Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

Risk Analysis Framework April 2009

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RISK ANALYSIS FRAMEWORK **April 2009**

© Commonwealth of Australia 2009
First edition published in January 2002
Version 2.1 published in January 2005
Version 2.2 published in November 2007
Version 3 published in April 2009

ISBN: 1-74186-863-7
Online ISBN: 1-74186-864-5
Publications Number: P3 -5122

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Layout and design: Giraffe Visual Communication Management

Photographs: CSIRO

A message from the Regulator

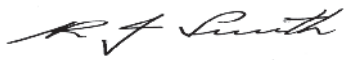
I am delighted to release this, the fourth update of the *Risk Analysis Framework* for the Office of the Gene Technology Regulator (OGTR). Regular observers of the OGTR *Risk Analysis Framework* will notice a gradual refinement of ideas from the first edition in 2002.

In Australia, gene technology is stringently regulated by laws that govern the research, development, trial and release of genetically modified organisms (GMOs) to protect human health and safety and the Australian environment. The *Risk Analysis Framework* explains our approach to the risk assessments and risk management plans that are required in support of decisions on applications to use GMOs.

While many different models for risk analysis exist, there is no international consensus on the appropriate model to use for GMOs. We have, therefore, taken as our starting point the most recent version of the Australian New Zealand Standard for Risk Management (AS/NZS 4360:2004), which is a generic standard for risk management.

This edition of the framework has benefited from the guidance of the Gene Technology Technical Advisory Committee and AS/NZS 4360 Committee members. Importantly, it is the culmination of many internal staff discussions about the evolving nature of the work of the OGTR. In particular, I thank Paul Keese, Peter Thygesen and Robyn Cleland who were responsible for the 2005 *Risk Analysis Framework* and who continue to be enthusiastic champions for the framework. Using this solid base Vidya Jagadish, Will Tucker, Ruth Myers, Andrea Robold, Michael Dornbusch and Elizabeth Flynn added insights based on practical experience of the last few years.

I commend the 2009 *Risk Analysis Framework* to you and welcome your feedback.



Dr Joe Smith
Gene Technology Regulator

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Executive summary

The *Gene Technology Act 2000* (the Act) and the Gene Technology Regulations 2001 (the Regulations), provide the legislative context for the use of risk analysis in regulating activities with a genetically modified organism (GMO) in Australia. In particular, the Act mandates preparation of a risk assessment and risk management plan in consideration of a licence application.

Licences are required for a proposed release of a GMO into the environment (DIR), and activities with certain types of GMO in a contained facility (DNIR). The decision on whether to issue a licence is made by the Gene Technology Regulator (the Regulator), an independent statutory office holder established by the Act.

The *Risk Analysis Framework* provides guidance on how the Regulator, together with staff under the Regulator's direction in the Office of the Gene Technology Regulator (OGTR), implements risk analysis of GMOs in accordance with the Act and the Regulations.

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

- provide a guide to the rationale and approach to risk analysis used by the Regulator
- enable a consistent and rigorous risk analysis approach to evaluating licence applications
- ensure that the use of risk analysis in the decision-making process is transparent to applicants and other stakeholders.

This version of the *Risk Analysis Framework* incorporates recent advances in risk analysis methodology and increased scientific knowledge, as well as regulatory experience gained with GMOs both here and overseas.

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 Act.

Risk analysis includes risk assessment, risk management and risk communication. Risk assessment identifies risks from plausible sets of circumstances that may result in harm to people or to the environment and estimating the level of risk on the basis of the seriousness and chance of harm. Risk management evaluates, selects and implements plans or actions to ensure that risks are appropriately managed. Risk communication is the exchange of information, ideas and views between the Regulator and stakeholders. Risk communication also conveys the rationale for decisions made by the Regulator.

The methodology used for risk analysis is based on the Australian New Zealand Standard 4360:2004, *Risk Management*.

Risk analysis integrates the assessment, management and communication of risks posed by, or as a result of, gene technology.

Establishing the risk context is the preparatory step that describes what will be done and how it will be done for the analysis of risk. In particular, the risk context defines the scope and boundaries, sets the broad terms of reference and criteria against which the significance of risk will be evaluated, as well as the structure and processes for the analysis. The risk context is established within the framework of the legislative requirements of the Act and Regulations.

All applications for licensed dealings with GMOs require case-by-case assessment by the Regulator and preparation of a risk assessment and risk management plan. Details of the GMO and the proposed activities, including any proposed controls, limits or containment measures form the specific context for the risk assessment and risk management plan. Details of the parent organism and the environment where activities with the GMO will occur form the comparative baselines for the risk assessment.

The risk context defines the parameters within which risk is assessed, managed and communicated.

The purpose of risk assessment is to identify and characterise risks to the health and safety of people or to the environment from dealings with GMOs, posed by or as the result of gene technology. The risk assessment identifies risk by considering what could go wrong and how harm might occur. Risks are then characterised by considering how serious the harm could be and how likely it is that harm may occur.

Risks are identified by considering a broad range of circumstances whereby the proposed dealings with a GMO are postulated to give rise to harm for people or to the environment through a plausible causal pathway between the GMO and an adverse outcome. Risks are then characterised in terms of the degree of seriousness and likelihood of potential harm, which are combined to estimate the level of risk as negligible, low, moderate or high.

There is a focus on scientific evidence in the risk assessment, involving extensive consultation with experts and other stakeholders, as well as consideration of knowledge gaps and other forms of uncertainty.

The risk assessment initially considers a wide range of possible risks, but puts greatest emphasis on more substantive risks, which receive more detailed characterisation. Risks that are estimated to be greater than negligible are then considered by risk management for control or mitigation.

Risk assessment identifies substantive risks and estimates the level of risk based on a combination of the likelihood and consequences of potential harm.

The purpose of risk management is to protect the health and safety of people and to protect the environment by controlling or mitigating risk. Risk management may be described as answering the questions: does anything need to be done about the risks? what can be done about it? and, what should be done about it? Risk management involves prudent judgments about which risks require management (risk evaluation), the choice and application of treatment measures, and ultimately whether the dealings with GMOs should be permitted.

Risk management includes preparation of a risk management plan by evaluating and treating risk, applying general risk management measures, and proposing licence conditions to give effect to management measures. In addition, risk management includes monitoring and reviewing to provide feedback on all steps in risk analysis and ensure the outcomes remain valid for future findings or changes in circumstances.

The risk assessment and risk management plan forms the basis upon which the Regulator decides whether to issue a licence. 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, a licence would be refused.

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

Risk communication is integral to the processes of risk assessment and risk management and involves development of an interactive dialogue between the Regulator and stakeholders.

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. In many instances differing perceptions of risk can influence the approach of stakeholders to particular issues. The Regulator can also seek advice on ethical and social issues raised by gene technology from the Gene Technology Ethics and Community Consultative Committee (GTECCC).

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 OGTR. The Risk Analysis Framework is part of the Regulator's commitment to clarity, transparency and accountability of decision-making processes and is supported by 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.

Abbreviations

APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine Inspection Service
AS/NZS	Australian Standard/New Zealand Standard
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DIR	dealings involving intentional release
DNIR	dealings not involving intentional release
EDD	emergency dealing determination
FAO	Food and Agriculture Organization
FSANZ	Food Standards Australia New Zealand
GM	genetically modified
GMAC	Genetic Manipulation Advisory Committee
GMO	genetically modified organism
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTMC	Gene Technology Ministerial Council
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
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
OIE	World Organisation for Animal Health
PC	physical containment
RARMP	risk assessment and risk management plan
TGA	Therapeutic Goods Administration
USEPA	United States Environmental Protection Agency
WHO	World Health Organization

Glossary

Notes: Terms marked with an asterisk* are defined by the *Gene Technology Act 2000;* risk-related terms are based on AS/NZS 4360:2004, *Risk Management*, except that risk is considered only in respect of adverse outcomes. NOTES provide further context for usage of some terms in this document.

consequence	Adverse outcome or impact of an activity. NOTE 1: Consequences are considered in relation to harm to the health and safety of people and the environment. NOTE 2: A consequence assessment determines the degree of seriousness of harm ranging from marginal to major.
deal with*	In relation to a GMO, means: a) conduct experiments with the GMO b) make, develop, produce or manufacture the GMO c) breed the GMO d) propagate the GMO e) use the GMO in the course of manufacture of a thing that is not the GMO f) grow, raise or culture the GMO g) import the GMO h) transport the GMO i) dispose of the GMO and includes possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).
environment*	Includes: a) ecosystems and their constituent parts b) natural and physical resources c) the qualities and characteristics of locations, places and areas.
gene technology*	Any technique for the modification of genes or other genetic material, but does not include: a) sexual reproduction b) homologous recombination, or c) any other technique specified in the regulations for the purposes of this paragraph.

genetically modified organism*	a) an organism that has been modified by gene technology b) an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology, or c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms, but does not include: d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy, or e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.
harm	Adverse outcome or impact. NOTE 1: Harm refers to an adverse outcome or impact for the health and safety of people or to the environment.
likelihood	Chance. NOTE 1: Likelihood is a general description of the probability, frequency or possibility of something happening. NOTE 2: A likelihood assessment determines the degree of chance that harm occurs ranging from highly unlikely to highly likely.
post release review	Ongoing oversight of general/commercial releases, focused on informing the findings of the risk assessment and risk management plan and providing feedback into risk analysis.
risk	Chance of harm from an activity. NOTE 1: In the context of the *Gene Technology Act 2000*, an activity is a 'dealing with a GMO' and risk is the potential for adverse outcomes to human health and safety and the environment from those dealings.
risk analysis	Overall process of risk assessment, risk management and risk communication.
risk analysis framework	Guidance on the systematic application of legislation, policies, procedures and practices to risk analysis.
risk assessment	Overall process of risk identification and risk characterisation. NOTE 1: Risk assessment is a specific requirement of the *Gene Technology Act 2000.* NOTE 2: The purpose of the risk assessment is to consider risks to the health and safety of people and the environment from dealings with GMOs, posed by, or as a result of, gene technology.
risk characterisation	Overall process of consequence and likelihood assessments for an identified risk, and risk estimation.
risk communication	Culture, processes and structures to communicate and consult with stakeholders regarding risks.

risk context	Parameters within which risk is assessed, managed and communicated. NOTE 1: The risk context defines the scope and boundaries, criteria against which risk will be evaluated, as well as the structure and processes for the analysis.
risk criteria	Terms of reference against which the significance of risk is evaluated.
risk estimate	Level of risk determined by a combination of consequence and likelihood assessments.
risk evaluation	Process of determining if risk requires risk treatment.
risk identification	Process of postulating risk scenarios and determining those that warrant detailed risk characterisation. NOTE 1: Risk identification replaces 'hazard identification' described in the previous version of the *Risk Analysis Framework* (OGTR 2007).
risk management	Mechanisms to control and mitigate risk. NOTE 1: The purpose of risk management is to protect the health and safety of people, and to protect the environment. NOTE 2: Components of risk management include preparation of a risk management plan and ongoing oversight through monitoring and reviewing.
risk management plan	Scheme for managing risk posed by dealings with a GMO. NOTE 1: The risk management plan refers to a specific requirement of the *Gene Technology Act 2000*. NOTE 2: The risk management plan is implemented through licence conditions.
risk scenario	Occurrence of a particular set of circumstances that may result in harm from an activity. NOTE 1: A risk scenario describes a plausible causal pathway through which dealings with a GMO could lead to harm. NOTE 2: A risk scenario includes points of human and environmental exposure to a changed attribute of the GMO or of its products, or to the introduced genetic material. NOTE 3: Risk scenario replaces the term 'event' described in the previous version of the *Risk Analysis Framework* (OGTR 2007).
risk treatment	Process of selection and implementation of measures to reduce risk.
stakeholders	Those people and organisations that may affect, be affected by, or perceive themselves to be affected by a decision, activity or risk.
states	Includes all state governments, the Australian Capital Territory and the Northern Territory governments.

uncertainty	Imperfect ability to assign a character state to an entity or activity; a form or source of doubt. NOTE 1: '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' refers to properties such as time, number, occurrences, dimensions, scale, location, magnitude, quality, nature, or causality; 'entity' refers to things such person, object, property or system; 'activity' refers to actions and processes such as assessment, calculation, estimation, evaluation, judgment, or decision; 'a form or source of doubt' is an informal definition of uncertainty. NOTE 2: Different types of uncertainty are relevant to risk analysis, including incertitude (uncertainty regarding knowledge), variability, descriptive and cognitive.

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CHAPTER 1 Introduction

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Chapter 1 Introduction

Australian governments have recognised the potential for gene technology to contribute to society as well as the concerns in the community over development and deployment of the new technology. In response, legislation was enacted to regulate activities with genetically modified organisms (GMOs), namely, the *Gene Technology Act 2000* (the Act) and the Gene Technology Regulations 2001 (the Regulations). This legislation, and corresponding state laws,[1] replaced a voluntary scheme administered by the Genetic Manipulation Advisory Committee (see Appendix A).

The Act also established an independent statutory office holder – the Gene Technology Regulator (the Regulator) – who is charged with making decisions about activities with GMOs in accordance with the legislation. In support of the decision-making process, the Regulator and staff under the Regulator's direction in the Office of the Gene Technology Regulator (OGTR), use risk analysis.

The *Risk Analysis Framework* is a key document for informing applicants, stakeholders and the public about the Regulator's approach to applying risk analysis. It explains why and how the Regulator undertakes risk analysis by:

- describing the Australian legislative context for risk analysis (this Chapter)
- describing the Regulator's approach to risk analysis, which is based on national and international standards and guidance (Chapter 2)
- outlining the methodology the Regulator uses when preparing a risk assessment and risk management plan in response to a GMO licence application (Chapters 3 to 5)
- discussing the Regulator's approach to risk communication (Chapter 6).

The term risk analysis is used to encompass all components of risk; namely, risk assessment, risk management and risk communication (FAO & WHO 2006).

risk analysis = risk assessment + risk management + risk communication

Risk assessment identifies risks from plausible sets of circumstances that may result in harm to people or to the environment and estimating the level of risk on the basis of the seriousness and chance of harm. **Risk management** evaluates, selects and implements plans or actions to ensure risks are appropriately managed. **Risk communication** is the exchange of information, ideas and views between the Regulator and stakeholders; it also conveys the rationale for decisions made by the Regulator.

1 Throughout this document use of the term 'state' refers to both states and territories, and reference to the Australian Government Act or Regulations or gene technology legislation also includes corresponding law enacted in other Australian jurisdictions.

The methodology used for risk analysis is based on the Australian New Zealand Standard 4360:2004, *Risk Management* (Standards Australia 2004) (see Chapter 2).

Object of the Gene Technology Act 2000

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.

Regulating dealings with GMOs

The Act regulates dealings with GMOs to protect people and the environment. GMOs include organisms (biological entities that are viable, capable of reproduction or capable of transferring genetic material) that have been modified by gene technology or have inherited the genetic modification.

