

Handbook on the Regulation of Gene Technology in Australia



Office of the **Gene Technology Regulator**

**A user's guide to the
Gene Technology Act 2000 and
related legislation**

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

www.aph.gov.au (Parliament House website)

www.ogtr.gov.au (IOGTR website)



IMPORTANT NOTE

This Handbook will be updated from time to time. Users should therefore assure themselves that they have access to the most recent version.

ACKNOWLEDGEMENT

The Interim Office of the Gene Technology Regulator acknowledges the work of Matthews Pegg Consulting Pty Ltd in preparing this Handbook, the Guidelines on the Transport of GMOs, the Guidelines on the Certification of Facilities/Physical Containment Requirements and the Guidelines for the Accreditation of Organisations.

Glossary of terms and acronyms used

AAT	the Administrative Appeals Tribunal
Accredited Organisation	means an organisation that is accredited under section 92 of the <i>Gene Technology Act 2000</i> . An accredited organisation can apply for licences to deal with GMOs
ADJR Act	<i>Administrative Decisions (Judicial Review) Act 1977</i>
AFFA	Agriculture Fisheries and Forestry Australia
ANZFA	Australia New Zealand Food Authority
AQIS	Australian Quarantine and Inspection Service
the Act	the Commonwealth <i>Gene Technology Act 2000</i>
CCI	confidential commercial information
CSCG	Commonwealth State Consultative Group on Gene Technology
dealings or deal with	has the same meaning as in the GT Act. Section 10 of the GT Act provides that “deal with” in relation to a GMO means the following: (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO; (d) propagate the GMO (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (g)
GM	genetically modified
GMAC	Genetic Manipulation Advisory Committee

GMO	genetically modified organism
GTCCC	Gene Technology Community Consultative Committee
GTTAC	Gene Technology Technical Advisory Committee
GTEC	Gene Technology Ethics Committee
IBC	Institutional Biosafety Committee
IOGTR	Interim Office of the Gene Technology Regulator
NHMRC	the National Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NLRD	Notifiable Low Risk Dealings
NRA	National Registration Authority
OGTR	Office of the Gene Technology Regulator (after 21 June 2001)
PC2	Physical Containment Level 2, as certified by the Regulator in accordance with the Regulator's <i>Guidelines for Certification of Facilities/Physical Containment Requirements</i>
PC3	Physical Containment Level 3, as certified by the Regulator in accordance with the Regulator's <i>Guidelines for Certification of Facilities/Physical Containment Requirements</i>
PC4	Physical Containment Level 4, as certified by the Regulator in accordance with the Regulator's <i>Guidelines for Certification of Facilities/Physical Containment Requirements</i>
Project supervisor	An appropriately qualified person within an organisation that is intending to 'deal with' a GMO
the Regulations	the Commonwealth Gene Technology Regulations 2001
the Regulator	the Gene Technology Regulator
TGA	the Therapeutic Goods Administration

Table of Contents

GLOSSARY	1
TABLE OF CONTENTS	3
ABOUT THIS HANDBOOK	7
CHAPTER 1: BACKGROUND INFORMATION ABOUT THE NATIONAL REGULATORY SCHEME FOR GMOs	8
Part A: Development of the national regulatory scheme	11
Part B: Instruments that form part of the national regulatory scheme	15
Part C: The six main components of the national regulatory scheme	25
CHAPTER 2: DEALINGS WITH GMOs THAT ARE, AND ARE NOT, REGULATED UNDER THE NATIONAL REGULATORY SCHEME	28
Part A: Dealings with GMOs that are regulated under the national scheme	28
Part B: Dealings with GMOs that are not regulated under the national scheme	31
CHAPTER 3: THE SYSTEM OF PROHIBITIONS AND APPROVALS FOR DEALINGS WITH GMOs	38
CHAPTER 4: EXEMPT DEALINGS WITH GMOs	43
Part A: Types of dealings with GMOs that are exempt	43
Part B: Responsibilities of individuals proposing to undertake exempt dealings with GMOs	53
Part C: Responsibilities of Accredited Organisations and IBCs	54

CHAPTER 5:	NOTIFIABLE LOW RISK DEALINGS WITH GMOs	56
	Part A: Types of dealings with GMOs that are NLRDs	56
	Part B: Transitional arrangements for work commenced before 21 June 2001 as GMAC Category B work	64
	Part C: Requirements for NLRDs proposed to commence after 21 June 2001	67
	Part D: Responsibilities of the Regulator	69
CHAPTER 6:	LICENSED DEALINGS WITH GMOs NOT INVOLVING THE INTENTIONAL RELEASE OF A GMO INTO THE ENVIRONMENT	72
	Part A: Types of dealings with GMOs that must be licensed by the Regulator	72
	Part B: Transitional arrangements for work commenced before 21 June 2001 and approved by GMAC	74
	Part C: Applying for a licence after 21 June 2001	77
	Part D: The Regulator's assessment process	79
	Part E: Rights and responsibilities of licence holders	85
CHAPTER 7:	LICENSED DEALINGS WITH GMOs INVOLVING THE INTENTIONAL RELEASE OF A GMO INTO THE ENVIRONMENT	90
	Part A: Types of dealings with GMOs that must be licensed by the Regulator	90
	Part B: Transitional arrangements for work commenced before 21 June 2001 and approved by GMAC	93
	Part C: Applying for a licence from 21 June 2001	96

	Part D: The Regulator's assessment process	100
	Part E: Rights and responsibilities of licence holders	108
CHAPTER 8:	DEALINGS WITH GMOs ON THE GMO REGISTER	113
CHAPTER 9:	TRANSPORT AND IMPORT OF GMOs	116
	Part A: Transport of GMOs	116
	Part B: Import of GMOs	120
CHAPTER 10:	ACCREDITATION OF ORGANISATIONS	125
	Part A: About accreditation of organisations	125
	Part B: Transitional arrangements for Accreditation of Organisations	127
	Part C: Applying for accreditation from 21 June 2001	129
	Part D: Criteria for accreditation and conditions of accreditation	130
CHAPTER 11:	CERTIFICATION OF FACILITIES	131
	Part A: About certification of facilities	131
	Part B: Transitional arrangements for certification of facilities	133
	Part C: Applying for certification of facilities from 21 June 2001	135
	Part D: Criteria for certification and conditions of certification	137
CHAPTER 12:	REGULATION OF HUMAN CLONING AND CERTAIN EXPERIMENTS INVOLVING HUMAN CELLS	138
	Part A: Regulation of human cloning	138
	Part B: Regulation of certain experiments involving human cells	140

CHAPTER 13:	REGULATION OF GM PRODUCTS	141
CHAPTER 14:	THE RECORD OF GMOs AND GM PRODUCT DEALINGS	144
CHAPTER 15:	CONFIDENTIAL COMMERCIAL INFORMATION	148
CHAPTER 16:	REVIEW OF DECISIONS MADE UNDER THE LEGISLATION	152
	Part A: Reviewable decisions	152
	Part B: Internal and external review	154
CHAPTER 17:	REPORTING, MONITORING AND ENFORCEMENT	156
	Part A: Reporting requirements for Accredited Organisations and licence holders	156
	Part B: Monitoring compliance with the legislation	159
	Part C: The Regulator's powers of enforcement	161
	Part D: Reporting of non-compliance with the legislation	165
CHAPTER 18:	THE REGULATOR'S WEBSITE AND THE GENE TECHNOLOGY INFORMATION MANAGEMENT SYSTEM	166
	Part A: The Regulator's website	166
	Part B: The Gene Technology Information Management System (GTIMS)	168
CHAPTER 19:	FEES AND CHARGES	170
APPENDICES		
APPENDIX 1:	Application forms	
APPENDIX 2:	Guidelines for the Accreditation of Organisations	
APPENDIX 3:	Guidelines for the Certification of Facilities/Physical Containment Requirements	

APPENDIX 4: Good Industrial Large Scale Practice (GILSP)

APPENDIX 5: Guidelines for the Transport of GMOs

**APPENDIX 6: Risk Analysis Framework for Licence
Applications before the Office of the Gene
Technology Regulator**

ABOUT THIS HANDBOOK

What is the purpose of this Handbook?

In December 2000, the Federal Government passed the *Gene Technology Act 2000* and associated Acts (the *Gene Technology (Consequential Amendments) Act 2000* and the *Gene Technology (Licence Charges) Act 2000*).

The legislation came into force on 21 June 2001.

The legislation is the Commonwealth's component of a new national scheme for the regulation of genetically modified organisms (GMOs) which will include legislation in every Australian jurisdiction.

This Handbook has been developed as a resource for organisations that conduct work with GMOs. The Handbook will help organisations to understand and comply with the requirements of the new regulatory system for GMOs.

The Handbook includes chapters on each of the key aspects of the scheme including:

- dealings with GMOs that are, and are not, regulated under the national regulatory scheme;
- exempt dealings with GMOs;
- notifiable low risk dealings with GMOs;
- licensed dealings with GMOs not involving the intentional release of a GMO into the environment;
- licensed dealings with GMOs involving the intentional release of a GMO into the environment;
- dealings with GMOs on the GMO Register;
- import and Transport of GMOs;
- accreditation of organisations;
- certification of facilities;

- regulation of human cloning and certain experiments involving human cells;
- regulation of GM products;
- the Record of GMOs and GM Product Dealings;
- confidential commercial information;
- review of decisions made under the legislation;
- reporting, monitoring and enforcement;
- the Regulator's website and the Gene Technology Information Management System; and
- fees and charges.

The Handbook also includes as Appendices:

- Application forms for organisations wishing to apply to deal with GMOs under the legislation;
- the *Guidelines for the Accreditation of Organisations*;
- the *Guidelines for the Certification of Facilities/Physical Containment Requirements*;
- the *Guidelines for Good Industrial Large Scale Practice*; and
- the *Risk Analysis Framework for Licence Applications before the Office of the Gene Technology Regulator*.

It is expected that the Handbook will be used as an ongoing resource for applicants or users of the regulatory scheme.

Copies of the Handbook may be obtained from the OGTR or from the Regulator's website at www.ogtr.gov.au



IMPORTANT NOTE

The Handbook is explanatory only and is provided only as an aid to the interpretation of the national regulatory scheme. Organisations and individuals undertaking

dealings with GMOs should also read and understand the *Gene Technology Act 2000* and the Gene Technology Regulations 2001 and, where necessary, obtain their own independent legal advice.

CHAPTER 1

BACKGROUND INFORMATION ABOUT THE NATIONAL REGULATORY SCHEME FOR GMOs

Part A: **Development of the national regulatory scheme**

Consultation on the proposed regulatory scheme for GMOs commenced in 1998 and has involved a number of stages.

Development of policy principles to underpin the national regulatory scheme

In November 1998, the Commonwealth State Consultative Group on Gene Technology (CSCG) circulated for public consultation a paper entitled "Regulation of Gene Technology". The CSCG is a Committee of government officials from all States and Territories and the Commonwealth.

Consultations were held throughout Australia seeking views about the broad policy principles that might underpin the new regulatory scheme. Some of the general features of the system of regulation were also discussed. As a result of these consultations, the CSCG agreed to a set of policy principles which the CSCG has used to guide it in developing the proposed regulatory system.

Development of the operational details for the national regulatory scheme

On the basis of the agreed policy principles, the CSCG worked to develop proposals for the operational details of the new regulatory system.

A discussion paper entitled “Proposed national regulatory system for genetically modified organisms – How should it work?” was released for public consultation in October 1999. This document set out the proposed approach to regulating GMOs, including the proposed scope and form of the legislation, the proposed management structures, the proposed system of regulation and the proposed mechanisms for maintaining transparency, accountability and community involvement in the system over time. The discussion paper was:

- advertised in a range of national and regional newspapers;
- direct-mailed to over 2,500 individuals and organisations including the groups referred to below as well as all MPs and Senators in Federal Parliament; and
- posted on the website of the IOGTR.

More than 200 written submissions were received on the Discussion Paper.

In addition, invitations to attend targeted consultations were sent to approximately 2,500 individuals and organisations across Australia.

The targeted consultations were held in all States and Territories during November and December 1999. At each session, participants were asked how the legislation could be more streamlined and reduce the impact on business, while maintaining the integrity of the system in terms of protecting public health and safety and the environment.

Consultations on the draft Gene Technology Bill 2000

On the basis of the consultations held in late 1999, an early draft of the Gene Technology Bill 2000 and an accompanying Explanatory Guide were released for public consultation in December 1999.

Once again, a call for public submissions was made in newspapers in all jurisdictions, on the IOGTR website and direct mailed to over 2,500 individuals.

Public forums were also held in all capital cities and also in Tamworth, Rockhampton and Albury-Wodonga. Over 750 people attended the public consultations and more than 160 written submissions were received.

During public consultations, officers from the IOGTR explained the impact of various parts of the draft Gene Technology Bill 2000 and sought comments on the ways that the proposed legislative system could be improved and any negative impacts minimised. The public forums gave rise to many suggestions for change and a range of options were discussed.

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.

Introduction and passage of the legislation through Federal Parliament

The Commonwealth Gene Technology Bill 2000 (and related legislation) was introduced into Federal Parliament on 22 June 2000. The Senate referred the Bill to the Senate Community Affairs References Committee who undertook a comprehensive inquiry into the legislation. The Inquiry included public hearings in Canberra, Adelaide, Hobart and Melbourne and received 124 submissions. In November 2000, the Committee released a report on the legislation entitled "A Cautionary Tale: Fish Don't Lay Tomatoes". A copy of the report is available from the Parliament House website at www.aph.gov.au.

During debate on the Gene Technology Bill 2000, a number of Senate amendments were made to the Bill and the legislation was passed by the Senate on 8 December 2000.

Consultation on draft of the Commonwealth Gene Technology Regulations

In August 2000, the draft Commonwealth Gene Technology Regulations and an accompanying Explanatory Guide to the draft Regulations was released for public comment.

Over 60 submissions on the draft regulations were received from a very wide range of groups and individuals including scientists, lawyers, environmental groups, consumer groups and industry bodies. Each submission received a detailed response from the IOGTR. The draft Regulations were also considered by the Genetic

Manipulation Advisory Committee (GMAC), the CSCG and various Parliamentarians.

As a result of the consultations on the draft Regulations, a number of changes were made to the Regulations and a revised draft was circulated for a second round of public consultation in January 2001.

As part of the second round of consultations on the Regulations, the IOGTR held consultations in each capital city with interested environment and consumer groups, organisations involved with gene technology (including Institutional Biosafety Committees) and with government agencies.

The IOGTR also received 77 submissions on the second draft of the Regulations. As with the consultations on the Bill, the draft Regulations and the Explanatory Guides (for both the August 2000 draft and the January 2001 draft) were placed on the IOGTR website, direct-mailed to approximately 4000 individuals and organisations who had registered (with GMAC or the IOGTR) an interest in receiving information on the regulation of GMOs, and advertised in newspapers across Australia.

Following further consideration of the Regulations by CSCG and GMAC, the Regulations were finalised and gazetted on 31 May 2001.

Part B: Instruments that form part of the national regulatory scheme

Summary

The **Gene Technology Act 2000** (the GT Act) describes the framework for the Australian system of regulation for GMOs and will be complemented over time by corresponding State and Territory legislation.

The **Gene Technology Regulations 2001** contain additional information about the operation of certain provisions in the GT Act.

The **Guidelines** operate alongside the GT Act and the Regulations. In effect, the Guidelines are the “operating instructions” issued by the Regulator as a result of powers conferred on the Regulator by the *Gene Technology Act 2000*.

Policy principles are documents issued by the Ministerial Council on Gene Technology. The Ministerial Council may issue policy principles on ethical issues and on designated areas established under State law for the purposes of preserving the identity of GM or non-GM crops for marketing purposes. The Regulator must not act inconsistently with policy principles issued by the Ministerial Council.

Policy guidelines are issued by the Ministerial Council to assist the Regulator in the performance of the Regulator’s functions. These will be guidance notes to the Regulator, and will not be prohibitive or akin to a direction, but will be advisory.

Codes of practice are issued by the Ministerial Council and may be applied by the Regulator as conditions of licence.

The **Gene Technology Agreement** is an agreement between the Commonwealth and States and Territories that establishes the Gene Technology Ministerial Council.

Section I: The Gene Technology Acts

In December 2000, Federal Parliament passed the *Gene Technology Act 2000* and its associated Acts, the *Gene Technology (Consequential Amendments) Act 2000* and the *Gene Technology (Licence Charges) Act 2000*.

These three Acts, together with corresponding legislation to be enacted in each State and Territory in Australia, as well as subordinate legislation and other instruments, will comprise the national scheme for the regulation of gene technology and GMOs in Australia.

The GT Act

The GT Act is the central piece of legislation that establishes the regulatory system for gene technology. Part 2 of this Chapter describes the six key components of the GT Act.

The Commonwealth *Gene Technology (Consequential Amendments) Act 2000*

The *Gene Technology (Consequential Amendments) Act 2000* complements the GT Act. 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 Gene Technology Regulator's advice on biosafety issues.

The *Gene Technology (Consequential Amendments) Act 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 Regulator 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 Regulator 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 Regulator (to be known as the Record of GMOs and GM Product Dealings).

The legislation amended by the *Gene Technology (Consequential Amendments) Act 2000* to effect the changes detailed above includes:

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

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

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

For more information regarding the regulation of GM products please refer to Chapter 13 of this Handbook.

The Commonwealth *Gene Technology (Licence Charges) Act 2000*

This Act is a very short one that simply establishes the capacity for Regulations to be made establishing annual charges to be paid by the holder of a GMO licence.

As detailed in Chapter 19 of this Handbook, as a result of the Commonwealth government's decision to defer any cost recovery for two years from the commencement of the Regulatory scheme, no Regulations will take effect under this Act for 2 years from 21 June 2001.

Corresponding State laws

It is anticipated that each State and Territory will enact complementary legislation to supplement the Commonwealth legislation. The corresponding laws are

currently being developed and introduced into the Parliaments of each State and Territory.

Each piece of legislation will be consistent, and will empower the Regulator to do all of the things set out in the Commonwealth GT Act.

In combination, the Commonwealth and State/Territory legislation enables consistent application of the scheme to all individuals and organisations in Australia.

The fact that the Regulator'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.

Section II: The Gene Technology Regulations

Regulations to complement the GT Act will commence when the GT Act commences. The Regulations provide additional detail to assist the interpretation and operation of the provisions in the GT Act. For example, the Regulations describe in detail the type of information that must be submitted in an application for a licence to deal with a GMO, and also set out the types of dealings with GMOs that are exempt from the national regulatory scheme and Notifiable Low Risk Dealings (NLRDs).

Section III: Technical and Procedural Guidelines

Relevant provision of the GT Act
Sections 27(d), 90 and 98

The Regulator is empowered under the GT Act to issue technical and procedural guidelines. The Regulator has issued three sets of technical and procedural guidelines:

- *Guidelines for the Accreditation of Organisations;*
- *Guidelines for the Certification of Facilities/ Requirements for Physical Containment;* and
- *Guidelines for the Transport of GMOs.*

All three Guidelines operate alongside the GT Act and the Regulations. The Regulator may also issue further Guidelines. If further Guidelines are issued, these will be direct-mailed to all Organisations undertaking dealings with GMOs and all IBCs and posted on the Regulator's website.

Section IV: Application Forms

The Regulator is empowered under the Act to issue application forms for various types of applications under the legislation.

The Regulator has issued application forms for:

- notification of a Notifiable Low Risk Dealing;
- application for licence for dealings with a GMO not involving intentional release of the GMO into the environment;
- application for licence for dealings with a GMO involving intentional release of the GMO into the environment;
- application for certification of a facility;
- application for accreditation of an organisation; and
- application for a declaration that certain information is confidential commercial information.

Copies of the application forms are available at Appendix 1 of this Handbook or from the OGTR or the Regulator's website at www.ogtr.gov.au.

Section V: Policy Principles, Policy Guidelines and Codes of Practice

Policy Principles

The GT Act provides that the Ministerial Council on Gene Technology may issue policy principles in relation to the following:

- ethical issues relating to dealings with GMOs;
- recognising areas, if any, designated under State law for the purpose of preserving the identity of one or both of the following:
 - GM crops;
 - non-GM crops;for marketing purposes;
- matters relating to dealings with GMOs prescribed by the regulations (at the commencement of the

<p>Relevant provision of the GT Act Section 21 - Ministerial Council may issue policy principles</p>

legislation, no other matters have been prescribed in the Regulations).

The policy principles will 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 Regulator 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, for example, the development of GM trees with fluorescent leaves. The policy principle will be clearly documented and subject to Parliamentary scrutiny. The Regulator must not accept any application that is inconsistent with the policy principle issued by the Ministerial Council. The Regulator must therefore not accept an application for genetically modified trees with fluorescent blue leaves.

At the commencement of the legislation, the Ministerial Council had not yet been established and as such no policy principles had been issued.

If, and when, the Ministerial Council makes policy principles these will be posted on the Regulator's website and will be direct mailed to everyone on the Regulator's mailing list and to all organisations dealing with GMOs.

Policy Guidelines

Policy guidelines will be issued by the Ministerial Council to assist the Regulator in the performance of the Regulator's functions. These will be guidance notes to the Regulator, and will not be prohibitive or akin to a direction, but will be advisory.

Unlike policy principles, the Regulator is not compelled to act in accordance with policy guidelines. However, the

Relevant provision of the GT Act

Section 23 - Ministerial Council may issue policy guidelines

Regulator must take the guidelines into account in considering an application made under the GT Act.

Example:

The Ministerial Council may issue policy guidelines to the Regulator about the matters to be taken into account when considering certain types of applications for GMO licences (for example, the colour of animals). While the Regulator must have regard to any such guidelines, they do not amount to a binding direction to the Regulator.

At the commencement of the legislation, the Ministerial Council had not yet been established and as such no policy guidelines had been issued.

If, and when, the Ministerial Council makes policy guidelines these will be posted on the Regulator's website and will be direct mailed to everyone on the Regulator's mailing list and to all organisations dealing with GMOs.

Codes of Practice

The Ministerial Council may also issue codes of practice as a guide 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 Regulator 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 the codes of practice are also disallowable instruments and subject to Parliamentary scrutiny.

