**Submission from the**
**Interim Office of the Gene Technology Regulator (IOGTR)**
**Therapeutic Goods Administration**
**Commonwealth Department of Health and Aged Care**

**to**

**The House of Representatives Standing Committee on Primary Industries and Regional Services**

# INQUIRY INTO PRIMARY PRODUCER ACCESS TO GENE TECHNOLOGY

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## SECTION 1: INTRODUCTION

This submission has been prepared by the Interim Office of the Gene Technology Regulator (IOGTR) in response to the Committee's invitation to submit information relevant to its inquiry into primary producer access to gene technology.

The IOGTR is an Office within the Therapeutic Goods Administration of the Department of Health and Aged Care. The IOGTR is responsible for giving effect to the Federal Government's decision to work with State and Territory Governments, and non-Government stakeholders, to establish an Office of the Gene Technology Regulator (OGTR) and related legislation, primarily to:

- regulate all aspects of the development, production and use of genetically modified organisms (GMOs) and their products, where no other existing regulatory body has responsibility; and

- work with other regulatory bodies to ensure the consistent application of standards and to harmonise genetic safety assessments across all systems of regulation.

The purpose of this submission is to provide the House of Representatives Standing Committee on Primary Industries and Regional Services with information relevant to the Committee's consideration of current regulatory arrangements which impact on primary producer access to gene technology.

In summary, this submission:

- references the legislative systems which currently regulate genetically modified products and explains the system of controls administered by the Genetic Manipulation Advisory Committee (GMAC) which underpin the operation of existing regulatory systems (Section 2);

- outlines the need to augment the administrative arrangements with more stringent controls, and outlines key aspects of the Federal Government's decisions concerning both interim arrangements (for the period September 1999 – January 2001) and the development of regulatory underpinning which will address the gaps in the current legislation (refer Section 3); and

- comments on the need for public information and education in relation to the regulation of GMOs (Section 4). This information may also be useful to the Committee's consideration of its eighth term of reference ("Opportunities to educate the community of the benefits of gene technology").

# SECTION 2: OVERVIEW OF CURRENT REGULATORY AND ADMINISTRATIVE ARRANGEMENTS

## 2.1 Legislative systems which currently regulate genetically modified products

Currently, genetically modified (GM) products in Australia are subject to controls under five regulatory systems[1]:

1. foods (including GM foods) are regulated under the *Australia New Zealand Food Authority Act 1991* (Cth), administered by the Australia New Zealand Food Authority (ANZFA), and accompanying State/Territory legislation;

2. therapeutic goods (including GM therapeutic goods) are regulated under the *Therapeutic Goods Act 1989* (Cth) administered by the Therapeutic Goods Administration (TGA);

3. agricultural and veterinary (agvet) chemicals (including GM agvet chemicals) are regulated under the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth), administered by the National Registration Authority (NRA), and accompanying State/Territory legislation;

4. industrial chemicals are regulated through the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cth), administered by the National Occupational Health and Safety Commission (NOHSC) and accompanying State/Territory legislation;

5. imports/exports are regulated under the *Quarantine Act 1908* (Cth), the *Imported Food Control Act 1992* (Cth) and the *Export Control Act 1982* (Cth) administered by the Australian Quarantine and Inspection Service (AQIS), and also under Wildlife Protection legislation administered by Environment Australia.

Further information on the five product regulatory systems is provided at Appendix B.

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[1] In addition to the five regulatory systems, human gene therapy research is overseen by the National Health and Medical Research Council (NHMRC) under statutory functions conferred on it by the *National Health and Medical Research Council Act 1992* (Cth). Pharmaceutical products related to human gene therapy are regulated by the Therapeutic Goods Administration. GMAC is involved where, for example, laboratory studies are being conducted on human tissues and cells (ie. at research stages prior to a GMO's referral to NH&MRC/TGA) or where patients will carry live genetically manipulated organisms that are capable of transmission from the patient. Further information on the oversight of human gene therapy is at **Appendix A**.

## 2.2 The Genetic Manipulation Advisory Committee

The work of the Genetic Manipulation Advisory Committee (GMAC) underpins all of the regulatory arrangements described in 2.1, as all research work in Australia involving the use of GMOs or genetic modification techniques is overseen by this Committee.

GMAC is an advisory body within the Health Portfolio (specifically the IOGTR). Its membership includes a wide range of experts in fields such as molecular biology, ecology, plant genetics, agriculture and bio-safety engineering. The Committee does not have statutory powers and controls imposed are to some extent voluntarily complied with by industry. A further discussion of breaches and sanctions is provided below and at Appendix E.

## 2.3 Role of GMAC in overseeing research and release of GMOs

One of GMAC's key responsibilities is to oversee all GMO research in Australia, with each case being considered by GMAC on its individual merits. The Committee's responsibility commences with examination of proposals for contained research into, or production of, GMOs (for example, laboratory work or large scale manufacture of GMOs) and extends through field trials of GMOs and into the general release of GMOs into the environment (for example, the commercial growing of GM crops or animals).

GMAC oversees the development and use of all novel genetic manipulation techniques. It is concerned not only with *in vitro* experiments involving recombinant DNA, but with any operation that results in organisms of novel genotype produced by genetic manipulation which fall under its scope of review. GMAC oversees 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.

Consideration of whether GMOs pose potential hazards to the community or the environment is an integral part of GMAC's responsibilities. Having identified a potential hazard, GMAC is also responsible for identifying appropriate procedures (including containment of organisms) by which the researchers and institutions undertaking such work can ensure safety. GMAC can also direct the research to cease if it is not satisfied that risks to health or the environment cannot be managed appropriately.

To mid-1999, GMAC has assessed just over 5000 proposals for small scale contained work, 40 proposals for large scale contained work, 116 proposals for field trials of GMOs, and 8 applications for general (commercial) release of GMOs. Only 3 general releases (from the 8 applications) have actually occurred so far: Bt cotton (which was subsequently regulated under the NRA legislation), a violet carnation, and a carnation with improved vase life.

There have been very few recorded breaches of the GMAC Guidelines (or those of GMAC's predecessors) over the past fifteen years (when formal record-keeping commenced) – and none which warranted GMAC's intervention to the extent of causing the research to cease. Most incidents reported to GMAC have involved either minor accidents, such as needle-stick injuries, rather than breaches of the Guidelines, or did not involve a release into the environment. In all cases, appropriate action was taken and there were no significant hazards identified to the environment or the community.

## 2.4 Role of GMAC in providing advice to other regulators

Another important function of the Committee is to provide advice to other government regulatory bodies regarding the biosafety and environmental implications of GMOs and GM products regulated by these bodies. (These bodies were referenced in section 2.1 of this submission).

For example, when Bt cotton was approved for general release by GMAC, the plant then needed a subsequent approval from the National Registration Authority (NRA). GMAC provided advice to the NRA on insect resistance issues, so that the NRA could include the need for a resistance management strategy in its approval.

## 2.5 Further information

A brief history of the oversight of gene technology research is at Appendix C.

A copy of GMAC's terms of reference, membership and committee structure is presented in Appendix D.

A table of incidents, including instances of non-compliance with GMAC's guidelines is at Appendix E.

# SECTION 3: INTERIM ARRANGMENTS, AND REGULATORY UNDERPINNING FOR CONTROL OF GENETICALLY MODIFIED ORGANISMS

## 3.1 The appropriateness of current regulatory and administrative arrangements in relation to GMOs

As gene technology develops, it is important to ensure that GMAC's oversight of research continues to be relevant to this technology and that it meets community expectations in terms of providing transparency and accountability.

Today, with new or novel GM products being developed through research, it is also important that GMAC's processes are as rigorous as possible when it comes to assessing the public health and safety risks, and the risks to the environment, of products that may not be covered by the existing regulators. Following are some examples of novel GM products which are the subject of current research, but which, if considered for commercial release, would not fall within the mandate of existing regulators:

- some microorganisms designed to decompose toxic substances (bioremediation);
- herbicide-resistant plants;
- ornamental plants modified to enhance particular characteristics; and
- sterile animals and fish with higher aggressiveness for feral animal control.

