

Explanatory Guide

to the Commonwealth

Gene Technology Bill 2000

Gene Technology
(Consequential Amendments)
Bill 2000

and

Gene Technology
(Licence Charges)
Bill 2000

July 2000

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Copies of the Gene Technology Bill 2000, the Gene Technology (Consequential Amendments) Bill 2000 and the Gene Technology (Licence Charges) Bill 2000 may be obtained from the IOGTR or may be downloaded from the following websites:

www.aph.gov.au (Parliament House website)
www.health.gov.au/tga/genetech.htm (IOGTR website)

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Introduction

1.1 What is the purpose of this Explanatory Guide?

In June 2000, the Federal Government introduced a package of three Bills into Federal Parliament for the regulation of gene technology in Australia - the Gene Technology Bill 2000, the Gene Technology (Consequential Amendments) Bill 2000 and the Gene Technology (Licence Charges) Bill 2000.

During public consultations on the development of the legislative scheme, many people told us that it would be helpful to have a “plain-English” guide available to accompany the legislation. Therefore, when we released for consultation the first draft of the Gene Technology Bill 2000 we also released the “Explanatory Guide to the draft Commonwealth Gene Technology Bill – December 1999”. We received a lot of positive feedback on the explanatory guide including a number of suggestions on how to make it even more “user-friendly”.

On the basis of this experience, we have drafted this guide to accompany the three gene technology Bills which have just been introduced into Federal Parliament. The guide:

- uses plain language so it can be more easily understood by people who may not be used to reading and interpreting legislation;
- provides information about the reasons behind important parts of the Bills, including why they are drafted the way that they are and what they are trying to achieve;
- helps to explain how other important documents interact with the Bills to create a national system for regulating GMOs (such as the Gene Technology Regulations, the proposed Gene Technology Agreement, and complementary State and Territory legislation);
- is in addition to the formal “Explanatory Memoranda” which have also been tabled in Parliament. Explanatory memoranda must be prepared for every Bill introduced into Parliament. They follow a strict format and explain each clause of a Bill. They also describe the anticipated impact of the regulation, through a Regulation Impact Statement. By contrast, this guide is less formal and summarises the legislation.

This guide is divided into a number of chapters. They are:

- **Chapter 2 – Gene technology and the need for legislation**
This chapter sets out what gene technology is, describes the current system for controlling gene technology in Australia and why we need legislation.
- **Chapter 3 – A summary of the proposed legislation**
This is an executive summary which describes key aspects of the Gene Technology Bill 2000. It will be useful to people who would like a ‘thumbnail sketch’ of the proposed legislation. It is also a good source of information for anyone needing to give brief information about the Bill to their organisation or others interested in the legislation.
- **Chapter 4 – Detailed explanation of the Gene Technology Bill 2000**
This Chapter has been divided into 12 parts to correspond with the 12 parts of the Gene Technology Bill 2000. It provides a simplified outline of each part of the Bill including a description of the main policy considerations.
- **Chapter 5 – Commonwealth Gene Technology (Consequential Amendments) Bill 2000**
This chapter describes the amendments that will be made to existing legislation (such as the *Therapeutic Goods Act* and the *Australia New Zealand Food Act*) to ensure the streamlined operation of the new gene technology legislation alongside this existing legislation.
- **Chapter 6 – Commonwealth Gene Technology (Licence Charges) Bill 2000**
This chapter describes the purpose of the Licence Charges Bill and cost recovery for the new regulatory system.
- **Chapter 7 – Commonwealth Gene Technology Regulations**
Regulations form part of a regulatory system but are contained in a separate document to the Bills. This chapter describes what will be covered in the regulations which will be publicly circulated in July 2000 for comments by September 2000.
- **Chapter 8 – Model State legislation**
This chapter describes the process and purpose of model State/Territory legislation and the matters to be included in such legislation.
- **Chapter 9 – Gene Technology Agreement**
This chapter describes the purpose of the proposed Inter-governmental agreement and the major issues it will address.

1.2 Acronyms used in this Guide

AFFA	Agriculture Fisheries and Forestry Australia
ANZFA	Australia New Zealand Food Authority
AQIS	Australian Quarantine and Inspection Service
CSCG	Commonwealth State Consultative Group on Gene Technology
GMAC	Genetic Manipulation Advisory Committee
GMO	genetically modified organism
GM	genetically modified
GTR	Gene Technology Regulator ¹ (also referred to as “the Regulator”)
GTTAC	Gene Technology Technical Advisory Committee
GTCCG	Gene Technology Community Consultative Group
GTEC	Gene Technology Ethics Committee
IGA	Intergovernmental Agreement on Gene Technology
IOGTR	Interim Office of the Gene Technology Regulator
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NRA	National Registration Authority for Agricultural and Veterinary Chemicals
RIS	Regulation Impact Statement
TGA	Therapeutic Goods Administration

¹ The full term is used in several places to distinguish the GTR from existing regulators.

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Gene technology and the need for legislation

2.1 What is gene technology?

For over 100 years, we have been using techniques for altering the properties (or genes) of living things through methods such as selective breeding, plant cloning or grafting and the use of microbial products in fermenting. The principle of altering various organisms is not new but gene technology provides new methods for doing so.

Gene technology is, in many ways, more precise than previous techniques and allows, for the first time, transfer of a single gene from one organism to another. It involves modifying organisms by adding or deleting one or more genes to create or change specific characteristics. Organisms created using gene technology are often called “genetically modified organisms” (GMOs). Some people also call them “genetically manipulated organisms” or “genetically engineered organisms”.

2.2 How is gene technology used?

Gene technology has a wide range of applications including:

- In research, for example, basic research in biology and medicine with micro-organisms and animals;
- Agricultural applications, for example, genetic modification of crops to incorporate pest resistance or herbicide tolerance, or the slowing of the ripening process in fruit and flowers;
- Production of therapeutic goods, for example, the modification of micro-organisms to produce products such as insulin;
- In medicine, for example, the identification and treatment of genetic disease;
- Bio-remediation, for example, using micro-organisms to decompose toxic substances and clean-up industrial sites or environmental accidents; and
- Industrial uses, for example, producing enzymes for use in paper pulp production.

2.3 What are the potential benefits of gene technology to Australia?

Supporters of gene technology identify a range of potential benefits from applications of gene technology in relation to agriculture, health and the environment:

- Some agricultural benefits include:
 - higher productivity and yield leading to lower or stable prices for consumers;
 - more efficient use of agricultural and veterinary chemicals;
 - savings in energy inputs to farm production;
 - recovery of degraded land; and
 - reduced use of chemical sprays, with less exposure of farm workers.

- Some health benefits include:
 - using gene technology for research into the cause of diseases, as a diagnostic tool and for preventing and treating diseases;
 - improved biopharmaceuticals (including cytokines, enzymes, hormones, monoclonal antibodies, blood coagulation factors, and vaccines) with advantages such as improved efficacy, greater availability, cheaper production, reduced allergenicity and reduced risks of transmission of infectious agents; and
 - potentially safer food with fewer food contaminants, allergens and natural toxic compounds.

- Some environmental benefits include:
 - lower use of chemicals/pesticides, reduced ground water contamination, reclaiming of polluted or salt-affected land;
 - higher agricultural productivity reducing the need for land clearing, thus protecting biodiversity;
 - producing biodegradable plastics and biodiesel; and
 - bio-remediation.

2.4 What are the potential risks of the technology?

The very characteristics of gene technology which produce many of the benefits (such as the ability to introduce genes from one species into a different species) are also those that cause concerns in the community. These concerns are related to potential unintended effects on the health of people or the environment.

Possible risks identified to date include:

- higher risks of allergic reactions to genetically modified food;
- unknown long term consequences that we may not be able to reverse or fix once the GMO is widely used;
- contamination of traditional or organic crops by neighbouring genetically modified crops;
- more agricultural chemicals used on genetically modified herbicide tolerant crops, possibly resulting in increased environmental damage;
- crops so strong that they become weeds or pests;
- GM animals such as pigs, which contain a growth hormone gene, escaping and becoming feral;
- effects of insect-resistant crops on non-target insects, such as butterflies; and
- transfer of genes for herbicide tolerance from GM crops to related species resulting in herbicide-resistant weeds.

There are also broader, non-scientific concerns that have been expressed about using gene technology, including ethical, social and moral concerns about the impact of 'humans playing God'.

2.5 Why is legislation needed for GMOs?

For the past 12 years, the use of gene technology has been overseen by the Genetic Manipulation Advisory Committee (GMAC). GMAC is a committee of experts (in fields such as molecular biology, ecology, plant genetics, agriculture and biosafety engineering) which reports to the Commonwealth Minister for Health. The system overseen by GMAC has no legislative backing; compliance with GMAC guidelines and GMAC recommendations is voluntary.

GMAC also plays an important role advising the existing regulators (such as the Therapeutic Goods Administration, the Australia New Zealand Food Authority and the National Registration Authority for Agricultural and Veterinary Chemicals) about the safety of GMOs as products (such as food, therapeutic goods and agricultural, veterinary and industrial chemicals).

While GMAC has provided reliable scientific advice about the risks posed by gene technology, and how to manage such risks, the system is not backed up by legislation. This means there is no legally enforceable way to audit or monitor the use of gene technology or penalise breaches.

Another important reason why legislation is needed is that the range of applications for gene technology is changing very rapidly. Certain GMOs are now being developed which do not fall neatly within the mandate of the existing regulators. Also, more GMOs are approaching the commercialization stage

when the producers of the GMOs will be seeking to release the GMO into the environment, either for the purposes of field trials or for commercial release.

Examples of activities with 'gap' GMOs which are currently overseen by GMAC but are not regulated under existing legislation include:

- the growing of GM agricultural crops;
- the growing or breeding of GM animals or fish;
- the use of GM micro-organisms designed to decompose toxic substances (bio-remediation); and
- the use of GM viruses and GM vaccines.

Some products of GMOs are also not covered by existing regulators. One example is stockfeed, which may be produced from genetically modified crops such as cotton.

To date, GMAC has provided advice directly to proponents on these 'gap' GMOs. However, as a result of the administrative nature of the GMAC system, governments have had limited capacity to either monitor proponents' compliance with GMAC advice, or to enforce compliance with that advice.

The objective of the gene technology legislation is to protect the health and safety of people and to protect the environment by identifying risks posed as a result of gene technology and by managing those risks. It does this by creating laws for certain dealings (or activities) with GMOs.

The Government's objectives also include:

- an efficient and cost effective approach regulating gene technology;
- continuing a science-based approach for risk assessment, but also including capacity for formal consideration of broader issues such as ethics;
- avoiding unnecessary duplication between the activities of the new GTR and existing regulators, and to generally improve the coordination between all regulators involved in the approval of GMOs and GM products;
- creating a more streamlined and certain pathway for industry seeking approval for GMOs and GM products that can be managed safely;
- enforceability of the arrangements for managing risk;
- greater transparency and accountability; and
- better ability to respond to stakeholder and community views.

2.6 Where did the ideas in the legislation come from?

For some time, public servants from the Commonwealth and all States and Territories have been working together to develop ways to regulate GMOs and

GM products. This work has taken place through a group of Commonwealth, State and Territory officials - the Commonwealth State Consultative Group on Gene Technology (CSCG).

The Bill developed in four stages:

- *Policy principles to underpin the legislative scheme*

In November 1998, a paper entitled *Regulation of Gene Technology* was circulated for limited public consultation. Officials traveled to each jurisdiction hearing views about the broad policy principles and some of the features of the system of regulation that people wanted. As a result of these consultations, the CSCG agreed a set of policy principles to guide development of the regulatory system.

- *Operational detail to inform the drafting of the legislation*

On the basis of the agreed policy principles and the first round of consultation, officials worked together to fill in the details about how the regulatory system should work. They looked at what sort of legislation was appropriate, how decisions would be made, how GMOs would be regulated and how the public would be kept informed and be able to provide input to the scheme.

In October 1999, the discussion paper “Proposed national regulatory scheme for genetically modified organisms – How should it work?” was:

- advertised in a range of national, State and Territory and regional newspapers;
- made available to 2,500 individuals and organisations notified by direct-mail;
- provided to all MPs and Senators in Federal Parliament; and
- posted on the website of the Interim Office of the Gene Technology Regulator.

Invitations to attend targeted consultations were sent to approximately 1,000 individuals and organisations across Australia including:

- Vice Chancellors of all Universities where research involving GMOs is conducted;
- all Institutional Biosafety Committees who currently oversee work with GMOs;
- all State/Territory Inter-Departmental Committees who are currently looking at issues related to GMOs including the proposed legislation;
- consumer groups, including the Australian Consumers Association and the Consumers Health Forum;
- environmental groups, including the Australian Conservation Foundation and Friends of the Earth;

- health professional groups, including the Australian Medical Association, and the Public Health Association of Australia;
- industry groups and companies, including the Australian Proprietary Medicines Association and AVCARE;
- retailers and food industry groups, including Woolworths, Goodman Fielder, and the Australian Supermarkets Association; and
- primary producer groups, including the Pork Council of Australia, the Australian Meat Council, Meat and Livestock Australia, State/Territory Farmers Associations, the Australian Poultry Industries Association, Australian Cotton CRC, and Dairy Farmers Associations.

The targeted consultations were held in all States and Territories during November and December 1999 and more than 130 written submissions were received on the discussion paper.

Information received from face-to-face consultations and written submissions was invaluable for indicating the types of issues that individuals and organisations felt should be addressed by the legislation (as well as those that people felt should be addressed in different ways).

- *The draft Commonwealth Gene Technology Bill*

On the basis of input provided by non-government stakeholders and the general community, as well as officers from Commonwealth agencies and States and Territories, a consultation draft of the Gene Technology Bill was prepared by the Commonwealth Office of Parliamentary Counsel during November and December 1999. The Bill was also prepared having regard to international precedents particularly in Canada, New Zealand, the United States of America and the European Community.

- *Consultation on the draft Commonwealth Gene Technology Bill*

The draft of the Gene Technology Bill (green cover) was released, along with a plain language explanatory guide, for public comment in late December 1999. Invitations to comment on the Bill and attend public consultations were sent to 2,500 individuals and organisations. Advertisements were also placed in newspapers in all States and Territories inviting people to attend the public forums. Public forums were held in all capital cities and three regional centres (Albury-Wodonga, Tamworth and Rockhampton) during February and March 2000 to provide an opportunity to discuss issues.

The enormous interest in gene technology was reflected both in the number of people attending the forums, and in the valuable input we received. A wide range of interested parties provided written submissions including:

- individuals;

- researchers;
- universities;
- consumer groups;
- environmental groups;
- organic Farmers;
- traditional Farmers;
- representatives of the agriculture industry;
- representatives of the gene technology industry;
- representatives of the food industry; and
- Commonwealth and State governments as well as local councils.

On the basis of these consultations, a number of changes were made to the draft Bill to reflect the issues and comments raised by the community. Where possible, this guide indicates those changes or where a re-think was necessary because of the strength of stakeholder sentiment about particular matters.

