HON WARREN TRUSS MP

Minister for Agriculture, Fisheries and Forestry

- 3 MAR 2001

Ms Fran Bailey MP
Chair
Standing Committee on Primary Industries and
Regional Services
Parliament House
CANBERRA ACT 2600

Dear Fran

I am writing to provide you with the Government's response to the report of the House of Representatives Standing Committee on Primary Industries and Regional Services on Primary Producer Access to Gene Technology - "Work in Progress: Proceed with Caution".

On 6th February 2001 the Prime Minister approved the response. In line with established procedures, I am now forwarding a copy of the Government response to the Committee and will arrange for tabling of this response as soon as possible.

Yours sincerely

WARREN TRUSS

Encl.

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GOVERNMENT RESPONSE

House of Representatives Standing Committee on Primary Industries and Regional Services Report on Primary Producer Access to Gene Technology, titled "Work in Progress, Proceed with Caution".

House of Representatives Standing Committee on Primary Industries and Regional Services Report on Primary Producer Access to Gene Technology, titled "Work In Progress, Proceed With Caution"

Government Response

Ch 2 Benefits and risks of gene technology in agriculture

1. The committee recommends the continued use of gene technology, but only with stringent regulation, constant and cautious monitoring, and public reporting.

Supported

The Government fully supports the recommendation that the use of gene technology continue in Australia, as this is consistent with the Government's biotechnology vision and goals. However the Government recognises that although the use of gene technology offers a vast range of benefits, there are potential human health and environmental risks that need to be rigorously assessed, managed and monitored through statutory regulation. Public consultation and reporting is also a key component of any regulatory system associated with the implementation of new technologies and use of new products, and should equally apply to the use of gene technology.

The Government's vision for the adoption of gene technologies in Australia is as follows:

> *Consistent with safeguarding human health and ensuring environment protection, that Australia capture the benefits of biotechnology for the Australian community, industry and the environment.*

This vision, which is based on the responsible use of biotechnology to drive economic and community benefit, is supported by the Government's goals for biotechnology which are:

- To ensure that in research into, and in applications of biotechnology
  - human health and the environment are safeguarded, in particular through a rigorous, efficient and transparent system of regulation for gene technology research and for genetically modified organisms and products; and
  - the highest ethical standards are observed.

- To ensure that the community has access to quality information about biotechnology, the potential risks and benefits of its applications, the ethical issues they raise, and has confidence in the way risks are assessed and managed
  - and that it can contribute to public policy in this area.

- To enhance the economic and community benefits of biotechnology through
  - an internationally competitive environment for investment and enterprise

development;
- stronger links between the biotechnology research sector and industries that apply biotechnology; and
- better management of intellectual property.

- To maintain and develop the infrastructure for generating biotechnology applications through
  - productive investment in biotechnology research and development;
  - world class education in biotechnology;
  - secure access to genetic and biological resources; and
  - conserving genetic and biological resources.

The Government believes that the continued use of gene technology in Australia must be underpinned by a comprehensive, rigorous and sound regulatory framework. The passage of the Gene Technology Bill, currently before the Parliament, is crucial to ensure this framework is achieved by building on the existing regulatory systems for managing gene technology of the Australia New Zealand Food Authority (ANZFA), the Australian Quarantine and Inspection Service (AQIS), the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), the Therapeutic Goods Administration (TGA) and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

The Gene Technology Bill 2000 (the Bill) proposes that the Gene Technology Regulator (GTR) have far reaching statutory powers to protect the health and safety of people and to protect the environment. Recognising the potential risks of gene technology, the proposed legislation sets out in detail how the use of this technology should be regulated and how risks should be managed. This includes:

- The appointment of the GTR who will administer, monitor and enforce the legislation and assess any risks posed by genetically modified organisms (GMOs), inform and advise other regulatory agencies, States and Territories and the public about GMOs and genetically modified (GM) products, and report to the Parliament annually.
- The establishment of 3 key advisory committees to assist the GTR and the Ministerial Council on Gene Technology. These are the Gene Technology Technical Advisory Committee (the scientific committee), the Gene Technology Community Consultative Group (the community committee), and the Gene Technology Ethics Committee (the ethics committee).
- The regulation of all 'dealings' (eg research, manufacture, production, commercial release and import) with live viable organisms that have been modified by techniques of gene technology, including the progeny (or descendants) of such GMOs.
- The monitoring of activities involving GMOs and enforcement of compliance, where necessary, with the conditions that the GTR imposes. The GTR will have legislative powers to implement a range of monitoring activities (depending on the level of risk), appoint inspectors with significant powers to investigate suspected breaches of the legislation, issue directions, cancel or suspend approvals, seek injunctions and make reports directly to Federal Parliament.
- The establishment of a centralised and publicly available database, the GMO Register, for the recording of all approvals of GMOs and GM products.

2. **The committee recommends that the Commonwealth government increase funding for research into the potential benefits and risks (environmental, health, social, economic and ethical) presented by genetically modified organisms.**

Supported In-principle

The Government recognises there is a need to continue research effort into impacts of GMOs, including on an integrated and broad-scale level that recognises the interdependence between risks and benefits. Further research at the basic and strategic level will be required as this new field of research matures. Some on-going effort should be maintained for public sector research agencies to study such long-term implications of GMOs beyond the scope of individual applications. However, some of the more applied research aimed at satisfying the requirement of the regulatory authority, could be met by those seeking to release GMOs into the environment.

The Commonwealth Scientific and Industrial Research Organisation (CSIRO) has developed a $3 million research program to study the environmental impacts of GMOs in order to enhance the knowledge base of gene technology at the ecosystem level.

The National Biotechnology Strategy will institute, through an Environmental Risk Project, an information system that ensures that potential risks from the introduction of genetically modified organisms (GMOs) are accurately assessed by regulators and appropriate management systems, including monitoring of impacts, are put in place. This project will involve collaboration between the Commonwealth departments of Environment and Heritage, Health and Aged Care, and CSIRO. In 2000-2001, the Government will fund the project with a total of $0.5m being provided by Environment Australia and IOGTR.

3. **The committee recommends that the Commonwealth government ensure that funding for research into improving agricultural productivity and sustainability is allocated equitably across all areas of research.**

Not supported.

Public sector research funding is allocated on a contestable basis across all areas of research. This includes Commonwealth funding provided through the university sector, the rural research and development corporations (RDCs) and CSIRO. These agencies recognise there are other technologies, besides gene technology, and approaches that contribute towards agricultural productivity and sustainability. Introducing a new mechanism to ensure equity between research funding allocations may undermine the existing contestable systems and cut across the relative needs of a wide range of stakeholders.

