Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

Risk Analysis Framework

January 2005

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A Message from the Regulator

Gene technology embraces a wide range of potential applications including medical and vaccine research, diagnosis and treatment of disease, environmental remediation, and the modification of plants and animals to incorporate new growth and compositional characteristics.

As a scientist, I am a firm believer in the appropriate use of science and technology. This includes having regulatory systems in place to ensure there are robust safeguards for the community and the environment, and the opportunity for people to input into the decision making process.

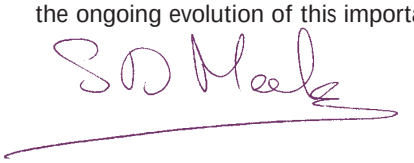
In Australia, gene technology is stringently regulated by law which governs the development, trial and release of genetically modified organisms (GMOs) to protect human health and safety and the Australian environment.

As the Gene Technology Regulator, I carefully assess and consult on every licence application to determine what risks may be associated with the development and use of GMOs. Where risks are identified, I impose strict conditions. Further information on our extensive evaluations is available in the published Risk Assessment and Risk Management Plans.

The principles of risk analysis are simple, but the differences between a hazard and a risk are often confused, and the level of complexity can vary depending upon disciplines involved. Gene technology is a relatively new and rapidly evolving area. Therefore the methodology for analysing risks from gene technology may appear different from long established methodologies, for example those used to assess hazardous chemicals or mechanical failure.

This revised Risk Analysis Framework provides an explanation of how I and my Office apply internationally recognised risk analysis practice in the context of our legislation. As such, it is a key reference for those working with gene technology in Australia and the general public to help understand how we identify, assess and address risks. It also incorporates a discussion of risk communication, including the terminology that we use and how we endeavour to present our findings in a way that facilitates input from others.

I am very grateful to all those who have provided advice and feedback during our consultation processes and look forward to further input and debate on the ongoing evolution of this important reference document.



(Dr) Sue D Meek
Gene Technology Regulator

EXECUTIVE SUMMARY

The framework for risk analysis under the Gene Technology Act 2000

The Gene Technology Regulator (the Regulator) is responsible for protecting human health and safety and the environment by identifying and managing risks posed by, or as a result of, gene technology, as required by the *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001* (the Regulations) and corresponding state law[1].

This *Risk Analysis Framework* (RAF) is a key explanatory document that provides guidance on how the Regulator, and staff under the Regulator's direction in the Office of the Gene Technology Regulator (OGTR), approach the risk analysis of genetically modified organisms (GMOs) under the Act and the Regulations. The legislation provides the scope and boundaries for risk analysis of GMOs, but is not explicit in directing how the Regulator should undertake risk analysis.

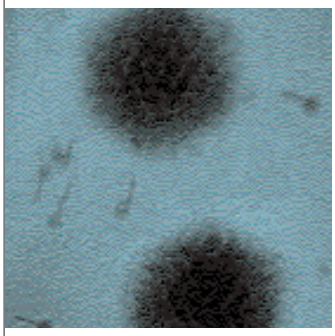
The purpose of the *Risk Analysis Framework* is to:

- provide a guide to the rationale and approach to risk analysis used by the Regulator;
- enable the application of a consistent risk analysis approach to evaluating licence applications;
- provide a clear guide to the provisions of the legislation that relate torisk assessment and risk management; and
- ensure that the risk analysis and decision-making processes are transparent to both applicants and the broader community.

The Risk Analysis Framework describes the principles of risk analysis used by the Regulator to protect human health and safety, and the environment, in accordance with the Gene Technology Act.

Risk Analysis

In this document the term 'risk analysis' is employed in its broadest sense to include risk assessment, risk management and risk communication. Risk assessment involves identifying sources of potential harm, assessing the likelihood that harm will occur and the consequences if harm does occur. Risk management evaluates which risks identified in the risk assessment process require management and selects and implements the plans or actions that are required to ensure that those risks are controlled. Risk communication involves an interactive dialogue between stakeholders and risk assessors and risk managers which actively informs the other processes.



Risk analysis = risk assessment + risk management + risk communication.

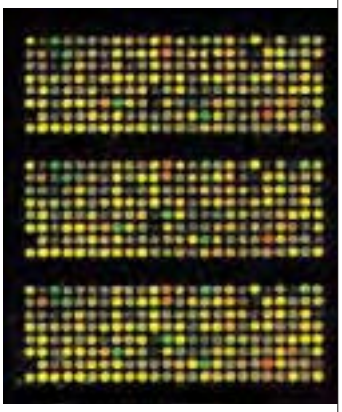
The Risk Analysis Framework has used the Australian and New Zealand Standard 4360:2004 on Risk Management (AS/NZS 4360:2004) to formulate a template for risk analysis that conforms to the requirements of the Act and takes account of Australia's international obligations with regard to GMOs.

The Regulator's decision whether, or not, to issue a license is based on a rigorous process of risk analysis with a focus on scientific evidence and extensive consultation with experts. All applications for licensed dealings with GMOs require case by case assessment by the Regulator and the preparation of a Risk Assessment and a Risk Management Plan (RARMP).

Due to the relatively short history of use of gene technology, the potential variety of GMOs and the complexity of the environments into which they may be introduced, the risk analysis process may rely on both quantitative and qualitative data.

Risk analysis integrates the assessment, management and communication of risk posed by, or as a result of dealings with GMOs.

[1] Throughout this document use of the term 'state' refers to both States and Territories, and reference to the Australian Government 'Act' or 'Regulations' also includes corresponding law enacted in other Australian jurisdictions.



Risk Assessment

The first step in risk assessment is establishing the risk context. The risk context includes: the scope and boundaries of the risk analysis as determined by the Act, the Regulations and the Regulator's approach to their implementation; the proposed dealings; and the nature of the genetic modification. It should be noted that consideration of potential harm does not include economic issues such as marketability and other trade considerations, which fall outside the scope of the Act. As the Regulator must consider risks to human health and safety and the environment arising from, or as a result of, gene technology, an appropriate baseline is, in most cases, a comparison with the unmodified parent organism and its place in the environment. In addressing harm it is important to define harm, and the criteria to assess harm. The RAF identifies a range of criteria as a starting point for considering how to assess harm and describes the types of data that could be employed as evidence for measuring potential adverse impacts.

Once the context of the dealings has been established the next step is to assess the risks. Risk assessment can be usefully considered as a series of simple questions: **What might happen? How might it happen? Will it be serious if it happens? How likely is it to happen? And finally, what is the risk?**

In the first instance, answering these questions involves hazard identification, a process that identifies sources of potential harm (what?) and the causal pathway through which that harm may eventuate (how?). This is followed by a consideration of the seriousness of the harm being realised (consequence) and the chance or probability (likelihood) that harm will occur. The hazard identification, consequence and likelihood assessments together lead to an appraisal of whether the hazard will result in a risk and to make a qualitative estimate of the level of that risk (risk estimate).

Although risk assessment is most simply presented as a linear process, in reality it is cyclical or iterative, with risk communication actively informing the other elements. For this reason, it is helpful to use terminology that clearly distinguishes between the likelihood assessment, consequence assessment and the risk estimate. Therefore, four different descriptors have been selected for each component that are designed to convey a scale of sequential levels.

The consistent application of this distinct terminology is intended to clarify the discussion of these components of the risk assessment.

The explanations of the descriptors for likelihood are based on those in AS/NZS 4360:2004. The explanations of the descriptors for consequence need to encompass adverse consequences of events relating to both human health and safety and the environment. They are relatively simple, in order to cover the range of different factors (severity, space, time, cumulative, reversibility) that may contribute to the significance of adverse consequences. The risk estimate is derived from the combined consideration of both likelihood and consequence.

The individual descriptors can be incorporated into a Risk Estimate Matrix (see below). The aim of the matrix is to provide a format for thinking about the relationship between the consequences and the likelihood of particular hazards. It is important to note that uncertainty about either or both of these components will affect the risk estimate.

RISK ESTIMATE MATRIX

LIKELIHOOD					
	Highly likely	Low	Moderate	High	High
	Likely	Negligible	Low	High	High
	Unlikely	Negligible	Low	Moderate	High
	Highly unlikely	Negligible	Negligible	Low	Moderate
		Marginal	**Minor**	**Intermediate**	**Major**
		CONSEQUENCES			

The matrix is designed to be used as a tool in arriving at the risk estimate. It is not a prescriptive solution for deciding on the appropriate risk estimate for any given adverse outcome or on the necessity for management conditions to be imposed, although risks estimated as 'High' or 'Moderate' will require management.

Risk assessment uses scientific evidence to estimate the level of risk based on a combination of both the likelihood and consequences of potential harm.

Risk Management

The risk management component of risk analysis builds on the work of the risk assessment and may be described as answering the questions: **does anything need to be done about the risk? What can be done about it?** And, **what should be done about it?** The RAF makes a distinction between risk assessment and risk management as separate and qualitatively different activities. While risk assessment deals as far as possible with objective evidence, risk management necessarily involves prudential judgements about which risks require management (risk evaluation), the choice and application of treatment measures, and ultimately whether the dealings should be permitted. Consequently, if there is uncertainty about risks (e.g. in early stage research) this may influence the management measures that are selected.

A consideration of the causal pathways for harm to occur, that were elucidated in the risk assessment, provides a basis for strategic selection of how, where and when to undertake risk treatment measures. This enables the identification of the points at which treatment can be most effectively applied to break the causal pathway and prevent adverse outcomes from being realised. While the focus of risk management is on prevention, the Regulator also addresses how to manage adverse outcomes if a particular risk is realised. Important considerations are whether the adverse consequences can be reduced or reversed, identifying measures that can achieve these ends, and including these in licence conditions or contingency plans.

Risk management actions undertaken by the Regulator are not limited to devising the risk management plan. Typically the pathway for intentional release involves a staged approach that starts in certified contained facilities and proceeds through strictly contained, small scale field trials before larger scale, reduced containment or commercial release. This enables information to be collected about the GMO at each stage of this step-by-step process in order to reduce uncertainty in risk assessments, and confirm the efficacy of containment measures. The results of this research may result in changes to licence conditions to better manage risk and will inform future evaluations of the same or similar GMOs.

The Regulator devotes considerable resources to monitoring for compliance with licence conditions to ensure that the risk management plan is implemented. A range of other measures that contribute to the totality of risk management are employed by the Regulator including cooperation with other Australian regulatory agencies and internal quality control and review within the OGTR.

To issue a licence the Regulator must be satisfied that risks can be managed to protect human health and safety and the environment. If the Regulator considers that risks posed by proposed dealings with a GMO cannot be managed, the application would be refused.

Risk management evaluates those risks that warrant control measures and determines the appropriate licence conditions to manage risk.

Risk Communication

Risk communication underpins the processes of risk assessment and risk management and the Act provides legislative mechanisms to ensure the clarity, transparency and accountability of the Regulator's decision-making processes and that there is public input into that process. Risk communication involves an interactive dialogue between risk assessors, risk managers and stakeholders. In many instances differing perceptions of risk can influence the approach of stakeholders to particular issues. The Regulator undertakes extensive consultation with a diverse range of expert groups and authorities and key stakeholders, including the public, before deciding whether to issue a licence.

The Regulator endeavours to provide accessible information to interested parties on applications, licences, dealings with GMOs, trial sites and the processes of risk assessment, risk management, monitoring and compliance undertaken by the Office. The Regulator can also seek advice on ethical and social issues raised by gene technology from the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee. The Regulator is committed to active risk communication. The RAF is an integral part of fulfilling that commitment and includes a risk communication charter.

Risk communication establishes an interactive dialogue between the Regulator and stakeholders to provide open, transparent and consultative risk-based regulation of GMOs.

Conclusion

The Risk Analysis Framework endeavours to communicate the context of risk analysis by discussing the provisions of the Act and Regulations as they relate to risk analysis, by enunciating the Regulator's approach to risk analysis and by describing both the concepts and process adopted by the Regulator and staff of the OGTR. Recent advances in risk analysis methodology and increased scientific knowledge and regulatory experience gained with GMOs both here and overseas have also been incorporated. It is a key explanatory document for the Regulator, staff of the OGTR, applicants, stakeholders, domestic and international regulatory bodies, and the Australian public.

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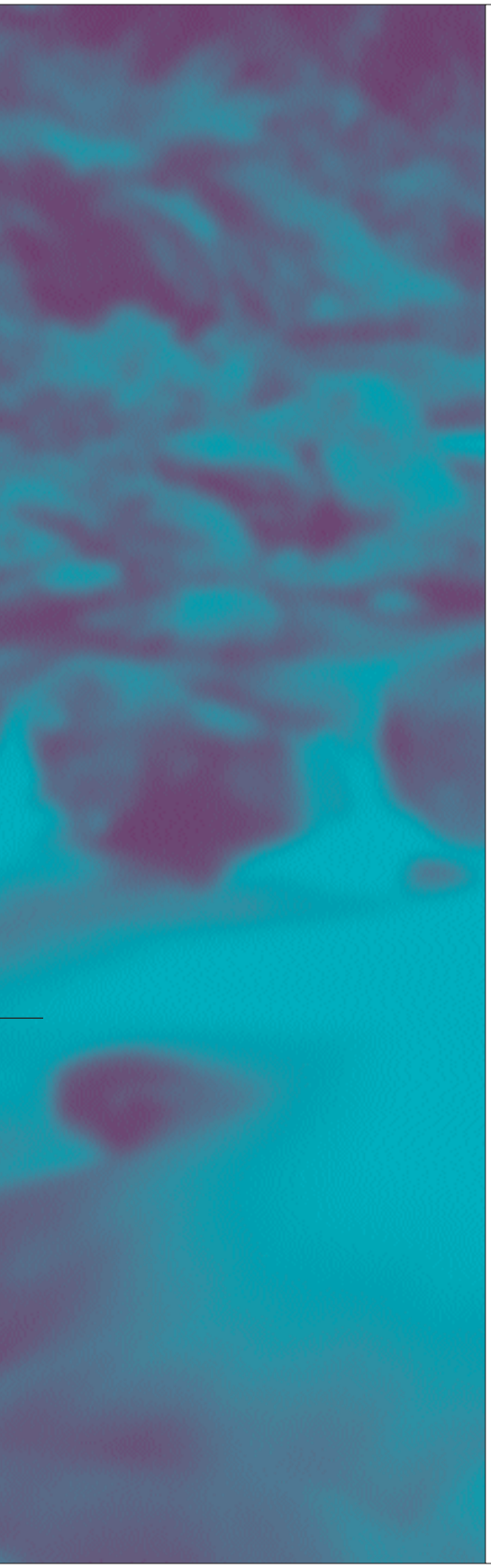
ABBREVIATIONS

APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine Inspection Service
AS/NZS	Australian Standard/New Zealand Standard
CCI	Confidential Commercial Information
CSCG	Commonwealth State Consultative Group on Gene Technology
DIR	Dealings involving Intentional Release
DNIR	Dealings Not involving Intentional Release
EPBC Act	*Environment Protection and Biodiversity Conservation Act 1999*
EU	European Union
FSANZ	Food Standards Australia New Zealand
GM	Genetically Modified
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically Modified Organism
GT	Gene Technology
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
GTMC	Gene Technology Ministerial Council
GTRAP	Gene and Related Therapies Research Advisory Panel
GTTAC	Gene Technology Technical Advisory Committee
HAZOP	Hazard and Operability Analysis
HHM	Hierarchical Holographic Modelling
IBC	Institutional Biosafety Committee
LGA	Local Government Authority
NGO	Non Governmental Organisation
NHMRC	National Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NLRD	Notifiable Low Risk Dealing
OCS	Office of Chemical Safety
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator
PC1-4	Physical Containment levels 1-4
RARMP	Risk Assessment and Risk Management Plan
SWOT	Strengths, weaknesses, opportunities and threats analysis
TGA	Therapeutic Goods Administration



GLOSSARY

(*terms defined as in Australia New Zealand Risk Management Standard AS/NZS 4360:2004)

Consequence

adverse outcome or impact of an **event**

NOTE 1 There can be more than one consequence from one event.

NOTE 2 Consequences can be expressed qualitatively or quantitatively.

NOTE 3 Consequences are considered in relation to harm to human health and the environment.

Context

parameters within which risk must be managed, including the scope and boundaries for the **risk assessment** and **risk management** process

Event*

occurrence of a particular set of circumstances

NOTE 1 The event can be certain or uncertain.

NOTE 2 The event can be a single occurrence or a series of occurrences.

Hazard*

source of potential harm

Hazard identification

the process of analysing hazards and the events that give rise to harm

Likelihood

chance of something happening

NOTE 1 Likelihood can be expressed qualitatively or quantitatively.

Quality control

to check, audit, review and evaluate the progress of an activity, process or system on an ongoing basis to identify change from the performance level required or expected and opportunities for improvement

Risk

the chance of something happening that will have an undesired impact

NOTE 1 Impact in terms of the Act is the chance of harm to human health and safety, or the environment due to or as a result of gene technology.

NOTE 2 Risk is measured in terms of a combination of the likelihood that a hazard gives rise to an undesired outcome and the seriousness of that undesired outcome.

Risk analysis
the overall process of **risk assessment**, **risk management** and **risk communication**

Risk analysis framework
systematic application of legislation, policies, procedures and practices to analyse risks

Risk assessment
the overall process of **hazard identification and risk estimation**

Risk communication
the culture, processes and structures to communicate and consult with **stakeholders** about **risks**

Risk estimate
a measure of **risk** in terms of a combination of **consequence** and **likelihood** assessments

Risk evaluation
the process of determining risks that require management

Risk management
the overall process of risk evaluation, risk treatment and decision making to manage potential adverse impacts

Risk management plan
integrates risk evaluation and risk treatment with the decision making process

Risk treatment*
the process of selection and implementation of measures to reduce risk

Stakeholders*
those people and organisations who may affect, be affected by, or perceive themselves to be affected by a decision, activity or risk

NOTE 1 The term 'stakeholder' may also include 'interested parties' as defined in AS/NZS ISO 14050 and AS/NZS ISO 14004.

States
includes all State governments, the Australian Capital Territory and the Northern Territory governments

Uncertainty
imperfect ability to assign a character state to a thing or process; a form or source of doubt

CHAPTER 1
INTRODUCTION

1. In setting up a regulatory system for gene technology the Australian Government recognised both the potential of the technology to contribute to society and concerns in the community over the development and deployment of the new technology. In June 2001 the legislative scheme for the regulation of genetically modified organisms (GMOs) in Australia commenced with the *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001* (the Regulations) and established the basis for corresponding State laws.

2. The object of the Act (Section 3) 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."

3. The Act establishes an independent statutory office holder – the Gene Technology Regulator (the Regulator) – who is charged with making decisions about the use of GMOs in accordance with the legislation. This document explains both how and why the Regulator undertakes risk analysis by:

- explaining the Regulator's role and responsibilities under Australian law;
- discussing the Regulator's approach to specific elements of the legislation; and
- outlining the framework used by the Regulator when undertaking risk analysis and preparing risk management plans for activities proposed to be undertaken with GMOs.

4. There are many definitions of 'risk analysis' with varying emphases and associated terminologies. In this document risk analysis is employed in its broadest sense to include **risk assessment, risk management** and **risk communication**[2].

risk analysis = risk assessment + risk management + risk communication

5. The object of the Act explicitly invokes the key components of risk analysis, risk identification (assessment) and risk management. The provisions of the Act and Regulations prescribe mechanisms by which the

three components are realised. Together they form the basis of risk analysis conducted by the Regulator.

6. The requirement for protection of people and the environment indicates that the focus of risk assessment and risk management should be identifying and controlling risk in order to prevent adverse consequences from occurring. In making decisions the Regulator is required to assess the risks arising from the development and use of GMOs (described as dealings[3]), identify those risks that require management and put in place measures that will adequately control those risks.

7. The Act and the Regulations provide the context and limits within which risk analysis is conducted. They also provide specific guidance on the processes that must be followed during that analysis. However the legislation is silent on much of the detail of the particular approach that the Regulator should adopt in undertaking risk analysis. This Risk Analysis Framework is intended to serve as a guide to how the Regulator and staff under the Regulator's direction approach the risk analysis of GMOs under the Act and the Regulations.

8. Risk assessment involves identifying sources of harm, and assessing the likelihood that harm will occur and the consequences if it does occur. Risk management refers to evaluating which risks require management and selecting and implementing the plans or actions that may be taken to ensure that those risks are controlled. Risk communication involves an interactive dialogue between stakeholders and risk assessors and risk managers.

9. The consideration of risk has been undertaken in a wide range of areas including meteorology, industrial chemicals, corporate governance, finance, insurance, human health and environment. Many of these have a long and documented history that provides specific information on the type and frequency of risks that are used in risk analysis. In some cases standards, guidelines and harmonised approaches have been adopted internationally (e.g. chemical assessment and financial management). Although there are many aspects common to all models of risk analysis, there are many variations in specific approaches. The deployment of gene technology is comparatively recent and, although there are commonalities between jurisdictions and regulatory authorities, there are also differences and there is no universally agreed approach to analysing risks that may be posed by GMOs.

[2]The terms risk analysis, risk management and risk assessment are used in different ways within different models of risk analysis. The definitions of these terms in relation to this document are considered in detail in Chapter 2.

[3]The term 'dealing' is intended to cover all aspects of possible uses, including importation, production, use, storage, transport and disposal of a GMO.

AIMS OF THE RISK ANALYSIS FRAMEWORK

10. *The Risk Analysis Framework* represents a key document for informing applicants, stakeholders, the public and other domestic and international regulatory bodies about the rationale and approach adopted by the Regulator in undertaking risk analysis and arriving at risk management decisions and licence conditions. It therefore forms an important part of the Regulator's overall risk communication because it further elaborates the context for assessments and decisions. It also serves as a unifying frame of reference for evaluators supporting the Regulator that will help to ensure consistency and rigour in the risk analysis process.

11. The aims of the *Risk Analysis Framework* are to:

- provide a broad outline of the approach to risk analysis used by the Regulator;
- enable the application of a consistent risk analysis approach to the evaluating licence applications;
- provide a clear guide to the provisions of the legislation that relate to risk assessment and risk management; and
- ensure that the risk analysis and decision-making processes are transparent to both applicants and the broader community.

12. The Framework has been divided into five Chapters. This first Chapter considers the object of the Act in a broad context and provides some background for risk analysis of GMOs as defined by the Act. The other Chapters will introduce the risk analysis model used by the Regulator and discuss the three major components of risk analysis: risk assessment, risk management and risk communication.

OVERVIEW OF THE REGULATORY SYSTEM ESTABLISHED BY THE ACT

13. To provide context for the Regulator's approach to risk analysis it is useful to have some background knowledge of the regulatory system established by the Act. This section will provide a broad outline of the process the Regulator must undertake in issuing a licence to deal with a GMO. More details can be found in Appendix B.

14. The Regulator is a statutory office holder reporting directly to the Australian Parliament and is supported by staff in the Office of the Gene

Regulator (OGTR). The implementation of the regulatory system is overseen by the Gene Technology Ministerial Council (GTMC) comprising representatives from all Australian jurisdictions. The Act establishes three committees whose role is to give advice to the Regulator on matters relating to gene technology. These are the Gene Technology Technical Advisory Committee (GTTAC), the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC).

15. The Act is a prohibitory scheme that prevents all dealings with GMOs unless they are expressly allowed. Dealings are allowed if they meet specific criteria (schedules 1 and 2 of the Regulations) or if a licence is granted by the Regulator.

16. *The Risk Analysis Framework* detailed in this document specifically relates to licence applications: those for Dealings Not involving Intentional Release (DNIR) of GMOs into the environment, i.e. that are undertaken in certified contained facilities; and those Dealings involving Intentional Release (DIR) of GMOs into the environment. The framework is not intended to relate directly to other dealings regulated under the Act because these are defined by the Regulations (see Appendix B).

17. The Act specifies that all licensed dealings require case by case assessment by the Regulator and the preparation of a Risk Assessment and Risk Management Plan (RARMP). The RARMP must take account of any risks to human health and safety and the environment posed by the dealing and address how these risks can be managed. The RARMP documents and communicates the Regulator's assessment of risks arising from the dealing and the management strategies that have been identified to ensure that the risks are controlled.