## 3.2 The Federal Government's May 1999 decisions

In May 1999, in the context of the Federal Budget, the Commonwealth Government announced that responsibility for overseeing the operation of GMAC would be transferred from the Industry, Science and Resources portfolio to the Health portfolio. With this decision, the Federal Minister for Health and Aged Care, the Hon Dr Michael Wooldridge MP, became responsible for:

- reviewing GMAC's operation, with a view to ensuring that appropriate mechanisms are in place to protect public health and safety and to protect the environment from any risks associated with research in relation to, or general release of, GMOs. The issue of arrangements for controlling general releases is particularly important.

  Over the past 25 years, many research projects have been conducted in Australia. As mentioned in section 2.2, only three general releases have been permitted. While general releases have been rare to date, the Government is aware that a number of research projects are now reaching the stage where general release may be sought. It was thought to be imperative, therefore, that a transparent and rigorous process be established before these releases are considered, to ensure that public health and safety, and environmental safety, are protected.

- working with State and Territory Governments to develop a national regulatory

framework to underpin these arrangements.

The Health portfolio is already responsible for much of the regulation of GMOs within existing frameworks, including through:

- the Therapeutic Goods Administration (TGA) in relation to therapeutics; and
- the Australia New Zealand Food Authority (ANZFA) in relation to foods.

The TGA is also responsible for undertaking the public health assessment of agricultural and veterinary chemicals on behalf of the NRA, and for household chemicals.

The Government's decision to establish the OGTR within Health reflects the Government's view that protecting the health and safety of the public, and protecting the environment, are of paramount concern, and are best achieved by having those responsible at arm's length from industry programs, or programs which are considering the potential benefits of the technology.

### 3.3 Interim Arrangements

Following from the Commonwealth Government's May 1999 decisions, an Interim OGTR has been established within the TGA of the Department of Health and Aged Care.

The IOGTR has worked closely with State and Territory Governments over the past four months, and has carefully considered what arrangements need to be in place to approve general (commercial) releases of GMOs. Much of this work is reflected in the legislative arrangements that are currently being developed, as set out in sections 3.4 and 3.5.

A key part of IOGTR's consideration has been to investigate and understand the community's concerns regarding risks associated with general (commercial) releases of GMOs, and to review current arrangements, to ensure that appropriate controls operate for the period from now until the legislative framework is fully operational.

As a result of this work, the Federal Government concluded that three areas could be improved to provide for greater rigour in relation to controls in this interim period:

(i) The procedure for considering/assessing applications for general release should be more transparent and accountable. From a public confidence perspective, this means making sure that is it clear and easy to understand how decisions are reached in relation to GMO approvals, including how the public can feed into the consideration process.

(ii) The "decision-maker" should be clearly identified. As the name suggests, GMAC is an advisory committee. It is important that the public understand that it is the Minister for Health and Aged Care (the Hon. Dr Michael Wooldridge MP), in consultation with the Minister for the Environment and other relevant Ministers, and, on behalf of Government, makes the decision.

(iii) There must be a mechanism for enforcing compliance with conditions of release. Currently, industry compliance is purely voluntary and from a public confidence perspective, there is no mechanism beyond the good will of industry to ensure that compliance occurs.

In August 1999, the Federal Minister for Health and Aged Care, Dr Wooldridge, announced that the Government would implement new arrangements for considering any application for the general release of a GMO. These arrangements will be administered by the IOGTR in

conjunction with the GMAC and will provide for even higher levels of transparency and accountability in relation to administrative endorsement of the general release of GMOs.

In summary, under these new arrangements, the IOGTR will:

- Revise GMAC's administrative processes to provide a high degree of transparency in terms of GMAC's consideration of applications and development of its recommendations on general (commercial) release proposals. This will include facilitating public involvement and increased involvement of non-Government groups and State and Territory Governments, during the assessment of applications;

- Revise GMAC's administrative processes to provide a high degree of accountability for its recommendations. This will include requiring GMAC to document (and provide evidence in support of) recommendations, and to address substantive concerns raised by the public, non-Government stakeholders and by the States and Territories;

- Revise GMAC's terms of reference and membership to reflect its new role and clarify its responsibility for providing scientific risk assessment advice on both biosafety and agricultural sustainability issues;

- Implement an administrative process whereby the Minister for Health and Aged Care will make decisions on the advice of IOGTR (in consultation with the Minister for the Environment, the Minister for Agriculture, Fisheries and Forestry and any other Minister with relevant responsibilities, including for protecting public health and safety) relating to the release of GMOs and where there will be public notification of these decisions;

- Establish interim review procedures in relation to administrative decisions;

- Establish agreements or contracts between the Commonwealth and the proponent of a general (commercial) release to provide for greater assurance of compliance with conditions the Minister establishes as part of an administrative approval for a general release;

- Be the co-ordination point between all Commonwealth agencies, and State/ Territory/Commonwealth endeavours, for the development of policy advice on the regulation of GMOs where no other agency has regulatory responsibility; and

- Adjust administrative arrangements for GMO research approvals as necessary and in the spirit of the general releases.

The interim arrangements will:

- augment the existing administrative arrangements by providing a more rigorous, transparent and accountable decision making system visible to the public for the commercialisation of GMOs;

- provide legally enforceable risk management conditions on release of commercialised gene technology products thereby providing added assurances of compliance by industry; and

- be a significant interim step towards a more comprehensive regulatory system for gene technology.

The interim arrangements for considering proposals for general release of GMOs into the environment will have four distinct phases: proposal receipt; risk analysis; recommendation; and post-release. To assist the Committee's understanding of the interim arrangements, we have included a document which details these phases at Appendix F. This document will form the basis for a plain English guide to the new interim arrangements, which will be released publicly later in September 1999.

### 3.4 Developing a national regulatory framework

While the new interim arrangements are very rigorous, and compare favourably with arrangements in place in countries such as Canada, the United States and member countries of the European Union, Australian Governments are keen to provide these arrangements with regulatory underpinning.

Considerable work has been undertaken by the Commonwealth, State and Territory Governments to develop this framework, and agreement has been reached on some key points.

All jurisdictions are agreed that the new legislation will be administered by the Office of the Gene Technology Regulator (OGTR) which will:

- be a strong, independent regulator;
- regulate all aspects of the development, production and use of genetically modified organisms (GMOs) and their products, where no other existing regulatory body has responsibility;
- work with other regulatory bodies to ensure the consistent application of standards and to harmonise assessments across all systems of regulation; and
- undertake or commission research in the area of risk assessments.

### 3.5 Progress towards establishing the national legislative framework

Since the establishment of the Interim OGTR, excellent progress has been made by all jurisdictions towards the establishment of the national legislative framework. In the past four months, all jurisdictions have agreed parameters for this legislation.

States, Territories and the Commonwealth have agreed that :

- Decisions taken by the Gene Technology Regulator (GTR) will be science based, clear, and accountable;
- The regulatory processes will involve significant public input into the development of guidelines and standards, as well as the assessment of individual applications. On the latter, there will be opportunities for any interested person to access information about individual applications for release proposals (including the full application, excluding commercial-in-confidence information) and to also understand how their views have been taken into account.
- The role currently played by GMAC will continue to be critical, as the GTR will draw advice

from such an expert, independent committee, which will identify potential and unacceptable risks, and recommend conditions for final approval by the Gene Technology Regulator. Under the legislative framework, the expert committee will be called the Gene Technology Advisory Committee (GTAC).

- With transparency and accountability a major aim of the system, gene technology risk assessments will be statutory processes, subject to accountability measures such as public and peer scrutiny. Arrangements will be developed to refer assessments to other bodies where appropriate.

- The existing statutory responsibility for formal risk assessment under each of the streams administered by other regulators will remain with each product regulator, with GTAC providing advice as appropriate to the regulators. The OGTR will work towards the harmonisation of biosafety assessments for GMOs across the product regulatory systems.

### 3.6 Consultation with interested groups and individuals

We are conscious that non-government groups and individuals will be very interested in the development of the national legislative framework, and in the detail about how this system will work.

Over the past four months, the IOGTR has worked closely with States and Territories to agree broad details about the legislation: in the absence of this broad agreement, consultation with non-government parties was not possible.

Agreement amongst jurisdictions on key issues, such as those outlined in section 3.5, has enabled the IOGTR to develop an Operational Detail paper which is a plain language guide which describes a proposed approach developed by the Commonwealth, States and Territories, in relation to key matters such as:

- Object and definitions;
- Governance, including the role function and composition of the Ministerial Council the GTR, Gene Technology Community Consultative Group and GTAC;
- The interaction between GTR and existing regulators;
- Proposed GTR regulation of GMOs including for research, imports, exports and release;
- Monitoring, compliance and enforcement mechanisms;
- Other issues such as treatment of commercial-in-confidence and cost recovery.