2.7 What happens now?

From July 2000 onwards:

The legislation will be considered by Federal Parliament. The legislation will be referred to a Senate Committee (the Community Affairs References Committee) for an inquiry into the legislation.

While the legislation is in Parliament, up-to-date information regarding the status of the legislation, and also details of the debates on the legislation, can be found on the Parliament House webpage at www.aph.gov.au.

In July 2000:

The government will release draft Commonwealth Gene Technology Regulations, to be made under the Gene Technology Bill 2000 when it becomes law.

People indicated that it is often difficult to understand how the legislation will work by simply looking at the draft Bill because a lot of the administrative detail is included in the regulations. An early draft of the regulations will therefore be made available for public comment.

The IOGTR will conduct national consultations on the draft regulations in late August 2000. The consultations will be advertised in newspapers in each jurisdiction and also on the IOGTR website and direct-mailed to all persons on the IOGTR/GMAC mailing list.

Between July 2000 and September 2000

Model State legislation will be released for public comment. The model state legislation will be substantially similar to the Commonwealth legislation (for more detail regarding the model State legislation please refer to Chapter 8).

The Gene Technology Intergovernmental Agreement which underpins the legislative scheme will also be released (for more detail regarding the Agreement please refer to Chapter 9).

January 2001:

Pending the passage of the legislation through Federal Parliament in 2000, the government expects that the new legislative system will be fully operational by 3 January 2001.

3

A Summary of the proposed legislation

This chapter summarises key aspects of the Gene Technology Bill 2000. While we urge you to examine the whole Guide, we also understand that some people will only require an overview of the Bill.

The views of stakeholders and the feedback received to date on key issues are reflected in Chapter 4 (Parts 1-12) as part of the detailed explanation of the various parts of the Bill.

3.1 What is the object of the Gene Technology Bill 2000?

This Bill is a major component of a national scheme to protect the public health and safety of people and to protect the environment from risks associated with gene technology. The scheme will operate by identifying and assessing risks posed by, or as a result of, gene technology, and by managing any risks through the regulation of certain dealings with genetically modified organisms (GMOs). The national scheme will be established by Commonwealth, State and Territory legislation.

3.2 What does the Gene Technology Bill 2000 do?

The Bill does six key things. It:

- (a) establishes a statutory officer, the Gene Technology Regulator (the GTR) to administer the legislation and make decisions under the legislation;
- (b) establishes a scientific committee, an ethics committee and a community committee to advise the GTR and the Ministerial Council on gene technology;
- (c) prohibits persons from dealing with GMOs (e.g. research, manufacture, production, commercial release and import) unless the dealing is:

- exempt;
 - a notifiable low risk dealing (that is, contained research work which has been demonstrated to pose minimal risk to workers, the general public or the environment);
 - on the Register of GMOs; or
 - licensed by the GTR.
- (d) establishes a scheme to assess the risks to human health and the environment associated with various dealings with GMOs, including opportunities for extensive public input;
- (e) provides for monitoring and enforcement of the legislation; and
- (f) creates a centralised, publicly available database of all GMOs and GM products approved in Australia (the Record of GMO and GM product dealings).

Each of these key components of the Bill is explored in a little more detail below.

(a) The Gene Technology Regulator

The legislative scheme will be administered by the Gene Technology Regulator (GTR). The GTR will:

- be an office holder with significant independence – similar to the Auditor-General and the Tax Commissioner;
- be appointed by the Governor-General only with the agreement of the majority of all jurisdictions;
- administer the legislation and assess any risks posed by GMOs;
- inform and advise other regulatory agencies, States and Territories and the public about GMOs and GM products;
- promote harmonised risk assessments for GMOs and GM products by regulatory agencies;
- monitor and enforce the legislation; and
- report to Parliament annually, and at any other time such a report is warranted, and will copy any such report to the States and Territories.

(b) The Committees

The legislation establishes three key advisory groups to assist the GTR and the Ministerial Council on Gene Technology:

- The **Gene Technology Technical Advisory Committee** (the scientific committee) will replace the current Genetic Manipulation Advisory Committee (GMAC). The committee will provide scientific and technical advice to the GTR or the Ministerial Council on matters including: gene technology, GMOs and GM products, and applications made under the legislation.

- The **Gene Technology Community Consultative Group** (the community committee) will be a broadly based consultative committee established to provide views to the Ministerial Council and the GTR on: community concerns regarding gene technology and the need for, and content of, policy guidelines and codes of practice to the development of the procedural and policy documents which will guide the GTR's decision-making.
- The **Gene Technology Ethics Committee** (the ethics committee) will provide advice to the GTR and the Ministerial Council on the ethics of gene technology, appropriate ethics guidelines and any necessary prohibitive directives.

(c) The prohibitions

- The legislation will regulate all 'dealings' (e.g. research, manufacture, production, commercial release and import) with live viable organisms that have been modified by techniques of gene technology, including the progeny (or descendents) of such GMOs which also share a genetically modified trait.

Example:

Growing crops and animals (including fish) that have been genetically modified; and laboratory research involving the genetic modification of animals, plants, bacteria and viruses.

- The legislation will also regulate some GM products, but only where the products are not regulated by an existing agency. On the whole, GM products are already regulated by agencies such as the TGA (therapeutic goods) and ANZFA (food products). The GM products which are not already covered by an existing national regulation scheme will be regulated by the GTR under the new legislation. An example is stock feed derived from a GM crop such as cotton.
- The legislation revolves around a system of prohibitions and approvals. Every dealing with a GMO will need to be licensed by the GTR, unless the dealing is an exempt dealing, a notifiable low risk dealing or on the Register of GMOs.
 - **Exemptions** – where the GTR is confident that a certain dealing involves a very low risk, the class of dealing with the GMO will be recorded in the regulations as exempt (e.g. contained research involving a very well understood process for creating and studying a GMO). This will mean that no licence is required, provided that the activity remains within the specified parameters. There will be no exemptions for any release of a GMO into the environment (e.g. field trials and commercial releases). This reflects the current approach under the GMAC system.

- **Notifiable low risk dealings** – the regulations will also set out categories of dealings with GMOs which are very low risk and which may proceed provided that certain conditions spelt out in the regulations are observed. This will include requirements that the specified dealings be undertaken only in contained facilities, overseen by Institutional Biosafety Committees and notified to the GTR. These will be similar to “class licences” and the conditions under which such dealings will operate will be clearly set out in the regulations.

The Bill does not allow dealings which involve the intentional release of a GMO into the environment to be prescribed as a notifiable low risk dealing.

- **Licences** – all dealings with GMOs (that are not exempt or low risk notifiable dealings) will need to be licensed by the GTR. The licensing system will be based on rigorous scientific risk assessment and extensive consultation with expert advisory committees, Government agencies and the public.
- **Register of GMOs** – dealings with GMOs may be entered on the GMO Register once they have been licensed for a certain period of time. Dealings will not be entered onto the Register until the GTR is satisfied that the dealings are sufficiently safe that they can be undertaken by anyone, and that safety does not depend on oversight by a licence holder.

(d) Risk assessment

Taking a hypothetical case, such as an application for the field trial of a genetically modified crop, this is a summary of the steps that would be taken by the GTR to assess the application.

Stage 1 – The applicant provides the GTR with a full data package containing all information required by regulations and explanatory guidelines. For example, the applicant provides information about: the parent organism; the characteristics of the GMO (including the methods used for modification, the vectors used etc); the new traits of the GMO (including the stability of the new organism); any health impacts of the GMO (including any increased toxic or allergenic effects); the proposed release (including information about the receiving environment); potential environmental impacts; proposed monitoring techniques; methods or procedures to minimise the spread or persistence of the GMO; and contingency planning in the case of any unexpected effects of the GMO.

Stage 2 – The GTR undertakes a preliminary check of the information to ensure that all relevant information has been included in the application and makes an

initial assessment of whether the activity may have a significant impact on the environment.

The GTR also checks to make sure that the application is consistent with policy principles. Policy principles are issued by the Ministerial Council, on the advice of the ethics committee or the community group. If the application is inconsistent with a policy principle (including any ethical guidelines issued by the Ministerial Council) or animal welfare legislation, the GTR must refuse to accept the application.

Stage 3 – If the GTR considers that the proposed dealing with the GMO may have a significant impact on the environment, the GTR calls for public submissions on the possible risks and means of managing the risks. The GTR would advertise in newspapers and in the Commonwealth Gazette, place notices on the GTR's website, and direct-mail all persons on the GTR's mailing list. The GTR also seeks advice on possible risks from the Commonwealth Environment Minister, the scientific committee, the States and Territories, relevant Commonwealth agencies and local councils.

Stage 4 – The GTR prepares a comprehensive risk assessment and risk management plan, based on the information provided by all parties and information generated by the GTR. In preparing the plan the GTR considers:

- advice from the scientific committee;
- information provided by State, Territory and local governments about any local or regional environmental issues;
- advice provided by the Commonwealth Environment Minister and State Environmental Protection Agencies;
- advice provided by health agencies, including the potential health effects of the GMO;
- advice provided by members of the public;
- the data provided by the applicant – if necessary, the GTR may also commission independent verification of such data;
- information generated by the Office of the GTR (including literature searches and any independent research conducted).

Full details of the GTR's risk assessment process will be detailed in guidelines issued under the legislation. Extensive public consultation will be undertaken on those guidelines.

Stage 5 – For all releases of GMOs into the environment (both low risk and higher risk), the GTR conducts a round of public consultation on the draft risk assessment and risk management plan (which is a draft determination). Again, the draft risk assessment and risk management plan would be advertised in newspapers, on the GTR's website, in the Gazette and direct-mailed to all interested persons. This second round of consultation enables public scrutiny of

the draft decision to ensure that the GTR has taken into account all relevant matters and has undertaken a comprehensive assessment of the application.

Stage 6 – The GTR makes a decision on the application and if the application is approved, applies conditions to manage any risks. For example, conditions may be applied about where the crop may be grown, measures for limiting the spread of the GMO, how the crop must be disposed of and the type and level of monitoring of the crop that is required.

(e) The monitoring and enforcement of conditions

One of the benefits of a legislative scheme is the capacity to properly monitor activities involving GMOs and to enforce compliance, where necessary, with the conditions that the GTR imposes.

The GTR will:

- have the capacity to commission independent research to monitor any risks posed by GMOs;
- implement a range of monitoring activities which will vary depending on the level of risk posed by the proposed dealing (for example, the GTR may require regular reporting, auditing, routine inspections or a combination of these depending on the level of risk posed by the dealing and the history of compliance with the legislation);
- be able to appoint inspectors with significant powers to investigate suspected breaches of the legislation; and
- possess a broad range of enforcement powers, including the ability to issue directions, cancel or suspend approvals, seek injunctions and make reports directly to Federal Parliament.

The legislation also imposes stringent penalties for breach of the legislation - up to \$1.1 million per offence for a corporation.

(f) The central database of GMOs

The legislation establishes a centralised and publicly available database for the recording of all approvals of GMOs and GM products (the Record of GMO and GM Product dealings).

The database will include information about:

- all licences issued by the GTR, including details of the licence holder, persons covered by the licence, dealings authorised by the licence and licence conditions; and
- all notifications given to the GTR by other regulators about GM products approved for sale in Australia. For example, if the Therapeutic Goods Administration approves a genetically modified medicine for sale in Australia this must be entered in the database.

4

Detailed Explanation of the Gene Technology Bill 2000

Part 1 - Preliminary

Summary of this Part

This Part sets out the object of the Bill and the mechanical or technical provisions of the Bill which deal with commencement, offences and the extension of the Bill to External Territories.

Key provisions in this Part and major changes as a result of consultation on the draft Bill

Object of the Act (clause 3); and
Regulatory framework to achieve object (clause 4)

During consultations on the draft Bill, stakeholders advised that:

- protecting public health and safety and the environment should be paramount;
- the inclusion in the object of references to 'Australia's international obligations' and the 'national interest' were confusing. People were concerned that such references would leave open the possibility that the national interest (such as trade considerations) could override the protection of health and the environment;
- while protection of health and the environment should be paramount, a secondary clause could be included which provides that the regulatory system:
 - should be as efficient and effective as possible – that is, it should not unnecessarily hinder the application of gene technology in Australia where the health of the public and the environment are not at risk; and

- be consistent with the existing Commonwealth and State/Territory regulatory schemes relevant to GMOs, including the existing schemes for the regulation of food, agricultural and veterinary chemicals and therapeutic goods.

On the basis of these comments, the object of the Act has been changed to remove the reference to the national interest. The object now states:

The object of this Act is to protect the health and safety of people, and to protect the environment, by identifying the risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

The secondary clause – that the object should be achieved through a regulatory system that is efficient and effective and which operates in conjunction with the other regulatory schemes – has been retained.

As suggested during consultations, the ‘environment’ has also been defined (in clause 10) to clarify that the environment includes all ecosystems and their constituent parts, natural and physical resources and the qualities and characteristics of locations, places and areas. This is a very broad definition of the environment which will ensure that the GTR must act to protect all animals (including insects, fish and mammals), plants, soils and ecosystems (both aquatic and terrestrial).

For a clause by clause explanation of this Part please refer to the Explanatory Memorandum to the Gene Technology Bill 2000

Part 2 - Interpretation and Operation of the Act

Summary of this Part

This Part achieves three main objectives. It:

- sets out the definitions used in the Act - these definitions determine the meaning of certain words whenever they are used in the Bill. The definitions define the scope of the legislation;
- sets out the formal mechanical provisions, which enable the legislation to operate as part of a national scheme in conjunction with State and Territory legislation;
- describes how policy principles, policy guidelines and codes of practice must be developed under the legislation by the Ministerial Council.

Key provisions in this Part and major changes as a result of consultation on the draft Bill

Definitions (Division 2)

During consultations on the draft Bill we received a lot of positive support for the definitions used in the Bill. Overall, people felt that it was important that the central definitions in the legislation (for the terms 'genetically modified organism', 'gene technology' and 'deal with') be drafted as broadly as possible to ensure maximum potential coverage of the legislation.

The definitions that attracted the most comment were the central definitions of "deal with", "genetically modified organism" and "gene technology".

Deal with, genetically modified organism and gene technology

Taken together, the effect of these definitions is that the legislation will regulate all 'dealings' (e.g. research, manufacture, production, commercial release and import) with:

- organisms (that is biological entities that are viable, capable of reproduction or capable of transferring genetic material) that have been modified by gene technology. GMOs may be organisms that have been modified by any means aside from:
 - sexual reproduction;
 - homologous recombination; and
 - techniques described in regulations.

- organisms that have inherited particular traits from an organism (the initial or parent organism) where those traits occurred in the parent organism because of gene technology. This enables the legislation to cover the progeny of GMOs where the progeny may have resulted from sexual reproduction but where the progeny continue to have traits that resulted from the gene technology of the initial or parent organism; and
- anything declared by the regulations to be a GMO. Stakeholders have expressed the strong view that the legislation be able to respond to changes in technology and be able to cover GM products where necessary. As a general rule most GM products are regulated by existing regulators (for example, GM therapeutic goods are regulated by the TGA and GM food products are regulated by ANZFA). This capacity to declare an organism to be a GMO would enable any organisms or products that fall “into the gaps” and are not regulated by existing regulators to be regulated by the GTR. So far, very few such products have been identified – one of them is GM stockfeed.