Ch 3 Understanding genetically modified organisms

4. **The committee recommends that all public education campaigns funded by the Commonwealth government recognise and address the environmental, economic, cultural, ethical and social concerns of the consumer.**

Supported

Biotechnology Australia's Public Awareness Program began by undertaking a major benchmarking survey to ascertain Australians' current level of awareness of biotechnology and gene technology, as well as their differing concerns. The Public Awareness Strategy developed as a result of this research is aiming to provide specific information to meet these concerns. This includes addressing social, ethical, environmental, and economic concerns, where relevant. CSIRO is contributing towards the government's public education campaigns and is specifically addressing consumer concerns.

In addition the Gene Technology Bill recognises the role and responsibilities of the GTR to address, and inform the public of, the potential environmental, economic, cultural, ethical and social concerns associated with GMOs.

5. **The committee recommends that government agencies, especially the Interim Office of the Gene Technology Regulator and the Australia New Zealand Food Authority, review the design of their internet sites to ensure they are user friendly. Sites should lay out clearly what they contain, be easily navigable, and present readily understood information which is updated regularly.**

Supported

Better design of websites is already under consideration and funds have been allocated towards improving agency websites.

Biotechnology Australia's own site is undergoing a major redevelopment to ensure a high level of interactivity, quality and information content, and accessibility by people in remote locations with possibly lower level internet connections.

Biotechnology Australia has provided funding to IOGTR to improve the design and content of its site. ANZFA is also aware of the ongoing need to improve their website, which has just recently been redesigned and will be regularly updated. The ANZFA executive has identified this as a high priority issue. Funding provided to Agriculture, Fisheries and Forestry – Australia (AFFA) and CSIRO has enabled redevelopment of their sites to be completed with respect to biotechnology.

The new IOGTR Website will combine the Gene Technology and Genetic Manipulation Advisory Committee (GMAC) sites and is to be more user-friendly, and easier to access and search. The new features will include facilities to enable the user to have easy or immediate access to key information such as gazette notices on proposed GMO field trials (which could

provide breakdowns by state and territory and breakdowns by product), commonly asked questions, fact sheets and 'hot topics'. It is anticipated that the new-look Website will be on-line by mid September 2000.

6. **The committee recommends that Biotechnology Australia, in its role as the coordinator of information about gene technology provided by government departments, monitor the efficiency and effectiveness with which material is presented. Biotechnology Australia should regularly publicise all information from the Gene Technology Regulator, including information about the regulator's role and function.**

Supported

Biotechnology Australia works with key regulators to achieve effective presentation of gene technology information. Biotechnology Australia also publishes information on the roles and functions of biotechnology regulatory bodies eg. 2.5 million Biotechnology Australia brochures distributed through supermarkets in January 2000 outlined the key regulators and their roles, as well as providing contact details for the regulatory bodies involved in gene technology.

Future information being developed by Biotechnology Australia in collaboration with the regulatory agencies will include explaining GM labelling regulations to both the general public and industry, and also explaining environmental safeguards associated with trialing/cultivating GM crops.

The effectiveness of public information is monitored via feedback mechanisms and research to ensure it is as efficient and effective as possible, and best meets the public's need for information. The IOGTR will continue to provide relevant and useful information to Biotechnology Australia in a timely manner.

7. **The committee recommends that Biotechnology Australia be made a statutory authority.**

Not supported

Biotechnology Australia is a small agency that works effectively as a collaborator between key Commonwealth departments. Making it a statutory authority would enhance neither its effectiveness nor its efficiency.

8. **The committee recommends that the Commonwealth government, through Biotechnology Australia:**
   - **monitor understanding and awareness of biotechnology; and**
   - **assess the effectiveness of its current public awareness campaign and the need for additional information.**

Supported

Biotechnology Australia's Public Awareness Program was developed on the basis of independent, in-depth market research. The Program will be reviewed at the end of the 2000-01 financial year, to effectively track attitudinal changes and the impact of the Program.

Complementing the Public Awareness Program, is ongoing monitoring and research conducted by Biotechnology Australia and other government agencies, to evaluate each major public awareness activity and to ensure its effectiveness. Ongoing feedback is obtained from the public via market research, the Gene Technology Information Service, letters, Biotechnology Australia's website and e-mail channel, and direct feedback at community forums.

9. **The committee recommends that information provided by Commonwealth agencies about gene technology:**
   - **detail the independence, transparency and accountability of the regulatory processes;**
   - **give equal prominence to information about the risks and benefits; and**
   - **detail how the regulation of gene technology is able to avoid or minimise risk.**

Supported

During the extensive consultations undertaken by the IOGTR on the draft Gene Technology Bill, stakeholders expressed the importance of enhancing the current GMAC processes to provide a system for the regulation of dealings with GMOs which:

- is open and transparent;
- draws on a range of advice from scientific experts, government agencies and others;
- is open to public input into decision making;
- is based on objective scientific risk assessment; and
- takes into account broader issues such as ethical issues.

These important issues have been taken into account in drafting the assessment and consultation processes for applications. The Bill clearly spells out the requirements for the independence, transparency and accountability of the regulatory processes.

Part 5 of the Bill requires that, in cases involving an intentional release of a GMO into the environment, the GTR publicly notify receipt of the application in the gazette and newspapers, and call for public submissions about the risks posed by the release.

The Bill stipulates that the risk assessment will include a risk analysis and a risk evaluation that will:

- identify any hazards to public health and safety or the environment which are associated with the release, based on objective information;
- estimate the probabilities of hazards occurring; and
- estimate the risk that is a function of the above two factors.

A risk management plan is to identify measures for managing any risks identified in the risk assessment. Adherence to this management plan would be expected to reduce the probability of hazards occurring. The risk management plan would also set up contingency plans to rapidly address any impacts of the release (eg flowing from a breach of a condition of licence).

Once a comprehensive risk assessment and risk management plan of that GMO has been completed, the GTR must notify the public that a risk assessment and risk management plan has been prepared and seek input on the document. The GTR is required to call for submissions on the assessment and plan through advertisement in newspapers, the Government Gazette and the IOGTR Website. The GTR would also direct-mail all persons who registered with the GTR to receive information. The GTR must also seek input on the draft plan from the scientific committee, States and Territories and relevant Commonwealth agencies, the Commonwealth Environment Minister and relevant local councils.

ANZFA, in cooperation with the Commonwealth, State and Territory Governments and the New Zealand Government, develops food standards and other regulatory measures for Australia and New Zealand. In Australia, ANZFA also does the following:

- Coordinates surveillance of food available in Australia.
- Coordinates food product recalls in cooperation with the States and Territories.
- Conducts research on matters that may be included in a food standard.
- Undertakes food safety education initiatives in cooperation with the States and Territories.
- Develops Codes of Practice for industry on any matter that may be included in a food standard.
- Develops risk assessment policies for foods imported into Australia.

In developing food standards ANZFA ensures a high level of participation through industry and public consultation.

Biotechnology Australia is continuing to work closely with Commonwealth departments and agencies to ensure that the information needs of the public are met. As well, Biotechnology Australia's Public Awareness Program provides information on both the risks and benefits of biotechnology applications.

