bt)/Roundup Ready® (RR) cotton plants, 1999)

Deltapine Australia Pty Ltd 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 planting an area of 5 hectares at 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-110 (AgrEvo Pty Ltd – Development of fungal disease resistant canola cultivars)

The canola lines (*Brassica napus*) to be released in this trial were genetically modified for tolerance to fungal diseases such as blackleg and Sclerotinia. In addition, the plants were

modified for resistance to the herbicide glufosinate-ammonium. The release involved a total area of 2 hectares over four sites in NSW, Victoria and Tasmania.

As in its assessment of previous proposals for field trials 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. With regard to the use of a herbicide-resistance gene in some of the canola plants, GMAC considered that management strategies would be needed to minimise the risk of emergence of herbicide-resistant weedy relatives of canola. However, for the current trial, the isolation and monitoring procedures were regarded as sufficient to minimise the risk of gene transfer to other plants.

*PR-111 (AgrEvo Pty Ltd – Development of photoperiod insensitive canola cultivars (*Brassica napus*))*

Overseas lines of canola are typically not suited to Australian growing conditions because they are adapted for growing in spring when the days are long, whereas the Australian canola season begins in autumn/winter. Day-length affects the flowering times of canola. Development of canola that is not sensitive to day-length for flowering would allow crossing of lines that normally flower at different times, thus providing access to new hybrid varieties. The current trial involved lines of canola modified to be insensitive to day-length and to be resistant to a herbicide. The modified canola was planted in a total area of 1 hectare at Wagga Wagga, NSW, and in the Moyne and Glenelg Shires, Victoria.

GMAC concluded that the trial would not present any significant risk to the environment or the community. As advised for other trials of herbicide-resistant canola, management strategies would be needed prior to general release to minimise the risk of emergence of herbicide-resistant weedy relatives of canola.

PR-112 (Deltapine Australia Pty Ltd – Winter nursery seed increase of INGARD® (Bt)/CryX cotton plants, 1999)

Deltapine Australia Pty Ltd submitted a proposal for a field trial of cotton plants that were genetically modified for resistance to insect pests. Two insect-resistance (Bt) genes were inserted into the plants. This strategy might give better control of pest insects and reduce the potential for resistance to develop in the pests. The trial involved planting an area of 0.1 hectare at Kununurra, Western Australia.

GMAC's assessment of the risks associated with this proposal was similar to its assessment for previous proposals involving insect-resistant cotton. Biosafety issues raised in GMAC's advice related to the potential for out-crossing of cotton with native species in northern Western Australia and the need for management strategies to delay insect resistance to the Bt toxin. The current trial was not considered to present significant risks to the environment or the community.

PR-113 (Agriculture Western Australia – Field tests of seed mixes for resistance management for transgenic peas)

Agriculture Western Australia submitted a proposal to continue work with a line of field pea that has been genetically modified for resistance to attack by the pea weevil (*Bruchus pisorum*), the major insect pest of peas. The aim of the current field trial was to generate data on strategies for growing the peas that will minimise the risk of development of resistance in pea weevils. This involved growing different mixtures of weevil-resistant and susceptible (unmodified) peas. The field trial was located in Northam and York, Western Australia, in a total area of 1 hectare.

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. GMAC advised that an integrated pest management strategy would be required prior to general release of the transgenic peas, to ensure that the potential for development of resistance in pea weevils is minimised. The aim of the current trial was to produce data for the development of such a management strategy.

GMAC's assessment was that this proposal posed no significant risk to the environment or the community.

*PR-114 (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 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 130 field pea plants were to be grown.

GMAC concluded that the trial would not present any significant risks to the environment or the community. The procedures to be used during the trial would ensure that the transgenic plants and their genetic material would be unlikely to disperse or persist in the environment. While noting that the line of pea to be used in this proposal was not intended for general release, GMAC 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.

*PR-115 (University of Western Australia – The field trialling of Basta® resistant lentils (*Lens culinaris *L.))*

The Centre for Legumes in Mediterranean Agriculture (CLIMA) submitted a proposal for a trial of lentils (*Lens culinaris* L.) that have been genetically modified for resistance to the herbicide glufosinate-ammonium (Basta®). It is intended that the use of the herbicide-resistant varieties will provide additional weed control options for lentil growers by enabling them to use Basta® on the lentils without killing the crop. The field trial was located at three sites in Western Australia.

GMAC concluded that the trial would not present any significant risks to the environment or the community. The procedures to be used during the trial would ensure that the transgenic plants and their genetic material would be unlikely to disperse or persist in the environment.

GMAC noted that further information on aspects of lentil biology, including pollen longevity, seed dormancy and potential pollinating insects, would be useful to GMAC in its assessment of future proposals involving transgenic lentils. 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-116 (University of Western Australia – The field trialling of Liberty® resistant peas (*Pisum sativum *L.))*

The purpose of this proposal was to assess a number of lines of transgenic peas, modified for resistance to the herbicide glufosinate-ammonium (Liberty®), for their performance in the field and their level of herbicide resistance. The herbicide-resistance trait would allow farmers to use Liberty® to kill weeds in pea crops without killing the crop itself. The field trial was to be carried out at three sites in Western Australia.

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

Extensions to previous proposals

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)*

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 involved 16 sites, comprising a total area of under 40 hectares, in the cotton-growing areas of northern NSW and Queensland.

PR-36X(5) (Cotton Seed Distributors – The field testing of cotton expressing CryIIA and CryIA(c) (INGARD®))

The aim of this extension 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 involved 25 sites, comprising a total area of up to 57.5 hectares, in the cotton-growing areas of northern NSW and Queensland.