18. The licensing system is based upon a rigorous process of risk analysis for each application, based on scientific evidence and extensive consultation with experts. This process informs the Regulator's decision on whether to issue a licence. For DIR licence applications the Regulator is required by the Act to seek advice from a range of expert agencies and authorities in the preparation and finalisation of a RARMP. These include State and Territory governments, GTTAC, a range of Australian Government agencies as prescribed by the Regulations, the Australian Government Environment Minister, any Local Government Authority (local council) that the Regulator considers appropriate and the public. For a licence to be issued, the Regulator must be satisfied that the release will not pose any risks to human health and safety or the environment that cannot be managed.

19. It is important to note that the Act is designed to operate in an integrated legislative framework with other regulatory authorities that have complementary responsibilities and specialist expertise (see below and Appendix C). This ensures that all aspects of the technology are regulated, avoids duplication and enables co-ordinated, consistent decision making.

20. Further details of these processes are described in Appendix B and C and are also available on the OGTR website (www.ogtr.gov.au). If the information cannot be found on the website, specific queries can be addressed to the OGTR freecall number 1800 181 030.

PRINCIPLES UNDERLYING THE REGULATORY FRAMEWORK

21. As well as defining the object of the Act, the legislation addresses how that object should be achieved. Section 4 states that it should be through a regulatory framework which:

> (aa) 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; and
> (a) provides an efficient and effective system for the application of gene technologies; and
> (b) operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products.

22. These three 'pillars' of the regulatory framework for gene technology (caution, an efficient and effective system and the role of other regulatory agencies) are given equal weight in the legislation and the Regulator is required to balance these in the implementation of the Act.

Caution

23. In Australia, and indeed internationally, there has been concern that gene technology may pose risks to people or the environment. Consequently there has been a cautious approach on the part of legislators to the widespread use of gene technology with an emphasis on determining if the technology, or those things derived from it, do indeed pose any risks to either people or the environment.

24. Regulatory measures to prevent harm are often invoked to deal with uncertainty. Part of this uncertainty arises from a lack of experience with

the products of novel technologies, particularly if their products may become persistent or ubiquitous. Section 4(aa) of the Act outlines a 'precautionary approach'. In this, it adopts the same phrasing as that used in relation to precaution in Principle 15 of the 1992 Rio Declaration on the Environment and Development. The main reason for a precautionary approach is to avoid irreversible damage if serious long-term adverse outcomes are likely to occur.

25. Advocates of precautionary regulation have argued for a gradual, step-by-step approach to new technologies until sufficient knowledge and experience is acquired (Bennet 2000; Klinke & Renn 2002). Critics argue that precautionary strategies invoke less scientifically rigorous information and can lead to arbitrary regulatory decisions (Sandin et al. 2002; van den Belt 2003). However, the Act indicates that the Regulator is required to take protective measures as a prudent and sound response in the face of a lack of full scientific certainty.

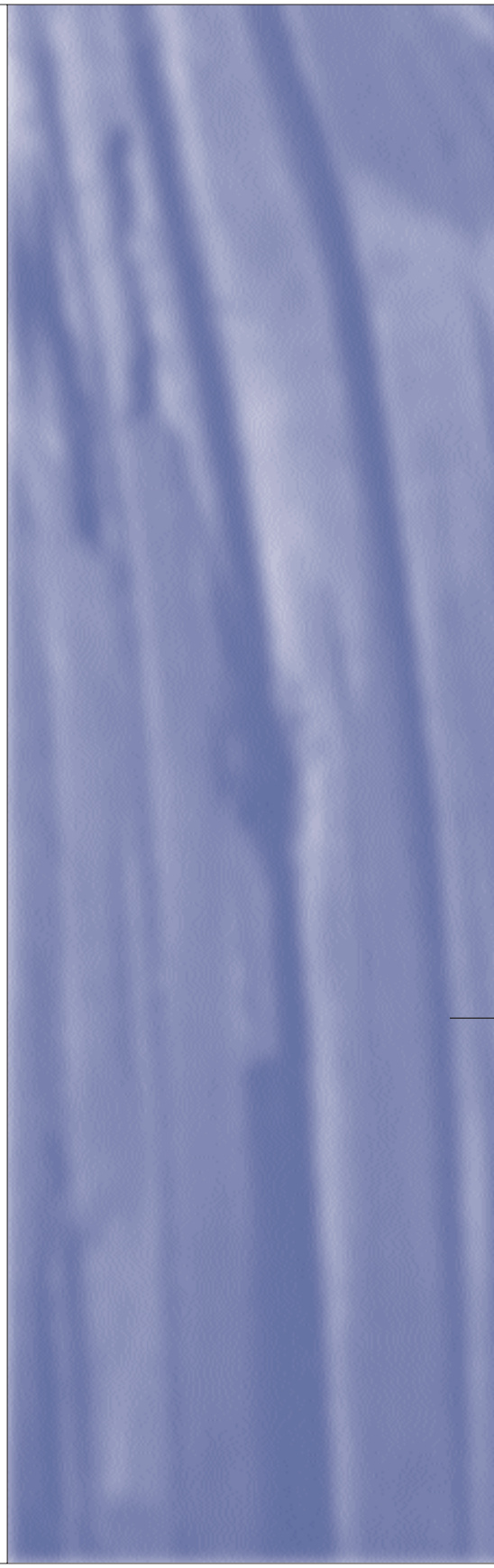
An efficient and effective system

26. The provision of an efficient and effective system of regulation for the application of gene technology is realised through several aspects of the legislation. These include: the classification of dealings such that the level of regulatory scrutiny is proportional to the level of risk; provision of a predictable process with specified statutory timeframes leading to reasonable, consistent and defensible decisions; and consultation with other agencies and government bodies to provide a coordinated and integrated approach to the regulation of GMOs. The latter also fulfils section 4(b).

Role of other regulatory agencies

27. The third principle of the legislation requires that in order to achieve the object of the Act the regulatory system should operate in an integrated way with existing Australian, State and Territory government regulatory schemes relevant to GMOs and GM products (section 4(b).

28. While the Regulator must consider risks relating to GMOs, other Australian Government agencies are charged with the responsibility of managing risks in other regulatory areas and hence use of a GMO may fall under the mandate of another agency. In such cases the requisite approval must be obtained from both regulators and the Regulator has a policy of aligning the decision making process in so far as is practicable. The OGTR and



other regulatory agencies work closely together to ensure thorough co-ordinated assessments of parallel applications are undertaken and, wherever possible, that the timing of decisions by both agencies coincide.

29. Examples of agencies that also have statutory responsibilities relevant to the regulation of GMOs include:

- the Australian Pesticides and Veterinary Medicines Authority (APVMA) regulates pesticides and veterinary medicines, including evaluation of product efficacy issues and trade from a residue perspective;
- Food Standards Australia New Zealand (FSANZ) is responsible for setting food standards, including mandatory pre-market safety assessments of GMOs and GM products in human food;
- Therapeutic Goods Administration (TGA) regulates the quality, safety and efficacy of therapeutic products, including human medicines containing GMOs or GM products;
- National Industrial Chemical Notification and Assessment Scheme (NICNAS) covers the evaluation of industrial chemicals, including GMOs and GM products; and
- Australian Quarantine Inspection Service (AQIS)/ Biosecurity Australia covers imported goods and quarantine including the importation of GMOs and GM products.

30. More details of these agencies, the products they regulate and the specific legislation under which they operate under are provided in Appendix C.

OTHER ATTRIBUTES OF THE REGULATORY FRAMEWORK

31. During consultations on developing the legislative system (Appendix A), a number of other characteristics were identified as integral to the regulatory system for GMOs in Australia (see the Explanatory Memorandum and Explanatory Guide to the Gene Technology Bill). The Act gives effect to these attributes without expressly referring to them. In the context of this Risk Analysis Framework these include:

- that it should be focused on science-based risk assessment;
- that a range of advice be available to the Regulator from scientific experts, government agencies and others;

- there should be openness and transparency in decision making;
- public input should be part of the decision making process; and
- broader issues such as ethical concerns should be taken into account.

32. Gene technology is based on specific scientific techniques. An assessment of risks requires, among other things, an understanding of those techniques and the material context in which they are used. In addition, the process of assessing risks requires a systematic approach that is based on scientific evidence.

33. The requirement to focus on objective scientific information is evident in the matters specified by the Act that the Regulator must have regard to when considering risks, and in the information specified in the Regulations that must be provided to the Regulator for the consideration of risks (schedule 4). The Regulator must also consult the GTTAC on applications and on associated RARMPs for DIR licences and may also consult them in relation to DNIR licences.

34. The Act specifies that the Regulator must seek advice from a wide range of different stakeholders, including State governments, local governments, a range of Australian government agencies and the Australian Government Environment Minister. More details of the consultation processes can be found in Appendix B and Chapter 5.

35. Openness and transparency are built into the Act though requirements for public availability of DIR licence applications, publication of DIR RARMPs, advertising, maintenance of the GMO Record which publishes decisions and licence conditions, availability of trial sites maps, appeal mechanisms for applicants, oversight by the Gene Technology Ministerial Council, and the requirement that the Regulator report quarterly to the Parliament.

36. Substantial opportunity for public input into decision making is provided by the Act through the requirements for public availability of DIR applications, the requirement for public consultation on DIR RARMPs, and the establishment of the GTCCC to provide advice to the Regulator (see also Chapter 5).

37. The Act provides for input to the Regulator on ethical issues by the establishment of the GTEC (see also Appendix B and Chapter 5).

UNDERSTANDING THE OBJECT OF THE ACT

38. The Act limits the scope of the risk analysis that the Regulator can conduct by focusing the object of the Act on managing risks to human health and safety and the environment that arise from, or as a result of, gene technology. The consultation during the development of the legislation and the debate during the parliamentary approval process can also inform a fuller understanding of the object of the Act. The Regulator's approach to specific provisions within the Act also further defines the scope of the risk analysis.

39. In considering the object of the Act, there are a number of components that warrant special focus in relation to risk analysis. The Act does not specifically define human health and safety although it does provide a definition of the environment. Some elaboration of both of these terms is informative in understanding the object of the Act and how to achieve it. In addition, many stakeholders have raised concerns over matters related to gene technology that are not within the scope of the Act. A consideration of the concept of 'utility' is relevant to these concerns. A broad discussion of 'protection' in relation to attaining the object of the Act is also useful.

Human health and safety

40. Under the Act, the primary function of regulation is to protect; namely, to keep people and the environment safe, that is, free from injury or harm that might be caused by the development and use of gene technology. The use of risk assessments in relation to human health typically identifies sources of potential harm and uses quantifiable outcomes such as death, disease or injury to gauge the magnitude and frequency (likelihood) of the outcomes. In considering risks to human health and safety, the Regulator will identify those circumstances that give rise to adverse outcomes on human health. Safety, in the sense of the absence of harm or injury, is an intrinsic component of protection and is therefore treated synonymously with protection.

The environment

41. The Act defines the environment (Part 2, Division 2, Section 10) as: 'ecosystems and their constituent parts, and natural and physical resources, and the qualities and characteristics of locations, places and areas.'

42. It should be noted that the definition of the environment in the *Gene Technology Act 2000* is less inclusive than that in the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act). Specifically,

social, economic and cultural matters are included in the definition of the environment under the EPBC Act but not under the *Gene Technology Act 2000*. However some of these matters can be considered through the Gene Technology Ministerial Council and the Gene Technology Ethics and Gene Technology Community Consultative Committees. The consideration of economic and other issues was intentionally excluded from the scope of assessments under the Act (see below).

43. The use of risk assessments in relation to the environment identifies sources of potential harm and uses outcomes such as disruption, impairment or damage to biological and non-biological systems to gauge the magnitude of that harm. In considering risks to the environment, the Regulator will identify those circumstances that give rise to adverse environmental outcomes.

Utility

44. Generally risk may have either positive or negative attributes. Classical economic risk analysis models include a consideration of benefit or utility against which the ultimate decision of acceptability of an action may be weighed against the risks of that action. This may often be most simply viewed as a monetary benefit but can also include benefits deriving from the use of a product, such as a food, vaccine or chemical. In the case of GMOs regulated under the Act, only adverse effects relating to harm to human health and safety and the environment can be considered by the Regulator.

45. Feedback from extensive stakeholder consultation during the development of the Act made it clear that the community wanted the regulatory system to focus exclusively on the evaluation of risks to human health and safety and the environment. This was to prevent economic considerations (*eg.* cost-benefit analyses, market access and agricultural trade implications), from compromising the regulatory system's focus upon the scientific evaluation of risks and the protection of human health and safety and the environment. As a result, economic and other benefit considerations were intentionally omitted from the scope of the assessments conducted under the Act.

46. At a practical level this has implications for the risks that the Regulator can consider. For instance, many risks posed by GMOs to agriculture are not unique to gene technology, e.g. land or water use modifications, and

may be of an economic, marketing or trade nature. Similar risks may also be posed by non-GM organisms. Constitutionally States have retained responsibility for economic development within their jurisdictions, hence there is provision within the Act (section 16) for the States and Territories to enact their own legislation that relates to marketing or other issues.

47. The exclusion of benefits also means that where there may be some beneficial impact on human health or the environment from the GMO, this does not form part of the Regulator's decision. An example of such a situation could be where the deployment of a GM crop resulted in reductions in the use of a pesticide or replacement of a potentially more harmful product. The Regulator may acknowledge that there may be such benefits, but does not consider them in the risk assessments that are prepared as part of the decision making process.

Protection

48. The Regulator is given powers and functions by the Act to protect. In general protection can include the following measures:

- prohibition of the activity, or parts thereof, from occurring;
- cautionary steps before the activity occurs;
- cautionary steps while the activity occurs;
- surveillance for adverse effects arising from the activity; and
- remediation of any adverse effects that do occur.

49. Together these regulatory tools form an umbrella of protection that provides overlapping safeguards for an activity such as a dealing with a GMO. These protective measures are taken at all stages of an activity, namely prior to an activity occurring, during an activity and after an activity.

50. Some of the protective measures applied to the regulation of gene technology under the Act include:

prohibition:

- all dealings with GMOs are prohibited unless allowed according to provisions in the Act;
- specific licence conditions can prohibit particular aspects of dealings, perhaps in certain regions or seasons; and
- provisions in the Act allow the Regulator to refuse, suspend or cancel a licence.

caution prior to the activity

- required as one operational principle in the regulatory framework of the Act (section 4(aa));
- screening of licence applications by Institutional Biosafety Committees prior to submission to the Regulator;
- widespread requests for advice from and consultation with the public, community representatives, ethicists, Australian government agencies, the Australian Government Minister for the Environment and scientific experts;
- high standards of scientific and regulatory expertise of risk assessors and risk managers;
- emphasis of risk assessments on credible, defensible evidence that is extensive and widely sourced;
- allowance for uncertainty in deriving an estimate of risk;
- requirements for certification of facilities, accreditation of organisations and assurances of applicant suitability prior to granting a licence;
- maintaining awareness of new scientific findings; and
- coordination with other regulatory agencies in maintaining comprehensive regulation of GMOs.

caution during the activity

- specific licence conditions to manage risk;
- research on GMOs in contained facilities prior to small scale release;
- managed, small scale releases prior to a large scale or commercial release;
- containment measures in licences that limit opportunities for GMO spread, persistence or gene transfer;
- research requirements in licences to address areas of scientific uncertainty;
- time limited licences; and
- provisions to ensure compliance with licence conditions. surveillance:
- requirement of applicant to provide sufficient information to allow traceability of the GMO and to provide exact coordinates of limited releases, or rooms/buildings used to contain GMOs;

- extensive monitoring of facilities and release sites; and
- reporting structures to provide any relevant information in Australia or overseas that may impact on risk associated with a GMO licence.remediation:
- provisions to vary a licence in response to undesired outcomes; and
- contingency/emergency plans to mitigate the impact of unintended harmful effects.

51. The Act confers upon the Regulator the authority to impose additional protective measures on dealings in response to new information or changed circumstances. In addition, there are extensive quality control measures to review and evaluate the rigour and effectiveness of risk assessment and risk management processes to ensure that all substantive risks are identified and managed.

52. Typically, the pathway for the approval of intentional release of GMOs into the environment involves a staged approach:

- initial laboratory-based research under stringent physical containment;
- small scale experimental releases (field trials) with conditions that ensure the release is limited and controlled in space and time; and
- general release, with or without specific controls.

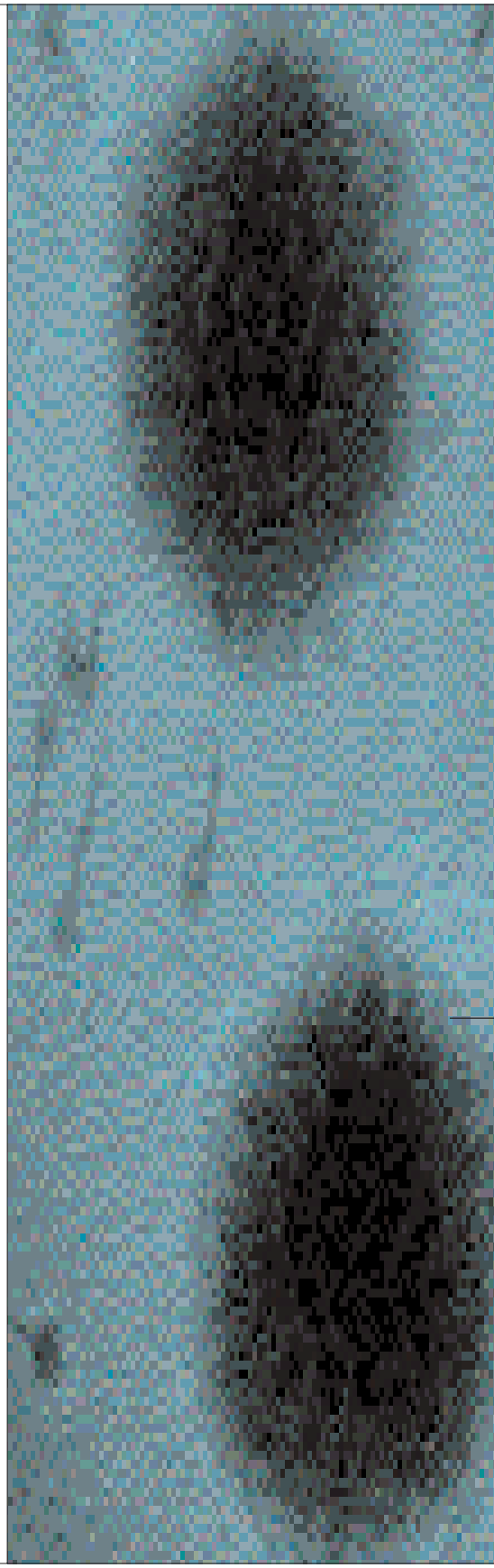
53. Each step in this staged process is supported by the experience and scientific data gathered and evaluated from the previous steps. This enables a body of evidence to be assembled about whether the GMO poses any risks, while also ensuring that human health and safety and the environment are protected.

54. Although protective measures should be sufficient to minimise exposure to harm, those measures should be commensurate with the potential harm. It is also important to note that all human activity involves some level of risk and it is rarely possible to achieve situations of zero risk.

SUMMARY

55. The regulatory scheme for gene technology is aimed at preventing harm to human health and safety and the environment. It achieves this through a prohibitive scheme that manages risks arising as a result of deployment of the technology, by identifying sources of potential harm and management measures that will control that harm.

56. The regulatory scheme operates in conjunction with other legislation. In addition, the Act recognises the importance of consultation, and requires expert advice to be sought from a variety of sources and public input into decision making. This *Risk Analysis Framework* is focused on providing guidance on the Regulator's approach to risk analysis.



CHAPTER 2
RISK ANALYSIS MODEL USED BY THE OGTR

57. This Chapter describes the model of risk analysis consistent with the Act that is used by the Regulator and OGTR. In addition it discusses two other matters, the use of quantitative risk assessment methodology and uncertainty.

58. There are three major elements of risk analysis. These are risk assessment, risk management and risk communication (Davies 1996) and each is integral to the overall process.

Risk assessment

59. For the purposes of this document risk assessment is defined as 'the overall process of hazard identification and risk estimation (likelihood and consequence assessments)'. The risk assessment process aims to identify and assess all risks that could result in harm to human health or the environment due to the proposed dealings with the GMO.

60. The three main steps involved in risk assessment include:

- **hazard identification** involving analysis of what, how, where and when something could go wrong and the causal pathway leading to that adverse outcome;
- consideration of the **likelihood** of an adverse outcome and the severity of that outcome **(consequences)**; and
- **risk estimation** to determine the chance that potential harm would be realised. The risk estimate is a combination of the likelihood and consequences of an adverse outcome and also incorporates consideration of uncertainty.

61. This risk assessment element of risk analysis is described in detail in Chapter 3.

Risk management

62. For the purposes of this document risk management is defined as 'the overall process of risk evaluation, risk treatment and decision making to manage potential adverse impacts'. This is discussed in detail in Chapter 4. Risk management includes risk evaluation, the process of identifying those

risks that warrant treatment to reduce the likelihood or severity of an adverse outcome. Under the Act, potential adverse effects involve consideration of risk posed by or as the result of gene technology. Risk management is a key mechanism used by the Regulator to regulate dealings with GMOs.

63. One of the Regulator's principal functions in risk management is to decide whether or not to allow certain dealings with GMOs (DIRs and DNIRs). The criteria for those decisions consider only harm to human health and safety and the environment. The Regulator does not consider utility of the GMO or any potential benefits derived from the proposed dealings.

64. Specific questions addressed as part of risk management include:

- Which risks require management?
- What conditions need to be in place to manage those risks?
- Which of the proposed management conditions will adequately control those risks?
- Is human health and safety and the environment adequately protected under the proposed licence conditions?

65. The three main steps involved in risk management include:

- **evaluating** the risks, selecting those that require management;
- identifying the **options** for risk treatment; and
- choosing the **actions** proposed for risk treatment

66. This risk management element of risk analysis is described in detail in Chapter 4.

Risk communication

67. For the purposes of this document risk communication is defined as 'the culture, processes and structures to communicate and consult with stakeholders about risks'. Specifically, it is the communication of the risks to human health and the environment posed by certain dealings with GMOs.

68. The principal functions of risk communication in the context of the Act are:

- to inform stakeholders of risks identified from proposed dealings with GMOs and the licence conditions proposed to manage those risks; and
- to establish effective dialogue with the gene technology advisory committees, agencies prescribed in legislation, and all interested and affected stakeholders.

69. That dialogue is used to ensure that the scientific basis for the risk assessments is sound, that the Regulator takes into account all of the necessary considerations to adequately protect human health and the environment including community based concerns, and that the functions and processes involving communication are monitored and continually improved.

70. This risk communication element of risk analysis is discussed in more detail in Chapter 5.

MODELS OF RISK ANALYSIS

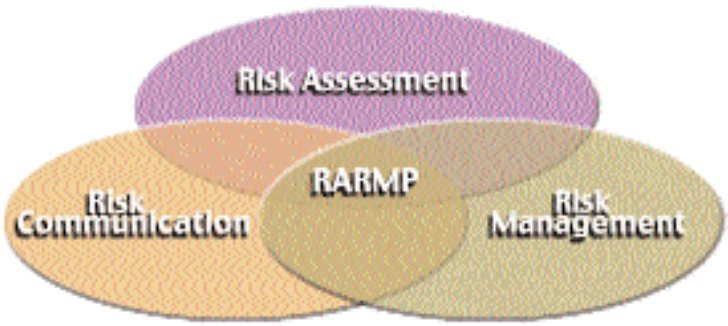
71. The Australian/New Zealand Standard on Risk Management 4360:2004 (AS/NZS 4360:2004) provides a generic template for risk analysis that is designed to be applicable across a range of disciplines. Elements from this and other models (OIE, 2004; FAO 2004; Codex Alimentarius Commission 2003) have been considered in formulating a specific model that best describes risk analysis within the parameters of the *Gene Technology Act 2000*.