To allow considered input from the community into the development of the legislation, as well as meaningful debate on matters covered by it, we have set aside a period of eight months for consultation on the regulatory framework. The Operational Detail paper will be available in late September 1999 and will form the basis for initial consultation with non-government groups and individuals on the proposed legislative framework.

IOGTR's consultation will include, but will not be confined to, consulting with researchers (including university based researchers and those in private enterprise), health professionals, environmental groups, the agriculture sector, industry, and consumer groups.

As the table on the following page reflects, the IOGTR will ensure that all components of the legislation including (the draft Commonwealth Bill and regulations) are available in a timely way to ensure maximum consultation with interested parties within the community. The IOGTR will also work to keep the Operational Detail paper up to date, as it is often easier to understand a plain language guide to a legislative framework, then it is to follow the intricacies of a draft Bill and Regulations.

## 3.7 Timing to complete the regulatory system

As section 3.7 indicates, the process of community consultation on the development of this legislation is particularly important. To avoid curtailing this consultation, the Government is not envisaging introducing the Bill into Federal Parliament until around April 2000. As the Commonwealth Bill is being developed, the Commonwealth will continue to work closely with States and Territories, which will be involved in preparing model State legislation throughout the period of Commonwealth consultation.

It is hoped that States and Territories are well placed to introduce complementary legislation at around the same time, or shortly after, the Commonwealth Bill is introduced into Federal Parliament.

In relation to the Commonwealth legislation, the Federal Government has indicated that the OGTR must be fully operational no later than 3 January 2001.

| Consultation phase | Timeframe |
|---|---|
| 1. Consultation on Operational Detail paper. This paper explains the overall operation of the proposed regulation of GMOs, in simple language. It does not distinguish between issues which will be dealt with in an Act, in Regulations, or in Guidelines. Nor does it use legal language. It is intended to give the reader an overview of the way the whole system will work. For example, how individuals or organisations can be involved in decision making, what is to be covered by the legislation, what sort of controls are envisaged. | Commences mid-September 1999 |
| 2. Consultation on an exposure draft of the Commonwealth Bill. The exposure draft will supplement the detail provided in the Operational Detail paper. People will be able to see how the intentions set out in the Operational Detail paper have been translated into a legal framework. People will be also able to see how issues raised through consultation on the Operational Detail paper have been reflected in legislation. | Commences around November 1999. |
| 3. Consultation on an exposure draft of the Commonwealth Regulations. Because a lot of the detail of any regulatory framework is set out in Regulations made under the Act, it is important that we consult widely on the draft Regulations, and that the draft is available while the Bill is still the subject of consultation – people have to be able to see how the two documents work together, and then comment on the framework as a whole. | Commences around December 1999. |
| 4. Consultation on the development of supporting and explanatory documents. Throughout the consultation phases, our thinking will be informed by the input received from non-government parties. It will be important to reflect these new ideas in revised drafts of the Operational Detail paper – we hope that this paper will eventually become the plain English guide to the operation of the scheme, recognising that it is important to have this simple guide as it is not always easy to follow legislation. | Commences in mid-September 1999 and is on-going throughout the consultation phases. |
| 5. Introduce the Gene Technology Bill into Federal Parliament. | April 2000. |

## 3.8 The proposed regulatory approach and implications for primary producers

The impact of the proposed regulatory approach can be illustrated with a few examples.

**Example 1: regulating GMOs that are not regulated by existing regulatory bodies.**

Florigene's 'violet carnation' is a well-known example of a genetically modified plant already released and available to the horticultural industry.

In the past such carnations have been subject to the scrutiny and control of GMAC.

The interim arrangements set out in section 3.3 establish a system which is even more effective as a result of greater community involvement in decisions concerning the general release of such GMOs, as well as enhanced transparency and accountability.

Under the national legislative framework referenced in sections 3.4 and 3.5, such GMOs will be regulated only through the proposed OGTR. It is an example of a 'gap' GMO, in that no existing regulator could regulate the commercial release of the genetically modified carnation under existing legislation.

**Example 2: regulating GMOs that are also controlled by another regulator**

Some herbicide-resistant crops currently being researched for use in Australian agriculture are also 'gap' products, and would be regulated in the same way that the Florigene carnations are controlled.

However, if a herbicide-resistant crop was also a potential food, the food safety aspects of the crop plants would also be regulated by ANZFA. Using a herbicide-resistant wheat crop as an example, the regulatory process would be as follows:

- Under interim arrangements, the IOGTR and GMAC would oversee all of the laboratory research involved in developing the genetically modified, herbicide-resistant wheat plant.

- IOGTR/GMAC's oversight would continue throughout the period that the herbicide-resistant crop was the subject of field. IOGTR/GMAC would continue to consider the environmental risks associated with the crop, together with any other possible human health and safety issues;

- At the time approval to grow the crop commercially was given, both ANZFA and IOGTR/GMAC would have an interest in the crop: ANZFA would be responsible for considering aspects of the crop that relate to food safety.

**Example 3: regulating imported GMOs**

An import control example is the shipment of Roundup Ready® soybeans imported through a Brisbane port about two years ago. Under existing arrangements, pest and disease risks of this bulk seed import were assessed by AQIS, and oversight was also provided by GMAC. Under new arrangements, environmental risks would be assessed by the proposed OGTR (with GTAC advice), and any statutory controls would be applied by AQIS and the OGTR, if needed. Food safety would be assessed by ANZFA, applying its new Food Standard.

# SECTION 4: RESPONSE TO THE INQUIRY'S EIGHTH TERM OF REFERENCE

The Inquiry's eighth Term of Reference 'Opportunities to educate the community of the benefits of gene technology' is also relevant to the Health portfolio.

## 4.1 GMAC

Balanced, unbiased, factual information should be freely available from government agencies concerning the science of gene technology and applications (actual and potential) of gene technology, and what the government is doing to ensure that GMOs are safe for humans and the environment.

In the past, GMAC has made information available by:

- publishing notices of the proposed releases in the Commonwealth of Australia Government Notices Gazette;
- circulating the description to interested individuals and organisations who have registered with GMAC for this purpose; and
- sending the description to the municipal council for the area of the release and to relevant State and Commonwealth bodies.

The Gazette Notice is reproduced on the GMAC web-page at www.health.gov.au/tga/gmac/gmachome.htm. Once GMAC makes its decision, it also releases a public information sheet about the deliberate release proposal (see the example at Appendix G).

In addition, information on GMAC's activities is included in the GMAC newsletter.

Most of the regulatory systems described in section 2.1 and at Appendix B have similar requirements for public notification and it is likely that the new gene technology regulatory system will incorporate comparable public notification requirements.

## 4.2 Interim arrangements

In announcing the interim arrangements for approval of general releases described in section, the Commonwealth Government has also announced that the IOGTR will implement a proactive, coordinated strategy for increasing public awareness of the controls governing the release of GMOs, and emphasise that Australian governments have a rigorous strategy for managing risks associated with GMOs.

The Commonwealth Government is keen to ensure the close involvement of State and Territory Governments in the public awareness strategy; and extensive consultation with non-Government groups such as the National Farmers Federation, scientists, researchers and other relevant individuals and bodies in the formulation of arrangements.

### 4.3 Biotechnology Australia

The Minister for Health and Aged Care is one of the five ministers who will oversee Biotechnology Australia. Consequently, the Health portfolio will assist in supporting a public information and awareness program to help Australians understand the opportunities offered by biotechnology and the way potential risks are handled, which is a key task of Biotechnology Australia. Public support is necessary for the adoption of biotechnology by industry, including agriculture. In particular, it is important that government information and awareness programs provide balanced information to the public on benefits, risks and their management. As ASTEC concluded in its 1993 report, 'Meeting the challenge of consultation will be just as important as solving problems of commercialisation'.

## SECTION 5: CONCLUSION

The new legislative framework being developed will protect human health and safety and the environment and allow primary producers to realise the benefits of gene technology where risks are adequately minimised. Effective and efficient regulation will deliver those GMOs that are safe onto the market for primary producer access to gene technology in a timely manner.