Ch 5 Research, development and commercialisation

10. The committee recommends that Agriculture, Fisheries and Forestry Australia develop a strategy for Commonwealth funding to facilitate and encourage the innovative use of gene technology in the development of commercially viable, emerging industries in agriculture, fisheries and forestry. This strategy should be drawn up in consultation with state and territory agriculture departments and the private sector.

Supported In-principle

The Government supports the innovative, and responsible use, of gene technology in the development of commercially viable industries in agriculture, fisheries and forestry. The use of biotechnology in these industries is viewed widely as an application technology that can assist in further improving yields and quality in traditional agriculture, fisheries and forestry industries, as well as facilitating emerging industries in areas such as the production of health and industrial products, and in assisting efforts to minimise or reverse environmental degradation.

As part of the development process for the Commonwealth Government's National Biotechnology Strategy, released in July 2000, the Department of Agriculture, Fisheries and Forestry – Australia (AFFA), developed an agrifood biotechnology strategy to ensure recognition of the key biotechnology issues facing rural industries and communities. AFFA convened a number of state and territory government and industry fora across Australia to identify these key issues. These were subsequently incorporated into the National Biotechnology Strategy.

Implementation of the National Biotechnology Strategy will commence in 2000-2001 and continue for at least the following three years. For the AFFA portfolio, a portion of the National Strategy funding has been identified for work on assessing the requirements and costs involved in segregating products that have been developed using gene technology, and for developing systems so products can be traced back to their origins. An industry-based committee will work with the Government to identify the requirements and costs of segregating gene technology products, and to provide information to industry and Government on market requirements. Commonwealth level liaison is presently underway on how best to progress these issues. Consultation will occur with the state and territory governments and industry, in the second half of 2000, on options for a work program.

11. The committee recommends that the Commonwealth government:

- **continue to contribute funding for the basic gene technology research required for applications to agriculture, fisheries and forestry; and**
- **seek more involvement, possibly through partnerships, of private sector involvement in this research.**

Supported

The Commonwealth agrees it has a key role in stimulating the early stage of the innovation and discovery process through funding of basic research that will lead to new applications for primary producers. The private sector should be more active in investing in such basic research that would enhance general knowledge and understanding of gene technologies, although there are good examples, such as in the cotton and grains industries, in which close, commercial relationships between public and private sector organisations provide beneficial outcomes to all parties.

The Research and Development Corporations (RDCs) within the AFFA portfolio represent a partnership between Government and the rural industries to pursue R&D that delivers a range

of industry and public benefits. The RDCs invest in a range of gene technologies from the basic/strategic end of the research spectrum through to very applied R&D, such as with the development and release of BT-cotton.

The RDCs are empowered to negotiate and participate in joint commercial ventures and readily do so when there is the possibility of positive industry and public benefits flowing from a successful venture. Such commercial arrangements must compete with many other potential worthwhile investments that are presented to RDC Boards.

12. The committee recommends that the Commonwealth government review the current arrangements in place regarding gene technology research and ownership of intellectual property to ensure maximum commercial benefit for Australian industry.

Not Supported

The Government believes that gene technology research (and related IP commercialisation issues) is no different from other research sectors, and should be treated no differently.

In relation to IP and the commercialisation of research, the Commonwealth Government has taken the following measures:

- All public funding bodies are required to include a provision in their programs that seeks to ensure that returns on public investment in research benefit Australia.
- One of Biotechnology Australia's priorities is improved management of biotechnology IP through appropriate training and information programs. This is being achieved through a successful series of IP seminars, production of an IP video, introduction of IP webpages on the Biotechnology Australia website, and IP education and training courses currently being developed.
- The National Health and Medical Research Council (NHMRC) recognises the need to ensure maximum benefit for Australia from its publicly funded research and has recently released draft guidelines for IP management and commercialisation for health and medical research to strengthen existing NHMRC requirements for IP protection.
- In order to ensure that Australia fully captures the benefits arising from its publicly funded research, the NHMRC is currently drafting guidelines for the management of intellectual property generated through health and medical research. This is aimed at strengthening the existing NHMRC requirements for intellectual property management and protection, and is aimed at enhancing the local commercialisation of discoveries in health and medical research.

13. The committee recommends that, in conjunction with the review proposed in Recommendation 12:

- **each research and development corporation review its practices in relation to commercialisation and ownership of intellectual property to maximise benefits to Australian industry; and**
- **the committee of the chairs and managing directors of the rural research and development corporations, in conjunction with Agriculture, Fisheries and Forestry Australia and industry, take a lead role in assessing and disseminating best practice arrangements.**

Supported

While noting that Recommendation 12 is not supported, the Government agrees that each RDC should continue to review its practices in relation to commercialisation and ownership of intellectual property.

The Government also agrees that the committee of the chairs and managing directors of the rural RDCs, in conjunction with Agriculture, Fisheries and Forestry Australia and industry, take a lead role in assessing and disseminating best practice arrangements. This issue was discussed at a recent meeting of the chairs and managing directors of the RDCs in August 2000, and they agreed to take a lead role in assessing and disseminating best practice arrangements.

14. The committee recommends that the Commonwealth government, in conjunction with state and territory governments and the private sector:

- **review the efficiency and effectiveness of plant breeding programs in Australia;**
- **identify ways of improving them; and**
- **promote their adoption, particularly where Commonwealth funding is provided.**

AND

15. The committee recommends that the Commonwealth government, in conjunction with state and territory governments and the private sector, consider the benefits of amalgamating some of the existing plant breeding programs.

Both 14 and 15 Supported In-principle

The Commonwealth recognises that plant breeding involves a range of considerations relating to the structure of agricultural industries and the markets in which they operate. The markets in which many agricultural industries operate are changing and evolving, and also influence the roles and interests of public and private interests in plant breeding.

Through its intellectual property laws (such as the *Plant Breeder's Rights Act 1994* and the *Patents Act)*, and arrangements for research and development (in particular the RDCs) the

Commonwealth already has in place effective mechanisms to promote investment in plant breeding in ways which balance private and public interests.

Research and development incentives exist through Commonwealth matching funding arrangements for the Research and Development Corporations and through the 125 percent research and development taxation concession.

The Commonwealth agrees that from time to time there may be a need to review the efficiency and effectiveness of specific plant breeding programs for different sectors and to identify ways to improve them, but sees no need for a wholesale review of all plant breeding in Australia. The Commonwealth considers that the existing mechanisms provide the overall framework through which to address the needs of different agricultural industries.

In the case of the wheat breeding programs cited by the Committee, the Commonwealth notes that reforms to wheat breeding are already taking place, and may result in some existing plant breeding programs being amalgamated. This review is being stimulated through public tendering processes initiated by Grains Research and Development Corporation (GRDC) in response to changed priorities of the stakeholders of GRDC, which include grains producers.