72. It should be noted that the terms 'risk analysis' as used in this document and 'risk management' as used in AS/NZS 4360:2004 are synonymous. The specific context in which the term 'risk management' has been incorporated in the Act precludes its use in accordance with AS/NZS 4360:2004 in a more general context. The use of 'risk analysis' to encompass risk assessment, risk management and risk communication is in line with terminology used by WHO, WTO, FAO and the Codex Alimentarius Commission (McNab 2001).

73. The model of risk analysis used by the OGTR consists of the three elements discussed above, namely risk assessment, risk management and risk communication. The model is constrained by the Act in which risk assessment and risk management are referred to as separate processes. The model recognises that there is overlap between the individual elements but also that certain functions required by the legislation are quite distinct within each of those elements.

74. These components can be represented as overlapping domains (Figure 2.1) whose functions are highly interdependent[4]. The Act provides the overarching context for applying risk analysis to licensed dealings with a GMO and the RARMP is the primary vehicle that integrates all three components in accordance with the Act and Regulations.

Figure 2.1 The model of risk analysis used by the OGTR



75. A feature of particular note is the central importance of the RARMP which represents the common ground between risk assessment, risk management and risk communication. The RARMP captures the relevant aspects of these individual elements into a multipurpose document that informs stakeholders of the dealing itself, contains the scientific information that forms the basis for the Regulator's decision and the risk management strategy applied to the dealing. However the RARMP does not encompass the full spectrum of actions that may be implemented to protect human health and safety and the environment to achieve the provisions of the Act.

76. The separation of risk assessment and risk management is critical to clearly distinguishing the evaluation of risk based on scientific evidence from assessing the significance of those risks in a wider context and determining appropriate management measures. However, it is recognised that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application (Codex Alimentarius Commission 2003).

COMPONENTS IN OGTR RISK ANALYSIS

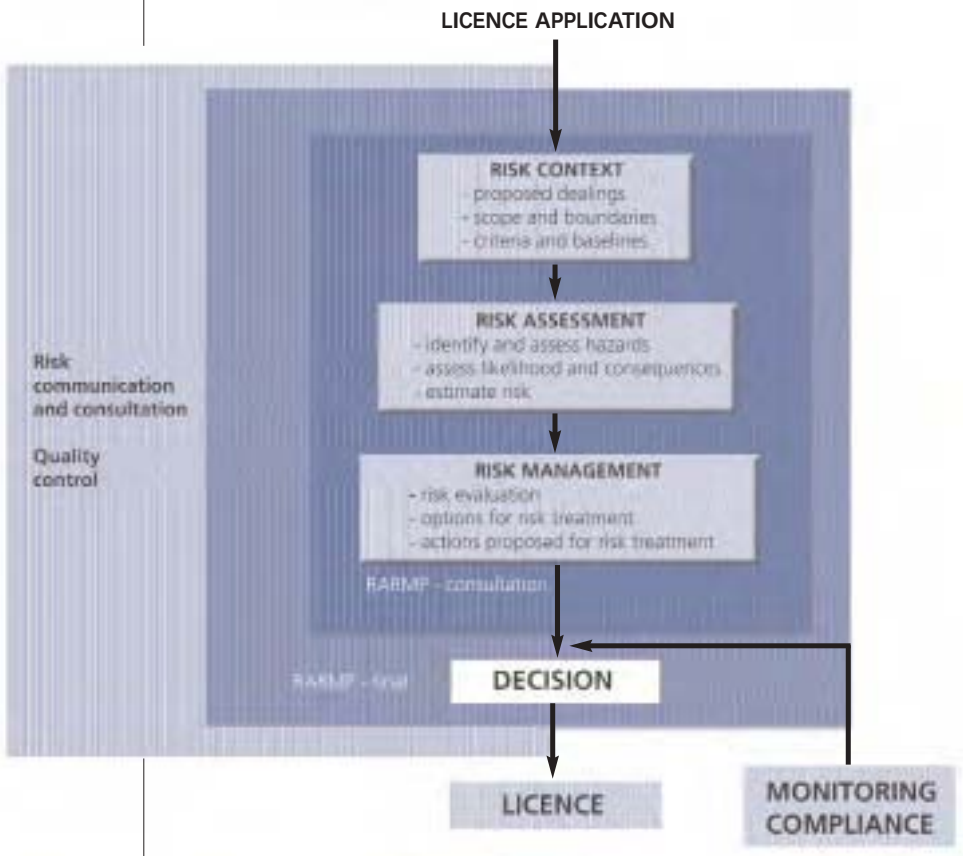
77. The overall integration of risk assessment, risk management and risk communication into a general process used to consider a licence application for dealings with a GMO is depicted in Figure 2.2. The individual components are based on the format of AS/NZS 4360: 2004 while observing the processes required to be undertaken by the Act.

78. There are three key steps in assessing the risks to human health and safety and the environment that may be posed by a dealing with a GMO proposed in a licence application. These are establishing the risk context, assessing the risks and then managing or treating those risks.

[4] The model adopts the Codex principles that the "risk analysis process should follow a structured approach incorporating the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication), each being integral to the overall process. There should be a functional separation of risk assessment and risk management, to the extent practicable, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest" (Codex Alimentarius Commission 2003).

Some individual components within each of these steps are also identified in Figure 2.2. The risk context includes: the scope and boundaries of the risk analysis determined by the Act and Regulations and the Regulator's approach to their implementation; the proposed dealings; the nature of the genetic modification; and the criteria and baselines for assessing harm. The risk assessment includes assessing hazards, likelihoods and consequences to arrive at a risk estimate. Risk management includes identifying the risks that require management, the options to manage those risks and then selecting the most appropriate options. A decision is made by the Regulator on whether to issue a licence on the basis of the risk assessment and that the risks identified can be managed.

Figure 2.2 The process of risk analysis as it relates to the consideration of a DIR licence application to deal with a GMO



79. These three elements form the basis of risk analysis under the Act and are drawn together in the consultation RARMP as shown by the surrounding box. The consultation version of the RARMP includes all matters relating to risk assessment and risk management considered by the Regulator, including the proposed risk management plan and implementation of that plan through specific licence conditions.

80 There can be either one or two consultations with the public on a DIR application (see Appendix B and Chapter 5). If the Regulator considers that the dealing may pose a significant risk to human health and safety or the environment the public must be consulted on both the application itself and then on the RARMP. If the Regulator does not consider the dealing to pose significant risks then the public must be consulted on the RARMP. A broad range of expert groups and authorities are prescribed in the Act to be consulted both on the application and the RARMP.

81. The final decision on issuing a licence is only made after consultation and consideration of comments provided by all key stakeholders. This feedback provides a key point of input by stakeholders into the decision making process. If necessary the RARMP is modified to incorporate or take account of stakeholders comments. When the decision has been made the final version of the RARMP incorporates the decision and the licence conditions attached to that decision and is made publicly available.

82. Figure 2.2 depicts the process of risk communication as surrounding and feeding in to all stages of the risk analysis process. This reflects the importance of risk communication in informing the Regulator's decision.

83. Quality control through internal and external review is also an integral part of every stage of the process (see Chapter 4).

84. Monitoring and review are undertaken as part of ensuring that the risks are managed once a licence is issued. This is undertaken both by the Regulator and by applicants, and the results feed back into the process. Compliance with licence conditions is also monitored by the Regulator.

85. The overall process of risk analysis is highly iterative and involves feedback both internally during the process and through communication and consultation.

QUALITATIVE AND QUANTITATIVE RISK ASSESSMENT

86. The aim of risk assessment is to apply a structured, systematic, predictable, repeatable approach to risk evaluation. This is the case for both qualitative and quantitative assessments.

87. The aim of quantitative risk assessment is to determine the probability that a given hazard will occur and the error associated with the estimation of that probability. In such an assessment the probability includes both the likelihood that a hazard will occur and the consequences if it did occur as

there is a direct relationship between the two. This type of analysis is appropriate to situations such as chemical and industrial manufacture where there is a long history during which information has been accumulated on the type and frequency of risks. It requires large amounts of data and extensive knowledge of the individual processes contributing to the potential risks to be accurate.

88. Environmental risk assessments are often qualitative because of their complexity, the number of inputs, and the necessity to deal with multiple receptors that can give multiple impacts. This is not to say that qualitative assessments do not employ quantitative data. On the contrary, qualitative assessments use quantitative information when it is available. In using qualitative assessments the maximum amount of information can be provided describing likelihood and consequence.

89. Quantitative assessments use numerical values that may be derived from:

- experimental data;
- by extrapolation from experimental studies on related systems;
- historical data; or
- inferred from models used to describe complex systems or interactions.

90. Qualitative assessments use relative descriptions of likelihood and adverse outcomes and can combine data derived from several sources, some of which may be quantitative.

91. The use of qualitative or quantitative approaches depends on the amount, type and quality of the data; the complexity of the risk under consideration; and the level of detail required for decision making. Some of the relative merits that distinguish the two approaches are listed in Table 2.1.

92. The weakness associated with qualitative assessments can be overcome by taking a number of precautions. Four specific weaknesses were identified in Table 2.1 and these can be controlled and minimised. Ambiguity can be reduced by using defined terminology for likelihood, consequences and risk (see Chapter 3). Potential variations between assessors can be reduced through quality control measures including internal and external review and sourcing expert advice. Differing viewpoints, perspectives and biases can be reduced through better descriptions of what the Act is trying to protect (see Chapter 3) and stakeholder input through consultation. Dealing with uncertainty is discussed below.

Table 2.1 Relative merits of quantative and qualitative risk assessments.

	Type of assessment	
	Qualitative	Quantitative
Strengths	• flexible – can be applied when there are insufficient data, a lack of theory, properties of risk are unable to be analysed numerically, high complexity, insufficient resources, and ethical constraints in obtaining the experimental data; • integrates a diverse range of analytical techniques; • allows assessors to make judgements that aid decision making; • useful where there is a lack of experience in observing adverse effects; and • more accessible to stakeholders.	• high objectivity; • assessor independent; • compatible with statistical interrogation; • allows ready comparisons; and • allows formal incorporation of some types of uncertainty.
Weaknesses	• subject to greater ambiguity; • estimates are more subject to variation between assessors; • more prone to heuristics and biases of inputs such as expert opinion; and • more difficult to incorporate uncertainty.	• use of numbers can lead to overconfidence; •can reinforce a sense of alienation between the Regulator and stakeholders; • the accuracy is illusionary if effects are serious but with little or indirect evidence; • inability to apply to complex situations without many simplifying assumptions; and • difficult to use when there are insufficient or poor quality data.

93. For GMOs, qualitative risk assessments are, in most instances, the most appropriate form because:

- the types of organisms and types of introduced genes are highly varied and often novel;
- potential human health and environmental adverse effects are highly varied;
- environmental effects arise within highly complex systems that have many incompletely understood variables; and
- adverse effects may occur in the long term and are therefore difficult to quantify.

94. Therefore qualitative risk assessment for GMOs provides the most feasible mechanism to assess risk for the majority of cases as there is insufficient data to apply quantitative methods. Models can be used to inform the process but are unable to approach the complexity of the systems involved or contribute definitive answers. Qualitative assessments are also more accessible for risk communication.

95. Nevertheless, there is an on-going requirement for testable and repeatable scientific evidence to support qualitative estimates of likelihood and consequences, which are determined according to measurable, objective criteria of harm to human health or the environment.

UNCERTAINTY

96. Regardless of whether qualitative or quantitative risk assessment is used, it must be based on evidence and is therefore subject to uncertainty. Uncertainty is an intrinsic property of risk and is present in all aspects of risk analysis, including risk assessment, risk management and risk communication (Hayes, 2004). A number of different types of uncertainty are discussed in more detail in Appendix D.

97. There is widespread recognition of the importance of uncertainty in risk analysis. In its narrowest use within risk assessments, uncertainty is defined as "a state of knowledge under which the possible outcomes are well characterised, but where there is insufficient information confidently to assign probabilities [likelihood] to these outcomes" (Renn et al. 2003).

98. It is recognised that both dimensions of risk (the potential adverse outcome or consequence and the likelihood), are always uncertain to some degree. Within this context, uncertainty has been interpreted more broadly as incertitude, which arises out of a lack of knowledge of either potential outcome or likelihood. However, uncertainty in risk analysis extends even more widely: there can also be uncertainty of how risk is perceived and how it is described and estimated. Therefore, uncertainty may be more usefully described in a broader sense that accords more with common usage.

99. Examples of uncertainty within the elements of risk analysis could include:

risk assessment

- uncertain nature of the GMO, such as the lack of knowledge of biochemical properties of the introduced genes, environment-specific performance of the GMO, its interaction with other biological entities and processes, or landscape changes over long time periods;
- uncertainty of the calculations within the risk assessment process, including assessment of hazards, likelihood and consequences; and

- uncertain descriptions used in qualitative risk assessments due to insufficient explanations of terminology, use of related terms that are not fully congruent or the use of the same term in different contexts.

risk management

- balancing the sufficiency of protective measures against their effectiveness; and
- decision making in the presence of incomplete knowledge and conflicting values.

risk communication

- uncertainty of communication effectiveness due to difference in knowledge, language, culture, traditions, morals, values and beliefs.

100. The processes in risk analysis that are particularly sensitive to this broadly defined form of uncertainty include establishing the risk context, estimating the level of risk, and decision making. Therefore, this broader consideration of uncertainty is useful for a number of reasons, including:

- applicability to qualitative risk assessments where the sources of uncertainty cover both knowledge and descriptions used by assessors;
- ensuring that information is not over- or under-emphasised during the preparation of a RARMP through the identification of uncertainty;
- highlighting areas where more effort is required to improve estimates of risk and apply appropriate cautionary measures;
- even with the best risk estimates, extending analysis of uncertainty to the decision making process will improve the quality of the decisions;
- helping to produce a clearer separation of the values and facts used in decision making;
- fulfilling an ethical responsibility of assessors to identify the limits of their work;
- developing trust between stakeholders through increased openness and transparency of the regulatory process; and
- increasing the opportunity for more effective communication about risk.

101. One aspect of uncertainty is related to the meaning of words (semantics) adopted by the Regulator. A clear definition of terms is a very important and practical means for reducing uncertainty that might arise simply as a result of ambiguity in language. Specific terms have been selected as unique descriptors of likelihood, consequence and risk (see Chapter 3). This will aid the clarity and rigour as well as the consistency and reproducibility of assessments. This will in turn enhance the intelligibility of documentation prepared by the Regulator, especially the RARMPs. It may be seen as a part of the scientific discipline and intellectual rigour that the Regulator seeks to bring to all levels and aspects of risk analysis. The use of consistent terminology has impacts at all levels of risk analysis: in having an agreed setting of context, of undertaking risk assessment, in risk treatment (especially for licence conditions which need to be intelligible, unambiguous and enforceable) and in risk communication.

SUMMARY

102. The model of risk analysis employed by the Regulator is broadly similar to AS/ANZ 4360:2004 and integrates the elements of risk assessment, risk management and risk communication into a structured, systematic, predictable, repeatable approach to the risk analysis of dealings with GMOs under the Act. This approach will employ quantitative information and evidence but will not depend on quantitative risk analysis.

103. In order to reduce ambiguity and improve consistency of risk assessments the Regulator will use specific terminology to describe and distinguish between likelihood, consequence and risk estimation (see Chapter 3). Where appropriate, uncertainty will be considered and factored into the process of risk analysis.

CHAPTER 3
RISK ASSESSMENT

104. Risk assessment is the overall process of identifying the sources of potential harm (**hazard**) and assessing both the seriousness (**consequences**) & the **likelihood** of any adverse outcome that may arise. It is based on hazard, consequence and likelihood assessments leading to an estimation of risk.

105. For the purposes of this document **risk** is defined as: 'the chance of something happening that will have an undesired impact'[5]. In the context of the Act, only hazards that arise as a result of gene technology and lead to an adverse outcome for humans or the environment can be considered by the Regulator.

106. Risk, as considered here, is concerned with assessing potential harm to human health and safety and the environment that might arise from the use of gene technology. Kaplan and Garrick (1981) suggest that risk is most usefully considered as a narrative that answers three questions: What can happen? How likely is it to happen? If it does happen, what are the consequences? Therefore, an estimate of the level of risk (negligible, low, moderate or high) is derived from the likelihood and consequences of individual risk scenarios that arise from identified hazards. In addition, uncertainty about likelihood and consequences of each risk scenario will affect the individual estimates of risk.

107. The individual steps in the process of risk assessment of GMOs are discussed in this Chapter. They consist of setting the context for the risk assessment, identifying the hazards that may give rise to adverse outcomes, assessing the consequences and likelihoods of such outcomes and arriving at a risk estimate. The risk assessment is an integral part of the RARMP and aims to identify the risks arising from the dealings with the GMO in order to derive the risk estimate(s) that can then be used to inform risk management (discussed in Chapter 4).

RISK ASSESSMENT CONTEXT

The purpose of risk assessment

108. The purpose of risk assessment under the Act is to identify risks to human health and the environment and estimate the level of risk based on scientific evidence. Risks to all living organisms and relevant ecosystems will be considered.

[5] This definition is taken from AS/NZS 4360: 2004 modified to include only risks leading to adverse impacts.

109. Risk analysis can be applied to many different types of risk and different methodologies have been applied to assess different risks. Assessment of risks to health and safety often takes the form of hazard identification, dose-response assessment and exposure assessment leading to risk characterisation. It draws on information from disciplines such as toxicology, epidemiology and exposure analysis.

110. Environmental risk assessment requires assessing harm not only to individuals and populations within a species but also to interactions within and between species in the context of biological communities and ecosystems. There may also be the potential for harm to the physical environment. Information can be sourced from studies of botany, zoology, entomology, mycology, microbiology, biochemistry, population genetics, agronomy, weed science, ecology, chemistry, hydrology, geology and knowledge of biogeochemical cycles, and therefore requires consideration of complex dynamic webs of trophic interactions.

111. A similar approach will be applied by the Regulator and OGTR, to assess risks to both human health and safety and the environment under the Act.

The scope of risk assessment

112. Risks that may be posed by gene technology are required to be considered in the context of the proposed dealing with GMOs and are assessed on a case by case basis. In the case of field trials, the scale of the release is limited in both space and time. In a commercial release the scale is not necessarily restricted and therefore a wider range of environmental and ecological settings is considered in the risk assessment.

113. An application submitted to the Regulator must contain information that defines the GMO and the dealings as set out in the Act and Regulations. The Act also defines what risks must be considered (see Chapter 1 and section 51(1)).

114. Other important factors in establishing the context for risk assessment are:

- the location of the dealings, including the biotic and abiotic properties of the site(s);
- size and time scale of the dealings
- the applicant's proposed management of the dealings to limit dissemination of the GMO or its genetic material;

- other GMOs already released; and
- particular vulnerable or susceptible entities that may be specifically affected by the proposed release.

115. In some instances, a particular gene may already be present naturally in the environment and this background exposure may be important. For example, many antibiotic resistance marker genes are derived from soil bacteria that are abundant in the environment. Therefore exposure to the protein encoded by such a gene derived from a GMO may be insignificant against this background.

Baselines

116. The Regulator can only consider risks posed by or as a result of gene technology. Therefore risks posed by a particular GMO need to be considered in the context of the risks posed by the unmodified parental organism in the receiving environment. For DIRs this may be considered by examining whether the GMO would cause an adverse outcome over and above that which would occur if the *status quo* were maintained, that is, if the GMO was not deployed in the environment. For DNIRs the contained facilities prevent exposure to the environment although the potential for unintentional release must be considered.

117. In order to establish a comparison between the properties and characteristics of the GMO and those of the unmodified organism an appropriate baseline is needed. For example, many crop plants are elite cultivars and the cultivar that the GM crop plant was derived from would usually provide the appropriate comparator. Such a plant will have a similar genetic background to the GM plant with the exception of the GM trait. It should be noted that conventional breeding can result in changes in the genetic background of cultivars.

118. In the context of contained dealings the parent organism itself can be pathogenic and the risks arising as a result of the genetic modification need to be considered against that baseline.

119. The environment in which the GMO is deployed is also relevant for intentional releases and it is important that an appropriate receiving environment is used as a baseline for comparison. For example, many of the GM plants approved for release to date are designed to function in an agricultural context that employs current growing and management practices and these will be considered in the risk assessment. Standards

such as Good Agricultural Practice may provide a benchmark for acceptable practices although it must be recognised that such practices may evolve and change over time.

120. An example where agricultural practice has changed as a result of deployment of GMOs is in the use of insecticidal cotton. At the time of initial release of GM insecticidal cotton, normal agricultural practice necessitated a heavy chemical regime. Initially a 60/30 distribution was mandated between non-GM and GM cotton. This ratio altered significantly with the approved uptake of new GM varieties, so the most appropriate baseline environment for comparison may change.

121. Where the conventional variety is the most widely grown cultivar it is relatively easy to establish the appropriate baseline for comparison. However, in some instances it may be that multiple baselines for comparison are necessary. This is increasingly likely with the deployment of new cultivars, both GM and non-GM. For instance, in the case of canola the existence of two herbicide tolerant varieties bred by conventional means that are widely grown across Australia had to be considered in assessing applications for the commercial release of herbicide tolerant GM varieties.

122. The receiving environment also may not be static over time and such change will be considered in the assessment. For instance, changes in agricultural practices in relation to cropping or chemical use patterns may affect the environment in which the GMO is to be deployed. There are several considerations that have some bearing in this context including: the dynamic nature of ecosystems; the process of natural succession in the evolution of ecosystems; and the inherent resilience of ecosystems because of their ability to accommodate change. Such factors are important in assessing the consequence component of risk estimation. In the first instance the appropriate time frame will be the proposed length of the application. This does not exclude the consideration of long term effects.

123. The Act requires a case by case assessment of applications for intentional environmental release and the selection of appropriate baseline(s) will form part of that process.

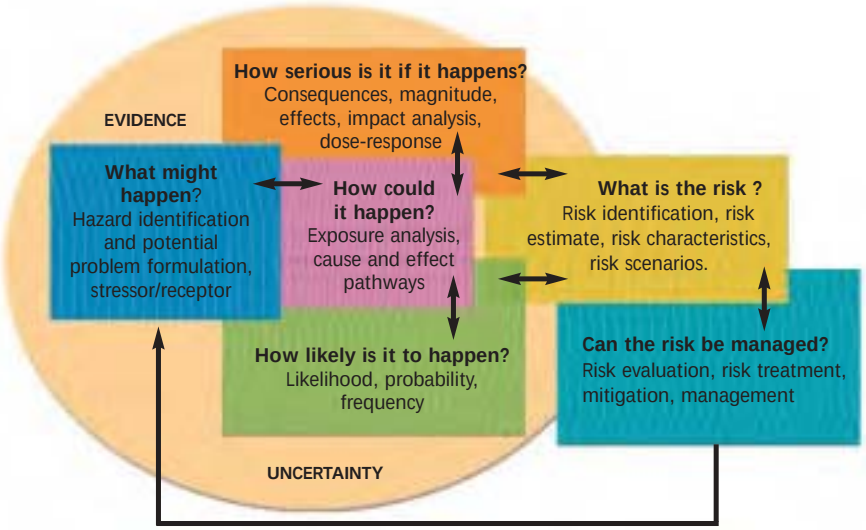
The methodology of risk assessment

124. Risk assessment is an iterative process (Figure 3.1) and involves the process of hazard identification, followed by likelihood and consequence assessment to achieve a final estimate of risk. However, likelihood and consequence assessments are usually considered in concert when establishing pathways that lead from a hazard to a potential adverse outcome.

The criteria for risk assessment

125. In assessing risk it is important to consider the criteria against which specific risks are assessed. This addresses the question of what counts as harm or an adverse outcome? How can harm be measured? In assessing harm as part of risk assessment there needs to be some way of detecting or measuring harm.

Figure 3.1 The risk assessment loop.



126. The legislation specifies matters that the Regulator must consider in preparing the risk assessment (section 51(1)(a)). These matters include:

- previous assessments;
- the potential of the GMO to be harmful to humans and other organisms;
- the potential of the GMO to adversely affect any ecosystems;
- transfer of genetic material to another organism;
- the spread or persistence of the GMO in the environment;

- whether the GMO may have a selective advantage in the environment; and
- whether the GMO is toxic, allergenic or pathogenic to other organisms.