At the current time, when the community and industry are considering the potential benefits of gene technology, it is critical that a balanced, rational, transparent and open regulatory system is developed in close consultation with the community and industry. Such a regulatory system will give effect to the Government's first order commitment to protect the health and safety of the community, and protect the environment, from any risks associated with gene technology

## APPENDIX A HUMAN GENE THERAPY AND OTHER APPLICATIONS OF GENE TECHNOLOGY TO HUMANS

The sixth system in Australia which relates to gene technology is the National Health and Medical Research Council (NHMRC) which develops guidelines on human gene therapy. While not directly relevant to the Committee's interest in primary producer access to gene technology, the following brief summary of the controls on human gene therapy is included to provide the Committee with a complete picture of Australia's administrative and regulatory systems for gene technology.

The National Health and Medical Research Council (NHMRC) within the Health portfolio administers the *National Health and Medical Research Council Act 1992* (Cth).

The objectives of this Act are to:

- raise the standard of individual and public health throughout Australia;
- foster the development of consistent health standards between the various States and Territories;
- foster medical research and training and public health research and training throughout Australia; and
- foster consideration of ethical issues relating to health.

Since 1994, all proposals involving human gene therapy have been considered by the Gene Therapy Research Advisory Panel (GTRAP)**,** a sub-committee of the NHMRC's Medical Research Committee. GTRAP also provides advice to researchers to facilitate the design of protocols for gene therapy; acts as a source of information to the community; and ensures the maintenance of a register of human gene therapy trials undertaken in Australia.

The responsibility for enacting legislation in the area of Assisted Reproductive Technology (and therefore cloning of human beings and embryo experimentation) lies with State and Territory Governments. Existing Guidelines (*Ethical Guidelines on assisted reproductive technology*) issued by the National Health and Medical Research Council place considerable restrictions on non-therapeutic research on embryos and prohibit the cloning of a human being.

In addition, the Australian Health Ethics Committee of NHMRC is preparing guidelines in the areas of genetic registers and associated genetic material, human somatic cell gene therapy and related technologies and ethical aspects of human genetic testing.

## APPENDIX B OVERVIEW OF PRODUCT REGULATORY SYSTEMS WHICH HAVE A RESPONSIBILITY FOR GENETICALLY MODIFIED ORGANISMS OR THEIR PRODUCTS

### FOOD

The Australia New Zealand Food Authority (ANZFA) is a statutory body established within the Health portfolio by the *Australia New Zealand Food Authority Act 1991* (Cth). ANZFA has statutory objectives in relation to developing food standards. (While ANZFA has made a separate submission to this inquiry detailing its regulatory responsibilities in relation to foods produced using gene technology, this summary is included to provide the Committee with a complete overview of all regulatory systems of relevance to GMOs).

In developing food standards, ANZFA must have regard to the objectives specified in the *Australia New Zealand Food Authority Act 1991.* The prime objective is the protection of public health and safety, while other objectives relate to consumer information and promoting trade and commerce.

ANZFA is responsible for developing food standards and making recommendations on these standards to a Ministerial Council: the Australia New Zealand Food Standards Council (ANZFSC). When a majority of Council members agree to a food standard, it is then adopted by reference and without amendment into the food legislation of every State and Territory, as well as New Zealand (thereby achieving consistency within Australia and between Australia and New Zealand). Hence, the regulatory responsibility for establishing food standards currently rests with the Ministerial Council.

Responsibility for enforcing food standards lies with the State and Territory health authorities and the Australian Quarantine and Inspection Service in Australia and the Ministry of Health in New Zealand.

In relation to genetically modified food, the Ministerial Council has recently approved Food Standard A18. This standard establishes a pre-market approval process for food produced using gene technology and is addressed in some detail in the ANZFA submission.

It should be noted that while ANZFA can regulate food products for sale for human consumption, some issues in relation to genetically modified food are beyond ANZFA's scope including:

- environmental impacts;
- biosafety issues;
- the safety and regulation of stockfeed.

### THERAPEUTIC GOODS

The import, export, manufacture and supply of therapeutic goods is regulated under the *Therapeutic Goods Act 1989* (Cth). The Act provides a national framework for the regulation of therapeutic goods in Australia to ensure their quality, safety, efficacy and timely availability. The Act is administered by the Therapeutic Goods Administration (TGA) within the Health portfolio. TGA has responsibility both for the pre-market approval of therapeutic goods and for

enforcement and compliance aspects.

The TGA legislative responsibility covers the manufacture of genetically modified therapeutic goods for use in humans. For example, TGA currently regulates genetically modified insulin and vaccines.

Under current arrangements, a genetically modified therapeutic good is assessed for quality, safety, efficacy and timely availability in the same way that a similar (but not genetically modified) therapeutic good is assessed. GMAC oversees the process of production of the therapeutic good at the stages where live GMOs are being used to produce the good. While the controls applied to all therapeutic goods, including genetically modified therapeutics, are stringent, the regulatory coverage of TGA does not extend to biosafety issues or other environmental issues relating to the genetic modification arising during production, where production of a therapeutic good involves use of live animals or crops in Australia. These aspects are also overseen by GMAC.

### AGRICULTURAL AND VETERINARY CHEMICALS

Agricultural and veterinary (Agvet) chemicals are regulated through a national scheme administered by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) within the Agriculture portfolio. The NRA takes advice from other regulatory agencies such as TGA and National Occupational Health and Safety Commission (NOHSC) as part of its assessment processes.

The Agvet regulatory scheme is centred around the Agvet Code which was established under the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) and provides for the evaluation, registration and review of agricultural and veterinary chemicals and their control up to the point of retail sale. Assessment of the chemicals includes a consideration of the public health, occupational health and environmental impact of their use. State and Territory Agriculture authorities retain responsibility for control of use activities, such as licensing of pest control operators and aerial spraying.

In many cases an Agvet chemical that been approved and registered for use by the NRA will also be assessed by ANZFA to determine maximum levels of residue. Should the crop be food it is referred to ANZFA for assessment and incorporation into food standards (that is, if it will result in a residue in the final food as sold). Therefore, responsibility for enforcement and compliance is shared between the Commonwealth, State and Territory Agriculture authorities and State and Territory Health authorities.

### INDUSTRIAL CHEMICALS

The National Occupational Health and Safety Commission (NOHSC) is a tripartite forum of government, employer and employee representatives established within the Employment portfolio. NOHSC regulates industrial chemicals under the *Industrial Chemicals (Notification and Assessment) Act 1989* which describes the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

The NICNAS requires that all industrial chemicals either manufactured or imported into Australia must be notified to NOHSC and undergo assessment. The assessments take into account occupational health and safety, public health and environmental aspects of the manufacture and use of the chemical. As a result of the assessment, NICNAS makes recommendations on the use and handling of the chemical. These recommendations are taken into account by the State and Territory authorities who have responsibility for the

handling, management and sale of industrial chemicals and chemical products under separate legislative arrangements.

The scope of this legislation is limited to industrial chemicals as defined in the Act and this definition of industrial chemicals explicitly excludes whole animals or whole plants. Therefore NOHSC would not regulate living genetically modified organisms although it may consider industrial chemicals produced by GMOs.

### IMPORT/EXPORTS OF GENETICALLY MODIFIED ORGANISMS

The Australian Quarantine and Inspection Service (AQIS) within the Agriculture portfolio is responsible under the *Quarantine Act 1908* (Cth) for ensuring that products imported into Australia do not lead to the introduction, establishment and spread of pests and diseases which many endanger plant, animal and human life or health. Proposals to import goods are assessed using an Import Risk Analysis. This process considers the pests and diseases of quarantinable concern that may be associated with an imported product.

The major issue in relation to the importation of GMOs is the extent to which genetic manipulation of an organism may be associated with pest or disease risks for the purposes of the Quarantine Act and regulations under that legislation.

Environment Australia regulates prescribed organisms under the *Wildlife Protection (Regulation of Imports and Exports) Act 1982* (Cth) to meet Australia's obligations under the Convention of International Trade on Endangered Species and to protect Australian flora and fauna. Although at this stage it is a fairly remote possibility, if a prescribed organism is also genetically modified, it would be subject to this Act.

The Australian Customs Service (ACS) and AQIS also have a general border control role. For example, under the Customs Act 1901 (Cth) ACS would not allow the importation of therapeutic goods without the relevant permit issued by TGA. AQIS also administers the *Imported Food Control Act 1992* to check compliance of imported foods with domestic food legislation.

In relation to the export of GMOs, AQIS administers the *Export Control Act 1992* and certifies that primary produce which is the subject of this Act complies with the requirements of the importing country.