The Commonwealth recognises there are also other market influences affecting the future of wheat and wheat breeding, including the privatisation of marketing arrangements through AWB Ltd and the granting of single desk selling to a subsidiary of that company. These arrangements are currently the subject of a National Competition Policy review. The Commonwealth sees no need for additional intervention by Commonwealth, State and Territory governments in respect of wheat breeding while these current reviews and reforms are taking place.

16. The committee recommends that the Commonwealth government, together with state and territory governments and industry, develop a policy for maintaining Australia's germplasm collections and continuing to make them accessible.

Supported In-principle

As acknowledged by the Committee, Commonwealth, State and Territory governments (through the Standing Committee on Agriculture and Resource Management) have in train a review of the roles and functions of the existing system of plant genetic resource collections for food and agriculture. This review is examining the need for and future role of the centres having regard to the developments in plant breeding and the roles, responsibilities and interests of stakeholders in the new plant breeding environment. It is also taking into account international developments which may affect the terms and conditions by which Australian researchers access material from other countries and from the collections of the International Agricultural Research Centres.

Plant genetic resource collections for food and agriculture are primarily managed by States and Territories, although there are also some CSIRO managed collections. The Commonwealth agrees with the Committee that the future of these centres is primarily a matter for the states that operate them. The Commonwealth supports development of a

national policy for their future operation which has a clearly defined charter with agreed functions, authorities and funding arrangements involving all governments and industry.

17. The committee recommends that the Commonwealth government continue to contribute to the operation of the international germplasm centres.

Supported

Through its overseas aid program under the Australian Centre for International Agricultural Research (ACIAR), the Commonwealth has been contributing to the operation of the international plant genetic resource collections of the International Agricultural Research Centres (IARCs) since 1992. Prior to 1992 funding was provided by AusAID (then AIDAB).

The plant genetic resources collections form an integral part of IARC Programs in genetic resources conservation and crop breeding. Approximately 35 per cent of IARC funding is involved in these programs. On this basis Australia's contribution (through ACIAR) to plant genetic resources conservation and development in IARCs is approximately AUS$3.5 million per annum. A further variable amount is provided as project funds by AusAID and Grains Research and Development Corporation.

The benefits to Australia of our investment in the plant genetic resources collections and crop breeding programs of the IARCs have been well documented. A 1995 study (Brennan & Fox) looking at the economic impact of CIMMYT (International Maize and Wheat Improvement Centre) wheats in Australia found that in 1993-94 over 90% of Australia's wheat area was sown to varieties incorporating CIMMYT germplasm. Over the past 30 years the study estimated this translated to Australia's wheat industry receiving an average of AUS$81 million per year as a result of the work of CIMMYT.

18. The committee recommends that the Commonwealth government:

- **play a major role in international negotiations to harmonise the International Undertaking on Plant Genetic Resources with the Convention on Biological Diversity; and**
- **take a position that balances the interests of those who wish to import genetic resources from overseas with maximising Australia's benefit from its native genetic resources.**

Supported

Australia is already actively involved in the ongoing negotiations in the Food and Agriculture Organisation to revise the International Undertaking on Plant Genetic Resources. The Commonwealth supports continued Australian involvement to ensure that Australian interests are represented in the outcome of these negotiations.

The negotiations are seeking to establish a new multilateral system in plant genetic resources for food and agriculture. Australia has important interests at stake in the revision outcome.

Australia's negotiating position recognises that we are both a source of, and an importer of, resources potentially covered by the Undertaking.

The revised Undertaking may help secure access to those overseas sources of plant genetic resources on which Australian agriculture depends for continued development and growth, while enabling Australia to benefit from access to its indigenous plant resources in line with its interests as a contracting Party to the Convention on Biological Diversity.

19. The committee recommends that the Commonwealth government:

- **monitor the impact of the new business tax arrangements on the level of investment in biotechnology; and**
- **implement further changes to taxation arrangements if further stimulus to invest is needed.**

Supported

The Government has recently made a number of major changes to the taxation system that will have the effect of stimulating investment by individuals and businesses. These changes will provide relatively greater incentives for investment in high-risk innovative businesses and new technologies, as they will enhance the returns to higher risk/return investments relative to low risk/return investments. The changes include a reduction in the company tax rate, capital gains tax (CGT) reforms reducing the CGT rate for individuals and superannuation funds, and other measures to promote investment in venture capital by superannuation funds and foreign pension funds.

The Government monitors venture capital markets eg. the Department of Industry, Science and Resources sponsored Price, Waterhouse & Coopers study on Venture Capital Availability released on 3 August 2000. The Government also monitors the impact of Innovation Investment Funds and Pooled Development Funds. Both programs have resulted in availability of substantial new equity capital for biotechnology over recent years.

The business tax changes represent a significant reform to the tax system and it will take some time before the full impact of the changes becomes evident. The Government will monitor the impact of new business tax arrangements and will further address impediments to investment if required.

20. The committee recommends that, when reviewing the impact of the new business tax arrangements on the level of investment in biotechnology, the Commonwealth government also review:

- **the contribution of grant programs and the 125 per cent tax concession for research and development; and**
- **the need for more support, through grants and taxation measures, for investment in the early stages of commercialisation.**

Supported In-principle

It is appropriate that the Government monitor the impact of business tax changes on levels of investment, including with respect to biotechnology. The changes represent a significant reform to the tax system and it will take some time before their full impact becomes evident.

The Government has recognised the need for additional support for early stage commercialisation through the Biotechnology Innovation Fund, an initiative under the National Biotechnology Strategy, for which $20m has been provided over three years from 2001. The contribution of grant programs and the cost/benefit ratio of the 125% tax concession for R&D are matters currently being examined by the National Innovation Summit Implementation Group (ISIG) and the Australian Science Capability Review being conducted by the Chief Scientist. Their initial reports have been released and are being considered by the Government. The findings of the Implementation Committee on the Health and Medical Research Strategic Review, also expected later this year, may also have implications for some of these and related matters.

21. The committee recommends that the Commonwealth government fund a specific incubator program to assist the application of biotechnology to agriculture.

Supported In-principle

The Commonwealth 2000/01 budget provided targeted assistance to initiatives under the National Biotechnology Strategy. The major initiative will be an early-stage funding program (the Biotechnology Innovation Fund) which will provide support at the proof-of-concept stage of technology and enterprise development. These programs provide assistance similar to that provided by incubators.

22. The committee recommends that the Commonwealth government continue to fund programs for increasing the numbers of people and the levels of skills in:

- **biotechnology research; and**
- **the business and management issues involved in the commercial use of the research.**

Supported

Commonwealth Government support for biotechnology R&D is estimated to exceed $250 million per annum. In the higher education sector alone, between $50 and $90 million of annual Commonwealth block funding is spent on biotechnology-related research. In addition, at least $35 million is awarded annually for biotechnology-related research in the higher education sector under a range of grant schemes including the Special Research Centres program.

Also, under the Science Lectureships Scheme (an initiative of the 1999 Budget), over $7 million has been awarded to universities for biotechnology related projects which involve cooperation with industry partners to design and deliver courses to address skill needs in this sector.