127. The Regulations also detail the specific information that must be supplied by the applicant that is relevant to risk assessment and risk estimation for particular types of GMOs (schedule 4). The Regulations therefore provide one source of criteria for determining adverse outcomes. International guidelines can also be used to give some indication of what might be considered harm (FAO 2004; OIE, 2002; Codex Alimentarius Commission 2003).

128. Adverse outcomes or harm arising from GMOs can be grouped into categories. Types of adverse outcomes that could potentially arise, along with attributes that could be used to measure that harm are listed in Table 3.1. It is important that observable, measurable properties are identified in order to accurately assess that harm has occurred.

Table 3.1. Examples of generic criteria for determining harm to human health and safety, or the environment.

ADVERSE OUTCOMES	MEASURABLE PROPERTIES
Harm to human health and safety: toxicity (including acute effects such as irritation & sensitisation and chronic effects such as mutagenicity) Carcinogenicity, teratogenicity, allergenicity, pathogenicity, endocrine & reproductive effects	Biochemical, physiological, physical or developmental abnormalities; frequency & age of morbidity; frequency of infection; age/weight ratio; mortality
Harm to protected species (including secondary impacts at different trophic levels)	Numbers & density (abundance); sites where present; mortality; frequency & age of morbidity; survival, fecundity, age/weight ratio; properties of habitat where it occurs
Harm to non-target species (including secondary impacts at different trophic levels)	Population morbidity; genotype frequency; abundance; yield/production
Irreparable loss of species diversity or genetic diversity within a species	Presence & abundance of species; genotype frequency; yield/production
Creating a new or more vigorous weed, pest or pathogen	Occurrence & biological properties, for example invasiveness or pathogenicity
Exacerbating the effects of an existing weed, pest or pathogen	Occurrence in new environment, new population or species of host; size/ frequency of attack or invasion; intensity of disease symptoms; yield/ production; species richness of the community where the weed, pest or pathogen occurs
Disruptive effects on biotic communities & ecosystems (including transient & permanent changes)	Species richness; diversity indices; extent & area; production; indices of food web structure; carbon, nitrogen & phosphorous fluxes
Disruption of rare, endangered or highly valued ecosystems (*eg.* aquatic & alpine environments, coral reefs, wetlands)	Extent & area; species richness; structure
Harm to the abiotic environment	Frequency of floods, low flows & fire; pollutant concentrations; physical damage

129. The generic criteria for specifying harm to human health and the environment listed in Table 3.1 are illustrative and intended neither as a requirement for all risk assessments, nor as precluding the use of other criteria. They are intended as a starting point for considering how to assess harm and describing the types of data that could be used as evidence for measuring potential adverse impacts. It is important to differentiate between adverse impacts and natural change due to the dynamic nature of biological systems (see Consequences section).

130. No list of generic criteria would be sufficient for all cases. Therefore the properties of the GMO, its location(s), the types of dealings and the management conditions employed will all be important in deciding which people and what particular local environmental attributes are most susceptible.

HAZARD ASSESSMENT – WHAT CAN GO WRONG?

131. For the purposes of this document a hazard is defined as 'a source of potential harm'. It can be an event or a substance or an organism.

132. Hazard identification underpins the process of risk assessment. In its simplest form it can be conceptualised as asking the question: **what can go wrong?** This process should be distinguished from risk estimation, which includes consideration of likelihood and consequences.

133. A critical stage of risk assessment is identifying all likely hazards in the process of the dealing with a particular GMO. Unidentified hazards may pose a major threat to health and the environment. It is important, therefore, that a comprehensive approach is adopted to ensure that the full range of hazards is identified.

134. A hazard needs to be distinguished from an adverse outcome and also from a risk. A hazard is a source of potential harm and only becomes a risk when there is some chance that harm will actually occur. These are important distinctions that can be difficult to establish clearly in some circumstances. For example, the hazard of catching a dangerous disease only becomes a risk if there is exposure to the organism that causes that disease. The adverse outcome only arises if infection occurs.

The chance that a hazard leads via a causal pathway to an adverse outcome = risk

135. Although a hazard is a source of potential harm, often particular circumstances must occur before that harm can be realised and before it can be considered a risk. Indeed, quite specific conditions may be required for the adverse outcome to eventuate. For instance, a gene encoding virus resistance in a plant could lead to increased weediness in the presence of the virus, but only if the viral disease is a major factor limiting the spread and persistence of the plant.

Hazard analysis

136. A number of hazard identification techniques are available that range from broad brush approaches to more targeted analysis. Techniques used by the Regulator and staff of the OGTR include, but are not limited to checklists, brainstorming, commonsense, previous agency experience, reported international experience, consultation, scenario analysis and inductive reasoning (fault and event trees). The AS/NZS 4360:2004 and Hayes et al (2004) contain details of a range of other techniques that have not been broadly applied in the context of biological systems. These include HAZOP (hazards and operability analysis), SWOT (strengths, weaknesses, opportunities and threats analysis), failure mode effect analysis, hierarchical holographic modelling (HHM, Hayes et al. 2004), multicriteria mapping, Delphi analysis and systems analysis.

137. Hazards can be considered from the top down, that is, the potential adverse outcomes are identified and the processes that may give rise to them described. Or they can be addressed from the bottom up, that is the biological, physical, chemical and human components and processes that make up the system to be studied are examined and potential adverse outcomes identified. Where risks have already been identified and characterised and are well understood it is possible to use deductive reasoning to identify hazards. However deductive techniques are unlikely to identify synergistic or antagonistic effects. In the case of new technologies such as those used to produce GMOs, where there is not a long history of use and potential hazards may still be unknown, inductive reasoning can provide a better strategy for hazard identification.

138. The process of hazard identification involves consideration of causal pathways that result in harm. Although it is important to identify all potential hazards it is also important to apply a test of reasonableness. The number of hazards that can be conceived as an intellectual exercise by varying circumstances, environmental conditions or chemical and physical processes is infinite but not all are realistic, likely to eventuate, or to result in identifiable harm.

139. In identifying hazards the Regulator will look specifically at:

- altered biochemistry;
- altered physiology;
- unintended change in gene expression;
- production of a substance toxic to humans;
- production of a substance allergenic to humans;
- survival and persistence off-farm;
- survival and persistence on-farm;
- unintended selection;
- unintended invasion;
- expansion into new areas;
- gene flow by sexual gene transfer;
- gene flow by horizontal gene transfer;
- production of a substance that is toxic to, or causes ill-health or mortality in non-target organisms;
- expression of a transgene that alters the infectivity or pathogenicity, host range, pathogen load, vector specificity of a disease agent to non-target organisms;
- interaction of introduced pathogenic genes or products with other pathogens;
- unintended effects on an existing non-GM weed, pest or pathogen;
- secondary effects (e.g. loss of GM trait efficacy such as pest or pathogen resistance, development of herbicide resistance);
- production (farming) practices;
- alteration to the physical environment including biogeochemical cycles; and
- intentional/unauthorised activities.

140. Not all of the above categories of hazard will be relevant to all GMOs and specific ones may warrant a more detailed consideration in one application than in others. Some hazards will have similar adverse outcomes and could be grouped on that basis.

141. In risk assessments for GM plant DIRs the main hazard groups considered include human health and that of other organisms (non-target), weediness, and gene transfer, with a number of other groupings that are GMO-specific. Some categories of hazard such as production practices may be best discussed throughout the RARMP rather than as a unique category. In RARMPs for DNIRs the main hazards often relate to the parent organism (e.g. a pathogenic bacterium or virus) itself rather than the GM trait.

Causal linkages

142. Once hazards have been identified it is important to establish that there is a causal link between the hazard and an adverse outcome. There should be an identifiable pathway or route of exposure that demonstrates that the hazard will cause the adverse outcome. There are several possible combinations:

- a single hazard gives rise to a single adverse outcome;
- a single hazard gives rise to multiple adverse outcomes;
- multiple hazards that act independently and give rise to a single adverse outcome; and
- multiple hazards that interact and give rise to single or multiple adverse outcomes.

143. The Regulator will also consider if any of the identified hazards have synergistic, additive, antagonistic, cumulative or aggregate effects from the GMO, in combination with both non GM organisms and other existing GMOs. Additive effects may occur where different hazards give rise to the same adverse outcome, which could increase the negative impact. Synergism arises when the effects are greater than when added. For example, a GMO expressing two insecticidal genes with different modes of action may have greater potency than the addition of the effects from the individual genes. Cumulative effects arise where there may be repeated exposure over time that may aggravate an established disease or state and antagonistic effects may occur where the GM trait alters the characteristics of the organism in opposing ways. For example, if a gene was introduced or modified to increase production of a particular compound but it also reduced growth rates, this would be regarded as an antagonistic effect.

144. Establishing the underlying causal linkage provides the foundation for likelihood and consequence assessments and makes it easier to identify where further information may be required or where there may be uncertainty. Other methods of linking a hazard to an adverse outcome are descriptions based on expert scientific knowledge, or by inference from experimental data and models.

145. Specific circumstances may be required for a hazard to eventuate, for instance, certain characteristics of the environment may be important such as soil type or rainfall and this must be taken into account. For instance, a plant may only become weedy in particular geographical locations, or a microorganism may only cause disease in a particular host organism.

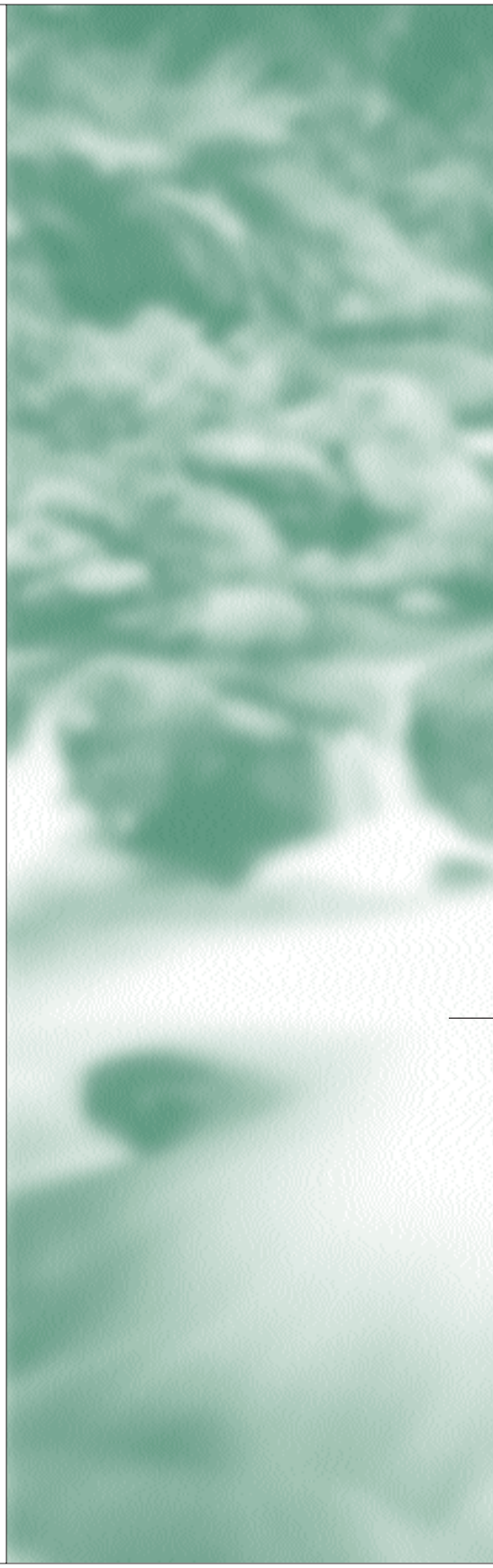
146. Factors that may be positively associated with the development of adverse effects will also be considered. These include enabling factors such as poor nutrition and precipitating factors such as the exposure to a specific disease agent or toxin. For example, someone who has a compromised immune system may be susceptible to a GM microorganism that is normally non-pathogenic in healthy individuals.

147. The Regulations require the Regulator to consider the short and the long term when assessing risks (subregulation 10(1)). The conduct of risk analysis by the Regulator does not attempt to fix durations that are either short or long term, but takes account of the likelihood and impact of an adverse outcome over the foreseeable future, and does not discount or disregard a risk on the basis that an adverse outcome might not occur for a long time.

148. An example of a short term effect is acute toxic effects on an organism due to direct exposure to the GMO. In contrast, increased weediness arising from gene flow from a GM plant is an example of what could be considered a long term effect as it develops over a number of generations. The timeframes considered by the Regulator will be appropriate to the GMO, its lifecycle and the type of adverse outcome under consideration. A GM cow that has a lifespan of many years may involve considerations on a longer timeframe than a GM mouse that has a significantly shorter lifespan, although the implications and long term consequences of the release of either would be also be considered.

Hazard selection

149. Hazards that warrant detailed estimation of likelihood and consequence to assess whether they pose a risk to human health and safety and the environment are determined by applying a number of criteria including



those specified by the Act and those of specific concern to stakeholders. Those that do not lead to an adverse outcome or could not reasonably occur will not advance in the risk assessment process. In some cases the adverse outcome may not be significant, in which case the hazard may be set aside. Thus, even at an early stage, consideration of likelihood and consequence becomes part of an iterative process in the cycle of risk assessment. Screening of hazards occurs throughout the risk assessment process, with those that do not require further consideration being set aside. It is also possible that additional hazards may be identified during other stages of the process, in which case if regarded as relevant, they will be considered.

150. Consultation with stakeholders on applications and RARMPs ensures all relevant hazards are identified. In particular, GTTAC has an important function in ensuring that the relevant hazards have been identified for further consideration.

151. Hazard selection should be comprehensive and rigorous. However, care should be taken to avoid over emphasis of unrealistic events. It should be relevant to the nature of the GMO and the spatial and temporal scale of the proposed release. The process should be iterative with feedback mechanisms between individual steps and take into account the spatial and temporal scale of the proposed release, previous relevant assessments and data collected from previous releases of the GMO, if available. It should also be transparent and consider stakeholder's concerns relevant to the health and safety of people and the environment.

CONSEQUENCES – WOULD IT BE A PROBLEM?

152. The consequence assessment stems from the question: **would it be a problem?** More specifically, if the hazard does produce an adverse outcome or event, i.e. is identified as a risk, **how serious are the consequences?**

153. The consequences of an adverse outcome or event need to be examined on different levels. For instance, harm to humans is usually considered on the level of an individual whereas harm to the environment is usually considered on the level of populations, species or communities. Consequences may have dimensions of distribution and severity. For example, if a genetic modification resulted in the production of a protein with allergenic properties, some people may have no reaction to that protein, others may react mildly while others may be seriously affected. That is, there may be a range of consequences from an adverse outcome, some people may be

more sensitive to a toxin than others, so the response may range from mild ill health in one individual to serious illness in another, with the most common response falling between these two extremes.

154. In considering consequences it is important to take into account factors including the variation and distribution in the severity of the consequences.

155. Assessing the significance of an adverse impact includes consideration of five primary factors:

- the severity of each potential adverse impact including the number, magnitude and probable severity of, in the sense of degree, extensiveness or scale: How serious is the impact?

  Does it cause a large change over baseline conditions? Does it cause a rapid rate of change – large changes over a short time period? Does it have long-term effects? Is the change it creates unacceptable?;

- the spatial extent to which the potential adverse impact may eventually extend (e.g. local, regional, national, global) as well as to other organisms;

- the temporal extent of the adverse impact, that is the duration and frequency – the length of time (day, year, decade) for which an impact may be discernible, and the nature of that impact over time (is it intermittent and/or repetitive? If repetitive, then how often and how frequently?);

- the cumulative adverse impact – the potential impact that is achieved when the particular project's impact(s) are added to impacts of other dealings or activities that have been or will be carried out; and

- reversibility – how long will it take to mitigate the adverse impact? Is it reversible and, if so, can it be reversed in the short or long-term?

156. Table 3.2 provides some examples of descriptions relating to a scale of adverse consequences related to human health and separate ones related to the environment. The explanations for consequences to human health focus on injury as the adverse outcome but could equally focus on the number of people affected or the spatial scale (local, regional, national) of the adverse impact. Adverse consequences to the environment encompass

a wide range of effects and the descriptions include some of elements from the factors listed above.

157. Change is an inherent part of any complex dynamic system, including biological systems. Therefore in assessing adverse consequences arising from a GMO it is important to distinguish change that may occur in the absence of the GMO from change occurring as a result of the GMO and to consider whether that change is undesirable. Furthermore, these changes could vary according to the environmental context (e.g. an agricultural setting as opposed to the undisturbed natural environment).

Table 3.2 Descriptors of adverse consequences to human health and the environment

	Consequences
Marginal	Minimal or no injury except to a few individuals that may require first aid Minimal or no degradation of the environment
Minor	Slight injury of some people that may require medical treatment Disruption to biologicalcommunities that is reversible and limited in time and space or number ofindividuals/populations affected
Intermediate	Injury to some people that requires significant medical treatment Disruption to biological communities that is widespread but reversible or of limited severity
Major	Severe injury to some people that may require hospitalisation or may result in death Extensive biological and physical disruption of whole ecosystems, communities or an entire species that persists over time or is not readily reversible

LIKELIHOOD – HOW LIKELY IS IT TO HAPPEN?

158. Likelihood is the chance of something happening. The likelihood assessment centres around the question: **will it happen?** And more specifically, **how likely is it to happen?** Likelihood is another major component of risk assessment. If an adverse event is not expected to occur in some relevant timeframe then its impact does not need to be analysed further.

159. Likelihood is expressed as a relative measure of both frequency (the number of occurrences per unit time) and probability (from zero to one, where zero is an impossible outcome and one is a certain outcome). Likelihood is expressed in the following terms for qualitative risk assessments, highly likely, likely, unlikely, highly unlikely.

160. Factors that are important in considering the likelihood of a hazard leading to an adverse outcome are:

- the circumstances necessary for the occurrence or presence of the hazard;
- the circumstances necessary for the occurrence of an adverse outcome;
- the actual occurrence and severity of the adverse outcome; and
- the persistence or spread of the adverse outcome.

161. Factors that contribute to the likelihood of an adverse outcome include:

- the survival, reproduction and persistence of the GMO; and
- the circumstances of the release, that is the environment, biotic and abiotic factors, and other organisms.

162. The frequency or probability of an initial event should not be considered alone if a chain of events leads to the adverse outcome. In this case each event in the chain, with an associated likelihood, depends on the previous event occurring in the first place. The overall likelihood will be lower than the likelihood of any individual event. Such conditional probabilities need to be factored into determining the final likelihood of an adverse outcome. Where the exposure pathway is complex it may be difficult to ascribe a single likelihood to the adverse outcome.

163. Assessing likelihood is more difficult for distant hazards where there may be many links in the chain of causal events. For instance, horizontal gene transfer from a GM plant or animal to a pathogenic microbe requires a large number of events to occur in sequence before the hazard will eventuate. However, the occurrence of the event (i.e. gene transfer) does not necessarily result in harm. There are further events necessary, including the ability of the newly modified microbe to survive, replicate, display a selective advantage and give rise to some identifiable harm. In such cases the effect of all combined likelihoods will substantially reduce the overall likelihood of an adverse outcome. In contrast, hazards close to a potentially adverse outcome, such as a gene product that is toxic to non-target organisms, can usually provide more robust estimates of likelihood, particularly as there is often a direct correlation between the dose of toxin and the severity of the adverse outcome and the mechanism of action may have been experimentally verified.

164. In the case of field trials there is a fixed period for the release but any potential for adverse effects beyond this period must also be considered. As with any predictive process, accuracy is greatest in the immediate future and declines into the distant future.

EVIDENCE – WHAT COUNTS?

165. Only applications containing sufficient information will be considered by the Regulator. In the absence of adequate information the Regulator may reject the application, request more information from the applicant or, if unable to proceed with the assessment, decide to stop the clock on the application until the information is provided.

166. A critical consideration related to evidence is how much and what data are required. It is important to distinguish between data necessary for the risk assessment and background information that does not directly inform the estimate of risk. Collection of data simply to have the information when that information serves no purpose is an inefficient use of resources.

167. The evidence used to assess an application comes from a variety of sources. The Regulations set out details of the information that the applicant is required to provide in the application. It can also include experimental data from other scientific literature relevant to the application, practical experience, reviews, theory, models, observations, anecdotal evidence and uncorroborated statements.

168. Previous assessments of a GMO by other regulatory agencies in Australia are considered. Where a recognised overseas regulatory agency has made an assessment of the same or a similar GMO, their findings will also be considered during the risk assessment. The OGTR has established links with relevant agencies that facilitate exchange of information. The OGTR also participates in the work of international agencies such as the OECD, to produce documentation that contributes to the harmonisation of regulatory activities between countries.

169. Other sources of qualitative information include:

- expert opinion, from committees/groups of experts, other regulatory authorities or from individual experts;
- information on potential hazards provided through public consultation; and
- published material on related situations.

170. The Regulator assesses information, including that provided by the applicant, against rigorous scientific standards. Emphasis is placed on quantitative data. Scientific studies by the applicant will be assessed for the appropriateness and quality of experimental design and data analysis and the conclusions must be substantiated by the data. All of these aspects are independently evaluated by appropriately qualified staff at the OGTR. There are internationally accepted standards that must be met for particular types of studies and data is assessed against these standards. For instance, in toxicological assessments experimental data from animal studies are used to extrapolate to humans using defined safety factors and environmental risk assessment is often based on effects on accepted test species.

171. Evidence is weighted by its source (e.g. a peer reviewed article in a recognised international journal will have more weight than an uncorroborated statement on a personal website) and by its content. This is presented graphically in Figure 3.2. Where statements have insufficient backing they may be given lesser weight or credence. In cases where there may be conflicting evidence with regard to adverse impacts, for instance some information showing a negative impact and some showing no effect, this will be considered in coming to a final conclusion.

Figure 3.2 Some types of evidence and their relative strength.

Validated studies conducted according to international protocols meeting defined standards

Peer reviewed experimental data on the GMO in the Australian environment

Peer reviewed experimental data on the GMO in other environments

Peer reviewed experimental data on the parent organism, modified traits or ecology

Peer reviewed experimental data on related, surrogate systems

Peer reviewed literature - strongly supported reports, models, theory

Peer reviewed literature - single reports, models, theory

Commissioned research data

General biological principles

Familiarity of expert opinion with GMO, parent organism, modified traits, ecology

Other scientific reports, specialist literature (e.g. beekeeping), government reports, etc

No information to indicate a problem

Unsubstantiated statements

172. Evidence can be judged to have both strength and weight. It can be weighted by the number of studies, a number of weaker pieces of evidence may counter-weigh a single strong piece of evidence, or by the depth of the studies, a detailed study may have more weight that a superficial one. The strength of the evidence can be considered through its relationship to the problem. If evidence is directly related to the problem it will be stronger than evidence that only has an indirect bearing on the problem. Thus if there are studies of the weediness of a particular species, this will have greater strength than information about the weediness of a related species.

173. In the absence of direct evidence indirect evidence is not excluded but will be weighted appropriately.

174. If data are unavailable or incomplete, the significance of that absence or incompleteness in undertaking an evaluation of the risks of a proposal will be considered. If the Regulator considers that the lack of data creates uncertainty around a level of risk that appears manageable, then further collection of data may be required under strictly limited and controlled field conditions. However, if the Regulator determines that the risk is not manageable, a licence will not be granted.

175. It is important to consider not only all available evidence and to use that, through logical deduction, to extend the value of that evidence, but also to consider uncertainty wherever it is apparent and take it into account.

RISK ESTIMATION – WHAT IS THE RISK?

176. Risk is measured in terms of a combination of the likelihood that a hazard will give rise to an adverse outcome and the seriousness (consequences) of that adverse outcome.

177. To reduce ambiguity of terminology used in qualitative risk assessments the Regulator will apply a set of distinct descriptors to the likelihood assessment, consequence assessment and the estimation of risk. The definitions are intended to cover the entire range of possible licence applications and should be regarded as relative. For instance, the consequences of a risk relating to human health will be very different to the consequences of a risk to the environment (see Table 3.2).