The definition of a GMO explicitly excludes:

- a human being - if the human being is only caught by the definition of a GMO because they have undergone somatic cell gene therapy. The first draft of the Bill defined GMO to exclude a human being (without any reference to somatic cell gene therapy). This caused a great deal of confusion because people assumed that the legislation therefore excluded any trials involving the use of GMOs in humans. On the contrary, the intent was to avoid the situation whereby a person who has undergone gene therapy becomes a GMO (because they would be an organism that has been modified by techniques of gene technology) and would then have to be licensed by the GTR. This has now been clarified.

In summary, the GTR will regulate all organisms modified by gene technology (including human cell lines, tissue samples etc). In relation to somatic cell gene therapy involving humans, the TGA and the NHMRC will have primary responsibility for overseeing any such trial, but the GTR will also be involved in order to ensure that there are no environmental risks posed by GMOs to be used as part of the human trials. A human who has undergone such somatic cell gene therapy would not, once they have completed the therapy, be considered to be a GMO under the Bill (by virtue of the exclusion in the definition of GMO described above).

- organisms declared by the regulations not to be genetically modified organisms. It is anticipated that, from the outset, the types of organisms declared not to be GMOs would include plants derived using protoplast fusion and organisms derived using various types of mutagenesis, such as chemical

mutagenesis. Again, it is important that the legislation be flexible enough to respond to changes in technology, as well as any anomalies in the application of the legislation.

The GTR as a “one stop shop”

A number of stakeholders felt that the legislation should regulate all dealings with GMOs and GM products, regardless of whether they are currently regulated by an existing regulatory agency.

The legislation addresses this concern by creating a one-stop shop for biosafety assessment of all GMOs and GM products. It does this by establishing a centralised national regulator who undertakes risk assessment of all GMOs and GM products.

The Gene Technology Bill 2000 regulates all dealings with live, viable organisms that have been modified by techniques of gene technology, regardless of whether these are also examined by other regulators. However, in the case of GM products that are not live and viable, where:

- these are not regulated by any other regulatory agency – the GTR will directly regulate those GM products (for example, stock feed);
- these are regulated by other regulatory agencies – the regulatory agency must seek, and take into account, the GTR’s advice and must notify the GTR of the decision regarding the GM product, so that the GTR can include the information on the record of GMO and GM product dealings, the comprehensive database of GMOs and GM products approved for use in Australia.

In essence, the suggestion that the legislation should deal with all GMOs and GM products has been reflected in the Bill, as the GTR will directly regulate all GMOs and if there are products flowing from such GMOs, these products will undergo a second round of assessment by the relevant regulatory agency with advice from the GTR.

The advantages of this approach are that it:

- recognises the roles of each of the existing regulators and the desirability of assessing GM products along with their non-GM counterparts under the relevant regulatory framework . For example, GM therapeutic goods are most appropriately assessed for safety, quality and efficacy under the therapeutic goods scheme, with advice on the safety aspects associated with the genetic modification of the pharmaceutical being provided by the GTR;
- ensures that like products are treated in a similar way (reducing market distortions) while also ensuring that any risks posed by gene technology are considered;
- ensures that the GTR acts as a centralised area of expertise on genetic safety and makes advice available to other regulators of GM products. This

- reduces costs to Government by eliminating the need for each regulatory agency to establish its own centre of expertise on gene technology;
- ensures that all aspects of the production, manufacture and sale of GMOs and GM products (in fact, all dealings) are regulated and that there are no 'gaps' in regulatory coverage. The system also ensures that the GTR either directly regulates, or provides advice to other regulators, on all GMOs and GM products;
 - minimises duplication by implementing strategies to improve the interface between regulators. For example, the legislation requires:
 - exchange of information between regulators;
 - the GTR to hold a centralised database of all approvals for GMOs and GM products; and
 - the GTR to work with other agencies to harmonise data requirements, assessment and standards in relation to risks posed by gene technology.

The national **scheme** (Divisions 3 and 4)

When Australian governments began to look at the options for regulating gene technology, several years ago, various alternatives were considered. For example, governments considered:

- continuing the current voluntary arrangements;
- enacting discrete legislation in each jurisdiction;
- enacting Commonwealth-specific legislation; or
- developing a nationally consistent scheme for the regulation of gene technology.

After detailed consideration, all governments strongly supported the development of a national scheme for gene technology, to be administered by a single central national regulator (the Gene Technology Regulator) responsible for managing any risks posed by GMOs to human health or the environment. This position was also strongly supported by stakeholder groups including industry, environment and consumer groups and primary producers.

Governments and stakeholders consider that a national scheme of legislation (relying on Commonwealth legislation and complementary legislation in each jurisdiction) is the only approach which:

- ensures maximum national consistency of gene technology regulation;
- ensures that the legislation applies equally to all companies, research institutions, and individuals, as well as Commonwealth and State/Territory agencies in Australia;
- provides a streamlined and certain pathway for businesses seeking approval for dealings with GMOs;
- minimises the costs of compliance to government and business that operate in more than one jurisdiction;

- minimises inefficiencies and distortions in the market place as the result of differing levels of regulation in different jurisdictions; and
- minimises discrepancies between jurisdictions and potential gaps or loopholes in legislative coverage that could undermine community confidence in the safe management of GMOs. The system ensures that the “lowest common denominator” does not prevail and that the regulatory approach affords the highest possible level of protection for the environment and human health.

How will the national scheme work?

The national scheme works in the following way:

- The Commonwealth Gene Technology Bill 2000 relies on a range of constitutional powers, including the corporations power, the trade and commerce power, the quarantine power, the census and statistics power, the powers of the Parliament and the incidental power. This ensures that from the first day of operation of the national scheme there is maximum coverage of people and activities. The powers relied on to support the Commonwealth Gene Technology Bill are detailed in clause 13 of the Bill.
- Each State and Territory will enact complementary legislation to supplement the Commonwealth legislation. Each piece of legislation will be consistent, and will empower the GTR to do all of the things set out in the Commonwealth Bill for bodies able to be constitutionally covered by the Commonwealth (e.g. corporations) and bodies and individuals able to be covered by the States (e.g. State agencies).
- When a State or Territory enacts a law that is substantially the same as the Commonwealth law, the Commonwealth law will “wind back” so that the State law (rather than the Commonwealth law) will apply to:
 - all higher education institutions;
 - state agencies; and
 - all individuals that might have been covered as a result of the use of the quarantine power (in relation to limiting the spread of pests and diseases).
- In combination, the Commonwealth and State legislation enables consistent application of the scheme to all individuals and organisations in Australia.
- The fact that the GTR’s powers will be derived from a combination of Commonwealth, State and Territory legislation will have minimal effect on the day-to-day operation and administration of the scheme.

Policy principles, policy guidelines and codes of practice (Division 4, Subdivision B)

During consultations on the draft Bill, a number of stakeholders expressed concern about the way the provisions relating to policy guidelines and codes of practice issued by the Ministerial Council had been presented. They considered that:

- it was not sufficiently clear what policy guidelines and codes of practice were;
- while it was important that Ministers play a role in policy-setting in relation to the legislative scheme, it was equally important that the GTR's independence be maintained. People considered that the Ministerial Council should not be able to override a decision of the GTR, which would be based on protection of health and safety and the environment, by issuing ad hoc policy guidelines (for example, on trade-related matters);
- regulatory certainty for industry was important, so if policy principles were to be made by the Ministerial Council (and expected to be observed by the GTR and by industry) then the requirements of the policy principles should be subject to consultation, be clearly articulated and finally subjected to Parliamentary scrutiny.

On the basis of this feedback, the provisions which address the Ministerial Council's issuing of policy documents have been redrafted, and the distinctions between policy principles, policy guidelines and codes of practice have been made clearer.

Policy principles:

- The Ministerial Council may issue policy principles on ethical issues relating to dealings with GMOs, and on other matters prescribed in regulations. However, matters prescribed in regulations must not compromise the primary focus on the health and safety of people and the protection of the environment.
- The policy principles must be developed in consultation with each of the committees established under the legislation, relevant Commonwealth and State agencies, industry groups and environmental, consumer and other groups.
- Once issued by the Ministerial Council, the policy principles will be subject to Parliamentary scrutiny as a disallowable instrument. This is important because the principles will, in effect, have legislative force.
- The GTR must not accept, or approve, any application that is inconsistent with a policy principle issued by the Ministerial Council.

Example:

The Ministerial Council may, on the advice of the Gene Technology Ethics Committee, issue a policy principle prohibiting certain applications of gene technology on ethical grounds. The policy principle will be clearly documented and subject to Parliamentary scrutiny. The GTR must not accept any application that is inconsistent with the policy principle issued by the Ministerial Council.

Another matter that people suggested Ministers could make policy principles on is GMO-free agricultural zones so as to protect Australia's diverse farming practices.

Policy Guidelines

- Policy guidelines will be issued by the Ministerial Council to assist the GTR in the performance of the GTR's functions. These will be guidance notes to the GTR, and will not be prohibitive or akin to a direction, but will be advisory.
- Unlike policy principles, the GTR is not compelled to act in accordance with policy guidelines. However, the GTR must take the guidelines into account in considering an application.

Example:

The Ministerial Council, may issue policy guidelines to the GTR about the matters to be taken into account when considering certain types of application for GMO licences. While the GTR must have regard to any such guidelines, they do not amount to a binding direction to the GTR and the GTR may act inconsistently with them if necessary.

Codes of Practice

- The Ministerial Council may also issue codes of practice as guidance to applicants (researchers and industry) regarding how work with GMOs should be conducted.
- Codes of practice must be developed in consultation with each of the committees established under the legislation, relevant Commonwealth and State agencies, industry groups and environmental, consumer and other groups.
- The GTR may apply a requirement that a code of practice be complied with as a condition of licence. As the codes of practice may, therefore, have some legislative effect (as it will be expected that they be complied with where the GTR so determines) the codes of practice are also disallowable instruments and subject to Parliamentary scrutiny.

Example:

The Ministerial Council may issue a code of practice for the ethical conduct of gene technology research or for the transport of GMOs. Unlike policy principles (which would be mandatory in nature and could, for example, prohibit certain work from occurring) and unlike policy guidelines (which would be used by the GTR to assist his/her decision making), the codes of practice would be developed for industry and research organisations with the expectation that they be observed. The GTR may also apply a condition of licence requiring compliance with a code of practice issued by the Ministerial Council.

Technical and procedural guidelines

- While not mentioned in this Part of the Bill, the Bill does provide the capacity for the GTR to issue technical or procedural guidelines (refer clause 27 - functions of the Regulator). For example, the GTR may issue technical or procedural guidelines about application requirements, the requirements for accreditation as an organisation or the certification of a facility.
- The technical and procedural guidelines issued by the GTR will be similar to those currently issued by GMAC. These guidelines explain GMAC requirements in some detail, and assist people to make applications and comply with GMAC requirements.

For a clause by clause explanation of this Part please refer to the Explanatory Memorandum to the Gene Technology Bill 2000

Part 3 - The Gene Technology Regulator

Summary of this Part

This Part establishes the statutory office of the Gene Technology Regulator (GTR) and specifies the GTR's functions and powers.

Key provisions in this Part and major changes as a result of consultation on the draft Bill

The need for the GTR to be a strong and independent regulator has been stressed by a wide range of stakeholders. There are a number of provisions in the legislation 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;
- manage his/her own monies as a part of a discrete fund; and
- be responsible for making all decisions on individual applications with no political interference (refer clause 25).

Of course, independence must be balanced against accountability. It is proposed that the GTR will be accountable:

- to the Federal Parliament (through annual reporting as detailed above);
- under the *Financial Management and Accountability Act 1997* for the management of the "GTR's Special Account"; and
- to applicants, licence holders and the general public through clear, open and transparent decision-making processes.

Functions of the Gene Technology Regulator

Clause 27 sets out the functions of the GTR as follows:

- a) to perform functions in relation to GMO licences as set out in Part 5 (e.g. the licensing of GMOs);
- b) to develop draft policy principles and policy guidelines, as requested by the Ministerial Council;
- c) to develop codes of practice;

- d) to issue technical and procedural guidelines in relation to GMOs;
- e) to provide information and advice to other regulatory agencies about GMOs and GM products;
- f) to provide information and advice to the public about the regulation of GMOs;
- g) to provide advice to the Ministerial Council about:
 - the operations of the GTR and the Gene Technology Technical Advisory Committee; and
 - the effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation.
- h) to undertake or commission research in relation to risk assessment and the biosafety of GMOs;
- i) to promote the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies;
- j) to monitor international practice in relation to the regulation of GMOs;
- k) to maintain links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia; and
- l) such other functions as are conferred on the GTR by the Act, the regulations or any other law.

For a clause by clause explanation of this Part please refer to the Explanatory Memorandum to the Gene Technology Bill 2000

Part 4 - Regulation of Dealings with GMOs

Summary of this Part

This Part describes the offences relating to unauthorised dealings with GMOs. The Part prohibits dealings with GMOs unless:

- the person undertaking the dealing is authorised to do so by a GMO licence;
- the dealing is a notifiable low risk dealing (as described in Part 6, Division 2);
- the dealing is an exempt dealing; or
- the dealing is included in the GMO Register.

The Part also sets out the offences for breach of a condition of a GMO licence.

The Part imposes heavier penalties on unlawful dealings that cause, or are likely to cause, significant damage to the health and safety of people or to the environment.

Key provisions in this Part and major changes as a result of consultation on the draft Bill

Dealings with GMOs must be licensed (Division 2)

This Division creates four main offences:

- **Offence for unauthorised dealings with a GMO**

A person must not deal with a thing they know to be a GMO without a licence authorising that dealing², unless:

- the dealing is a notifiable low risk dealing³;
- the dealing has been specifically exempted from the application of the legislation under the regulations⁴; or
- the dealing has been placed on the GMO Register⁵.

² Part 5 of the Bill describes the licensing process for GMOs.

³ Notifiable low risk dealings are described in Part 6 of the Bill. Notifiable low risk dealings will be prescribed in regulations. A person may undertake notifiable low risk dealings (subject to meeting conditions prescribed in the regulations) without the need to apply for a licence. In essence, notifiable low risk dealings are subject to “class” approvals.

⁴ Exempt dealings will be prescribed in the regulations. Exempt dealings will be based on the existing GMAC exemptions for very low risk work conducted in contained facilities.

⁵ The GMO Register is established under Part 6. Dealings with certain GMOs may be entered on the Register if after a period of licensing and monitoring of any risks, the GTR determines that the

Establishing the offence

During consultations on the draft Bill, a number of people expressed concern at the way the offences were drafted, requiring the prosecution to establish knowledge or recklessness before an offence could be established. We have addressed this concern by providing for two levels of offences – one that requires the establishment of knowledge or recklessness and one that does not (a strict liability offence).