The National Biotechnology Strategy includes specific strategies aimed at:

- Improving management of research, intellectual property, and technology within established firms and new enterprises.
- Developing programs and systems to foster entrepreneurship.
- Monitoring emerging skill needs in the biotechnology sector developing appropriate responses.

23. The committee recommends that Biotechnology Australia, in conjunction with other agencies, develop and deliver educational programs and materials targeted at small producers and breeders. These programs and materials should cover:
- **the business and intellectual property issues relating to the breeding of agricultural genetically modified organisms; and**
- **the practical aspects of using genetically modified organisms in agriculture.**

Supported

Biotechnology Australia is running a series of rural forums to address the information needs of farmers and others involved in rural commercialisation. Panels of experts have included scientists, regulators and agricultural & farming associations. These panels have sought to address practical aspects of biotechnology in agriculture. Biotechnology Australia liaises with AFFA and IOGTR in developing material particular to their portfolio stakeholders.

In July 2000, the Bureau of Rural Sciences in AFFA released two publications on what is happening with gene technology in Australian agriculture and on common questions and answers on science, research, regulatory and commercial issues associated with gene technology. These initial publications will be followed up with further information documents and educational programs for a range of agricultural stakeholders, including small breeders and producers. The Australian Bureau of Agricultural and Resource Economics (ABARE), also located in AFFA, will also continue its program to analyse market trends for gene technology and information to assist breeding and production decisions. As noted in recommendation 10, AFFA is also developing a work program to address a number of gene technology issues in agriculture, that will benefit small breeders and producers as well as larger market participants.

The government agreed last year to make a contribution from the Biotechnology Australia budget allocation to help establish a centre at the Australian National University to build capacity in IP management and policy as it relates to agricultural biotechnology. The primary funding for the Australian Centre for Intellectual Property in Agriculture comes from the GRDC and the ANU.

The establishment of this Centre will:
- provide training (undergraduate, postgraduate and 'in-service'), and support for domestic/international policy development of IP, assets and strategies to industry professionals, researchers, research managers, funders, legal professionals and students;

- develop tools (eg procedures, protocols, databases) for the agrifood industries and their research partners to evaluate the effect of IP rights on research and commercialisation and, in so doing;
- assist the agrifood industries to merge their intellectual asset management and business strategies through education, training and policy development.

The issues that the Centre will address for the grains industry (a reflection of the initial major support being provided by the GRDC) are not limited to that industry. They relate to the agrifood industries generally, and to all sectors where biotechnology has an application. The Commonwealth support will allow the concept to be piloted and a demonstration to the public and private sectors of strategic and proactive approaches to IP. These programs could also involve small breeders and producers, which is an issue the government will consider as the Centre is developed.

Ch 6 Intellectual property

24 The committee recommends that IP Australia:

- **avoid issuing broad patents;**
- **raise the thresholds for granting patents so that they are equivalent to the highest set by overseas countries; and**
- **screen patent applications more rigorously.**

Supported In-principle

The Government is committed to having a patent system which meets the needs of all Australians and to this end is continually improving the system. In this context, the issues raised in this recommendation are currently being considered in a number of fora:

- The Advisory Council on Industrial Property Report *Review of Enforcement of Industrial Property Rights*.
- The recommendations arising from the Innovation Summit including those concerning the legislative framework for, and appropriate administration of, IP systems.
- The Intellectual Property and Competition Review (IPCR) Committee Interim Report. It is expected that the Committee's final report, due to be released on 30 September 2000, will also contain recommendations on these issues.

Detailed consideration of the issues raised in this recommendation will be made in light of the above work.

25. The committee recommends that the Patent Act 1990 be amended:

- **to give effect to the changes proposed in Recommendation 24; and**
- **to clarify that the long term interests of end users are as important as the rights of intellectual property owners to benefit from their investment in that intellectual property.**

Supported In-principle

See response to recommendation 24.

26. The committee recommends that IP Australia develop and implement mechanisms for sharing skills with other patent offices.

Supported

IP Australia already liaises closely with other patent offices and participates in multilateral fora (for example the World Intellectual Property Organization) which consider these issues. For example, IP Australia is currently participating in a benchmarking study with other patent offices, focusing on the quality of search and examination.

IP Australia, in partnership with DFAT, has contributed to a training program within the Asia-Pacific region which is partly aimed at building up the skills of patent offices in the region as they implement new laws concerning biotechnology patenting. Australia has taken the lead in the APEC Experts Group on Intellectual Property Rights (IPEG) for the exchange and compilation of patent office guidelines and other detailed material on biotechnology patenting practices, with a view to facilitating training and practical harmonisation.

27. The committee recommends that research institutions that receive Commonwealth funding and do not at present acknowledge and reward their researchers for innovative output that leads to commercial success, be required to do so as a condition of receiving public funding.

Supported In-principle

The Government agrees that it is becomingly increasingly important that research institutions acknowledge and reward researchers for innovative output that leads to commercial success. Considerable research is being undertaken to determine the best strategy for addressing this issue.

The Government is adopting a number of strategies to develop a more favourable environment for research commercialisation.

In the higher education sector, the Commonwealth approach is to give institutions flexibility and autonomy to manage their own research activities and set their own priorities, including incentive structures for their employees. Most higher education institutions have in place IP policies which specify the way in which financial rewards from the commercialisation will be shared with researchers. The Australian Research Council's Condition of Grant require that IP resulting from Commonwealth funded research be handled in accordance with the policies of the institutions receiving the grants.

The Commonwealth Departments of Employment, Training and Youth Affairs (DETYA), Industry, Science and Resources (ISR) and Health and Aged Care (HAC) have jointly funded a consultancy study on the impediments to participation by public sector researchers in the

commercialisation of technology. Funding agencies such as the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) are developing strategies for dealing with commercialisation issues arising from the research they fund.

Organisations such as CSIRO already have mechanisms in place to ensure researchers are acknowledged and rewarded for their efforts that are performed as part of their employment. CSIRO uses a range of recognition rewards (such as annual medals for excellence in research adoption) instead of monetary rewards, as most innovative outputs are the result of a team effort.

The Innovation Summit Implementation Group (ISIG) is also considering ways in which incentives for researchers to commercialise their research may be improved. The government will consider ISIG's recommendations when developing its Innovation Action Agenda due for release by the end of 2000.

28. The committee recommends that, in international negotiations, the Commonwealth government support the strengthening of the provisions of the Agreement on Trade Related Aspects of Intellectual Property and assist in establishing stronger intellectual property systems in developing countries in Asia.

Supported In-principle

In 1999, the WTO TRIPS Council commenced a review of the provision in the TRIPS Agreement that gives WTO Members the option of excluding from the scope of patentable subject matter plant and animal inventions. This review has mostly comprised an exchange of information on national approaches to implementing TRIPS provisions, and has highlighted that a number of countries have taken a similar approach to Australia in providing patent protection beyond the TRIPS minimum standard. Negotiations with a view to amending this aspect of the TRIPS Agreement may occur at some time in the future.