PR-44X(3) (Cotton Seed Distributors – Seed increase of cotton expressing CryIIA and CryIA(c) (INGARD®))

The aim of this extension was to increase seed stocks of cotton modified for resistance to insect pests for evaluation in future trials. These trials are in anticipation of a potential cotton industry in northern Australia in coming years. Approximately one million plants were trialled in an area of 10 hectares at Kununurra and Broome, Western Australia.

PR-47X(4) (Deltapine Australia Pty Ltd – Winter nursery seed increase of Bt transgenic cotton plants, 1999)

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

PR-49X(3) (CSIRO Plant Industry – Field testing a new line of genetically engineered lupin seeds expressing sunflower seed albumin)

In previous proposals, field trials have been conducted using lupins that have been modified for increased content of sulfur-containing amino acids in their seed. The aim of this extension was to assess the agronomic performance of a new line of modified lupins under field conditions. The new line of lupins differs from those used in previous proposals in that one of the marker genes is not present and a more popular lupin cultivar has been used. Approximately 5500 lupin plants were grown in an area of 0.1 hectare at Wongan Hills, Western Australia.

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)

This extension continued the examination of the field performance of cotton plants modified to be resistant to damage from spray drift of the herbicide 2,4-D sprayed on neighbouring crops. A total of approximately 15 000 plants in an area under 0.15 hectare were trialled at Myall Vale NSW.

PR-55X(3) (CSIRO Plant Industry – The planned release of transgenic cotton expressing tolerance to the herbicide glyphosate)

This extension was to continue monitoring the 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 500 000 plants were grown in a total area under 5 hectares, on up to 10 sites, in the cotton-growing regions of NSW and Queensland.

PR-55X(4) (Cotton Seed Distributors – The planned release of transgenic cotton expressing tolerance to the herbicide glyphosate)

In this extension, the field performance of cotton plants modified for tolerance to the herbicide glyphosate (Roundup®) was assessed. Approximately 50 million transgenic plants, in a total area of less than 500 hectares, were planted on up to ten commercial farms in the Namoi Valley, NSW.

PR-62X(4) (AgrEvo Pty Ltd – Development of glufosinate-ammonium tolerant canola cultivars)

The aim of this extension was to produce seed from lines of canola *(Brassica napus*) that had been genetically modified for tolerance to the herbicide glufosinate-ammonium. A total

of approximately 500 hectares of transgenic canola was grown at 25 sites in southern Australia.

PR-63X(4) (AgrEvo Pty Ltd – Release of glufosinate-ammonium tolerant hybrid and open-pollinated canola cultivars)

The aim of this extension was to allow 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. A total of approximately 1200 hectares of the transgenic canola was to be grown at up to 122 sites in canola-growing regions of Western Australia, South Australia, Victoria, Tasmania and NSW.

PR-64X (Agriculture Victoria Plant Biotechnology Centre – Evaluation of transgenic white clover for field resistance to alfalfa mosaic virus)

This extension to the original proposal aimed to determine whether immunity to alfalfa mosaic virus observed in primary transgenic white clover plants also occurs in the progeny derived from these plants under field conditions. The trial consisted of 336 plants to be planted at each of two sites at Hamilton in Victoria and Howlong in NSW.

PR-69X(2) (CSIRO Plant Industry – The planned release of transgenic cotton expressing tolerance to the herbicide bromoxynil)

The aims of this extension were to continue breeding for commercially useful cultivars of the herbicide-tolerant cotton; to continue integrated weed management studies with the cotton; and to examine the fate of the herbicide (bromoxynil) applied to the transgenic plants. For this proposal, 50 000 modified cotton plants were planted in an area under 1 hectare at the Australian Cotton Research Institute at Myall Vale in NSW.

PR-71X(2) (Deltapine Australia Pty Ltd – Winter nursery seed increase of Roundup Ready® transgenic cotton plants, 1999)

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(2) (Monsanto Australia Ltd – Planned release of transgenic canola expressing tolerance to the herbicide glyphosate)

The aim of this extension was to continue breeding and variety-testing of potential commercial lines of canola modified for tolerance to the herbicide glyphosate. In addition, the trial included examination of options for weed management in glyphosate-tolerant canola. A total of approximately 150 hectares of the transgenic canola were grown at up to 35 sites in Queensland, South Australia, NSW, Tasmania, Victoria and Western Australia.

PR-78X (CSIRO Plant Industry – Assessment of potatoes resistant to potato leafroll virus (PLRV) and potato virus Y (PVY))

This extension aimed to evaluate further the resistance of genetically modified potatoes to potato leafroll virus and potato virus Y in the field. These viruses, transmitted by aphids, are serious pathogens of Australian potatoes. The trial involved 960 transgenic plants released over two sites at Ginninderra Experiment Station in Hall, ACT, and the Institute for Horticultural Development in Toolangi, Victoria.

*PR-79X (AgrEvo Pty Ltd – Development of fungal disease resistant canola cultivars (*Brassica napus*))*

The aim of this extension to the original proposal was to continue the evaluation of strategies for obtaining fungal disease tolerance in canola. The trial comprised a total of 2 hectares, at Wagga Wagga in NSW during winter and either Devonport (Tasmania) or Portland or Warrnambool (Victoria) during spring.