Relevant provision of the GT Act

Section 24 - Ministerial Council may issue codes of practice

Example:

The Ministerial Council may issue a code of practice for the ethical conduct of gene technology research, detailing matters that applicants must take into account to ensure that any research proposed accords with certain ethical requirements. 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 Regulator 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 Regulator may also apply a condition of licence requiring compliance with a code of practice issued by the Ministerial Council.

At the commencement of the legislation, the Ministerial Council had not yet been established and as such no codes of practice had been issued.

If, and when, the Ministerial Council makes codes of practice these will be posted on the Regulator’s website and will be direct mailed to everyone on the Regulator’s mailing list and to all organisations dealing with GMOs.

Section VI: The Gene Technology Agreement

Relevant provision of the GT Act
Section 10 – Definitions

The national scheme will be underpinned by an Inter-governmental 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:

- describes the main components of the co-operative national scheme and commits participating governments to introduce substantially similar legislation in each jurisdiction;

- sets out the functions and membership of the Gene Technology Ministerial Council. The Ministerial Council will comprise one representative from the Commonwealth and each of the States and Territories. Each jurisdiction will decide which Minister will represent that jurisdiction on the Ministerial Council. This may be a health, environment or agriculture Minister. It will, however, be the responsibility of each member to provide a “whole of Government” perspective on behalf of their jurisdiction. The Commonwealth government will be represented by the Health Minister.

The Ministerial Council will:

- issue policy principles, policy guidelines and codes of practice to underpin the activities of the Regulator and the operation of the regulatory framework;
- consider and agree to changes to the national legislative framework (as required);
- discuss matters related to gene technology regulation with other relevant Ministerial Councils;
- provide advice on the appointment and dismissal of the Regulator; and
- oversee periodic reviews of the legislative framework.

The Ministerial Council will not be involved in decision making on individual applications;

- provides for the maintenance of a nationally consistent scheme over time, including provisions for the amendment of the gene technology legislation;
- describes 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; and

- provides for the review of the implementation and effectiveness of the national scheme as soon as possible after four years operation of the GT Act.

Part C: **The six main components of the national regulatory scheme**

Relevant provisions of the GT Act
Sections 3 and 4

What is the object of the GT Act?

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

The GT Act provides that the object of the Act is to be achieved through a regulatory framework which:

- provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation;
- provides an efficient and effective system for the application of gene technologies; and
- operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products.

What does the GT Act do?

In summary, the GT Act does six key things. The GT Act:

- establishes a statutory officer, the Gene Technology Regulator (the Regulator) to administer the legislation and make decisions under the legislation;
- establishes the Gene Technology Technical Advisory Committee, the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee to advise the Regulator and the Ministerial Council on gene technology;
- prohibits persons from dealing with GMOs (e.g. research, manufacture, production, commercial release and import) unless the dealing is authorised in accordance with the Act;

- 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;
- provides for monitoring and enforcement of the legislation; and
- creates a centralised, publicly available database of all GMOs and GM products approved in Australia (the Record of GMO and GM product dealings).

What does the Regulator do?

The legislative scheme is administered by the Regulator.

The Regulator:

- is an independent office holder appointed by the Governor-General with the agreement of the majority of all jurisdictions;
- administers the legislation and assesses any risks posed by GMOs;
- informs and advises other regulatory agencies, States and Territories and the public about GMOs and GM products;
- promotes harmonised risk assessments for GMOs and GM products by regulatory agencies;
- monitors and enforces the legislation; and
- reports to Parliament annually and quarterly, and at any other time such a report is warranted, and will copy any such report to the States and Territories.

What are the roles and functions of the statutory Committees?

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

- The **Gene Technology Technical Advisory Committee** (GTTAC) replaces the current Genetic

Relevant provision of the GT Act
Section 27 - Functions of the Regulator

Relevant provision of the GT Act
Part 8 – Division 2 – The Gene Technology Technical Advisory Committee

Manipulation Advisory Committee (GMAC). The GTTAC provides scientific and technical advice to the Regulator or the Ministerial Council on matters including: gene technology, GMOs and GM products, and applications made under the legislation.

Relevant provision of the GT Act

Part 8 – Division 3 –
The Gene Technology
Community
Consultative Committee

Relevant provision of the GT Act

Part 8 – Division 4 –
The Gene Technology
Ethics Committee

- The **Gene Technology Community Consultative Committee** (the GTCCC) is a broadly based consultative committee from which the Ministerial Council and the Regulator may seek advice 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 Regulator's decision-making.
- The **Gene Technology Ethics Committee** (the GTEC) is a broadly based committee from which the Regulator and the Ministerial Council can seek advice on the ethics of gene technology, appropriate ethics guidelines and any necessary prohibitive directives.

More information available about the Committees is available from the Regulator's website at www.ogtr.gov.au.

CHAPTER 2

DEALINGS WITH GMOS THAT ARE, AND ARE NOT, REGULATED UNDER THE NATIONAL REGULATORY SCHEME

Part A: Dealings with GMOs that are regulated under the national scheme

What does the legislation regulate?

In summary, the legislation regulates all “dealings” with “GMOs”.

The legislation prohibits all dealings with GMOs, subject to a system of authorisations described in the legislation.

A person who deals with a GMO (without an appropriate approval) is guilty of an offence under the legislation.

What is a “dealing” with a GMO?

“Deal with”, in relation to a GMO, is defined in the GT Act to mean;

- (a) conduct experiments with the GMO
- (b) make, develop, produce or manufacture the GMO;
- (c) breed the GMO;
- (d) propagate the GMO;
- (e) use the GMO in the course of manufacture of a thing that is not the GMO;
- (f) grow, raise or culture the GMO; and
- (g) import the GMO;

and includes the possession, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (g).

In summary the legislation regulates all “dealings” (or activities) with GMOs.

Relevant provisions of the GT Act
Part 4 – Division 2 – Dealings with GMOs must be licensed

Relevant provisions of the GT Act
Section 10 - Definitions

What is a “GMO”?

“**Genetically modified organism**” (or GMO) is defined in the GT Act to mean:

- (a) an organism that has been modified by gene technology; or
- (b) an organism that has inherited traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or
- (c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the Regulations to be genetically modified organisms ;

but does not include:

- (d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or
- (e) an organism declared by the Regulations not to be a genetically modified organism, or that belongs to a class of organism declared by the Regulations not to be genetically modified organisms.

In order to understand the definition of GMO it is important that two further terms are understood – “organism” and “gene technology”.

“**Organism**” is defined in the GT Act to mean a biological entity that is viable, capable of reproduction or capable of transferring genetic material.

“**Gene technology**” is defined as any technique for the modification of genes or other genetic material, but does not include sexual reproduction, homologous recombination or any other techniques specified in the Regulations.

In summary, the legislation regulates:

- biological entities that are viable, capable of reproduction or capable of transferring genetic material that have had their genes or genetic material modified by any technique aside from:
 - sexual reproduction;
 - homologous recombination; or
 - techniques described in the 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. This provision was included in the definition to enable the legislation to be able to respond to changes in technology and to be able to cover GM products (that is non-viable products of GMOs) where necessary.

This capacity to declare an organism to be a GMO enables any organisms or products that are not regulated by existing regulators (such as the TGA and ANZFA) to be regulated under the scheme. At the time of commencement of the legislation, no such things have been prescribed.

Part B: Activities and organisms that are not regulated under the national scheme

Relevant provisions of the GT Act
Section 10 - Definitions

What is not regulated under the legislation?

In summary, the legislation does not regulate:

- human beings, if the human being is a GMO only because the human being has undergone somatic cell gene therapy;
- somatic cell nuclear transfer (cloning) if the transfer does not involve genetically modified material; and
- organisms that are prescribed in the Regulations as not being GMOs.

Why does the legislation not apply to human beings that have undergone somatic cell gene therapy?

The definition of GMO specifically excludes human beings if the human being is only caught by the definition of a GMO because they have undergone somatic cell gene therapy. This does not mean that the use of GMOs as part of clinical trials involving humans is not regulated. It simply means that a person who has undergone gene therapy is not considered to be a GMO themselves. Without this provision the person who has undergone gene therapy would be a GMO because they would be an organism that has been modified by techniques of gene technology.

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 Regulator 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 GT Act (by virtue of the exclusion in the definition of GMO described above).

Why does the legislation not apply to somatic cell nuclear transfer (cloning)?

Regulation 4 of the GT Regulations clarifies that cloning (somatic cell nuclear transfer) is not included within the definition of 'gene technology' as defined in the GT Act.

This is because somatic cell nuclear transfer does not involve the modification of genes or other genetic material. It involves the replication or duplication of genetic material.

As such the legislation does not regulate such work regardless of whether it occurs in plants, animals or humans.

If the work not only involves cloning but also involves genetic modification (e.g. the insertion or deletion of genes that may pose new biosafety risks), then such genetic modification is regulated under the Act.



IMPORTANT NOTE

While cloning is not caught within the definition of gene technology (for the purposes of the GT Act), the GT Act does ban cloning of whole human beings. For more information on this, please refer to Chapter 12.

What organisms are declared by the regulations not to be genetically modified organisms?

The definition of GMO (in section 10 of the GT Act) includes capacity for the regulations to declare that certain organisms are not GMOs for the purposes of the legislation.

This provision recognises that the definitions of GMO and gene technology in the GT Act are cast very broadly, and that the definition of GMO may capture things that were never intended to be regulated under this legislation.

To address this situation, the Regulations set out those organisms that are not caught by the regulatory scheme.

The organisms set out in the Regulations include organisms that:

- can occur in nature; or
- do not pose any unique biosafety risks to the environment or human health and safety.

Part 1 of Schedule 1 of the Regulations sets out those organisms that are not GMOs for the purposes of the legislation.

For ease of reference, Box 1 describes the organisms that are not GMOs for the purposes of the legislation. The items included in Box 1 mirror the Items in Part 1 of Schedule 1 of the Regulations. Some examples of the types of organisms that are not GMOs have also been included in the Box.

The organisms listed in Schedule 1 of the Regulations (and replicated in Box 1) are not considered to be GMOs for the purposes of the legislation and as such no approval is required from the Regulator for work only involving such organisms.

BOX 1 - ORGANISMS THAT ARE NOT GMOs

Item 1

A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).

Example:

A new variety of wheat that has been produced by bombarding cells with ionising radiation or exposing them to chemical mutagens that cause mutations in the DNA of the cells. By chance, some of the mutations might lead to desirable changes in the characteristics of the wheat plants. This technique has been used for many years to produce new varieties of plants.

Item 2

A recombinant organism formed through integration into chromosomal or extrachromosomal DNA sequences of a genetic element that:

- (a) occurs naturally in the species concerned; and
- (b) moves sporadically between genome sites.

Example:

Some species contain naturally occurring pieces of DNA that can spontaneously move around within the DNA of that organism. When these pieces of DNA move around they may cause changes in the characteristics of that organism, but the modified organism that results is not considered a GMO because the process is one that occurs in nature.

Item 3

An organism that:

- (a) results from the fusion of 2 animal cells; and
- (b) is unable to form a viable whole animal.

Example:

Hybridomas created to produce monoclonal antibodies. These are cultured cells, growing in a petri dish, that have resulted from fusing an antibody-producing cell with a cancer cell. The cell culture is used in the laboratory to produce a particular antibody that can be used in research.

Item 4

An organism that results from protoplast fusion involving only non-pathogenic bacteria or non-pathogenic yeast.

Example:

An organism that results when cells from two strains of yeast (that are known not to cause disease) are fused together after their cell walls have been removed.

Item 5

A plant formed by:

- (a) embryo rescue; or
- (b) *in vitro* fertilisation; or
- (c) zygote implantation; or
- (d) protoplast fusion.

Example:

A new variety of plant formed by one of the methods listed. These methods are standard techniques that have been used for many years by plant breeders to produce new varieties with desirable characteristics.

Item 6

An organism that results from exchange of DNA if:

- (a) the donor species is also the host species; and
- (b) the vector DNA does not contain any heterologous DNA.

Example:

For example, the transfer of naturally occurring plasmids within a single species where the plasmid does not contain any DNA from other species.

Item 7

An organism that results from an exchange of DNA between the donor species and the host species if:

- (a) such exchange can occur by naturally occurring processes; and
- (b) the donor species and the host species are both mentioned in the same group in Part 2 of this Schedule; and
- (c) the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange.

Example:

Certain species naturally exchange DNA. Part 2 of Schedule 1 of the Regulations (as replicated in Box 2) describes such species. If the work involves exchange of DNA between such species (where such exchange can occur naturally) the resulting organism is not a GMO.

BOX 2 - SPECIES KNOWN TO EXCHANGE DNA BY A KNOWN PHYSIOLOGICAL PROCESS

Group 1

Alcaligenes
Campylobacter coli
Campylobacter fetus
Campylobacter jejuni
Citrobacter (including levinea)
Enterobacter
Erwinia
Escherichia
Klebsiella
Pseudomonas aeruginosa
Pseudomonas fluorescens
Pseudomonas mendocina
Pseudomonas putida
Rhizobium
Salmonella (including arizona)
Serratia marcescens
Shigella
Yersinia enterocolitica

Group 2

Bacillus amyloliquefaciens
Bacillus atterimus
Bacillus globigii
Bacillus licheniformis
Bacillus nato
Bacillus niger
Bacillus pumilus
Bacillus subtilis

Group 3

Streptomyces aureofaciens
Streptomyces coelicor
Streptomyces rimosus

Group 4

Streptomyces cyaneus
Streptomyces griseus
Streptomyces venezuela

Group 5

Streptococcus mutans DNA and Streptococcus lactis DNA - in a one-way transfer into Streptococcus sanguis

Group 6

Streptococcus faecalis
Streptococcus mutans
Streptococcus pneumoniae
Streptococcus pyogenes
Streptococcus sanguis

Group 7

Bacillus cereus
Bacillus thuringiensis

CHAPTER 3

THE SYSTEM OF PROHIBITIONS AND APPROVALS FOR DEALINGS WITH GMOs

What types of approvals are there for dealings with GMOs?

In summary, the legislation prohibits all dealings with GMOs unless the dealings with GMOs are “approved” in one of four ways.

Subject to certain conditions and requirements being complied with, a person may deal with a GMO if the dealings with the GMO are:

- exempt dealings;
- notifiable low risk dealings;
- on the GMO Register; or
- licensed by the Regulator.

Following is a brief summary of the four different types of “approvals” for dealings with GMOs under the legislation:

- **exempt dealings with GMOs** – these are dealings with GMOs that have been assessed over time as posing negligible risks. Such dealings with GMOs do not require licensing (and a case by case risk assessment by the Regulator) because the dealings are known to pose low risk. As an additional precautionary measure, exempt dealings must be contained within a facility and must not involve the intentional release of the GMO into the environment. For more information about exempt dealings with GMOs please refer to Chapter 4.
- **notifiable low risk dealings** – these are dealings with GMOs that have been assessed over time as posing low risks provided certain risk management conditions are complied with. NLRDs must be: notified to the Regulator; conducted within a facility certified to be at

least Physical Containment Level 2; undertaken within an Accredited Organisation; and if transported, must be transported in accordance with Guidelines issued by the Regulator for the transport of GMOs. NLRDs with GMOs must not be released into the environment. For more information about NLRDs please refer to Chapter 5.

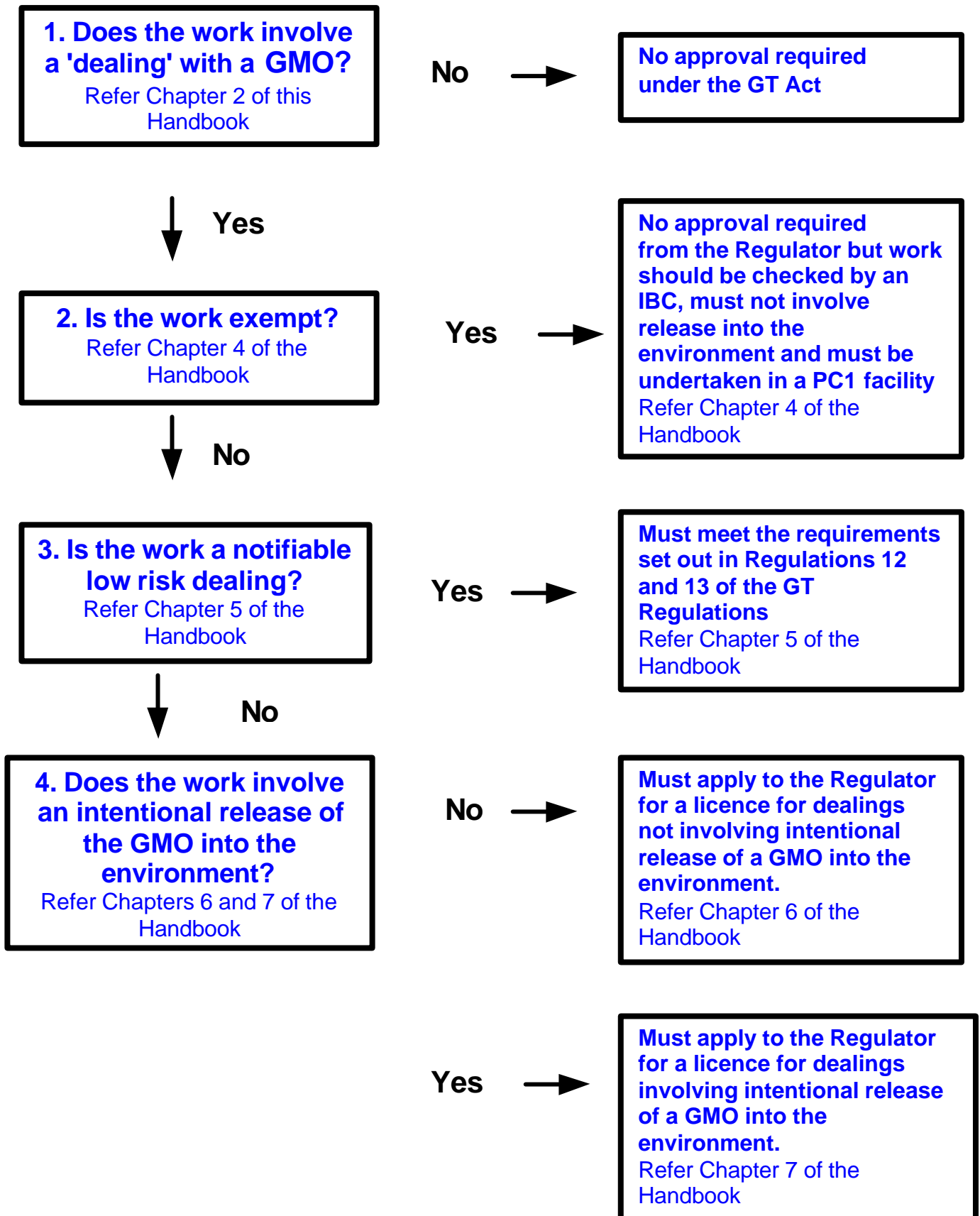
- **licences** – all dealings with GMOs (that are not exempt, NLRDs or on the GMO Register) will need to be licensed by the Regulator. There are two types of licences that may be issued by the Regulator – licences for dealings with GMOs that do not involve the intentional release of a GMO into the environment and licences for dealings with GMOs that do involve the intentional release of a GMO into the environment. For more information about licensing of GMOs, please refer to Chapters 6 and 7.
- **GMO Register** – 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 Regulator 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. For more information about the GMO Register please refer to Chapter 8.

How do I know what type of approval I need under the legislation to deal with a GMO?

You should consult the GT Act and Regulations and Chapters 4 to 8 of this Handbook.

If you have any uncertainty at all about what type of GMO you are dealing with or what type of approval you need under the regulatory scheme, you should contact the OGTR.

DECISION TREE FOR “APPROVALS” FOR DEALINGS WITH GMOs



What if I deal with a GMO without the appropriate approval?

The legislation establishes offences for unauthorised dealings with a GMO.

The legislation provides that a person must not deal with a thing they know to be a GMO without a licence authorising that dealing, unless:

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

The legislation describes 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 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. This is called a strict liability offence; or
- 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.

The penalties for unauthorised dealings with GMOs are:

- 500 penalty units (\$55,000 for an individual and \$275,000 for a body corporate) or 2 years imprisonment;
- 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 units¹ (\$220,000 for an individual and \$1.1 million for a body corporate) or 5 years imprisonment;

- for strict liability offences - 200 penalty units in the case of an aggravated offence and 50 penalty units in any other case.

The legislation also establishes offences for:

- breach of conditions of a licence;
- breach of conditions for NLRDs; and
- breach of conditions on the GMO Register.

Part 4, Division 2 of the GT Act describes these offences.

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

CHAPTER 4

EXEMPT DEALINGS WITH GMOs

Part A: Types of dealings with GMOs that are exempt

What dealings with GMOs are exempt?

Relevant provisions of the GT Regulations
Regulation 6 – Dealings exempt from licensing

A dealing with a GMO is only an exempt dealing if it meets all of the following conditions:

- it is mentioned in Part 1 of Schedule 2 of the GT Regulations;
- it does not involve genetic modification, other than a modification described in Part 1 of Schedule 2 of the GT Regulations;
- it is conducted in accordance with Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology) for Physical Containment Level 1; and
- it does not involve an intentional release of the GMO into the environment.



IMPORTANT NOTE

All of the conditions described above must be met in order for dealings with a GMO to be exempt. If any of them are not met then the work is NOT an exempt dealing with a GMO.

Each of these requirements for exempt dealings are explored below.

Part 1 of Schedule 2 of the Regulations

Part 1 of Schedule 2 of the Regulations prescribes the dealings with GMOs that are exempt. Box 3 (below) sets out the exempt dealings and includes examples of such dealings and guidance notes about the exempt dealings. Box 4 mirrors Part 2 of Schedule 2 that sets out approved

host/vector systems. Host/vector systems are referenced in the exempt dealings with GMOs contained in Box 3.

Work must not involve any other genetic modification

Exempt dealings with GMOs must only involve the type of work described in Part 1 of Schedule 2 (refer Box 3). If any other genetic modification is involved (for example, any subsequent genetic modification), the work is not exempt.