This enables the prosecution to pursue lower penalties (refer below) for technical breaches of the legislation (without the necessity to prove knowledge or recklessness) and higher penalties for more serious breaches of the legislation where the Criminal Code requires that knowledge or recklessness be established.

In other words the prosecution can either establish that:

- the person dealt with the GMO knowing that it is a GMO and the fact that they dealt with the GMO without a licence or without the dealing being a notifiable low risk dealing, exempt dealing or dealing on the GMO Register, is sufficient. It is not necessary to establish that they knowingly or recklessly dealt with the GMO without approval under the legislation; or

If the prosecution is unable to establish knowledge or recklessness, then the prosecution may pursue a lower penalty (refer below).

- the person dealt with the GMO knowing that it is a GMO and also knowing that the dealing with the GMO was unauthorised or being reckless as to whether the dealing is so unauthorised.

If the prosecution can establish such a “mental element” to the offence, then the prosecution may pursue a higher penalty (refer below).

Penalties:

- For strict liability offences – 200 penalty units in the case of an aggravated offence and 50 penalty units in any other case.
- In any other case – 500 penalty units (\$55,000 for an individual and \$275,000 for a body corporate).
- If the offence is an aggravated offence (that is, one that causes significant damage, or is likely to cause significant damage, to the health and safety of people or the environment) – 2,000 penalty units⁶ (\$220,000 for an individual and \$1.1 million for a body corporate).

GMO no longer requires licensing based on the fact that the dealings with the GMO present minimal risk.

⁶ Where penalties are referenced in this Part, the reference is to the maximum penalty that may be applied. 1 penalty unit is equal to \$110.

- **Offence for breach of conditions of a licence**

A holder of a GMO licence is guilty of an offence if they do something, or fail to do something, that results in a breach of a condition of licence. A similar offence exists for persons covered by a GMO licence who do something, or fail to do something, which results in a breach of a condition of licence.

Establishing the offence

As for the offences in relation to unauthorised use of a GMO (detailed above) the offences associated with a breach of a condition of licence are also tiered. That is:

- in the case of a serious offence - the prosecution would need to establish that the licence holder or the person covered by the licence, intentionally took an action (or failed to take an action) that they knew (or they were reckless as to knowing) contravened a condition of licence. A large penalty could then be imposed; and
- in the case of a less serious or technical breach – the prosecution would just need to establish that the licence holder took action (or failed to take action) and that contravened the licence. In such a case a penalty could be imposed without the need to establish any “mental element” of knowledge or recklessness.

Penalties:

- If the offence is an aggravated offence (that is, one that causes significant damage, or is likely to cause significant damage, to the health and safety of people or the environment) – 2,000 penalty units (\$220,000 for an individual and \$1.1 million for a body corporate)
- In any other case – 500 penalty units (\$55,000 for an individual and \$275,000 for a body corporate).
- For strict liability offences – 200 penalty units in the case of an aggravated offence and 50 penalty units in any other case.

- **Offence for breaching conditions on the GMO Register**

A person is guilty of an offence if the person deals with a GMO knowing that it is a GMO, and the dealing is in breach of a condition specified on the GMO Register relating to the dealing.

Establishing the offence

The prosecution must establish that the person dealt with the GMO knowing that it is a GMO. However, strict liability applies in relation to establishing that the dealing is on the GMO Register and that the dealing contravened a condition on the Register. That is, the prosecution does not need to establish

that the person knew that the dealing contravened a condition relating to the dealing as specified on the Register.

Penalties

- In any case – 50 penalty units. The lower penalty recognises that dealings with GMOs are only entered on the GMO Register after a period of licensing and after the GTR is satisfied that any risks are minimal and that it is no longer necessary for the GMO to be licensed directly. As such the penalty for breach of any condition is smaller than the penalties for breach of a condition of licence.

- **Offence relation to notifiable low risk dealings**

A person is guilty of an offence if they deal with a GMO knowing that it is a GMO, that the dealing is a notifiable low risk dealing, and that the dealing has been undertaken in contravention of the regulations (which describe the conditions to be observed in relation to notifiable low risk dealings).

Establishing the offence

Strict liability applies in relation to establishing that the dealing is a notifiable low risk dealing and that the dealing was not undertaken in accordance with the conditions prescribed in the regulations. That is, the prosecution only needs to show that the person dealt with the GMO knowing it was a GMO. If what they did was in breach of the regulations, it is not necessary to establish that they knew what they did was in breach or were reckless as to whether it was in breach.

Penalties

- In any case - 50 penalty units. As for the lower penalties applying to dealings in breach of conditions on the GMO Register, the lower penalty for breach of conditions relating to notifiable low risk dealings recognises that any risks associated with the dealing are minimal.

For a clause by clause explanation of this Part please refer to the Explanatory Memorandum to the Gene Technology Bill 2000

Part 5 - Licensing System

Summary of this Part

This Part is one of the most critical in the Bill – it sets up the licensing system and explains how a person can apply to the GTR for a licence authorising certain dealings with GMOs. The Part has been divided into a number of Divisions that aim to walk the reader through the various stages of the licensing process.

The Part sets out the processes to be followed when the GTR is assessing applications involving two kinds of dealings:

- (a) those that involve the intentional release of a GMO into the environment; and
- (b) those that do not involve the intentional release of a GMO into the environment.

Key provisions in this Part and major changes as a result of consultation on the draft Bill

During consultations, the majority of stakeholders strongly supported the current GMAC system and the results GMAC has achieved in its assessment of applications for contained research work. They supported the clarity of the guidelines and the efficiency and timeliness of advice from GMAC. It is also worth noting that some stakeholders have expressed views which were more critical of GMAC. In drafting the Bill, we have worked to build on the strengths of the GMAC system in relation to contained work.

Stakeholders expressed somewhat different views with respect to applications involving the releases of GMOs into the environment. Here, stakeholders strongly expressed the importance of enhancing GMAC processes to provide a system for the regulation of such dealings 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.

We have attempted to address these important issues in drafting the assessment process for applications which is detailed in Part 5 of the Bill.

In summary, the licensing process is as follows:

(a) Application

An applicant applies for a licence to deal with a GMO and includes all of the supporting information which is requested by the GTR.

(b) Initial Screening

The GTR undertakes an initial screening of the application before accepting the application. This initial screening would check to ensure that all of the information requested has been provided and that the application is not inconsistent with policy principles issued by the Ministerial Council (including ethical principles). If the application does not contain the necessary information or is inconsistent with a policy principle, the GTR is not required to consider the application.

(c) If the application does not involve an intentional release of a GMO into the environment (e.g. research undertaken in a contained laboratory):

The GTR assesses the application and prepares a risk assessment and risk management plan. In preparing the risk assessment and risk management plan, the GTR may seek the advice of the scientific committee, State, Territory and Commonwealth agencies, local councils and any other person depending on the complexity of the application to undertake contained work.

This process essentially reflects the current practice in relation to applications for contained work. The GMAC Secretariat currently receives approximately 300-350 applications per year which detail proposals for contained work. Some of these applications are relatively routine and can essentially be determined by the Secretariat. Others raise more complex issues and, in those cases, advice is required from GMAC. Similarly, under the new system it is anticipated that the technical scientific staff within the GTR's office will be able to advise the GTR on simple applications with assistance from the scientific committee without other advice being necessary.

(d) If the application does involve an intentional release of a GMO into the environment (e.g. a field trial or a commercial release of a GMO):

(i) Consultation on application

Where the application relates to a proposed intentional release of a GMO into the environment, the GTR must consult the scientific committee, State, Territories and Commonwealth agencies, the Commonwealth Environment Minister and local councils in making his/her assessment.

In addition, where the GTR is satisfied (from a preliminary examination of the application) that the application may pose significant risks, the GTR must also publicly notify receipt of the application in the gazette and newspapers, and call for public submissions about the risks posed by the dealing.

(ii) Preparation of a risk assessment and risk management plan

Using all of the information that the GTR receives in written submissions from the public and advice from the scientific committee and others, the GTR must prepare a comprehensive risk assessment and risk management plan.

The risk assessment will include a risk analysis and a risk evaluation. It will:

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

Following the estimation of risk, a risk management plan would be prepared to identify measures for managing any risks identified in the risk assessment. Adherence to this management plan, once completed, 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 (for example, flowing from a breach of a condition of licence).

Example:

In some cases the risks will be sufficiently great that refusing the work to proceed will be the only measure that can appropriately manage the risk. In other cases, containment, use of barriers and other mechanisms will be appropriate to manage the risk. In other cases, there may be no risks that require management.

The GTR may also do anything else necessary to inform himself/herself of any risks posed by the proposed dealings with the GMO. For example, the GTR may call public hearings, commission independent research, undertake literature reviews, and consult international experts.

(iii) Public notification of risk assessment and risk management plans

Once the GTR has completed his/her risk assessment and risk management plan, the GTR must notify the public that a risk assessment and risk management plan (the draft determination) has been prepared and seek input on the document. The GTR must 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.

(e) Matters to be taken into account in making a decision

After taking all the necessary steps, the GTR must make a decision on the application. The GTR must not issue a licence unless he/she is satisfied that any risks posed by dealings to be authorised can be managed in a way which protects public health and safety and the environment. In addition the GTR must not issue a licence:

- if the issuing of a licence is inconsistent with a policy principle issued by the Ministerial Council; and
- unless the GTR is satisfied that the applicant is a suitable person to hold a licence. In assessing the suitability of the applicant, the GTR looks at any relevant convictions of the person, any revocation or suspension of relevant permits or licences issued under a law of the Commonwealth, a State or a foreign country and the capacity of the person to meet any proposed licence conditions.

After taking all the relevant matters into account, the GTR makes a decision. If the GTR issues a licence, the licence may:

- cover a range of dealings (e.g. growing, harvesting, transporting and selling a GM crop);
- cover a number of people (e.g. the GMO seed manufacturer, the seed seller and the farmer); and
- apply conditions on any, or all, of the dealings by various people.

(f) Conditions of licence

Licences issued by the GTR may be subject to four different types of conditions. These are conditions:

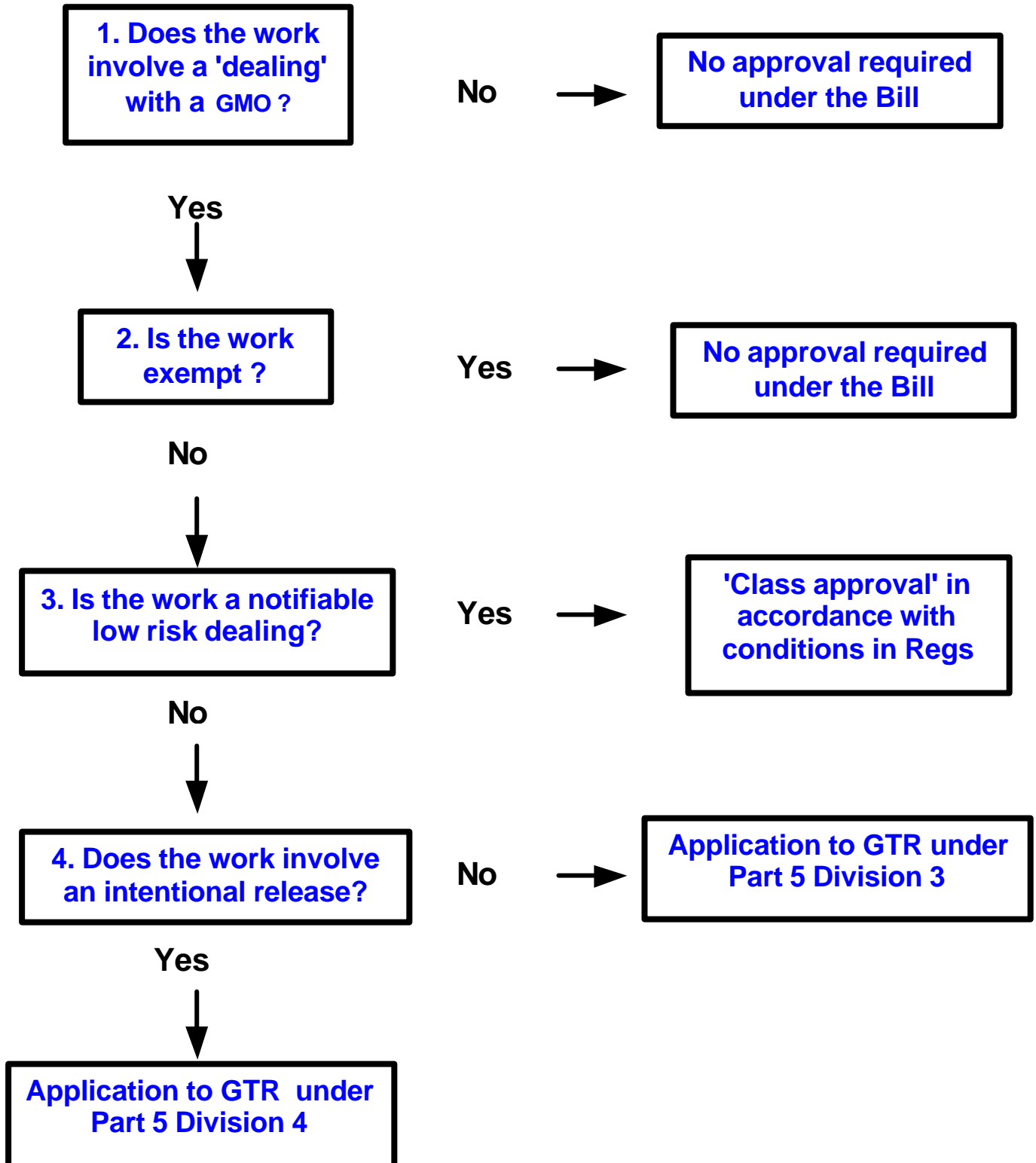
- set out in the Act - there are currently three such conditions described in clauses 63, 64 and 65. These statutory conditions require all licence holders to:
 - inform anyone covered by a licence of the conditions that relate to them. This is a minimum requirement. Conditions applied on a case-by-case basis may set out exactly how such people are to be informed (e.g. through labelling, training etc.);
 - allow the GTR, or a person authorised by the GTR, to enter premises for the purposes of auditing and monitoring;
 - inform the GTR of any additional information that becomes available regarding risks to public health and safety and the environment or contraventions of the legislation;
- prescribed by the regulations;
- imposed by the GTR at the time of issuing the licence. The GTR may impose any conditions that are necessary to manage risk, as assessed on a case-by-case basis. The GTR may limit where the GMO is used, who uses the GMO and how it is used. For example, the GTR may require specific containment measures, waste disposal methods and reporting requirements; and
- imposed by the GTR after the licence is issued.