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

The aims of this extension were to begin integrated weed management studies on cotton modified for tolerance to the herbicide Basta®; to continue residue studies on plants sprayed with commercial formulations of Basta®; and to begin agronomic evaluation and breeding of new lines of transgenic cotton. Approximately 15 000 transgenic cotton plants were planted at the Australian Cotton Research Institute at Myall Vale, NSW.

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

The aim of the extension was to increase seed stocks and conduct breeding trials of genetically modified canola for use in the Canadian breeding program. The canola plants have been modified to provide a new genetic system for making hybrid varieties (which produce higher yields than standard varieties) and for tolerance to the herbicide glufosinate-ammonium. A total of approximately 281 hectares of transgenic canola was grown at a number of sites in Tasmania, Victoria, South Australia and NSW.

PR-85X(2) (AgrEvo Pty Ltd – Release of glufosinate-ammonium tolerant hybrid and open-pollinated canola cultivars)

The aim of this extension was to allow seed production from lines of canola that have 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. A total of approximately 51 hectares of the transgenic canola was to be grown in Wagga Wagga, NSW, and Mt Gambier, South Australia.

PR-86X (CSIRO Entomology – Stability, dispersal and transmission of a genetically marked Helicoverpa armigera *singly-enveloped nucleopolyhedrovirus (HaSNPV) in the cotton agro-ecosystem)*

This extension to the original proposal aimed to use a genetically 'marked' nucleopolyhedrovirus (HaSNPV) to gain a better understanding of the patterns of viral spread and persistence in the environment. Genetically modified strains of this virus, which infects insects, might eventually be used as biological control agents against insect pests of cotton. The trial which was to have taken place under the original proposal (PR-86) was aborted due to heavy rainfall and premature maturity of the cotton crop. For this extension, a maximum area of 216 square metres of cotton was to be treated with 2.4×10^{11} virus particles at Myall Vale in NSW.

PR-87X (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)*

Under this extension, the field efficacy and agronomic performance of cotton modified for resistance to insect pests were to be assessed under the conditions at Kununurra and Broome in Western Australia. A major aim is the development of an integrated pest management (IPM) system for transgenic cotton in the Kimberley region, as a precursor to the eventual re-introduction of cotton as a commercial crop in the Kimberley. The trial involved a total area of approximately 1000 hectares.

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

Barley yellow dwarf virus (BYDV) is the most important viral disease affecting cereals in Australia and around the world. The aim of the proposal was to further evaluate the resistance of three types of transgenic barley to BYDV infection in the field, and to monitor pollen spread from the transgenic plants. The trial involved a total of 780 transgenic plants in two plots of about 10 square metres at the Ginninderra Experiment Station at Hall in the ACT.

PR-89X (*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 extension to the original proposal was to begin evaluation of different transgenic varieties and agronomic management principles for a potential cotton industry in northern Australia based on transgenic INGARD® (insect-resistant) cotton. The material used until now has been the most advanced breeding lines being evaluated for use in the eastern States, but it may be necessary to breed lines specifically for northern Australia. Thirteen hectares of transgenic cotton were to be planted at the Department of Agriculture Research Station in Kununurra, Western Australia, and 35 hectares at the Katherine Research Station in Katherine, Northern Territory.

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

The aim of this extension was to allow seed production from lines of Indian mustard (*Brassica juncea*) that have been genetically modified to provide a new system for making hybrid varieties. The plants were also modified for tolerance to the herbicide glufosinate-ammonium. Trial sites of 1 hectare each were to be planted at Wagga Wagga, NSW, with ten further sites possibly to be planted in South Australia, Victoria and Tasmania (a total of up to 11 hectares).

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

The aim of this extension was to continue evaluation of canola that has been genetically modified for resistance to fungal diseases. The canola plants were also modified for tolerance to the herbicide glufosinate-ammonium. A total of approximately 20 hectares of the transgenic canola was to be grown at Wagga Wagga (NSW) and either Devonport (Tasmania) or Portland or Warrnambool (Victoria).

PR-94X (Cotton Seed Distributors – The seed increase of INGARD® cotton expressing glyphosate tolerance)

The aim of this extension was to increase seed supplies of cotton that has been modified to be tolerant both to the herbicide glyphosate and to insect pests. Approximately 3 million transgenic cotton plants were to be grown in an area of up to 10 hectares at Bourke in NSW.

General release proposals

GR-8 (CLIMA, University of Western Australia – The general release of LibertyLink® lupin: Merrit 36.4.3.2)

The Centre for Legumes in Mediterranean Agriculture (CLIMA) submitted a proposal for general release of narrow-leaf lupins that have been genetically modified for resistance to the herbicide glufosinate-ammonium (Liberty®). Use of the herbicide-resistant variety is expected to provide additional weed control options for lupin growers by enabling them to use glufosinate-ammonium on lupin crops without killing the crops.

GMAC's assessment was that the general release of LibertyLink® lupins would not raise any significant concerns for the safety of the environment or the community. Data provided by the proponent confirmed that lupins do not hybridise with other species and have only a low level of out-crossing within the species. There is only a limited geographical overlap between crop and wild populations of lupins.

However, GMAC advised CLIMA that further details would be required on the management of LibertyLink® lupins in farming systems before general release proceeded. These would include detailed directions to farmers on use and management of the crop, including procedures for monitoring and reporting of adverse effects. The use of Liberty® on the crop would require the approval of the National Registration Authority for Agricultural and Veterinary Chemicals.