To 'deal with' a GMO, as defined in section 10(1) of the Act, is to conduct experiments with; make, develop, produce or manufacture; breed; propagate; use in the course of manufacture of a thing that is not the GMO; grow, raise or culture; import; transport; dispose of the GMO; and includes the possession, supply or use of the GMO for the purposes of, or in the course of any of the above.

Regulation of dealings[2] is achieved by prohibiting dealings with GMOs unless:

- the person undertaking the dealing is authorised to do so by a GMO licence
- the dealing is specified in an emergency dealing determination
- the dealing is a notifiable low risk dealing
- the dealing is an exempt dealing, or
- the dealing is included in the GMO Register

Two categories of GMO licence include:

- dealings that involve intentional release of a GMO into the environment, DIR – including limited and controlled releases, such as field trials, and general/commercial releases
- dealings that do not involve intentional release of a GMO into the environment, DNIR – for GMOs in contained facilities, such as laboratories, glasshouses, aquaria, insectaries or animal houses that are certified to a specified level of physical containment (PC).

2 Descriptions of emergency dealing determination, notifiable low risk dealing, exempt dealing and GMO register are provided in Appendix A.

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Before issuing a licence, the Regulator must prepare a risk assessment and a risk management plan in relation to the dealings proposed to be authorised by the licence (sections 47(1) and 50(1)). Risk analysis may also be conducted for the other permitted classes of regulated dealings, as well as in relation to applications to vary an existing licence. The risk analysis framework described here is primarily intended to inform consideration of applications for DIR and DNIR licences.

Identifying and managing risks

Risk is defined[3] as 'the chance of harm from an activity'. In the context of the Act, harm refers to adverse impacts for the health and safety of people, or to the environment, while activity refers to 'dealing with' a GMO. The Regulator considers risks that can be attributed to the use of gene technology. Australia's regulation of dealings with a GMO is therefore triggered by the process of genetic modification, rather than by a novel trait.

Other processes may also give rise to organisms with the same or similar novel trait. For instance, wheat with improved water use efficiency (that is, increased drought tolerance) could be generated by chemical or radiation mutagenesis, wide crosses, genetic modification or by conventional breeding practices. Experience with organisms that have similar traits generated without use of gene technology may provide useful information for considering potential risks from dealings with a GMO.

Risks are identified using a comparative risk assessment, whereby risk from a GMO is considered relative to the parent organism within the specific environment in which a dealing with a GMO takes place (receiving environment). The focus of the assessment is whether modified properties of the GMO arising from gene technology increase the level of risk, or give rise to additional risks. For instance, a parent organism may already have weedy or pathogenic characteristics; these characteristics form part of the baseline against which risk is identified.

Protection

The risk management goal, as directed by the object of the Act, is to protect the health and safety of people and to protect the environment. The Act emphasises protection over approval of a dealing. However, regulatory oversight also continues after approval is granted through mechanisms such as granting licences with specific obligations and restrictions; monitoring for compliance with licence conditions; adverse effects/events reporting; and, in the case of commercial/general releases, provisions for post release review (see Chapter 5).

3 Definitions of risk related terms are provided in the Glossary.

Some of the protective measures applied to regulation of gene technology include:

- Caution before authorisation of a dealing:
  - dealings with GMOs are prohibited unless allowed according to provisions in the Act
  - provisions in the Act allow the Regulator to refuse a licence
  - consultation with state governments, the public, Australian Government agencies, the Australian Government Environment Minister and scientific experts
  - scientific and regulatory expertise within the OGTR
  - emphasis of risk assessments on credible evidence
  - consideration of uncertainty in preparation of risk assessment and risk management plans
  - requirements for certification of facilities, accreditation of organisations and assurances of applicant suitability before granting a licence
  - maintaining awareness of new scientific findings
  - maintaining knowledge of assessments and decisions of overseas agencies that regulate GMOs.

- Caution after authorisation of a dealing:
  - specific licence conditions to manage risk (section 62)
  - licence conditions that limit and control the dealings
  - legislative requirements for compliance with licence conditions
  - provisions in the Act that allow the Regulator to suspend, vary or cancel a licence
  - requirements for the applicant to provide sufficient information to identify the GMO and to provide locations of rooms/buildings used to contain GMOs, exact coordinates of limited and controlled releases, information on locations and volumes on general/commercial releases
  - monitoring of facilities and release sites
  - statutory licence conditions such as reporting of additional information as to any risks to the health and safety of people, or to the environment, contravention of the licence, or unintended effects
  - post release review for general/commercial releases of GMOs
  - maintaining awareness of new scientific findings
  - contingency/emergency plans.

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The pathway for development of a GMO intended to be released into the environment would typically follow a staged approach:

- initial laboratory-based research under physical containment
- small scale experimental releases (such as field trials) with conditions to limit and control the release in space and time
- general/commercial release, with or without specific controls
- inclusion on the GMO Register with or without specific conditions.

Regulatory approval for each stage is supported by the experience and scientific data gathered and evaluated from the previous stages. This enables a body of evidence to be assembled about potential risks, while ensuring that human health and safety and the environment are protected.

Although protective measures are intended to shield from harm, all activities and decisions involve some level of risk. Protective measures should, therefore, be commensurate with the potential level of risk.

Protection goals – the health and safety of people and the environment

The object of the Act seeks to protect the health and safety of people and to protect the environment. Therefore, risks are identified in relation to the potential of harm for the health and safety of people, or to the environment.

Risk to the health and safety of people includes consideration of the occupational health and safety of workers dealing with the GMO, as well as the general public who may come into contact with a GMO. The risk will depend on the effects of the genetic modification and exposure of people to the GMO, or the introduced genetic material and/or its products. In particular, there is consideration of increased toxicity, allergenicity, disease or injury by the possible production of a toxin or allergen. Similarly, potential risk may arise from an increased production of an endogenous toxin or allergen.

Adverse impacts on the health of people may also occur through production of other types of compounds (for example, antinutrients that interfere directly with absorption of vitamins, minerals and other nutrients); or reduced production of key nutrients or other compounds that promote good health (such as antioxidants).

Section 10 of the Act defines the environment as including:

(a) ecosystems and their constituent parts

(b) natural and physical resources, and

(c) the qualities and characteristics of locations, places and areas.

Risk to the environment includes consideration of effects on biotic and abiotic components of the environment. Adverse impacts on the environment may result from:

- increased weediness or pestiness
- impaired health of organisms due to toxicity or disease
- reduced quality of biotic components (for example, reduced biodiversity)
- reduced quality of abiotic components such as soil, water, or air
- disruption of ecosystem processes (such as increased salinity or altered fire regimes).

Different risks may be identified for different parts of the environment; for example, the potential for increased weediness of a GMO may differ between agricultural and undisturbed environments.

Regulatory framework to achieve the object of the Act

The legislation also provides a regulatory framework to achieve the object of the Act (section 4), namely:

(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

(a) provides an efficient and effective system for the application of gene technologies

(b) operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products.

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 a novel technology, particularly if its products may become persistent or widespread. Section 4(aa) of the Act outlines a 'precautionary approach'.

Advocates of precautionary regulation have argued for a gradual, step-by-step approach to managing new technologies until sufficient knowledge and experience is acquired to provide confidence in its safety (Bennet 2000; Klinke & Renn 2002). However, 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). Nevertheless, a plausible causal pathway would need to be established to indicate threats of serious or irreversible environmental damage from a GMO.

The regulatory framework also provides for an efficient and effective system of regulation for application of gene technology, section 4(a), and is supported by several components of the legislation. These include:

- classification of dealings such that the level of regulatory scrutiny is proportional to the potential level of risk
- provision of a predictable process with specified statutory timeframes leading to reasonable, consistent and defensible decisions
- consultation with other agencies and government bodies to provide a coordinated and integrated approach to regulation of GMOs.

The latter also addresses section 4(b), which requires that the regulatory system should operate in an integrated way with existing Australian, state government regulatory schemes relevant to GMOs and GM products (see Appendix A).

In addition to the Regulator, the Australian Government agencies that have statutory responsibilities relevant to regulation of GMOs and GM products include:

- Australian Pesticides and Veterinary Medicines Authority (APVMA), which regulates pesticides and veterinary medicines, including evaluation of product efficacy issues, environmental safety and effects on trade from a residue perspective
- Food Standards Australia New Zealand (FSANZ), which is responsible for setting food standards, including mandatory pre-market safety assessments of GMOs and GM products in human food
- Therapeutic Goods Administration (TGA), which regulates the quality, safety and efficacy of therapeutic products, including human medicines containing GMOs or GM products
- National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which covers evaluation of industrial chemicals, including relevant GMOs and GM products, for occupational health and safety and environmental safety
- Australian Quarantine Inspection Service (AQIS) and Biosecurity Australia, which have responsibility for imported goods and quarantine risks. Imported GMOs must meet relevant import conditions as well as being approved for import by the Regulator.

In addition, the Department of the Environment, Water, Heritage and the Arts administers the *Environment Protection and Biodiversity Conservation Act 1999*, which includes protection of matters of national environmental significance, such as nationally threatened species and ecological

communities, migratory species, Ramsar[4] wetlands, World Heritage properties, National Heritage places, Commonwealth marine areas, and nuclear actions. Proposals for release of GMOs into the environment, which are likely to have a significant impact on a matter of national environmental significance, as defined in the *Environment Protection and Biodiversity Conservation Act 1999*, will require formal assessment and approval by the Australian Government Environment Minister.

Purpose of the Risk Analysis Framework

Within the legislative context of the Act and Regulations, the purpose of this *Risk Analysis Framework* is to:

- provide a guide to the rationale and approach to risk analysis used by the Regulator
- enable a consistent and rigorous risk analysis approach to evaluating applications for DIR and DNIR licences
- ensure the use of risk analysis in the decision-making process is transparent to applicants and to other stakeholders.

A summary of the gene technology regulatory system and certain legislative requirements relevant to risk analysis is provided in Appendix A. A summary of considerations in the application of risk analysis for DIRs is provided in Appendix B.

4 An intergovernmental treaty, which provides the framework for national action and international cooperation for conservation and wise use of wetlands and their resources, was signed in Ramsar, Iran, in 1971.

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CHAPTER 2 Risk analysis model used by OGTR

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Chapter 2 Risk analysis model used by OGTR

This Chapter describes the risk analysis model used by the Regulator, and the national and international sources that informed development of the model. In addition, the role of uncertainty in risk analysis is discussed. Finally, guiding principles the Regulator uses for risk analysis are provided.

Models of risk analysis

The AS/NZS 4360:2004, *Risk Management* (Standards Australia 2004) has been developed to guide organisations that deal with risk. According to AS/NZS 4360:2004, risk management is the overarching term that is equivalent to risk analysis (as described in this framework). A number of international organisations and treaties (such as the World Organisation for Animal Health (OIE), the International Plant Protection Convention, and the Codex Alimentarius Commission) provide standards and guidance for risk analysis in the specific areas of human health and environmental risks.

The logic and rationale for health and environmental risk assessments are generally based on a 1983 report from the US Academy of Sciences National Research Council, which has become known as the 'Red Book' (Jardine et al. 2003; National Research Council 1983; National Research Council 2008).

Annex III of the Cartagena Protocol on Biosafety (Secretariat of the Convention on Biological Diversity 2000) also provides guidance for risk assessments of GMOs; however, it does not detail how to perform the assessments.

OGTR risk analysis model

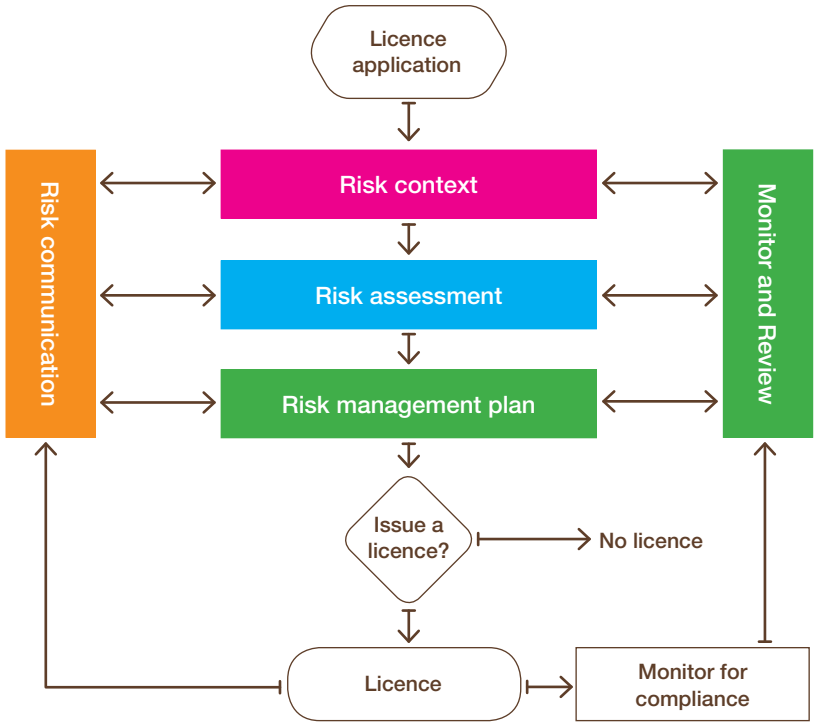
The Australian New Zealand Standard on Risk Management 4360:2004 (Standards Australia 2004) provides a generic model for risk analysis that is designed to be applicable across a range of disciplines. Elements from this and other models (Codex Alimentarius Commission 2003; FAO & WHO 2006; OIE 2004) have been considered in formulating a specific model for the Regulator that best supports risk analysis within the parameters of the Act.

Risk is generally considered in the context of uncertain outcomes, which may be positive or negative. Therefore, some risk analysis approaches incorporate some form of cost–benefit calculation. However, the object of the Act aims to protect the health and safety of people and to protect the environment. Accordingly, the Regulator considers risks only in terms of adverse outcomes.

The risk analysis methodology the Regulator uses for GMO licence applications may be depicted as a series of steps based on AS/NZS 4360:2004 (see Figure 2.1). However, this process is not necessarily

linear as there is significant iteration of each step during preparation of a risk assessment and risk management plan (RARMP) for each licence application.

Figure 2.1: Risk analysis methodology for GMO licence applications



Components in risk analysis

Risk context

Risk context is defined as the 'parameters within which risk is assessed, managed and communicated'. The risk context establishes the scope and boundaries, terms of reference against which the significance of risk will be evaluated, as well as the structure and processes for the analysis (see Chapter 3).

Risk assessment

Risk assessment is defined as the 'overall process of risk identification and risk characterisation'. The risk assessment considers potential harm to the health and safety of people or to the environment from dealings with GMOs posed by or as the result of gene technology.

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Risk identification considers when, where, how and why a dealing with the GMO could lead to harm due to gene technology, while risk characterisation examines the seriousness and likelihood of harm, and estimates the level of risk as negligible, low, moderate or high (see Chapter 4).