(g) Entry on Record of GMOs and GM product dealings

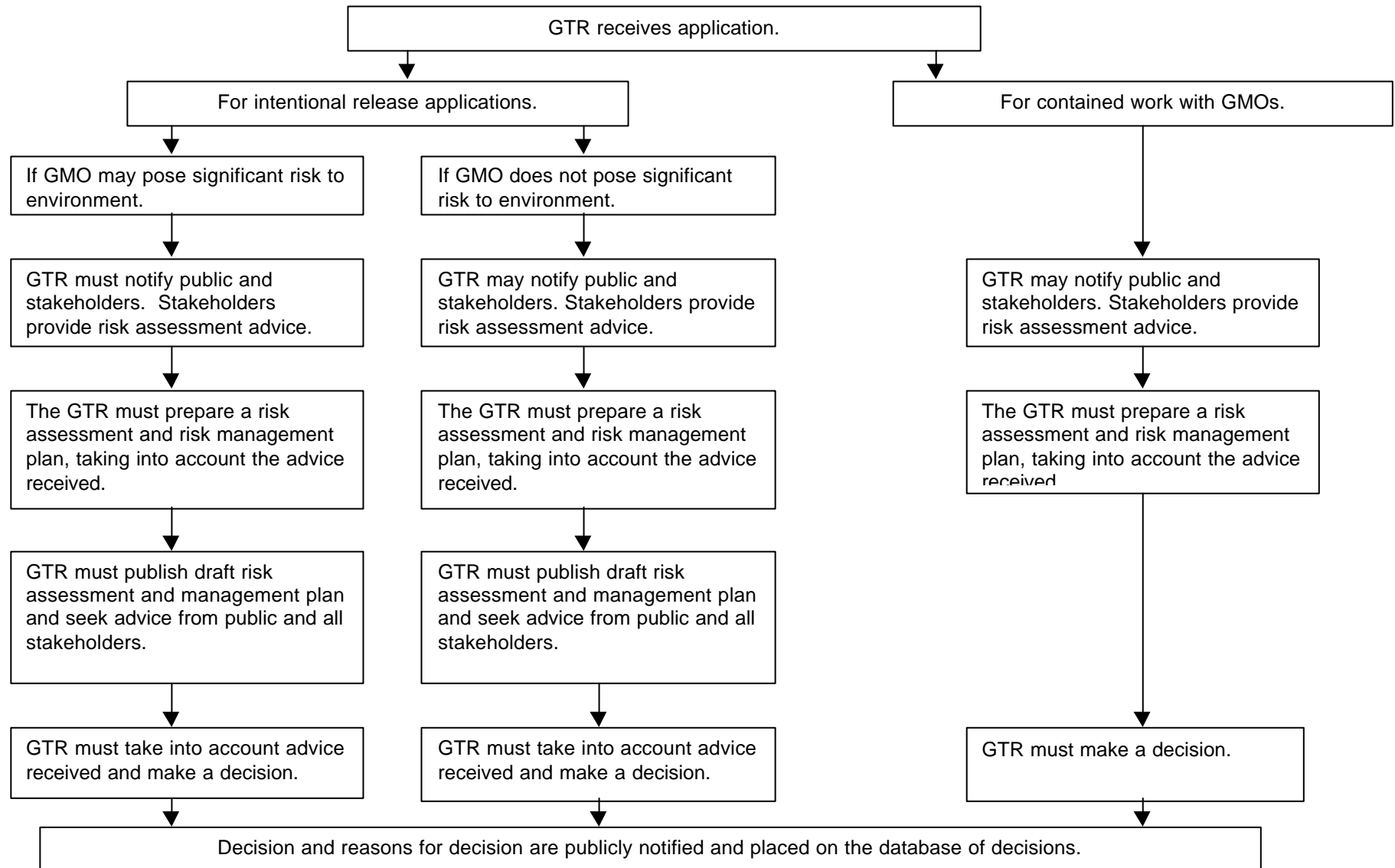
Once the GTR has made a decision on the licence application, the details of the licence approval will be entered on a publicly accessible Record of GMOs and GM product dealings. The Record is described in more detail in Part 9.

For a clause by clause explanation of this Part please refer to the Explanatory Memorandum to the Gene Technology Bill 2000

**DECISION TREE FOR POTENTIAL APPLICANTS
TO THE GENE TECHNOLOGY REGULATOR**



GTR APPROVAL PROCESS – LICENCE FOR INTENTIONAL RELEASE OF A GMO



Part 6 – Regulation of notifiable low risk dealings and dealings on the GMO Register

Summary of this Part

This Part describes the system of regulation for:

- very low risk contained activities (notifiable low risk dealings); and
- dealings that have undergone a period of licensing, monitoring of any risks and a determination that the GMO no longer requires licensing based on the fact that the dealings with the GMO present minimal risk (dealings on the GMO Register).

This recognises that different types of dealings with GMOs present varying levels of risk, and that different levels of assessment and regulatory oversight are appropriate in relation to each.

Key provisions in this Part and major changes as a result of consultation on the draft Bill

Notifiable low risk dealings (Division 2)

In summary, the system of regulation for notifiable low risk dealings will operate as follows:

- regulations will be made describing types of dealings with GMOs that are 'notifiable low risk dealings' for the purposes of this Bill. Before prescribing certain dealings with GMOs as being notifiable low risk dealings the GTR must take into account:
 - whether the GMO is 'biologically contained' (because it has a reduced ability to survive or reproduce without human intervention);
 - whether the dealing involves minimal risk (taking into account such things as the properties of the GMO as a pathogen or pest and its capacity to produce toxic proteins); and
 - whether proposed conditions will be adequate to manage any risk associated with the proposed dealing.

A dealing with a GMO may not be prescribed as a notifiable low risk dealing if the dealing involves release of the GMO into the environment – notifiable low

risk dealings may only be dealings that are conducted within contained facilities.

It is anticipated that the dealings prescribed in the regulations as notifiable low risk dealings will be based on the existing GMAC Category B activities.

- regulations will also set out conditions which must be complied with by people undertaking notifiable low risk dealings. The regulations will require that the activities be notified to the GTR; that they be supervised by an Institutional Biosafety Committee and that the activities occur within a certified containment facility.

Example:

If a person is proposing to carry out low risk research activities they would check the Schedule to the Gene Technology Regulations to determine whether the activity proposed to be undertaken is a notifiable low risk dealing. If the proponent believes that the activity is a notifiable low risk dealing (in accordance with the regulations) they would go to their IBC for verification that the dealing is a notifiable low risk and for the IBC's consideration of whether the proposed work will be carried out in accordance with the conditions set in the regulations in relation to notifiable low risk dealings.

If the IBC is satisfied that the work is a notifiable low risk dealing and is to be undertaken in accordance with the prescribed conditions then the work may proceed. The IBC and the proponent must, however, notify the GTR providing information about the work being undertaken. This provides for an extra checking mechanism and if the GTR is not satisfied that the work has been appropriately classified as a notifiable low risk dealing, the GTR may take appropriate action (including requiring the work to cease and the applicant to seek a licence to undertake the work). The GTR may also monitor compliance with the conditions prescribed in the regulations through reporting requirements, auditing and/or spot checks.

The proposed system for regulation of notifiable low risk dealings with GMOs was discussed in some detail during consultations on the draft Bill. Generally, there was considerable support, particularly in the research community, for the way that GMAC has dealt with low risk research involving GMOs.

There was also a strong call from researchers that the existing system for contained work be maintained so that unnecessary costs were not incurred for work that is largely low risk. The assessment process proposed for notifiable low risk dealings and dealings with GMOs that do not involve a deliberate release into the environment, was generally supported. It was seen as a streamlined way for dealing with low risk activities, based on the current GMAC processes, but with capacity for more comprehensive assessment where necessary.

The GMO Register (Division 3)

The purpose of the GMO Register is to enable certain dealings with GMOs to be undertaken without the requirement for a licence to be held by a named individual or organisation. Dealings with GMOs may be entered on the GMO Register once they have been licensed for a certain period of time, and once the GTR is satisfied that the dealings with the GMO are sufficiently safe that they can be undertaken by anyone without the safety of the dealings being dependent on oversight by a licence holder.

Example:

A company who wished to market a flower that had been genetically modified to extend vase life would initially apply for a licence to do so. If any risks posed by the flower could be managed, the GTR would grant the applicant a licence subject to, as a minimum, conditions requiring provision of any further information about risks or unintended effects by the licence holder and a requirement that the GTR be allowed to enter premises to undertake auditing and monitoring.

After a period of time (for example, 5 years), the GTR could re-examine the licence and determine that, on the basis of the absence of risks posed by the flower, it is no longer appropriate for the flower to be subject to the licensing regime and that the flower should be entered on the Register, enabling unrestricted use.

The concept of a GMO Register was not included in the consultation draft of the Gene Technology Bill. The provisions were however included to address concerns raised by stakeholders in relation to the licensing system.

One of the concerns raised was that if a GMO has been growing in Australia for a long period of time, was used by a very large number of people (for example, a GM flower that was grown and sold in Australia and would be “dealt with” by millions of people including those who sell the flower and buy the cut flower) and had been demonstrated to be safe, then it was unreasonable to expect one company (the licence holder) to continue to have to hold a licence to enable the flower to be grown, sold and used by millions of people. Particularly if there were no longer any conditions that were necessary to be observed to manage any risks posed by the flower and hence no direct oversight of dealings necessary by the licence holder. The point was raised that if the licence holder chose to surrender the licence, then all of the dealings with the GMO by millions of people would be “illegal” under the Bill.

The GMO Register was developed to address this concern by enabling the GTR to enter GMOs on the Register after a period of licensing and demonstration of the absence of risk. The effect of entry on the Register is that anyone may deal with the GMO (without the need for there to be a single licence holder).

For a clause by clause explanation of this Part please refer to the Explanatory Memorandum to the Gene Technology Bill 2000

Part 7 - Certification and Accreditation

Summary of this Part

This Part describes the requirements and process by which the GTR will:

- approve facilities (through ‘certifying’ the facility to a certain level of containment) so that dealings with GMOs can take place within the contained facility; and
- accredit organisations that are able to demonstrate that they have established, and will maintain, an operational Institutional Biosafety Committee (IBC) in accordance with the GTR’s guidelines. Companies, research institutions and government departments will need to gain accreditation from the GTR before they will be permitted to undertake any research or commercial activities involving gene technology.

Key provisions in this Part and major changes as a result of consultation on the draft Bill

Certification of facilities (Division 2)

Much of the current research work with GMOs occurs in facilities such as laboratories or animal houses. At present, GMAC requires that this work only occur in facilities that are of a certain “containment” level. That is, the facility must provide a level of physical containment for the work, with the appropriate level of containment depending on the nature of the work being undertaken.

This is done through the design of the facility, and the equipment and procedures used in the facility. Currently, GMAC issues technical guidelines about the requirements for physical containment levels PC2, PC3 and PC4, (PC4 being the highest level of containment). The GMAC guidelines describe matters such as required laboratory procedures, laboratory equipment and signs, laboratory planning and construction, and decontamination procedures.

We have received a great deal of positive feedback on the effectiveness of these arrangements. In designing the new provisions, we have attempted to capture the essence of the current arrangements and not add unnecessary additional requirements.

Division 2 essentially provides a regulatory framework for the current GMAC system of certification of containment facilities.

In summary, the system of certification will operate as follows:

- the GTR may require, as a condition of licence, that work is only conducted in facilities of a certain containment level;
- organisations may apply to have a facility certified to a certain containment level (e.g. Physical Containment Level PC2, PC3 or PC4) to enable them to conduct contained work with GMOs. The application would need to meet the formal requirements which will be set out in guidelines to be issued by the GTR;
- the GTR may certify a facility to a specified containment level if the facility meets the containment requirements specified in guidelines issued by the GTR;
- the certification of a facility is subject to any conditions specified in writing by the GTR. For example, the GTR may require re-certification after a certain period of time (for example, 5 years). This is the current practice of GMAC in relation to certification of facilities; and
- the GTR may vary the certification already provided to a facility by adding or removing conditions, and may also suspend or cancel a certification.

Example:

If a university wished to conduct research work involving viral vectors which can infect humans, they would need to apply for a licence under Part 5. After assessing the licence application, the GTR may decide that the only way the risks can be adequately managed is to apply a condition requiring that the work only occur within a facility certified to Physical Containment Level PC4. To meet the conditions of licence, the University would either have had its facilities certified previously to PC4, or would have to seek certification of the facilities to that level. An application for certification would only need to be made by the University once (not every time they seek a licence to undertake work), unless they wished to upgrade their facilities and seek certification to a higher containment level.

Accredited organisations (Division 3)

At present, significant work is done by Institutional Biosafety Committees (IBCs) which are established within Universities, other research institutions and companies. The responsibilities of IBCs include: overseeing work within institutions; providing information and advice about the work to GMAC; and inspecting laboratories.

It is important that the current valuable role of the IBCs is maintained under the new arrangements. In articulating the role of IBCs in legislation, we are also conscious of the need to:

- distinguish the role of the IBCs and the GTR;
- minimize the exposure of individual members of the IBCs to liability, since they are generally voluntary committees within larger organisations;

- recognise that it is the responsibility of the organisation to establish and maintain IBCs;
- ensure that the IBCs are established, and operate, in accordance with guidelines issued by the GTR;
- ensure that IBCs are actively supported by the parent organisation; and
- ensure that IBCs have a level of independence from the organisations in which they sit. One way of doing this is appointing lay people to sit on IBCs, as currently occurs.

Some stakeholders consider that private companies should not be allowed to establish IBCs. We think that the emphasis of the GTR should be on ensuring that its guidelines for accreditation and the operation of the IBCs are well developed, rigorous and the subject of monitoring by the GTR. If these key objectives are achieved, the IBCs will be an effective and useful adjunct to the GTR, regardless of whether the parent organisation is a University, research institute or company.

With these objectives in mind, Division 3 provides for the Accreditation of Organisations. In summary, the system of Accreditation of Organisations will operate as follows:

- an organisation (such as a University, company or Government department) may apply for accreditation if it can prove that it has established and will be able to maintain an IBC in accordance with guidelines issued by the GTR;
- the GTR may accredit organisations, taking into account:
 - whether the organisation has established an IBC in accordance with guidelines issued by the GTR;
 - whether the organisation will be able to maintain an IBC in accordance with the guidelines; and
 - whether the organisation has indemnity arrangements in place for IBC members who are either volunteers or laypeople;
- the accreditation of an organisation may be subject to conditions; and
- the GTR may vary, cancel or suspend the accreditation.

The IBCs will never be responsible for performing the licensing functions of the GTR. The GTR will always be responsible for undertaking risk assessments, issuing licences, determining the classes of dealings with GMOs that are exempt or notifiable low risk dealings, and monitoring compliance with the legislation.