‘Unintended’ release proposals

UR-2 (Australian National University – Clinical trial of fowlpox virus vaccines expressing the gag/pol antigens of HIV-1 and human interferon gamma)

This proposal is discussed above (see page 15). The Release Subcommittee agreed with the Scientific Subcommittee’s assessment that the Release Subcommittee was not an appropriate forum for review of clinical trials of human vaccines. The Release Subcommittee would have an interest in a vaccine trial only if it involved significant environmental exposure to a live vaccine organism; the role of the Scientific Subcommittee and GTRAP would be to ensure that the vaccine organism was effectively contained.

The Release Subcommittee agreed that the current proposal presented no significant biosafety risks.

Other proposals received

Nine new deliberate release proposals, eleven extensions to previous proposals, and one general release proposal were received late in the reporting period and will be assessed in the next reporting period. These proposals were:

- PR-117 (Queensland Department of Primary Industries – Genetic transformation of lettuce for resistance to viruses)
- PR-118 (Deltapine Australia Pty Ltd – Regulatory trials for efficacy, crop safety and environmental impact with CryIA(c)/CryX and CryX, 1999-2000)
- PR-119 (AgrEvo Pty Ltd – Development of fungal disease resistant canola cultivars)
- PR-120 (AgrEvo Pty Ltd – Development of methods to reduce anti-nutritional factor content in canola cultivars)
- PR-121 (AgrEvo Pty Ltd – Development of canola cultivars with modified plant architecture)
- PR-122 (AgrEvo Pty Ltd – Development of canola cultivars with reduced yield loss)
- PR-123 (CSIRO Plant Industry – Preliminary field evaluation of transgenic cotton expressing the CryIA(c) and CryX delta-endotoxins from *Bacillus thuringiensis*)
- PR-124 (CSIRO Plant Industry – Release of transgenic cotton expressing tolerance to the herbicide Basta®)
- PR-125 (AgrEvo Pty Ltd – Field evaluation and seed increase of LibertyLink® tomatoes)
- PR-36X(6) (CSIRO Plant Industry – The 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(7) (Cotton Seed Distributors – Seed increase of transgenic cotton expressing CryIIA and CryIA(c))
- PR-51X(4) (Deltapine Australia Pty Ltd – Agronomic yield trials, progeny row selection and seed increase of Bt cotton plants, 1999-2000)

- PR-54X(4) (CSIRO Plant Industry – Release of genetically engineered cotton plants with tolerance to spray drift damage caused by the herbicide 2,4-D)
- PR-55X(5) (CSIRO Plant Industry – The release of transgenic cotton expressing tolerance to the herbicide glyphosate)
- PR-69X(3) (CSIRO Plant Industry – Release of transgenic cotton expressing tolerance to the herbicide bromoxynil)
- PR-81X (CSIRO Plant Industry – Release of INGARD® cotton expressing glyphosate tolerance and CryIIA)
- PR-83X(3) (Deltapine Australia Pty Ltd – Agronomic yield trials, progeny row selection and seed increase of Roundup Ready® (RR) and Roundup Ready® (RR)/INGARD® (Bt) cotton plants, 1999-2000)
- PR-94X(2) (Cotton Seed Distributors Ltd – The seed increase of INGARD® cotton expressing glyphosate tolerance)
- PR-99X (CSIRO Plant Industry – Field evaluation of transgenic cotton for enhanced tolerance to waterlogging)
- PR-100X (CSIRO Plant Industry – Evaluation of sub-clover stunt virus promoters under field conditions)
- GR-9 (Monsanto Australia Limited – Commercial release of Roundup Ready® cotton (general release))

Public Liaison Subcommittee

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

GMAC Membership

Professor Byron Lamont completed his term of appointment during the reporting period. Professor Peter Hudson and Ms Sally White were not available to accept reappointment to the Committee when their terms of appointment expired. Dr Annabelle Bennett resigned due to other commitments during the reporting period.

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.

GMAC and its Secretariat provided input into the process to develop a new statutory system for the regulation of gene technology. This included participation in Interdepartmental Committees and the Commonwealth-State Consultative Group on Gene Technology.

Standards Australia

GMAC members Dr Ian Parsonson and Mr David Martin continued to provide liaison between GMAC and Standards Australia through their membership of the Standards Australia Subcommittee on Safety in Laboratories (Microbiology). GMAC and Standards Australia aim to maintain consistency, as far as possible, between the requirements of the GMAC Guidelines and the Australian/New Zealand Standard AS/NZS 2243.3 (*Safety in Laboratories, Part 3: Microbiology*).

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 Agriculture, Fisheries and Forestry. The Working Group met once during the reporting period.

The Working Group completed its task in March 1999 with production of the document *Good Agricultural Practice Guidelines for the Use of Genetically Modified Plants.* The Guidelines 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 are 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 genetically modified plants. A mechanism for implementation of the Guidelines is under consideration.

Guests at GMAC meetings

Dr Mark Gibbs from the Australian National University and Professor Bob Symons from the Waite Institute at the University of Adelaide attended the Scientific Subcommittee meeting on 4 September 1998. They were invited to the meeting to participate in a discussion on the risks associated with transgenic plants modified by insertion of viral genes.

Ms Naomi Stevens, Ms Marion Sheers and Mr Colin Sharpe, representing Avcare, attended the Release Subcommittee meeting on 11 August 1998. They gave a presentation on the Avcare view of a strategy for management of herbicide-resistant crops.

Dr Peter Christian and Dr Andy Richards from CSIRO Entomology, and Dr Robyn Russell, Acting Chair of the IBC at CSIRO Entomology, attended the Release Subcommittee meeting on 21 May 1999. They discussed with the Subcommittee the risks associated with release of a toxin-expressing insect virus. Dr Ken Winkel, from the Australian Venom Research Unit, Department of Pharmacology, University of Melbourne, was also present to provide expert advice.