178. The explanations of descriptors used to delineate likelihood are based on those of AS/NZS 4360:2004 and have been chosen to encompass

consequences to both humn health and safety and the environment. They are relatively simple in order to cover the range of different factors (severity, space, time, cumulative, reversibility) that may contribute to the significance of adverse outcomes. The individual description can be incorporated into a Risk Estimate Matrix (Figure 3.3)

LIKELIHOOD ASSESSMENT

Highly likely - is expected to occur in most circumstances
Likely - could occur in many circumstances
Unlikely - could occur in some circumstances
Highly unlikely - may occur only in very rare circumstances

CONSEQUENCE ASSESSMENT

Marginal - there is minimal or no negative impact
Minor - there is some negative impact
Intermediate - the negative impact is substantial
Major - the negative impact is severe

RISK ESTIMATE

Negligible - risk is insubstantial and there is no present need to invoke actions for mitigation
Low - risk is minimal, but may invoke actions for mitigation beyond normal practices
Moderate - risk is of marked concern that will necessitate actions for mitigation that need to be demonstrated as effective
High - risk is unacceptable unless actions for mitigation are highly feasible and effective

Figure 3.3 Risk Estimate Matrix

RISK ESTIMATE MATRIX

LIKELIHOOD					
	Highly likely	Low	Moderate	High	High
	Likely	Negligible	Low	High	High
	Unlikely	Negligible	Low	Moderate	High
	Highly unlikely	Negligible	Negligible	Low	Moderate
		Marginal	**Minor**	**Intermediate**	**Major**
		CONSEQUENCES			

179. Risk matrices are often asymmetrical because not all risks have the same mathematical relationship between likelihood and consequence. In addition, there may be other factors that influence the relationship such as sensitive subpopulations, a range of responses or a distribution of the frequency of the impact.

180. The descriptors nominated above for likelihood, consequence and the risk estimate will be applied for all licence applications. However, they must be considered in the context of the proposed dealing. Comparisons between licence applications are only possible in the broadest sense even for the same categories of hazard. For example, the introduction of a gene that expresses a therapeutic agent in an elite variety of potato known to be sterile could be considered a lower risk compared with the introduction of the same gene into a partially outcrossing plant such as white lupin, because of the decreased potential for spread and persistence of the introduced gene. Direct comparison with risks from other substantively different GMOs such as a GM virus may not be instructive. It is important to note that uncertainty about either or both of these components will affect the risk estimate.

181. The aim of the Risk Estimate Matrix is to provide a guide to thinking about the relationship between the consequences and the likelihood of particular hazards. Likelihood and consequence assessments are combined to give a risk estimate. The risk matrix is designed to be used as a tool in arriving at the risk estimate. It is not a prescriptive solution for deciding on the appropriate risk estimate for any given adverse outcome. For example, an adverse outcome such as increased pathogenicity due to gene exchange may vary widely in severity from event to event. Neither should it be used to set predetermined management conditions for a particular risk level. Rather it should be used to inform the risk evaluation process (see Chapter 4).

182. The descriptors for the risk estimate are designed to relate specifically to risk assessment applied in the context of a proposed dealing with a GMO. These descriptors may not necessarily have the same meaning in a compliance context where establishing an appropriate response to non-compliance is required.

183. The risk estimate for an individual hazard, group of hazards or risk scenarios is used in considering the strategies that may be required in order to manage those risks. The next Chapter will discuss risk management.

CHAPTER 4
RISK MANAGEMENT

THE RELATIONSHIP BETWEEN RISK ASSESSMENT AND RISK MANAGEMENT

184. The risk assessment component of risk analysis may be viewed as providing the answers to a set of questions:

- **'What might happen? How might it happen?'** – hazard identification and risk characterisation; and
- **'How likely is it to happen? What harm will occur if it happens?'** – risk estimation.

185. The risk management component of risk analysis builds on the work of the risk assessment and may be described as answering the questions:

- **'Does anything need to be done about it?';**
- **'What can be done about it?'; and**
- **'What should be done about it?'.**

186. The risk assessment provides the estimate of the risks, including the likelihood of occurrence and the absolute and/or relative magnitude of the harm that could result, as well as the degree of uncertainty that applies to their likelihood and/or consequences.

187. The risk management component of risk analysis involves identifying those risks that require management, the range of options that could effectively treat the risks, deciding on the actions that will provide the required level of management, and implementing the selected measures.

188. The conclusions of the risk assessment may already include indications of risks that require management, especially if the magnitude of the consequences is great. As indicated in Chapter 3, risks with estimates of high or moderate would generally invoke a requirement for management. The risk assessment may also provide a starting point for selection of risk treatment measures in that it is aimed at **understanding** risks, and therefore it may provide insights into the available mecahisms to manage risks and the relative merits of those mechanisms.

189. The consideration of whether particular risks require management will be informed by review of the conclusions of the risk assessment, consideration of the risks *per se* in the context of management, or as a result of consultation with stakeholders. In the case of consultation on licence applications the Regulator receives advice on the RARMP which may relate to risk assessment, risk management or both.

190. While there is overlap and interaction between risk assessment and risk management, it is important to recognise them as separate and qualitatively different processes. This conceptual separation ensures the integrity and objectivity of the risk assessment, which is the scientific process of investigating phenomena using the body of evidence to estimate the level of risk and taking account of any uncertainty associated with that assessment.

191. Risk management, while based on the risk assessment, necessarily deals with prudential judgements about which risks require management, and the selection and application of treatment measures to control risks. This separation also contributes to the intellectual rigour and transparency of the whole risk analysis process. In practice there is a feedback between risk assessment and risk management – the two components are intimately related and often iterative (as indicated in Figures 2.2 and 3.1, and provided by consultation on the RARMP).

192. Risk management ultimately includes the decision on whether to proceed with an activity, and in the case of risk analysis undertaken by the Regulator, whether or not a licence should be issued for the proposed dealings with GMOs.

Risk management and uncertainty

193. Chapters 2 and 3 and Appendix D highlight the importance of explicitly recognising and considering uncertainty in risk analysis. The risk assessment process will identify uncertainty with respect to the likelihood and consequence of risks. Any proposed risk treatment measures should take account of this uncertainty.

194. The Regulator adopts a cautious approach that encompasses the credible boundaries of uncertainty based on the best available evidence in:

- determining the necessary level of risk management;
- assessing the effectiveness of available risk treatment options; and
- the selection of the most appropriate measures to treat risk.

LEGISLATIVE REQUIREMENTS

195. The management of risks to human health and safety or the environment that may be posed by GMOs is central to the object of the Act and corresponding State legislation, and the assessment of risks provides the necessary foundation required to achieve effective risk management. In relation to decisions on licence applications section 56 of the Act requires that:

> "The Regulator must not issue a licence unless the Regulator is satisfied that any risks posed by the dealings proposed to be authorised by the licence are able to be managed in such a way as to protect: (a) the health and safety of people; and (b) the environment."

196. This emphasis on ensuring that risks are managed is also contained in a number of other provisions of the Act: suspension; cancellation; and variation of licences, certification of facilities, and accreditation of organisations.

197. It is also important to note that all human activity involves some level of risk and it is rarely possible to achieve situations of zero risk. All regulatory agencies seek to control as far as possible the risks associated with the regulated activity by applying measures to manage risks. While the Gene Technology Act 2000 is prohibitory in the first instance, it also contemplates and provides the regulatory framework for the use of gene technology (section 4(a)) that guards against harm to human health and safety and the environment.

198. The object of the Act contemplates the authorisation of dealings with GMOs, even where actual risks are identified with those dealings, so long as the risks can be managed in such a way as to protect human health and safety and the environment. The requirement for protection indicates that the focus of risk management should be controlling risk so as to prevent adverse consequences from occurring.

199. As discussed in Chapter 1, the Regulator is required to conduct a risk assessment and prepare risk management plan in relation to all applications for licensed dealings (i.e. DNIRs and DIRs). However, as illustrated in Fig 2.1, the risk management undertaken by the Regulator is not restricted to the RARMP, the RARMP is informed by, and relies on, other measures.

200. Risk management within the context of the Act may be considered as four separate, though not mutually exclusive, areas:

- ***risk management plans*** **-** the requirement for a risk management plan in relation to all licence applications which identifies risks requiring management and the measures chosen to treat those risks. The licence typically includes specific licence conditions imposed by the Regulator to implement the risk management plan.
- ***decision making*** by the Regulator – the ultimate determination of whether to authorise a dealing with a licence. The Regulator must not issue a licence unless satisfied that risks posed by the dealing can be managed in such a way as to protect the health and safety of people and the environment. This requirement to be satisfied that risks are managed also applies to decisions on variation, suspension, cancellation and transfer of licences and to the certification of facilities and accreditation of organisations.
- ***general risk management measures*** **-** specific statutory (i.e. the Act and Regulations) and related risk management policies or measures established by the Regulator (e.g. guidelines, policies) or Ministerial Council (e.g. policy principles, codes of practice). These may apply generally to various GMO dealings and related activities as 'default' measures not just to specific licence applications.
- ***quality control and review*** **-** measures to provide assurances that the procedures put in place by the Regulator will adequately identify and manage risk posed by or as the result of gene technology. These activities include monitoring for compliance with risk treatment measures mandated by licence conditions.

THE RISK MANAGEMENT PLAN

201. The risk management component of the RARMP is based on the risk assessment and in particular, the risk estimates derived from that process. The risk management plan provides part of the basis for the Regulator to make a decision on whether to issue a licence by providing an answer to the question: **'can the risks posed by a proposed dealing be managed in such as way as to protect the health and safety of people and the environment?'**

What does the risk management plan address?

202. The preparation of a risk management plan may be informed by considering a number of general questions, including:

- **'which risks require management?';**
- **how many treatment measures are available?'** – there may be many approaches to achieve the same objective and some measures may not be compatible with others;
- **'how effective are the measures?'** – this question may be informed by the risk assessment;
- **'how feasible or practical are the measures?';**
- **'do the measures themselves introduce new risks or exacerbate existing ones?'** - a treatment measure to address one risk may introduce a new one. For example applying a tourniquet can reduce the amount venom from a snake bite that enters the bloodstream, but it can also lead to damage to the limb because of reduced blood flow; and
- '**which treatment measure(s) provide the optimum and/or desired level of management for the proposed dealing?'.**

203. The Regulations require the Regulator to consider the short and the long term when assessing risks (subregulation 10(1), see also Chapter 3) and this approach is also adopted in devising and implementing risk management conditions.

Risk evaluation

204. Risk evaluation is the process of deciding which risks require management. As outlined in Chapter 3, risks estimated as High and Moderate will generally require specific management.

205. Risks assessed as Low may require management, and this would be decided on a case by case basis. In such cases the nature of the GMO, the nature of the risk, especially the consequences, as well as the degree of uncertainty relating to either likelihood or consequences, will be important considerations. If there is uncertainty about risks (e.g. in early stage research) this may influence the management measures that are selected.

206. Risks that have been assessed as negligible are considered, on the basis of present knowledge, not to pose a sufficient threat to human health and safety or the environment to warrant the imposition of management conditions.

207. Chapter 3 laid out some general criteria for harm that could be employed to determine what risks require management. The Act does not contain specific criteria, but it does identify what may be considered the extremity of harm: imminent risk of death, serious injury, serious illness, or serious damage to the environment (section 72(6)). Given the potential variety of GMOs it is not possible to develop a 'one size fits all' set of criteria and therefore a case by case approach is taken by the Regulator.

208. Factors that may affect the determination of the relative significance of a risk include the severity of the consequences, the size of the group exposed to the risk, whether the consequences are reversible and the distribution of the risk (e.g. demographically, temporally and geographically). It is also important to recognise that there are a number of other factors that may influence the perception of the risk which are particularly pertinent to GMOs, including whether the risk is voluntary or involuntary, familiar or unfamiliar and the degree of personal exposure. These issues relate to risk communication and are considered in greater detail in Chapter 5.

Protection

209. In line with the overarching objective of protection, the Regulator prioritises preventative over ameliorative or curative risk treatment measures, i.e. the risk treatment measures will be focussed on preventing the risk being realised rather than on measures to repair or reduce the harm that would result.

210. The risk assessment includes a consideration of the causal pathway(s) necessary for any given risk to be realised. This understanding of how the hazard might be translated into harm and the nature of the harm provides valuable information for identifying risk treatment options. For example, a knowledge of the causal pathway enables the identification of 'weak links' in the chain where treatment may be most easily and/or effectively applied. (Logic tree analyses such as diagrammatic Fault and Event trees are examples of formal, systematic tools that are used in hazard identification and can also be applied to risk treatment).

211. While the focus of risk management will be on treatment measures to prevent risks being realised, attention will also be paid to the important

questions of **'what can be done if a particular risk is realised?' and 'what actions would need to be undertaken to reduce, reverse or repair damage or harm?'.** Where possible management conditions for dealings that involve moderate or high risk estimates were being considered, it would be important to establish whether harm or damage that might result could be reversed, and that not only preventative measures but also curative or ameliorative actions be identified. For example, if a GMO produced a protein toxic to humans it would be important to establish if a medical treatment existed to treat the toxicity. Such remedial measures should be included in contingency or emergency plans. The requirement for licence holders to have contingency plans is a standard licence condition.

212. Redundancy in risk treatment options, for example by establishing measures which 'break' more than one point in a causal pathway, will increase the effectiveness of risk management. It is important to note that in such cases the failure of a single risk treatment measure will not necessarily result in an adverse outcome being realised. For example a standard preventative condition in relation to GM seeds is double containment, often related to managing a risk of potential weediness. However even if the double containment was breached and seed spilled, the weediness risk would not be realised, because clean up measures would be invoked.

Risk treatment

213. Once the risks that require management have been identified, then options to reduce, mitigate or avoid risk must be considered. Options to reduce exposure to the GMO or its products, and limit opportunities for the spread and persistence of the GMO, its progeny or the introduced genes must be considered.

214. For DIRs, setting limits on the size and location of the release and the length of time for the dealings will be an important risk treatment option. Other measures could include specifying physical controls (e.g. fences), isolation distances, monitoring zones, pollen traps, post release cleanup and specific monitoring requirements (e.g. removal of sexually compatible species from the release site). For DNIRs, risk treatment measures could include the level of physical containment of the facility in which the dealings may be undertaken (e.g. PC1, PC2 etc), and conditions for storage transport and disposal of the GMO or its products.

215. It is important to note that the background exposure to the introduced gene or its product informs the consideration of the risks that require treatment. Where exposure occurs naturally, the significance of exposure to the GMO may be reduced (see Chapter 3, risk context).

216. The range of suitable containment and/or isolation measures will depend on the nature of the:

- organism (e.g. seed longevity);
- trait (the characteristics of the GMO conferred by the modification);
- introduced genes (including ability to identify/detect the GMO and modified genes);
- proposed dealings;
- environmental conditions at the site of environmental releases;
- normal production and management practices; and
- controls proposed by the applicant.

217. Once measures have been identified they must be evaluated to ensure that they will be effective and sufficient over time and space. That is, they will be feasible to implement, able to operate in practice, will meet currently accepted requirements for best practice (e.g. Good Agricultural Practice, Good Laboratory Practice), will manage the risks to the level required and can be monitored. The type of measures will be commensurate with the risks identified.

218. These measures may be either preventative or curative/ameliorative, i.e. either the measures will seek to treat risk by putting in place measures that will prevent, with some degree of certainty, a hazard being realised, or on the other hand where a hazard may be realised and harm ensue, but the measures proposed will redress that harm or reduce it.

219. As noted in Chapter 1, the research and development pathway for GMOs intended for release to the environment normally proceeds via staged releases. Following such an incremental pathway contributes to overall risk management because it enables a cautious and systematic approach to minimising uncertainty. The Regulator may impose conditions on small scale, early stage 'field trial' releases that limit the dealings in space and time (i.e. only at a specified location and in a specified timeframe) in order to address any uncertainty regarding either the

likelihood or consequence considered in the risk estimate. Typically these conditions include measures to limit the dissemination or persistence of the GMO or its genetic material. Such releases are described by the Regulator as 'limited and controlled'.

220. The scale of any release is a key factor in setting the context for the risk analysis, and for risk management in particular, because limiting the scale effectively reduces the exposure to potential adverse consequences.

221. The most appropriate options available to manage the risk are selected. It is possible to envisage a number of options that may provide different levels of management of a specific risk. Equally, one management strategy may control a number of risks. The Regulator must be satisfied that the risks would be managed by the proposed options before a licence can be issued. This may include options that manage the risks most comprehensively and/or ones that are judged to provide a sufficient level of management.

222. Any identified uncertainty in aspects of the risk assessment or risk treatment measures must be addressed in determining the appropriate risk management. Uncertainty in risk estimates may be due to insufficient or conflicting data regarding the likelihood or severity of potential adverse outcomes. Uncertainty can also arise from a lack of experience with the GMO itself. For example, plants including GM plants, perform differently when grown under ideal growth conditions (e.g. glasshouses) compared to performance in the open environment as evidenced by 'field trials'. Risk treatment measures would be devised to take account of such uncertainty, for example, the size of a reproductive isolation distance for a GM plant would be based on the overall distribution of pollen, not just on the median distance pollen might travel.

223. The Act allows the Regulator to impose licence conditions to require the collection of data or conduct of research (Section 62(2)(h). Typically the pathway for intentional release involves a staged approach that starts in certified contained facilities and proceeds through strictly contained, small scale field trials before larger scale, reduced containment or commercial release. This enables information to be collected about the GMO at each stage of this step-by-step process in order to reduce uncertainty in risk assessments, and confirm the efficacy of containment measures. The results of this research may result in changes to licence conditions to better manage risk and will inform future evaluations of the same or similar GMOs. Results of such research might provide the basis for the diminution in the scale of risk treatment measures necessary to manage a particular risk.

224. In some instances other agencies will have the legislative mandate for the control of risks from GMOs that the Regulator has also identified as requiring management. In these cases the Regulator liaises closely with that agency to ensure that the risks are managed satisfactorily . Further information on the interaction with other regulatory agencies is provided under General Risk Management Measures below and in Appendix C.

Licence conditions

225. The treatment measures that comprise the risk management plan for dealings with a GMO are typically imposed as conditions in the licence. As noted earlier, section 62(2)(a-o) of the Act enables the Regulator to impose licence conditions in relation to a range of issues, including, for example, the scope of the dealings and actions to be taken in the case of release of a GMO from a contained environment. There is a legal requirement for the licence holder to comply with these conditions. Clarity in the formulation of licence conditions is therefore critical for a number of reasons:

- the conditions must be as clear and unambiguous as possible to ensure that the treatment measures or controls are applied as intended so that the risk is managed effectively;
- that the intent and specific requirements of the conditions are clear to the licence holder so that compliance with the conditions can be demonstrated; and
- that the compliance with the conditions can be enforced by the Regulator, and non-compliance identified, and where necessary or appropriate, that remedial and/or punitive actions be undertaken.

226. The ability to identify the GMO and the introduced genes is an important consideration for risk management so that preventative and/or ameliorative treatment measures can be applied with confidence. The requirement to provide the Regulator with a reliable method to detect the GMO and the introduced genes is a standard licence condition included in risk management plans.

227. Applicants are required to have contingency plans in place in case of emergency. The nature of such plans will vary depending on the licence and nature of the dealings. For instance, many large scale facilities are required to have a physical barrier in place (bunding) capable of containing volumes greater than the maximum volume of the fermentation tank(s)

that will contain any spills and also specific emergency procedures. There is a requirement in all licences that the Regulator is informed if there is an unintentional release of the GMO.

Notification requirements

228. The Act requires a licence holder to notify the Regulator of any new information regarding the risks posed by the dealing, any non-compliances with the licence, and any unintended effects of the dealings (section 65). This requirement is a statutory condition of all licences.

229. It is also a condition of all licences that the licence holder inform persons covered by a licence of the conditions and their obligation to comply with the conditions (section 63).

DECISION MAKING

230. As explained in Chapter 1, a defining characteristic of the Australian system for regulating gene technology is the establishment of an independent, statutory office holder, the Gene Technology Regulator (the Regulator). The Regulator is charged with making decisions on whether or not to authorise dealings with GMOs, either by issuing or refusing to issue a licence, or by suspending, cancelling, transferring or varying a licence. The basis for each of these decisions is whether or not the Regulator is satisfied that any risks posed by the dealings can be managed in such a way as to protect the health and safety of people and the environment.

231. As noted previously, there are no 'one size fits all' solutions for the risk assessment and risk management of GMOs, and the Regulator adopts a case by case approach, weighing the available evidence against any uncertainty of likelihood or consequence, and the availability of management measures, to arrive at a prudential judgement.

232. As applications for new GMOs with novel attributes are considered by the Regulator, the appropriate criteria, baselines and endpoints against which these risk analyses are conducted have to be formulated. In this regard, the various components of the regulatory system provide the Regulator with a range of 'decision support mechanisms'. For DIRs in particular, the Regulator must seek advice from GTTAC, the Australian Government Environment Minister, States, and prescribed Australian Government regulatory agencies. In addition the Regulator can seek advice from the GTEC and GTCCC. The Gene Technology Ministerial Council may

also provide the Regulator with specific guidance through policy principles, policy guidelines and codes of practice.

233. The steps the Regulator must take in the decision making process for DIRs are:

- receive application and check for completeness;
- decide if the risk may be sufficiently significant to warrant a first round of public consultation;
- consult on the application with prescribed agencies, local councils, GTTAC, and the public if there may be a significant risk, to identify issues that should be taken into account in the RARMP;
- prepare a RARMP;
- seek comment on the RARMP from all the prescribed agencies consulted on the application and the public;
- consider all the information in the context of the Act, Regulations and any relevant Policy Principles, and make a decision;
- publish the decision, including the licence conditions, if approved, and issue a licence.

234. The steps the Regulator must take in the decision making process for DNIRs are :

- receive application and check for completeness;
- prepare a RARMP (the Regulator may consult GTTAC and the relevant State government);
- consider all the information in the context of the Act, Regulations and any relevant Policy Principles, and make a decision;
- publish the decision, including the licence conditions, if approved, and issue a licence.

235. The key factors in making the decision include:

- setting the criteria for the RARMP (refer to Chapter 3);

- establishing the risks to human health and safety and the environment that require management (see above); and
- establishing licence conditions that define the scope and boundaries of the permitted dealings and manage the risks.

236. Another important factor the Regulator must consider before issuing a licence is whether the applicant would be able to implement effectively all of the conditions considered necessary to manage the risks associated with the proposed dealing.

237. Before issuing a licence the Regulator must be satisfied that the applicant is a suitable person (whether a natural person or a body corporate) to hold a licence (see Appendix B). In this matter the Regulator must have regard to any relevant convictions of persons or the body corporate or any revocation or suspension of a licence or permit relating to laws about the health and safety of people or the environment, and to the capacity of the person to meet the conditions of the licence (section 58).

238. After a licence is issued it can be varied, suspended or cancelled according to provisions under the Act (sections 68-72). This enables the Regulator to respond to new information or changed circumstances that affect the level of risk. The licence holder or the Regulator can instigate these procedures. The Regulator must give the licence holder 30 days notice in writing before varying, suspending or cancelling a licence. However in the case of a risk of imminent death, serious illness, serious injury, or serious damage to the environment, the Regulator may impose these decisions immediately and initiate remedial action.

GENERAL RISK MANAGEMENT MEASURES

239. As noted earlier, risk management plans do not constitute the totality of risk management implemented under the Australian regulatory system for gene technology. Other activities and systems contribute to the overall management of risk achieved by the Regulator, licence holders and other agencies by providing a range of risk management mechanisms defined by the Act and subordinate legislation.

240. The Act and Regulations provide for a range of defined measures including those that contribute to the overall management of risk achieved by the Regulator, licence holders and other agencies:

- arrangements for classes of dealings (exempt, NLRD, GMO Register);
- Institutional Biosafety Committees and Accreditation of organisations;
- certification of facilities to specified physical containment levels;
- statutory (i.e. legally binding) requirements to notify the Regulator of adverse and unintended consequences;
- the Regulator's powers for monitoring dealings with GMOs and to direct individuals or organisations to undertake actions necessary to protect the health and safety of people and the environment;
- statutory decisions other than for licence applications;
- punitive sanctions for non-compliance;
- the Regulator issuing technical and procedural guidelines and the Ministerial Council issuing policy principles, policy guidelines and codes of practice; and
- consultation and coordination with other regulatory agencies.