Risk management

Risk management is defined as the 'mechanisms to control and mitigate risk'. It includes preparation of a risk management plan, which includes measures to reduce the level of certain risks identified in the risk assessment; and monitoring and reviewing, which considers the effectiveness of outcomes from each step in the analysis. It also provides for ongoing improvements to accommodate future findings and changes in circumstances (see Chapter 5).

Risk communication

Risk communication is defined as the 'culture, processes and structures to communicate and consult with stakeholders about risks'. Specifically, it is communication of the risks to human health and the environment posed by certain dealings with GMO, and includes extensive consultation with experts and specified stakeholders during preparation of risk assessment and risk management plans for DIRs. In some cases the Regulator may also consult with experts on DNIR applications.

The risk assessment and risk management plan prepared for each licence application forms the basis upon which the Regulator decides whether to issue a licence. Stakeholders are informed of licences issued, proposed locations of authorised releases, the decision-making processes followed, and information sources accessed (see Chapter 6).

Terminology

The literature on risk analysis, as well as national and international standards and guidance documents, use a variety of terms to describe similar concepts (FAO & WHO 2006; Hill 2005; National Research Council 1983; OIE 2004; Raybould 2006; Romeis et al. 2008; Standards Australia 2004; USEPA 1998). The main risk analysis terms used in this framework are described in Table 2.1, which also provides alternative terms used in the literature to describe components with similar functions.

Table 2.1: Comparison of terms used to describe components of risk analysis

Terms described here	Related terms described in other risk frameworks
RISK ANALYSIS	**RISK MANAGEMENT**
Risk context	**Planning**
Risk assessment	
Risk identification	Problem formulation, risk hypothesis, hazard identification, conceptual model, hazard identification
Risk scenario	
Risk characterisation	Risk analysis, risk profile, risk estimate
Consequence assessment	Dose response, hazard, effect assessment, stressor-response
Likelihood assessment	Exposure assessment, probability, chance, frequency
Risk estimate	Risk calculation, risk characterisation
Risk evaluation	
Risk management	
Risk treatment	Risk control
Monitoring and review	
Risk communication	

Sources: FAO & WHO 2006; Hill 2005; National Research Council 1983; OIE 2004; Raybould 2006; Romeis et al. 2008; Standards Australia 2004; USEPA 1998

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. In addition, risk assessment is based on evidence, which is also subject to uncertainty. There are a number of different types of uncertainty (Bammer & Smithson 2008; Clark & Brinkley 2001; Hayes 2004). These include:

- incertitude – uncertainty of knowledge, its acquisition and validation
- variability – uncertainty that expresses the inherent randomness or indeterminacy of a thing, quality or process
- descriptive – uncertainty of descriptions that may be in the form of words (linguistic uncertainty), models, figures, pictures or symbols
- cognitive – uncertainty of mental processes, including bias, perception and sensory uncertainty.

Examples of **incertitude** include incomplete knowledge or data gaps, limited sample size, measurement error (systematic or random), sampling error, ambiguous or contested data, unreliable data (such as mislabelled, misclassified, unrepresentative or uncertain data), use of surrogate data (such as extrapolation from animal models to humans), and ignorance of ignorance that gives rise to unexpected findings or surprise.

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Risk assessment of licensed dealings for GMOs is evidence-based, primarily using information that is derived from scientific research. Consequently, incertitude is a major component of uncertainty in risk assessments. However, in principle, incertitude can be reduced by more effort through obtaining additional relevant data.

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, microorganisms, landscapes. Randomness can arise from spatial variation, temporal fluctuations, manufacturing variation, genetic heterozygosity or gene expression fluctuations. Indeterminacy results from 'a genuine stochastic relationship between cause and effect(s), apparently non-causal or non-cyclical random events, or badly understood non-linear, chaotic relationships' (Klinke & Renn 2002).

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

The principal forms of **descriptive** uncertainty include vagueness, ambiguity, underspecificity, contextual uncertainty 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 uncertainty can take several forms, including bias, variability in risk perception (see Chapter 6), uncertainty due to limitations of our senses (contributing to measurement error) and as unreliability. Cognitive uncertainty 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 2003; Kahneman & Tversky 1996).

Use of clearly specified terms can reduce cognitive uncertainty in some circumstances through dialogue to clarify meanings of terms, openness and transparency of the decision-making process, and exploration of underlying assumptions.

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).

However, uncertainty can also be considered more broadly. It is recognised that both dimensions of risk (the potential adverse outcome or consequence and the likelihood), are always uncertain to some degree, including the language to describe risk. Within this context, uncertainty includes incertitude, variability and descriptive uncertainty. In addition, uncertainty extends throughout risk analysis, including:

- risk assessment
  - uncertain characteristics of the GMO, such as knowledge gaps in the biochemical and physiological outcomes of expression 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 risk scenarios, likelihood and consequences
  - uncertainty in the use of the risk estimate matrix to derive an estimate of the level of risk
  - uncertain descriptions used in qualitative risk assessments due to insufficient explanations of terminology, use of related terms that are not fully congruent, or use of the same term in different contexts.

- risk management
  - adequacy, relevance and effectiveness of protective measures
  - 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.

Consideration of different types 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
- ensuring that information is not over- or under-emphasised during preparation of a risk assessment and risk management plan through identification of uncertainty
- highlighting areas where more effort is needed to improve estimates of risk and apply appropriate cautionary measures
- more honestly informing the decision-making process
- helping produce a clearer distinction of the values and facts used in decision making

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- developing trust between stakeholders through increased openness and transparency of the regulatory process
- increasing the opportunity for more effective communication about risk.

Guiding principles of risk analysis

When undertaking risk assessments, risk management actions or risk communication, a number of principles are used to guide risk analysis to ensure the goals of the gene technology regulatory scheme are achieved. These principles are consistent with those described by the Australian Government Department of Health and Ageing for environmental health risk assessment (enHealth 2002), and include:

- Legal – all actions taken must satisfy the requirements of the Act.
- Protective – all actions associated with the risk analysis should support the risk management goal of protecting the health and safety of people and the environment.
- Transparent – risk analysis for GMOs should be coherent, open to public scrutiny, describe the risk assessment, risk management and risk communication processes and assumptions, and acknowledge and incorporate consideration of uncertainty.
- Consultative – communication and consultation with the community and prescribed agencies should take place to identify and address issues and concerns.
- Robust – the risk analysis methodology should be generally applicable to all regulated dealings, no matter the species of GMO or the type of modified trait.
- Consistent and repeatable – risk assessment, risk management and risk communication documents should be in a common format but recognise the unique character of each case. The processes and considerations used to develop these documents should be clearly explained so that, in similar cases, different people can arrive at similar conclusions.
- Current – taking account of accrued international experience of gene technology broadly, and similar GM traits and recipient species specifically.
- Defensible – wherever possible, the risk analysis should use relevant, nationally and internationally accepted criteria, standards or guidelines that have been endorsed by relevant Commonwealth and state agencies.
- Use of sound judgment – scientific judgments and policy-based decisions should be clearly identified so others may understand the role of judgment in interpreting evidence and managing risks.

- Efficacious and efficient – only relevant information should be incorporated into the risk analysis. Information should also be appraised for its quality. The resources expended on the risk assessment should be commensurate with the level of risk of the proposed dealings.
- Cautious – the risk assessment should be cautious to avoid failing to identify relevant risks and to provide thorough consideration of all substantive risks that are identified. The risk management process should display caution in determining management actions for risks, with the goal of protecting human health and safety and the environment.
- Ethical – the risk analysis process should be consistent with the principles outlined by the Gene Technology Ethics Committee (see below).
- Credible and useful – the results of the risk analysis process should be presented in a format that helps the Regulator make decisions, stakeholders interpret decisions, and the risk management actions be effectively performed.
- Accountable – the Regulator is accountable to Parliament for the risk assessment and risk management plan provided for each licence application. In addition, evaluator(s) and inspector(s) should be accountable for the information, interpretation and conclusions provided to the Regulator and should abide by the Australian Public Service Code of Conduct and Values.
- Continuous improvement – evaluation and management staff should receive ongoing training to maintain scientific expertise and best practice in risk analysis. In addition, risk analysis methodologies should be evaluated and reviewed as appropriate to take account of progress in this area, both in Australia and internationally.
- Timely – risk analyses should meet statutory timeframes.

In addition to these general principles, the former Gene Technology Ethics Committee issued a document describing nine key ethical principles that should guide researchers and others involved in gene technology (GTEC 2006), namely:

- Treat integrity as the guiding value in the search for, and application of, knowledge and benefits and in regard to the obligations of, and intentions underlying, the national regulatory system and other relevant guidelines and regulations (Principle 1).
- Take responsibility for ensuring that activities within their control do not cause damage to the Australian environment or to areas beyond the limits of the national jurisdiction; to achieve this, there must be a thorough assessment of the long-term side effects of applications of gene technology (Principle 2).

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- Minimise risks of harm or discomfort to humans and animals likely to be adversely affected by gene technology (Principle 3).
- Assess and respect the environmental and health needs of present and future generations (Principle 4).
- Conduct research in a manner that protects the environment, including protection of genetic diversity, organisms, species, natural ecosystems, and natural and physical resources (Principle 5).
- Act justly towards others, and demonstrate respect for human beings (as individuals and group members) in all activities associated with gene technology, including obtaining proper consent (Principle 6).
- Promote equitable access to scientific developments and sharing knowledge, and recognise the value of benefit sharing (Principle 7).
- Conduct research in a manner that promotes the benevolent and avoids the malevolent uses of gene technology (Principle 8).
- Conduct gene technology research after appropriate consultation and ensuring transparency and public scrutiny of the processes (Principle 9).

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CHAPTER 3 Risk context

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Chapter 3 Risk context

This Chapter describes the role of the risk context in risk analysis and how it is applied in preparation of a risk assessment and risk management plan for licence applications.

The risk context defines the parameters within which risk is assessed, managed and communicated by defining what will be done in risk analysis and how it will be done. In particular, the risk context defines the scope and boundaries, sets the broad terms of reference and criteria against which the significance of risk will be evaluated, and describes the structure and processes for the analysis. The risk context is established within the framework of the legislative requirements of the *Gene Technology Act 2000* and Gene Technology Regulations 2001.

Defining the appropriate parameters is the key to identifying relevant risks, accurately assessing the level of risk, and implementing suitable measures to manage risk in an efficient, efficacious and transparent manner.

Scope and boundaries

The Act and Regulations provide the scope and boundaries for risk analysis of applications for DIR and DNIR licences in relation to:

- the subject of regulation – dealings with a GMO
- the trigger for regulation – use of gene technology
- means for regulating dealings – such as licences
- protection goals – health and safety of people, the environment
- method to achieve protection goals – identifying and managing risks
- matters to consider when preparing risk assessment and risk management plan
- nature and extent of consultation
- types and nature of licence conditions that can be imposed
- functions and powers of the decision maker (the Regulator)
- nature and extent of monitoring and enforcing compliance with licence conditions
- definition of key terms – such as deal with, environment, gene technology, GMO.

These areas are covered in detail in Chapter 1 and Appendix A. The Explanatory Memorandum to the Gene Technology Bill 2000 also provides additional contextual explanation.

Policy principles, policy guidelines and codes of practice issued by the Ministerial Council (sections 21–24) may also determine the scope and boundaries for risk analysis.

Certain issues, such as impacts on trade, social and cultural effects, as well as benefits that may be derived from gene technology or food labelling, are outside the scope of the analysis.

The boundaries for risk analysis of DIRs and DNIRs are also determined, in part, by other Australian regulatory agencies, as they relate to health and safety of people and/or to 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 pesticide use for agricultural and domestic purposes, including use on GMOs and management of pesticide 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 A contains detailed information about the interaction between the Regulator and other agencies.

Setting the terms of reference

The terms of reference against which the significance of risk is evaluated should be established before preparing the risk assessment and risk management plan. The legislative requirements, objectives and the scope and boundaries of the analysis form the basis for broad terms of reference.

The legislation specifies matters the Regulator must consider in preparing the risk assessment (section 51(1)(a) and regulation 10) including consideration of both the short- and long-term outcomes from the proposed dealings with a GMO. 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
- whether the GMO is toxic, allergenic or pathogenic to other organisms.

Other factors that should also be clearly established as a part of the risk analysis include:

- the nature and types of consequences that may occur and how they will be measured
- how likelihood is defined in the likelihood assessment (see Table 4.2)
- how consequence is defined in the consequence assessment (see Table 4.3)

- how the level of risk is to be determined (see Figure 4.3)
- the timeframe of the likelihood and/or consequence
- what level of risk may require treatment
- if combinations of multiple risks should be taken into account
- the types of uncertainty and how they will be considered.

These factors are discussed further in Chapter 4.

The broad terms of reference can be elaborated upon to sequentially develop generic and then specific criteria against which risk can be evaluated during the risk assessment. Generic criteria for the nature and types of consequences (see Table 3.1) provide a starting point for the consequence assessment and a basis for development of specific consequence assessment criteria. They are essential since licence applications can relate to any type of organism and any type of genetic modification and it is not possible to define specific criteria for all potentially adverse outcomes to the health and safety of people or to the environment before the risk assessment.

The suite or combinations of generic consequence criteria that are considered are developed with reference to elements of the risk assessment context such as the properties of the GMO and the types of dealings. For example, if a GMO for intentional release is not capable of producing pollen, there may be no reason to further consider consequence assessment criteria relating to transfer of genetic material to other organisms via pollen.

If, however, an initial assessment against the generic criteria identifies a need for further detailed investigation, more specific consequence criteria are then developed as a part of preparing a risk assessment and risk management plan. For instance, generic consequence criteria such as 'negative effects on organisms' and 'creating a new weed' (see Table 3.1) would be relevant for preparing a risk assessment of a GM crop with an introduced *Bt* gene that confers resistance to attack by certain insect pests. During the risk assessment potential risks might be identified that are then assessed against more specific consequence criteria such as 'increased mortality of non-pest Lepidoptera' and 'reduced establishment of other plants'.

Examples of specific consequence criteria that might be developed during preparation of the risk assessment and risk management plan are provided in Table 3.1. The specific consequence criteria form the basis for identifying measurable properties that can be used to assess the occurrence of harm, whether to an individual, population, species, community, habitat or ecosystem. In developing specific consequence criteria it is important to differentiate between effects that simply reflect the dynamic nature of biological systems from those effects that are considered harmful.