For example, Part 1 of Schedule 2 provides that all dealings with certain gene knockout mice (provided no advantage is conferred on the adult animal) are exempt. In other words, a researcher may transport the mice, store the mice, conduct experiments (not involving gene technology) with the mice etc. The researcher cannot however do any other genetic modification on the gene knockout mice. If this is proposed then a licence must be obtained from the Regulator.

Work must be conducted in accordance with Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology) for Physical Containment Level 1

Copies of the Australian Standard are available from the OGTR or from the Regulator's website.

Work must not involve an intentional release of the GMO into the environment.

For the purposes of the legislation, a dealing with a GMO involves the intentional release of a GMO into the environment if the GMO is intentionally released into the environment, whether or not it is released with provision for limiting the dissemination or persistence of the GMO or its genetic material in the environment.

It is the responsibility of all people undertaking exempt dealings with GMOs to make sure that the work does not involve the intentional release of the GMO into the environment. If the work does involve the release of the GMO into the environment then the work is NOT exempt and must be licensed by the Regulator.

Can I apply for exemption status for dealings with GMOs that are not on the list of exemptions?

The dealings with GMOs that are included on the list of exemptions will be reviewed regularly. In addition, any member of the public may, at any time, make a submission to the Regulator proposing that certain dealings with GMOs be removed from the list of exemptions, or be included on the list of exemptions. Before making changes to the list of exemptions, the Regulator will undertake a full analysis of any risks posed by the dealings to determine whether they are justified in being removed from, or added to, the list of exemptions.

Public comment may be sought on the proposed changes to the exempt dealings with GMOs. If people have reasons (based on the presence or absence of risks to the health and safety of people or the environment) to support changes to the dealings included on the list of exemptions, these will be examined in detail by the Regulator. Where necessary, changes will be made to the list of exemptions.

How do the exempt dealings under the new legislative scheme differ from exempt work under the GMAC system?

The exemptions described in Part 1 of Schedule 1 of the Regulations have been based on the current exemptions described in the GMAC Guidelines for Small Scale Genetic Manipulation Work. The GMAC exemptions have been developed over the last 20 years, based on the experience of the Committee in assessing applications.

The exemptions apply to a very limited number of dealings with GMOs that:

- have been assessed over time as presenting no significant biosafety risks to public health and safety (including occupational health and safety) or the environment; and
- are undertaken within contained facilities (that is, they do not involve intentional release of a GMO into the environment).



IMPORTANT NOTE

Despite being based on the GMAC exemptions, the exempt dealings described in Part 1 of Schedule 2 of the Regulations are not identical to the GMAC exemptions. People proposing to undertake exempt dealings with GMOs should therefore consult the list closely.

BOX 3 – DEALINGS EXEMPT FROM LICENSING

Item 1

Any dealing with gene-knockout mice (that is, mice whose genetic modification involves deletion or inactivation of a specific gene), if no advantage is conferred on the adult animal:
(a) by the deletion or inactivation of the gene concerned; or
(b) for mice that also carry a selectable marker gene – by the selectable marker gene.

Examples:

Gene knock-out mice are mice that have genes removed from the genome (or 'knocked out' of their DNA) so that the effects of the loss of the gene may be studied.

Guidance Notes:

- An important limitation on this exemption is that in order to be exempt, the removal of genes from the mouse must not be able to give rise to an advantage in the modified adult mouse over wild type unmodified mice. If it is likely that an advantage would be conferred on the mouse as a result of the deletion of the gene, then the work is not exempt.

Item 2

Any dealing with a whole animal, if:
(a) naked recombinant nucleic acid has been introduced into its somatic cells; and
(b) the introduced nucleic acid is incapable of giving rise to infectious agents.

Examples;

The introduction of naked recombinant nucleic acid into an animal's somatic cells does not involve manipulation of the animal's genome. The significance of this is that because the genome has not been manipulated and the introduction is only through somatic cells, then the modified material will not be present in the genome of subsequent generations.

An example of this technique is using DNA as vaccines to vaccinate animals against disease. This is a technique that has the potential to be safer than current non-GMO vaccines which use live, weakened strains of an organism (eg the polio vaccine).

Guidance notes:

In order to satisfy as exempt under this item, 4 important criteria must be met:

- the work must involve whole animals;
- the whole animal must be a GMO only because naked recombinant nucleic acid has been introduced into the animal's somatic cells. If any other type of modification has been made to the animal (and such modification is not also exempt) then the work is not exempt;
- the introduced nucleic acid must be incapable of giving rise to infectious agents; and
- the work must not involve intentional release of the GM animal into the environment.

Item 3

Any dealing with an animal into which genetically modified somatic cells have been introduced, unless the cells:

- (a) are capable of giving rise to recombinant infectious agents; or
- (b) contain viral sequences that could recombine with, or be complemented by, genomes of introduced superinfecting viruses.

Guidance Notes:

This exemption only applies if:

- the modification does not involve any changes to the germ cells of the animal and hence any changes are not capable of being passed on to the next generation;
- the somatic cells that have been introduced are incapable of giving rise to infectious agents and do not contain viral sequences that could recombine with, or be complemented by, genomes of introduced superinfecting viruses;
- the dealings with the GMO do not involve the intentional release of a GMO into the environment.

Gene therapy of an animal where the genetically modified somatic cells contain whole viral genomes is therefore not exempt.

Item 4

Any dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 10 litres of GMO culture, if:

(a) the donor DNA:

- (i) is not derived from micro-organisms capable of causing disease in human beings, other animals, plants or fungi, or is fully characterised and will not increase the virulence or host range of the host or vector; and
- (ii) is not an oncogene; and
- (iii) does not code for a toxin for vertebrates with an LD50 of less than 100µg/kg; and
- (iv) does not code for a toxin for vertebrates with an LD50 of 100µg/kg or more, if the intention is to express the toxin at high levels; and
- (v) is not uncharacterised DNA from a micro-organism that produces toxins with an LD50 of 100 µg/kg or less; or

(b) the donor DNA includes a viral sequence or viral sequences, but:

- (i) is missing at least 1 gene essential for viral multiplication that is not available in the cell into which the DNA is introduced and that will not become available through subsequent breeding; and
- (ii) is incapable of complementing a defect in the host/vector system.

Guidance Notes:

This exemption only applies if:

- the dealing does not involve the production of more than 10 litres of GMO culture (if the production of more than 10 litres of culture is envisaged then such work must be licensed by the Regulator); and
- the dealing involves a host/vector system mentioned in Part 2 of Schedule 2 AND the conditions relating to the donor DNA (as detailed above are met). For example the donor DNA must not be an oncogene, must not code for dangerous toxins etc. If the donor DNA is any of these things then the work will not be exempt; and

- the dealing does not involve any other type of genetic modification.

Item 5

Any dealing involving shot-gun cloning of mammalian DNA in a host/vector system mentioned in Part 2 of Schedule 2.

Examples:

The formation of libraries of mammalian DNA fragments cloned into approved host/vector systems as has occurred extensively in major genome sequencing projects such as the Human Genome.

Guidance Notes:

This exemptions only applies if the dealing involves shot-gun cloning of mammalian DNA in a host/vector system mentioned in Part 2 of Schedule 2.



IMPORTANT NOTE

Please note that the Regulator will be issuing further Guidelines for work with toxins, work with hazardous fragments of DNA and work involving GM viruses for gene transfer into animal and human cells. These will be available as an Appendix to this Handbook and also from the OGTR and the OGTR website.

BOX 4: HOST/VECTOR SYSTEMS FOR EXEMPT DEALINGS

Item	Class	Host	Vector
1	Bacteria	<i>Escherichia coli</i> K12 or <i>E. coli</i> B-any derivative that does not contain: (a) conjugative or generalized transducing phages; or (b) genes able to complement the conjugation defect in a non-conjugative plasmid	1. Non-conjugative plasmids 2. Bacteriophage (a) lambda (b) lambdoid (c) Fd or F1 (eg M13)
2		<i>Bacillus subtilis</i> or <i>B. licheniformis</i> -an asporogenic strain with a reversion frequency of less than 10^{-7}	Plasmids and phages whose host range does not include <i>B. cereus</i> , <i>B. anthracis</i> or any other pathogenic strain of bacillus
3		<i>Pseudomonas putida</i> -strain KT 2440	Certified plasmids: pKT 262, pKT 263, pKT 264
4		<i>Streptomyces</i> -specified species: (a) <i>S. coelicolor</i> (b) <i>S. lividans</i> (c) <i>S. parvulus</i> (d) <i>S. griseus</i>	1. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives 2. Actinophage phi C31 and derivatives
	Fungi	<i>Neurospora crassa</i> -laboratory strains	All vectors
		<i>Pichia pastoris</i>	All vectors
		<i>Saccharomyces cerevisiae</i>	All vectors
		<i>Schizosaccharomyces pombe</i>	All vectors
		<i>Kluyveromyces lactis</i>	All vectors
		<i>Trichoderma reesei</i>	All vectors
	Slime moulds	<i>Dictyostelium</i> species	<i>Dictyostelium</i> shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2
	Tissue culture	Mammalian (including human) cells and cells of aquatic organisms	Non-viral vectors or defective viral vectors (including retrovirus or retroviral-helper combinations that cannot infect human cells)

5

Avian cells

Avipoxvirus vectors (attenuated vaccine strains)

Plant cell cultures

Non-tumorigenic disarmed Ti plasmid vectors in *Agrobacterium tumefaciens* or non-pathogenic viral vectors

Insect cell cultures, such as *Spodoptera frugiperda*, if the recombinants are also inclusion-negative (eg polyhedrin minus)

Baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedrin minus

Any host mentioned, or of a kind mentioned, in any of items 1 to 4

Any non-biological vector (for example, electrocorporation or particle bombardment)

Part B: Responsibilities of individuals proposing to undertake exempt dealings with GMOs

Is approval needed from the Regulator to undertake dealings with GMOs that are exempt?

No. To undertake exempt dealings with a GMO, it is not necessary to seek a licence or other approval from the Regulator.

However, you should consult your organisation's Institutional Biosafety Committee (IBC) to ensure that you have correctly identified the work that you will be undertaking as an exempt dealing with a GMO.

What steps must I take before I undertake exempt dealings with GMOs?

Step 1 – Check that the work proposed to be undertaken falls within the list of exempt dealings in Part 1 of Schedule 2 of the Regulations (as described in Box 3 above).

- If the work is on the list of exempt dealings with GMOs, proceed to Step 2.
- If the work proposed is not on the list of exempt dealings with GMOs, check to see if it is on the list of NLRDs (refer Part 2 of this Chapter). If it is not a NLRD, a licence from the Regulator must be sought in order to undertake the work with the GMO (refer Part 3 of this Chapter).
- If uncertain as to whether the work is on the list of exempt dealings with GMOs, proceed to Step 2.

Step 2 – If the work is to be conducted by a person working within an Accredited Organisation, the IBC should be consulted to ensure that the work has not been mis-classified and is in fact exempt. If there are any doubts, consult the OGTR.

- If the IBC (or the OGTR) confirms that the proposed work is exempt, the work may be undertaken provided it does not involve an intentional release of the GMO into the environment AND the Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology) for Physical Containment Level 1 is complied with (Refer to Step 3).
- If the IBC (or the OGTR) confirms that the proposed work is not on the list of exempt dealings with GMOs, the work should not commence. Check to see if it is on the list of NLRDs (refer Part 3 of this Chapter). If it is not a NLRD, a licence must be sought from the Regulator to undertake the work with the GMO.

Step 3 – Ensure compliance with the conditions that apply to exempt dealings with GMOs (refer below).

What conditions must I comply with while I am undertaking exempt dealings with GMOs?

When you are conducting exempt dealings with GMOs you must make sure that you do so in accordance with the Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology) for Physical Containment Level 1. Copies of the Standard are available from the OGTR and on the Regulator's website.

The organisation or IBC may request information from you to enable them to prepare an annual report to the Regulator which includes information about exempt dealings.

What do I have to do when I finish the exempt dealings with GMOs?

If you cease doing the work (that is, if the project is completed or abandoned) you should advise your IBC as soon as possible.

Part C: Responsibilities of Accredited Organisations and IBCs

What are the responsibilities of Accredited Organisations and IBCs in relation to exempt dealings with GMOs?

Proformas
To assist IBCs with record keeping, the OGTR will provide appropriate proformas for this purpose.

In order to minimise the possibility of mis-classification of dealings with GMOs as 'exempt', all researchers working within Accredited Organisations proposing to undertake exempt dealings with GMOs are advised to consult their IBC.

The *Guidelines for Accreditation of Organisations* issued by the Regulator set out the conditions of accreditation of organisations. One of the conditions relates to the role of IBCs in relation to exempt dealings with GMOs.

The conditions of accreditation provide that the IBC shall assist the person in appropriately classifying the work as exempt and will keep a brief record of their consideration of the work. The Accredited Organisation is required to provide a list of exempt dealings to the Regulator annually.



IMPORTANT NOTE

If the individual proposing to undertake exempt dealings with GMOs or the IBC has any doubts regarding the classification of the work as exempt, the issue should be referred to the Regulator for advice.

Checklist for Exempt Dealings with GMOs

- Check to make sure that the dealings with the GMO is on the list of exempt dealings in Part 1 of Schedule 2 of the GT Regulations (as described in Box 3 of this Handbook).
- Check to make sure that the dealings with the GMO do not involve any other type of genetic modification other than the types listed in Part 1 of Schedule 2 and that the work does not involve intentional release of the GMO into the environment.
- Submit the work proposal to the relevant IBC so that the IBC can check to make sure that the work has not been mis-classified. If you or your IBC have any doubts, contact the OGTR before commencing the work with the GMO.
- Once you are certain that the work is an exempt dealing with a GMO you may commence the work provided you undertake the work in accordance with the Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology) for Physical Containment Level 1.
- Your IBC should report annually to the OGTR about exempt dealings with GMOs (refer Chapter 17 of this Handbook for information about reporting requirements). You must inform your IBC if you complete or abandon the exempt dealings with GMOs.

CHAPTER 5

NOTIFIABLE LOW RISK DEALINGS WITH GMOs

Part A: Types of dealings with GMOs that are NLRDs

What dealings with GMOs are notifiable low risk dealings?

Relevant provisions of the GT Regulations
Regulation 12 –
Notifiable low risk
dealings Definitions

The GT Regulations provide that a dealing with a GMO is a NLRD if:

- (a) it is a dealing of a kind mentioned in Part 1 of Schedule 3 (other than a dealing also mentioned in Part 2 of Schedule 3); and
- (b) it does not involve an intentional release of a GMO into the environment.

Box 5 (below) sets out the NLRDs and includes guidance notes about the NLRDs.

Box 6 (below) sets out the types of dealings with GMOs that **are not** NLRDs. If the work, despite falling in Box 5, also falls in Box 6, the work is not a NLRD and **must be licensed by the Regulator**.

NLRDs must not involve the intentional release of a GMO into the environment. If release is proposed the work is not a NLRD and must be licensed by the Regulator.

The only dealings that have been included on the list of NLRDs are those that have been assessed over time as presenting minimal biosafety risks when the conditions of NLRDs are complied with.



IMPORTANT NOTE

Just because you meet these criteria does not mean that you can automatically commence NLRDs with a GMO.

You must observe the steps detailed in Part C of this Chapter.

Can I apply for dealings with GMOs to be treated as NLRDs if they are not on the list of NLRDs?

The dealings with GMOs that are included on the list of NLRDs will be reviewed regularly. In addition, any member of the public may, at any time, make a submission to the Regulator proposing that certain dealings with GMOs be removed from the list of NLRDs, or be included on the list of NLRDs.

Before making changes to the list of NLRDs, the Regulator will undertake a full analysis of any risks posed by the dealings to determine whether they are justified in being removed from, or added to, the list of NLRDs.

Public comment may be sought on the proposed changes to NLRDs. If people have reasons (based on the presence or absence of risks to the health and safety of people or the environment) to support changes to the dealings included on the list of NLRDs, these will be examined in detail by the Regulator. Where necessary, changes will be made to the list of NLRDs.

How do NLRDs under the new legislative scheme differ from Category B work under the GMAC system?

Under the former voluntary arrangements overseen by GMAC and the IOGTR, GMAC issued guidelines setting out “Category B” activities that required IBC assessment, and notification to GMAC, before the work could commence.

The category of activities with GMOs that is now known as NLRDs has been based on the existing GMAC arrangements for Category B activities.

A number of the GMAC Category B activities have, however, been limited in terms of how they are expressed in the Regulations. It is therefore important that any organisation continuing work that was previously Category B, consult the Regulations to make sure that the work is a NLRD. Further information is provided below

regarding the transitional arrangements for work that was previously Category B and is not a NLRD with a GMO.

IMPORTANT NOTE

Please note that the Regulator will be issuing further Guidelines for work with toxins, work with hazardous fragments of DNA and work involving GM viruses for gene transfer into animal and human cells. These will be available as an Appendix to this Handbook and also from the OGTR and the OGTR website.

BOX 5: Notifiable low risk dealings with GMOs

The following kinds of dealings are notifiable low risk dealings:

Item a

- (a) any dealing involving whole animals (including non-vertebrates) that:
- (i) involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and
 - (ii) does not involve gene-knockout mice.

Guidance Notes:

Dealings with GMOs only fall within this category of NLRDs if:

- the dealings involve whole animals that are GMOs because of modification of the genome of the oocyte or zygote or early embryo;
- they do not also fall within Part 2 of Schedule 3 (as set out in Box 6). For example, the dealings with the GMO will not be NLRDs if the dealings involve a viral vector to produce a transgenic animal that secretes or produces recombinant viral agents.

Gene-knock out mice do not fall within this category of NLRD because they will either:

- be exempt (if no advantage is conferred on the adult animal); or
- require licensing by the Regulator if an advantage is conferred on the adult animal.

Item b

- (b) any dealing involving a genetically modified flowering plant, if:
- (i) the dealing does not involve the plant being grown to flowering stage; or
 - (ii) for a dealing that does involve the plant being grown to flowering stage:
 - (A) the plant is male sterile and is unable to set seed; or
 - (B) if the plant is male sterile and can set seed – all vents and drains in the facility are screened with mesh or filters that block the escape of viable pollen and seed; or
 - (C) before flowering, all inflorescences are wholly enclosed in bags designed to prevent escape of viable pollen and seed; or
 - (D) if the plant can be wind-pollinated – all vents and drains in the facility are screened with mesh or filters that block the escape of viable pollen and seed; or
 - (E) if the plant can be vector-pollinated only – all vents and drains in the facility are screened with mesh or filters that block the escape of viable seed and exclude pollen vectors from the facility.

Examples:

As an example, if work involves canola being grown to flowering stage, then provided the plant is not male sterile and can set seed and can be vector pollinated only, the work will only be a NLRD if either inflorescences are bagged as per condition (C) or all vents and drains are screened to prevent seed escaping and exclude pollen vectors as per condition (E).

If *Arabidopsis thaliana* is being grown, while it is predominantly self-pollinating, there is a finite possibility of it being wind pollinated therefore either conditions (C) or (D) must be met to prevent pollen and seed escaping. Plants that are non-flowering including gymnosperms (such as conifers), ferns, fungi, mosses and lichens are not NLRDs and a licence must be held in order to undertake the work.

Guidance notes:

Dealings with GMOs only fall within this category of NLRDs if:

- the dealings involve a GM flowering plant; and
- the dealings do not involve the plant being grown to flowering stage OR if the plant is grown to flowering stage, the appropriate precaution for the particular type of flowering plant is adopted (as detailed at A-D). It is important that observance of the appropriate requirement detailed at A-D is in addition to the general requirements that the work be conducted in a PC2 facility; and
- the dealings do not also fall within Part 2 of Schedule 3 (as set out in Box 6). For example, the dealings with the GMO will not be NLRDs if the dealings involve:
 - cloning or transfer of fragments of a viral or viroid genome that is capable, in the host vector system to be used, of giving rise to infectious agents that are capable of infecting cells of human, animal, plant or fungal origin;
 - recombination between whole viral genomes, viroids, or complementing fragments of such genomes (if one or more fragments contain virulence or pathogenic determinants).
 - the use of a viral vector (except a vector that is used in the dealing as part of a host/vector system mentioned in Part 2 of Schedule 2) containing one or more inserted sequences, that codes for a product known to play a role in the regulation of cellular growth or to be toxic to mammalian cells; or
 - the production of dangerous toxins, for example, if it produces toxins of low toxicity in large quantities or if the gene encodes a highly toxic toxin; and
- the dealings do not involve an intentional release of a GMO into the environment. That is, this category of NLRD does not apply to field trials of GM plants.

Please note that there is an error in (b)(ii)(A). A plant that is male sterile cannot produce viable pollen and as such the requirement for screening relates only to the blocking of seed and not viable pollen.

Item c

- (c) any dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if:
- (i) the host is incapable of causing disease in human beings, animals, plants or fungi; and
 - (ii) the vector is incapable of causing disease in human beings, animals, plants or fungi.

Guidance notes:

Dealings with GMOs only fall within this category of NLRDs if:

- the dealings involve a host and vector that are not mentioned in Part 2 of Schedule 1 (refer Box 4); and
- both the host and the vector are incapable of causing disease in human beings, animals, plants or fungi; and
- the dealings do not also fall within Part 2 of Schedule 3 (as set out in Box 6). For example, the dealings with the GMO will not be NLRDs if the dealings involve:

- the use of a viral vector (except a vector that is used in the dealing as part of a host/vector system mentioned in Part 2 of Schedule 2) containing one or more inserted sequences, that codes for a product known to play a role in the regulation of cellular growth or to be toxic to mammalian cells; or
- the production of dangerous toxins, for example, if it produces toxins of low toxicity in large quantities or if the gene encodes a highly toxic toxin; and
- the dealings do not involve the intentional release of the GMO into the environment.

Item d

- (d) any dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if, although the host or vector is capable of causing disease in human beings, animals, plants or fungi, the donor DNA is fully characterised and will not increase the virulence of the host or vector.