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 and non-government organisations in other countries, including the United Kingdom, New Zealand, Japan and China, 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 Victoria and Tasmania was held in Melbourne on 22 March 1999. 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 Ms Brady (GMAC Secretariat). The seminar was attended by members from most of the IBCs operating in Victoria and Tasmania. 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.

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. A GMAC newsletter was issued in October 1998. An Annual Report for the period 1997-98 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 (from July 1999):

http://www.health.gov.au/tga/gene/gmac/gmac.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. A complete description of the roles and responsibilities of IBCs can be found in the GMAC Guidelines.

There are 89 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:

- Sydney University of Technology
- Aeronautical and Maritime Research Laboratory

- CSIRO Plant Industry Horticulture Unit (Merbein)
- CSIRO Floreat Park.

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 IBC of Monsanto Australia Limited notified GMAC of an unintentional breach of GMAC guidelines involving their institution. The breach related to planting of herbicide-resistant (Roundup Ready®) canola (*Brassica napus*) under deliberate release proposal PR-77X. A site at Guyra in NSW was mistakenly planted with *Brassica rapa* in addition to the *Brassica napus* plants. When the mistake was discovered by the IBC, the *Brassica rapa* plants were immediately destroyed and disposed of in accordance with GMAC's advice and guidelines. A series of procedural reforms have been initiated by the IBC to ensure that that similar incidents do not happen in the future.

GMAC became aware during the reporting period that researchers at the Institute for Horticultural Development of Agriculture Victoria were developing insect-resistant fruit trees without having submitted a proposal to GMAC for the work. The work was a continuation of a proposal that had been submitted a number of years ago, involving introduction of marker genes into fruit trees. The pest-resistant trees were developed in contained facilities and no release into the environment had taken place. This breach of the Guidelines therefore posed no risk to the environment.

The IBC of GroPep Pty Ltd informed GMAC of an incident that resulted in loss of liquid containing genetically manipulated microorganisms to the sewer. The liquid contained *Escherichia coli* cells carrying a gene for a human growth factor. The incident resulted from a misunderstanding of the Standard Operating Procedures for the work. GroPep Pty Ltd has undertaken a number of follow-up activities and revised its procedures to ensure that this type of incident will not recur. GMAC agreed that the procedures instituted after the incident were appropriate and was confident that the incident had not presented a significant biosafety hazard.

Database records

GMAC maintains a record of IBC membership, certified containment facilities 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 from the Budget of the Department of Industry, Science and Resources. It receives no funding from other sources, nor does it have a granting function. No revenue is generated.

Expenditure (nearest thousand dollars) on the Committee (sitting fees, travel and other expenses) for 1998-99 was $160 000. The Department of Industry, Science and Resources also met the salaries and running costs of the GMAC Secretariat.

Members are paid according to Remuneration Tribunal Determination 3 of 1999.

Staffing

At 30 June 1999, the Secretariat had five full-time staff members: three scientists and two administrative staff members. The Secretariat will re-locate from the Department of Industry, Science and Resources to the Department of Health and Aged Care on 1 July 1999. 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 a previous reporting period (1996-97) and was finalised in 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 (deliberate) 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 Research Advisory Panel is maintained by cross-membership between the Committees; two members of GMAC's Scientific Subcommittee are members of the Gene Therapy Research Advisory Panel.

During 1993-94 GMAC increased the information it makes available on deliberate release proposals via its Public Information Sheets. The Public Information Sheets now contain a greater level of detail on deliberate 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. Following the 1998 Federal election, the portfolio expanded to become the Department of Industry, Science and Resources. The Minister responsible for GMAC is the Hon Nick Minchin MP, Minister for Industry, Science and Resources.

The Budget of 11 May 1999 announced the transfer of responsibility for GMAC from the Minister for Industry, Science and Resources to the Minister for Health and Aged Care. GMAC will be administered from the new Interim Office of the Gene Technology Regulator, which will also be responsible for continuing negotiations on the development of a statutory framework for regulation of gene technology.

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.)

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 Australia New Zealand Food Authority and the

Therapeutic Goods Administration. Where there is uncertainty about the responsible agency for a specific organism, authorities which might 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 four sets of Guidelines for small scale work, large scale work, deliberate release work, and activities with the potential for unintended release. 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 would cooperate with the States and Territories to introduce a national regulatory framework for genetic manipulation work ('gene technology'), providing 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
Professor Angela Delves BAppBiol, PhD	Pro-Vice Chancellor, Southern Cross University
Professor Ashley Dunn MPhil, PhD, FAA	Head, Molecular Biology Program, Ludwig Institute for Cancer Research
Professor Peter Langridge BSc, PhD	Research Leader, ARC for Basic and Applied Plant Molecular Biology, Waite Agricultural Research Institute
Dr John Manners BSc, PhD, DIC	Senior Research Scientist, CSIRO Tropical Agriculture
Mr David Martin Diploma of Mechanical Engineering	Retired Biocontainment Engineer, Australian Animal Health Laboratory, CSIRO
Dr John Oakeshott BSc, PhD	Head of Molecular Biology, CSIRO Entomology
Dr 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	Associate Professor and Reader, Faculty of Law, Adjunct Associate Professor and Reader, Faculty of Medicine University of Melbourne
Dr Jan Tennent BSc, PhD	Unit Leader, CSIRO Division of Animal Health, CRC for Vaccine Technology Unit

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 responsible for the function. The level of remuneration is determined by the Remuneration Tribunal.