Table 3.1: Criteria for the nature and types of consequences and how they might be measured

Generic criteria for consequences	Examples of specific consequence criteria developed during consideration of a licence application (assessment endpoints)	Examples of measurable properties for specific consequence criteria (measurement endpoints)
Negative effects on the health and safety of people	Increased production of endogenous glycoalkaloids Production of an allergen Production of an immunosuppressant compound	Biochemical, physiological, physical or developmental abnormalities; frequency and age of morbidity; frequency of infection; growth rate; mortality
Negative effects on valued organisms (including protected species and secondary impacts)	Reduced population size of valued lepidopteron Production of a chemical toxic to protected marsupials	Population morbidity; genotype frequency; presence and abundance; yield/production; biochemical, physiological, physical or developmental abnormalities
Negative effects on species diversity or genetic diversity within a species	Formation of monoculture in natural environments	Presence and abundance of species; genotype frequency; yield/production; biochemical, physiological, physical or developmental abnormalities
Creating a new or more vigorous weed, pest or pathogen	Reduced establishment of other organisms Increased host range of 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 and ecosystems	Production of an allelopathic chemical	Species richness; diversity indices; extent and area; production; indices of food web structure; carbon, nitrogen and phosphorous fluxes
Degradation of the abiotic environment	Reduced soil water table level Hotter, more frequent fire regimes	Frequency and intensity of floods, low flows and fire; pollutant concentrations; physical damage; soil structure

Note: The criteria listed in this table are illustrative and intended neither as a requirement for all risk assessments, nor as precluding the use of other criteria; they are 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.

Structures and processes

Many structures and processes are relevant to establishing the risk context for DIRs and DNIRs including legislated processes for preparing a risk assessment and risk management plan (see Appendix A); the choice of risk analysis methodologies; and development of the case-specific context for risk assessment, risk management and risk communication that is relevant to each licence application.

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Risk analysis methodology

The risk analysis methodology described in this *Risk Analysis Framework* form part of the risk context. In particular, the Regulator identifies risks posed by or as a result of gene technology by using comparative risk assessment methodology. Therefore risks posed by a particular GMO need to be considered in relation to the parent organism in the receiving environment. For example, non-GM crop species already present risks to the health of people (for example, gluten in wheat or allergens in soybeans or peanuts) or to the environment (for example, some pasture species have a degree of weediness). These risks associated with the parent organism form part of the baseline against which the GMO is assessed to determine whether gene technology has increased the level of risks or poses additional risks. Similarly, where the parent microorganism is a pathogen (a common occurrence in DNIR applications) a consideration of the potential changes to pathogenicity of the GM microorganism relative to the parent organism is required.

Preparation of a risk assessment and risk management plan

When preparing a risk assessment and risk management plan (RARMP) the Regulator considers the risk assessment context, the risk management context, and the risk communication context.

Risk assessment context

The Act requires a case-by-case assessment for applications for DIR (section 50) and DNIR (section 47(1)) licences. Establishing the risk assessment context includes consideration of certain information specific to each licence application, namely:

- GMO – details of the genetic modification and trait changes
- proposed dealings – proposed activities with the GMO, proposed controls and limits (for DIRs) or containment measures (for DNIRs)
- parent organism – details of the comparator (for example, origin and taxonomy, production and uses, biological characterisation, ecology)
- receiving environment – baseline information (for example, environmental conditions, production or work practices, presence of sexually compatible relatives, presence of similar genes)
- previous releases – previous risk assessment or experience gained with a particular GMO in the course of previous dealings in Australia or overseas.

Information on the GMO, including the nature of the genetic modification and any novel or altered phenotypic properties forms an essential part of the risk assessment context. This may include information on:

- the genetic elements introduced into the parent organism, the source organism and any known adverse effects it may have on human health and safety or the environment, and changes to the genetic elements before introducing them into the parent organism

- method of genetic modification
- number of copies of the introduced genetic material present in the GMO and stability in subsequent generations
- any conventional breeding of the GMO with sexually compatible relatives
- new or altered properties or traits of the GMO, the intended effect of the genetic modification and if they are observed
- any observable unintended effects in the GMO.

The proposed dealings with the GMO provide the starting point for identifying risks. In addition, any proposed controls or containment measures to limit the spread and persistence of the GMO provide an important frame of reference to determine which people or environmental components are expected to come into contact with the GMO, introduced genetic material, or GM product.

The parent organism and receiving environment form part of the baseline for a comparative risk assessment. Information on the parent species that is considered in relation to the GMO may include taxonomy, origin, means of production and uses, morphology, development, biochemistry, abiotic and biotic interactions with the environment, weediness, pestiness and/or pathogenicity, and the potential for gene transfer to sexually compatible relatives present in Australia. Relevant information from studies undertaken in Australia and overseas is included.[1]

However, selecting the appropriate comparator is not always straightforward. Alternative comparators may include isogenic line (identical genotype except for the introduced genetic material), the same cultivar, subspecies, and/or strain, another widely available or local cultivar, subspecies, and/or strain, any member of the same species, or even multiple species. A range of factors influence selection of the appropriate comparator, such as:

- information on the parent organism may be lacking or it is not present in the Australian environment
- the GMO proposed for release has undergone several generations of conventional breeding following genetic modification with genotypes distinct from the parent organism
- the GMO is developed through hybridisation between different species.

1 In the case of most DIRs, a biology document on the parent species is available on the OGTR website at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>.

For instance, insect-resistant GM pima cotton (*Gossypium barbadense*) was developed by crossing non-GM pima cotton with GM upland cotton (*G. hirsutum*) (OGTR 2007). Following further breeding, the new GMO displayed many of the characteristics of pima cotton but still contained some of the upland cotton genes. In this case, both species were considered to be the parent organism and their characteristics were used in the comparative assessment.

The environment into which the GMO is released is also relevant for intentional releases. Information from an appropriate environment should be used for comparison. For example, the current growing and management practices applied to a GM crop plant, or the abundance of gene(s) already present naturally in the environment used in genetic modification will be considered in developing the baselines for the risk assessment.

Antibiotic resistance marker genes commonly used in the selection process for generating GM plants are derived from soil bacteria abundant in the environment. Therefore, exposure to an antibiotic resistance gene, or to the protein encoded by such a gene, derived from a GMO, may or may not be significant against the naturally occurring background.

However, receiving environments are not static and change over time due to factors such as the dynamic nature of ecosystems, climate change, or changes in agricultural practices. For example, normal agricultural practice for cotton prior to release of GM insecticidal cotton included intensive pesticide use with multiple applications per growing season. By 2008 about 90 per cent of the cotton grown in Australia was genetically modified, requiring lower and fewer applications of pesticides. Reduced chemical application has also led to reports of changes in the abundance of non-pest insects in cotton growing areas. These changes form part of the baseline considerations when developing the risk context for analysis of a specific licence application.

Risk management context

Establishing the risk management context for consideration of a licence application includes consideration of:

- protection goals against which measures to manage risk, including proposed controls or containment measures, are evaluated
- matters to consider when preparing a risk management plan about the ways to protect the health and safety of people and the environment, and relevant advice (sections 47(3)(4), 51(2), 52)
- decision-making processes to decide whether to issue a licence (sections 55, 56, 58)
- types and nature of licence conditions that may be imposed, including adverse and unintended consequences (sections 62(2), 64, 65).

These factors are described in more detail in Chapter 5 and Appendix A.

The Act and the Regulations also provide for a range of other structures and processes for developing the risk management context including:

- certification of facilities to specified physical containment levels
- 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 (sections 146, 153)
- sanctions for non-compliance
- technical and procedural guidelines.

For example, the Act empowers the Regulator to issue technical and procedural guidelines in relation to GMOs (sections 27(d), 90, 98). The Regulator has issued guidelines for storage and disposal of GMOs, transport of GMOs, certification of physical containment facilities, and accreditation of organisations.

In addition to these guidelines, the Regulator sets out operational policies that provide guidance for other matters relating to risk management (such as policy on post-harvest crops).

Risk communication context

The risk communication context provides details of who is consulted, when, in what capacity (for example, as a Gene Technology Technical Advisory Committee (GTTAC) member or as an expert in a specified area), on what matters, and in what manner. In addition to consultation with the stakeholders designated in the Act and Regulations, the Regulator can seek advice from any other person that he/she considers appropriate.

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CHAPTER 4 Risk assessment

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Chapter 4 Risk assessment

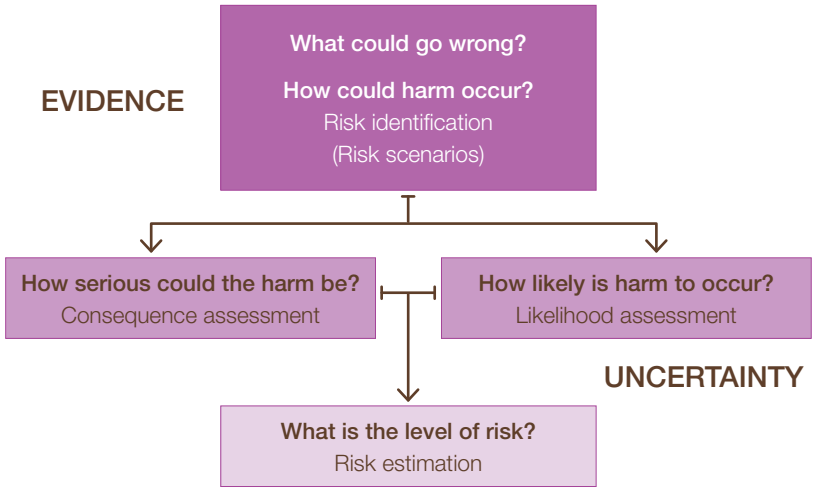
This Chapter explains the risk assessment methodology the Regulator uses to consider applications for DIR and DNIR licences. The purpose of the risk assessment is to identify and characterise risks to the health and safety of people or to the environment from dealings with GMOs, posed by or as the result of gene technology.

Risk assessment can be usefully viewed as a narrative that answers a set of key questions (see Figure 4.1), namely:

- What could go wrong? How could harm occur? (Risk identification) Initially a broad range of circumstances is considered, whereby the proposed dealings with a GMO are postulated to give rise to harm for people or the environment (risk scenarios). Each risk scenario describes a plausible causal pathway between the GMO and an adverse outcome.
- How serious could the harm be? (Risk characterisation – consequence assessment) An identified risk undergoes an assessment of the seriousness of potential harm via the particular risk scenario.
- How likely is the harm to occur? (Risk characterisation – likelihood assessment) An identified risk is also assessed with regard to chance of the occurrence of a series of individual steps in a risk scenario that may lead to harm. The assessment will derive the chance of harm from the overall series of individual steps.
- What is the level of risk? (Risk characterisation – risk estimation) The level of risk (negligible, low, moderate or high) of identified risk is estimated by a combination of both the seriousness and likelihood of harm.

Scientific and technical information to answer these questions, as well as consideration of uncertainty, in particular knowledge gaps, occurs throughout the risk assessment process.

Figure 4.1: Considerations for risk assessment



In practice, the risk assessment process tends to be highly iterative and the steps depicted in Figure 4.1 can be viewed as part of a complete cycle. The risk assessment steps may be repeated as the result of:

- ongoing accumulation of information (such as data requested from the applicant, expert advice, consultation, or literature searches)
- development of more specific consequence criteria when more substantive risks are identified
- consideration of potential interactions between postulated risk scenarios, or
- in response to the monitor and review process (see Chapter 5).

For instance, consultation with stakeholders (see Chapter 6 and Appendix A) on a risk assessment may identify additional risks, or provide further information relevant to risk characterisation or estimating the level of an identified risk. In particular, the scientific advisory body to the Regulator, GTTAC, has an important function in providing scientific and technical advice on applications for DIR licences and some DNIR licences.

The degree of consideration given to each cycle of the process should correlate with the degree of risk; greater consideration should be given to risks that are potentially more substantial.

The results obtained in the risk assessment process are used to prepare the risk management plan (see Chapter 5).

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Risk identification

Risk identification is the 'process of postulating risk scenarios and determining those that warrant detailed risk characterisation'. Risks are identified within the context established for the risk assessment (see Chapter 3), taking into account any proposed controls or limits for DIRs, or containment measures for DNIRs; relevant baseline information on the parent organism and/or other suitable comparator; and the receiving environment.

Postulating risk scenarios

Initially, risk identification considers a wide range of circumstances whereby the GMO or GM product, or the introduced genetic material, could come into contact with people or the environment. Consideration of these circumstances leads to postulating plausible causal or exposure pathways from dealings with a GMO to potential harm for people, or the environment (risk scenarios).

Therefore, a risk scenario can be viewed as a 'what if' statement that describes a possible set of circumstances that might give rise to harm in the future. For instance, a risk scenario might describe the chance of a particular disease occurring in people culturing a pathogenic GM microorganism in the event of accidental creation and inhalation of aerosols. The scenario would also consider how the genetic modification might increase the infectivity or severity of the disease compared to the parent organism. Many possible risk scenarios can be formulated (for example, Hayes et al. 2004), but only those considered as potentially substantive are included in the risk assessment.

In addition, interactions between risk scenarios may give rise to synergistic, additive or antagonistic effects. For instance:

- synergism arises when the combined effects are greater than the sum of the individual effects (for example, a GMO expressing two insecticidal genes with different modes of action may have greater potency than the addition of the effects from individual genes)
- additive effects may occur where different scenarios lead to the same adverse outcome, which could increase the negative impact
- antagonistic effects may occur where the GM trait alters the characteristics of the organism in opposing ways (for example, over-expression of a gene may lead to its silencing).

The postulation of risk scenarios may also include consideration of downstream effects. For example, growing a GMO (that is, a dealing as defined in the Act) may result in gene flow to other organisms by sexual or horizontal gene transfer. The recipient organism may then give rise to risks that are distinct from growing the GMO, but are contingent upon the

occurrence of the proposed dealing. For instance, transfer of a stress tolerance gene from a GM plant to a sexually compatible species via pollen may increase the weediness of the recipient species.

Dealings such as importing, growing or transporting a GMO may be needed for other purposes (such as food for people or for stock). However, most end uses of GMOs (such as food, pesticides, therapeutics and industrial chemicals) are regulated through other legislation. In accordance with an integrated regulatory system, the Regulator only considers risks from downstream effects if they are not covered by complementary legislation (such as for stock feed, nutritional trials, some biocontrol agents or bioremediation).

The techniques available for developing a comprehensive set of risk scenarios range from checklists and brainstorming to targeted analysis. Techniques the Regulator uses may include previous agency experience, reported international experience, consultation, scenario analysis and inductive reasoning (fault and event tree analysis). The Australian standard for Risk Management (Standards Australia 2004) and Hayes (2004) contain details of a range of other structured decision-making techniques that may be useful in postulating risk scenarios for proposed dealings with GMOs.

The type of information used to establish the risk assessment context includes the genotypic and phenotypic properties of the GMO, the proposed dealings, the parent organism, the receiving environment, and any relevant previous releases. Information on other factors might also be applicable to postulating risk scenarios, but not all will be relevant to all risk assessments or require the same degree of consideration. The factors include:

- altered biochemistry
- altered physiology
- unintended change in gene expression
- production of a substance toxic or allergenic to humans
- survival and persistence at the release site
- survival and persistence outside the release site
- 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 other organisms
- expression of an introduced gene that may alter the infectivity or pathogenicity, host range, pathogen load or vector specificity of a disease agent to other organisms
- interaction of introduced pathogenic genes or products with other pathogens
- unintended effects on an existing non-GM weed, pest or pathogen
- secondary effects (such as development of herbicide resistance in related species as a result of gene flow)
- production (such as farming) practices

- alteration to the physical environment including biogeochemical cycles
- unauthorised activities.