Guidance notes:

Dealings with GMOs only fall within this category of NLRDs if:

- the dealings involve a host and vector that are not mentioned in Part 2 of Schedule 2 (refer Box 4); and
- the donor DNA is fully characterised; and
- the donor DNA will not increase the virulence of the host or vector; and
- the dealings do not also fall within Part 2 of Schedule 3 (as set out in Box 6). For example, the dealings with the GMO will not be NLRDs if the dealings involve:
 - the introduction into a microorganism of genes that determine pathogenicity; or
 - cloning or transfer of fragments of a viral or viroid genome that is capable, in the host/vector system to be used, of giving rise to infectious agents that are capable of infecting cells of human, animal, plant or fungal origin; or
 - recombination between whole viral genomes, viroids, or complementing fragments of such genomes (if one or more fragments contain virulence or pathogenic determinants).
 - the use of a viral vector (except a vector that is used in the dealing as part of a host/vector system mentioned in Part 2 of Schedule 2) containing one or more inserted sequences, that codes for a product known to play a role in the regulation of cellular growth or to be toxic to mammalian cells; or
 - the production of dangerous toxins, for example if it produces toxins of low toxicity in large quantities or if the gene encodes a highly toxic toxin; and
- the dealings do not involve an intentional release of a GMO into the environment.

Item e

- (e) any dealing involving a host/vector system mentioned in Part 2 Schedule 2, if the gene inserted:
- (i) is a pathogenic determinant; or
 - (ii) is uncharacterised DNA from a micro-organism that is capable of causing disease in human beings, animals, plants or fungi; or
 - (iii) is an oncogene

Guidance notes:

Dealings with GMOs only fall within this category of NLRDs if:

- the dealings involve a host/vector system mentioned in Part 2 of Schedule 2 (refer Box 4); and
- the gene inserted is a pathogenic determinant, is uncharacterised DNA from a micro-organism that is capable of causing disease in human beings, animals, plants or fungi or is an oncogene; and
- the dealings do not also fall within Part 2 of Schedule 3 (as set out in Box 6). For example, the dealings with the GMO will not be NLRDs if the dealings involve:
 - cloning or transfer of fragments of a viral or viroid genome that is capable, in the host/vector system to be used, of giving rise to infectious agents that are capable of infecting cells of human, animal, plant or fungal origin; or
 - recombination between whole viral genomes, viroids, or complementing fragments of such genomes (if one or more fragments contain virulence or pathogenic determinants); or
 - the use of a viral vector (except a vector that is used in the dealing as part of a host/vector system mentioned in Part 2 of Schedule 2) containing one or more inserted sequences, that codes for a product known to play a role in the regulation of cellular growth or to be toxic to mammalian cells; or
 - the production of dangerous toxins, for example if it produces toxins of low toxicity in large quantities or if the gene encodes a highly toxic toxin; or
 - the cloning of uncharacterised DNA from toxin producing microorganisms; and
- the dealing does not involve an intentional release of a GMO into the environment.

BOX 6: DEALINGS (HIGHER RISK) THAT ARE NOT NOTIFIABLE LOW RISK DEALINGS

A dealing of any of the following kinds, or involving a dealing of the following kinds, is not a notifiable low risk dealing:

- (a) a dealing involving cloning of DNA encoding a toxin for vertebrates having an LD50 of less than 100 µg/kg;
- (b) a dealing involving high level expression of toxin genes, even if the LD50 is greater than 100 µg/kg;
- (c) a dealing involving cloning of uncharacterized DNA from toxin-producing micro-organisms;
- (d) a dealing involving a viral vector (except a vector that is used in the dealing as part of a host/vector system mentioned in Part 2 of Schedule 2), containing one or more inserted sequences, that codes for a product known to play a role in the regulation of cellular growth or to be toxic to mammalian cells;
- (e) a dealing involving, as host or vector, a micro-organism that is capable of causing disease in humans, animals, plants or fungi, unless:
 - (i) the host/vector system is a system mentioned in Part 2 of Schedule 2; or
 - (ii) the dealing involves only the cloning of DNA that is fully characterised and is known not to increase the virulence of the host and vector;
- (f) a dealing involving the introduction into a micro-organism, other than a host mentioned in Part 2 of Schedule 2, of genes that determine pathogenicity;
- (g) a dealing involving the introduction into a micro-organism, other than a host mentioned in Part 2 of Schedule 2, of genes whose expressed products have a heightened risk of inducing an autoimmune response;
- (h) a dealing involving cloning or transfer of fragments of a viral or viroid genome that are capable, in the host/vector system to be used, of giving rise to infectious agents that are capable of infecting cells of human, animal, plant or fungal origin;
- (i) a dealing involving recombination between whole viral genomes, viroids or complementing fragments of such genomes (if one or more fragments contain virulence or pathogenic determinants);
- (j) a dealing involving use of a viral vector to produce a transgenic animal, plant or fungus that secretes or produces infectious recombinant viral agents;
- (k) a dealing involving the production of more than 10 litres of GMO culture;
- (l) a dealing that is inconsistent with a policy principle issued by the Ministerial Council.

Part B: Transitional arrangements for work commenced before 21 June 2001 as GMAC Category B work

How do the transitional arrangements operate for work commenced before 21 June 2001 as GMAC Category B?

To minimise disruptions flowing from the commencement of the new system, the legislation describes transitional arrangements in relation to dealings with GMOs that were previously GMAC Category B.

The legislation provides that rather than going through the usual process of notifying the Regulator before work with NLRDs may commence (as described in Part C of this Chapter), work may proceed as an NLRD if the organisation has a notice from GMAC in relation to the NLRDs and certain other criteria are met as described below.

What do I have to do to make sure that I come within the transitional arrangements for NLRDs?

You must check that:

- you have a notice from IOGTR (on behalf of GMAC) in relation to dealings with GMOs that you are proposing to continue after 21 June 2001; and
- the work falls within the list of NLRDs in Part 1 of Schedule 3 of the Regulations (as described in Box 5); and
- the work does not also fall within Part 2 of Schedule 3 (as described in Box 6). If the work falls within Part 2 of Schedule 3 then the work is not a NLRD and must be licensed by the Regulator.

Unless all of these preconditions are met, you must not continue the work after 21 June 2001 without a licence from the Regulator.

If you have any queries you should contact your IBC or the OGTR.

What conditions must I comply with while I am undertaking NLRDs with GMOs under a notice issued by GMAC?

At any time that you are conducting NLRDs with GMOs you must ensure that;

- the dealings are conducted within a contained facility certified to at least PC2, and of appropriate design for containing the type of GMO proposed (or otherwise certified by the Regulator as being suitable for containing the particular GMO); and
- the dealings are properly supervised (for example by the Accredited Organisation or IBC within which the work is conducted), and a record of the details of the dealings retained; and
- any transport of the GMO is conducted in accordance with the Regulator's *Guidelines for the Transport of GMOs*. A copy of the Guidelines is included as an Appendix to this Handbook and is available from the OGTR or the Regulator's website; and
- if the dealing involves organisms that may produce disease in humans, the NLRDs must be conducted in accordance with vaccination requirements set out in the Australian Standard AS/NZS2243.3:1995 (Safety in laboratories: microbiology).

Please note that you will also need to comply with any other relevant State or Commonwealth laws. For example, if you are working with animals you will be required to comply with relevant State/Territory animal welfare legislation and may require approval from an Animal Ethics Committee.

How long will the transitional arrangements operate for?

The notice from GMAC will be valid for up to two years, during which time you will have to re-notify the Regulator of the NLRDs if you are planning to continue them after 20 June 2003.

It is anticipated that during the second year of the new system, that is from July 2002, the Regulator will

commence a rolling schedule of re-notification of NLRDs. The OGTR will advise you about when you are expected to re-notify NLRDs. The process for re-notification will mirror that described below in relation to new NLRDs.

Part C: Requirements for NLRDs proposed to commence after 21 June 2001

Relevant provisions of the GT Regulations
Regulation 13 –
Requirements in relation to notifiable low risk dealings

What steps must I take in order to undertake NLRDs with GMOs?

Step 1 - Check to make sure that:

- the work you are proposing to undertake falls within the list of NLRDs in Part 1 of Schedule 3 of the Regulations (as described in Box 5) ;
- the work does not also fall within Part 2 of Schedule 3 (as described in Box 6). If the work falls within Part 2 of Schedule 3 then the work is not a NLRD and must be licensed by the Regulator; and
- the work does not involve the intentional release of a GMO into the environment.

If one or more of these requirements is not satisfied then the work proposed to be undertaken is not a NLRD with a GMO and an application must be made to the Regulator for a licence to undertake the work before dealings with the GMO commence.

Step 2 – Prepare detailed information about the proposed dealings with the GMO in accordance with the Regulator’s information requirements as set out in Part 3 of Schedule 3 of the Regulations. Notification forms detailing the required information are included in Appendix 1 of this Handbook (printed on beige paper) and are available from the OGTR or from the Regulator’s website.



IMPORTANT NOTE

For the purposes of completing the form, the proponent organisation will be the Accredited Organisation and the proponent’s project supervisor will be the person proposing to undertake the NLRDs or oversee the conduct of the NLRDs.

Step 3 – Once the notification form has been completed it must be submitted to the relevant IBC (the IBC for the Accredited Organisation). The IBC will check the

information that has been prepared and append supporting information to the notification.

Step 4 – Once the IBC has completed its evaluation, the IBC will, within 14 days of the IBC's assessment, provide the information contained in the notification, including the IBC's supporting information, to the Regulator.

Step 5 – NLRDs with the GMO may commence only once the proponent's project supervisor has received written notification from the IBC that a notification has been provided to the Regulator. NLRDs with GMOs MUST NOT commence without this notice from the IBC.

What conditions must be complied with for the conduct of NLRDs with GMOs?

At any time that a person is conducting NLRDs with GMOs the person must ensure that:

- the dealings are conducted within a contained facility certified to at least PC2 and of appropriate design for containing the type of GMO proposed (or otherwise certified by the Regulator as being suitable for containing the particular GMO); and
- the dealings are properly supervised (for example, by the Accredited Organisation or IBC within which the work is conducted), and a record of the details of the dealings retained; and
- any transport of the GMO is conducted in accordance with the Regulator's *Guidelines for the Transport of GMOs* (a copy of the Guidelines is included as an Appendix to this Handbook, is available from the OGTR or the Regulator's website); and
- if the dealing involves organisms that may produce disease in humans, the NLRDs must be conducted in accordance with vaccination requirements set out in the Australian Standard AS/NZA2243:3:1995 (Safety in laboratories: microbiology).

Part D: Responsibilities of the Regulator

What will the Regulator do in relation to NLRDs?

Once the relevant IBC has notified the Regulator about the NLRD (and all of the supporting information has been submitted to the Regulator), the Regulator will examine this to ensure that the work has been correctly classified by the proponent organisation and the IBC.

If the Regulator has any concerns, he/she may contact the relevant IBC or project supervisor to seek clarification of any matters or to request further information.

If the work has been incorrectly classified, the Regulator can direct that the work cease and that the proponent apply to the Regulator for a licence to undertake the work.

As detailed in Chapter 17, the Accredited Organisation will also be required to report on the NLRDs annually to the Regulator. The Regulator will review such reports to ensure that everything is in order.


Will the Regulator monitor compliance with the conditions of NLRDs?


Yes. For more information regarding the way that the Regulator will monitor compliance and the remedies available to the Regulator in the event of non-compliance, please refer to Chapter 17 of this Handbook.

Checklist for NLRDs with GMOs

- Check to make sure that the dealing with the GMO is on the list of NLRDs in Part 1 of Schedule 3 of the GT Regulations (as described in Box 5 of this Handbook).
- Check to make sure that the dealings with the GMO are NOT on the list of dealings in Part 2 of Schedule 3 of the GT Regulations (as described in Box 6). If the dealings with the GMO are on this list then the work is NOT an NLRD and must be licensed by the Regulator (refer Chapter 6 of this Handbook).
- Check to make sure that the dealings with the GMO do not involve the intentional release of a GMO into the environment.
- Complete the form for the “Notification of a NLRD”. The form is available at Appendix 1 to this Handbook and is printed on beige paper. The form is also available from the OGTR or from the Regulator’s website.
- Submit the “Notification” form to the relevant IBC (for the Accredited Organisation). The IBC must complete certain information on the form and include supporting information. The form must also be signed by the project supervisor, the Chair of the IBC and the CEO (or delegate) of the Accredited Organisation.
- Once the form is completed, the IBC must forward the entire completed form to the Regulator within 14 days of the IBC’s evaluation (and completion of the relevant information on the form). The IBC must notify the project supervisor, in writing, that the notification form has been sent to the Regulator.
- If the project supervisor has received advice from the IBC that the notification form has been sent to the Regulator, work with the GMOs may commence PROVIDED that the conditions for NLRDs are complied with.
- NLRDs, when undertaken, must comply with the following requirements:
 - the NLRDs must be conducted in a facility certified by the Regulator to at least PC2 and of appropriate design for containing the particular type of GMO;

- the dealings must be properly supervised and a record of the details of the dealings retained;
- any transport of the GMO must be conducted in accordance with the Regulator's *Guidelines for the Transport of GMOs*; and
- if the dealing involves organisms that may produce disease in humans, the NLRDs must be conducted in accordance with the vaccination requirements set out in the Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology).

 The Accredited Organisation (usually through the IBC) will be required to report annually to the OGTR about NLRDs with GMOs (refer Chapter 17 of this Handbook for information about reporting requirements). Project supervisors must inform the IBC if the work with GMOs (NLRDs) is completed or abandoned.

 If you have any queries or concerns at any time, please contact the OGTR on 1800 181 030.

CHAPTER 6

LICENSED DEALINGS WITH GMOs NOT INVOLVING THE INTENTIONAL RELEASE OF A GMO INTO THE ENVIRONMENT

Part A: Types of dealings with GMOs that must be licensed by the Regulator

What dealings with GMOs must be licensed by the Regulator?

All dealings with GMOs that are not exempt dealings, NLRDs or on the GMO Register, must be licensed by the Regulator.

There are two types of licence that may be sought depending on the type of dealings with GMOs that are proposed:

- a licence for dealings not involving the intentional release of a GMO into the environment (typically laboratory-based research projects); and
- a licence for dealings involving the intentional release of a GMO into the environment.

Section 10 of the GT Act defines “intentional release of a GMO into the environment”. A dealing with a GMO involves the intentional release of a GMO into the environment if the GMO is intentionally released into the open environment, whether or not it is released with provision for limiting the dissemination or persistence of the GMO or its genetic material in the environment.

In essence, what this means is that if you are proposing to undertake work within a certified facility (so that the GMO is physically contained and is not released into the environment), you should apply for a licence in accordance with this Part.

If you are proposing to release the GMO into the environment (for example, a field trial of a crop or a commercial release of a GMO), you should apply for a licence of the type described in Part 7 of this Chapter.

How does this differ from the former GMAC system?

Under the GMAC system, there were three categories of work that required consideration and approval from GMAC:

- Category A work as described in the *GMAC Guidelines for Small Scale Genetic Manipulation Work*;
- Work involving unintentional release of a GMO into the environment; and
- Field Trials and General (commercial) release.

Category A work (small and large scale) is now required to be licensed as work not involving intentional release of the GMO into the environment. Conditions will be applied by the Regulator to ensure that the GMO is not unintentionally released.

Work that was previously categorised as involving unintentional release of a GMO into the environment may be licensed either as dealings involving intentional release of a GMO or dealings that do not involve the intentional release of a GMO into the environment. This will depend on whether the GMO can be effectively contained to ensure that it is not inadvertently released into the environment. If such work is proposed, the proponent should contact the OGTR for further advice.

Work that was previously categorised as field trials or as the general (commercial) release of a GMO will be required to be licensed as work that involves the intentional release of a GMO into the environment (refer Chapter 7).

Part B: Transitional arrangements for work commenced before 21 June 2001 and approved by GMAC

What are the transitional arrangements for dealings with GMOs that commenced prior to 21 June 2001 with approval from GMAC?

To minimise disruptions flowing from the commencement of the new system, the legislation describes transitional arrangements in relation to dealings with GMOs that are covered by a “GMAC advice to proceed” issued by the GMAC before the commencement of the legislation.

If a “GMAC advice to proceed” has been issued by the GMAC in respect of certain dealings with GMOs, the advice to proceed is taken, for the purposes of the legislation, to be a licence. This is sometimes referred to as a “deemed” licence.

How will I know if the dealings with GMOs that I am undertaking have been “deemed” to be licensed under the Act?

In May 2001 the IOGTR, on behalf of GMAC, wrote to all organisations undertaking work that was classified by GMAC as either Category A (small and large scale) work or work with GMOs involving unintentional release.

The information from the IOGTR included:

- a letter explaining the transitional arrangements for existing work with GMOs that does not involve the intentional release of a GMO into the environment;
- a summary of information that the GMAC/IOGTR holds regarding the dealings with the GMO;
- a draft “GMAC Advice to Proceed”, including the conditions of the advice to proceed (that is a draft “deemed” licence); and
- a request for certain supplementary information.

In June 2001 the IOGTR (on behalf of GMAC) issued the final “GMAC Advice to Proceeds”. In effect, the “GMAC Advice to Proceed” is a licence under the new regulatory system.

How long will the “deemed” licences last?

The “GMAC Advice to Proceed” or “deemed” licences will operate for up to two years, during which time organisations will have to re-apply for a licence in accordance with the Regulator’s application requirements, if they wish to continue dealings with the GMO after 20 June 2003.

It is anticipated that during the second year of the operation of the new system (from July 2002) the Regulator will commence a rolling schedule of reassessment of “deemed” licences. Organisations will be notified and advised about when they are expected to reapply for a licence.

It is likely that a quarter of all organisations will be requested to reapply by August 2002, another quarter by October 2002, another quarter by December 2002 and another quarter by February 2003. There will be no disadvantage to those organisations expected to reapply earliest, as all organisations will be reapplying before the commencement of any cost recovery regime, and before the imposition of any fees for licences.

What conditions apply to “deemed” licences/ “GMAC Advice to Proceed”?

During the transitional period of two years, the holder of a GMAC Advice to Proceed (and persons covered by the GMAC Advice to Proceed) must observe the conditions contained in the GMAC Advice to Proceed.



IMPORTANT NOTE

If you are undertaking dealings with GMOs in accordance with a GMAC Advice to Proceed (a “deemed” licence under the transitional arrangements), you must check the details of the GMAC Advice to Proceed to make sure that you are complying with all of the conditions detailed in the advice.

FEES AND COST RECOVERY
The Commonwealth Government has agreed to postpone any cost recovery of the new regulatory scheme for two years, until 20 June 2003. Consultation on arrangements to take effect from 21 June 2003 will commence in 2002.

Who must comply with the conditions contained in the GMAC Advice to Proceed?

The holder of the GMAC Advice to Proceed and all persons covered by the GMAC Advice to Proceed must comply with the conditions prescribed in the advice.

The GMAC Advice to Proceed describes the persons covered by the advice. In most cases, this is the holder of the GMAC Advice to Proceed, the project supervisor and anyone authorised by the holder of the GMAC Advice to Proceed or the project supervisor.

Part C: **Applying for a licence after 21 June 2001**

Who should apply for a licence?

Generally speaking, the licence applicant will be an Accredited Organisation as opposed to an individual researcher. An Accredited Organisation is one that has been accredited by the Regulator having satisfied certain criteria, including in relation to having access to a properly constituted IBC.

For more information regarding the Accreditation of Organisations, please refer to Chapter 10 of this Handbook or the Regulator's *Guidelines for the Accreditation of Organisations*.



IMPORTANT NOTE

This is one key difference between the former GMAC system of controls on GMOs and the new regulatory system. In the past individual researchers often made applications to GMAC for approval of certain work. Under the new regulatory system, applications should be made by the Accredited Organisation within which the individual researcher works. If granted, the licence holder would be the Accredited Organisation and the licence would “cover” certain persons or classes of persons, including the project supervisor or principal researcher.

How does an organisation apply for a licence from the Regulator to undertake dealings with a GMO that do not involve the intentional release of a GMO into the environment?

Step 1 - Prepare a package of information in accordance with the Regulator's information requirements detailed in Part 1 of Schedule 4 of the GT Regulations. Application forms are available from the OGTR or from the Regulator's website.

Step 2 – Once the application has been prepared, the application must be submitted to the Organisation's IBC for consideration.

Step 3 – Once the IBC has considered the application they will need to append supporting information to the application. Details of the supporting information required is included in Part 1 of Schedule 4 and will also be included on the application forms.

Step 4 - The application must be signed by the Chair of the IBC. The application must also be signed by the CEO or delegate of the Organisation and by the project supervisor.

Step 5 – Once all of the information required by the Regulator has been completed, the application may be forwarded to the Regulator. A copy of the application must be retained by the Organisation. Please note that Organisations may also have internal clearance processes to be complied with before the application is forwarded to the Regulator.



IMPORTANT NOTE

You will also need to comply with any other relevant State or Commonwealth laws. For example, if you are working with animals you will be required to comply with relevant State/Territory animal welfare legislation and may require approval from an Animal Ethics Committee.

What if the application contains confidential commercial information?

If the application contains confidential commercial information, the applicant may include with the application for a licence, an application for a declaration that certain information contained in the application is confidential commercial information. For more information regarding how to apply for a declaration that information is confidential commercial information, please refer to Chapter 15 of this Handbook.

Part D: The Regulator's assessment process

What does the Regulator do when he/she receives an application?

The Regulator undertakes an initial screening of the application before accepting the application. This initial screening involves checking 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. For more information about policy principles, refer Part B of Chapter 1.

If the application does not contain the necessary information or is inconsistent with a policy principle, the Regulator is not required to consider the application.

If the Regulator is satisfied that the application meets his/her basic requirements, the Regulator may proceed to assess the application.

How does the Regulator assess the application?

The Regulator assesses the application by preparing a risk assessment and risk management plan.

The preparation of the risk assessment involves identifying any hazards that may be posed by the GMO and the level of risk posed by such hazards based on an assessment of the likelihood and consequence of the hazard occurring.

The risk management plan details how any risks posed by the GMO may be able to be managed to ensure that unacceptable risks are not realised. For more information regarding risk assessment and risk management plans, please refer to the Regulator's *Risk Analysis Framework for Licence Applications before the Office of the Gene Technology Regulator*. A copy of the Framework is included as an Appendix to this Handbook or is available as a stand-alone document from the OGTR or the Regulator's website.