For the present, Australia's emphasis has been on improving international understanding of the complex issues involved, and the practicalities of biotechnology IP protection, so as to facilitate a more productive negotiating environment in the future. Australia has promoted a similar constructive discussion of biotechnology IP issues in the parallel work of the World Intellectual Property Organization.

The Government is committed to ensuring that existing TRIPS standards are implemented and enforced effectively by WTO Members, and that any future revision of the TRIPS Agreement be consistent with our international trade interests and domestic policy settings. The Government is consulting closely with Australian industry and other domestic stakeholders in developing a comprehensive view of Australian interests in this area. A comprehensive public discussion paper on all current TRIPS issues was published in June 2000 to promote these consultations.

Australia has been active, through APEC and various bilateral arrangements, in supporting the development of TRIPS-consistent IP systems in developing countries in our region. The mutual benefits that would accrue from the effective and comprehensive implementation of

existing TRIPS standards in IP administration and enforcement in the Asia-Pacific region are very significant, and Australian IP right holders have highlighted this as an immediate practical priority, as against future negotiating outcomes. Australia has taken a lead role in the APEC Intellectual Property Rights Expert Group (IPEG), the key regional body for IP policy dialogue and technical cooperation towards stronger IP protection. It has led the development of an APEC policy dialogue on biotechnology IP issues, in order to strengthen general policy understanding of the potential benefits of IP protection in this area, as the basis for further progress towards stronger and more harmonised IP systems.

To bolster this process further, Australia has undertaken extensive training activities on biotechnology IP protection, including an APEC-wide training course in 1998, which was strongly supported by Australian industry, training missions to Vietnam and Thailand in 2000, and the creation of a modular training package for extensive use throughout the region.

29. The committee recommends that the effectiveness of the initiatives to upgrade the level and volume of intellectual property skills in Australia be monitored, reviewed, and improved when gaps in required skills are identified.

Supported

Biotechnology Australia is, with advice from the Biotechnology Consultative Group (BIOCOG), developing a strategy for increasing the effectiveness of IP management by biotechnology companies and researchers in research institutions. Outcomes achieved so far include:

- Preliminary review to determine level of IP education as a component of biotechnology courses in Australian universities;
- A study benchmarking the availability of biotechnology IP management training courses for companies and researchers;
- A research study to identify the needs of innovators in research institutes and fledgling biotechnology companies;
- A successful seminar series on biotechnology IP management held in ACT and all States except Tasmania;
- Production of an IP management training video, based on the above seminar, that is being provided to biotechnology companies , researchers, and university commercialisation companies;
- Information on IP management for biotechnology companies prepared for the BA website (with links to primary sources of information); and
- Work has begun to develop one day professional education and training courses in IP awareness and IP management skills.

Many biotechnology courses now have coverage of IP issues and Biotechnology Australia will continue to monitor the adequacy of these activities.

Ch 7 Regulation

30. The committee recommends that the Office of the Gene Technology Regulator report to the Parliament at least quarterly for the first three years of its existence.

Supported

The IOGTR sees the need to be open, transparent and accountable as a fundamental element to gain public trust in the gene technology regulatory system. In May 2000, the IOGTR advised the Minister for Health and Aged Care of its intention to report quarterly on the activities of the IOGTR.

The first report, covering the January-March and April-June 2000 quarters, was provided to the Minister for Health and Aged Care on 14 July 2000.

31 The committee recommends that, if and when a revised standard for labelling genetically modified foods is instituted, the Australia New Zealand Food Authority evaluate:

- **the use made by the public of label information; and**
- **the public's views on the usefulness of the information provided.**

Supported

On 28 July 2000, the Australia New Zealand Food Standards Council (ANZFSC) agreed to new labelling rules for genetically modified (GM) foods.

A draft standard based on the ANZFSC decisions is being considered by all Ministers. Subject to their final endorsement, it is hoped to gazette it to give it legal status in September 2000. To give food manufacturers and importers time to ascertain the status of their products and revise their labels, the new standard will take effect twelve months from gazettal – that is, in September 2001.

Once the form of the Standard is approved by ANZFSC, ANZFA will redraft the Protocol for Compliance and Enforcement.

ANZFSC, at the request of ANZFA, made a commitment to review the Standard three years from the date of gazettal.

ANZFA is already considering ways in which to evaluate the use made of the labels by consumers as well as the usefulness of the information provided, but collecting this data cannot begin until twelve months from gazettal.

32. The committee recommends that the Australian Quarantine and Inspection Service certify both non genetically modified and genetically modified produce for export.

Supported In-principle

The role of AQIS in the area of export certification is based on the statutory controls under the *Export Control Act*, obligations under international treaties or if government certification is required by the government of the importing country. The position of AQIS on the certification issue is that if a statement can be made on the basis of supportable evidence, and providing that AQIS is the appropriate certifying body representing the Government, then a certificate could be issued. It is critical to maintain the integrity of AQIS certification as any loss of reputation can have an adverse effect on trade in all Australian products to a country or region.

For GM or non-GM products the difficulty for AQIS in providing certification is the issue of supportable evidence. On provision of a commodity specific statement from the Genetic Manipulation Advisory Council (GMAC), AQIS has provided some certification, for wheat and other grain exports, based on the fact there are no commercial GM plantings of these crops in Australia. Industry has been warned that GMAC's future capacity to make this statement is limited, and a traceable and auditable identity preservation system will be required to enable AQIS to provide certification. AQIS will address this issue through further consultation with relevant industries.

For AQIS to provide certification procedures for GM and non-GM exports, industry would have to develop very effective identity preservation and documentation systems to ensure AQIS could audit the integrity of the supply chains. Until such systems are developed, the ability of AQIS to issue such certification is very limited. However, as noted in recommendation 10, a portion of the National Biotechnology Strategy funding has been allocated to AFFA to develop a work program to assess the requirements and costs involved in segregating products that have been developed using gene technology, and for developing systems so products can be traced back to their origins. This work program will involve input from AQIS to ensure any segregation systems meet its export certification requirements.

33. The committee recommends that the Commonwealth government, together with industry representatives, play an active part in negotiations to implement the Biosafety Protocol in such a way that:

- **apparent contradictions between the protocol and World Trade Organization arrangements are clarified and addressed; and**
- **Australia's interests in freely trading genetically modified organisms are maximised, without jeopardising public safety.**

Supported

The Government advised the 5th Conference of the Parties to the Convention on Biological Diversity in Nairobi, 15-26 May, that it was continuing to assess the implications of the Protocol for Australia and consulting with States and Territories, industry and NGOs. Only when these processes have been completed can a decision on signature be taken.