Regulation 10 requires the Regulator to consider the short and the long term when assessing risks. The Regulator does not fix durations, but takes account of the likelihood and impact of an adverse outcome over the foreseeable future, and does not disregard a risk on the basis that an adverse outcome might only occur in the longer term.

Identifying risks that require further characterisation

Risk identification should be comprehensive and rigorous; however, care should be taken to avoid overemphasising insubstantial risk scenarios. Risks that warrant detailed consequence and likelihood assessments to determine the level of risk they pose to human health and safety or to the environment are generally identified by considering the questions:

- Is the potential harm attributable to gene technology? Any harm not posed by or resulting from the use of gene technology cannot be considered.
- Is there a plausible and observable pathway linking the proposed dealings to the potential harm? In cases where no plausible or observable pathways link the proposed dealings to the potential harm, the risk scenario should not advance in the risk assessment process.
- Is the risk substantive? That is, is the possible level of risk greater than negligible after an initial consideration of the chance and seriousness of harm?

Risk identification aims to include all risks that will require risk treatment. However, in the absence of extensive experience with impacts from a particular GMO, identifying all substantive risks whose level of risk is greater than negligible is based on predicting the chance and seriousness of harmful scenarios that are yet to occur.

It is important to avoid underestimating or missing substantive risks. The approach the Regulator uses involves consulting a number of people with varying expertise in the risk assessment process and by extensive internal and external review of the risk assessment.

The Regulator, therefore, takes a cautious approach, which includes postulating and considering an extensive list of potential risk scenarios. As a result, some identified potential risks can subsequently be classified as negligible risks after more detailed consequence and likelihood assessments.

Risk characterisation

Risk characterisation determines the level of risk by a combination of the chance (likelihood assessment) and seriousness (consequence assessment) of harm from dealings with a GMO. The likelihood and consequence assessments are based on inferences from the available scientific and technical information, and include consideration of uncertainty.

Quantitative and qualitative assessment

Likelihood and consequence assessments can be either quantitative (reporting risks numerically) or qualitative (reporting risks descriptively). For instance, likelihood can be expressed as a relative measure of either probability (from zero to one, where zero is an impossible outcome and one is a certain outcome) or frequency (the number of occurrences per unit of time). For qualitative assessments, likelihood is expressed in terms of highly likely, likely, unlikely and highly unlikely.

Quantitative risk assessment determines the conditional probabilities of risk and the associated statistical error (uncertainty). This type of analysis can be appropriate where there is a history of accumulated information, such as with chemical and industrial manufacturing. Quantitative risk assessments are most useful for addressing narrowly defined risks with relatively simple pathways leading to well specified adverse outcomes. However, some forms of structured decision making (for example, Bayesian belief networks) attempt to quantify probabilities in more complex situations.

Quantitative assessments use numerical values, which may be derived from:

- experimental data
- extrapolation from experimental studies on related systems
- historical data, or
- inference from models used to describe the systems and its interactions.

By contrast, risk assessments of biological systems are often qualitative because the complex, dynamic and variable nature of such systems limits the degree of certainty that can be ascribed to our knowledge of them. There is often a degree of uncertainty about the mechanisms that may lead to an adverse outcome, making it impossible to quantify the probability of the adverse outcome occurring (van der Sluijs et al. 2005). Qualitative assessments can incorporate quantitative data where it is available. By using qualitative assessments, the maximum amount of information can be used in describing likelihood and consequence.

Qualitative assessments use relative descriptions of likelihood, consequence and risk estimate, and can combine data derived from various sources, including quantitative data.

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Use of qualitative or quantitative approaches depends on the amount, type and quality of available data; the complexity of the risk under consideration; and the level of detail needed to make a decision. Some of the relative merits that distinguish the two approaches are listed in Table 4.1.

Table 4.1: Relative merits of qualitative and quantitative risk assessments

	Type of assessment	
	Qualitative	**Quantitative**
Strengths	• Flexible – can be applied when there are data gaps, a lack of theory, properties of risk are unable to be analysed numerically, high complexity, limited resources, or ethical constraints in obtaining the experimental data. • Integrates a diverse range of analytical techniques. • Allows assessors to make judgments that aid decision making despite data gaps and uncertainty. • Useful where there is a lack of experience in observing adverse effects. • Accessible to a wide range of stakeholders.	• High objectivity. • Typically repeatable and testable. • Greater consistency between assessors. • Compatible with statistical interrogation. • Allows formal incorporation of some types of uncertainty.
Weaknesses	• Subject to greater ambiguity, vagueness and under-specificity (linguistic uncertainty). • Estimates are more subject to variation between assessors. • More prone to heuristics and biases of inputs such as expert opinion. • More difficult to incorporate uncertainty.	• Use of numbers can lead to overconfidence. • Not readily accessible to a range of 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. • Difficult to use when there are insufficient or poor quality data.

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

- there is a lack of long-term experience with particular organisms and/or introduced genes/traits
- potential adverse effects relating to human health and safety and the environment are highly varied
- environmental effects arise within highly complex systems that have many incompletely understood variables
- adverse effects may occur in the long term through indirect routes and are therefore difficult to quantify.

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.

The four weaknesses of qualitative assessments identified in Table 4.1 can be controlled and minimised in several ways; and use of defined terminology for likelihood, consequences and risk can reduce ambiguity. Potential variations between assessors can be reduced through quality control measures including internal and external review and sourcing of expert advice. Differing viewpoints, perspectives and biases can be reduced through better descriptions of what the Act is trying to protect and through stakeholder input via effective consultation.

Nevertheless, there is an ongoing requirement for testable and repeatable scientific evidence to support qualitative estimates of likelihood and consequences, which are determined according to measurable, observable criteria of harm to human health and safety or to the environment. For example, when assessing risks to human health and safety, toxicological or epidemiological data may be used where harm may arise from the presence of toxins, allergens or other chemicals that could have adverse effects on human health, such as enzyme inhibitors or anti-nutrients.

Likelihood assessment

The likelihood assessment determines the degree of chance that harm will occur, and is expressed as highly likely, likely, unlikely and highly unlikely (see Table 4.2). If harm is not expected to occur then risk is considered insubstantial and the impact needs no further analysis. However, care needs to be exercised when considering the remote possibility of risks that may have extreme adverse impacts.

Table 4.2: Scale for the likelihood assessment

Likelihood	Likelihood assessment definitions
Highly unlikely	May occur only in very rare circumstances
Unlikely	Could occur in some circumstances
Likely	Could occur in many circumstances
Highly likely	Is expected to occur in most circumstances

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Factors that are important in considering the likelihood of harm occurring as a result of a dealing with the GMO are related to circumstances whereby people or susceptible entities in the environment are exposed to the GMO, the introduced gene(s) or products of the introduced gene(s). Following exposure, there is consideration of the likelihood of adverse effects.

Assessing likelihood is more difficult for complex exposure pathways where many links between the individual steps of the risk scenario may exist. 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. However, occurrence of the gene transfer does not necessarily result in harm. Further steps are necessary, including the ability of the newly modified microbe to survive, replicate, display a selective advantage and give rise to some identifiable harm, such as increased virulence. In such cases, the combined likelihoods will be a substantially lower overall likelihood of an adverse outcome occurring than the likelihood of an individual step.

In contrast, scenarios that outline a simpler route 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.

Identifying all steps in a causal pathway leading to potential harm may be relevant for deriving an overall assessment of the chance that harm occurs. For instance, a causal pathway leading to increased weediness might be postulated, but involve many steps, including transfer of the introduced genetic material from the GMO into a sexually compatible relative, survival and increased fitness of the hybrid, followed by spread and persistence of the recipient species, which then results in harm (for example, reduced establishment of native plants in a protected area). If several steps have only a small chance of occurring, then the overall pathway has an extremely limited chance of occurring due to the combination of several low probability steps. Alternatively, one step may have almost no chance of occurring (for example, the co-occurence of a sexually compatible relative is not expected due to incompatible climate requirements between the GMO and its relative), which results in a low overall probability even if all other steps have a reasonable chance of occurring.

In the case of limited and controlled releases there is a fixed period for the intentional release but any potential for adverse effects beyond this period must also be considered. As with any predictive process, accuracy is often greater in the shorter rather than longer term.

Consequence assessment

Consequence is an 'adverse outcome or impact of an activity' and is considered in respect of harm to people or to the environment. A consequence assessment determines the degree of seriousness of harm (see Table 4.3). The seriousness of harm is dependent on the scale at which impacts are considered. Harm to humans is usually considered at the level of an individual, whereas harm to the environment is usually considered at the level of populations, species or communities.

The potential existence of vulnerable individuals, populations, species, communities or ecosystems is also considered. For example, if a genetic modification resulted in production of a protein with allergenic properties, some people may have no reaction to that protein, others may react mildly, while others may be severely affected.

Assessing the seriousness of harm for people or to the environment may include consideration of the:

- Magnitude of each potential adverse impact including the degree, extensiveness or scale of the harm: does it cause a large change over baseline conditions? Does it cause a rapid rate of change? Does it have long-term effects?
- Spatial extent of the potential adverse impact (for example, local, regional, national), including potential spread in the long term.
- Temporal occurrence of the impact: is it likely in the short or long term?
- 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?)
- Reversibility – how long would it take to mitigate the adverse impact? Can the adverse impact be reversed and, if so, how long would it take?

Table 4.3 provides a descriptive scale for the seriousness of harm in relation to the health of people and in relation to the environment. The explanations are relatively simple in order to cover the range of possible licence applications and potential risks. This variety of potential risks may be affected by different factors (magnitude, space, time, reversibility) that may contribute to the significance of adverse outcomes. Where appropriate and necessary, those descriptors may be defined in more detail for specific risks.

Table 4.3: Consequence assessment scale for the health of people and the environment

Consequences	Consequence assessment definitions relating to the health of people and the environment
Marginal	Minimal adverse health effects. Minimal or no damage to the environment or disruption to biological communities.
Minor	Adverse health effects that are reversible. Damage to the environment or disruption to biological communities that is reversible and limited in time and space or numbers affected.
Intermediate	Adverse health effects that are irreversible. Damage to the environment or disruption to biological communities that is widespread but reversible or of limited severity.
Major	Adverse health effects that are severe, widespread and irreversible. Extensive damage to the environment or extensive biological and physical disruption of whole ecosystems, communities or an entire species that persists over time or is not readily reversible.

Quality of evidence

The Regulator will only consider applications containing sufficient information. The applicant must supply information as prescribed by the regulations (if any) and as specified in writing by the Regulator (section 40) (for example, in the application forms). In the absence of adequate information the Regulator may not consider the application or may request further information from the applicant. If the Regulator is unable to proceed with the assessment without the requested information, the time spent waiting for the information does not count towards the period within which the Regulator must make a decision on the application (as specified in the Regulations).

The Regulator also undertakes a thorough review of the relevant scientific literature in preparing the risk assessment and risk management plan. In addition to advice from GTTAC and other prescribed agencies, the Regulator may also consult other relevant experts for information or request further information from the applicant.

It is important to consider the quality of the evidence (WHO 2008), including how much and what type of data are needed. Determining the quality of the evidence includes consideration of:

- appropriateness – the degree to which the data are relevant and applicable to the risk assessment question
- reliability – the accuracy and integrity of experimental design, methodology, and statistical analysis used to report data and conclusions
- transparency – the clarity and completeness with which all key data, methods and processes, as well as the underlying assumptions and limitations, are documented and available

- expertise – the standing of the author(s) or expert(s) presenting the data
- strength – how much data there is to support the conclusion in the scientific literature; whether there is conflicting data and the strength of the conflicting data
- robustness – if data from disparate sources, experiments or researchers support similar conclusions.

Each piece of information may be ranked differently against these criteria and, where contradictory information exists, the Regulator must judge the relative strength of each piece. Some information may be redundant or not of high enough value to be used as evidence.

Factors that may influence the relevance and value of the information include whether the:

- subject of the experiment is identical, similar or different to the GMO being assessed
- experiment is addressing a question relevant to the risk assessment
- experiment was performed in Australia or overseas.

Scientific papers published in peer-reviewed journals generally provide some assurance of quality; however, even such papers can vary in quality. It is important to check that the conclusions of the authors or experts presenting particular evidence are supported by associated data and by other data reported by different authors. A judgment may also be made about the expertise of the authors or experts presenting the data.

Peer-reviewed papers are often regarded as high value evidence, but they are not automatically accepted and used in the risk assessment without further evaluation. Their appropriateness, transparency and robustness are all factors in determining how much reliance is placed on each piece of evidence.

Figure 4.2 illustrates how the Regulator may view the value of some different types of information. Information may be ranked low in one criterion but high in others. The overall value of the data for the risk assessment is open to the Regulator's judgment.

Figure 4.2: Some types of information and their relative values as evidence

	Reliability	Appropriateness
Increasing value ↑	Validated studies conducted according to international protocols meeting defined standards.	Experimental data on the GMO and/or parent organism in the Australian environment.
	Peer reviewed literature – strongly supported reports, models, theories.	Experimental data on the GMO and/or parent organism overseas.
	Peer reviewed literature – single report, model, theory.	Experimental data on modified traits in other organisms.
	General biological principles.	Experimental data on related, surrogate systems.
	Opinion of an expert familiar with the GMO, parent organism, modified traits, ecology.	
	Other technical reports, specialist literature (for example, beekeeping), government reports, etc.	
	No information to indicate a problem.	
	Unsubstantiated statements.	

The combined weight of evidence may also influence the risk assessment, a single strong piece of information (as judged by the above criteria) may stand on its own or a number of weaker pieces of evidence may support each other in order for the Regulator to have sufficient confidence in the information. In addition, judgment is needed to determine the sufficiency of the data to achieve a reliable and robust estimate of risk following a consideration of uncertainty. Collection and assessment of unnecessary or excessive data is an inefficient use of resources for applicants and the Regulator.

Where a regulatory agency of another country has made an assessment of the same or a similar GMO, their findings will also be considered during the Regulator's risk assessment (regulation 10(1)(a)). The Regulator has established links with relevant agencies that facilitate exchange of information. The Regulator also participates in work by international agencies, such as the OECD, to produce documentation that contributes to harmonisation of regulatory activities between countries, which simplifies consideration of other countries assessments.

It is important to consider not only the available information, but also uncertainty associated with the evidence. For example, if data regarding a proposed dealing with the GMO are unavailable, inconsistent or incomplete, the significance of that absence, inconsistency or incompleteness will be considered in the risk assessment process.

Risk estimation

An estimate of the level of risk (see Table 4.4) is derived from a combination of the chance and seriousness of harm to human health and safety or to the environment from dealings with a GMO. Figure 4.3 describes the risk matrix used to estimate the level of risk from a combination of outcomes of likelihood and consequence assessments.