The role of the IBCs will be to assist the GTR in the performance of these statutory functions as follows:

- reviewing all proposals for new research within the institution;
- assisting applicants to prepare licence applications in accordance with the GTR's guidelines and providing advice to the GTR regarding the IBC's assessment of the proposal;

- in relation to notifiable low risk dealings, assisting the proponent to identify whether the proposed work falls within a class of dealings prescribed as notifiable low risk. If this were the case, the IBCs would notify the GTR about the work and oversee the work in accordance with the GTR's guidelines;
- regularly auditing procedures relating to GMOs within organisations and institutions;
- inspecting facilities;
- notifying the GTR of any breaches of the legislation that come to light; and
- notifying the GTR of any accidents or incidents, and the steps taken to deal with them.

The Accreditation of Organisations, and the establishment of IBCs, will not abrogate the GTR's responsibility to monitor compliance with the legislation. All accredited organisations and IBCs will be independently monitored by the GTR, including through annual reports.

For a clause by clause explanation of this Part please refer to the Explanatory Memorandum to the Gene Technology Bill 2000

Part 8 - The Committees

Summary of this Part

This Part provides for the establishment of the:

- Gene Technology Technical Advisory Committee (the scientific committee);
- Gene Technology Community Consultative Group (the community committee); and
- Gene Technology Ethics Committee (the ethics committee).

The Part also sets out the functions and membership of the Committees.

Key provisions in this Part and major changes as a result of consultation on the draft Bill

The Gene Technology Technical Advisory Committee (Division 2)

At present GMAC provides recommendations on all applications for contained research, field trials and general releases involving GMOs.

The new scientific committee will replace GMAC, and will be responsible 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.

During consultations, various suggestions were made about the proposed scientific committee, such as:

- the membership of the committee should include expertise in several fields not currently represented on GMAC, for example, a public health professional and someone with experience in risk assessment;
- the committee should be able to draw on additional expertise where necessary, to assist in the preparation of advice on applications. This was viewed as particularly important, since the rapid development of the technology, and its application across an ever-broadening group of organisms, would mean it would be difficult for the 'core' committee members to have the relevant expertise on all the applications that might come before them for advice;
- the committee should include members with a variety of perspectives, including experts supporting both 'reductionist' and 'holistic' approaches to the issues; and

- clear conflict of interest and disclosure of interest provisions will need to apply to committee members.

These suggestions have been reflected in the provisions describing the membership and functions of the scientific committee. To summarise:

- it will be comprised of up to 20 members appointed by the Commonwealth Minister for Health following consultation with the GTR, other relevant Commonwealth Ministers, State/Territory Ministers and relevant scientific, consumer, health, environmental and industry organisations;
- members will include experts in relevant scientific fields including risk assessment, public health and ecology and a layperson;
- members may be supplemented by additional expert advisers appointed by the Minister 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;
- it will be able 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;
- members will be paid in accordance with a determination of the Remuneration Tribunal;
- members will be subject to strict disclosure of interest provisions which will be contained in regulations made under the Bill. Regulations will also describe the way in which matters are to be resolved by the committee, reporting requirements and procedures for convening meetings of the committee.

The Gene Technology Community Consultative Group (Division 3)

Given the high level of community interest in gene technology, it is important that both the GTR and the Ministerial Council remain “in touch” with community views on issues surrounding the regulation of gene technology. Both the GTR and Ministers will benefit from the community’s input into the development of the policy guidelines and codes of practice which will underpin the regulatory scheme.

This Part therefore establishes the Gene Technology Community Consultative Group (the community committee) to fulfill this role. The committee will:

- be responsible for advising 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;

Example:

The Committee may:

- advise on how they think community consultations might most effectively be undertaken;
- provide their views on matters such as the transfer of genes from animals to plants;
- provide advice on draft codes of practice developed by the GTR;
- suggest that certain policy principles be developed where none exist; and
- raise issues of ethical concern that they wish to be examined by the ethics committee.

- comprise up to 12 members who possess skills or experience relevant to gene technology. This may include skills or experience in areas like environmental issues, consumer issues, the impact of gene technology on the community, and public health issues;
- be subject to strict disclosure of interest provisions in the same way as the members of the scientific committee. Regulations will also describe the way in which matters are to be resolved by the committee, reporting requirements and procedures for convening meetings;
- be paid in accordance with a determination of the Remuneration Tribunal. During consultations, community members considered it important that community representatives on committees be properly remunerated for their contribution to the legislative scheme.

The Gene Technology Ethics Committee (Division 4)

During consultations, stakeholders expressed a range of views about the proposed ethics committee, including:

- the consideration of ethics issues must be quite separate from the GTR's consideration of scientific issues;
- a properly constituted ethics committee should provide expert advice direct to the Ministerial Council and should also develop ethical guidelines to underpin the new scheme;
- the committee should develop ethical guidelines only after comprehensive community consultation (including consultation with the community committee), and those guidelines should then be observed by all people undertaking, or proposing to undertake, work with GMOs and GM products; and
- there should be cross-membership between all of the committees.

Following consultations, various options for the establishment of an ethics committee were considered. These included utilising the existing Australian Health Ethics Committee (AHEC), which is established under the National Health and Medical Research Council. However, given the limitations of the *National Health and Medical Research Council Act 1992* (Cth) it was not possible to extend the functions of the AHEC to examine the ethics of gene technology

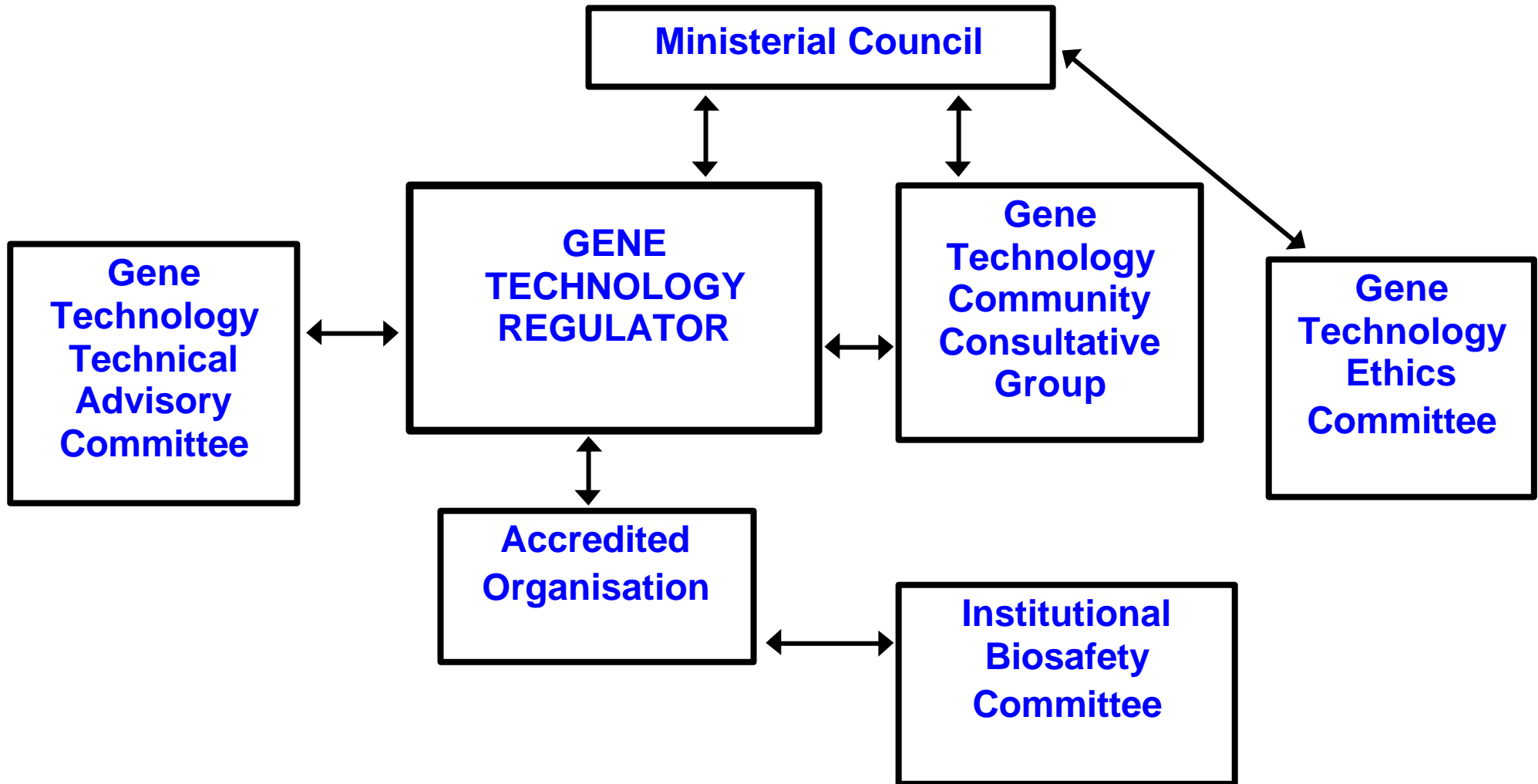
(including any environmental ethics issues) without significant changes to the *National Health and Medical Research Council Act 1992*.

A new and separate ethics committee has therefore been established in the Gene Technology Bill 2000. The 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;
- comprise up to 12 members with expertise in matters such as ethics and the environment, health ethics, applied ethics, law, religious practices, and animal health and welfare. The committee will also include a member of the scientific committee and a member of AHEC;
- be able to draw on expert advisers, who may be appointed by the Minister on an ad hoc or ongoing basis to assist the work of the Committee;
- be subject to strict disclosure of interest provisions, in the same way as the members of the other committees. Regulations will also be made to regulate the way in which matters are resolved by the Committee, reporting requirements and procedures for convening meetings of the Committee; and
- be paid in accordance with a determination of the Remuneration Tribunal.

For a clause by clause explanation of this Part please refer to the Explanatory Memorandum to the Gene Technology Bill 2000

PROPOSED GOVERNANCE STRUCTURE FOR GENE TECHNOLOGY REGULATION



Part 9 - Administration

Summary of this Part

Part 9 of the Bill provides for various administrative matters relating to the appointment and conditions of the GTR, financial matters and matters relating to staff.

Some of the provisions are technical provisions which will support the smooth operation of the legislation. Other provisions have been inserted to guarantee the independence and accountability of the GTR. For example:

- the GTR may make reports directly to Parliament;
- the GTR must report annually to Parliament;
- a Gene Technology Account is established for which the GTR is responsible; and
- the GTR is appointed by the Governor-General following agreement by a majority of State and Commonwealth Ministers.

Part 9 also establishes the Record of GMOs and GM product dealings, and provides for the review of notifiable low risk dealings and exemptions described in the regulations.

Key provisions in this Part and major changes as a result of consultation on the draft Bill

Appointment and conditions of the GTR (Division 2).

This Division provides that the GTR:

- must be appointed by the Governor-General, who is advised by the Commonwealth Minister for Health. In turn, the Minister for Health will be advised by the Gene Technology Ministerial Council. Before advising the Governor-General, the Health Minister must be satisfied that a majority of State and Territory Ministers support the appointment. As this is a national scheme, it is important that all jurisdictions have input into the decision regarding the person who will administer the legislation on behalf of all jurisdictions. This process is also important for ensuring the independence of the GTR;
- holds office for terms of not less than 3 years or more than 5 years, although the GTR may be re-appointed;
- may have his/her appointment terminated by the Governor-General on specified grounds. The grounds for termination described in the legislation

- are consistent with Commonwealth Government policy and with termination provisions prescribed for other statutory office holders; and
- must 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.

The Division also sets out procedures for acting appointments and how the terms, conditions and remuneration of the GTR will be determined.

Money (Division 3)

This Division 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 which 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.

Staffing (Division 4)

This Division provides that:

- the 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 but once selected the staff will be employed under the certified agreement of the relevant Departmental Secretary with their positions being funded by the GTR;
- the GTR may engage consultants - on terms determined by the GTR – to assist in carrying out the functions of the office; and

- the GTR may be assisted by Commonwealth public servants and officers of Commonwealth authorities and officers of State Departments and authorities made available to the GTR to assist with the performance of his/her functions.

Reporting Requirements (Division 5)

This Division provides that the GTR:

- must report annually to the Commonwealth Minister for Health, who must table the report in Parliament. The report must also be provided to the responsible Minister in each State and Territory and posted on the GTR's website;
- may make a report to Federal Parliament on any matter relating to the GTR's functions. For example, the GTR may wish to make a report in relation to a very serious breach of the legislation by a particular licence holder, or to report on some other urgent matter. This is a significant power that is rarely bestowed on statutory office holders. The Chief Executive Officer of the Australian Radiation Protection and Nuclear Safety Agency is one of the few statutory office holders with such a power.

Consistent with the IOGTR's commitment to report quarterly during the interim arrangements (before this legislative scheme takes effect), the GTR will also make public reports quarterly.

Record of GMO and GM Product Dealings (Division 6)

During consultations, stakeholders supported the involvement of the public at various stages in the decision-making process for individual licence applications (as is reflected in Part 5 of the Bill). They also expressed the need for information about the final approval to be made available to "complete the feedback loop" and provide for maximum accountability and transparency.

This Division requires the GTR to keep a publicly available "Record of GMO and GM Product Dealings" (to be known as 'the Record').

The Record will include information (excluding confidential commercial information) about:

- all licences granted by the GTR, including the name of the licence holder, the persons covered by the licence, the dealings authorised by the licence and the GMO to which those dealings relate and any licence conditions;
- notifiable low risk dealings notified to the GTR;
- GM products approved by other regulators such as the National Registration Authority (for GM agricultural and veterinary chemicals), the Therapeutic Goods Administration (for GM therapeutics), the National Industrial Chemicals Notification and Assessment Scheme (for GM industrial chemicals) and the Australia New Zealand Food Authority (for GM foods).

The Record will be available on the GTR's website and members of the public may also request extracts of the Record from the GTR. The public will have ready access to information about all GMOs and GM products being used in Australia.

Reviews of notifiable low risk dealings and exemptions (Division 7)

As detailed in Part 6 of the Bill, notifiable low risk dealings and exempt dealings will be described in regulations made under the Bill.

Recognising that the technology is changing very rapidly, it is important to regularly review the GMOs and dealings prescribed as notifiable low risk dealings and exempt dealings. This will keep notifiable low risk dealings and exemptions up to date with the latest scientific developments and information regarding any risks. It is equally important that the community (including the research community) be able to input into this process.

This Division therefore sets out a process for the GTR to:

- undertake a review of the dealings with those GMOs which have been included in the regulations as notifiable low risk dealings or exempt dealings;
- publish a notice inviting written submissions on whether certain dealings should remain on (or be added to) the list of notifiable low risk dealings and exemptions; and
- make recommendations to the Ministerial Council, following a review, that the regulations be amended to either add new dealings with GMOs to the schedules of notifiable low risk dealings and exemptions or remove current entries from the schedules.

Provisions describing this review process were not included in the consultation draft of the Bill. The suggestion that review processes were needed for notifiable low risk dealings and exemptions included in the Bill was made by a member of the public during consultations, and was then canvassed at subsequent consultations. As the suggestion was favorably received at those consultations, review provisions were included in the draft Bill.