Does the Regulator undertake any consultation on the application?

In preparing the risk assessment and risk management plan, the Regulator may seek the advice of the Gene Technology Technical Advisory Committee, State, Territory and Commonwealth agencies or any other person that the Regulator considers necessary.

Based on the experience of GMAC, it is expected that the Regulator will receive approximately 350-400 applications per year for a licence for dealings with GMOs that do not involve the intentional release of a GMO into the environment.

The Regulator will seek the advice of the Gene Technology Technical Advisory Committee in relation to licence applications for contained work. If the Committee does not consider that it has adequate expertise to advise on a particular application, the Committee will seek the assistance of relevant experts to inform their advice to the Regulator.

What if the Regulator requires further information from the applicant?

The Regulator may at any time request further information from the applicant. This will be done by way of written notice from the Regulator to the applicant. The written notice will include details of the information that the Regulator requires and the timeframe within which the Regulator requires such information.

The timeframe in which the Regulator must consider the application is suspended while the Regulator is awaiting further information from the applicant.

If the applicant does not provide the further information within the specified timeframe, the Regulator may refuse to further consider the application.

What does the Regulator need to take into account when making his/her decision?

After preparing the risk assessment and risk management plan (and taking all other necessary steps), the Regulator must make a decision on the application.

The Regulator must not issue a licence unless he/she is satisfied that any risks posed by the dealings to be authorised by the licence can be managed in a way which protects public health and safety and the environment.

In addition, the Regulator must not issue a licence:

- if the issuing of a licence would be inconsistent with a policy principle issued by the Ministerial Council; and
- unless the Regulator is satisfied that the applicant is a suitable person to hold a licence. In assessing the suitability of the applicant, the Regulator will look 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 applicant to meet any proposed licence conditions.

After taking all the relevant matters into account, the Regulator will make a decision. The Regulator may refuse to issue a licence or may issue the licence subject to certain conditions.

What conditions of licence will be applied by the Regulator?

Conditions that will be applied to all licences

All licences issued by the Regulator will be subject to the statutory conditions that are set out in the GT Act. These conditions apply to all licences issued by the Regulator.

The conditions in the GT Act 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 Regulator, or a person authorised by the Regulator, to enter premises for the purposes of auditing and monitoring; and
- inform the Regulator of any additional information that becomes available regarding risks to public health and safety and the environment or contraventions of the legislation.

In addition the Regulations may set out conditions that are applied to all (or certain subsets) of licences. At the commencement of the legislation the Regulations do not prescribe any such conditions.

Conditions that will be likely to be applied to all licences

As a matter of policy, in most cases, the Regulator will apply the following conditions:

- that the holder of the licence be an Accredited Organisation. For more information about the Accreditation of Organisations, please refer to the Regulator's *Guidelines for the Accreditation of Organisations* or Chapter 10 of this Handbook;
- conditions relating to the transport of the GMO, if transport is proposed as one of the dealings with the GMO. The Regulator has issued *Guidelines for the Transport of GMOs*. These Guidelines include standard conditions for the transport of various type of GMOs. The Regulator may require as a condition of licence that these Guidelines be complied with. Alternately, the Regulator may apply additional or different conditions for the transport of GMOs if this is necessary based on the risks posed by the particular GMO. For more information about the requirements for the transport of GMOs, please refer to the Regulator's *Guidelines for the Transport of GMOs* that are included as an Appendix to this Handbook;
- that the work be conducted in a facility certified by the Regulator. For more information about the certification of facilities please refer to the Regulator's *Guidelines for the*

Certification of Facilities/Requirements for Physical Containment or Chapter 11 of this Handbook; and

- that the holder of the licence prepare and submit an annual report to the Regulator about the dealings with the GMO authorised by the licence. More information about the reporting requirements of licence holders is included in Chapter 17 of this Handbook.

Other conditions applied on a case-by-case basis

The Regulator may also impose any other conditions that are necessary to manage risk, as assessed on a case-by-case basis.

The Regulator may limit where the GMO is used, who uses the GMO and how it is used. For example, the Regulator may require specific containment measures, waste disposal methods and/or other reporting requirements.

How long will the Regulator take to make a decision?

The Regulations provide that the Regulator must issue, or refuse to issue, a licence within 90 days after the day of receipt of the application (for a licence that does not involve intentional release of a GMO into the environment).

The Regulations also provide for circumstances under which the minimum timeframes for considering the application will be suspended, and the permitted 90 days will be adjusted upward as necessary.

The time for considering the application will be suspended when the Regulator:

- is waiting for further information which has been requested in writing from the applicant; or
- has called for a public hearing; or
- is considering a request from the applicant that information provided by the applicant is confidential commercial information; or

- is seeking advice from the Gene Technology Ethics Committee (GTEC) on a relevant issue. The Regulator may specify a time period within which such advice is required and for the duration of that period, the timeframe for consideration of the application is suspended.

Saturdays, Sundays and public holidays in the Australian Capital Territory are not counted when calculating the proposed permitted time frames. In other words, only working days are counted for the purposes of determining the timeframe for the Regulator's assessment of an application.

How will the Regulator notify his/her decision to the applicant and to the public?

The GT Act provides that the Regulator must notify the applicant in writing of the Regulator's decision (including any conditions imposed by the Regulator, if applicable).

Relevant provision of the GT Act
Section 59 -
Notification of licence decision

If the Regulator issues a licence, the Regulator must also put certain details of the licence on the publicly available database of GMOs called the Record of GMOs and GM Product Dealings. For more information regarding the Record of GMOs and GM Product Dealings, please refer to Chapter 14.

Part E: Rights and responsibilities of licence holders

Can the licence applicant seek a review of a decision made by the Regulator?

Yes. If the Regulator refuses to grant an application, the licence applicant may seek review of the Regulator's decision. Alternately, if the Regulator grants the licence but imposes conditions that are not acceptable to the applicant, the applicant may seek review of the Regulator's decision to impose certain conditions.

Further information regarding rights of review are detailed in Chapter 16 of this Handbook.

If a licence has been granted, when can dealings with the GMO commence?

Dealings with the GMO may commence when the applicant receives notification from the Regulator, provided that any conditions imposed by the Regulator can also be complied with from the time of notification.

One very important condition that will be applied to all licences issued by the Regulator is that the licence holder must inform anyone covered by the licence of any conditions of the licence that relate to them. This is a minimum requirement. The Regulator may also impose additional conditions setting out how the licence holder must inform people covered by the licence of the relevant licence conditions, (for example, through labelling, training etc.).

If the Regulator has approved the dealings with the GMO, do I need approval from any other Regulator?

An approval from the Regulator does not give a licence holder an absolute right to undertake the work with the GMO.

Approvals from other Regulators may also be necessary depending on the particular dealings and the particular GMO.

Other approvals may be required from the relevant local council or State Government or from Commonwealth Government Regulators.

It is the responsibility of organisations dealing with GMOs to ensure that any other relevant Commonwealth, State or local government legislation is complied with.

Can a licence be varied once it has been issued by the Regulator?

Relevant provisions of the GT Act

Section 71 – Variation of licence

Yes. The GT Act provides that the Regulator may at any time, by notice in writing given to the licence holder, vary a licence.

The variation may be a minor one (for example, changing the contact details of the licence holder) or more significant (for example, imposing additional conditions or removing or varying conditions that were previously imposed by the Regulator).

The Regulator may vary a licence in one of two circumstances:

- if the licence holder applies to the Regulator for a variation of the licence; or
- if the Regulator decides that a variation is necessary.

The Act specifically provides, however, that the Regulator must not vary a licence so as to authorise dealings involving the intentional release of a GMO into the environment if the original licence (in relation to which the variation is sought) is a licence for dealings with a GMO that do not involve the intentional release of a GMO into the environment.

Before the Regulator can unilaterally vary a licence, the Regulator must give written notice of the proposed variation to the licence holder.

Relevant provisions of the GT Act

Section 72 – Regulator to notify of proposed variation

The notice may request relevant information from the organisation and must invite a written submission from the licence holder, within a designated timeframe. The Regulator must consider any written submissions made.

The requirement that the Regulator provide prior notice of the variation to the licence holder may be waived where the Regulator considers that the action is necessary to avoid an imminent risk of death, serious illness, serious injury or serious damage to the environment.

Checklist for Licensed Dealings with GMOs Not Involving Intentional Release of the GMO Into the Environment

- Check to see if the proposed dealings with the GMO are on the list of exempt dealings with GMOs, on the list of NLRDs or on the GMO Register. If the proposed dealings with the GMO are not exempt, NLRDs or on the GMO Register, the proposed dealings with the GMO must be licensed by the Regulator before work may commence.
- If the dealings with the GMO do not involve the intentional release of a GMO into the environment, the application form entitled “Application for licence for dealings with a GMO not involving intentional release of a GMO into the environment (Contained dealings)” must be completed. The form is included at Appendix 1 of this Handbook (printed on white paper) or is available from the OGTR or from the Regulator’s website.
- Submit the completed application form to the relevant IBC. The IBC must complete certain information on the form and include supporting information. The form must also be signed by the project supervisor, the Chair of the IBC and the CEO (or delegate) of the Organisation.
- If there is any information in the application that is considered to be confidential commercial information, an application should also be made to the Regulator for a declaration that such information is confidential commercial information. A separate application form must be submitted to the Regulator for such a declaration. A copy of the application form for a declaration for confidential commercial information is included at Appendix 1 of this Handbook or is available from the OGTR or from the Regulator’s website. For more information about applying for a declaration in relation to confidential commercial information please refer to Chapter 15 of this Handbook.
- Once the licence application form is completed (and, if relevant, the application for a declaration in relation to confidential commercial information) and signed by all relevant parties, it may be submitted to the Regulator. Remember to keep a copy of the full application within the Organisation.

- During assessment of the application, the Regulator may request further information from the applicant.
- Dealings with the GMO must not commence unless the applicant has received written notification that the application has been approved and has received a licence from the Regulator. The licence will detail a number of conditions that must be complied with in relation to the dealings with the GMO. These conditions must be complied with.
- The licence holder (usually through the IBC) will be required to report annually to the OGTR about licenses for dealings with GMOs (refer Chapter 17 of this Handbook for information about reporting requirements). Project supervisors must inform the IBC if the licensed work with GMOs is completed or abandoned.
- If you have any queries or concerns at any time, please contact the OGTR on 1800 181 030.

CHAPTER 7

LICENSED DEALINGS WITH GMOs INVOLVING THE INTENTIONAL RELEASE OF A GMO INTO THE ENVIRONMENT

Part A: **Types of dealings with GMOs that must be licensed by the Regulator**

What dealings with GMOs must be licensed by the Regulator?

All dealings with GMOs that are not exempt dealings, NLRDs or on the GMO Register, must be licensed by the Regulator.

This Part relates to licences for dealings with GMOs that involve the intentional release of a GMO into the environment.

Section 10 of the GT Act defines “intentional release of a GMO into the environment”. A dealing with a GMO involves the intentional release of a GMO into the environment if the GMO is intentionally released into the open environment, whether or not it is released with provision for limiting the dissemination or persistence of the GMO or its genetic material in the environment.

If you are proposing to release the GMO into the environment you should apply for a licence of the type described in this Part.

For example, you must seek a licence under this Part if you are proposing to:

- grow a GM crop in a field as part of a field trial;
- grow a GM crop commercially;
- release a GM fish into a waterway; or

- release a GM micro-organism into the environment (by way of bio-remediation).

Does this Chapter apply to field trials of GMOs and also commercial releases of GMOs?

Yes. Under the new regulatory scheme, there is no distinction between field trials and commercial releases of GMOs in terms of the type of licence that must be sought.

Either type of release of the GMO must be licensed by the Regulator as dealings with a GMO involving intentional release of the GMO into the environment.

While the licence application process is the same for both types of dealings with GMOs, the Regulator's assessment processes, and conditions applied to the license, will differ.

For example, if an applicant is applying for a licence to test a particular GMO in the field (as opposed to in a laboratory or a glasshouse), the Regulator will need to be satisfied that there are certain mechanisms in place to ensure that there is no dissemination of the GMO or of its genetic material from the trial site and into the broader environment.

For example, the Regulator may apply conditions:

- limiting the geographic area, and size of the trial, in which the GMO may be released;
- requiring isolation zones to be in place to separate the GM crop from other like crops;
- requiring monitoring of the trial site and the surrounding area at regular intervals to ensure that the GMO has not spread beyond the trial site area; and
- requiring post-trial monitoring of the trial site to ensure that the GMO that has been the subject of the trial does not persist in the environment beyond the period of the trial.

If an applicant is applying to commercially release a GMO in Australia, the Regulator must be satisfied that the safety of the GMO has been tested in Australia through field trials of the GMO that have been subject to conditions to ensure that

the GMO, while being trialed, is not disseminated into the environment.

As such it is expected that before applying to the Regulator to commercially release a GMO throughout Australia (or in certain regions of Australia), the GMO will have been previously licensed by the Regulator as a field trial under strict conditions. The results of the field trials will be used by the Regulator as part of his/her assessment of whether it is safe for the GMO to be more generally commercially released in Australia.

Similarly if an organisation overseas wishes to import GMOs into Australia for commercial growing in the Australian environment, the Regulator would first require that field trials of the GMO be conducted under strict conditions to ensure that the GMO is safe to be commercially released in Australia. Information gained from the field trials (and information about the suitability of the applicant based on their conduct of the trials) would be used by the Regulator as part of his/her assessment of any subsequent application for commercial release of the GMO.

Part B: Transitional arrangements for work commenced before 21 June 2001 and approved by GMAC

What are the transitional arrangements for dealings with GMOs that commenced prior to 21 June 2001 with approval from GMAC?

To minimise disruptions flowing from the commencement of the new system, the legislation describes transitional arrangements in relation to dealings with GMOs that are covered by a “GMAC Advice to Proceed” issued by the GMAC before the commencement of the legislation.

If a “GMAC Advice to Proceed” has been issued by the GMAC in respect of certain dealings with GMOs, the GMAC Advice to Proceed is taken, for the purposes of the legislation, to be a licence. This is sometimes referred to as a “deemed” licence.

How will I know if the dealings with GMOs that I am undertaking have been “deemed” to be licensed under the Act?

In May 2001 the IOGTR, on behalf of GMAC, wrote to all organisations undertaking work that was classified by GMAC as either field trials or general (commercial) release.

The information from the IOGTR included:

- a letter explaining the transitional arrangements for existing work with GMOs that involves the intentional release of a GMO into the environment;
- a summary of information that the GMAC/IOGTR holds regarding the dealings with the GMO;
- a draft “GMAC Advice to Proceed”, including the conditions of the GMAC Advice to Proceed (that is, a draft “deemed” licence); and
- a request for certain supplementary information.

In June 2001 the IOGTR (on behalf of GMAC) issued final “GMAC Advices to Proceed”. In effect, these “GMAC Advices to Proceed” are licences under the new regulatory system.

How long will the “deemed” licences last?

The “GMAC Advices to Proceed” or “deemed” licences will operate for up to two years, during which time organisations will have to re-apply for a licence in accordance with the Regulator’s application requirements, if they wish to continue dealings with the GMO after 20 June 2003.

It is anticipated that during the second year of the operation of the new system (from July 2002), the Regulator will commence a rolling schedule of reassessment of “deemed” licences. Organisations will be notified and advised about when they are expected to reapply for a licence.

It is likely that a quarter of all organisations will be requested to reapply by August 2002, another quarter by October 2002, another quarter by December 2002, and another quarter by February 2003. There will be no disadvantage to those organisations expected to reapply earliest, as all organisations will be reapplying before the commencement of any cost recovery regime, and before the imposition of any fees for licences.

What conditions apply to “deemed” licences/ “GMAC Advice to Proceed”?

During the transitional period of two years, the holder of a GMAC Advice to Proceed (and persons covered by the GMAC Advice to Proceed) must observe the conditions contained in the GMAC Advice to Proceed.



IMPORTANT NOTE

If you are undertaking dealings with GMOs in accordance with a GMAC Advice to Proceed, you must check the GMAC Advice to Proceed to make sure that you are complying with any of the conditions detailed in the advice. Failure to comply with the conditions of the GMAC Advice to Proceed may attract penalties under the legislation.

FEES AND COST RECOVERY
The Commonwealth Government has agreed to postpone any cost recovery of the new regulatory scheme for two years, until 20 June 2003. Consultation on arrangements to take effect from 21 June 2003 will commence in 2002.

Who must comply with the conditions contained in the GMAC Advice to Proceed?

The holder of the GMAC Advice to Proceed and all persons covered by the GMAC Advice to Proceed must comply with any conditions prescribed in the advice.

The GMAC Advice to Proceed describes the persons covered by the advice. In most cases, this is anyone authorised by the holder of the GMAC Advice to Proceed or by the project supervisor.

Part C: **Applying for a licence after 21 June 2001**

Who should apply for a licence?

Generally speaking, the licence applicant will be an Accredited Organisation rather than an individual researcher or project supervisor. An Accredited Organisation is one that has been accredited by the Regulator after having satisfied certain criteria, including in relation to having access to a properly constituted IBC.

For more information regarding the Accreditation of Organisations, please refer to Chapter 10 of this Handbook or the Regulator's *Guidelines for the Accreditation of Organisations*.



IMPORTANT NOTE

This is one key difference between the former GMAC system of controls on GMOs and the new regulatory system. In the past, individual researchers often made applications to GMAC for approval of certain work. Under the new regulatory system, applications should be made by the Accredited Organisation within which the individual researcher works. If granted, the licence holder would be the Accredited Organisation and the licence would “cover” certain persons or classes of persons, including the project supervisor or principal researcher.

How does an organisation apply for a licence from the Regulator to undertake dealings with a GMO that involve the intentional release of a GMO into the environment?

Step 1 - Prepare a package of information in accordance with the Regulator's information requirements detailed in Part 2 of Schedule 4 of the GT Regulations. Application forms are included at Appendix 1 of this Handbook (printed on blue paper) and are available in hard copy from the OGTR or electronically from the Regulator's website.

Step 2 – Once the application has been prepared, the application must be submitted to the Organisation’s IBC for consideration.

Step 3 – Once the IBC has considered the application they will need to append supporting information to the application. Details of the supporting information required are included in Part 2 of Schedule 4 of the GT Regulations and are also included on the application forms.

Step 4 - The application must be signed by the Chair of the IBC and by the project supervisor. The application must also be signed by the CEO (or delegate) of the Accredited Organisation. The delegate of the CEO may be anyone that the organisation considers appropriate and who holds a delegation on behalf of the CEO. It is important that the CEO of the Organisation (or the CEO’s delegate) signs the application because the Accredited Organisation will be the licence holder and will have responsibilities under the licence. It is therefore important that the Organisation is fully cognisant of such obligations.

Step 5 – Once all of the information required by the Regulator has been completed, the application may be forwarded to the Regulator. A copy of the application must be retained by the Organisation. Please note that Organisations may also have internal clearance processes to be complied with before the application is forwarded to the Regulator.



IMPORTANT NOTE

You will also need to comply with any other relevant State or Commonwealth laws. For example, if you are working with animals you will be required to comply with relevant State/Territory animal welfare legislation and may require approval from an Animal Ethics Committee.

What if the application contains confidential commercial information?

If the application contains confidential commercial information, the applicant may include with the application for a licence, an application for a declaration that certain information contained in the application is confidential

commercial information. For more information regarding how to apply for a declaration that information is confidential commercial information, please refer to Chapter 15 of this Handbook. Application forms for declarations that information is confidential commercial information are available at Appendix 1 of this Handbook, from the OGTR, or from the Regulator's website.

Is a new application necessary each time a GMO is proposed to be released into the environment or can an existing approval be extended to include new work?

As part of an application for a licence involving the release of a GMO into the environment, the Regulator requires the applicant to submit information about the number of GMOs proposed to be released, the proposed number of releases, and the proposed commencement and completion date of the release(s).

If the Regulator approves the licence application, the Regulator may set conditions about the number of GMOs to be released, the size of the sites to be used, the location of the sites and the number of releases permitted.

If, having completed the release of the GMO in accordance with the conditions of the licence, the proponent wishes to undertake further releases of the GMO, the proponent must apply to the Regulator to do so.

If the proposed new release poses additional, new or different risks to the environment (for example, because the size of the release is to increase or the location of the release is to change), the proponent must submit to the Regulator a new application for licence. This is important because the Regulator must undertake a full assessment of the additional or different potential risks to the environment.

If, however, the proposed changes to the release are minor and do not pose any additional or different risks to the health and safety of people or to the environment, then the proponent may submit an application to the Regulator to vary an existing licence to enable the additional work to occur.

If the Regulator has any concerns about any additional or different risks that may be posed, as a result of the change to

the existing licence, the Regulator may reject an application for a variation to the licence and require the proponent to submit a full new licence application to the Regulator.

Example:

The Regulator may approve the field trial of a GMO on three sites in Victoria. If the proponent wishes to extend this approval to include 15 new sites in New South Wales and Queensland, the Regulator would probably require a new application to be submitted. This is because there would probably be environmental factors unique to New South Wales or Queensland that require a detailed consideration by the Regulator, before approval is granted. There may also be issues in terms of the applicant's capacity to manage a much larger trial of GMOs.

If, however, the applicant wishes to vary the existing licence to include one more site in the same region of Victoria, it may be appropriate for the proponent to apply to the Regulator for a variation of his/her existing licence, if no additional risks to the health and safety of people or the environment are posed as a result of the variation. The Regulator will examine this as part of his/her consideration of the proposed variation, and if the Regulator considers that there may be additional risks as a result of the change, a variation to the licence will not be permitted.

Part D: The Regulator's assessment process

What does the Regulator do when he/she receives an application?

The Regulator undertakes an initial screening of the application before accepting the application. This initial screening involves checking 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. For more information about policy principles, refer Part B of Chapter 1.

If the application does not contain the necessary information or is inconsistent with a policy principle, the Regulator is not required to consider the application.

If the Regulator is satisfied that the application meets his/her basic requirements, the Regulator may proceed to assess the application.

How does the Regulator assess the application?

Step 1 – Consideration of whether the proposed dealings with the GMO may pose significant risks to the environment or to the health and safety of people.