Table 4.4: Scale for the level of risk

Risk estimate	Risk estimate definitions
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 4.3: Risk matrix to estimate the level of risk from a combination of outcomes of likelihood and consequence assessments

		RISK ESTIMATE			
LIKELIHOOD ASSESSMENT	Highly likely	Low	Moderate	High	High
	Likely	Low	Low	Moderate	High
	Unlikely	Negligible	Low	Moderate	Moderate
	Highly unlikely	Negligible	Negligible	Low	Moderate
		Marginal	Minor	Intermediate	Major
		CONSEQUENCE ASSESSMENT			

Risk matrices should generally keep the number of risk categories within the matrix to a minimum and the inherent sources of uncertainty associated with formulation of a risk matrix should be reduced (Cox 2008). Accordingly, the risk estimate matrix presented here has been slightly modified from the matrix in previous versions of the *Risk Analysis Framework*.

The Regulator applies a set of distinct descriptors to the likelihood assessment (see Table 4.2), consequence assessment (see Table 4.3) and risk estimate (see Table 4.5) to reduce ambiguity of terminology used in qualitative risk assessments. Application of these descriptors to identified risks must be considered in the context of the proposed dealings, including the introduced trait, the parent organism and the receiving environment. Comparisons between licence applications are only possible in the broadest sense, even for related scenarios. It is important to note that uncertainty about likelihood and/or consequences will affect the risk estimate.

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Significant risk

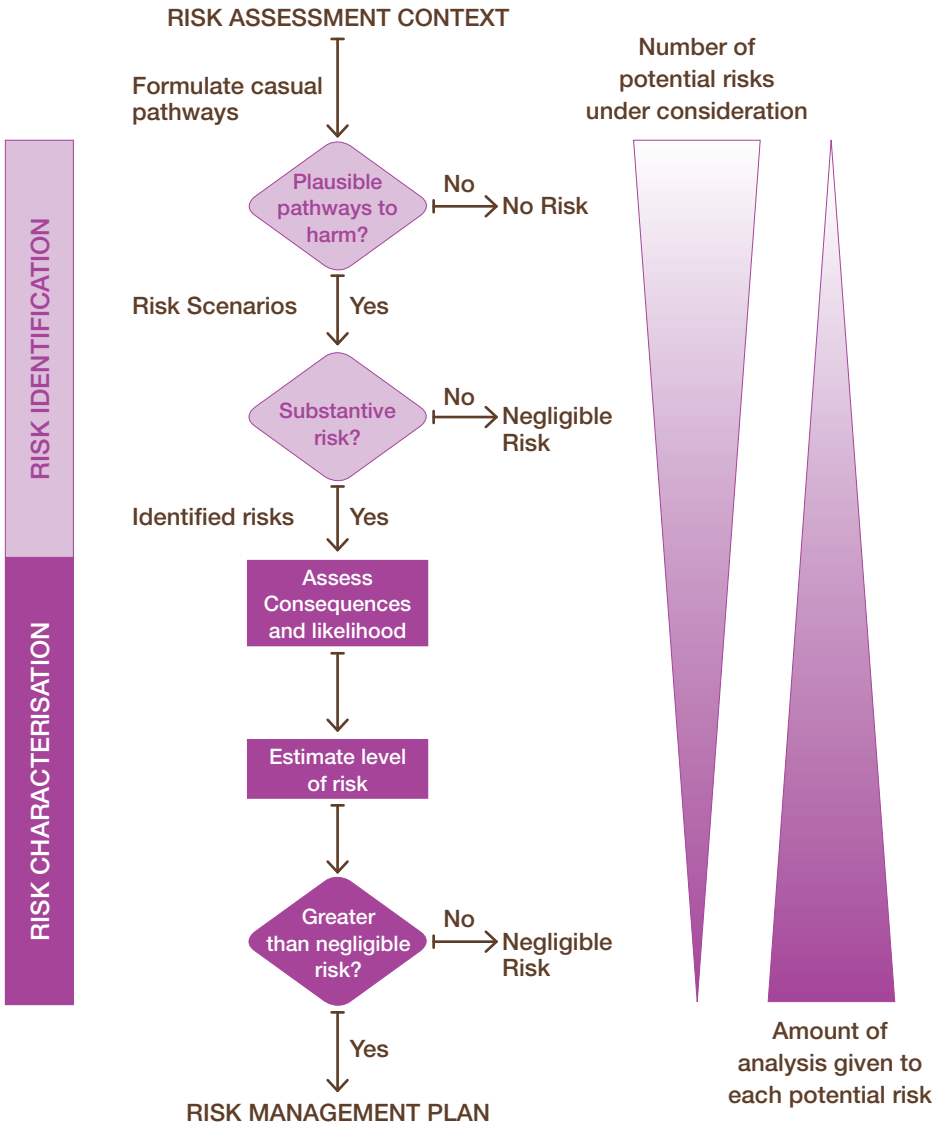
After preparing the risk assessment for DIRs, the Regulator considers whether one or more dealings proposed to be authorised by the licence may pose a significant risk to the health and safety of people or to the environment under section 52(2)(ba) of the Act. If the Regulator determines there is a significant risk, there is a longer period of consultation.

Although determination of significant risk is made on a case-by-case basis, it is expected that in most cases risk would be considered significant if the risk requires control or mitigation measures. These risks correspond to a level of risk that the Regulator has estimated as either moderate or high. In some cases risks estimated to be low, but evaluated as requiring risk treatment, may also be determined as significant. In contrast, risks considered to not need mitigation (that is, negligible risks) would not be expected to be considered significant.

Summary

Typically, the methodology used for preparing a risk assessment in relation to DIR and DNIR licences is an iterative process that places increasing focus on risks that are more substantive and usually require more information, more detailed characterisation, and a closer examination of uncertainty (se Figure 4.4). The numbers of risks that involve more detailed assessment and warrant consideration of risk treatment are, therefore, fewer than in earlier phases.

Figure 4.4: Summary of methodology used for preparing a risk assessment for DIRs and DNIRs



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CHAPTER 5 Risk management

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Chapter 5 Risk management

This Chapter explains the risk management approach the Regulator uses to inform decisions on applications for DIR and DNIR licences. The purpose of risk management is to protect the health and safety of people and to protect the environment by controlling or mitigating risk.

Risk management encompasses:

- preparing a risk management plan – includes evaluating and treating risk, general risk management measures, and proposed licence conditions
- monitoring and reviewing – measures to assess the effectiveness of all steps in risk analysis, including post release review of general/commercial releases of GMOs.

The risk assessment (see Chapter 4) and risk management plan form the basis upon which the Regulator decides whether to issue a licence.

Risk management plan

The risk management plan provides 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?'

Preparation of a risk management plan may be informed by considering a number of general questions, including:

- Which risks need managing?
- What measures are available for managing risk?
- How effective are the measures?
- How feasible, practical or compatible are the measures?
- Which treatment measure(s) provide the optimum and/or desired level of management for the proposed dealing?
- Do the measures themselves introduce new risks or exacerbate existing ones?

When preparing the risk management plan, the Regulator also takes into account relevant advice from stakeholders specified in the Act (see Appendix A).

Consistent with the overarching objective of protection, the Regulator prioritises preventative risk treatment measures over ameliorative or curative ones; that is, the risk treatment measures will be focused on preventing the risk being realised, rather than on measures to reduce or repair the harm that would result.

The risk assessment includes consideration of the causal pathway(s) necessary for any given risk to be realised. This understanding of how dealings with the GMO might result in harm and the nature of the harm provides valuable information for identifying risk treatment options. For example, knowledge of the causal pathway enables identification of 'weak links' in the chain where treatment may be most easily and/or effectively applied.[1]

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 could be done if a particular risk were 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.

Redundancy in risk treatment options, for example by establishing measures that 'break' more than one point in a causal pathway, would increase the effectiveness of risk management. It is important to note that in such cases failure of a single risk treatment measure would not necessarily result in realisation of an adverse outcome. For example, a standard preventative condition in transporting 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, it is unlikely that the weediness risk should be realised, because clean up measures would be invoked.

Risk evaluation

The purpose of risk evaluation is to determine, based on risk assessment outcomes, which risks need treatment. Risk is evaluated against the objective of protecting the health and safety of people and the environment. Risk evaluation may also aid consideration of whether the proposed dealings should proceed, need further assessment, or require collection of additional information during the release.

1 Logic tree analyses, such as diagrammatic fault and event trees, are examples of formal, systematic tools used in risk identification that can also be applied to risk treatment.

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Factors used to determine which risks need treatment may include:

- risk criteria
- estimate of the level of risk
- uncertainty associated with the risk estimate
- interactions between potential risks.

Risk evaluation compares the estimate of risk against the likelihood and consequence criteria, which are continually reviewed during preparation of the risk assessment. In the process of more detailed characterisation of identified risks, the generic criteria for the nature and types of consequences described in Table 3.1 become more clearly specified.

According to the Australian New Zealand Risk Management Guidelines (Standards Australia 2004) three categories of risk, which may relate to the risk estimate, can be elucidated for the purposes of risk evaluation, namely:

- risks generally considered intolerable save in extraordinary circumstances (expected if risk is estimated as moderate or high)
- risks generally considered as tolerable, but may require reduction if practicable (expected if risk is estimated as low)
- risks generally considered as broadly acceptable (expected if risk is estimated as negligible).

Risk estimated as low may or may not require treatment, depending on the specific circumstances, such as the nature of the risk, degree of uncertainty, advice during consultation, or the nature of the risk treatment measures.

Uncertainty associated with either the consequence or likelihood assessments affects the accuracy of the risk estimate. For instance, if a large degree of uncertainty exists, risk estimated as low may require further studies or specific risk reduction measures.

The Regulator may, where appropriate, consider interactions between potential risks due to synergistic, additive, antagonistic, cumulative or aggregate effects. In most cases, the combination of effects is not expected to be significant when the associated risks are estimated to be negligible.

Risk treatment

When risk requires treatment, options to reduce, mitigate or avoid the risk are identified and assessed, and selected management measures are implemented through licence conditions. 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.

For DIRs, the scale of the release is an important consideration in selecting risk treatment options because this influences the level of exposure to

potential adverse consequences. Other measures could include specifying physical controls (such as fences), isolation distances, monitoring zones, pollen traps, post release cleanup and specific monitoring requirements (such as removal of sexually compatible species from the release site). Again, it is important to note that such measures will be applied to all limited and controlled releases in order to restrict the release to the size, duration and location(s) as requested by the applicant, and is crucial to establishing the risk context for assessing risk.

For DNIRs, risk treatment measures could include the level of physical containment of the facility in which the dealings may be undertaken (that is, PC1, PC2, etc.), and specific work practices that reduce exposure (such as using face masks or not using sharps).

The range of suitable controls and limits will depend on the nature of the:

- proposed dealings
- control and limits proposed by the applicant
- nature and properties of the organism (such as seed longevity)
- trait (the characteristics of the GMO conferred by gene technology)
- introduced genes (including ability to identify/detect the GMO and introduced genes)
- environmental conditions at the site of releases
- normal production and management practices.

Once measures have been identified they must be evaluated to ensure they will be effective and sufficient over time and space. Specifically, they must:

- be feasible to implement and able to operate in practice
- meet currently accepted requirements for best practice (for example, good agricultural practice, good laboratory practice, good manufacturing practice)
- manage the risks to the level required for the requested duration of the dealings and period of the licence
- be able to be monitored.

Selection of risk management measures is made according to their efficacy and efficiency, commensurate with the level of risk. If risk treatment measures are selected for an identified risk, then risk should be reduced sufficiently such that any residual risk does not compromise protection of the health and safety of people and the environment.

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.

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 about 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 (such as in 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 instance, the size of a reproductive isolation distance for a GM plant would be based on the overall distribution of pollen, and not just on the median distance pollen might travel.

In the case of DIRs, the Regulator endeavours to assist GMO developers by identifying data that may be needed to assess applications for future proposed releases that are larger in scale and/or have fewer restrictions, as in the case of general/commercial releases. In addition, section 62(2)(h) of the Act allows the Regulator to impose licence conditions to require collection of data or conduct of research. The findings of such research may result in changes to licence conditions to better manage risk and will inform future evaluations of the same or similar GMOs.

In some instances the Regulator may identify risks from GMOs that other agencies regulate (such as insect resistance management or therapeutic efficacy). In which case the Regulator will liaise closely with that agency to ensure 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 A.

The risk management plan may also evaluate certain measures to manage risk, including:

- proposed controls and limits for DIRs
- proposed containment measures for DNIRs
- risk treatment measures
- any new or increased risk from measures to manage risk.

Applications for DIR licences may include means proposed to control the spread and persistence of the GMO and its genetic material in the environment, and limit the release to the size, location and duration. Similarly, applications for DNIR licences include means proposed to contain the GMO and its genetic material, including physical containment to a specified level (that is, PC1, PC2, PC3 or PC4). These proposed measures to manage

potential risks are evaluated against criteria established to protect the health and safety of people and the environment. In some cases additional or modified measures to manage risk may be required. However, in some cases the proposed measures may be evaluated as excessive or not required for protecting the health and safety of people or to the environment.

In addition, a measure to manage one risk may introduce a new risk or increase the level of risk; for example, applying a tourniquet to a snakebite victim's limb can reduce the amount of snake venom that enters the bloodstream, but it can also lead to limb damage through reduced blood flow.

General risk management measures

Other statutory requirements contribute to the overall management of risk, including:

- suitability of the applicant
- identification of the persons or classes of persons covered by the licence
- existence of contingency plans
- existence of reporting structures, including a requirement to inform the Regulator if the applicant becomes aware of any additional information about risks to the health and safety of people or to the environment.

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 A). The Regulator must have regard to any relevant convictions of persons or 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).

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 (bunding) in place capable of containing volumes greater than the maximum volume of the fermentation tank(s) that will contain any spills and also specific emergency procedures. All licences include a requirement that the Regulator be informed if there is an unintentional release of the GMO.

All licences also 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.

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If the risks associated with the authorised dealings are identified, the Regulator may vary licence conditions, or if necessary, suspend or cancel the licence.

In cases of non-compliance with licence conditions arising from monitoring, the Regulator may instigate an investigation to determine the nature and extent of non-compliance. If proven, a range of remedies is available that include provision for criminal sanctions of large fines and/or imprisonment for failing to abide by the legislation, conditions of the licence or directions from the Regulator, especially where significant damage to health and safety of people or to the environment could result.

Licence conditions

Section 62(2)(a–o) of the Act enables the Regulator to impose licence conditions for 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. These licence conditions are imposed as a means of implementing the risk management plan and other statutory requirements. The licence holder is legally required to comply with these conditions. Formulation of clear and unambiguous licence conditions is therefore critical to ensure:

- treatment measures or controls are applied as intended and to manage risk effectively
- licence holders understand the specific requirement so compliance with the conditions can be demonstrated
- the Regulator can enforce compliance with the conditions, and identify non-compliance, and where necessary or appropriate, undertake remedial and/or punitive actions.

The ability to identify the GMO and the introduced genes is an important consideration for risk management so 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 its modified genes is included in all risk management plans.