## APPENDIX C. HISTORY OF OVERSIGHT OF GENE TECHNOLOGY RESEARCH IN AUSTRALIA 1975-1999

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 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 (GMAC) 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 (GMOs). 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 GMAC 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.

On 11 March 1996, responsibility for GMAC was transferred from Administrative Services in the Finance portfolio to the Industry, Science and Tourism portfolio. On 11 May 1999, responsibility for GMAC was transferred to the Health and Aged Care portfolio.

## CHRONOLGY OF SIGNIFICANT EVENTS

| | |
|---|---|
| 1975 | Australian Academy of Science Committee on Recombinant DNA (ASCORD) formed and drew up the first Australian guidelines for the conduct of gene technology research. |
| 1981 | Recombinant DNA Monitoring Committee (RDMC) established. Produced three sets of guidelines, which still exist today, albeit in modified form. |
| 1986 | RDMC reported on a five year review to the Minister for Industry, Technology and Commerce. |
| 1987 | Genetic Manipulation Advisory Committee established to replace Recombinant DNA Monitoring Committee. |
| 1989 | Law Reform Commission of Victoria released its report *Genetic Manipulation.* |
| 1990 | Minister for Industry, Technology and Commerce wrote to House of Representatives Standing Committee on Industry, Science and Technology proposing an inquiry into the development, use and release into the environment of genetically modified organisms. |
| 1990 | A special Premiers' Conference agreed to the development of a national approach to the assessment and control of genetically modified organisms. |
| 1992 | Release of report *Genetic Manipulation: The Threat or the Glory?* (February). |
| 1992 | Ministerial Statement on Government Response to report (October). |
| 1992 | First meeting of Commonwealth-State Consultative Group (officials) discussing legislative options for the regulation of genetic manipulation. |
| 1994 | Eighth meeting of Commonwealth-State Consultative Group (September). |
| 1994 | Initial drafting of legislation began. |
| 1995 | Acting Prime Minister wrote (March) to State and Territory leaders seeking advice on form of legislation preferred and noting Commonwealth preference for the adoptive/complementary legislative model. This was specifically rejected by WA and some jurisdictions failed to respond: negotiations on the legislative drafting process broke down. |
| 1997 | Ministers for Industry, Science and Tourism, Primary Industries and Energy, and the Environment announced the Federal Government's preferred package of measures to provide uniform and comprehensive regulation of gene technology. The government's proposal was to develop a national regulatory framework that would provide protection for humans and the environment, assure scientifically based risk assessment, and specify a clear regulatory path for industry, investors and researchers. The Commonwealth's proposal provided for renewed consultations with the States and Territories (October). |
| 1999 | Commonwealth Government announced the creation an Office of the Gene Technology Regulator within the Health and Aged Care portfolio and of Biotechnology Australia within the Industry, Science and Resources portfolio. |

## Appendix d. GMAC Terms of Reference, membership and committee structure

### GMAC's 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.

## GMAC membership

GMAC is an expert committee largely comprising scientists with expertise in fields that are relevant to risk assessment of genetic manipulation work. Experts are drawn from the fields of molecular biology, ecology, plant genetics, microbial genetics, animal genetics, agriculture, virology, entomology and biosafety engineering. In addition to scientists, the Committee includes other members from the wider non-scientific community, with backgrounds in law and a lay member. It is important to recognise that GMAC members are appointed for their specific expertise, rather than as representatives of interest groups. The Committee usually has 18–20 members, and its work is largely conducted through its four subcommittees.

## GMAC's subcommittees

GMAC's four subcommittees are the Scientific Subcommittee, the Large Scale Subcommittee, the Release Subcommittee and the Public Liaison Subcommittee.

- The Scientific Subcommittee reviews the molecular aspects of all proposals covered by GMAC's guidelines (small scale contained work, large scale contained work and deliberate commercial or release work). Proposals for small scale contained work in laboratories are assessed by the Scientific Subcommittee on an ongoing basis.
- 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.
- 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 the Guidelines. It provides advice to relevant Commonwealth, State and local government agencies, as well as to the proponents. The Subcommittee also consults with and provides information on deliberate release proposals to interested members of the public.
- The Public Liaison Subcommittee relates the activities of GMAC to the general public, as well as providing general information on other relevant topics, including international regulatory issues.

Note: GMAC's terms of reference and membership are currently under review by the Minister for Health and Aged Care. Under consideration are: expanding GMAC's membership to include a plant virologist, an animal virologist and an expert in public health; and expanding GMAC's terms of reference to allow consideration of post-general release management issues.

## APPENDIX E. INCIDENTS AND BREACHES REPORTED IN GMAC'S ANNUAL REPORTS

| *Year* | *Incident or breach* |
|---|---|
| 1983-84 | None |
| 1984-85 | None |
| 1985-86 | Small scale contained work commenced before a proposal was submitted to GMAC.* |
| 1986-87 | None |
| 1988-89 | None |
| 1989-90 | Genetically modified pigs were removed from experimental facilities for transport to abattoirs, without Institutional Biosafety Committee (IBC) approval or notification to GMAC.*<br>Work with a full-length copy of human immunodeficiency virus DNA began without IBC or GMAC approval.* |
| 1990-91 | Two incidents involving needle-stick injuries with human immunodeficiency virus were reported. |
| 1991-92 | Between 1986 and 1988 strains of a soil bacterium containing a genetically modified transposon were released in field trials at two sites without GMAC approval.* |
| 1992-93 | A facility not registered for large scale work was used for a project with footrot vaccine antigen which required C1-Large Scale containment.* |
| 1993-94 | Vaccinia virus carrying a gene for Interleukin-2 was administered to a melanoma patient before GMAC had received further details on the proposed trial as requested.* |
| 1994-95 | An accident occurred involving a spill from a waste tank in a PC2-animal facility holding sheep that had been inoculated with genetically modified rumen bacteria.<br>Small scale work requiring PC3 containment took place in a facility not certified as PC3*<br>A vaccinated worker suffered a needle-stick injury with genetically modified vaccinia virus. |
| 1995-96 | A defective shipping container carrying a genetically modified vaccinia virus/ human immunodeficiency virus construct was received by an institution.<br>A worker suffered a needle-stick injury involving a breast cancer cell line over-expressing parathyroid hormone-related protein. |
| 1996-97 | Genetic manipulation work with a fungal pathogen began without notification of the relevant IBCs and the modified fungal pathogen was used to inoculate bananas in a non-certified glasshouse.* |
| 1997-98 | Planting of genetically modified lupins was carried out intentionally, before receipt of GMAC advice and without IBC approval.*<br>Genetically modified lupins were inadvertently planted without IBC approval.*<br>A genetically modified piglet was removed and euthanased without IBC approval.* |

Breaches are indicated by *.

Note: Incidents/accidents are not breaches of the Guidelines.

## APPENDIX F INTERIM ARRANGEMENTS FOR GENERAL (COMMERCIAL) RELEASES OF GENETICALLY MODIFIED ORGANISMS

The process for considering proposals for general release of GMOs into the environment will have four distinct phases: proposal receipt; risk analysis; recommendation; and post-release.

### (I) PROPOSAL RECEIPT PHASE

#### (a) Administrative processes: registering and acknowledging proposals

Proposals for general release will be submitted to IOGTR, in accordance with defined application requirements (which will be revised to reflect the arrangements outlined in this paper). The IOGTR will also require that proposals be received by certain specified dates, to allow these to be considered at scheduled meetings of GMAC's Scientific and Release Subcommittees. The deadlines for submission of proposals will be notified to Institutional Biosafety Committees, and made publicly available, in advance for each calendar year.

When IOGTR receives a proposal, it will follow usual administrative processes including, for example, establishing a file for the proposal, assigning a reference number, and checking the proposal for completeness (including adequacy of the information provided).

The IOGTR will acknowledge receipt of the proposal. If the proposal is incomplete, the IOGTR will notify the proponent and provide an opportunity to supply the necessary information.

#### (b) Consultation with members of the public, interested organisations and other agencies

Once the administrative procedures are complete, IOGTR will prepare a brief description of the proposal, which will include contact details of the proponent, should any interested party wish to seek further information on the proposal.

The description will be published in the Commonwealth *Government Notices Gazette* and the Public Notices section of *The Australian* newspaper. If the proposal seems to have particular relevance to a particular jurisdiction(s) (eg. State, local government area) the IOGTR will also arrange to notify that area(s) via public notice.