241. Statutory decisions other than those related to licence applications are addressed under 'Decision Making'. These general risk management elements are described in more detail below.

Dealings not requiring licences

242. Appendix B describes how the regulatory system addresses GMO dealings that are not covered by licences: exempt dealings; notifiable low risk dealings (NLRDs); and dealings on the GMO Register. Exempt dealings and NLRDs are subject to prescribed risk management measures, such as conduct in appropriate levels of physical containment in certified facilities. The Regulations contain extensive detail on Exempt dealings and NLRDs. Dealings on the GMO Register must have previously been assessed through the licensing system, however conditions may still be imposed (see Appendix B for details).

Institutional Biosafety Committees and Accreditation

243. The Act contains provisions for organisations undertaking dealings with GMOs to be 'accredited' by the Regulator. In order to achieve accreditation, the Regulator requires an organisation to have access to an appropriately constituted, established and maintained Institutional Biosafety Committee (IBC). The process of accreditation also assures the Regulator that the organisation has the appropriate resources, facilities, internal quality assurance processes, and qualified personnel in place to effectively deal with GMOs. In the context of risk management this ensures that organisations and individuals can implement and maintain the management conditions the Regulator may impose.

244. The IBCs are a very important component of the Australian system for regulating gene technology. All licence applications must first be reviewed by an IBC, and the IBC must provide the Regulator with an evaluation report setting out its advice as to the completeness of the proponent's hazard identification and proposed risk management strategies. IBCs comprise people with a range of expertise relevant to the GMOs and dealings undertaken by the organisation and provide an independent quality assurance mechanism to ensure that the information that reaches the Regulator as part of an application is as comprehensive and accurate as possible.

245. Further details on IBCs and accreditation are provided in Appendix B. The Guidelines for the Accreditation of Organisations are available from the OGTR website (www.ogtr.gov.au).

Certification

246. Certain dealings must be undertaken in facilities that meet defined standards to ensure adequate containment of GMOs. Guidelines have been developed by OGTR based on the Australian/New Zealand Standard for safety in laboratories AS/NZS 2243.3:2002 (AS/NZS 2243.3:2002) that specify the physical containment requirements of facilities and also the practices that must be adhered to by properly trained personnel in those facilities.

Guidelines

247. The Act empowers the Regulator to issue technical and procedural guidelines detailing the conduct of dealings with GMOs. Such guidelines are legislative instruments and must therefore be complied with. The Regulator has issued guidelines for: transport of GMOs; certification of contained facilities; and accreditation of organisations.

Monitoring for compliance

248. Monitoring plays a vital role in ensuring that risks to human health and safety or the environment posed by GMOs are managed. The Act gives the Regulator extensive monitoring powers (section 152). Where risks requiring management have been identified and treatment measures have been imposed by the legislation, in licence conditions, or in guidelines, monitoring is important to verify that those treatment measures or obligations are being applied so that risks are, in fact, managed.

249. Monitoring is not only undertaken by the OGTR, but also by licence holders, accredited organisations and IBCs, to ensure that licence conditions and other requirements are implemented and are effective.

250. All licences contain reporting provisions in case of unexpected events occurring or new information becoming available relating to the GMO and the dealings. The licence holder is required to provide regular reports to the Regulator and to report any changes in circumstances and any unintended effects, new risks or contravention of conditions.

251. Specific monitoring and compliance activities undertaken by the OGTR directed to risk management include:

- *Routine Monitoring* of limited and controlled environmental releases and certified facilities, including spot (unannounced) checks;
- *Profiling* of dealings to assist strategic planning of monitoring activities (e.g. conducting inspections of GM plants during the flowering period);
- *Education and awareness* activities to enhance compliance and risk management planning of licence holders and organisations;
- *Audits and Practice Reviews* in response to findings of routine monitoring;
- *Incident reviews* in response to 'self reported' non-compliance; and
- *Investigations* in response to allegations of non-compliance with conditions or breach of the legislation.

252. In the case of monitoring of limited and controlled releases of GMOs to the environment, the focus of effort, by both the licence holder and OGTR, is to ensure that the dealings are in fact limited, including extensive post-release monitoring until the OGTR is satisfied that GMOs have effectively been removed from the release site.

253. Where, as a result of monitoring activities, changes in the risks associated with the dealing are identified, the Regulator has a number of options, including directive or punitive measures (see below). The options adopted by the Regulator will depend on the nature of the change in the risk profile that has been identified.

Compliance powers and punitive measures

254. The Act authorises the Regulator to direct licence holders or persons covered by a licence to undertake actions necessary to protect the human health and safety or the environment (section 146), i.e. to undertake risk management. The Regulator may also vary the conditions of the licence or, if necessary, cancel or suspend the licence.

255. In cases of non-compliance with licence conditions, the Regulator may also instigate an investigation to determine the extent of non-compliance. The Act has extensive provisions for enforcement to ensure compliance (sections 145).

256. The Act provides for criminal sanctions of large fines and/or imprisonment as punitive measures for failing to abide by the legislation, conditions of licence or directions from the Regulator (e.g. sections 32-37), and especially where significant damage to human health and safety or the environment would result (section 38). As a result of the investigation, the Regulator may impose the above sanctions or refer the matter to the Director of Public Prosecution.

257. The availability of these punitive measures may be considered part of the overall risk management approach as they stress the importance attached to managing risks posed by GMOs and provide an incentive for compliance.

Cooperation with other Australian regulatory agencies

258. Other Australian regulatory agencies have specific responsibility for some aspects of dealings with GMOs or GM products as they relate to human health and safety and/or the environment. The Regulator would

generally not impose management conditions that would ordinarily be the responsibility of another agency. For example, the APVMA is responsible for regulating all herbicide use for agricultural, industrial and domestic purposes as well as use on GMOs, including managing herbicide resistance. Similarly, a therapeutic agent that is a GMO (such as a live vaccine) would need to be licensed for intentional release to the environment by the Regulator and would also be registered through the TGA for administration to humans. Conditions relating to prescription of dose would be imposed by the TGA. Appendix C contains detailed information regarding the interaction between the Regulator and other agencies.

QUALITY CONTROL AND REVIEW

259. In addition to the various risk management processes described above, attention to quality control and quality assurance by the Regulator and OGTR in the conduct of all aspects of risk analysis contributes to achieving the management of risks posed to human health and safety and the environment by GMOs.

260. Quality control operates at administrative, bureaucratic and legislative levels in the risk analysis process under the Act. There are a number of feedback mechanisms to maintain the effectiveness and efficiency of risk assessment and risk management, and which consider the concerns of all interested and affected stakeholders. These comprise both internal and external mechanisms.

261. Internal processes of quality control and review include:

- standard operating procedures for specific administrative processes;
- internal peer review of RARMPs;
- merit based selection processes for OGTR staff; and
- conflict of interest declarations and procedures for OGTR staff and expert committee members.

262. External processes of quality control and review include:

- expert scrutiny by GTTAC of applications and RARMPs;
- external scrutiny and review through the extensive consultation processes with Australian Government agencies and the

Environment Minister, State governments, relevant councils, interested parties and the public on all DIRs;

- oversight by the Ministerial Council;
- external, independent selection of the Regulator and advisory Committee members, and Ministerial Council agreement on these appointments;
- accountability to the Australian Parliament through the provision of quarterly reports; and
- review by administrative appeals mechanisms.

263. A critical aspect of this overall quality assurance is that the Regulator and OGTR maintain the expertise and capacity to undertake the risk analysis of GMOs. This is achieved through the qualifications and skills of staff, remaining up to date on developments in gene technology and relevant scientific disciplines by reference to the scientific literature, and monitoring determinations, experience and policy developments of agencies regulating GMOs in other countries.

264. This quality assurance contributes to identifying situations where treatment measures are not adequately managing the risks, either as a result of non-compliance or because of changed circumstances and/or unexpected or unintended effects; and facilitates an ongoing review of the conclusions of risk assessment and of the risk treatment options. Identifying changed circumstances enables a reassessment of the risks posed by the dealings and the treatment measures in the light of experience, and for risk management to be modified where necessary. Such review activities may also provide important information for the risk assessment of subsequent licence applications for the same or related GMOs.

265. Quality control forms an integral part of all processes and procedures used by the Regulator to ensure protection of human health and the environment according to the Act.

SUMMARY

266. Risk management in relation to dealings with GMOs in Australia is supported by a range of measures. The legislation provides for a number of defined measures such as establishing classes of dealings, requirements for specified levels of physical containment, accreditation of organisations including the maintenance of an IBC and regular reporting. For dealings requiring a licence the Regulator prepares a risk management plan, and measures determined as necessary to manage risks may be included as enforceable conditions of the licence. Significant effort is expended by the OGTR and licence holders to monitor GMO dealings and facilities, in particular to ensure that risk management measures are being applied effectively. The Act empowers the Regulator to take immediate action if there is imminent risk of death, serious injury or illness or serious damage to the environment. The Regulator and OGTR have a range of quality control and review mechanisms that enable risk assessments and risk management measures to be amended in response to new information.

CHAPTER 5
RISK COMMUNICATION

267. There is wide recognition that communication plays an integral and important part in the process of risk analysis. Risk communication is the interactive process of exchange of information and opinion between individuals, groups and institutions concerned with risk. These exchanges may not be related exclusively to risk but may also express concerns, opinions or reactions to risk messages or to legal or institutional arrangements for risk management (National Research Council 1989).

268. The aim of risk communication is to promote a clear understanding of all aspects of risk and the particular positions of interested parties. Specifically, it aims to provide information about risk to help people make up their own minds, to minimise conflicts, to improve understanding of perceptions and positions with regard to risk, and to achieve equitable outcomes. It is to provide all parties with a better understanding of the issues, it is not to change basic values and beliefs (Gough 1991).

269. The present regulatory system for gene technology is significant both within Australia and internationally in incorporating legislative requirements for government transparency and providing the opportunity for public input into the risk assessment process. This chapter briefly discusses the way risk is perceived, outlines the consultative processes that led to the development of the Act, describes the present communication processes between stakeholders and the Office as mandated by the Act, and sets out a communication charter to demonstrate the commitment of the Regulator to communicate effectively with stakeholders.

RISK PERCEPTION

270. Public perceptions of the risks associated with gene technology range across a wide spectrum of positions and include ethical concerns such as 'meddling with nature' and social issues, such as claims that multinational corporations might seek to achieve market dominance by controlling access to the technology. In many instances the debate over gene technology has raised heated arguments both for and against its use. One of the reasons that the regulatory system was established was in response to community concerns about gene technology, and an associated desire for a nationally consistent, legally enforceable decision making process. The current regulatory system for gene technology replaced a voluntary system that

was overseen by the Genetic Manipulation Advisory Committee (GMAC). The Australian gene technology legislation is consistent with international trends for regulatory systems to incorporate high levels of independence, transparency, accountability and strong enforcement capabilities.

271. Different societal organisations and individuals perceive risk in different ways and may have different attitudes to risk. Perception of risk can be influenced by material factors (gender, age, education, income, personal circumstances), psychological considerations (early experiences, personal beliefs, attitudes to nature, religious beliefs) and cultural matters such as ethnic background. Across a spectrum of risk, attitudes can be broadly categorised as risk averse, risk neutral or risk taking and will be dependent on the specific risk involved.

272. Generally the perception of risk by individuals is dependent on a large number of factors including knowledge of the risk, its impact on that individual, the potential for long term consequences, the potential for widespread effects, the extent the individual can influence the risk and possible benefits (if any) that might accrue to individuals, groups or society as a whole. If the risk arises as part of a familiar situation where factors increasing or decreasing the risk are well known and methods to control or reduce the risk are readily available, the risk will probably not be perceived as a threat. If the risk is unknown, there is potential for long term impact over a wide area and the individual feels powerless in the situation, the risk is likely to be perceived as high. The availability of information, the knowledge that concerns will be heard and the opportunity for involvement in decisions are therefore, all likely to increase the acceptance of risk. Table 5.1 summarises some of these elements

Table 5.1. Factors in the perception of risks as either tolerable or threatening

Risks may be seen as tolerable if they are:	Risks may be seen as threatening if they are:
voluntary	involuntary
controlled	uncontrolled
familiar	unfamiliar
immediate	some time in the future
short term	long term
minor consequences	severe consequences
reversible	irreversible
personal involvement	no involvement
benefits	costs
probable	improbable

273. There has been considerable research by social scientists into the way risks are estimated and perceived by different members of the community. Often technical experts and scientists have very different perceptions and estimations of risks than other people. Although it is accepted that experts may arrive at a better quantitative assessment of risks where they have specialist knowledge, the way they estimate risks outside their area of expertise is no different to that of other members of the community and can be influenced by subjective values.

274. Risk perception is fundamental to an individual's acceptance of risk. For instance, there is a level of risk associated with car travel but many people continue to drive to work each day and it is an accepted form of transport. Commercial air travel is also accepted as a form of transport but many people may perceive it as more risky than car travel although the probability of death is actually higher with car travel. These perceptions arise due to greater familiarity with cars, greater individual control in operating a car and a greater chance that any one car accident is less likely to be fatal than for any one airline accident. Therefore, the perception and assessment of risk by an individual is a complex construction involving a number of factors that are weighed & balanced to achieve a final position.

275. Some factors that may contribute to disagreement in risk assessment and risk management are summarised in Table 5.2

Table 5.2. Sources of conflict in risk assessment and risk management

	Sources of Conflict
Values	The parties have different underlying values, beliefs and views of the world
Interests	The parties have different interests: commercial, environmental or social
Language	The language used by scientists or experts may not be accessible to stakeholders
Knowledge	There are differing views on what is known and not known
Lack of transparency or openness	Stakeholders are not provided with relevant or sufficient information or included in the decision making process

276. Historically a number of approaches have been employed in endeavouring to gain community understanding and acceptance of certain risks that government or business believe are required for economic prosperity, contribute to society as a whole or are worthwhile in some way even though some risk may be involved. An understanding of the importance of risk communication has evolved in parallel with these attempts and has been elegantly encapsulated by Fischhoff (1995).

He argued that it is not enough just to present the facts, or just to communicate and explain the facts, or to demonstrate that similar risks have been accepted in the past, or to bring stakeholders on board; but that all were required for effective risk communication. All these things are important and lead to the conclusion that stakeholders' views should be treated with respect as they provide a valid and required input into risk assessment and risk management. The Regulator recognises and accepts that there are a wide range of views on gene technology across the community and believes that all stakeholders have legitimate positions.

277. In terms of risk communication, key outcomes of the consultations which are given effect in the Act are the establishment of three Committees to advise the Regulator (scientific, community and ethics) and public consultation during the assessment of licence applications. The Act therefore provides a direct mechanism for two-way interaction between a government decision maker, the Regulator, and stakeholders. The forms of communication undertaken by the OGTR as prescribed by the Act, are shown in Table 5.3. Additional activities that exceed the requirements of the legislation are listed in Table 5.4.

Table 5.3. Communication undertaken by OGTR as prescribed in the Act

Communication required by the Act	Form of communication
Public consultation on application if significant risk (Section 49)	Gazette, newspapers, website
Must supply a copy of the application if requested (Section 54)	Copy of the application - Commercially Confidential Information (CCI) and personal information removed
Consult States and Territories, GTTAC, prescribed agencies, the Environment Minister, appropriate local councils on matters to be considered in the RARMP	Letter and application summary (copy of the application if requested)
Invite submissions from the public on consultation RARMP	Gazette, newspapers, website
Consult States and Territories, GTTAC, prescribed agencies, the Environment Minister, appropriate local councils on the consultation RARMP	Letter and copy of RARMP
Notify the applicant of the decision	Letter and licence
Location of trial sites	Website
Quarterly Reports	Publication as a booklet; website
GMO Record	Website
Maintain information on authorised GMO dealings and GM product approvals	Website

Table 5.4. Communication undertaken by OGTR additional to that prescribed under the Act

Additional communication undertaken by OGTR	Form of communication
Client register	Early bird notification (if no Section 49) of application, consultation on RARMPS
Questions & Answers, biology & ecology documents	Website (hardcopies available)
Extended advertising	Published notices in metropolitan, regional & rural press
Consult additional stakeholders on applications (*eg.* DAFF)	Letters, email, face to face meetings
Notify stakeholders of licence decisions	Letter to States and Territories, Government agencies, the Environment Minister, appropriate local councils, client register, website
Monitoring	Site visits, practice reviews, discussions with licence holders
Consult widely on other matters (*eg.* this document)	Letters, briefings, presentations, face to face meetings
Ministerials, briefs	Letters, emails
Establish cooperative relationships with other government regulatory agencies	MOUs, informal (sometimes daily) consultations, briefs, meetings
1800 telephone number	Verbal queries
Email address	Email queries
IBC training	Presentations & discussions
Conferences, forums, public addresses, workshops	Written & oral presentations by Regulator and OGTR staff
Website	Maintain information on current & former applications; evaluation processes; field trial sites; publications; monitoring and compliance protocols *etc.*

COMMUNICATION PATHWAYS

278. To be effective risk communication requires an exchange of knowledge rather than a one way transfer of information. It is most effective when it is two-way and when there is opportunity for input into decisions. Successful communication requires active involvement, in practice however time and resources can limit the extent of dialogue. The Office allocates greater resources to communication activities where there is a perception of greater risk such as those involving intentional release of GMOs into the environment, in particular, commercial releases.

Stakeholders

279. The release of GMOs into the Australian environment is of significant interest to a wide spectrum of the community, including State and local governments, NGOs, community groups, businesses, companies and individuals. The Act stipulates specific organisations with which the Regulator must consult in preparing a DIR RARMP. Under the Act the Regulator is obliged to consult with State governments, local councils, a number of prescribed Australian government agencies (FSANZ, AQIS, NHMRC, NICNAS, APVMA, TGA), the Environment Minister and the public. In addition, the Office maintains a client register of people and organisations (approximately 1200) that have registered to receive information from the Office on issues relating to the regulation of gene technology. Identified stakeholders are shown in Table 5.4. The form of communication with specific stakeholders and potential constraints on effective communication that potentially applies to all groups is shown in Table 5.5.

Table 5.5. Stakeholders with interests in gene technology

Group	Stakeholders
Research	Pro/Vice Chancellors of Universities R&D, CEOs/Directors of research institutes, Institutional Biosafety Committees (IBCs), CSIRO, Cooperatives Research Centres (CRCs), esearch 7 Development Corporations (RDC)s, other research groups
Industry	Retailers, food industry, proponents of the technology
Primary producers	National and State/Territory Farmers Federations, peak farming organisations (often include industry representation)
Interest groups	Environmental groups (Australian Conservation Foundation, Friends of the Earth, Greenpeace), consumer groups (Australian Consumers Association, Consumers Health Forum), health professionals
Prescribed agencies under the Act	FSANZ, AQIS, NHMRC, NICNAS, OCS, APVMA, TGA (see Appendix C)
Government	State and Territory governments, local governments, the Environment Minister, Department of Agriculture, Fisheries and Forestry, Department of Foreign Affairs & Trade, Department of Prime Minister & Cabinet
The public	

Table 5.6 The forms of communication with stakeholders and potential constraints on that communication

Stakeholders	Form of communication	Constraints on effective communication
Applicant	Application form Informal/formal discussions CCI application RARMP- consultation & final Licence	*different language,* *different knowledge,* *different interests,* *values,* *beliefs,* *unclear requirements or explanations,* *lack of understanding,* *lack of context* *uncertainty,* *limited resources*
Experts	Meetings/Informal/discussions Letters requesting advice	
Prescribed agencies	MOUs Informal/formal discussions Letters requesting advice, or notification	
Local councils	Letters requesting advice	
Governments	MOUs Informal/formal discussions Letters requesting advice	
Public	1800 telephone number Advertisements Website Email Client register	

Consultation on applications

280. During the development of the Act it was apparent that, where dealings with GMOs were undertaken in containment (DNIRs), stakeholders were less concerned in having direct input into the decision making process. The requirement for consultation on DNIRs is therefore more limited in scope than those for DIRs. The Regulator consults GTTAC on identified DNIR applications and the State government where the dealing would occur. The Regulator also provides information to stakeholders through the GMO record on the dealing, including the aims, a description of the project and the date of issue and expiry of the licence.

281. The process of consultation on DIR licence applications provides an opportunity for stakeholders, including the public, to have direct input into the decision making process. There is always at least one round of public consultation on any application for a DIR licence and comments from prescribed expert groups and authorities are sought on two occasions.

282. When an application for a DIR licence is received, the Regulator makes a preliminary assessment under section 49 of the Act, on whether the proposed dealing may pose significant risks to human health and safety and the environment. This determines whether comments are sought from the public on the application. If the Regulator considers that the proposed dealing does *not* pose significant risks, the public is not requested to comment on the application. However an Early Bird notification is sent out to those on the OGTR mailing list and placed on the website advising when the consultation RARMP is expected to be released for comment. State governments, local governments that may be affected, prescribed Australian Government agencies and relevant others, the Environment Minister and GTTAC are asked to identify issues that should be taken into account in preparing the RARMP.

283. Once the consultation version of the RARMP is prepared it is provided to all expert groups and authorities consulted previously for comment. Public comment is sought by placing advertisements in a range of publications, more diverse than that required by the Act. Publications include national, metropolitan, regional and rural newspapers, in addition to the Australian Government Gazette, notification on the website and by writing directly to interested parties. The consultation period specified in the Act is 30 days. However this is often extended to 6 weeks for field trials of a new GMO and 8 weeks for a proposed commercial release.

284. Under section 51 of the Act the Regulator is obliged to take account of any submission received when preparing the RARMP. Each submission received by the Office on a particular application is analysed to identify matters relating to risks to human health and safety or the environment that require detailed consideration. As part of the response to stakeholders and to ensure that all concerns have been considered, summaries are prepared that identify the issues raised and where they are addressed in the RARMP. The resolution of specific concerns and issues relating to risks to human health and safety and the environment may involve intensive discussions between the stakeholder and staff of the Office and can (and often does) lead the Regulator to request further information from the applicant. In addition, the Act gives the Regulator wide powers to seek further information from a variety of sources and to involve other relevant groups and experts.

285. The consultation version of the RARMP is then finalised, taking into account the feedback received to ensure that relevant issues of concern are addressed in as much detail as possible and practical. If deficiencies, such as new risks, inaccurate assessments, or better risk management strategies, were identified through the consultation process the RARMP would be reworked to address them.

286. Comments provided by stakeholders to date have covered many different issues, including general concerns regarding the use of gene technology that cannot be addressed in relation to the assessment of an individual application. The Office endeavours to address such concerns through documents such as this *Risk Analysis Framework*, by providing a detailed outline of the rationale behind the process of risk analysis and risk management undertaken by the Office and by making the documents underpinning the Regulator'a decisions (the RARMPs) readily available.

287. Some issues raised by stakeholders (eg. economic matters and issues to do with marketing or marketability) are excluded from consideration by the Regulator (see Chapter 1), whereas, other issues may fall under the jurisdiction of other regulatory agencies. For instance, food safety is the responsibility of FSANZ and herbicide use is regulated by the APVMA (see Appendix C). Where there is complementary regulatory responsibility then there may be some discussion of these in the RARMP although they will not be considered directly in making the decision and no licence conditions will be imposed that duplicate another agency's role.

288. Having finalised the RARMP and taken into account all relevant matters raised in submissions received, the Regulator must be satisfied that the proposed dealing does not pose a risk to human health & safety or the environment before issuing a licence that allows that dealing to proceed.

Social and ethical issues

289. As a relatively new area, gene technology generates significant public interest and has the potential to raise ethical issues important to society as a whole. In the past, ethical issues have often been ignored or dealt with in a fragmented manner. The Regulator is able to seek advice from both the ethics committee (GTEC) and the committee comprising members of the public (GTCCC).

290. The function of GTEC is to provide advice to the Regulator on ethical issues associated with gene technology. The committee comprises twelve members with expertise in matters such as ethics and the environment, bioethics, health ethics, applied ethics, law, religion and animal health and welfare.

291. The GTCCC was established to look beyond science and advise the Regulator on issues of concern to the community and ensure that these are addressed in the policy underpinning the regulatory scheme. This committee comprises twelve members who possess skills and experience in areas of environmental issues, community issues and the impact of gene technology on the community.