The Nairobi meeting also agreed on a program of work to prepare for entry into force of the Protocol. An Inter-governmental Committee on the Cartagena Protocol (on Biosafety or ICCP) is to meet in Montepellier, France from 11-15 December 2000 to commence this work. It is likely to meet a second time in 2001, before entry into force of the Protocol, which is

expected in 2002. All countries will be able to participate in the ICCP regardless of signature/ratification. A distinction is likely to be made between Parties and non-Parties for the ongoing negotiations once the Protocol has entered into force.

Currently, Australia is not a large exporter of genetically modified organisms (GMOs), but this may change in coming years as GMO research continues and if more GM crops are developed and planted by farmers. Australian agriculture is dependent on access to the latest technological developments to maintain its international competitive advantage. Therefore, as a user and developer of GM products and processes, Australia has a strong interest in an open and fair international regulatory system for trade in GMOs, backed by fair and workable harmonised rules for intellectual property protection, and consumer acceptance of gene technology.

The Government's initial view is that there is nothing in the Biosafety Protocol that would require or allow a country to act inconsistently with its WTO obligations. This means that there is a requirement on countries that are Parties to both the WTO and the Protocol to respect their obligations under both treaties. This is particularly relevant when applying the "precautionary approach", where there should be no conflict between the Protocol and the WTO, as the WTO can accommodate reasonable use of precaution in science-based decision making as envisaged in the Protocol. Therefore, the Government sees no conflict between the Biosafety Protocol and WTO trade agreements and believes that the two can operate side-by-side. Countries should respect their obligations under both treaties and not adopt measures which would be inconsistent with either agreement.

The Government is nevertheless concerned that some countries may seek to misuse or abuse the Protocol for trade protectionist purposes. The Government will therefore remain vigilant as to how countries, particularly Australia's trading partners, may implement the Protocol.

The Government's approach to the Biosafety Protocol has sought to balance our interests as one of the twelve mega-diverse countries in the world and as a significant exporter of agricultural commodities. This approach will be maintained through the implementation phase of the Biosafety Protocol.

34. The committee recommends that the Genetic Manipulation Advisory Committee and its successor, the Gene Technology Technical Advisory Committee, continue to take a cautious approach to approving the use of genetically modified agricultural organisms.

Supported In-principle

At present GMAC provides recommendations on all applications for contained research, field trials and general releases involving GMOs. Under the new system, a new scientific committee, the Gene Technology Technical Advisory Committee (GTTAC) will replace GMAC. However, GTTAC will not approve individual applications. GTTAC will have responsibility for providing expert scientific advice to the GTR on applications made under the legislation. The scientific committee will also advise the GTR and the Ministerial Council on other matters related to gene technology, GMOs and GM products and on the need for, and

proposed content of, policy principles, policy guidelines, codes of practice and technical and procedural guidelines for GMOs and GM products.

Membership of GTTAC will include experts in several fields not currently represented on GMAC, eg. occupational health and safety, clinical medicines, pharmacology and toxicology. As with GMAC, the scientific committee will also have a lay person member. All members will be subject to strict disclosure of interest provisions which will be contained in regulations made under the Bill.

The GTR will be responsible for decision making on a case-by-case basis. The requirements in the legislation (including the need for extensive consultation, detailed risk assessment and risk management, and comprehensive monitoring and enforcing) will be ensure that a cautious approach is adopted for the approval of GMOs.

In addition the establishment of the ethics and community consultative groups to advise on policy ensures that the policy underpinning the legislation is not only cautious but also takes into account broader matters such as ethical and social concerns regarding gene technology. For example:

- The Gene Technology Community Consultative Group (the community committee) will advise the GTR and the Ministerial Council about GMOs, specifically on matters of general concern, and the need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines for GMOs and GM products.

- The Gene Technology Ethics Committee will advise the GTR and the Ministerial Council on ethical issues relating to gene technology, and the need for and content of policy principles and codes of practice which will cover dealings with GMOs. Once developed by the committee, the policy principles and codes of practice will be issued by the Ministerial Council. The policy principles will be prohibitive in nature (describing activities which must not be conducted on ethical grounds) and the codes of practice will be permissive in nature. The codes of practice will describe the types of ethical considerations which must be taken into account by researchers proposing to undertake work involving gene technology.

35. **The committee recommends that the Commonwealth government:**
    - **ensure that there is sufficient in house capacity in the Gene Technology Technical Advisory Committee to provide timely and effective risk assessment of genetically modified organisms;**
    - **give it the authority to coopt independent expertise when required; and**
    - **make these assessments public.**

Supported

The Gene Technology Bill prescribes requirements that comprehensively address this recommendation:

a) The legislation provides that the in-house staff necessary to assist the GTR are to be made available by the Secretary of the Department of Health. This means that the GTR will recruit staff to ensure that he/she attracts suitably skilled and qualified employees. The in-house scientific experts within the OGTR will be responsible for conducting the risk assessment with input of expert advice from the GTTAC and other stakeholders.

GTTAC, comprising up to 20 members, is required to have a wide range of expertise necessary for the regulation of GMOs. Apart from a lay person, each member must have skills or experience in one or more of the following areas:

Molecular biology	Ecology
Plant/microbial/animal/human	Virology
Entomology	Agriculture/aquacultural systems
Biosafety engineering	Public health
Occupational health and safety	Risk assessment
Clinical medicines	Biochemistry
Pharmacology	Plant/animal pathology
Botany	Microbiology
Animal biology	Immunology
Toxicology	

In addition, the GTR may also be assisted by Commonwealth public servants, officers of Commonwealth authorities, officers of State Departments and authorities made available to the GTR to assist with the performance of his/her functions. The terms on which other Commonwealth agencies and State governments will make staff available to the GTR will be negotiated on a bilateral basis.

b) The Bill provides for the Minister to appoint additional experts to advise GTTAC on an ad hoc or ongoing basis. These advisers may be appointed to assist the committee in its deliberations on specific applications or classes of applications.

- In addition, GTTAC also has the power to establish subcommittees to assist in the performance of its functions. At present, GMAC has two main sub-committees: the Release Sub-committee and the Scientific Sub-committee. It is anticipated that these sub-committees will be re-established under the new system.

c) As part of the regulatory process, risk assessments and risk management plans for GMO proposals for general release to the environment will be made public. As outlined under the response to recommendation 9, before finalising the assessment, the GTR must notify the public, through a variety of media and direct mailing, that a draft risk assessment and risk management plan has been prepared for a GMO and seek input on the document. The public will have the opportunity to comment on the draft. Further, a record of GMOs and GM product dealings will be established to provide the public with detailed information about all GMOs and GM products approval for use in Australia.

36. The committee recommends that all novel crops, whether bred by conventional means or by gene technology, should be assessed and regulated for their impact on the environment and human and animal health.

Supported In-principle

The government accepts that novel crops, that are bred by gene technology, should be assessed and regulated for their impact on the environment and human and animal health. This will be rigorously carried out and underpinned by the gene technology legislation. However, the Gene Technology Bill does not cover crops that are not considered to be a genetically modified organism under the definition of the legislation, whether they are 'novel' crops or not.