The description will also be forwarded to interested individuals and organisations that have registered with GMAC for this purpose, and to relevant Commonwealth and State agencies including:

- Environment Australia who will provide an environmental risk assessment;
- Agencies that may have a statutory responsibility for approving the end-use of GMOs as products (for example, the National Registration Authority for Agricultural and Veterinary Chemicals, the Australia New Zealand Food Authority, and the Therapeutic Goods Administration);
- Agencies with direct responsibility for matters relevant to IOGTR's consideration of the application; and
- State agencies such as departments responsible for health, the environment, industry and

agriculture, as well as Premiers' departments.

The description of the proposal will also be placed on the IOGTR and GMAC Internet homepages.

The description will make it clear that a copy of the proposal will be made publicly available. Sections of the proposal that contain commercial-in-confidence material will be deleted from the publicly available copy. The description will include information on how the full proposal can be accessed.

A period of 30 days will be available for comment on the proposal. Comments on both scientific and broader issues (such as economic, trade or ethical issues) will be invited.

The IOGTR will be responsible for acknowledging all comments received as a result of this phase of the process.

Following this phase, IOGTR will refer the proposal, together with all scientific issues raised during the consultation phase, to GMAC with a request that GMAC carry out a risk analysis of the proposal and provide advice to the Minister for Health and Aged Care.

As set out later in this document, non-scientific issues (including economic, trade and ethics issues) will be considered by IOGTR in preparing recommendations to the Minister, once GMAC's scientific advice has been received.

Once a proposal has been forwarded to GMAC, the IOGTR conducts a literature search to identify risk assessments conducted for similar proposals in other countries and other relevant data. This information will be provided to GMAC.

## (II) RISK ANALYSIS PHASE

### (a) Scope of GMAC's analysis

GMAC will provide advice to the Minister on a proposal based on GMAC's consideration of the risks that the proposal poses to public health, the environment, or the sustainability of agricultural systems in Australia. Risk can be defined as the combination of the consequences of an adverse effect and the likelihood that the adverse effect will occur. GMAC's assessment will include a consideration of whether any risks identified can be managed to reduce the risks to an acceptable level.

In developing advice to the Minister, GMAC will be empowered to seek input from any other individual or agency with relevant expertise.

In assessing environmental risks, GMAC will take into account not only the direct effects of the released GMO but also potential secondary effects. These might include, for example, the development of insect populations with resistance to an insecticide, changes in numbers of prey or parasites of a GMO, or indirect effects through changes in ecosystems. In assessing risks to the sustainability of Australian agricultural systems, GMAC's consideration will include an assessment of the interactions between different genetically manipulated crops that may be released into the same farming system and impacts of use of agricultural chemicals that may affect the sustainability of use of the GMO.

GMAC will not conduct a cost-benefit analysis for a proposal. If significant and unacceptable risks that cannot be adequately managed are identified, GMAC's recommendation will be that

the proposal does not proceed, regardless of the likely benefits of the proposal. Where there is scientific uncertainty about the risks posed by a proposed general release, GMAC will recommend a precautionary approach to management of risks. GMAC may recommend that the proposal not proceed until further information is available to enable an adequate risk assessment to be made.

### (b) Process for GMAC's analysis

Proposals for general release will be considered initially by GMAC's Scientific Subcommittee and then by GMAC's Release Subcommittee. In considering the proposal, the Release Subcommittee may take into account:

- Advice from the Scientific Subcommittee's assessment of risks associated with the GMO at the molecular level;
- the information provided by the proponent in the proposal;
- the advice of other experts consulted by GMAC;
- risk assessments conducted for similar proposals in other countries;
- data from published literature; and
- comments on scientific issues provided through the consultation process (described in phase i).

GMAC will consider proposals on a case-by-case basis. In the future, however, as familiarity with particular types of GMOs develops, assessments will build on past decisions as appropriate.

In cases of scientific uncertainty on risks, GMAC will use its expert judgment in developing advice for the Minister. In all cases, GMAC will ensure that the rationale for its recommendations is documented (see below). GMAC will generally make its recommendations on the basis of consensus. If consensus is not achievable, difference of view will be identified in the publicly available documentation.

### (c) Information taken into account by GMAC

#### ➢ proponent's submission

The information requirements for a general release proposal are currently set out in GMAC's *Guidelines for the Deliberate Release of Genetically Manipulated Organisms* and the *Good Agricultural Practice Guidelines for the use of Genetically Modified Plants*. (The latter was developed by a Working Group established under the SCARM).

The information to be provided by the proponent relates to the properties of the GMO (including molecular, phenotypic and ecological data), the nature of the release, and the possible risks that the release may pose. For general release of crop plants, information relating to the effects of the release on farm management practices, as specified in the *Good Agricultural Practice Guidelines for the Use of Genetically Modified Plants*, is also currently required.

These information requirements will be up-dated to reflect the new transparent arrangements set out in this document. It will be necessary to liaise with GMAC, as well as other Portfolios such Environment Australia and Agriculture, Fisheries and Forestry Australia, to ensure that it is clear how a range of documents currently under development, as well as those referenced above, work together within the GMAC consideration of a proposal.

In addition, data from field trials that precede the general release proposal will be an important component of the proposal. The assessment of the proposal by the IBC responsible for the release (as detailed in the proposal Cover Sheet) will also be taken into account by GMAC.

GMAC will continue to require that information provided in proposals is relevant, sufficiently detailed, and of high quality. Proponents will have to ensure that a proposal includes a full assessment of the possible impacts of the proposed release of the GMO in the Australian environment and of how the proponent believes these risks can be managed.

Proposals will need to be written to scientific standards. For example, assertions of fact are to be referenced to published literature or to data provided in reports on previous proposals. All relevant data from previous field trials and from assessments made of similar proposals by overseas agencies should be provided. Proposals should include recent and comprehensive literature searches. When a matter is controversial or there is any doubt about the answer, proponents are expected to provide both sides of the issue, even when the proponent believes that one side is demonstrably correct. If possible, quantitative estimates should be given of the magnitude of potential risks.

Extensions or amendments to previous general release proposals submitted to GMAC may be in the form of an abbreviated proposal detailing only the differences between the original proposal and the extension. Proposals will be considered by GMAC as extensions to previous proposals only where the risks associated with the new proposal are similar to those associated with the original proposal. In general, any change in the gene construct in the GMO to be released will require submission of a full new proposal.

GMAC will review and assess the information contained in the proposal, including the proponent's assessment of any potential risks and their management, and will take into account the scientific basis or authority for the information provided. GMAC may request further information or clarification from the proponent where necessary. In some cases, proponents may be invited to attend the GMAC Release Subcommittee meeting to discuss the proposal with GMAC.

### ➢ Environmental risk assessment

IOGTR will request environmental risk assessments on general release proposals to be undertaken by Environment Australia in accordance with the *Environment Protection (Impact of Proposals) Act 1974*, and will ensure that the assessments are taken into account in the consideration of the proposals. The advice developed by GMAC, concerning an application, will need to clearly address all issues raised by Environment Australia. As set out under 'phase (iii)', IOGTR will need to be satisfied that these issues have been fully addressed.

### ➢ Consultation with other experts

GMAC may seek additional advice on specific scientific issues from external experts in relevant fields. In doing so, GMAC will obtain the necessary assurances that confidential material will be treated as such by those consulted. Experts may be invited to attend meetings of the Release Subcommittee to provide assistance to the Subcommittee in its consideration of the proposal.

### ➢ International information

GMAC will take into account relevant information (such as approvals and assessments) that is available from overseas regulatory agencies. In doing so, GMAC will also consider the rigour and quality of such information and the extent to which it reflects Australian circumstances,

particularly the Australian natural environment.

GMAC may also take into account standards, guidelines and other documents produced by international organisations such as the OECD.

### ➢ Literature reviews

Proposals are expected to include current and complete literature searches to substantiate any claims made. However, GMAC may undertake a further literature search if this is considered necessary to support its assessment of the proposal.

### ➢ Comments from the public, interested organisations and other agencies

Comments on scientific issues will be taken into account by GMAC in its assessment of the proposal and in formulating a recommendation to the Minister. The scientific basis on which comments in submissions are made will be described.

Comments on non-scientific issues will be provided to the Minister by the IOGTR at the same time as GMAC's recommendation on scientific grounds. The Minister may take into account these broader issues in reaching a decision on the proposal.