Four GMAC members completed their terms of appointment during the year: Dr Annabelle Bennett, Professor Peter Hudson, Professor Byron Lamont and Ms Sally White.

Members of Subcommittees

Scientific Subcommittee

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

Large Scale Subcommittee

Professor Millis (Chair)
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.

Release Subcommittee

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

Public Liaison Subcommittee

Vacant (Chair)
Professor Delves
Professor Millis
Associate Professor Skene

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 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 for each IBC, as at 30 June 1999. Proposals are denoted as SS (small scale contained work), LS (large scale contained work), PR (deliberate release proposals, including general releases and extensions to deliberate release proposals), and UR (proposals for activities with the potential for unintended release). Included in the table are some proposals that were still under assessment by GMAC at the time of printing. The listed IBCs represent the main institutions registered with GMAC. Some committees may in turn supervise other institutions.

		Current projects			
Institution	**IBC Chair**	**SS**	**LS**	**PR**	**UR**
Australian Capital Territory					
Australian National University	Prof P Board	57	0	1	1
CSIRO Entomology	Dr P Christian	20	0	2	0
CSIRO Plant Industry	Dr A Richardson	35	0	42	0
CSIRO Wildlife and Ecology	Dr K Williams	28	0	0	0
New South Wales					
Applied Horticultural Research Pty Ltd	Dr G Rogers	0	0	0	0
Australian Red Cross Blood Service - NSW	Prof Y Cossart	4	0	0	0
Biotech Australia Pty Ltd	Dr D Irving	24	5	0	0
Charles Sturt University, Riverina	Dr G McKenzie	6	0	0	0
Children's Medical Research Institute/Royal Alexandra Hospital for Children	Prof P Rowe	18	0	0	0
Cotton Seed Distributors	Mr G Windeatt	0	0	3	0
CSIRO Animal Production	Dr I Franklin	15	0	0	0
CSIRO Molecular Science - Sydney Lab	Dr P Molloy	13	0	0	0
Johnson & Johnson Research	Dr W Gerlach	8	0	0	0
Macquarie University	A/Prof J Whalley	12	0	0	0
NSW Agriculture, Elizabeth Macarthur Agricultural Institute	Dr P Kirkland	15	0	0	0
Royal North Shore Hospital	Dr R Pritchard	14	0	0	0
Royal Prince Alfred Hospital	Prof J Seale	24	0	0	0
Southern Cross University	Prof A Delves	6	0	0	0
St Vincent's Hospital	Prof J Eisman	28	0	0	0
University of New England	Dr B Cheetham	4	0	0	0
University of New South Wales	Prof A Lee	37	1	0	0
University of Newcastle	A/Prof R Rose	32	0	0	0

University of Sydney	Dr A Weiss	56	0	0	0
University of Technology, Sydney	Dr A Simpson	0	0	0	0
University of Western Sydney, Hawkesbury	A/Prof J Bavor	2	0	0	0
University of Western Sydney, Macarthur	Dr M Campbell	1	0	0	0
University of Western Sydney, Nepean	A/Prof E Deane	0	0	0	0
University of Wollongong	A/Prof R Lilley	11	0	0	0
Westmead Hospital	Dr P O'Connell	26	0	0	0
Northern Territory					
Menzies School of Health Research	Prof D Kemp	24	0	0	0
Queensland					
Australian Institute of Marine Science	Dr R Reichelt	1	0	0	0
Bureau of Sugar Experiment Stations	Dr C Ryan	11	0	1	0
CSIRO Tropical Agriculture	Dr B Barendse	26	0	1	0
Deltapine Australia Pty Ltd	Mr K Flower	3	0	13	0
ForBio Research	Ms B Morris	15	0	0	0
Griffith University	Mr J Urquhart	10	0	0	0
James Cook University	Dr G Burgess	3	0	0	0
Pacific Seeds Pty Ltd	Dr B Hare	0	0	0	0
Progen Industries	Mr J Grew	0	0	0	0
Queensland Department of Primary Industries	Dr P Young	31	0	2	0
Queensland Health	Mr L Smythe	5	0	0	0
Queensland Institute of Medical Research	Dr G Lawrence	64	0	0	0
Queensland University of Technology	A/Prof P Timms	26	0	0	0
Royal Brisbane, Royal Children's and Royal Women's Hospitals	Dr J Rowell	21	0	0	0
University of Southern Queensland	Dr T Mukkur	15	0	0	0
University of Queensland	Prof M McManus	139	0	4	0
South Australia					
BresaGen Ltd	Dr R Clay	2	8	0	0
CSIRO Plant Industry, Horticulture Research Unit	Dr J Jackson	5	0	1	0
CSIRO Land and Water	Mr P Lee	7	0	0	0
Flinders University/Flinders Medical Centre	Dr J Oliver	43	0	0	0
GroPep Pty Ltd	Dr F Ballard	3	0	0	0
Institute of Medical and Veterinary Science	Dr Z Rudzki	54	0	0	0
North Western Adelaide Health Service (Queen Elizabeth Hospital)	Prof D Grove	13	0	0	0
University of Adelaide	Prof R Milbourne	54	0	2	0
University of South Australia	Dr W Woods	5	0	0	0