The Regulator must first consider whether the proposed dealings with the GMO may have a significant impact on the environment or on the health and safety of people.

For the purposes of determining whether the proposed dealings with the GMO may pose significant risks to the health and safety of people or to the environment, the Regulator must have regard to:

- (a) the properties of the organism to which the dealings relate before it became, or will become, a GMO;
- (b) the effect, or the expected effect, of the genetic modification that has occurred, or will occur, on the properties of the organism;

Relevant provision of the GT Act

Section 49 – Dealings that may pose significant risks to the health and safety of people or the environment

- (c) provisions for limiting the dissemination or persistence of the GMO or its genetic material in the environment;
- (d) the potential for spread or persistence of the GMO or its genetic material in the environment;
- (e) the extent or scale of the proposed dealings; and
- (f) any likely impacts of the proposed dealings on the health and safety of people.

If the Regulator considers that the GMO may pose significant risks to the health and safety of people or the environment, the Regulator must release the application for a formal round of public consultation (refer Step 2).

If the Regulator does not consider that the dealings with the GMO may pose significant risks to the health and safety of people or to the environment, then the Regulator does not have to undertake a first formal round of public consultation on the application. However, the Regulator must still make the application available to anyone who requests it and must still undertake public consultation on the Regulator's risk assessment and risk management plan (refer Step 6).

Step 2 – Public Consultation on the application

If the Regulator considers that the proposed dealings with the GMO may pose significant risks to the environment or to the health and safety of people, the Regulator must call for public submissions on the application, including consultation on the possible risks involved and the means of managing these risks.

The Regulator must advertise in newspapers and in the Commonwealth Gazette and place notices on the Regulator's website. In addition the Regulator will direct-mail all persons on the Regulator's mailing list.

Step 3 – Consultation with Environment Minister, States and Territories etc.

Regardless of whether the Regulator decides that the proposed dealings with the GMO may pose significant risks to the environment or to the health and safety of people, the Regulator must seek advice on possible risks from:

- the Commonwealth Environment Minister;
- the Gene Technology Technical Advisory Committee;
- the States and Territories;
- relevant Commonwealth agencies; and
- local councils that the Regulator considers appropriate.

The Regulator must provide a copy of the application (excluding any information that the Regulator has declared to be confidential commercial information) to anyone that requests a copy.

Step 4 – Any other actions that the Regulator considers necessary

The Regulator may also take any other actions that the Regulator considers necessary to help inform him/her about the risks posed by the proposed dealings with the GMO. For example, the Regulator may call public hearings, commission independent research, undertake literature reviews, and consult international experts.

Step 5 – Preparation of a risk assessment and risk management plan

The Regulator must prepare a risk assessment and risk management plan in relation to the proposed dealings with the GMO.

The preparation of the risk assessment involves identifying any hazards that may be posed by the GMO and the level of risk posed by such hazards based on an assessment of the likelihood and consequence of the hazard occurring.

The risk management plan details how any risks posed by the GMO may be able to be managed to ensure that unacceptable risks are not realised.

For more information regarding risk assessment and risk management plans, please refer to the Regulator's *Risk Analysis Framework for Licence Applications before the Office of the Gene Technology Regulator*. A copy of the

Framework is included as an Appendix to this Handbook or is available as a stand-alone document from the OGTR or the Regulator's website.

In preparing the risk assessment and risk management plan, the Regulator must take into account any advice that the Regulator receives from the public, the Commonwealth Environment Minister, the Gene Technology Technical Advisory Committee, the States and Territories, relevant Commonwealth agencies and local councils.

Step 6 – Consultation on the draft risk assessment and risk management plan

Once the Regulator has completed his/her risk assessment and risk management plan, the Regulator must notify the public that a risk assessment and risk management plan (the draft decision) has been prepared and seek input on the document. The Regulator must call for submissions on the assessment and plan through advertisement in newspapers, the Government Gazette and on the IOGTR website. The Regulator will also direct-mail all persons who registered with the Regulator to receive information.

The Regulator must also seek input on the draft risk assessment and risk management plan from the scientific committee, States and Territories and relevant Commonwealth agencies, the Commonwealth Environment Minister and from relevant local councils.

The Regulator must provide a copy of the draft risk assessment and risk management plan (excluding any information that the Regulator has declared to be confidential commercial information) to anyone that requests a copy.

What if the Regulator requires further information from the applicant?

The Regulator may at any time request further information from the applicant. This will be done by way of written notice from the Regulator to the applicant. The written notice will include details of the information that the Regulator requires and the timeframe within which the Regulator requires such information.

The time limit imposed by the Regulations for considering an application does not include the days during which the Regulator is awaiting a response to his/her request for additional information.

If the applicant does not provide the further information within the specified timeframe, the Regulator may refuse to further consider the application.

What does the Regulator need to take into account when making his/her decision?

After preparing the risk assessment and risk management plan (and taking all other necessary steps), the Regulator must make a decision on the application.

The Regulator must not issue a licence unless he/she is satisfied that any risks posed by dealings to be authorised by the licence can be managed in a way which protects public health and safety and the environment.

In addition the Regulator 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 Regulator is satisfied that the applicant is a suitable person to hold a licence. In assessing the suitability of the applicant, the Regulator will look 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 Regulator makes a decision. The Regulator may refuse to issue a licence or may decide to issue the licence subject to certain conditions.

What conditions of licence will be applied by the Regulator?

Conditions that will be applied to all licences

All licences issued by the Regulator will be subject to the statutory conditions that are set out in the GT Act. These conditions apply to all licences issued by the Regulator. The 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 Regulator, or a person authorised by the Regulator, to enter premises for the purposes of auditing and monitoring; and
- inform the Regulator of any additional information that becomes available regarding risks to public health and safety and the environment or contraventions of the legislation.

In addition, the Regulations may set out conditions that are applied to all (or certain subsets) of licences. At the commencement of the legislation the Regulations do not prescribe any conditions.

Conditions that will be likely to be applied to all licences

As a matter of policy, in most cases, the Regulator will apply the following conditions:

- that the holder of the licence be an Accredited Organisation. For more information about the Accreditation of Organisations, please refer to the Regulator's *Guidelines for the Accreditation of Organisations*;
- conditions relating to the transport of the GMO, if transport is proposed as one of the dealings with the GMO. The Regulator has issued *Guidelines for the Transport of GMOs*. These Guidelines include standard conditions for the transport of various types of GMOs. The Regulator may require as a condition of licence that these Guidelines are complied with. Alternately, the Regulator may apply additional or different conditions for the transport of GMOs if this is necessary based on the risks posed by the particular GMO. For more information

about the requirements for the transport of GMOs, please refer to the Regulator's *Guidelines for the Transport of GMOs* that are included as an Appendix to this Handbook; and

- that the holder of the licence notify all neighboring property owners that a field trial of GMOs is to be conducted on neighboring land;
- that the holder of the licence prepare and submit an annual report to the Regulator about the dealings with the GMO authorised by the licence. For more information about reporting requirements, please refer to Chapter 17.

Other conditions applied on a case-by-case basis

The Regulator may also impose any other conditions that are necessary to manage risk, as assessed on a case-by-case basis. The Regulator may limit where the GMO is used, who uses the GMO and how it is used.

For example, the Regulator may require specific measures for limiting the dissemination of the GMO in the environment, post-trial monitoring, waste disposal methods and additional reporting requirements.

How long will the Regulator take to make a decision?

The Regulations provide that the Regulator must issue, or refuse to issue, a licence within 170 days after the day of receipt of the application (for a licence that involves the intentional release of a GMO into the environment).

The Regulations also provide for circumstances under which the minimum timeframes for considering the application will be suspended, and the permitted 90 days will be adjusted upward as necessary.

The time for considering the application will be suspended when the Regulator:

- is waiting further information which has been requested in writing from the applicant; or
- has called for a public hearing; or

- is considering a request from the applicant that information provided by the applicant is confidential commercial information; or
- is seeking advice from the Gene Technology Ethics Committee (GTEC) on a relevant issue. The Regulator may specify a time period within which such advice is required and for the duration of that period, the timeframe for consideration of the application is suspended.

Saturdays, Sundays and public holidays in the Australian Capital Territory are not counted when calculating the Regulator's timeframe for assessment of an application.

How will the Regulator notify his/her decision to the applicant and to the public?

The GT Act provides that the Regulator must notify the applicant in writing of the Regulator's decision (including any conditions imposed by the Regulator, if applicable).

If the Regulator issues a licence, the Regulator must also put certain details of the licence on the publicly available database of GMOs called the Record of GMOs and GM Product Dealings. For more information regarding the Record of GMOs and GM Product Dealings, please refer to Chapter 14.

Relevant provision of the GT Act
Section 59 -
Notification of licence decision

Part E: Rights and responsibilities of licence holders

Can the licence applicant seek review of a decision made by the Regulator?

Yes. If the Regulator refuses to grant an application the licence applicant may seek review of the Regulator's decision. Alternately, if the Regulator grants the licence but imposes conditions that are not acceptable to the applicant, the applicant may seek review of the Regulator's decision to impose certain conditions.

Further information regarding rights of review are detailed in Chapter 16 of this Handbook.

If a licence has been granted, when can dealings with the GMO commence?

Dealings with the GMO may commence provided that any conditions imposed by the Regulator can be complied with.

The organisation proposing to undertake the dealings with the GMO must also ensure that they have any other necessary approvals from other Regulators in relation to the GMO (refer below).

One very important condition that will be applied to all licences issued by the Regulator is that the licence holder must inform anyone covered by the licence of any conditions of the licence that relate to them. This is a minimum requirement. The Regulator may also impose additional conditions setting out how the licence holder must inform people covered by the licence, of the relevant licence conditions. For example, through labelling and training.

If the Regulator has approved the dealings with the GMO, do I need approval from any other Regulator?

An approval from the Regulator does not give a licence holder an absolute right to undertake the work with the GMO.

Approvals from other Regulators may also be necessary depending on the particular dealings and the particular GMO.

Other approvals may be required from the relevant local council or from State Government or Commonwealth Government Regulators.

For example:

- the import of GMOs into Australia will not only require the approval of the Regulator but may also need the approval of Australian Quarantine and Inspection Service (AQIS) under the *Quarantine Act 1908*;
- GMOs that are therapeutic goods will not only require the approval of the Regulator but may also require the approval of the Therapeutic Goods Administration;
- GMOs proposed to be sold as food must be approved by the Australia and New Zealand Food Authority; and
- certain State legislation and local government ordinances may have application, including land management legislation, waste disposal legislation and animal welfare legislation.

It is the responsibility of organisations dealing with GMOs to ensure that any other relevant Commonwealth, State or local government legislation is complied with.

Can the licence be varied once it has been issued?

Yes. The GT Act provides that the Regulator may at any time, by notice in writing given to the licence holder, vary a licence.

The variation may mean imposing additional conditions or removing or varying conditions that were previously imposed by the Regulator.

The Regulator may vary a licence in one of two circumstances:

- if the licence holder applies to the Regulator for a variation of the licence; or

**Relevant provisions
of the GT Act**

Section 71 – Variation
of licence

- if the Regulator decides that a variation is necessary.

Before the Regulator can unilaterally vary a licence, the Regulator must give written notice of the proposed variation to the licence holder.

The notice may request relevant information from the organisation and must invite a written submission from the licence holder, within a designated timeframe. The Regulator must consider any written submissions made.

The requirement that the Regulator provide prior notice of the variation to the licence holder may be waived where the Regulator considers that the action is necessary to avoid an imminent risk of death, serious illness, serious injury or serious damage to the environment.

Relevant provisions of
the GT Act

Section 72 – Regulator
to notify of proposed
variation

Checklist for Licensed Dealings with GMOs Involving the Intentional Release of a GMO Into the Environment

- Complete the application form entitled “Application for licence for dealings with a GMO involving intentional release of a GMO into the environment”. The form is included at Appendix 1 of this Handbook (printed on blue paper) or is available from the OGTR or from the Regulator’s website.
- Submit the completed application form to the relevant IBC. The IBC must complete certain information on the form and include supporting information. The form must also be signed by the project supervisor, the Chair of the IBC and the CEO (or delegate) of the applicant organisation.
- If there is any information in the application (including filed trial locations) that is considered to be confidential commercial information, an application should also be made to the Regulator for a declaration that such information is confidential commercial information. A separate application form must be submitted to the Regulator for such a declaration. A copy of the application form for a declaration for confidential commercial information is included at Appendix 1 of this Handbook or is available from the OGTR or from the Regulator’s website. For more information about applying for a declaration in relation to confidential commercial information, please refer to Chapter 15 of this Handbook.
- Once the licence application form is completed (and, if relevant the application for a declaration in relation to confidential commercial information) and signed by the IBC Chair, by the project supervisor and by the CEO (or delegate) of the organisation, it may be submitted to the Regulator. Remember to keep a copy of the full application within the organisation.
- During assessment of the application, the Regulator may request further information from the applicant.
- Dealings with the GMO must not commence until the applicant has received written notification that the application has been approved and has received a licence from the Regulator. The licence will detail a

number of conditions that must be complied with in relation to the dealings with the GMO. These conditions must be complied with.

- Approval may also be required under other Commonwealth, State or local government legislation.
- The licence holder will be required to report annually to the OGTR about the dealings with the GMOs, authorised by the licence (refer Chapter 17 of this Handbook for information about reporting requirements). More frequent reporting may also be required, in accordance with additional conditions of licence. Project supervisors must inform the IBC if the licensed work with GMOs is completed or abandoned.
- If you have any queries or concerns at any time, please contact the OGTR on 1800 181 030.

CHAPTER 8

DEALINGS WITH GMOs ON THE GMO REGISTER

What is the purpose of the GMO Register?

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.

The GMO Register was developed to address the following concern. If, for example, a GMO flower has been growing in Australia for a long period of time, is used by a very large number of people and had been demonstrated to be safe, then it is unreasonable to expect one company to continue to hold a licence to enable the flower to be grown, sold and used by millions of people. This is particularly so if there were no longer any conditions that were necessary to be observed in order to manage any risks posed by the flower, and hence no direct oversight of dealings necessary by the licence holder.

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

What types of dealings with GMOs may be entered on the GMO Register?

Dealings with GMOs may be entered on the GMO Register if:

- they have been licensed and the Regulator is satisfied that the dealings with the GMO are sufficiently safe that they can be undertaken by anyone without the need for the dealings to be licensed; or

- the GMO is a GM product. That is, a non-viable product of a GMO that has been declared, under the Regulations, to be a GMO.

What is the effect if a GMO is entered on the GMO Register?

If a GMO is entered on the GMO Register then, subject to any minimal conditions that may also be entered on the GMO Register, anyone may undertake any dealings with that GMO without the need to be covered by a licence. Once a GMO has been entered on the GMO Register the GMO may be used for an indefinite period of time (unless the Regulator removes the GMO from the GMO Register on the basis of new information about possible risks).

Are there any GMOs on the GMO Register?

At the commencement of the legislation (21 June 2001), there were no GMOs entered on the GMO Register.

How do I apply to have a GMO entered on the Register?

Generally speaking the Regulator will initiate the placement of GMOs on the GMO Register. However, a licence holder may apply to the Regulator to have GMOs that have been licensed, placed on the GMO Register.

How does the Regulator decide whether to place a GMO on the GMO Register?

The GT Act provides that the Regulator must not place a GMO on the GMO Register unless the Regulator is satisfied:

- (a) that any risks posed by the dealing are minimal; and
- (b) that it is not necessary for persons undertaking the dealing to hold, or be covered by a GMO licence, in order to protect the health and safety of people or the environment.

In satisfying himself/herself of these matters, the Regulator must have regard to:

- (a) any data available to the Regulator about adverse effects posed by the dealing;
- (b) any other information as to risks associated with the dealing of which the Regulator is aware, including information provided to the Regulator by a licence holder or by another person;
- (c) whether there is a need for the dealing to be subject to conditions; and
- (d) any other information in relation to whether the dealing should be authorised by a GMO licence.

Is the GMO Register publicly available?

Yes. Any dealings with GMOs that are entered on the GMO Register will also be entered on the Record of GMOs and GM Product Dealings. The Record is a comprehensive database of all GMOs and GM products approved for use in Australia. The Record will also include any conditions that apply in relation to dealings with GMOs that are on the GMO Register.

In addition, anyone may request at any time a copy of the information that is on the GMO Register.

For more information about the Record of GMOs and GM Product Dealings, please refer to Chapter 14 of this Handbook.

CHAPTER 9

TRANSPORT AND IMPORT OF GMOs

Part A: Transport of GMOs

IMPORTANT NOTE

Detailed information about requirements for the transport of GMOs is included in the *Guidelines for the Transport of GMOs*. If you wish to transport GMOs it is important that you consult the Guidelines. A copy of the Guidelines is included as an Appendix to this Handbook.

The information contained in this Part of the Handbook is a summary of the information contained in the Guidelines.

What does “transport” a GMO mean?

The GT Act regulates all “dealings” with GMOs including the transport of GMOs.

“Transport” is not defined in the GT Act but is defined in the Regulator’s *Guidelines on the Transport of GMOs*. In summary, for the purposes of the Guidelines, transport is taken to mean “to carry or convey from one place to another” and includes:

- all movements of a GMO from a certified facility to any location outside the certified facility; and
- all movements from a location specified in a licence (such as a field trial site) to another location.

The *Guidelines for the Transport of GMOs* do not apply to transport:

- from a place in a certified facility to another place within the same certified facility (for example, from one side of a PC2 laboratory to the other); or
- from a place in a location specified in a licence to another place within the same location (for example, from one part of a field trial site to another part of the same site).

When can I transport a GMO and how do I get approval to transport a GMO?

This depends on what type of GMO you are dealing with and whether it is an exempt GMO, NLRD, on the GMO Register or a licensed dealing with a GMO.

In summary:

- If the GMO that you are intending to transport is on the list of **exempt dealings**, you do not need any approval from the Regulator to transport the exempt GMO and you do not need to comply with the *Guidelines for the Transport of GMOs*. Exempt dealings must not, however, involve an intentional release of the GMO into the environment and must be conducted in accordance with Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology) for Physical Containment Level 1.
- If the GMO that you are intending to transport is on the list of **Notifiable Low Risk Dealings (NLRDs)**, you must notify the Regulator that you are intending to deal with the GMO (which may include transporting the GMO). If the GMO is on the list of NLRDs, all dealings with the GMO (including transport) may be conducted provided all conditions are complied with. This includes the conditions contained in the Regulations, as well as the conditions contained in the *Guidelines for the Transport of GMOs*.
- If the GMO that you are intending to deal with is on the **GMO Register**, you may deal with the GMO provided that you comply with any conditions that are noted on the GMO Register. As at the date of commencement of the legislation (21 June 2001), there are no dealings with GMOs on the GMO Register.

The **GMO Register** is different to the Record of GMOs and GM Product Dealings. **The GMO Register** is another form of approval by the Regulator, mainly for GMOs that have been licensed but no longer require licensing. By contrast, the Record of GMOs and GM Product Dealings is a publicly available database of all GMOs and GM products approved to date in Australia.

- If the GMO is not on the list of exemptions, not on the list of notifiable low risk dealings and not on the GMO Register – you must not transport the GMO unless you have a licence from the Regulator or are covered by a licence from the Regulator that allows you to transport the GMO.

What are the conditions that apply to the transport of GMOs?

The transport of any GMOs that are on the list of NLRDs must be undertaken in accordance with the conditions for transport set out in the *Guidelines for the Transport of GMOs*.

In relation to licensed dealings with GMOs, the Regulator may apply whatever conditions are necessary in order to manage any risks posed by the GMO (including by transport of the GMO).

The Regulator may:

- require that any transport of the GMO be conducted only in accordance with the conditions for the transport of GMOs detailed in the *Guidelines for the Transport of GMOs*; or
- impose additional conditions if he/she considers it necessary to manage the risks posed by the GMO; or
- impose lesser conditions in relation to the transport of GMOs if, given the negligible risk posed by the GMO, it is not necessary to comply with the conditions prescribed in the *Guidelines for the Transport of GMOs*. For example, the Regulator may apply lesser conditions to transport in the case of GMOs approved for intentional release into the environment where such approval is for the commercial release of the GMO rather than for field trials.

In relation to licensed dealings with GMOs, the individual licence will describe the conditions that apply to the transport of the GMO. If the licence provides that the *Guidelines for the Transport of GMOs* must be complied with, then any person transporting the GMO which is described in the licence must comply with the conditions detailed in those Guidelines.

Who must comply with the conditions for transport of GMOs set out in the *Guidelines for the Transport of GMOs*?

In summary, the following people must comply with the conditions for transport of GMOs contained in the *Guidelines for the Transport of GMOs*:

- anyone undertaking a NLRD with a GMO;
- in relation to a licence that specifically provides that the *Guidelines for the Transport of GMOs* must be complied with:
 - the holder of the licence; and
 - anyone covered by the licence;
- in relation to an Advice to Proceed issued by GMAC that specifically provides that the *Guidelines for the Transport of GMOs* must be complied with:
 - the holder of the GMAC Advice to Proceed; and
 - anyone covered by the GMAC Advice to Proceed.



IMPORTANT NOTE

If a licence issued by the Regulator (or a GMAC Advice to Proceed) provides that transport of the GMO must be in accordance with the conditions contained in the *Guidelines for the Transport of GMOs*, then it will be the responsibility of the licence holder (or holder of the GMAC Advice to Proceed) to make sure that people transporting the GMO are:

- covered by the licence (or the GMAC Advice to Proceed);
- aware of the relevant conditions for transport of GMOs contained in the *Guidelines for the Transport of GMOs*; and
- properly trained, where necessary, to enable them to comply with the conditions of transport.

Part B: Import of GMOs

Is the import of GMOs regulated under the GT Act?

Yes. One of the “dealings” with GMOs that is regulated under the GT Act is the import of GMOs.

This means that anyone wishing to import a GMO into Australia must have approval to do so. The type of approval necessary will depend on the type of GMO that is intended to be imported. That is, whether the GMO is on the list of exempt dealings with GMOs, a NLRD with a GMO, on the GMO Register or licensed by the Regulator.