For a clause by clause explanation of this Part please refer to the Explanatory Memorandum to the Gene Technology Bill 2000

Part 10 - Enforcement

Summary of this Part

This Part sets out the power of the GTR to:

- issue written directions to licence holders and persons covered by a licence, requiring them to take action to comply with the Act; and/or
- seek an injunction restraining a person from engaging in conduct that would be an offence under the Act.

The Part also deals with forfeiture to the Commonwealth of goods involved in the commission of an offence.

Key provisions in this Part and major changes as a result of consultation on the draft Bill

The issues of enforcement and remediation were raised consistently during consultations and in written submissions. On the whole people agreed that although the enforcement provisions would in all likelihood only rarely be used, the legislation needed to provide for a range of enforcement alternatives in the event of a significant breach of a licence.

This Part describes the power of the GTR to issue directions to licence holders and seek injunctions against licence holders to either compel them to do something or restrain them from doing something that is in breach of the legislation. These powers are in addition to the general capacity of the GTR to:

- vary a licence to impose additional conditions where necessary;
- suspend or cancel a licence;
- report a suspected breach of the legislation directly to Parliament; and
- prosecute an offence against the legislation.

Power to give directions to licence holders (clause 146)

This clause addresses the issue of remediation (or “clean up”) in the case of a problem arising from the release of a GMO. The GTR has a right to recover the costs which he/she incurs as a result of the need to remediate following a breach of condition.

If a licence holder or a person covered by a licence does not act in accordance with the legislation, and their actions are likely to cause, or are causing, harm to the health and safety of people or to the environment, then the GTR may give

written directions to the person directing them to comply with the legislation. If the person does not take the necessary action within a specified period of time, the GTR may take additional steps, or direct that necessary steps be taken, to ensure compliance with the legislation.

This provision effectively enables a “clean-up” or remediation to be undertaken, either by the GTR or by the licence holder under the direction of the GTR.

The clause further provides that if costs are incurred by the GTR in taking steps to bring the activity back into compliance with the legislation, such costs may be recovered from the licence holder or the person covered by the licence (as applicable).

Example:

If a genetically modified virus has been released in breach of a condition of containment, the GTR can direct the licence holder to immediately re-contain the virus and test the surrounding areas to ensure the virus is re-contained. If the licence holder doesn't have the necessary skills and expertise to re-contain the virus, the GTR may employ specialised persons to do so, and recover the costs associated with this from the licence holder.

This clause should also be read in conjunction with clause 158, which enables an inspector to take immediate action where there is an imminent risk of danger to health and safety of people or to the environment. In such circumstances, the inspector can take such steps as are necessary without first giving written notice to the licence holder or applicant requiring them to take the necessary steps. Such action, by the inspector or others, is also cost recoverable from the offending party.

Injunctions (clause 147)

This clause allows the GTR, or any other person, to apply to the Federal Court for an injunction to restrain a person from engaging in conduct that would be an offence under the legislation. It also describes the powers of the Court in granting such an injunction.

Forfeiture (clause 148)

This is a formal provision which has the effect that if a person is convicted of an offence under the Act, the Court may order that the things used in the commission of the offence be forfeited to the Commonwealth.

Recovery by third parties and strict liability

During consultations, there was significant discussion about whether the legislation should provide for strict liability for damage caused by the introduction

of a GMO or product thereof. This would mean that third parties who were harmed by the introduction of a GMO could directly recover (possibly through a compensation fund) for personal injury, damage to property or financial loss, without having to establish a common law action such as negligence.

It is not currently the policy of Australian governments to support the imposition of a strict liability regime in relation to any damage suffered by third parties. All jurisdictions consider that the legislation should not provide remedies for third parties where they may have been affected by the release of a GMO. Where a third party is adversely affected by the release of a GMO, that person's recourse would be through common law actions such as negligence, nuisance or trespass. This is consistent both with the approach adopted in other comparable Australian schemes (e.g. therapeutic goods and agricultural and veterinary chemicals) and also with international precedents.

For a clause by clause explanation of this Part please refer to the Explanatory Memorandum to the Gene Technology Bill 2000.

Part 11 - Powers of inspection

Summary of this Part

This Part describes:

- the process for appointment of inspectors;
- the powers and obligations of inspectors;
- the rights and responsibilities of an occupier of premises when an inspector seeks to exercise powers; and
- procedures relating to monitoring warrants and offence-related warrants.

Key provisions in this Part and major changes as a result of consultation on the draft Bill

The main role of inspectors will be to investigate suspected breaches of the legislation, and to gather evidence to assist in the prosecution of such offences.

Most of the provisions in this Part are technical provisions which set out the processes for appointment of inspectors, the powers and obligations of inspectors, and procedures relating to warrants and search warrants.

The provisions have been based on standard Commonwealth provisions which are contained in similar legislation. These provisions establish criminal offences and therefore require provisions which regulate the investigation of suspected breaches. Similar provisions are contained in the *Therapeutic Goods Act 1989*, the *Environment Protection and Biodiversity Conservation Act 1998* and Food Acts in most States and Territories.

As these types of provisions are quite common in both State and Commonwealth legislation, and the precise wording of each reflects the current drafting practice of government, detailed explanations of each of the Divisions of this Part have not been included in this Guide.

For a clause by clause explanation of this Part please refer the Explanatory Memorandum to the Gene Technology Bill 2000

Part 12 - Miscellaneous

Summary of this Part

This Part provides for:

- review of decisions by the GTR and the Administrative Appeals Tribunal;
- procedures in relation to the protection of confidential commercial information;
- how the state of mind of a body corporate (or a person) shall be established in relation to the prosecution of an offence under the legislation;
- transitional provisions describing how existing approvals by the Genetic Manipulation Advisory Committee will be treated under the new legislation; and
- the making of regulations to support the Bill once it becomes law.

Key provisions in this Part and major changes as a result of consultation on the draft Bill

Review of decisions (Division 2)

During consultations, very polarised views were expressed on the issue of review of decisions. Some people felt that 'merits' review by the Administrative Appeals Tribunal (AAT) under the *Administrative Appeals Tribunal Act 1975* (Cth) should only be open to people directly affected by a licence decision (such as the applicant or licence holder) and others felt that this should be extended to third parties.

In drafting the legislation, we were conscious of the need to ensure transparency and accountability of the GTR, while at the same time not encouraging extensive use by third parties of a right of review that could be costly and greatly diminish certainty of decision making for people or organisations who have been granted a licence.

The effect of Division 2 of the Bill is that certain persons may seek review of decisions made under the legislation. Essentially, those people would include:

- licence applicants and licence holders;
- applicants for certification and holders of certification (for example, universities or companies who have sought certification to a certain containment level of facilities owned by them); and
- applicants for accreditation and holders of accreditation (for example, universities and institutions who have sought accreditation, recognising that they have established and maintained an Institutional Biosafety Committee within their institution).

If the relevant decision has been made by a delegate of the GTR (for example, one of the senior staff members of the GTR) the person seeking a review of the decision would have to apply to the GTR for an initial review of the decision. The GTR would look closely at the delegate's decision and could substitute his/her decision where appropriate.

If the GTR made the decision personally (or if a person has sought review by the GTR and seeks further review of the decision) an application for further review may be made to the AAT. The AAT undertakes merit reviews of administrative decisions.

The AAT may:

- stay the operation or implementation of a decision until the AAT hearing;
- affirm the decision made by the decision maker;
- vary the decision;
- set aside the decision;
- substitute its own decision; or
- remit the matter to the original decision maker with directions or recommendations for re-making the decision.

Review by the Federal Court under the *Administrative Decisions Judicial Review Act 1977 (Cth) (ADJR Act)*

Unlike the AAT, which examines the 'merits' of the case, under the ADJR Act the Federal Court examines questions of law in relation to administrative decisions, in particular the process by which decisions have been made.

Any person "aggrieved" by a decision made under the Gene Technology Act (once proclaimed) will be able to apply to the Federal Court for review of questions of law in relation to the making of the decision. The legislation will not affect the ability of anyone to seek review under the *Administrative Decisions Judicial Review Act (ADJR)*. Anyone wishing to have a decision reviewed by the Federal Court under the ADJR Act must establish "standing" or a "special interest" as required by the Federal Court. While this is judged on a case-by-case basis, the general position is that an applicant must be able to show an interest above and beyond that of ordinary members of the public.

Confidential commercial information (Division 3)

During consultations, we received a number of submissions about the types of information that should be made available by the GTR, and the types of information that should be protected as confidential commercial information. We heard that:

- as a general principle the public should have a right to information submitted as part of an application for a licence, and that the relatively free availability of information would help to ensure that the GTR's decision-making remained appropriate, transparent and accountable;
- the general public should have ready access to the same types of information that they could access through an application under the *Freedom of Information Act*; and
- there should be appropriate protection for information which is commercially sensitive, and this could best be guaranteed by an assessment of confidential information being made by the GTR on a case-by-case basis. Researchers also made the point that, while details about work being conducted in universities may not be commercially confidential, the intellectual value of research could be greatly diminished if full details were made publicly available.

On the basis of these comments, we have attempted to strike a balance between the legitimate protection of confidential information and the need for a high level of transparency, openness and accountability of decision-making by the GTR.

Division 3 of this Part sets out the process for establishing the confidentiality of certain information.

A person may apply to the GTR for a declaration that certain information is confidential commercial information. The GTR assesses the application and may declare the information to be confidential commercial information if he/she is satisfied that the information:

- is a trade secret;
- has commercial or other value which could be destroyed or diminished if the information were disclosed; or
- is about the commercial or financial affairs of a person, organisation or undertaking that if disclosed could unreasonably affect the person, organisation or undertaking.

The GTR may choose not to declare information to be confidential commercial information if he/she is satisfied that the public interest in the disclosure outweighs the prejudice that the disclosure may cause to the person.

If the GTR is satisfied that the information falls into one of the categories described above, the GTR may issue a declaration that the information is confidential commercial information.

The effect of a declaration is that the information is not made publicly available by the GTR. For example, the confidential information would not be made available in response to a public request for an application, and the information would also not be placed on the Record of GMOs and GM Product dealings.

If the GTR refuses to declare that information is confidential commercial information, the applicant has the opportunity to withdraw the application or seek review of the decision before the information is released publicly.

Conduct by directors, employees and agents (Division 4)

This Division contains the formal provisions that establish how the state of mind of a body corporate (or a person) must be established for the prosecution of an offence under the legislation.

For example, if it is necessary to show that a licence holder (being a body corporate) engaged in certain activities (such as unlicensed dealings with GMOs), it is sufficient to show that the conduct was undertaken by a director, employee or agent of the body corporate, and that the director, employee or agent had the requisite knowledge of what they were doing.

Transitional provisions (Division 5)

This Division describes “transitional arrangements” in relation to dealings with GMOs approved prior to the commencement of the Bill. The effect of the transitional arrangements is that if a dealing with a GMO received advice to proceed from the Genetic Manipulation Advisory Committee before the commencement of the licensing provisions of this Bill, then that dealing is deemed to be licensed under the Gene Technology Bill. The licence is taken to be subject to any conditions imposed by the Genetic Manipulation Advisory Committee’s advice to proceed. During the transitional period, all of the other provisions in the legislation (including those relating to the imposition of additional conditions, reporting, monitoring and enforcement) also apply to the ‘deemed’ licences.

The ‘deemed’ licence continues to be in force until the period ending at the earliest of the following times: the time the advice to proceed expires, at the end of two years beginning when the Bill received Royal Assent, or when the licence is cancelled or surrendered.

If, at the time when the licence ceased to be in force, the licence holder wished to continue the dealings with the GMO, the licence holder would need to apply to the GTR for another licence.

During consultations on the draft Bill there was strong support for including transitional provisions in the legislation. Transitional provisions:

- avoid the need for the GTR to re-assess hundreds of existing approvals as soon as the legislation takes effect;
- minimise costs to industry associated with having to re-apply for assessment having already undergone an assessment by GMAC;

- ensure that anyone undertaking work assessed by GMAC must also comply with the new statutory conditions of licence and be subject to the monitoring and enforcement provisions of the legislation; and
- ensure that the GTR will review and re-assess all approvals granted by GMAC within a two year period.

Other (Division 6)

This Division enables the Governor-General to make regulations to support the operation of the Bill. More information about the proposed Regulations is included in the Chapter 7 titled “Commonwealth Gene Technology Regulations”.

For a clause by clause explanation of this Part please refer the Explanatory Memorandum to the Gene Technology Bill 2000

Case Studies – How will the Bill apply to various people undertaking activities with GMOs?

Case Study 1:

Researchers who want to undertake work with exempt GMOs

- The regulations will describe exempt activities (such as certain contained research).
- Exempt activities will be based on the current GMAC arrangements.
- No approval will be required from the GTR.

Case Study 2:

People who want to undertake notifiable low risk dealings

- Certain low risk contained work will be described in regulations as notifiable low risk dealings (NLRDs).
- NLRDs will be based on the current GMAC Category B activities.
- The organisation or institution within which NLRDs are proposed to be undertaken must be accredited by the GTR. The GTR will accredit organisations if they have, and can maintain, an Institutional Biosafety Committee (IBC) in accordance with guidelines issued by the GTR. An organisation need only apply for accreditation once – once they are accredited they do not need to apply every time they wish to undertake a NLRD.
- The NLRDs must only be undertaken in a facility that has been certified by the GTR to a minimum of physical containment level 2 (PC2).
- Each NLRD must be considered by the IBC and notified to the GTR.
- The GTR will monitor compliance with the conditions applied to NLRDs (e.g. that the activity is undertaken in a certified PC2 laboratory and overseen by an IBC).

Case Study 3:

People undertaking higher risk work with GMOs within laboratories or other contained facilities

- All existing GMAC approvals will be carried over into the new system. Further approval from the GTR will not be required until the approval from GMAC expires or until 2 years after the Gene Technology Act commences, whichever is the sooner.
- People who want to undertake higher risk contained work with GMOs must:
 - submit an application (in accordance with guidelines issued by the GTR) to their IBC for initial consideration; and
 - submit the application and the IBCs comments to the GTR for assessment.
- The GTR will undertake a risk assessment of the proposed work and apply any necessary conditions to manage the risks posed by the work. The conditions would include a requirement that the facility in which the work is proposed to be undertaken be certified to the necessary containment level.
- The GTR will monitor compliance with conditions imposed.

Case Study 4:

Importers of GMOs

- In addition to requiring approval from the Australian Quarantine Inspection Service (AQIS) to import the GMO, the importer must apply for a licence from the GTR before the GMO is imported. Alternately the end user of the GMO may apply for a licence on behalf of the importer.
- The assessment process employed by the GTR will depend on whether the GMO is to be imported for release into the environment or for use in a contained environment (e.g. to be processed into food).
- If the GMO is being imported for processing, the GTR will undertake a risk assessment of the GMO and apply any necessary conditions to manage the risks posed by the GMO. Such conditions would include a requirement that the GMOs be contained so that they cannot escape into the environment during transport to the facility in which the GMOs are to be used.
- If the GMO is intended for release into the environment, the GTR will undertake the risk assessment process described in Case Study 5.
- The importer may also need approval from ANZFA if the imported GMO is to be used in food.