Women's and Children's Hospital	Dr W Carey	7	0	0	0
Tasmania					
Tasmanian Department of Primary Industry and Fisheries	Mr D Munro	3	0	2	0
University of Tasmania	Prof H Muller	5	0	0	0
Victoria					
Aeronautical and Maritime Research Laboratory	Dr D Paul	0	0	0	0
AgrEvo Pty Ltd	Mr R Harris	0	0	18	0
AMRAD Burnley	Dr L Ward	11	0	0	0
Austin Repatriation Medical Centre	Dr C White	26	0	0	0
CSIRO Australian Animal Health Laboratory	Dr G Abraham	33	0	0	0
CSIRO Health Science and Nutrition - Parkville Lab	Dr D Hewish	5	0	0	0
CSIRO Plant Industry Horticulture Unit, Merbein	Dr R Walker	0	0	0	0
CSL Limited	Mr K Healy	12	0	0	0
Deakin University	Prof P Hamilton	0	0	0	0
Florigene Pty Ltd	Prof L Stubbs	18	0	5	0
La Trobe University	Dr J Jenkin	31	0	2	0
Ludwig Institute for Cancer Research	Dr M Hibbs	55	0	0	0
Monash University	A/Prof V Krishnapillai	135	0	0	0
Monsanto Australia Limited	Dr W Blowes	2	0	4	1
Peter MacCallum Cancer Institute	Dr J Radley	21	0	0	0
RMIT University	Dr T Stevenson	1	0	0	0
Royal Children's Hospital	Mr A Holt	21	0	0	0
Royal Melbourne Hospital Research Foundation	Prof A Dunn	76	0	0	0
Southern Cross Biotech	Mr D Hughes	1	0	0	0
St Vincent's Hospital	Dr M Gillespie	8	0	0	0
University of Melbourne	Prof M Hynes	71	0	0	0
Victoria University of Technology	Prof R Fairclough	0	0	0	0
Victorian Department of Agriculture	Dr R Condron	12	0	0	0
Walter & Eliza Hall Institute of Medical Research	Dr A Cowman	27	0	0	0
Western Australia					
Agriculture Western Australia	*Vacant*	1	0	3	0
CSIRO Floreat Park	Dr N Adams	0	0	0	0
Curtin University of Technology	A/Prof J Warmington	8	0	0	0
Murdoch University	Dr P O'Brien	25	0	0	0
Princess Margaret Children's Medical Research Foundation	Prof W Thomas	13	0	0	0

Royal Perth Hospital	Dr P Cannell	5	0	0	0
University of Western Australia	Prof G Yeoh	73	0	3	0

Total number of IBCs	89
Total number of current projects	
Small scale	1681
Large scale	13
Deliberate release	109
Activities with potential for unintended release	2

APPENDIX 5. SMALL SCALE PROPOSAL DETAILS 1981 - 30 JUNE 1999

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
1998/99	277	15	0	7	299
Total	**4604**	**172**	**0**	**125**	**4901**

* 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 falling under GMAC's scope. 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

APPENDIX 6. LARGE SCALE PROPOSAL DETAILS 1981 - 30 JUNE 1999

Of the 37 large scale proposals assessed between 1981 and 30 June 1999, 15 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
University of New South Wales

APPENDIX 7. DELIBERATE RELEASE PROPOSAL DETAILS 1981 - 30 JUNE 1999

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
QLD 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
QLD Department of Primary Industries	PR-24	Contained field growth of grafted apple stock transformed for kanamycin resistance
QLD Department of Primary Industries	PR-24X	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
QLD 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-36X(4)	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*
Cotton Seed Distributors	PR-36X(5)	The field testing of cotton expressing CryIIA and CryIA(c) (INGARD®)*
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*)
QLD 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*
Cotton Seed Distributors	PR-44X(3)	Seed increase of cotton expressing CryIIA and CryIA(c) (INGARD®)*
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
Deltapine Australia Pty Ltd	PR-47X(4)	Winter nursery seed increase of Bt transgenic cotton plants, 1999*

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
CSIRO Division of Plant Industry	PR-49X(3)	Field testing a new line 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-54X(3)	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-55X(3)	The planned release of transgenic cotton expressing tolerance to the herbicide glyphosate*
Cotton Seed Distributors	PR-55X(4)	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 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
AgrEvo Pty Ltd	PR-62X(4)	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
AgrEvo Pty Ltd	PR-63X(4)	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
Agriculture Victoria Plant Biotechnology Centre	PR-64X	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
CSIRO Division of Plant Industry	PR-69X(2)	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
Deltapine Australia Pty Ltd	PR-71X(2)	Winter nursery seed increase of Roundup Ready® transgenic cotton plants, 1999*
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 Australia Ltd	PR-77X	Planned release of transgenic canola expressing tolerance to the herbicide glyphosate
Monsanto Australia Ltd	PR-77X(2)	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)
CSIRO Division of Plant Industry	PR-78X	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
AgrEvo Pty Ltd	PR-79X	Development of fungal disease resistant canola cultivars (*Brassica napus*)*
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®
CSIRO Division of Plant Industry	PR-82X	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
AgrEvo Pty Ltd	PR-85X	Small and large scale seed increase of a genetically modified canola (*Brassica rapa*) with a new hybridisation system*
AgrEvo Pty Ltd	PR-85X(2)	Release of glufosinate-ammonium tolerant hybrid and open-pollinated canola cultivars*
CSIRO Division of Entomology	PR-86	Dispersal ecology of a genetically marked *Helicoverpa armigera* singly-enveloped nucleopolyhedrovirus (HaSNPV) in the cotton agro-ecosystem