### ➢ New information

Proponents will be required to inform GMAC of any new scientific information relevant to the risks associated with the release that becomes available either during or following GMAC's assessment of the proposal. On the basis of such information, or other relevant information that becomes available to GMAC from other sources, GMAC may amend or review its advice on the proposal. GMAC will advise interested individuals and organisations of any such amendments or reviews.

## (III) RECOMMENDATION PHASE

On completion of its assessment of the scientific risks associated with a general release proposal, GMAC will provide advice to the IOGTR (as the agent of the Health Minister). The advice will summarise GMAC's assessment of the risks and advise IOGTR on whether GMAC considers the risks are acceptable and/or manageable. As set out under 'phase (ii)', the IOGTR will need to be satisfied that all substantive issues raised by all parties during the course of GMAC's consideration of a proposal have been substantially addressed. This is particularly important in relation to, for example, issues concerning the environmental impact of a general release. These matters will be raised by Environment Australia (and others with an interest in this matter) and it is important that the IOGTR be satisfied that these matters have been given due consideration and a response generated for each. Should the IOGTR not be satisfied that this is the case, the IOGTR will require additional consideration of the matters by GMAC.

IOGTR will consider GMAC advice, and will also factor in non-scientific issues raised in submissions from members of the public and other organisations or agencies (including State and Territory agencies) (as part of phase i) in preparing briefings to the Minister for Health and Aged Care.

In taking a decision on general release of a GMO, the Minister for Health and Aged Care will consult with the Minister for the Environment, the Minister for Agriculture, Fisheries and Forestry and other Ministers with relevant responsibilities for protecting public health and safety. This will ensure that a whole-of-Government approach is taken to these decisions, and

that the Government's objective of promoting public health and safety and protecting the environment is met.

In particular, in consulting the Minister for the Environment and Heritage, that Minister may designate any environmentally significant proposal under the Environment Protection (Impact of Proposals) Act 1974, and decide if an Environment Impact Statement (EIS) or Public Environmental Report (PER) will be required. While the assessment process described in phase (ii) (risk analysis) will endeavour to address any environmental concerns prior to making a recommendation, each case will be considered on its merits by the Minister to ensure that due process requirements are met.

### (a) Issuing of advice to other agencies, Public Information Sheet and risk analysis report

Following the Minister's decision on the proposal, IOGTR will advise relevant agencies with statutory responsibility for end-product regulation of scientific issues that these agencies might wish to take into account in their assessment of the product.

IOGTR will make available a summary of GMAC consideration and the Minister's decision in the form of a Public Information Sheet on the proposal. A more detailed analysis of GMAC's assessment of the proposal and the rationale for its advice (including literature consulted and additional expert advice obtained) will also be made publicly available. IOGTR (with advice from GMAC in relation to all scientific matters) will provide a written response to all submissions it receives on a proposal.

## (IV) POST-RELEASE PHASE

Once the Minister has approved a general release and conditions relating to that release, the Commonwealth will enter into a contract with the proponent. The contract will:

- specify all conditions that the proponent must comply with;
- identify a comprehensive strategy by which the Commonwealth will monitor the proponent's compliance with these conditions; and
- articulate the cost of the Commonwealth's compliance monitoring strategy, and mechanisms by which the proponent will meet these costs.

Details of the contract, excluding commercial in confidence information but including the comprehensive strategy for monitoring the proponent's compliance with conditions, will be made publicly available.

An important component of the post-release strategy, which will be articulated in the contract, will include an approved management plan. Under the management plan, the proponent will be responsible for the use of the GMO to a very great degree. The proponent will, for example, have to provide approved education and training to farmers intending to grow the genetically modified crop, as well as to other interested parties. The proponent will also have to enter into a series of contractual arrangements with end users (such as farmers) which will dictate the way in which the GMO can be grown, harvested and so on, consistent with the Government's compliance conditions.

In addition to monitoring and surveillance detailed in the contract, the Commonwealth will reserve the right to undertake any spot checks of compliance with conditions it believes are necessary. The contract with the proponent (and any subsequent contracts between the

proponent and the end-user) will guarantee the Commonwealth access to the GMO at any time the Commonwealth deems necessary. These contracts will also bind the proponent to taking any remedial steps deemed necessary by the Commonwealth, should it be demonstrated that conditions have been breached.

## ➢ REPORTING

In addition to other public information described in this document, the IOGTR will publish, annually, details concerning all GMOs approved for general release, conditions attached to those approvals, and details of the IOGTR's monitoring and enforcement actions.

## ➢ REVIEW OF DECISIONS

A mechanism whereby the Government could review the decision taken by the Minister for Health and Aged Care will be established.

| COMPARISON OF EXISTING AND PROPOSED ARRANGEMENTS | | |
|---|---|---|
| **Element of process** | **Previous arrangements** | **New interim arrangements** |
| Notification of receipt and submissions sought | Advertised in Commonwealth *Government Notices Gazette*<br><br>GMAC mailing list<br><br>GMAC Home page<br><br>Interested government agencies (Commonwealth, State/Territory and Local Govt) | Advertised in Commonwealth *Government Notices Gazette* and *The Australian* Newspaper and appropriate regional press<br><br>Expanded IOGTR/GMAC mailing list<br><br>IOGTR & GMAC Home page<br><br>Relevant government agencies (Commonwealth, State/Territory and Local Govt) |
| Full proposal available to the public | Not available | Available except for commercial-in-confidence information |
| Acknowledgment of all submissions received | All comments acknowledged by GMAC | All comments acknowledged by IOGTR |
| Assessment of scientific and safety issues | Conducted by GMAC experts<br><br>- public health<br><br>- environmental | Conducted by GMAC experts<br><br>- public health<br><br>- environmental<br><br>- sustainability of farming system<br><br>- full literature search<br><br>- extensive reference to overseas regulatory practice |

| | | |
|---|---|---|
| Environmental risks assessment | GMAC advice with informal in put from Environment Australia | GMAC and Environment Australia formal advice (and in some case, EIS) in accordance with the *Environment Protection (Impact of Proposals) Act 1974* |
| Consideration of non-scientific and non-safety issues | No consideration | Public comment invited and addressed by IOGTR (in consultation with other agencies and expert bodies) to consider and provide recommendations |
| Management of risks | Precautionary approach | Precautionary approach building in environmental risk and public health risk assessment processes |
| Documented rationale for decisions | Summary of decisions made publicly available | Full account of rationale for decisions made publicly available |
| Publicly accountable decisions by Minister | No decision by the Minister | Decision by Minister |
| Consultation with relevant Ministers | No consultation | Consultation with Ministerial colleagues ( Environment, Agriculture, Industry etc). |
| Advice on risk analysis and conditions of general release to other regulatory agencies | Advice provided | Advice provided |
| Written responses to all submissions received | Responses to all submissions received | Responses to all submissions received |
| Enforcement of risk management conditions | Voluntary | Legal contracts with proponent to ensure compliance with release conditions |
| Independent Monitoring | Ad hoc arrangements | Management plan to include government monitoring and auditing of compliance |

## APPENDIX G EXAMPLE OF GMAC PUBLIC INFORMATION SHEET ON A DELIBERATE RELEASE PROPOSAL

***PR-109: Winter nursery seed increase of Ingard® (Bt)/ Roundup Ready® (RR) cotton plants, 1999***

| | |
|---|---|
| **ORGANISATION** | DELTAPINE AUSTRALIA PTY LTD<br>PO BOX 196<br>NARRABRI NSW 2390 |
| **CONTACT PERSON** | G F SMART<br>TELEPHONE: (067) 92 5233, FACSIMILE: (067) 92 5235 |
| **ORGANISM** | COTTON (*GOSSYPIUM HIRSUTUM*) |
| **LOCATION** | ORD RIVER IRRIGATION AREA, KUNUNURRA, WESTERN AUSTRALIA |
| **SCALE** | 5 HECTARES |
| **EXPECTED DATE OF RELEASE** | APRIL 1999 – OCTOBER 1999 |

### BRIEF SUMMARY OF THE AIM AND NATURE OF THE PLANNED RELEASE

The proposal aims to increase seed supplies of several lines of cotton that have been 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 planned release proposals involving genetically modified cotton, and cotton carrying the insect-resistance gene (INGARD® cotton) was approved for limited general release in parts of eastern Australia in 1996. The long-term goal of the work is to develop commercial cotton cultivars which are resistant to Roundup® and to insect damage.