Monitor and review

The purpose of monitoring and reviewing all steps in risk analysis is to ensure the right things are done, each step is done correctly, and that the outcomes remain valid in the light of future findings or changes in circumstances. A number of both internal and external feedback mechanisms can be used to maintain the effectiveness and efficiency of risk assessment and risk management, and which consider the concerns of all interested and affected stakeholders.

Internal processes of monitor and review include:

- standard operating procedures for specific administrative processes
- internal peer review of DIR and DNIR risk assessment and risk management plans
- merit based selection processes for the OGTR staff
- conflict of interest declarations and procedures for the OGTR staff and expert committee members.

External processes of monitor and review include:

- expert scrutiny by GTTAC of certain licence applications and risk assessment and risk management plans
- external scrutiny and review through the extensive consultation processes with Australian Government agencies and the Environment Minister, state government agencies, relevant councils, interested parties and the public on all DIR risk assessment and risk management plans
- 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 provision of quarterly and annual reports
- review by administrative appeals mechanisms.

A critical aspect of overall quality assurance is that the Regulator and the 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, attending conferences, and monitoring the determinations, experience and policy developments of agencies regulating GMOs in other countries.

Monitoring and reviewing 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.

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Ongoing oversight provisions

Some general/commercial release DIR licences, particularly those requesting unrestricted release, may incorporate a requirement for ongoing oversight in the risk management plans which may be achieved through identified post release review activities.

Accordingly, the Regulator may impose licence conditions that require the licence holder to supply, or enable the Regulator to collect, specific information on the progress of the release.[2] This provides a mechanism for 'closing the loop(s)' in the risk analysis process, or for verifying findings of the risk assessment and risk management plan, by monitoring specific indicator(s) of harm that would usually have been identified in the risk assessment. Potential 'triggers' for this component of post release review may include where the risk estimate is greater than negligible, or there is uncertainty (for example, lack of consensus among expert advisers).

A second component of post release review is establishment and maintenance of an adverse experience/effects reporting page on the OGTR website to collect information about possible adverse effect(s) of released GMOs on human health and the environment. This could result in reports over the short and long term about any DIR licence. Credible information would form the basis of further investigation.

A third component of post release review is the review of risk assessment and risk management plans any time after the licence is issued. Such reviews would take into account any relevant new information or may be triggered by findings from either of the other components of post release review. The purpose of the review would be to ensure the findings of the risk assessment and risk management plan remained current. If the review findings justified either an increase or decrease in the initial risk estimate(s), or identified new risks to people or to the environment that needed managing, this could lead to review of the risk management plan and changes to the licence conditions.

Decision making

Preparation of the risk assessment (Chapter 4) and the risk management plan are essential components of decision making in relation to DIR and DNIR licence applications.

The Regulator, as an independent, statutory office holder, is charged with making decisions on whether to issue a licence to authorise dealings with GMOs, which includes imposition of licence conditions. The Regulator also decides on suspending, cancelling, transferring or varying a licence. Each

2 Such conditions would be additional to the notification requirements imposed on licence holders under section 65 of the Act (see 'General risk management measures').

of these decisions is based on whether 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.

There are no one-size-fits-all solutions for the risk assessment and risk management of GMOs; 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 prudent judgment.

To support the decision-making process for DIR applications the Regulator must seek advice from GTTAC and a wide range of agencies and authorities (see Figure A1). In addition, the Regulator can seek advice from GTECCC; and the Gene Technology Ministerial Council may also provide the Regulator with guidance through policy principles, policy guidelines and codes of practice. In relation to DNIR licences, the Regulator may consult GTTAC, the states, relevant Australian Government agencies, and anyone else the Regulator thinks appropriate.

The steps the Regulator must take in the decision-making process for DIRs and DNIRs are provided in Appendix A.

The key factors in making the decision include:

- setting the terms of reference for the risk assessment
- establishing the risks to the health and safety of people or to the environment that require management
- determining licence conditions that define the scope and boundaries of the proposed dealings and manage the risks.

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

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.

Monitoring for compliance

Sections 152 and 153 of the Act give the Regulator extensive powers for monitoring compliance with the Act and Regulations. Where risks requiring management have been identified and treatment measures imposed through licence conditions, or in guidelines, monitoring is necessary in order to verify that those treatment measures or obligations are being applied and that risks are being appropriately managed.

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Specific monitoring activities to support compliance with the Act and Regulations include:

- routine monitoring of limited and controlled environmental releases and certified facilities
- unscheduled monitoring of limited and controlled environmental releases and certified facilities (spot checks)
- profiling of dealings to aid strategic planning of monitoring activities (such as conducting inspections of GM plants during the flowering period)
- conducting education and awareness activities to enhance compliance and risk management planning of licence holders and organisations
- conducting audits and practice reviews in response to findings of routine monitoring
- incident reviews in response to 'self reported' non-compliance
- investigations in response to allegations of non-compliance with conditions or breach of the legislation.

The Act stipulates, as a condition of every licence, that a person who is authorised by the licence to deal with a GMO, and who is required to comply with a condition of the licence, must allow inspectors and other persons authorised by the Regulator to enter premises where a dealing is being undertaken for the purpose of monitoring or auditing the dealing. Unannounced spot checks and audits can apply at any time irrespective of non-compliance.

In the case of controlled and limited DIRs, post-harvest monitoring continues until the Regulator is satisfied that all the GMOs resulting from the authorised dealings have been removed from the release sites.

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CHAPTER 6 Risk communication

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Chapter 6 Risk communication

Effective communication is an integral component of risk analysis. Risk communication is defined as the 'culture, processes and structures to communicate and consult with stakeholders about risks'. Such exchanges may not relate exclusively to risk but may also consist of expression of concerns, opinions or reactions to risk messages or to legal or institutional arrangements for risk management (National Research Council 1989).

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 decisions, to minimise conflicts, to improve understanding of perceptions and positions, 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).

This Chapter discusses the way risk is perceived, outlines the consultative processes that led to development of the Act, describes the present communication processes between stakeholders and the OGTR (as mandated by the Act), and sets out a risk communication charter to demonstrate the Regulator's commitment to effective communication with stakeholders.

Risk perception

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 Australian regulatory system for gene technology replaced a voluntary system that was overseen by 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.

Different organisations and individuals perceive risk in different ways and may have different attitudes to risk. Perception of risk can be influenced by:

- material factors, such as gender, age, education, income, and personal circumstances

- psychological considerations, such as early experiences, personal beliefs, attitudes to nature, religious beliefs
- 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.

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 to which 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 6.1 summarises some of these elements.

Table 6.1: 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

Social scientists have conducted considerable research into the way different members of the community estimate and perceive risk. Often technical experts and scientists have very different perceptions and estimations of risks to 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.

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Risk perception is fundamental to an individual's acceptance of risk. For instance, despite the level of risk associated with car travel, it continues to be an accepted form of daily transport. And, while commercial air travel is also an accepted form of transport, many people may perceive it as more risky than car travel, although the probability of death is actually higher with car travel in relation to the distance travelled. These perceptions exist due to people's greater familiarity with cars, greater control in operating a car, and a greater chance that a car accident is less likely to be fatal than an airline accident. It can be seen, therefore, that an individual's perception and assessment of risk is a complex construction involving a number of factors that are weighed and balanced to achieve a final position.

Some factors that may contribute to disagreement in risk assessment and risk management are summarised in Table 6.2.

Table 6.2: Sources of conflict in risk assessment and risk management

Sources of conflict	Possible explanations
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 that scientists or experts use 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.

Historically, a number of approaches have been employed 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. Fischhoff (1995) 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 the community holds many and varying views on gene technology and believes all stakeholders hold legitimate positions.

In terms of risk communication, the Act allows for two committees (scientific, and ethics and community) to advise the Regulator. The Act also requires public consultation during the assessment of licence applications for DIRs.

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 are shown in Table 6.3; additional communication activities the OGTR undertakes that exceed the requirements of the legislation are listed in Table 6.4.

Table 6.3: Communication undertaken by the OGTR as prescribed by legislation

Communication required by the Act	Form of communication
Must supply a copy of the application if requested (section 54)	Copy of the application (commercially confidential information and any relevant convictions removed)
Consult states, GTTAC, prescribed Australian Government agencies and Environment Minister, appropriate local councils on matters to be considered in the RARMP (section 50) unless it is a limited and controlled release application) (section 50A)	Letter and application summary (copy of the application if requested)
Invite submissions from the public on consultation RARMP for a minimum of 30 days or at least 50 days if the dealing may pose a significant risk (section 52)	Advertisements in Australian Government Gazette, national newspaper, website
Consult states, GTTAC, prescribed Australian Government agencies and Environment Minister, appropriate local councils on the consultation RARMP in the same timeframes as public (section 52(3))	Letter and RARMP summary (copy of consultation RARMP if requested)
Location of trial sites for DIRs (section 138)	Website
Notify the applicant of the decision (section 59)	Letter and licence (if approved)
Maintain GMO Record (information on authorised GMO dealings and GM product approvals) (section 138)	Website
Quarterly and annual reports (sections 136A and 136)	Publication as a booklet; tabled in the Parliament, website, copy of latter sent to states

Notes: DIR = dealings involving intentional release; GMO = genetically modified organism; GTTAC = Gene Technology Technical Advisory Committee; OGTR = Office of the Gene Technology Regulator; RARMP = risk assessment and risk management plan.

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Table 6.4: Communication undertaken by the OGTR in addition to that prescribed by legislation

Additional communication undertaken by OGTR	Form of communication
Notifications of receipt of applications and release of consultation RARMPs	Client register, advertisements in state, regional and local newspapers and specialist publications
Questions and answers, biology and ecology documents and executive/technical summaries of RARMPs	Website (hardcopies available on request)
Consult additional stakeholders (such as the Department of Agriculture, Fisheries and Forestry) on DIR applications	Letters, email, face-to-face meetings
Notify stakeholders of licence decisions	Letters to states, prescribed Australian Government agencies and Environment Minister, appropriate local councils, public submitters, client register, website
Monitoring	Protocols on website, practice reviews, discussions with licence holders,
Consult widely on related matters (for example, this document)	Letters, briefings, presentations, face-to-face meetings
Ministerial correspondences, briefs	Letters, emails
Establish cooperative relationships with other Australian Government regulatory agencies	Memoranda of understanding, informal consultations, briefs, meetings
1800 telephone number	Verbal queries
Email address	Email queries
Advise/update regulated organisations	IBC training nationally, dedicated section contains relevant information on website
Conferences, forums, public addresses, workshops	Oral and written presentations by Regulator and OGTR staff
Quarterly and annual reports	Release notified via website and posted, copies of former sent to states, copies of latter circulated to prescribed stakeholders and accredited organisations/IBCs

Notes: DIR = dealings involving intentional release; IBC = Institutional Biosafety Committee; OGTR = Office of the Gene Technology Regulator; RARMP = risk assessment and risk management plan.

Communication pathways

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; however, in practice, time and resources can limit the extent of dialogue. The OGTR 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, general/commercial releases.

Stakeholders

Release of GMOs into the Australian environment is of significant interest to a wide spectrum of the community, including state and local governments, non-government organisations, 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 state governments, local councils, a number of prescribed Australian Government agencies (FSANZ, AQIS, NICNAS, APVMA, TGA), the Environment Minister and the public. In addition, the OGTR maintains a client register of people and organisations[1] that have registered to receive information from the OGTR on issues relating to regulation of gene technology. Identified stakeholders are shown in Table 6.5. The form of communication with specific stakeholders and potential constraints on effective communication that need to be addressed for different groups is shown in Table 6.6.

Table 6.5: Stakeholders with interests in gene technology

Group	Stakeholders
Research	Pro/Vice Chancellors R&D of universities, CEOs/Directors of research institutes, Institutional Biosafety Committees, CSIRO, Cooperative Research Centres, research and development corporations, other research groups
Industry	Retailers, food industry, proponents of the technology
Primary producers	National and state 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, lobbyists, consultants, regulatory affairs advisors
Prescribed agencies under the Act	FSANZ, AQIS, NICNAS, APVMA, TGA (see Appendix A)
Government	State and local governments, the Australian Government Environment Minister, Department of Agriculture, Fisheries and Forestry, Department of Foreign Affairs and Trade, Department of Prime Minister and Cabinet, Department of Innovation, Industry, Science and Research, National Health and Medical Research Council and Human Genetics Advisory Committee
The public	

Notes: APVMA = Australian Pesticides and Veterinary Medicines Authority; AQIS = Australian Quarantine Inspection Service; FSANZ = Food Standards Australia New Zealand; NICNAS = National Industrial Chemicals Notification and Assessment; TGA = Therapeutic Goods Administration.

1 At December 2008, approximately 800.

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Table 6.6: Forms of communication with stakeholders and potential constraints on that communication

Stakeholders	Form of communication	Constraints on effective communication
Applicant	Application form	Different language styles
	Informal/formal discussions	Different knowledge base
	Commercially Confidential Information application	Different interests, values, beliefs
	RARMP – consultation and final licence	Unclear requirements or explanations
Experts	Meetings, informal discussions	Lack of understanding
	Letters requesting advice	Lack of context
Prescribed agencies	Memoranda of understanding	Uncertainty
	Informal/formal discussions	Limited resources
	Letters requesting advice or notification	
Local councils	Letters requesting advice	
Government	Memoranda of understanding	
	Informal/formal discussions	
	Letters requesting advice	
Public	1800 telephone number	
	Advertisements	
	Website	
	Email	
	Client register	

Consultation on applications

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

The process of consultation on DIR licence applications provides an opportunity for stakeholders to have direct input into the decision-making process.

When an application for a DIR licence is received, the Regulator makes a determination about whether it qualifies as a limited and controlled release application (section 50A). A notification is sent to those on the OGTR mailing list and placed on the website advising when the consultation RARMP is expected to be released for comment.

The Regulator consults on DIR licence applications with state and local governments in the area in which the release is proposed to occur, prescribed Australian Government agencies and the Environment Minister, and GTTAC. If it is not a limited and controlled release, the public is also consulted.

Section 51 of the Act requires the Regulator to take account of submissions received on the applications under section 50 of the Act in preparing the consultation version of RARMPs. Each submission the OGTR receives on a particular application is analysed to identify matters relating to risks to human health and safety or to the environment that require detailed consideration. As part of the response to stakeholders and to ensure all relevant concerns have been considered, summaries are prepared that identify the issues raised and where they are addressed in the RARMP; these are included as appendices to the RARMP. Resolution of specific concerns and issues relating to risks to human health and safety and to the environment may involve intensive discussions between the stakeholder and OGTR staff and often leads the Regulator to seek 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.

Before releasing the RARMP for consultation, the Regulator must determine whether the proposed dealings may pose a significant risk to the health and safety of people or to the environment. The minimum consultation period specified in the Act is 30 days if the Regulator is satisfied that the dealings do not pose a significant risk. If the Regulator considers that the proposed dealings may pose significant risk(s), a minimum 50-day consultation period is specified (section 52(2)).