IMPORTANT NOTE

It is important to note that the requirements for import of GMOs, as detailed below, are in addition to any requirements under the *Quarantine Act 1908* as administered by Agriculture Fisheries and Forestry Australia (AFFA) and the Australian Quarantine and Inspection Service (AQIS).

More information about the regulation of live viable organisms (including GMOs) by AFFA/AQIS is available on the AFFA website at www.affa.gov.au.

Who will need to seek approval to import the GMO?

Again, this will depend on the type of GMO proposed to be imported and whether it is on the list of exemptions, NLRDs or the GMO Register or licensed by the Regulator.

In general, it is anticipated that the organisation wishing to conduct dealings with the GMO in Australia (ie. conduct experiments with the GMO, breed or propagate the GMO etc), will seek approval from the Regulator to undertake dealings with the GMO and as part of this approval they will also seek approval from the Regulator to import the GMO, if this is necessary.

The importer would then be one of the persons covered by the licence (or by the notification to the Regulator of a NLRD) for the purposes of importing the GMO.

What if I want to import a GMO that is on the list of exempt dealings with GMOs?

If the GMO is on the list of exempt dealings with GMOs, the GMO may be imported into Australia without the need to seek express approval from the Regulator. Exempt dealings with GMOs must not however involve the intentional release of the GMO into the environment. For more information about the requirements for exempt dealings with GMOs, please refer to Chapter 4 of this Handbook.

A person seeking to import a GMO that is exempt under the new regulatory scheme will be required to complete a declaration (in a form issued by the Regulator) providing basic information about the GMO and verifying that the GMO is on the list of exempt dealings.

This form will be made available by the Regulator and must be presented to AQIS officers when the GMO is being imported into Australia. Further information about this process will be available in a brochure to be prepared by the Regulator and made available to importers of GMOs.

What if I want to import a GMO that is on the list of NLRDs?

If the GMO is on the list of NLRDs, then the GMO may be imported into Australia provided that the requirements for NLRDs have been met and the conditions for NLRDs are complied with. For more information about the requirements for NLRDs, please refer to Chapter 5 of this Handbook.

In summary, NLRDs with GMOs must be notified to the Regulator. As part of the notification, proponents are required to submit to the Regulator detailed information about the proposed dealings with the GMO including whether import of the GMO is proposed as part of the work with the GMO. The information provided to the Regulator must also include supporting information from the relevant IBC for the organisation conducting the dealing.

In order to import a GMO (that is on the list of NLRDs) it is important that the importer is covered by a notification provided by an organisation in respect of the particular GMO.

When the importer imports the GMO they will be required to complete a declaration (in a form provided by the Regulator) providing information about the GMO and verifying that the GMO is one in respect of which a notification has been made to the Regulator. The importer will be required to include the notification number issued by the Regulator (in respect of the NLRD) on the declaration form.

The declaration form will be made available by the Regulator and must be presented to AQIS officers when the GMO is being imported into Australia. Further information about this process will be available in a brochure to be prepared by the Regulator and made available to importers of GMOs.

The GMO must also be imported in accordance with the conditions applying to all NLRDs with GMOs. The conditions that are most relevant to the import of GMOs that are on the list of NLRDs are the conditions relating to the transport of GMOs. Any transport of GMOs (including transport in the course of importing a GMO) must be conducted in accordance with the Regulator's *Guidelines for the Transport of GMOs*. The Guidelines set out the packaging, handling and accounting procedures to ensure that the GMO is contained during transport.

What if I want to import a GMO that requires licensing by the Regulator?

If the GMO is not exempt, on the list of NLRDs with GMOs or on the GMO Register, the GMO must not be imported into Australia unless it has been licensed by the Regulator. Chapters 6 and 7 of this Handbook set out the requirements for licensing of dealings with a GMO.

If the GMO proposed to be imported has not been licensed by the Regulator then the importer/importing agent, or the organisation on whose behalf the GMO is being imported, must seek a licence from the Regulator before the GMO may be imported into Australia.

If the GMO proposed to be imported has been licensed by the Regulator the importer/importing agent, must make sure

that the licence covers import of the GMO (as one of the “dealings” with the GMO that is authorised by the licence) and that the importer/importing agent is a person covered by the licence.

When an importer imports the GMO they will be required to complete a declaration (in a form provided by the Regulator) providing information about the GMO and verifying that the GMO is one in respect of which a licence has been issued. The importer will be required to include the licence number issued by the Regulator on the declaration form.

The declaration form must be presented to AQIS officers when the GMO is being imported into Australia. Further information about this process will be available in a brochure to be prepared by the Regulator and made available to importers of GMOs.

Importers will also be required to import the GMO in accordance with the conditions set out in the licence issued by the Regulator. In particular, the conditions relating to transport of the GMO. Unless the licence otherwise provides, transport of the GMO must be in accordance with the Regulator’s *Guidelines for the Transport of GMOs*. The Guidelines set out the packaging, handling and accounting procedures to ensure that the GMO is contained during transport. A copy of the Guidelines is included as an Appendix to this Handbook. It is, however, important that importers check the licence that has been issued by the Regulator in respect of the GMO to make sure that they comply with all of the conditions relevant to import of the GMO.

If I am authorised under the GT Act to import a GMO, will I also need approval from AQIS?

Yes, you may.

Under the *Quarantine Act 1908*, products imported into Australia are subject to controls to manage the risk of introduction, establishment and spread of pests and diseases that may endanger Australia’s plant, animal and human health environment. The pest and disease risks associated with GMOs (for example, GM plant material) will be assessed by AFFA/AQIS. This is in addition to the

assessment undertaken by the Regulator in relation to all possible risks posed by the GMO.

If you are proposing to import a GMO into Australia, you should have a look at the AFFA website at www.affa.gov.au to ensure that you comply with the requirements of the *Quarantine Act 1908*.

CHAPTER 10

ACCREDITATION OF ORGANISATIONS

IMPORTANT NOTE

Detailed information about accreditation of organisations is included in the *Guidelines for Accreditation of Organisations*. It is important that any organisation seeking accreditation consult the *Guidelines for Accreditation of Organisations* included as an Appendix to this Handbook.

The information contained in this Chapter of the Handbook is a summary of the information contained in the Guidelines.

Part A: About accreditation of organisations

What is the purpose of accreditation?

In summary, accreditation is the precondition that an organisation must meet before it applies for a licence to deal with GMOs or undertake NLRDs with a GMO. This is because, for most licences with GMOs, the Regulator will apply a condition of licence that the licence holder must be an Accredited Organisation.

If an organisation is accredited, this means the Regulator is satisfied that the organisation has, or has access to, a properly constituted and maintained IBC. The Regulator is also satisfied that the IBC is ready to assist the organisation in meeting the legislated requirements for dealings with GMOs, including the need to provide information back to the Regulator.

Accreditation assures the Regulator that the organisation has basic quality assurance systems in place. Such systems are essential to the conduct of dealings with GMOs.



IMPORTANT NOTE

It is important to note that it is the **organisation** that is responsible for ensuring compliance with the Regulator's conditions of accreditation. It is expected that the IBC will assist the organisation, but ultimate responsibility for compliance with the conditions of accreditation rests with the Accredited Organisation.

Part B: Transitional arrangements for accreditation of organisations

What are the transitional arrangements for accreditation of organisations?

Under the new regulatory system it is important that organisations that work with GMOs are accredited by the Regulator. Such organisations will have access to a properly constituted and maintained IBC that is able to provide advice to both individual researchers and to the Regulator.

To minimise disruptions to existing work approved under the GMAC system, the legislation includes arrangements for “deeming” certain organisations to be accredited for a limited period of time.

These “deemed” accreditations will only apply in relation to organisations where an IBC has been operating in accordance with GMAC guidelines before the commencement of the new legislation, or to organisations that already have arrangements for access to an IBC established within another organisation.

How long will the “deemed” accreditations last?

“Deemed” accreditations will operate for up to two years, during which time organisations will have to apply for accreditation in accordance with the Regulator’s application requirements. Before being granted accreditation, organisations will need to satisfy the Regulator that they meet all of the criteria for accreditation set out in the Regulator’s *Guidelines for the Accreditation of Organisations*.

It is important to note that during the transitional period, accreditation can be suspended or cancelled by the Regulator, if this is necessary.

It is anticipated that during the second year of the new system, that is from July 2002, the Regulator will commence a rolling schedule of reassessment of the accreditation of organisations. Organisations will be notified and advised about when they are expected to reapply for accreditation. It

is likely that a quarter of all organisations will be requested to reapply by August 2002, another quarter by October 2002, another quarter by December 2002 and another quarter by February 2003.

What ‘rules’ will operate in relation to a deemed accreditation?

“Deemed” accreditations issued by the IOGTR/GMAC will provide that the conditions of accreditation are those set out in the Regulator’s *Guidelines for the Accreditation of Organisations*.

Part C: Applying for accreditation from 21 June 2001

Who will need to apply?

If your organisation did not receive a “deemed” accreditation and your organisation wishes to undertake notifiable low risk dealings with GMOs or apply for licences to deal with GMOs, your organisation must seek accreditation from the Regulator. You will not require accreditation if you are an individual or an organisation covered by a licence issued to an Accredited Organisation.

How does an organisation apply for accreditation?

An organisation may seek accreditation by applying to the Regulator. To be accredited, an applicant must meet the Regulator’s criteria for accreditation, as set out in the *Guidelines for the Accreditation of Organisations*. Application forms for accreditation set out a number of questions to be answered by applicants. The application forms are available on the Regulator’s website or may be obtained from the OGTR.

All queries about the process of applying for accreditation, and the way the Regulator’s criteria can be met, should be directed to the OGTR.

If the Regulator is satisfied that the organisation meets the criteria for accreditation, what conditions of accreditation will the Regulator impose?

If the Regulator is satisfied that the organisation meets the criteria for accreditation, the Regulator may impose any conditions that he/she considers necessary. In general, accreditations will be subject to the set of conditions detailed in the *Guidelines for the Accreditation of Organisations*. However, on a case by case basis, the Regulator retains the capacity to impose additional conditions or to vary any of the standard conditions.

Part D: Criteria for accreditation and conditions of accreditation

Please refer to the Regulator's *Guidelines for Accreditation of Organisations* for both the criteria for accreditation and the conditions of accreditation. The Guidelines are included as an Appendix to this Handbook.

CHAPTER 11

CERTIFICATION OF FACILITIES

IMPORTANT NOTE

Detailed information about certification of facilities is included in the *Guidelines for Certification of Facilities/Requirements for Physical Containment*. It is important that any organisation seeking certification of facilities consult the *Guidelines for Certification of Facilities/Requirements for Physical Containment* included as an Appendix to this Handbook

The information contained in this Chapter of the Handbook is a summary of the information contained in the Guidelines.

Part A: About certification of facilities

What is the purpose of certification of facilities?

Depending on the particular GMO, organisations may wish to conduct work in a range of different work settings. The type of facility that will be appropriate to the particular GMO will depend on:

- the type of GMO being used - for example, it may be most appropriate to conduct work with GM micro-organisms in a laboratory, to conduct work with plants in a plant house, and to conduct work with insects in an insectary;
- the risks posed by the particular GMO, or the particular work proposed to be conducted with the GMO. Depending on the type of GMO that is being used, and the risks posed by that particular GMO, the level of physical containment required to prevent the GMO from being released into the environment will vary. The

experimental procedures that must be complied with, in order to ensure the safety of workers, will also vary.

The purpose of certification is to satisfy the Regulator that the facility which is proposed to be used to contain the GMO meets the Regulator's requirements for physical containment.

If the facility I work in is certified by the Regulator does that automatically mean that I can undertake work with GMOs?

No. Just because a facility has been certified by the Regulator as suitable for containing particular types of GMOs, it does not mean that work with GMOs may automatically proceed in such a facility.

As detailed in Chapter 3 of this Handbook, a person must not undertake "dealings" with GMOs unless those dealings are:

- exempt;
- notifiable low risk dealings;
- licensed by the Regulator; or
- on the GMO Register.

The GT Act and the GT Regulations set out the requirements for each of the different categories of dealings with GMOs.

The work may not commence until **ALL** of the requirements prescribed in the Regulations have been met. It is certainly not sufficient that one of the conditions, that is that the work must be conducted in a facility certified by the Regulator, has been met.

Part B: Transitional arrangements for certification of facilities

What are the transitional arrangements for certification of facilities?

To minimise disruptions to existing work approved under the GMAC system, the legislation includes arrangements for “deeming” certain facilities to be certified for a limited period of time.

These “deemed” certifications only apply to facilities that received a “Notice that a Facility is Certified to a Specified Containment Level” from the IOGTR, on behalf of GMAC, before the commencement of the legislation on 21 June 2001.

If you are proposing to undertake work with GMOs in accordance with a ‘GMAC Advice to Proceed’ or in accordance with transitional arrangements for notifiable low risk dealings, you must make sure that the facility that you are working in has been “deemed” to be certified and is the subject of a notice issued by the IOGTR on behalf of GMAC.

If you have any concerns regarding this, please contact your IBC in the first instance. They are likely to be able to help you because they have been in receipt of the information provided by the IOGTR about the transitional arrangements for certification of facilities.

You can also contact the IOGTR to confirm whether the facility has been “deemed” to be certified and to what level of physical containment (ie PC2, PC3 or PC4).

How long will the “deemed” certification last?

The period of time during which the “deemed” certification will operate will depend on the type of facility that has been deemed to be certified.

For a PC2 facility, the “deemed” certification will last for up to 2 years. This applies to all PC2 facilities except PC2 Large Scale facilities.

For all other facilities, including PC3, PC4, PC2 Large Scale or other facilities, the “deemed” certification will last for a maximum of one year.

During this transitional period of between one and two years, organisations will have to apply for re-certification of their facilities in accordance with the Regulator’s application requirements.

It is anticipated that the Regulator will commence a rolling schedule of reassessment of the certification of facilities. Organisations will be notified and advised about when they are expected to reapply for certification of facilities. There will be no disadvantage to those organisations expected to reapply earliest, as all organisations will be reapplying before the commencement of any cost recovery regime, and before the imposition of any fees for the certification of facilities.

What conditions will operate in relation to “deemed” certifications?

The notice of certification from the IOGTR, which was issued on behalf of GMAC before the commencement of the scheme, describes the conditions that must be complied with by holders of a certification in respect of facilities “deemed” to be certified.

In essence, the conditions that must be complied with in respect of facilities that are operating under a “deemed” certification are the conditions prescribed in the Regulator’s *Guidelines for the Certification of Facilities/Physical Containment Requirements*.

Part C: Applying for certification of facilities from 21 June 2001

Who will need to apply?

It is expected that the applicant for certification will be the owner of the facility or the organisation managing the facility. In most cases it is expected that this will be the relevant Accredited Organisation.

In summary, the organisation that is proposing to undertake dealings with GMOs in the facility will in most cases be the organisation that seeks certification of the facility. If granted certification, that organisation will be the holder of the certification for the purposes of the GT Act.

How does an organisation apply for certification of a facility?

An organisation may seek certification of a facility by applying to the Regulator.

In order for a facility to be certified, an applicant must meet the Regulator's criteria for certification, as set out in the Regulator's *Guidelines for the Certification of Facilities/Requirements for Physical Containment*.

Application forms for certification of facilities are included in Appendix 1 of this Handbook and are also available from the OGTR or from the Regulator's website. The application form sets out a number of questions to be answered by applicants. The questions will seek responses from the applicant to ensure that the criteria for certification detailed in the *Guidelines for the Certification of Facilities/Requirements for Physical Containment* are met.

If the Regulator is satisfied that the facility meets the criteria for certification, what conditions of certification will the Regulator impose?

If the Regulator is satisfied that a facility meets the criteria for certification, the Regulator may impose any conditions that he/she considers necessary.

In general, facilities will be subject to the conditions detailed in the *Guidelines for the Certification of Facilities/ Requirements for Physical Containment*. That is, the requirements for physical containment. However, on a case by case basis the Regulator retains the capacity to impose additional conditions or vary any of the standard conditions if this is necessary.

**Part D: Criteria for certification and
 conditions of certification**

Please refer to the Regulator's *Guidelines for Certification of Facilities/Requirements for Physical Containment* for both the criteria for certification and the conditions of certification.

CHAPTER 12

REGULATION OF HUMAN CLONING AND CERTAIN EXPERIMENTS INVOLVING HUMAN CELLS

Part A: Regulation of human cloning

How does the legislation regulate cloning of human beings?

As detailed in Chapter 2 of this Handbook, the definition of gene technology, as applied to the national regulatory scheme, does not cover cloning of humans, animals or plants. This is because cloning does not involve the modification of genes or other genetic material. It involves the replication or duplication of genetic material.

Despite the regulatory scheme not applying to cloning, the legislation does include a general prohibition on the cloning of human beings.

Section 192B of the GT Act provides that a person is guilty of an offence, if:

- (a) the person engages in conduct; and
- (b) the person knows that, or is reckless as to whether the conduct will result in the cloning of a whole human being.

Cloning of a whole human being is defined to mean “the use of technology for the purpose of producing, from one original, a duplicate or descendant that is, or duplicates or descendants that are, genetically identical to the original”.

This prohibition was included as the result of amendments to the GT Act made in the Senate. At the time of the amendments, the Government clarified that:

- the prohibition on human cloning is included as a “stop-gap” measure until all States and Territories have

nationally consistent legislation in place to comprehensively ban the cloning of human beings;

- the National Health and Medical Research Council (NHMRC) will work with States and Territories to develop such legislation;
- such legislation will embrace the recommendations of the NHMRC's *Ethical Guidelines on Assisted Reproductive Technology*, which state as unacceptable "experimentation, with the intent to produce two or more genetically identical individuals, including development of human embryonal stem cell lines with the aim of producing a clone of individuals"; and
- once States and Territories have legislation in place banning human cloning, the prohibition in the GT Act will be repealed.

What are the penalties for non-compliance with the ban on human cloning?

The legislation describes a maximum penalty of 2000 penalty units or 10 years imprisonment. 2000 penalty units is equivalent to \$220,000 for individuals and \$1.1 million for corporations.

Part B: Regulation of certain experiments involving human cells

What types of experiments involving human cells are prohibited under the legislation?

Section 192C of the GT Act provides that a person is guilty of an offence if:

- (a) the person engages in conduct; and
- (b) the person knows that, or is reckless as to whether, the conduct involves carrying out experiments or research that involves putting human cells, or a combination of human cells and animal cells, into animal eggs.

Section 192D of the GT Act provides that a person is guilty of an offence if:

- (a) the person engages in conduct; and
- (b) the person knows that, or is reckless as to whether, the conduct involves carrying out experiments or research that involves putting a combination of human cells and animal cells into human uterus.

The penalties for non-compliance are 2000 penalty units or 10 years imprisonment. 2000 penalty units is equivalent to \$220,000 for individuals and \$1.1 million for corporations.

CHAPTER 13

REGULATION OF GM PRODUCTS

Relevant provision
of the GT Act
Section 10 -
Definitions

What are GM products?

A GM product is defined in the GT Act as “a thing other than a GMO derived or produced from a GMO”.

In essence, a GM product is a non-viable product of a GMO that cannot propagate or grow in the environment.

Some examples of GM products include:

- GM food that is not live or viable (for example, processed food);
- GM therapeutics that are not live or viable but have been derived from live or viable GMOs (for example, insulin); and
- GM agricultural and veterinary chemicals that are not live or viable GMOs, but have been produced from GMOs.

The essential difference between GMOs and GM products is that GMOs are organisms that are viable, capable of reproduction or capable of transferring genetic material. GM products are derived from GMOs but are not viable, capable of reproduction or capable of transferring genetic material.

Who regulates GM products?

Generally speaking, the GT Act 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, these are generally regulated by other regulatory agencies.

The relevant product regulators are:

- the National Registration Authority in the case of GM agricultural and veterinary chemicals;
- the Therapeutic Goods Administration in the case of GM therapeutics;
- the National Industrial Chemicals Notification and Assessment Scheme in the case of GM industrial chemicals; and
- the Australia New Zealand Food Authority in the case of GM foods.

How do these product Regulators interact with the Gene Technology Regulator?

The *Gene Technology (Consequential Amendments) Act 2000* amended the legislation of these other regulators to require that:

- when the relevant regulatory agency receives an application for approval of a GM product, the agency must seek the advice of the Gene Technology Regulator; and
- when the relevant regulatory agency is considering the application, the agency must take into account any advice provided by the Gene Technology Regulator; and
- the relevant authority must notify the Gene Technology Regulator of the decision regarding the GM product, so that the Gene Technology Regulator 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. For more information about the Record of GMO and GM Product Dealings, please refer to Chapter 14 of this Handbook.

Can the Regulator regulate GM Products if necessary?

Yes. As part of an application for licence for dealings involving an intentional release of a GMO into the environment, the applicant must provide the Regulator with information about details of proposed uses of the GMO or of GM products derived or produced from the GMO.

When the Regulator receives an application to deal with a GMO, the Regulator must examine all the potential risks of the GMO, including any risks that may be posed by any products produced or derived from the GMO.

If the Regulator considers it necessary, based on an assessment of the biosafety risks posed by a GM product, the Regulator may apply a condition of licence imposing limitations on how the GM product may be used.

For example, an applicant may apply for a licence to undertake field trials of GM cotton. Following harvest of the GMO, the applicant may wish to use cotton seed that has been rendered unviable as animal feed. Before allowing an applicant to use a GM product in such a way, the Regulator will consider any biosafety risk associated with the proposed dealings with the GM product. If necessary, the Regulator will apply any relevant conditions or may prohibit the use of the GM product as animal feed.

CHAPTER 14

THE RECORD OF GMO AND GM PRODUCT DEALINGS

What is the Record of GMO and GM Product Dealings?

In summary, the Record of GMO and GM Product Dealings (the Record) is a complete list of all GMOs approved by the Regulator and of all GM products approved by other product Regulators.

The purpose of the Record is to provide the public with ready access to information about all GMOs and GM products being used in Australia.

The Record will contain information about:

- NLRDs notified to the Regulator;
- all licences granted by the Regulator;
- all dealings with GMOs on the GMO Register; and
- 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).

What information will be on the Record in relation to NLRDs?