Other forms of communication

292. The mandate of the Regulator under the Act is to implement the regulatory system for gene technology and there are both explicit requirements for communication prescribed by the legislation and implicit requirements deriving from obligations of public duty as an office of government. It should be noted that the Regulator is neither a proponent nor opponent of gene technology, but an impartial decision-maker who is required to communicate to the Australian Parliament and people on matters relating to the risk assessment and risk management of GMOs.

293. The Regulator is committed to providing information to interested parties on applications, licences, dealings with GMOs, trial sites and the processes of risk assessment, risk management, monitoring and compliance undertaken by the Office. The primary mechanism for providing information about the Office to interested people is the OGTR website and the Quarterly Report. Documents that provide essential background information for the Office, such as the biology and ecology of plant species that have been modified by gene technology, are also available on the website.

294. The website also provides extensive information on the operation of the Office including various application forms, Certification Guidelines, the GMO Record, maps of trial sites and links to the legislation. There is a 'What's New' page that provides quick access to new publications, upcoming events and advice on opportunities to comment on RARMPs. The Office also provides a freecall number (1800 181 030) for anyone wanting to make enquiries, request hard copies of documents, or with particular concerns.

295. The Regulator's Quarterly Report provides details on the applications considered, monitoring activities undertaken, the work of the three advisory committees & summarises other OGTR activities in relation to reviews, research, FOI requests and consultant contracts managed during each quarter.

296. In addition, the Office provides regular training for IBCs to assist them and applicants in recognising particular categories of dealings under the Act and in administrative matters. The Office has regular contact with applicants on a range of matters, both scientific and administrative. Because of provisions of strict penalties under the Act for non-compliance and breaches of the legislation, the Office endeavours to educate and inform applicants to minimise the likelihood of such events.

297. The Office provides information on the *regulation* of gene technology. The primary government source of more general information on gene technology is Biotechnology Australia (www.biotechnology.gov.au). Agricultural biotechnology information is available from the Department of Agriculture, Fisheries & Forestry (www.daff.gov.au), and information on the environmental aspects of gene technology is available on the Department of Environment & Heritage website (http://www.deh.gov.au/).

RISK COMMUNICATION CHARTER

298. Effective risk communication requires the active participation of all stakeholders, including government. This charter presents the principles of risk communication that the Office aims to uphold and demonstrates the Regulator's commitment to active risk communication.

299. The Regulator and the OGTR aim to:

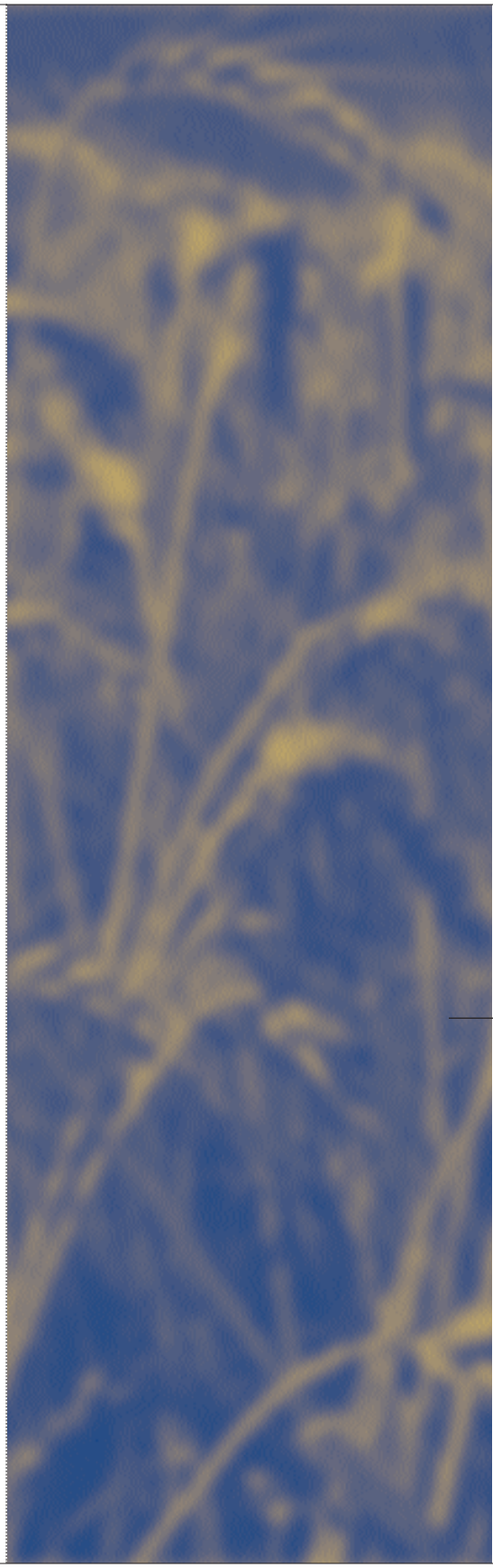
- raise awareness of Australia's regulatory system for gene technology nationally and internationally;
- undertake rigorous, scientifically based risk assessment and risk management of dealings with GMOs in an open and transparent manner;
- actively communicate the reasoning behind licence decisions in an open and objective manner in plain language;
- actively listen and respond in a timely manner to stakeholder concerns;
- communicate consideration of social and ethical issues relating to gene technology by GTEC and GTCCC and action taken on such issues by the Regulator or the Ministerial Council; and
- periodically review OGTR communication strategies & practices to ensure effective, appropriately targeted and efficient communication with stakeholders.

APPENDIX A
THE DEVELOPMENT OF THE ACT

300. The oversight of gene technology in Australia began on a voluntary basis with the formation of the Committee on Recombinant DNA that was set up by the Australian Academy of Science in the mid 1970s. This was followed by the Recombinant DNA Monitoring Committee which was established in 1981 in the federal Department of Science. These two committees comprised a range of scientific experts that effectively provided a peer review assessment of proposals to conduct experiments with GMOs between 1975 and 1987.

301. The work of these organisations was consolidated into the Genetic Manipulation Advisory Committee (GMAC) in 1987. GMAC was an administrative body founded on the initiative of the then Minister for Industry, Technology and Commerce. It was funded federally and charged with the task of assessing risks to human health and the environment in connection with gene technology and providing advice to proponents on how risks associated with work with GMOs could be managed. It also provided advice to statutory agencies responsible for product approvals that contained GMOs, or contained things that were derived from GMOs. While GMAC had no statutory powers or functions its advice was consistently sought and complied with by Australian researchers. Although GMAC had no enforcement powers, compliance with its recommendations was a condition of research and development funding from the Australian Government.

302. With the advent of significant advances in the application of the technology, increased commercial involvement, and elevated community concern about GMOs, the Australian Government, together with the States and Territories, initiated a cooperative process to develop a uniform, national approach to the regulation of gene technology in November 1998. Public and other stakeholder comment was sought on a paper entitled 'Regulation of Gene Technology' that was prepared by the Commonwealth State Consultative Group on Gene Technology (CSCG). These consultations contributed to the preparation of a discussion paper by the CSCG entitled 'Proposed national regulatory system for genetically modified organisms – How should it work?'



303. The discussion paper was advertised widely in 1999 in national, State, Territory and regional newspapers; mailed directly to over 2500 individuals and organisations representing a wide range of interests and all MPs and Senators in the Australian Parliament; and posted on the interim OGTR website. More than 200 written submissions were received. This initial development of the Act was informed by Australia's first consensus conference where a range of community representatives were invited to provide comment on the management of GMOs (Clark & Brinkley 2001).

304. In December 1999 a draft Gene Technology Bill 2000 and accompanying Explanatory Memorandum were released for public comment. Public forums were held in all capital cities and a number of regional centres. Over 750 people attended and more than 160 written submissions were received. Such extensive consultation in the development of the regulatory scheme reflects the emphasis placed on community input and participation in the decision making process in relation to gene technology. This process generated strong agreement about what should be included and excluded from the scope of the legislation. In setting up the regulatory scheme the government sought to recognise and balance both the potential of gene technology to contribute to society and community concerns over the development and deployment of the technology.

305. On 21 June 2001 the *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001* (the Regulations) came into effect establishing the national legislative scheme for the regulation of gene technology in Australia. The system is underpinned by an intergovernmental agreement signed by all Australian jurisdictions that commits the States and Territories to pass corresponding laws.

APPENDIX B
THE REGULATORY SYSTEM

306. *The Gene Technology Act 2000* (the Act) and *Gene Technology Regulations 2001* (the Regulations) and corresponding State and Territory laws provide a nationally consistent system to regulate the use of gene technology in Australia. The legislation establishes an independent statutory office holder, the Gene Technology Regulator, who is charged with administering the Act and making decisions about the development and use of GMOs under the Act.

307. The purpose of this Appendix is to:

- outline the types of dealings that are defined by the Act and the Regulations and corresponding state and territory laws;
- the procedure followed for each type of application; and
- the other administrative factors which assist the Regulator in managing risk, such as certification and accreditation.

TYPES OF DEALINGS

308. To 'deal with' a GMO is defined in the Act (Part 2, Division 2, section 10(1)) and includes (but is not limited to): experiment with, manufacture, breed, propagate, grow, culture, import, and to possess, supply, use, transport, or dispose of a GMO.

309. A GMO is defined as any organism that has been modified by gene technology, or offspring derived from such an organism, or anything declared as a GMO in the Regulations.

310. The Act (section 31) is a prohibitory scheme that makes dealing with a GMO a criminal offence unless the dealing is:

- an Exempt dealing;
- a Notifiable Low Risk Dealing (NLRD);
- authorised by a licence; or
- included on the GMO Register.

311. Exempt dealings and NLRDs are not considered to pose risks that require direct scrutiny by the Regulator in the form of case by case risk assessment These kinds of dealings are routine laboratory techniques involving GMOs that were in use when the Act came into force and have been used safely for many years or represent minimal risk dealings when performed in contained conditions.

312. The Act states that the Regulator must prepare a risk assessment and risk management plan (RARMP) for all applications involving dealings that require a licence, as part of the process of making a decision on whether to issue a licence (sections 47 and 50).

313. Dealings authorised by a licence are further categorised into Dealings Not Involving Intentional Release (DNIRs) and Dealings Involving Intentional Release (DIRs).

314. A representation of the classes of dealings, outlining the level of risk and the predetermined management conditions (e.g. containment) is set out in Table B1 below.

Table B1 Classes of GMO dealings under the Gene Technology Act 2000

Category	Risk	Licence Required	Physical containment
GMO Register	≤ minimal[6]	No, but must be previously licensed	Possibly (containment conditions might still be required)
Exempt	< minimal	No, must notify IBC	Yes PC1
NLRD	minimal	No, dealings must be approved by IBC; OGTR notified	Yes PC2 (usually)
DNIR	≥ minimal	Yes, dealings must be approved by IBC; RARMP prepared, licence decision bythe Regulator	Yes ≥ PC2 (usually)
DIR	≥ minimal	Yes, dealings must be approved by IBC; RARMP prepared, extensive consultation, licence	No (although where releases are limited and controlled containment measures will be required, and licence conditions will apply)

315. The licensing system is centred on a rigorous process of risk assessment based on scientific evidence. For those dealings that involve an intentional release of a GMO into the environment (DIR), the legislation requires extensive consultation with expert groups and authorities, government agencies and the public. More data must be submitted for assessment and a more rigorous assessment process is set out than is required for dealings not involving intentional release of a GMO into the environment (DNIR).

Time frames

316. Under section 43(3) of the Act the Regulator must issue or refuse to issue a licence within a time limit prescribed by the Regulations. Similarly the Regulations prescribe a timeframe for consideration of applications to accredit organisations and to certify facilities. These statutory timeframes are shown in Table B2. They do not include weekends or public holidays in the Australian Capital Territory or periods where the Regulator has requested more information from the applicant, including information to resolve a CCI claim, and cannot proceed with the decision making process until that information has been provided.

Table B2 Timeframes under the Act

Category	Time frame
DNIR	90 working days (Regulation 8)
DIR	170 working days (Regulation 8)
Accreditation	90 working days (Regulation 16)
Certification	90 working days (Regulation 14)

Dealings involving minimal[6] risks

317. **The GMO Register**[7] is a Register provided by the Act (Part 6, Division 3) that lists dealings with a GMO that are, or have been, authorised by a licence previously but have a history of safe use. To be included on the Register the Regulator must be satisfied that risks posed by the specific dealings are negligible to human health and safety or to the environment and because of this, the applicant no longer needs to hold a GMO licence for that dealing. After inclusion on the Register these dealings would no longer require authorisation by a licence from the Regulator but may still have conditions attached to their registration. There are currently no GMO dealings on the GMO Register. The principles of risk analysis set out in this Framework are applicable to the determination of whether a GMO should be placed on the GMO Register.

318. **Exempt dealings** are dealings with GMOs that have been assessed over time as posing negligible risks to people or the environment. They comprise basic molecular biology techniques that are used extensively in laboratories worldwide. The criteria for Exempt dealings are specified in the Regulations (schedule 2). A record of exempt dealings is maintained by the IBC of the organisation undertaking the dealing. Such dealings may only be undertaken in a facility which meets the PC1 standards in the Australian/New Zealand Standard 2243 (AS/NZS 2243.3 2002) or higher and are reported to the OGTR in the organisation's annual report.

6 The term 'minimal' has been used in the Act and Regulations in relation to these dealings and the GMO Register, however the legislation does not provide any definition of 'minimal'. Chapter 3 of this Framework proposes a vocabulary of terms and definitions to be used by the Regulator in conducting risk analysis, including attributions for relative risk estimates. The term minimal is not proposed for this use.

7 It is important to note the difference between the GMO Record and the GMO Register. The GMO Record is a comprehensive listing of all dealings with GMOs including licensed dealings, NLRDs and GM products. The GMO Register lists GMOs that no longer require a licence and will only ever be a subset of dealings included on the GMO Record.

If dealings fall within the classification in the Regulations for exempt dealings, they are not considered to require a case by case risk assessment. Examples of Exempt dealings include:

- dealings with GM mice where only specific mouse genes have been deleted or inactivated; or
- introduction of naked pieces of DNA into cells of whole animals, as long as this is incapable of giving rise to infectious agents; or
- shot-gun cloning of mammalian genes e.g. cloning of kangaroo genes into laboratory strains of E. coli.

319. **Notifiable Low Risk Dealings** (NLRDs) are dealings with GMOs that have been assessed over time as posing negligible risks provided certain management conditions are met. The criteria for NLRDs are specified in the Regulations (Schedule 3). Such dealings may only be undertaken in a facility certified by the Regulator (usually PC2 or higher). The dealing must be considered by an IBC and the Regulator notified of the approval of the dealing within 14 days. NLRDs are included on the Record of GMO and GM Product Dealings (see below) but do not require case by case risk assessment. Examples of NLRDs include:

- dealings with whole animals that produce a new GM animal and where the new trait can be passed on to the animal's offspring, but the animal is housed in contained conditions; or
- dealings with GM flowering plants where all pollen and seed are contained.

Licensed Dealings

320. Any dealing not Exempt, NLRD or on the GMO Register must not be conducted unless licensed.

321. Licence applications are considered on a case by case basis by the Regulator, who must consider whether the risks posed by the dealing can be managed to protect human health and safety and the environment. The Regulator must make a decision on whether to issue a licence to allow the conduct of that dealing and the management conditions to be imposed to manage any risks.

322. The legislation sets out a series of actions the Regulator must take into account in consideration of applications for licences for both for contained dealings (DNIRs) and those involving intentional release (DIRs).

The Act details steps that must be taken in regard to the assessment of the application, while the Regulations detail the information that must be provided by the applicant.

323. For both DNIRs and DIRs the Regulations require the applicant to identify risks that the dealings may pose to human health and safety and the environment and any measures proposed to manage those risks. Both also require the IBC to have scrutinised the application to provide an evaluation report assessing the risk identification and the management proposals of the applicant.

324. The legislation requires the Regulator to prepare a RARMP for both DNIR and DIR applications. The risk assessment takes account of any risks to human health and safety and the environment posed by the dealing and the risk management plan determines how these risks can be managed.

325. The requirements of the legislation have been framed to place greater scrutiny on dealings that involve release to the environment (DIRs). The Regulator may impose conditions on all licences. In relation to field trials under limited and controlled conditions, measures are imposed to limit the persistence and spread of the GMO and its genetic material. Non-compliance with conditions placed on licences issued under the Act is a criminal offence.

326. For both DNIR and DIR applications the applicant must provide information specified in the Regulations as to their suitability to hold a licence. This information includes any relevant convictions, revocations or suspensions of licences under laws relating to human health and safety or the environment and an assessment of the applicant's capacity to manage any risks posed by the proposed dealings.

Dealings not involving intentional relase (DNIRs)

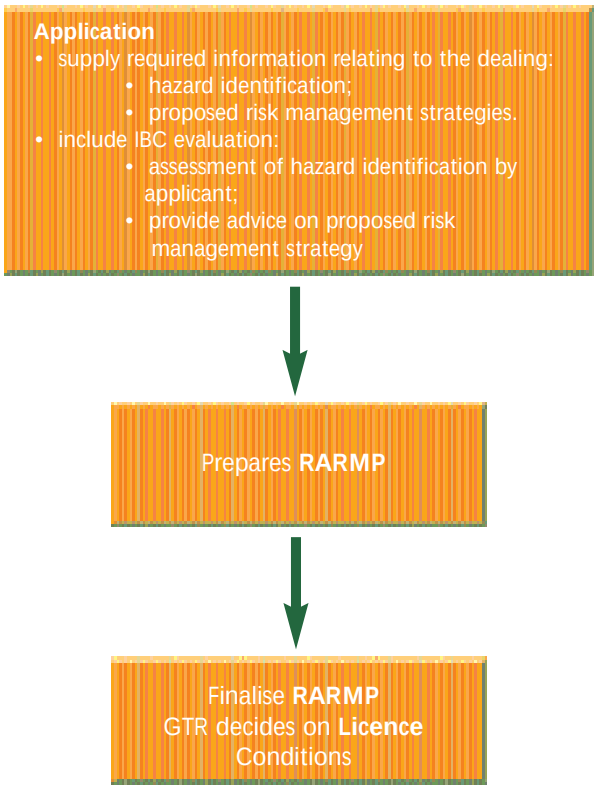
327. DNIRs usually take place under specified physical containment conditions in certified facilities, which minimise risks to the environment. The Act requires an assessment of the risks of the dealing and preparation of a RARMP with associated licence conditions to manage the risks for DNIR applications.

328. The legislation does not require the Regulator to consult in relation to DNIR licence applications. Presently, advice is sought from the Gene Tecnology Technical Advisory Committee (GTTAC) and the State(s) in which the dealings are proposed to take place during the preparation of the RARMPs for all new DNIR applications.

329. The Regulator considers the RARMP in deciding whether to issue a licence and in determining the licence conditions that should be imposed. Typical licence conditions require the applicant to conduct the dealing in certified facilities, to follow particular handling requirements (e.g. avoiding the use of 'sharps' and using biosafety cabinets), to train and supervise staff, to dispose of and transport the GMO appropriately, and to have, and implement contingency plans.

330. As a guide to the legislative requirements, the process required in respect of such applications is described in Figure B1 below.

Figure B1: DNIR assessment process



Dealings Involving Intentional Release (DIRs)

331. The Act makes no distinction between small-scale 'field trial' releases under limited and controlled conditions and releases intended to be of a general or commercial scale.

332. This Framework specifies the approach taken to risk analysis, which forms an integral part of each RARMP. As a guide to the requirements, the process adopted in respect of such applications is described in Figure B2.

333. **Stage 1** – The applicant must prepare comprehensive information about the proposed dealings with the GMO, possible hazards and consequent risks posed by the dealings with the GMO and proposed ways that each of the risks can be managed. The Regulator's information requirements are set out in detail in the Regulations and the application forms for intentional release dealings with the GMOs. The applicant must ensure that all responses are supported by appropriate data and literature citations. Wherever possible quantitative data should be provided. It is expected that the applicants will collect relevant data during contained work and early trials for dealings involving intentional release of GMOs.

334. **Stage 2** – The IBC reviews the application and provides the Regulator with an evaluation report setting out its advice as to the completeness of the applicant's hazard identification, risk assessment and proposed risk management strategies. The IBC's role is to ensure the quality of applications submitted to the Regulator.

335. **Stage 3** – Section 49 of the Act requires the Regulator to make an initial consideration of whether any of the proposed dealings in a DIR application may pose a significant risk to the health and safety of people or the environment. Under Section 49(2) of the Act the Regulator must consider:

(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 modifications that have occurred, or will occur, on the properties of the organism;

(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.

336. **Stage 4** – If the Regulator considers that the proposed dealings with the GMO could have a significant impact on the health and safety of people or the environment, the Regulator must call for public submissions on the application including seeking advice on the possible risks and means of managing the risks. In addition, if the Regulator deems it necessary,

public submissions can be invited on any application, for example for a novel GMO. The Regulator is required to advertise in a national newspaper, in the Australian Government Gazette and place notices on the Regulator's website. In practice the Regulator advertises more broadly, including regional newspapers and specialist interest press and will advise, by mail or email, to all persons that have registered their interest in receiving such information on the OGTR mailing lists.

337. 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.

338. **Stage 5** – Irrespective of whether the Regulator initially considers that the dealing may pose significant risks or not, the Regulator must seek advice on matters relevant to the preparation of the RARMP under section 50 of the Act from the Australian Government Environment Minister, GTTAC, the States and Territories, prescribed Australian Government agencies (Appendix C) and appropriate Local Government Authorities (LGAs). The Regulator usually consults with LGAs where the release is proposed to occur.

339. In addition, the Regulator also routinely seeks advice from other relevant Australian Government agencies such as the Department of Agriculture, Fisheries and Forestry; the Department of Industry, Tourism and Resources; and the Department of Foreign Affairs and Trade (see Chapter 5).

340. While the Office of the Gene Technology Regulator is located within the Department and Health and Ageing portfolio, the Australian Government Environment Minister receives special mention in the legislation in recognition of the relevance of that portfolio's responsibilities and role in administering the *Environment Protection and Biodiversity Conservation Act 1999* (the EPBC Act). The Regulator is required to consult with the Australian Government Environment Minister on each DIR application and the RARMPs prepared in relation to each DIR application. The Department of the Environment and Heritage is included in the consultation process via the support it provides to the Environment Minister.

341. **Stage 6** – The actual risk assessment process is shaped to some extent by the data requirements set out in the Regulations, however the Regulator can require submission of any data required to comprehensively identify hazards and evaluate risks posed by the dealing. The Regulator is specifically permitted by the legislation to seek and take into account any other relevant information such as independent research, independent

literature searches, the advice of any person or group, request more information from the applicant or to hold a public hearing. (Acceptable evidence is discussed in some detail in Chapter 3).

342. **Stage 7** – The Regulator must prepare a RARMP in relation to the proposed dealings with the GMOs.

343. The preparation of the risk assessment involves identifying any hazards that may be posed by the dealings with the GMOs, and estimates the level of risk posed by such hazards based on the likelihood of the event occurring and the likely consequences of that occurrence.