CSIRO Division of Entomology	PR-86X	Stability, dispersal and transmission 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
Agriculture Western Australia	PR-87X	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-88X	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*
CSIRO Division of Plant Industry	PR-89X	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*
AgrEvo Pty Ltd	PR-90X	Development of herbicide tolerant *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
AgrEvo Pty Ltd	PR-93X	Development of fungal disease resistant canola cultivars*
CSIRO Division of Plant Industry	PR-94	Winter seed increase of INGARD® cotton expressing glyphosate tolerance
Cotton Seed Distributors	PR-94X	The 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
Deltapine Australia Pty Ltd	PR-98	Queensland cotton Flinders River cotton project 1998-1999*
CSIRO Division of Plant Industry	PR-99	Field evaluation of transgenic cotton for enhanced tolerance to waterlogging*

CSIRO Division of Plant Industry	PR-100	Evaluation of subclover stunt virus promoters under field conditions*
CSIRO Division of Plant Industry	PR-101	Genetic engineering of Verticillium wilt tolerance of cotton*
CSIRO Division of Plant Industry	PR-102	Transgenic wheats with modified grain qualities*
CSIRO Division of Plant Industry	PR-103	Field trial of transgenic poppy, *Papaver somniferum**
CSIRO Division of Plant Industry Horticulture Unit	PR-104	Evaluation of transgenes in grapevine*
CSIRO Division of Plant Industry	PR-105	Field evaluation of transgenic lines of field peas (*Pisum sativum* L.) with resistance to pea weevil (*Bruchus pisorum*) *
University of Adelaide	PR-106	Evaluation of the performance of transgenic barley under field conditions*
University of Adelaide	PR-107	Evaluation of the performance of transgenic wheat under field conditions*
QLD Department of Primary Industries	PR-108	Field assessment of transgenic papaya for virus resistance*
Deltapine Australia Pty Ltd	PR-109	Winter nursery seed increase of INGARD® (Bt)/Roundup Ready® (RR) cotton plants, 1999*
AgrEvo Pty Ltd	PR-110	Development of fungal disease resistant canola cultivars
AgrEvo Pty Ltd	PR-111	Development of photoperiod insensitive canola cultivars (*Brassica napus*) *
Deltapine Australia Pty Ltd	PR-112	Winter nursery seed increase of INGARD® (Bt)/CryX cotton plants, 1999*
Agriculture Western Australia	PR-113	Field tests of seed mixes for resistance management for transgenic peas*
CSIRO Division of Plant Industry	PR-114	Field evaluation of transgenic lines of field pea (*Pisum sativum* L.) for resistance to Ascochyta blight*
University of Western Australia	PR-115	The field trialling of Basta® resistant lentils (*Lens culinaris* L.) *
University of Western Australia	PR-116	The field trialling of Liberty® resistant peas (*Pisum sativum* L.) *
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
CLIMA, University of Western Australia	GR-8	The general release of Liberty Link® lupin: Merrit 36.4.3.2*
Monsanto Australia Ltd	IR-1	IR-1: Application to import transgenic soybean
Australian National University	UR-2	Clinical trial of fowlpox virus vaccines expressing the gag/pol antigens of HIV-1 and human interferon gamma*

* Assessed by GMAC in this reporting period (1998-99).

The table below shows the location of deliberate release proposals in Australia.

Locations of Deliberate Releases of Genetically Manipulated Organisms in Australia (to 30 June 1999)

State	Organism
ACT	Barley
	Clover
	Field pea
	Potato
	Pseudomonas
	Rhizobium
	Wheat
New South Wales	Baker's yeast
	Canola
	Clover
	Cotton
	Field pea
	Fowlpox virus
	Helicoverpa armigera singly-enveloped nucleopolyhedrovirus
	Indian mustard
	Potato
	Tobacco
Northern Territory	Cotton
Queensland	Apple
	Bovine herpes virus 1
	Canola
	Cotton
	Papaya
	Pineapple
	Potato
	Pseudomonas
	Sugarcane
	Tomato
South Australia	Barley
	Canola
	Field pea
	Indian Mustard
	Potato
	Pseudomonas
	Wheat
Tasmania	Canola
	Indian Mustard
	Poppy
	Potato
Victoria	Canola
	Carnation
	Clover
	Field pea
	Grapevine
	Indian Mustard
	Potato
	Rose
	Tomato
	Salmonella
Western Australia	Canola
	Clover
	Cotton
	Field pea
	Lentil
	Lupin
	Salmonella

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 Resources (Science and Technology Division). For the reporting period, location details of the Secretariat were:

Street address:

20 Allara Street
CANBERRA ACT 2601

Postal address:

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 1999 were:

Dr Andina Faragher (Secretary)
Dr Deborah Maguire (scientific adviser)
Ms Catherine Brady (scientific adviser)
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, October 1998

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 14 part-time members.
- Members are appointed by the relevant Minister (currently the Minister for Industry, Science and Resources) for a term determined by the Minister.
- GMAC has no *ex officio* members.
- Members are paid in accordance with Remuneration Tribunal Determination 3 of 1999.
- GMAC produces an Annual Report.
- There is no review pending.
- Secretariat support to the Committee is provided by the Department of Industry, Science and Resources.

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
GTRAP	Gene Therapy Research Advisory Panel
HIV	Human Immunodeficiency Virus
IBC	Institutional Biosafety Committee
NHMRC	National Health and Medical Research Council
RDMC	Recombinant DNA Monitoring Committee
SCARM	Standing Committee on Agriculture and Resource Management

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