Case Study 5:

People proposing to release a GMO into the environment (either for research purposes or for commercial use).

- An application must be made to the GTR in accordance with requirements set out in regulations and guidelines issued by the GTR.
- The GTR will:
 - undertake an initial examination of the application to ensure that all of the necessary information has been included and that the application is not inconsistent with policy principles issued by the Ministerial Council (for example, on ethics);
 - call for public comment on the application (if the application involves the release of a GMO into the environment that may pose significant risks to the environment);
 - seek advice on the application from the Commonwealth Environment Minister, relevant Commonwealth agencies, States and Territories and the Gene Technology Technical Advisory Committee;
 - prepare a comprehensive risk assessment and risk management plan;
 - make the risk assessment and risk management plan (the draft decision) available for public comment and seek advice from the Commonwealth Environment Minister, relevant Commonwealth agencies, States and Territories and the Gene Technology Technical Advisory Committee;
 - take into account all submissions, relevant policy guidelines issued by the Ministerial Council and the suitability of the applicant and make a decision on the application.
- If the application for licence is approved, the GTR would impose conditions to manage any risks posed by the GMO.
- Each person who wanted to use the GMO would not need to apply for a separate licence. Only the first person who proposes to release the GMO into the environment would apply for a licence and, if approved, this would cover all persons who deal with the GMO.
- Details of the decision will be included on a publicly available record.
- The GTR will monitor compliance with conditions imposed.

5

Commonwealth Gene Technology (Consequential Amendments) Bill 2000

The Gene Technology (Consequential Amendments) Bill 2000 is another important component of the new national scheme for the regulation of gene technology.

As detailed in Chapter 3, the Gene Technology Bill 2000 creates a regulatory framework for the assessment of all activities involving live, viable genetically modified organisms. The Bill does this by establishing a centralised regulator undertaking biosafety assessment of all GMOs and GM products.

The Gene Technology (Consequential Amendments) Bill 2000 compliments the Gene Technology Bill 2000. It ensures that all existing regulators of GM products (such as the Therapeutic Goods Administration and the Australia New Zealand Food Authority) have access to the GTR's advice on biosafety.

The Gene Technology (Consequential Amendments) Bill 2000 requires that the existing regulators of GM products, which operate under the existing schemes for the regulation of food, therapeutic goods, and agricultural, veterinary and industrial chemicals must:

- seek advice from the GTR in relation to any application for approval of a GM product;
- take such advice into account in decision-making under relevant legislation; and
- notify the GTR of all decisions made in relation to GM products to enable those decisions to be entered on a central, publicly available database of all GMOs and GM products, held by the GTR (to be known as the Record of GMOs and GM Product Dealings).

The legislation that will be amended by the Gene Technology (Consequential Amendments) Bill 2000 to effect the changes detailed above includes:

- a) the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the *Agricultural and Veterinary Chemicals (Code) Act 1994*;
- b) the *Australia and New Zealand Food Authority Act 1991*;
- c) the *Industrial Chemicals (Notification and Assessment) Act 1989*; and
- d) the *Therapeutic Goods Act 1989*.

The amendments to existing legislation which are contained in the Gene Technology (Consequential Amendments) Bill 2000 will ensure that:

- any duplication of effort and resources between existing regulators flowing from the creation of the GTR is minimised;
- a clear interface is put in place between the GTR and the existing regulators; and
- the existing regulators of GM products have access to the GTR's comprehensive advice on biosafety.

The Gene Technology (Consequential Amendments) Bill 2000 also adds information declared by the GTR to be confidential commercial information (as discussed in Part 12) to the list of information that is exempt from release under the *Freedom of Information Act 1982*. This ensures that information assessed to be confidential by the GTR is also protected under the *Freedom of Information Act 1982*.

6

Commonwealth Gene Technology (Licence Charges) Bill 2000

The Commonwealth Government's current policy on cost recovery for the new scheme is that it be 100 per cent cost recovered from the first day of operation, which is anticipated to be 3 January 2001.

During consultations to date, we have heard strong views on this issue:

- researchers were concerned that cost recovery would further stretch already limited budgets and inhibit "blue skies" research;
- small biotechnology companies indicated that cost recovery would provide large multinationals with a competitive advantage and disadvantage fledgling companies;
- large companies expressed concern that they would cross-subsidise others;
- consumer groups expressed concern that full cost recovery may make the GTR a "captive" of industry; and
- others emphasised the strong public interest in ensuring the safety of all GMOs, and therefore it would be appropriate for Australian Governments to pay at least part of the costs of the regulatory system.

The issue of cost recovery will be considered by Governments shortly. In the meantime, the legislation has been drafted in a way which will enable fees and charges to be levied in a range of ways:

- Certain fees for services are described in the Gene Technology Bill 2000 – for example, application fees and fees for certification of facilities to a certain containment level. These fees will be detailed in regulations to be made under the Gene Technology Bill once it becomes law.
- Other charges - such as annual charges - will be described in a separate bill, the Gene Technology (Licence Charges) Bill. This Bill is a very short one which simply sets up the capacity for the GTR to charge annual fees. The fees themselves will be set out in regulations under the Bill.

When will the fees and charges be determined?

In late May and early June 2000, the IOGTR undertook a competitive selection process to contract a consulting firm to cost the proposed regulatory system. The consulting firm KPMG was the successful tenderer, and the firm has already commenced an independent analysis of the costs associated with the regulatory system. This study is being conducted in a number of stages.

Stage 1 – involves an evaluation of the fees and charges regimes of existing regulators (such as the National Registration Authority and the Therapeutic Goods Administration) and a comprehensive assessment of the estimated costs of each of the components of the proposed regulatory scheme for GMOs and GM products, as reflected in the Gene Technology Bill 2000 and the Gene Technology (Consequential Amendments) Bill 2000.

Stage 2 – involves the development of a costing model (based on Activity Based Costing) which will identify the ‘cost drivers’ (that is, all of the components of the regulatory system which have costs associated with them) and the expected ‘throughput’ of the regulatory system during the first five year period. The number of applications received by the GTR will be critical in many ways, because it will help to shape the type of administrative and scientific unit the Office of the GTR will become.

Stage 3 – Once KPMG have identified the likely costs of the regulatory scheme, extensive consultation will be undertaken in each jurisdiction with relevant Commonwealth and State/Territory Government agencies, industry stakeholders (including biotechnology companies, universities and other organisations undertaking research) and other non-government stakeholders. This consultation period will rigorously test the accuracy of the costing model developed.

Stage 4 – Following the consultations, and any revisions to the costing model which are required as a result, KPMG will present a number of options for the modeling of fees and charges.

Governments will consider these options, and regulations will then be developed which reflect the proposed fees and charges regime. Further consultation will then be undertaken on the proposed regulations with a view to finalising the fees and charges regime by November 2000.

7

Commonwealth Gene Technology Regulations

During consultations, many people pointed out that it is often difficult to understand how legislation will work just by looking at the Bill. This is because a lot of the administrative detail is included in regulations which support the Bill. Many stakeholders therefore requested that draft regulations be made available while the legislation is still under consideration by Parliament, so that the complete legislative package could be scrutinised.

Over the past few months, government officials have been working with the Genetic Manipulation Advisory Committee to develop draft regulations.

It is proposed that the regulations will:

- Provide further information about some of the definitions used in the Gene Technology Bill 2000. For example, the regulations will describe:
 - techniques that are techniques of gene technology for the purposes of the definition of gene technology;
 - things declared by the regulations to be GMOs (e.g. any GM products that are not regulated by existing agencies such as stock feed); and
 - things declared by the regulations not to be GMOs.
- Describe the exemptions under the legislation. That is, the types of dealings with certain GMOs that are sufficiently low risk that they do not require oversight by the GTR.
- Set out the dealings with GMOs that are notifiable low risk dealings and the conditions which will apply to such notifiable low risk dealings.
- Describe the types of information that must be provided by an applicant for a licence.
- Provide further information about the scientific, ethics and community committees including:
 - term of appointments;
 - resignation;

- termination of appointment;
- disclosure of interest;
- procedures for convening meetings;
- constitution and quorums; and
- records and reporting.

An early draft of the regulations will be made publicly available in July 2000. The IOGTR will undertake national consultations on the draft regulations in late August 2000. Details of the consultations will be advertised in newspapers in each State and Territory, on the IOGTR website and direct-mailed to people on the IOGTR/GMAC mailing list.

Once KPMG have completed their report on fees and charges (described in Chapter 6) regulations will also be drafted describing application fees or fees for services. Consultation on this additional component of the regulations will be undertaken at a later date.

8

Model State legislation

As referenced throughout this Guide, the Commonwealth Gene Technology Bill 2000 is only one component of a national scheme for gene technology.

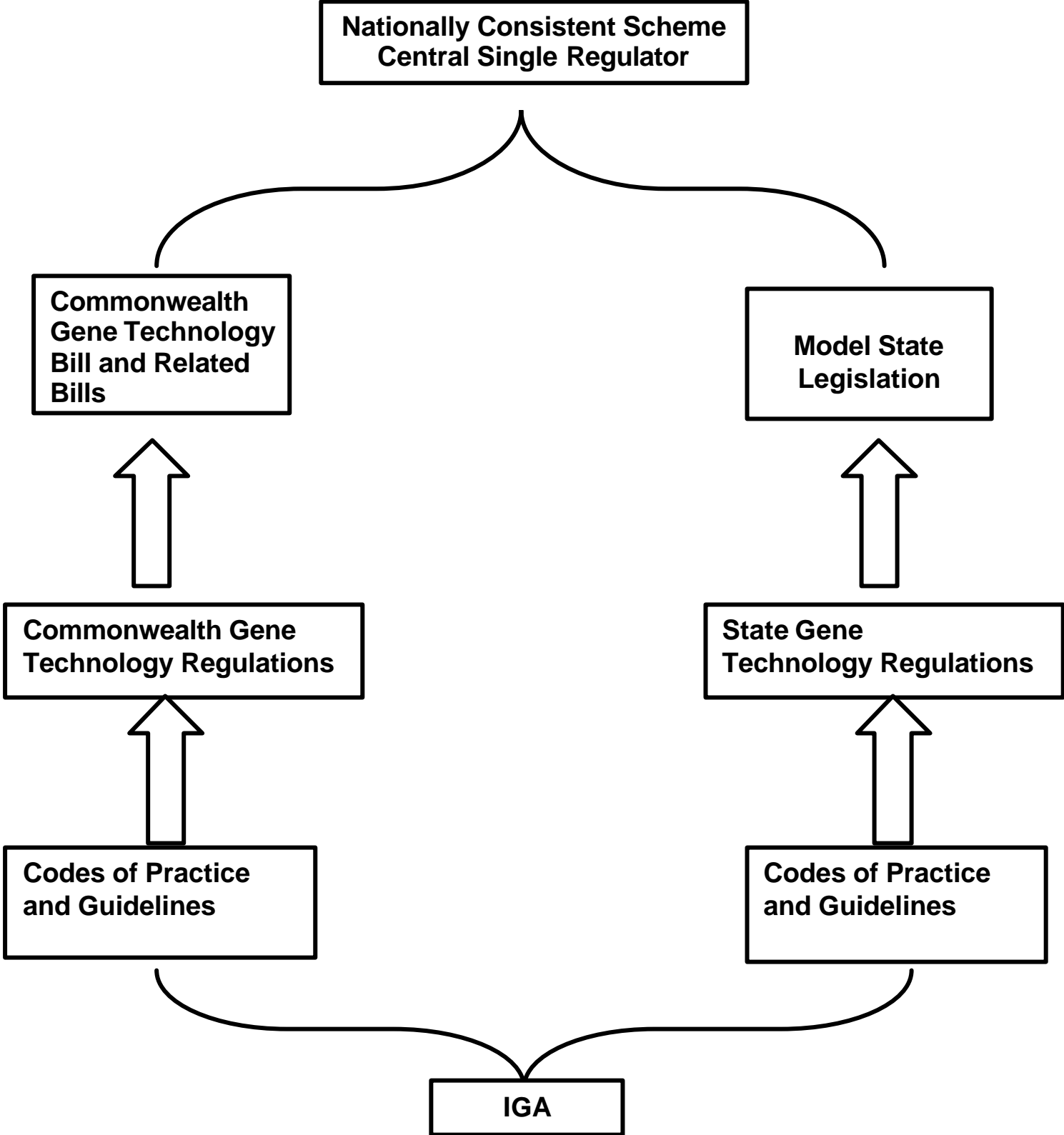
Each State and Territory will also enact legislation that is essentially the same as the Commonwealth legislation. This will enable the scheme to operate effectively and consistently across all jurisdictions.

It is anticipated that States and Territories will enact their legislation in one of two ways. They will either:

- 'apply' the Commonwealth law. This means that a State or Territory Parliament would introduce a very short Bill into their Parliament which would apply the Commonwealth law as a law of that State or Territory; or
- enact a substantive law in substantially the same terms as the Commonwealth legislation.

Model state legislation, which will be prepared by Parliamentary drafters within State and Territory governments, will be available for public consultation and consideration by late July 2000. This timeframe may vary across States and Territories.

NATIONAL SCHEME



9

Gene Technology Agreement

The national scheme will be underpinned by an Intergovernmental Agreement. By setting out many of the understandings between governments which have allowed the scheme to be developed, the Agreement will help to minimise the number of disputes which may arise during the operation of the scheme.

The Gene Technology Agreement will:

- describe the main components of the co-operative national scheme and commit all governments to introduce substantially similar legislation in each jurisdiction;
- set out the functions and membership of the Gene Technology Ministerial Council. The Council will:
 - (a) issue policy principles, policy guidelines and codes of practice to underpin the activities of the GTR and the operation of the regulatory framework;
 - (b) consider and agree changes, as required, to the national legislative framework;
 - (c) discuss matters related to gene technology regulation with other relevant Ministerial Councils;
 - (d) provide advice on the appointment and dismissal of the GTR; and
 - (e) oversee periodic reviews of the legislative framework.

The Ministerial Council will not be involved in decision making on individual applications. The Council will comprise one or more Ministers from each jurisdiction and the Commonwealth. At this stage, no decision has been made regarding the portfolio interests to be represented on the Council. It will, however, be the responsibility of each member to provide a “whole of Government” perspective on behalf of their jurisdiction;

- provide for the maintenance of a nationally consistent scheme over time, including provisions for the amendment of the gene technology legislation;
- describe the roles and responsibilities of each of the jurisdictions in the administration and enforcement of the scheme, including arrangements for the reimbursement of costs incurred by jurisdictions for services provided as part of the legislative scheme;

- provide for the review of the implementation and effectiveness of the national scheme no later than five years after the commencement of the scheme;

Pending consideration of the Gene Technology Agreement by governments in all jurisdictions, it is anticipated that the Gene Technology Agreement will be made publicly available in July 2000.