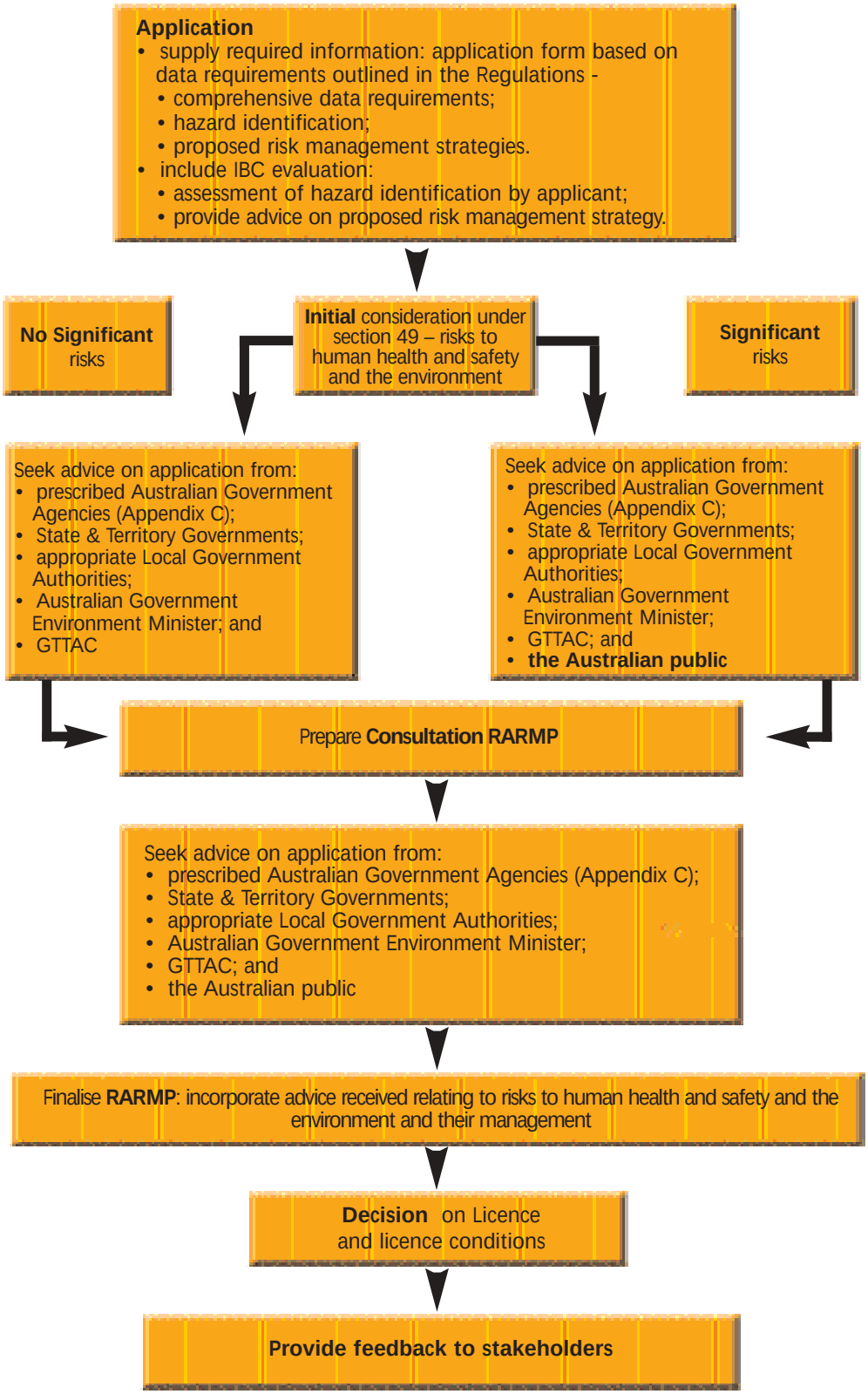
344. The risk management plan evaluates which of the risks to human health and safety and the environment posed by the dealing with the GMO require management, and considers how they may be able to be managed. This provides the basis for conditions that may be applied to the licence and draft conditions are included in the consultation version of the risk management plan.

345. **Stage 8** – Once the Regulator has prepared the RARMP under section 52 of the Act the Regulator must notify the public and invite written submissions on the document through advertisements in a national newspaper, the Australian Government Gazette and the Regulator's web site. The legislation requires that the Regulator provide at least 30 days to receive public submissions, however the Regulator's policy is to allow 6 weeks for limited and controlled field trial applications and 8 weeks for commercial release applications or for controversial GMOs.

346. Under section 52(3) of the Act the Regulator must also seek advice on the RARMP from all the expert groups and authorities that were consulted on the application, and the Australian Government Environment Minister.

347. **Stage 9** – The Regulator then finalises the RARMP, taking into account the advice provided in relation to the consultation version of the RARMP in accordance with section 56(2) of the Act. The Regulator then makes the decision on issuing the licence and any conditions to be imposed, based upon the finalised plan, having regard to any policy principles issued by the Gene Technology Ministerial Council (GTMC). The Regulator must notify the applicant in writing that a licence decision has been made. The Regulator also publishes the finalised RARMP on the Regulator's website, advises all expert groups and authorities and people or organisations that have made submissions and notifies registered recipients on the OGTR mailing list.

Figure B2: DIR assessment process



THE GMO RECORD

348. The Act requires the Regulator to maintain a 'Record of GMOs and GM Product Dealings' (the 'GMO Record', Section 138). Details of licences issued (both DNIR and DIR), information about NLRDs and information about GM Products approved or regitered by other regulatory authorities, are included on the GMO Record.

349. The GMO Record is currently divided into separate sections for the recording of:

- GM products – those used in food processing, therapeutics, and pesticides and veterinary medicines;
- Notifiable low risk dealings – NLRDs;
- Contained dealings – DNIR licences; and
- Intentional releases – DIR licences.

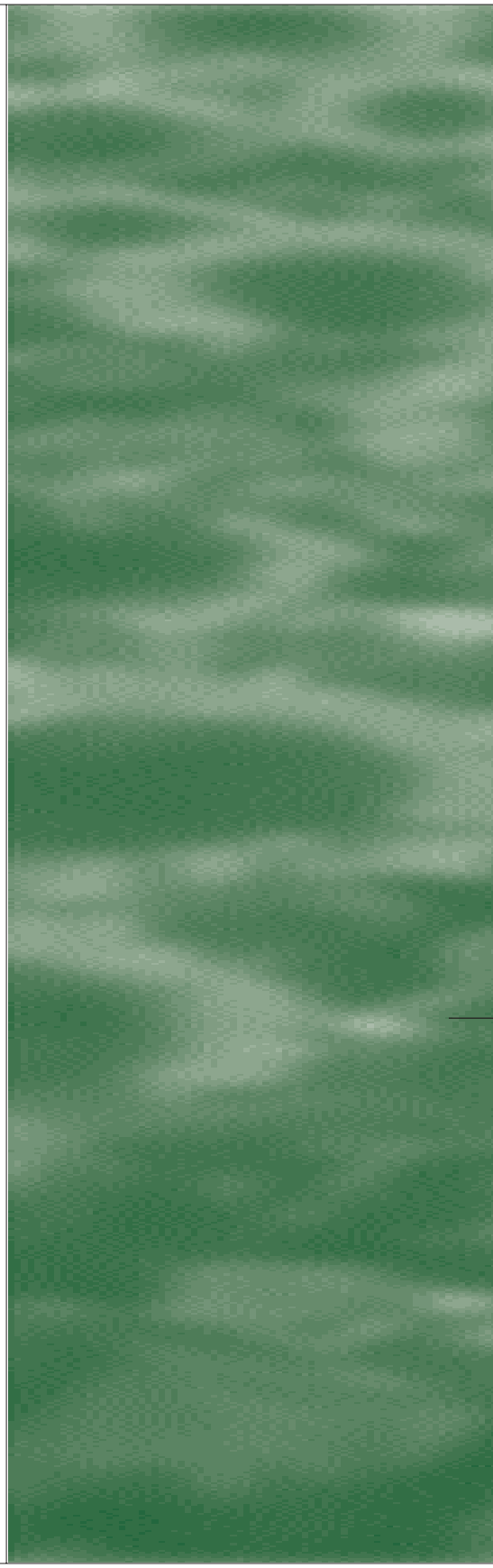
350. The Record can be accessed through the Regulator's website at: http://www.ogtr.gov.au/gmorec/index.htm

ROLE OF THE GENE TECHNOLOGY MINISTERIAL COUNCIL

350. The implementation of the legislation and the role of the Regulator are overseen by the Gene Technology Ministerial Council (GTMC). The GTMC was established by the Gene Technology Agreement 2001 (the Agreement) between the Australian Government and the governments of all States and Territories. The Agreement also commits State and Territory Governments to enacting corresponding State and Territory legislation.

351. The role of the GTMC is to provide policy input into the implementation and operation of the regulatory scheme. In addition the Council provides advice to the Australian Government Minister for Health and Ageing on the appointment of the Regulator and appointment of members of the Gene Technology Committees (see below). The GTMC is supported by the Gene Technology Standing Committee, and the Regulator is supported by the Office of the Gene Technology Regulator (OGTR).

352. The Act provides for the GTMC to issue policy principles in relation to ethical issues relating to GMOs and the recognition of areas designated under State law for the purpose of preserving the identity of either GM crops or non-GM crops for marketing purposes (section 21).



353. In relation to the latter on 31 July 2003 the GTMC issued its first policy principle: Gene Technology (Recognition of Designated Areas) Principle 2003 which came into effect on 5 September 2003.

GENE TECHNOLOGY COMMITTEES

354. The legislation creates three committees to provide advice to the Regulator and the Gene Technology Ministerial Committee (GTMC): the Gene Technology Technical Advisory Committee (GTTAC), the Gene Technology Community Consultation Committee (GTCCC) and the Gene Technology Ethics Comittee (GTEC). Membership of the committees consists of persons with either expertise in one or more scientific fields (GTTAC) or with skills and experience in areas relevant to gene technology as specified in the Act.

GTTAC – provides scientific and technical advice, on the request of the Regulator or the GTMC, on:

- gene technology;
- GMOs and GM products;
- applications made under the Act;
- biosafety aspects of gene technology; and
- the need for and content of policy principles, policy guidelines, codes of practice and technical and procedural guidelines.

GTCCC – provides advice at the request of the Regulator or the GTMC, on:

- matters of general concern in relation to GMOs; and
- the need for and content of policy principles, policy guidelines, codes of practice and technical and procedural guidelines.

GTEC – provides advice at the request of the Regulator or the GTMC, on:

- ethical issues relating to gene technology;
- the need for and content of codes of practice in relation to ethical conduct when dealing with GMOs; and
- the need for and content of policy principles relating to dealings with GMOs that should not be conducted for ethical reasons.

ACCREDITATION AND CERTIFICATION

356. Accreditation of organisations and certification of individual physical containment facilities assists in the management of risk that may be associated with dealings with GMOs by providing an administrative system in which to monitor and oversee their development and use.

357. An organisation undertaking certain dealings with GMOs will be required to be accredited by the Regulator (sections 91-98). The process of accreditation enables the Regulator to assess if the organisation has the resources and the internal processes in place to enable it to effectively oversee work with GMOs. Before an organisation can be accredited, it must have established, or have access to, an appropriately constituted IBC.

358. IBCs provide on-site scrutiny of negligible risk dealings that do not require case by case consideration by the Regulator. IBCs are required to comprise a range of suitable experts and an independent person and they provide a quality assurance mechanism that reviews the information submitted by applicants to the Regulator. The *Guidelines for the Accreditation of Organisations* and *Guidelines for the Certification of Facilities/Physical Containment Requirements* are available from the OGTR website (www.ogtr.gov.au).

359. The legislation allows the Regulator to certify laboratory or production facilities (sections 83-90) to ensure that they meet appropriate standards for containment of GMOs and that procedures and practices are carried out by trained and competent staff. Guidelines for certification of each type of facility (laboratory, plant house, aquaria etc) at the various levels of physical containment (PC) levels 1 to 4, are developed by the Regulator and must be complied with before a facility can be certified. All certified facilities must be inspected before certification and annually by the IBC. The OGTR inspects all high level facilities (large scale PC2, PC3 and PC4) before certification and re-certification.

APPENDIX C
COORDINATION WITH OTHER REGULATORY AGENCIES

360. Australia's gene technology regulatory system does not operate in isolation but rather it is part of an integrated legislative framework. While the Regulator must consider risks to human health and safety and the environment relating to the development and use of GMOs, other agencies have responsibility for regulating GMOs or GM products as part of a broader or different mandate. In addition, these agencies have relevant and complementary expertise.

361. During the development of the gene technology legislation (refer Appendix A), it was determined that the activities of the Regulator should not override existing legislation or result in duplication. Hence, the Act incorporates a requirement for the Regulator to consult with other agencies on DIR applications, and was accompanied by consequential amendments of the other relevant acts, relating to mutual consultation and exchange of information regarding their assessments and approvals.

362. Accordingly, where other agencies approve non-viable products derived from GMOs, advice on these decisions is supplied to the Regulator for placing on the GMO Record.

363. There are situations where approval of particular dealings with a GMO will require approval by both the Regulator and another regulatory body. The respective roles of these agencies are listed along with the relevant legislation in Table C1.

364. For example, while the Regulator must licence the release of a GMO that is used in human medicine into to the environment, the Therapeutic Goods Administration (TGA) would have to authorise its administration to people.

365. Similarly, while the Regulator must approve the environmental release of GM insecticidal or herbicide-tolerant plants in to the environment, the Australian Pesticides and Veterinary Medicines Authority (APVMA), which is responsible for the regulation of all agricultural chemicals, must register the insecticidal gene or approve the application of the herbicide to which the GM plants are tolerant.

366. Although the focus and responsibility of other agencies that regulate products that are, or are derived from GMOs, are distinct from those of the Regulator, where there is a requirement for regulation, the Regulator has a policy of aligning the decision making processes in so far as is practicable. The OGTR and other regulatory agencies work closely together to ensure thorough coordinated assessments of parallel applications are undertaken and, wherever possible, that the timing of decisions by both agencies coincide.

367. An example of where this can not apply is when Food Standards Australia New Zealand (FSANZ) is asked to assess the safety of a GM product that will be imported for use in human food before an application to grow the GMO from which it was derived in Australia is submitted to the Regulator.

368. The areas of joint responsibility between the various regulatory agencies that regulate GMOs or GM products are illustrated schematically in Figure C1.

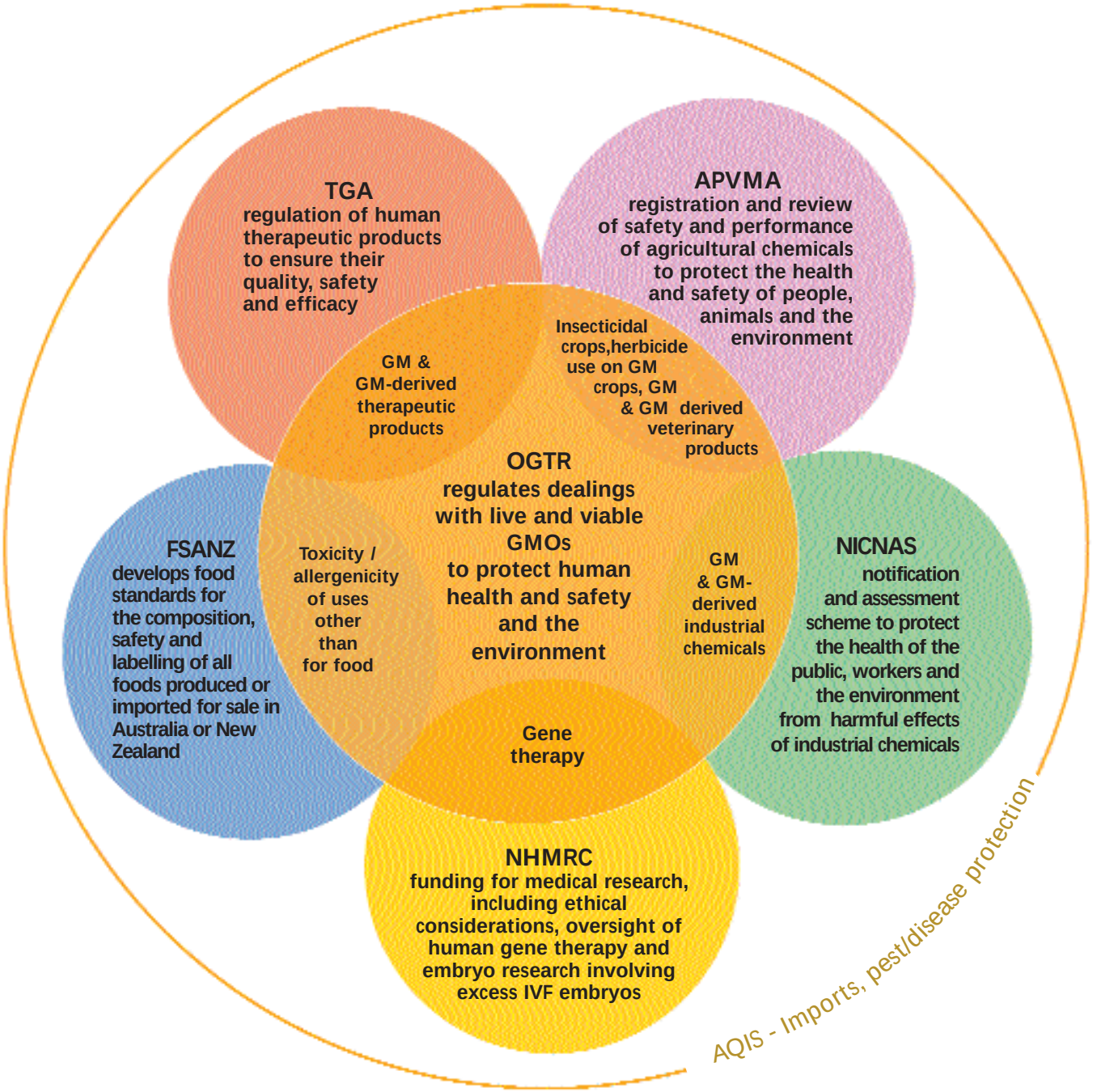
Table C1 Regulatory Agencies in Australia with a role in regulating gene technology

GMO/GM Products	Agency	Portfolio	Scope	Relevant Legislation
GMO dealings	OGTR Gene Technology Regulator & Office	Health & Ageing	OGTR provides a national scheme for the regulation of GMOs in Australia, in order to protect human health & safety and the environment by identifying risks posed by or as a result of gene technology, and to manage those risks by regulating certain dealings with GMOs.	Gene Technology Act 2000
Medicines, medical devices, blood & tissues	TGA Therapeutic Goods Administration	Health & Ageing	TGA administers legislation that provides a national framework for the regulation of therapeutic products in Australia & ensures their quality, safety & efficacy.	Therapeutic Goods Act 1989
Health & Medical Research	NHMRC National Health & Medical Research Council	Health & Ageing	NHMRC provides funding for health & medical research, advises the community & governments on a range of health and health-related ethical issues. Through its oversight of the Gene & related Therapies Research Advisory Panel (GTRAP), the NHMRC has a specific advisory role in relation to human clinical research using gene therapy or GM cells & tissues.	Research involving Human Embryos Act 2002; Prohibition of Human Cloning Act 2002
Food	FSANZ Food Standards Australia & New Zealand	Health & Ageing	FSANZ is responsible for food standards, including mandatory approvals for the safety and labelling of food produced using gene technology before it can be sold.	Food Standards Australia New Zealand Act 1991

Table C1 Regulatory Agencies in Australia with a role in regulating gene technology (contd.)

GMO/GM Products	Agency	Portfolio	Scope	Relevant Legislation
Agricultural & Veterinary Chemicals	APVMA Australian Pesticides & Veterinary Medicines Authority	Agriculture, Fisheries & Forestry	APVMA operates the national system that evaluates, registers & regulates all agricultural chemicals (including those that are, or are used on GM crops) and veterinary therapeutic products. Assessments consider human and environmental safety, product efficacy (including insecticide and herbicide resistance management), and trade issues relating to residues.	Agricultural & Veterinary Chemicals (Code) Act 1994; Agricultural & Veterinary Chemicals Administration Act 1994
Industrial Chemicals	NICNAS/OCS National Industrial Chemicals Notification & Assessment Scheme; Office of Chemical Safety	Health & Ageing	NICNAS provides a national notification & assessment scheme to protect the health of the public, workers & the environment from the harmful effects of industrial chemicals.	Industrial Chemicals (Notification & Assessment) Act 1989
Quarantine	AQIS Australian Quarantine & Inspection Service	Agriculture, Fisheries & Forestry	AQIS regulates the importation into Australia of all animal, plant & biological products that may pose a quarantine pest &/or disease risk.	Quarantine Act 1908; Imported Food Control Act 1992

Figure C1: Overlap between the activities of the OGTR in relation to GMOs and GM Products and other regulatory agencies in Australia



APPENDIX D
UNCERTAINTY

369. One useful taxonomy for uncertainty based on Clark and Brinkely (2001) and others (Hayes, 2004) distinguishes at least five types of uncertainty that can be applied to risk analysis of GMOs. These include:

epistemic - uncertainty of knowledge, its acquisition and validation.

370. Examples of epistemic uncertainty include incomplete knowledge, limited sample size, measurement error (systematic or random), sampling error, ambiguous or contested data, unreliable data (e.g. mislabelled, misclassified, unrepresentative or uncertain data), use of surrogate data (e.g. extrapolation from animal models to humans), ignorance of ignorance that gives rise to unexpected findings or surprise.

371. Risk assessment of licensed dealings for GMOs is evidence-based, primarily using information that is derived from scientific research. Consequently, epistemic uncertainty is a major component of uncertainty in risk assessments.

descriptive - uncertainty of descriptions that may be in the form of words (linguistic uncertainty), models, figures, pictures or symbols (such as those used in formal logic, geometry and mathematics).

372. The principal forms of descriptive uncertainty include vagueness, ambiguity, underspecificity, contextual and undecidability. Qualitative risk assessments can be particularly susceptible to linguistic uncertainty. For example the word 'low' may be ambiguously applied to likelihood of harm, magnitude of a harmful outcome and to the overall estimate of risk. Furthermore, the word 'low' may be poorly defined both in meaning (vagueness) and coverage (underspecificity).

cognitive (including bias, perception and sensory uncertainty)

373. Cognitive uncertainty can take several forms, including bias, variability in risk perception (see Chapter 5), uncertainty due to limitations of our senses (contributing to measurement error) and as unreliability. Cognitive unreliability can be viewed as guesswork, speculation, wishful thinking, arbitrariness, debate, or changeability. Based on the work of Kahneman and Tversky in the 1970s and 1980s, bias is revealed as how people and organisations do respond to uncertainty rather than should respond (Kahneman & Tversky 1996; Kahneman 2003).

entropic (complexity) - uncertainty that is associated with the complex nature of dynamic systems that exist far from thermodynamic equilibrium (Nicolis & Prigogine 1989), such as a cell, an organism, the ecosystem, an organisation or physical systems (e.g. the weather).

374. Uncertainty due to complexity arises when dealing with a system in which the outcome is dependent on two or more processes that are to some degree independent. Complexity is typically coupled to incomplete knowledge (epistemic uncertainty) where there is an inability to establish the complete causal pathway.

375. Therefore, additional knowledge of the system can reduce the degree of uncertainty. However, complex systems are characterised by non-linear dynamics that may display sensitive dependence on initial conditions. Consequently, a deterministic system can have unpredictable outcomes because the initial conditions cannot be perfectly specified. Complexity is listed as one of the four central challenges in formulating the European Union (EU) approach to precautionary risk regulation (Renn et al. 2003).

intrinsic - uncertainty that expresses the inherent randomness, variability or indeterminacy of a thing, quality or process.

376. Randomness can arise from spatial variation, temporal fluctuations, manufacturing variation, genetic difference or gene expression fluctuations. Variability arises from the observed or predicted variation of responses to an identical stimulus among the individual targets within a relevant population such as humans, animals, plants, micro-organisms, landscapes, etc. Indeterminacy results "from a genuine stochastic relationship between cause and effect(s), apparently noncausal or noncyclical random events, or badly understood nonlinear, chaotic relationships" (Klinke & Renn 2002).

377. A critical feature of intrinsic **uncertainty** is that it cannot be reduced by more effort such as more data or more accurate data. In risk management, safety factors and other protective measures are used to cover this type of uncertainty.

378. All five types of uncertainty may be encountered in a risk analysis context. To encompass this broader application, uncertainty can be defined as 'imperfect ability to assign a character state to a thing or process; a form or source of doubt'. Where:

'imperfect' refers to qualities such as incomplete, inaccurate, imprecise, inexact, insufficient, error, vague, ambiguous, under-specified, changeable, contradictory or inconsistent;

'ability' refers to capacities such as knowledge, description or understanding;

'assign' refers to attributes such as truthfulness or correctness;

'character state' may include properties such as time, number, occurrences, dimensions, scale, location, magnitude, quality, nature, or causality;

'thing' may include a person, object, property or system; and

'process' may include operations such as assessment, calculation, estimation, evaluation, judgement, or decision.

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