Plant breeding programs in Australia are very rigorous in ensuring that any non GM novel crops are tested in contained conditions, followed by field trials to ensure that any crop expressing a novel trait does not pose new risks to human health and the environment beyond the parent organisms from which the novel crop was derived. Regulation of the development and use of non GM novel crops is mostly captured under state and territory legislative instruments, such as land management and human health and safety acts of parliament and subordinate legal instruments. In addition, Commonwealth approval under the Environment Protection and Biodiversity Conservation Act 1999 would be required if planting or other actions involving such novel crops were likely to have a significant impact on a matter of national environmental significance.

AQIS regulates the importation of GM and other novel seeds that pose a threat to Australia's unique human, animal, plant and natural environment status. The practicalities of border control operations restrict the level of detail to which certain novel crops, such as hybrid and cultivar varieties below the species level, can be regulated. However there is statutory requirement that importers declare whether they are intending to bring in a new novel crop, and as such, no novel crops are allowed into Australia without the human, animal, plant and environmental health risks being rigorously assessed. Bringing living organisms into Australia without quarantine clearance is a serious breach of the Quarantine Act 1908 (as amended in 1999) and sanctions apply to offenders. AQIS also takes monitoring and compliance issues very seriously and has a program in place to deal with these issues.

37. The committee recommends that the Commonwealth government ensure that:

- **the independent status of the Gene Technology Regulator is clearly prescribed in the new gene technology legislation;**
- **sufficient funding is provided to enable him/her to fully discharge his/her duties; and**
- **the Gene Technology Regulator is publicly accountable.**

Supported

All of these issues are adequately specified in the Gene Technology Bill.

a) The need for the GTR to be a strong and independent regulator has been stressed by a wide range of stakeholders during the consultations of the initial draft of the Bill. The IOGTR has made sure that this is reflected in the proposed legislation. There are a number of provisions in the Bill which, when taken together, will ensure that the GTR has sufficient independence. For example, the GTR will:
   - be appointed by the Governor-General on the advice of the Commonwealth Minister for Health who must have approval for the recommendation from a majority of States and Territories;
   - report directly to Federal Parliament annually and at any other time, as required. The power to report directly to Federal Parliament on any matter is a significant power and one that is vested in a very limited number of statutory office holders;
   - not be subject to direction from anyone in relation to whether or not a particular application for a GMO licence is issued or refused; or the conditions to which a particular GMO licence is subject;
   - be required to give written notice to the Minister of all financial or other interests that the GTR has or acquires that could conflict with the proper performance of the GTR's functions under the Bill and regulations.
   - manage his/her own monies as a part of a discrete fund;
   - have the capacity to undertake or commission research in relation to risk assessment and the biosafety of GMOs;
   - be responsible for making all decisions on individual applications with no political interference; and
   - have the power to hire appropriately qualified staff, sufficient to meet the statutory obligations set out in the legislation.

b) The Bill provides that the GTR may charge for services provided by the GTR in the performance of the GTR's functions and establishes a special Gene Technology Account. The establishment of a discrete account to be administered by the GTR in the performance of his/her functions provides another level of independence to the GTR. Rather than the GTR's monies being part of a Departmental appropriation, they will be quite discrete. The GTR will be solely responsible for the administration of the Gene Technology Account. Monies that must be credited to the Gene Technology Account include:
   - monies appropriated by the Parliament for the GTR;
   - amounts equal to amounts received by the Commonwealth under the Gene Technology (Licence Charges) Act 2000;
   - amounts equal to fees received by the Commonwealth by way of licence application fees and fees associated with applications for certification of facilities;
   - amounts equal to amounts received by the Commonwealth in connection with the performance of the GTR's functions; and
   - amounts recovered by the Commonwealth as the result of the GTR recovering costs associated with a remediation exercise.
     - The IOGTR has let a consultancy, following a competitive tendering process, to cost the functions of new regulations, consider the cost impact on stakeholders and develop models for recovering costs from proponents. A selection panel comprising representatives from Victoria, Queensland and three Commonwealth agencies reviewed tenders submitted by eight companies.

- The consultancy will run from June to September 2000 and will conduct targeted consultations with all States and Territories, as well as relevant non-government stakeholders over the coming months. A final report will be submitted in September 2000. This report will further inform government consideration of the cost recovery policy and approach.

c) The IOGTR fully appreciates that independence, as indicated in a) above, must be balanced against accountability. This vital aspect of gene technology regulation is provided for by the Bill which requires that the GTR be accountable:
   - to the Federal Parliament (through annual reporting as detailed above);
   - to all jurisdictions that are part of the national scheme through the Ministerial Council on Gene Technology. One of the functions of the GTR is to provide advice to the Ministerial Council on the operations of the GTR and the scientific advisory committee and also on the effectiveness of the legislative framework for the regulation of GMOs;
   - under the *Financial Management and Accountability Act 1997* for the management of the a 'Special Account', the Gene Technology Account; and
   - to applicants, licence holders and the general public through clear, open and transparent decision-making processes.

House of Representatives Standing Committee on Primary Industries and Regional Services
"Work in Progress, Proceed with Caution"

Government Response to the Dissenting Report – Peter Andren MP

The dissenting report recommends:

There be a five year moratorium on the development of GMOs in Australia to enable adequate independent research to be carried out on health and environment impacts and consumer demand.

Not supported

Development of a GMO involves many phases of research and regulatory scrutiny. Such research and development has been conducted under close government scrutiny and in a way which is designed to minimise the risks of potential adverse outcomes to health and environment. The initial research and development phases provide, in addition to generic research and other information sources, some of the data used to determine levels of human health and environmental risks.

Without undertaking the initial contained and small scale field research into GMOs, it is very difficult to understand, as recommended in the second part, how adequate data can be obtained to determine the health and environmental impacts in Australian conditions.

A similar contradiction emerges with the call for the moratorium so consumer demand research can be undertaken. The government has addressed consumer food choice issues through the recent decision of the ANZFSC to require comprehensive labelling for GM food and food ingredients, where novel DNA and protein is present in the final food.

The role of government is to help ensure the potential risks associated with GMOs/biotechnology are identified, and the appropriate management of potential human health and environmental impacts are developed, implemented and enforced. Provision of information is also important so people are in a position to make informed decisions.

The Government takes these responsibilities very seriously and has introduced a number of initiatives to assist in addressing the issues, such as the strengthening of the regulation of this technology through the development of the Gene Technology Bill, and the development of a National Biotechnology Strategy.

Broader issues which would need to be assessed include the effects of a moratorium on the scientific research base in Australia, capital and venture markets, competitive and comparative advantages in the agricultural sector, and employment and national income. In addition, the usual problems that are encountered under prohibition style moratoriums should also be contemplated, such as the development of 'black-markets'.

Given the above considerations, the Government believes that a general or partial moratorium on GMO development in Australia would not be of benefit in the short or long term.