The Record contains the following information regarding NLRDs:

- the name of the organisation proposing to undertake the NLRD;

- the kind of NLRD, by reference to the descriptions in Part 1 of Schedule 3 of the GT Regulations;
- the identifying name given to the proposed undertaking by the organisation (that is, the project title of which the dealing is a part); and
- the date of the notification of the dealing to the Regulator.

What information will be on the Record in relation to licensed dealings with GMOs?

The Record contains the following information in respect of licensed dealings with GMOs:

- the name of the licence holder;
- the persons covered by the licence;
- the dealings authorised by the licence;
- the GMO to which the dealings relate including:
 - the common name and the scientific name of the parent organism involved; and
 - details of the introduced trait in the GMO.
- any licence conditions; and
- the date on which the licence was issued and its expiry date (if any).

What information will be on the Record in relation to dealings with GMOs on the GMO Register?

At the commencement of the legislation, no dealings with GMOs have been entered on the GMO Register.

If at some future time, certain dealings with GMOs are entered on the GMO Register, the Record will include:

- a description of the dealing(s) on the GMO Register;

- a description of the GMO to which the dealing(s) relate; and
- any conditions to which the dealing(s) with the GMO are subject.

What information will be on the Record in relation to GM products approved by other regulators?

The Record contains the following information in respect of GM products approved by other regulators (ANZFA, TGA, NICNAS and the NRA):

- the name of the organisation producing the GM product;
- a description of the GM product by reference to the relevant legislation under which the GM product was approved (for example, whether it is a therapeutic good approved under the *Therapeutic Goods Act 1989*);
- a description of the GM product by reference to its common name as a product, or type or class of product (for example, vegetable oil);
- information about the GM product including:
 - the common name and the scientific name of the parent organism involved;
 - details of the introduced trait in the GM product; and
 - the identity of the introduced gene responsible for conferring the introduced trait.
- the date on which the decision of the other regulator (for example, ANZFA) enabling supply of the GM product in Australia, takes effect; and
- details of any conditions attaching to the decision from the other regulator (for example, labelling conditions in the case of food products).

How do I access the Record?

The Record will be available on the Regulator's website.

When the Regulator's website is fully functional, users of the website will be able to search the Record for:

- type of GMO or GM product;
- type of modified trait (eg insect resistance, herbicide tolerance);
- the organisation conducting the dealings with the GMO;
and
- type of dealing with the GMO (NLRD, licensed or dealings on the GMO Register).

In addition, members of the public that do not have access to the internet may request extracts of the Record from the Regulator.

For more information about the Regulator's website, please refer to Chapter 18.

CHAPTER 15

CONFIDENTIAL COMMERCIAL INFORMATION

Relevant provisions of the GT Act
Part 12, Division 3 – Confidential commercial information

How do I apply for treatment of information as confidential commercial information?

The Act provides that a person may apply to the Regulator for a declaration that specified information is confidential commercial information (CCI) for the purposes of the GT Act.

In essence, a person may apply for treatment of any information provided to the Regulator as CCI.

For example:

- applicants for a licence may apply for parts of their application to be treated as CCI;
- applicants for certification or accreditation may apply for parts of their applications to be treated as CCI;
- people providing information to the Regulator as part of a notification of a NLRD may apply for parts of their notifications to be treated as CCI; or
- people making submissions to the Regulator may seek a declaration that parts of their submissions are CCI.

On what grounds may I apply for treatment of information as CCI?

The Act sets out criteria that the Regulator must be satisfied of before the Regulator may declare that certain information is CCI.

The applicant must satisfy the Regulator that the information specified in the application is:

- (a) a trade secret;
- (b) any other information that has a commercial or other value that would be, or could reasonably be expected to be destroyed or diminished if the information were disclosed;

Relevant provisions of the GT Act
Section 185 – Regulator may declare that information is confidential commercial information

- (c) other information that:
 - (i) concerns the lawful commercial or financial affairs of a person, organisation or undertaking; and
 - (ii) if it were disclosed, could unreasonably affect the person, organisation or undertaking.

Application forms for CCI are included in Appendix 1 of this Handbook and are available from the OGTR or from the Regulator's website.

If the information for which I am seeking a declaration meets these criteria will the information automatically be treated as CCI?

Not necessarily. Before declaring that information is CCI the Regulator must also consider whether the public interest in disclosure outweighs any prejudice that the disclosure would cause.

If the Regulator considers that the public interest warrants disclosure of the information, the Regulator may refuse to declare that the information is CCI, even if the criteria detailed above have been met.

What about information relating to the location of field trial sites?

Under the GT Act, information about the location of field trial sites is treated a little bit differently to other CCI information.

The GT Act assumes that it is in the public interest to release the location of field trial sites and that this assumption should only be overturned in very limited and exceptional circumstances.

The GT Act provides that the Regulator must refuse to declare that information is CCI if the information relates to one or more locations at which field trials involving GMOs are occurring, or are proposed to occur, unless the Regulator is satisfied that significant damage to the health and safety of people, the environment or property would be likely to occur if the locations were disclosed.

As such if an applicant wishes to establish that field trial sites are CCI, they must satisfy the Regulator that:

- the information is CCI (in accordance with the criteria detailed above);
- the public interest in disclosure does not outweigh the prejudice that the disclosure would cause; and
- significant damage to the health and safety of people, the environment or property would be likely to occur if the locations were disclosed.

If the Regulator is satisfied that the information is CCI and that significant damage to the health and safety of people, the environment or property would be likely to occur if the locations were disclosed, the Regulator must make publicly available a statement of reasons for the making of the declaration, including but not limited to:

- the reasons why the Regulator was satisfied that the information was CCI;
- the reasons why the Regulator was not satisfied that the public interest in disclosure of the information outweighed the prejudice that the disclosure would cause; and
- the reasons why the Regulator was satisfied that significant damage to the health and safety of people, and the environment or property would be likely to occur if the locations were disclosed.

Will the information automatically be released if the Regulator declares that the information is not CCI?

No. If the Regulator refuses an application for treatment of information as CCI, the Regulator must treat the information as CCI until any review rights under the legislation are exhausted. For more information regarding review rights, please refer to Chapter 16.

What is the effect if the Regulator declares certain information to be CCI?

If the Regulator declares certain information to be CCI, the Regulator must not publicly release such information.

This means that the information to which the declaration of CCI relates would not:

- in the case of applications for licence for dealings involving the intentional release of a GMO into the environment, be released for public consultation;
- appear on the Record of GMOs and GM Product Dealings;
- be accessible by way of a request for access to information under the *Freedom of Information Act 1982*. The *Gene Technology (Consequential Amendments) Act 2000* adds information declared by the Regulator to be CIC 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 Regulator is also protected under the *Freedom of Information Act 1982*.

Relevant Provision

Section 187 of the GT Act - Confidential commercial information must not be disclosed

Even if the Regulator declares certain information to be CCI, the Regulator may disclose the information:

- to any of the following in the course of carrying out duties or functions under the legislation:
 - the Commonwealth or a Commonwealth authority;
 - a State agency; or
 - the Gene Technology Technical Advisory Committee.
- by order of a court;
- with the consent of the person who applied to have the information treated as CCI.

CHAPTER 16

REVIEW OF DECISIONS MADE UNDER THE LEGISLATION

Part A: Reviewable decisions

Who may seek review of a decision under the Act?

Relevant provisions of the GT Act

Section 179 – meaning of terms (reviewable decisions and eligible persons)

In summary, the following people may seek review of a decision made by the Regulator:

- licence applicants and licence holders;
- applicants for certification and holders of certification;
- applicants for a declaration for treatment of information as confidential commercial information; and
- applicants for accreditation and holders of accreditation.

What decisions are reviewable?

The following decisions are reviewable decisions for the purposes of the legislation:

- to refuse to issue a licence;
- to impose a licence condition;
- to suspend or cancel a licence;
- to vary a licence;
- to refuse to certify a facility;
- to specify a condition of certification;
- to vary a certification;

- to suspend or cancel a certification;
- to refuse to accredit an organisation;
- to specify a condition of an accreditation;
- to vary an accreditation;
- to suspend or cancel an accreditation;
- to refuse to declare information to be confidential commercial information; and
- to revoke a declaration that information is confidential commercial information.

How do I exercise my rights of review?

When the Regulator makes a reviewable decision, the Regulator must provide a written notice to the relevant person containing:

- the terms of the decision; and
- the reasons for the decision; and
- a statement setting out the particulars of the person's review rights.

As detailed above, the notice will include information about the persons review rights and how and when such review rights may be exercised.

Part B: Internal and external review

Who reviews the decision?

If the relevant decision has been made by a delegate of the Regulator (for example, one of the senior staff members of the Regulator) the person seeking a review of the decision would have to apply to the Regulator for an initial review of the decision.

The Regulator would look closely at the delegate's decision and could substitute his/her decision where appropriate.

If the Regulator made the decision personally, the person may seek a review by the Regulator but also has a right to seek further review by the Administrative Appeals Tribunal (the AAT).

Review of the Regulator's decision by 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 GT Act will be able to apply to the Federal Court for review of questions of law in relation to the making of the decision.

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.

The GT Act explicitly provides that for the purposes of the ADJR Act, a State or Territory is taken to be a person aggrieved by a decision of the Regulator. This means that a State or Territory may apply for review of the Regulator’s decision (on a matter of law) to the Federal Court. For example, if the Regulator did not follow the requirements of the legislation and failed to take into account advice provided by a State or Territory in relation to a licence application, the State or Territory would be able to seek review of the Regulator’s decision by the Federal Court.

CHAPTER 17

REPORTING, MONITORING AND ENFORCEMENT

Part A: Reporting requirements for Accredited Organisations and licence holders

The reporting requirements for organisations will be described in the conditions of accreditation of organisations and individual licences.

Annual reporting by Accredited Organisations

As a condition of accreditation, the Regulator requires Accredited Organisations to provide annual reports to the Regulator about the conduct of exempt dealings, NLRDs and licensed dealings undertaken by the Organisation.

In summary, Accredited Organisations will be required to report on:

- membership of the IBC (including members' qualifications and positions within the organisation);
- current exempt, NLRD, and licensed dealings being conducted;
- certified PC2, PC3, PC4, PC2-LS and PC4-LS laboratories, plant houses, animal houses, bird houses, insectaries and aquaria;
- for PC3, PC4 and large scale facilities, the date of last inspection, period of room use and projects for which it has been used, staff training, a list of current manuals and inspection dates for various aspects of the facilities;

- any other matter to which the Accredited Organisation deems it necessary to draw the Regulator's attention.

The Regulator will issue detailed guidelines regarding the requirements for annual reporting. These Guidelines will be available from the OGTR or from the Regulator's website.

Accredited Organisations must also report incidents or breaches of conditions for carrying out exempt dealings and NLRDs. This includes, for example, mis-classified work that has been undertaken, work that has not been undertaken in appropriate containment facilities, work that has not complied with the required Australia Standard or accidental releases into the environment. Where there are risks to human health or the environment, such incidents must be reported to the Regulator immediately.

The Regulator will issue guidelines about the reporting of non-compliance including timeframes for reporting.

It is envisaged that the relevant IBC in relation to the Accredited Organisation will assist the Organisation to meet the Regulator's reporting requirements.

Annual reporting by licence holders

All licence holders will also be required to report annually to the Regulator about the conduct of the licensed dealings with the GMO. The Regulator will issue detailed guidelines regarding the requirements for annual reporting. These Guidelines will be available from the OGTR or from the Regulator's website.

In most cases the licence holder will also be the Accredited Organisation. As such organisations may choose to prepare one annual report addressing the Regulator's requirements for reporting in relation to accreditation as well as reporting requirements in relation to individual licences.

It is envisaged that the relevant IBC in relation to the Accredited Organisation will assist the organisation to meet the Regulator's reporting requirements.

The Regulator may also require additional reporting, as a condition of licence. For example, the Regulator may require

regular reporting of the results of post trial monitoring of GMOs released into the environment as part of a field trial.

Reporting non-compliance with the legislation

It is a statutory condition of ALL licences that the licence holder must inform the Regulator if he or she:

- becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence;
- becomes aware of any contraventions of the licence by a person covered by a licence; or
- becomes aware of any unintended effects of the dealings authorised by the licence.

Organisations undertaking dealings with GMOs must have internal monitoring mechanisms in place to identify any non-compliance by persons covered by the licence. The Regulator will issue guidelines about the reporting of non-compliance including timeframes for reporting etc.

Part B: Monitoring compliance with the legislation

How will the Regulator monitor compliance with the legislation?

The Regulator will use a variety of tools to monitor compliance with the legislation including:

- auditing reports prepared by Accredited Organisations and licence holders (as described in Part 1 of this Chapter);
- undertaking routine and on-the-spot monitoring; and
- undertaking inspections in response to reports of an alleged breach of the legislation.

Each of these types of monitoring are explored in more detail below.

Auditing

The Regulator will undertake a paper audit of all of the reports provided to the Regulator as a condition of accreditation or licence.

This will involve reviewing the information provided and identifying any gaps in information or any matters that may be of concern to the Regulator. If the Regulator has any concerns regarding the report, the Regulator may request additional information from the organisation.

If the report highlights particular concerns, the Regulator may decide that a monitoring visit is warranted.

Routine and on-the-spot monitoring

The Regulator may undertake routine or on-the-spot (that is, unannounced) monitoring of:

- conditions of NLRDs with GMOs;
- conditions of licence;
- conditions of certification of facilities; and
- compliance with conditions of accreditation.

Inspections in response to reports of an alleged breach

The Regulator may become aware of a possible breach of the legislation in a range of ways.

The Regulator may be informed through:

- self reporting by the relevant organisation;
- auditing a report provided by an organisation;
- a report made by a member of the public; and
- a monitoring visit conducted by the Regulator or staff of the Regulator.

The GT Act provides that the Regulator may appoint inspectors to investigate suspected breaches of the legislation, and to gather evidence to assist in the prosecution of such offences.

Relevant provisions of the GT Act

Part 11 – Powers of Inspection

The GT Act sets out the powers and obligations of inspectors and procedures relating to warrants and search warrants.

Will members of the public be able to report alleged breaches of the legislation to the Regulator?

Yes. Members of the public will be able to report alleged breaches of the legislation to the Regulator.

Reports of possible breaches of the legislation should be made in writing by fax, email or letter to the OGTR.

Part C: The Regulator's powers of enforcement

What will the Regulator do in the case of non-compliance with the legislation?

The Regulator has a range of options open to him or her in the event of non-compliance with the legislation.

The options adopted by the Regulator will depend on the type of non-compliance and the significance of the non-compliance including in terms of possible risks to the health and safety of people or risks to the environment.

Some of the options open to the Regulator include:

- varying the licence conditions, conditions of accreditation or conditions of certification, as appropriate;
- suspending the licence, accreditation or certification, as appropriate;
- cancelling the licence, accreditation or certification, as appropriate;
- issuing directions to the licence holder;
- seeking an injunction to restrain the offending party from continuing a breach of the legislation;
- reporting a suspected breach of the legislation directly to the Commonwealth Parliament; and
- pursuing a prosecution under the legislation.

The course of action selected by the Regulator will depend on the particular circumstances and the severity of the breach of the condition.

It is anticipated that the Regulator will issue enforcement protocols. These will be available from the OGTR or the Regulator's website

Why would the Regulator vary conditions of licence, accreditation or certification in response to non-compliance?

In response to non-compliance, the Regulator may decide to vary the conditions of licence, certification or accreditation to require the holder of the instrument to take additional precautions to ensure that non-compliance does not recur.

This course of action may be appropriate where the non-compliance with the legislation has been minor and did not give rise to increased risks to the health and safety of people or to the environment.

When would the Regulator suspend or cancel a licence, accreditation or certification?

The GT Act provides that the Regulator may, by notice in writing, suspend or cancel a licence, accreditation of an organisation or certification of a facility, if the Regulator believes on reasonable grounds that a condition of the licence, certification or accreditation has been breached.

Before the Regulator can suspend or cancel a licence, certification or accreditation, he/she must give written notice of the proposed suspension or cancellation to the holder of the licence, certification or accreditation.

The notice may request relevant information from the organisation and must invite a written submission from the holder of the licence, certification or accreditation, within a designated timeframe. The Regulator must consider any written submissions.

The requirement for the Regulator to provide prior notice of the suspension or cancellation may be waived where the Regulator considers that the action is necessary to avoid an imminent risk of death, serious illness, serious injury or serious damage to the environment.

When would the Regulator issue directions to licence holders?

The legislation provides that 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 Regulator 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 Regulator may take additional steps, or direct that necessary steps be taken, to ensure compliance with the legislation.

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

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

The legislation also provides that an inspector may take immediate action where there is an imminent risk of danger to the 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 requiring them to take the necessary steps. Such action, by the inspector or others, is also cost recoverable from the offending party.

When would the Regulator pursue a prosecution under the legislation?

In response to non-compliance with the legislation the Regulator may approach the Director of Public Prosecutions (DPP) to pursue a prosecution under the legislation. The DPP would advise as to whether there is sufficient evidence to pursue a prosecution under the legislation.

A successful prosecution could result in the imposition of a fine or imprisonment term.

It is anticipated that the Regulator will issue a prosecution policy, developed in consultation with the DPP. This will be available from the OGTR or the Regulator's website

Part D: Reporting of non-compliance with the legislation

Will the Regulator publicly report non-compliance with the legislation?

Yes. The GT Act requires that the Regulator must report annually and quarterly on the operations of the Regulator. As part of such reporting the Regulator must include information on breaches and auditing/monitoring.

Annual and quarterly reports must be provided to the Minister and laid before each House of Parliament. It is also a requirement of the legislation that the Reports be given to each State and Territory.

The Regulator is also able to produce any other reports about matters relating to the Regulator's functions and have these tabled in either House of Parliament.

These reports may relate to breaches or auditing/monitoring activities. It is a requirement of the legislation that a copy of these reports also be provided to the Minister and to each State and Territory.

It is anticipated that other administrative reporting activities are likely to occur under the new legislative scheme. Under the former GMAC system, the IOGTR prepared and released public information bulletins on activities within the office including reports on audits of organisations. It is anticipated that the Regulator will continue this practice and that information bulletins about the results of the Regulator's monitoring activities will be posted on the Regulator's website.

CHAPTER 18

THE REGULATOR'S WEBSITE AND THE GENE TECHNOLOGY INFORMATION MANAGEMENT SYSTEM

Part A: The Regulator's website

What is the Regulator's website address?

The Regulator's website address is www.ogtr.gov.au.

What is included on the Regulator's website?

The OGTR website includes:

- general information about the role and functions of the OGTR and the Regulator;
- the Record of GMOs and GM Product Dealings in Australia. Please refer to Chapter 14 for more information about the comprehensive database of all GMOs and GM Products approved in Australia;
- information about the three Committees established under the legislation – the Gene Technology Technical Advisory Committee, the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee;
- history and background about the former administrative system of controls for GMOs managed by the Genetic Manipulation Advisory Committee;
- the Regulator's quarterly and annual reports;

- applications submitted by applicants, and risk assessment and risk management plans prepared by the Regulator, in respect of licence applications for dealings with GMOs involving the intentional release of the GMO into the environment; and
- contact details for the OGTR.

The OGTR website will be updated regularly and will provide visitors to the site with an opportunity to comment on the site and how it may be improved over time.

By late 2001, the OGTR website will also include links to the Gene Technology Information Management System (GTIMS), as described below.

Part B: The Gene Technology Information Management System (GTIMS)

What is GTIMS?

GTIMS is an electronic information management system that has been developed specifically for the OGTR.

GTIMS contains two main components:

- a public access component; and
- a component for Accredited Organisations.

What is in the public access component of GTIMS?

The public access component of GTIMS will include

- the Record of GMOs and GM Product Dealings. As detailed in Chapter 14, the Record is a comprehensive database of all GMOs and GM products approved in Australia.

GTIMS will enable members of the public to search for information on the Record in a variety of ways. People may search by GMO, by State, by modified trait, by type of dealing etc; and

- current applications for licences for dealings involving the intentional release of a GMO into the environment and current risk assessment and risk management plans prepared by the Regulator in respect of such applications.

As detailed in Chapter 7, one of the important components of the Regulator's assessment process for dealings with GMOs involving the intentional release of a GMO into the environment, is the requirement that the Regulator seek public comment on such applications, and on the Regulator's risk assessment and risk management plan in relation to the applications.

What is the component of GTIMS for Accredited Organisations?

GTIMS enables Accredited Organisations to:

- prepare notifications of NLRDs, applications for licence and applications for certification of facilities online;
- submit applications to the Regulator electronically;
- review applications that the organisation has submitted to the Regulator, including the status and progress of such applications; and
- review a list of all NLRDs notified to the Regulator and all licences approved by the Regulator for the Organisation.

Will anyone in the Organisation be able to access this component of GTIMS?

No. Each organisation will need to apply to the OGTR to be granted access to this component of GTIMS. The OGTR will grant access to a “Systems Administrator” within the organisation. The Systems Administrator will have access to this component of GTIMS and will be able to grant access to others within the Organisation. The Regulator must be notified of all persons granted access to this component of GTIMS. No organisation will be able to see the details of any other organisation.

Will applications entered by organisations on GTIMS be secure?

Yes. Not only will access be password protected, but the system will also be SSL encrypted.

When will GTIMS be available?

GTIMS will be available from September 2001.

CHAPTER 19

FEES AND CHARGES

Are there any fees or charges associated with applications made under the legislation?

No. Not for the first two years of the operation of the scheme (from 21 June 2001).

When the GT Act (and related Acts) were passed by Parliament the Commonwealth government agreed to defer the implementation of any cost recovery regime for a period of two years from the commencement of the legislation. As such, there will be no fees or charges to clients of the regulatory system until at least 21 June 2003.

Until 20 June 2003, the operations of the Regulator will be wholly funded by the government.

Will there be any fees or charges in the future and, if so, how will they be determined?

During the development of the regulatory scheme for gene technology, a consulting firm was commissioned to provide a costing for the scheme together with options for fees and charges.

During the first two years of operation of the OGTR, when the agency will be fully government funded, the OGTR will undertake an activity based costing exercise to further refine the fees and charges model. In its second year of operation, the OGTR will consult widely with stakeholders on any proposed fees and charges to commence from 21 June 2003.