Glyphosate is a broad spectrum herbicide that has no residual soil activity and very low mammalian toxicity. It is already used in cotton, but its use must be controlled to prevent drift of the herbicide onto cotton foliage. The development of glyphosate-tolerant cotton plants would allow glyphosate to be used on both pre-emergent and post-emergent cotton to control broadleaf and grass weeds. In addition to providing more effective weed control, glyphosate-tolerant cotton plants may allow substitution of glyphosate for the residual herbicides currently used, and may eliminate the need for hand-chipping of weeds.

The insecticidal gene used in the transgenic plants produces a protein that is toxic to the major caterpillar pests of cotton in Australia, but is not toxic to other animals, including humans. The insect-resistance gene should provide effective control of insects and therefore reduce the need for use of chemical pesticides on the crop.

### ORGANISM

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

## GENETIC MODIFICATION AND ITS EFFECT

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

The modified cotton plants also contain the CryIA(c) delta-endotoxin gene from the bacterium *Bacillus thuringiensis* (Bt). The protein resulting from expression of this gene is toxic to the major caterpillar pests of cotton. When the plants are attacked by insect pests which are susceptible to the toxin, the toxin initially inhibits insect feeding and subsequently results in the death of the insect pests. The target pests are two species of *Helicoverpa*, major pests in the cotton industry.

The plants also contain a 'marker' gene, neomycin phosphotransferase, which encodes resistance to the antibiotics kanamycin and neomycin. This marker gene, from the bacterium *Escherichia coli*, was inserted to allow selection of the transgenic plants from the non-transgenic plants during regeneration of the plants in tissue culture.

Another bacterial gene, encoding resistance to the antibiotics streptomycin and spectinomycin, is also present in the transgenic plants, but is not expressed in the plants.

## VECTOR

The DNA was introduced into cotton on a plasmid carried by the vector *Agrobacterium tumefaciens* (a bacterium). The vector is 'disarmed' since it lacks the genes which encode the tumorigenic functions of *A. tumefaciens*. This type of vector has been used frequently in Australia without causing any biosafety problems. The cotton lines to be used in this proposal were derived by conventional crossing between transgenic plants containing the Roundup®-tolerance gene and the CryIA(c) gene.

## PROCEDURES FOR RELEASE

A maximum of 5 hectares of transgenic cotton will be grown at Kununurra in the Ord River Irrigation Area of Western Australia. The trial area will be fully irrigated during the growing period and grown during the dry season. The trial site will be separated by at least 50 metres from breeding lines of transgenic or non-transgenic cotton and seed production fields.

Planting will be carried out using an experimental cone planter or a precision row planter. Normal agronomic practices for ground preparation, plant nutrition, weed control and disease control will be used before and during the trial. One application of glyphosate will be applied to a small selection of the developing transgenic plants to verify the presence of the herbicide-resistance gene in the plants.

## PROCEDURES FOLLOWING RELEASE

After the trial, single plant selections will be hand-harvested while large seed increase lines will be machine-picked. The harvested seed cotton will be ginned and delinted. The seed will be retained for use in future trials. Plants not selected for further research and development will be machine-harvested and the seed from these plants will be destroyed after ginning.

The plant material remaining after harvest will be destroyed using the local farmers' cultural practices. The site will be monitored for six months and any volunteer cotton plants that emerge will be destroyed by mechanical or herbicide (other than glyphosate) treatment. After this period the trial site will be either fallowed for a further period or planted to an alternative crop.

## TRANSPORT

The seed will be transported by road freight to the release site in small envelopes or calico bags placed inside shipping boxes. Harvested seed cotton will be transported from the trial site to the gin in wool packs. The delinted seed cotton will be fumigated prior to dispatch to Queensland in wool packs according to quarantine requirements. All seed movements will be monitored.

## SUMMARY OF RISK ASSESSMENT AND GMAC'S RECOMMENDATIONS

The risk of transfer of the introduced genes to other cotton plants or other species related to cotton is low. Cotton is largely self-pollinated and cross-pollination is rare. When cross-pollination occurs it is mediated by insects, usually honeybees. Vegetative propagation of cotton does not occur in the field, and cotton seeds do not have long-term survival in soils.

No *Gossypium* species are recognised as weeds in Australia. However, there are two wild Australian species of *Gossypium* (*G. sturtianum* and *G. australe*) whose distribution overlaps that of cultivated cotton. *G. australe* is found throughout the Kimberley region but is not known to occur on the black soils in the irrigation area. The proponent claims that no native species of cotton occur within the immediate vicinity of the proposed trial site.

Gene transfer to wild *Gossypium* species is unlikely due to genome incompatibility, the relatively isolated distribution of Australian native *Gossypium* species and different breeding systems. Hybrids resulting from artificial crosses between cotton and wild Australian species are generally sterile, unstable and of poor fitness, and are difficult to maintain, even under glasshouse conditions. GMAC advised the proponents that, before general release of transgenic cotton in the Ord River Irrigation Area, careful consideration would be given to any recent data on the potential for successful crossing between *Gossypium hirsutum* and related native species. GMAC would also consider the issue of whether cotton itself has the potential to establish as a weed in northern Western Australia.

As in its assessment of previous proposals involving release of cotton modified for resistance to insect pests, GMAC noted the need for resistance management strategies to delay the emergence of insect pests with resistance to the Bt toxin. Research on this issue is in progress under other proposals, including the limited general release of Bt cotton in eastern Australia (proposal GR-3).

A major biosafety issue associated with the release of herbicide-resistant plants is the possible development of herbicide resistance in weeds. GMAC considers that ultimate general release of herbicide-resistant crops should only take place in the context of a national coordinated strategy for the deployment of such crops. The national strategy will require that integrated management practices are developed to minimise the likelihood of emergence of herbicide-resistant weeds.

## CONCLUSION

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

## OTHER AGENCIES ADVISED BY GMAC

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

## DATE OF GMAC ADVICE

5 January 1999

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

## Brief summary of deliberate release proposal in lay terms

### PR-109: Winter nursery seed increase of Ingard® (Bt)/ Roundup Ready® (RR) cotton plants, 1999

Cotton plants have been developed that are resistant to attack by caterpillars. Large amounts of chemical pesticides are currently used on cotton crops to control caterpillar pests. The new insect-resistant cotton crop should be more environmentally friendly because it will require less spraying with the chemical pesticides. The gene that provides resistance to the caterpillars is from a bacterium. It produces a protein that is toxic only to caterpillars.

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

Both the insect-resistance gene and the Roundup-resistance gene have now been introduced into the same line of cotton plants. In this proposal, Deltapine Australia Pty Ltd intends to increase supplies of the seed from the modified cotton plants. The long-term goal of this work is to develop commercial cotton varieties that are resistant to Roundup and to insect damage. In the current trial, an area of 5 hectares will be planted to the modified cotton at Kununurra in the Ord River Irrigation Area of Western Australia. The seed harvested from the plants will be stored for later use.

GMAC has assessed the proposal and has concluded that the risks to the community or the environment are very low. It is very unlikely that the modified cotton plants could spread their genes into other plants. However, if the plants were to be released on a large scale, there is a chance that caterpillar pests could become resistant to them. Researchers at other organisations are developing management plans that will make this less likely. There is also a chance that use of Roundup on the crop will increase when the crop is grown commercially, and that this could result in weeds that are resistant to Roundup. GMAC has emphasised to Deltapine that integrated weed management practices must be in place before the crop is released commercially.

## ABBREVIATIONS

ACS.....Australian Customs Service
ANZFA .....Australia and New Zealand Food Authority
AQIS .....Australian Quarantine and Inspection Service
Bt.....*Bacillus thuringiensis* (soil bacterium used to create insect-resistant plants)
CSCG.....Commonwealth-State Consultative Group
GM .....genetically modified
GMAC .....Genetic Manipulation Advisory Committee
GMO .....genetically modified organism
GTAC .....Gene Technology Advisory Committee
GTRAP.....Gene Therapy Research Advisory Panel
NICNAS .....National Industrial Chemical Notification and Assessment Scheme
NOHSC .....National Occupational Health and Safety Commission
NRA .....National Registration Authority for Agricultural and Veterinary Chemicals
OGTR.....Office of the Gene Technology Regulator
TGA.....Therapeutic Goods Administration