Under section 52, the consultation version of the RARMP is provided to all relevant expert groups, agencies and authorities for comment. Public comment is also sought by placing advertisements in a range of publications, more diverse than required by the Act. Publications include national, metropolitan, regional and rural newspapers, the Australian Government Gazette, notification on the OGTR website and by writing directly to interested parties.

The consultation version of the RARMP is then finalised, taking into account the feedback received in a similar way to feedback on the application (section 56(2)) to ensure relevant issues of concern are addressed in as much detail as possible and practical. If deficiencies, such as new risks,

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inaccurate assessments, or better risk management strategies, were identified through the consultation process, the RARMP would be reworked to address them.

Comments provided by stakeholders to date have covered widely diverse issues, including general concerns about the use of gene technology that cannot be addressed while assessing an individual application. The OGTR 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 assessment and risk management undertaken by the OGTR and by making the documents underpinning the Regulator's decisions (the RARMPs) readily available.

Some issues stakeholders have raised (such as economic, marketing or marketability questions and concerns) are outside the scope of assessments required by the Act; some may fall within the jurisdiction of other regulatory agencies. For instance, FSANZ is responsible for food safety and the APVMA regulates herbicide use. Where complementary regulatory responsibility exists, there may be some discussion of this in the RARMP. However, it will not be considered directly in making the decision, and no licence conditions will be imposed that duplicate another agency's role.

Social and ethical issues

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 GTECCC was established to advise the Regulator on ethical issues and issues of concern to the community (section 106). The committee comprises 12 members with expertise in community consultation, risk communication, the impact of gene technology on the community, issues relevant to businesses developing or using biotechnology, issues relevant to gene technology research, issues relevant to local government, issues of concern to consumers, law, religious practices, human health, animal health and welfare, primary production, ethics, and environmental issues (section 108).

Other forms of communication

The mandate of the Regulator under the Act is to implement the regulatory system for gene technology; 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. The Regulator is neither a proponent for 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.

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 OGTR. The primary mechanism for providing information about the OGTR to interested people is the OGTR website and the Quarterly Report. Documents that provide essential background information for the OGTR, such as the biology of plant species that have been modified by gene technology, are also available on the website.

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

The Regulator's quarterly and annual reports provide details on applications considered, monitoring activities undertaken, and the work of advisory committees; they also summarise other activities of the OGTR in relation to reviews, research, freedom of information requests, and consultant contracts managed.

In addition, the OGTR provides regular training for Institutional Biosafety Committees (IBCs) on particular administrative matters and to help them and applicants recognise particular categories of dealings under the Act. The OGTR has regular contact with applicants on a range of matters, both scientific and administrative. The OGTR endeavours to foster a cooperative compliance culture, educating and informing applicants to minimise the likelihood of breaches of the legislation and subsequent application of strict penalties under the Act for non-compliance.

The OGTR provides information on the regulation of gene technology. Agricultural biotechnology information is available from the Department of Agriculture, Fisheries and Forestry,[2] and information on the environmental aspects of gene technology is available from the Department of the Environment and Water Resources.[3]

Risk communication charter

Effective risk communication requires the active participation of all stakeholders, including government. This charter presents the principles of risk communication that the OGTR aims to uphold and demonstrates the

2 See <http://www.daff.gov.au>.

3 See <http://www.environment.gov.au>.

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Regulator's commitment to active risk communication. These principles align with the principles outlined in Chapter 2 that guide the whole of the risk analysis process and with the OGTR Service Charter.[4]

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 stakeholders' concerns
- communicate consideration of social and ethical issues relating to gene technology by GTECCC and action taken on such issues by the Regulator or the Ministerial Council
- periodically review the OGTR communication strategies and practices to ensure effective, appropriately targeted and efficient communication with stakeholders.

4 See <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/about-charter-1>.

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APPENDIX A

Appendix A Gene Technology Regulatory System

The purpose of this Appendix is to:

- provide background to development of the current gene technology regulatory system
- outline the types of dealings that are defined by the Act and the Regulations and corresponding state laws
- provide the procedure followed for each type of application
- indicate other administrative factors, such as certification and accreditation, that help the Regulator manage risk.

Development of the regulatory system

Voluntary oversight

Oversight of gene technology in Australia began on a voluntary basis with formation of the Committee on Recombinant DNA set up by the Australian Academy of Science in the mid 1970s. In 1981 the Recombinant DNA Monitoring Committee was established 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.

The work of these committees 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 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, Australian researchers consistently sought and complied with its advice. Although GMAC had no enforcement powers, compliance with its recommendations was a condition of research and development funding from the Australian Government.

Development of legislation

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, initiated a cooperative process to develop a uniform, national approach to regulating gene technology in November 1998. Public and other stakeholder comment was sought on a paper entitled ‘Regulation of Gene Technology’ prepared by

the Commonwealth State Consultative Group on Gene Technology (CSCG). These consultations contributed to preparation of a discussion paper entitled 'Proposed national regulatory system for genetically modified organisms – How should it work?'

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

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 development of the regulatory scheme reflects the emphasis the government placed on community input and participation in the decision-making process relating 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 the potential of gene technology to contribute to society with community concerns over development and deployment of the technology.

Some outcomes of the public consultation relevant to risk analysis include:

- a focus on science-based risk assessment
- availability of a range of advice to the Regulator from scientific experts, government agencies and others
- openness and transparency in decision making
- opportunities for public input as part of the decision-making process
- that broader issues, such as ethical concerns, should be taken into account.

On 21 June 2001 the national legislative scheme for regulation of gene technology in Australia commenced with enactment of the *Gene Technology Act 2000* (the Act) and the Gene Technology Regulations 2001 (the Regulations). The system is underpinned by the Intergovernmental Agreement on Gene Technology (Gene Technology Agreement) signed in 2001 by all Australian jurisdictions and which commits the states to pass corresponding laws.

Review of legislation

In 2005–06, as required by section 194 of the Act, the Gene Technology Ministerial Council (GTMC) commissioned an independent review of the Act and of the Gene Technology Agreement. The review panel conducted extensive public and stakeholder consultation, and found that the Act and the national regulatory scheme had worked well in the five years following its introduction, and that no major changes were needed. However, it suggested a number of minor changes, aimed at improving operation of the Act.

The *Gene Technology Amendment Act 2007* implemented the changes agreed in the All Governments' Response to the recommendations of the review. The Gene Technology Amendment Regulations Bill 2007 gave effect to changes directly affecting the Regulations, and made consequential amendments necessitated by amendments to the Act. The majority of these amendments commenced on 1 July 2007, amending the *Gene Technology Act 2000* and the Gene Technology Regulations 2001, respectively.

The *Gene Technology Amendment Act 2007* introduced changes in six main areas, namely:

- assessment of applications for intentional release – streamlining the process for the initial consideration, and introduction of limited and controlled release provisions
- licence variations – providing clarification on the circumstances in which licence variations can be made
- a new provision – Emergency Dealing Determinations (EDD) – giving the minister the ability to expedite approval of a dealing with a GMO in an emergency
- committees – improving the mechanism for providing advice to the Regulator and the GTMC on ethical issues and issues of concern to the community
- Regulator's powers to direct – clarifying the circumstances under which the Regulator can direct a person to comply with the Act
- inadvertent dealings – providing a streamlined process for the Regulator to issue a licence to persons who find themselves inadvertently dealing with an unlicensed GMO, for the purpose of disposing of that GMO.

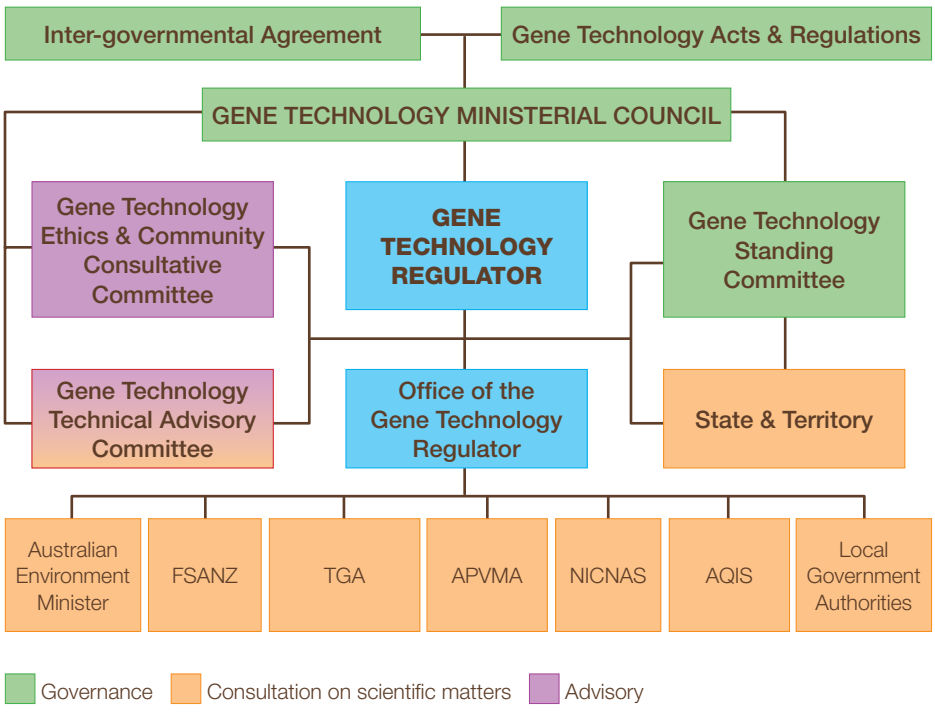
The Regulator conducted a technical review and subsequently introduced the Gene Technology Amendment Regulations Bill 2006, which amended the Regulations. The review was based on the operational experience of the OGTR in implementing the legislation between 2001 and 2005, and extensive consultation with accredited organisations. The amendments resulted in changes to the classification and containment requirements for some low risk dealings with GMOs.

Operation of the regulatory system

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

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 GTMC, comprising representatives from all Australian jurisdictions, oversees implementation of the regulatory system (see Figure A1). The Act establishes two committees whose role is to give advice to the Regulator and the GTMC on matters relating to gene technology. These are the Gene Technology Technical Advisory Committee (GTTAC), and the GTECCC.[1]

Figure A1: Australian gene technology regulatory system



1 Amendments to the legislation replace the Gene Technology Ethics Committee and Gene Technology Community Consultative Committee with GTECCC from 1 January 2008.

Types of dealings

To 'deal with' a GMO is defined in section 10(1) of the Act as:

> conduct experiments with, make, develop, produce or manufacture, breed, propagate, use in the course of manufacture of a thing that is not the GMO, grow, raise or culture, import, transport, dispose of the GMO; and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the above.

A GMO is defined as any organism that has been modified by gene technology, or offspring of such an organism that has inherited the introduced trait, or anything declared as a GMO in the Regulations.

Section 31 of the Act prohibits dealings with GMOs unless it is:

- an exempt dealing
- a notifiable low risk dealing (NLRD)
- authorised by a licence
- included on the GMO Register
- specified in an emergency dealing determination (EDD).

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 have been used safely for many years or pose minimal risks when performed in contained conditions.

The Regulator may issue three types of licences under the Act, namely:

- dealings not involving intentional release (DNIR)
- dealings involving intentional release (DIR), or
- inadvertent dealings.

The DIR licence applications may also qualify for a streamlined process for limited and controlled releases (such as field trials) that involve research and incorporate measures to restrict dissemination and persistence of the GMO and its introduced genetic material in the environment (section 50A).

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

The Act (Part 5) allows the Regulator to grant a temporary licence to a person inadvertently dealing with an unlicensed GMO for the purpose of disposing of the GMO. This does not require preparation of a RARMP before issuing the licence (section 49).

Dealings on the GMO Register (Part 6, Division 3 of the Act) are dealings that have been authorised by a licence previously, have a history of safe use, and no longer require a licence from the Regulator to protect health and safety of people or to the environment.

The minister may issue an EDD to exempt specified dealings from the licensing requirements for a limited period, where the GMO is likely to address an actual or imminent threat to the health and safety of people or to the environment, and any risks associated with using the GMO for that purpose could be adequately managed.

A representation of the classes of dealings, outlining the predetermined management conditions (such as containment), which are based on the level of risk, is set out in Table A1.

Table A1: Classes of GMO dealings under the *Gene Technology Act 2000*

Category	Licence required	Containment
Exempt	**No**	**No intentional release to the environment**
NLRD	No, dealings must be assessed by IBC; notified in annual report	Yes PC1 or PC2 (usually)
DNIR	Yes, applications must be assessed by IBC; RARMP prepared and licence decision by the Regulator	Yes ≥PC2 (usually)
DIR (except for limited and controlled releases)	Yes, applications must be reviewed by IBC; consultation on application, RARMP prepared, consultation on RARMP and licence decision by the Regulator	Containment measures may be required, determined on a case-by-case basis and other licence conditions will apply
DIR (limited and controlled)	Yes, applications must be reviewed by IBC; RARMP prepared, consultation on RARMP and licence decision by the Regulator	Containment measures will be required based on size/scope of release sought by applicant; and other licence conditions will apply
Inadvertent dealing	Yes, licence decision by the Regulator only for the purposes of disposal of the GMO	Containment and/or disposal measures will apply
GMO Register	No, but must be previously licensed Review of related RARMPs	Containment measures may be required
EDD	No, determination by the minister, subject to advice of threat and utility of GMO from competent authorities and risk assessment advice from the Regulator	Containment and/or disposal measures may be included in EDD conditions

Notes: DIR = dealings involving intentional release; DNIR = dealings not involving intentional release; EDD = emergency dealing determination; GMO = genetically modified organism; IBC = Institutional Biosafety Committee; NLRD = notifiable low risk dealing; PC = physical containment; RARMP = risk assessment and risk management plan.

The licensing system is based on a rigorous process of risk assessment using science-based evidence. For those dealings that involve an intentional release of a GMO into the environment (DIR), the legislation requires extensive consultation with experts, agencies and authorities, 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).

The Regulator may adapt the risk assessment methodology described in Chapter 4 that are prepared in relation to inadvertent dealings (section 40A of the Act), proposed emergency dealing determinations (section 72B), inclusion of dealings on the GMO Register (section 79) or variations to existing licences (section 71), as well as to review of NLRDs (section 140) and exempt dealings (section 141).

Timeframes

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 timeframes for consideration of applications to vary licences, to accredit organisations and to certify facilities. These statutory timeframes are shown in Table A2. 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 resolving a Commercially Confidential Information claim, and cannot continue assessment until that information has been provided.

Table A2: Timeframes under the *Gene Technology Act 2000*

Category	Timeframe
DNIR	90 working days (Regulation 8)
DIR (except for limited and controlled releases)	255 working days (Regulation 8)
DIR – limited and controlled, no significant risk	150 working days (Regulation 8)
DIR – limited and controlled, significant risk	170 working days (Regulation 8)
Licence variation	90 days (Regulation 11A)
Accreditation	90 working days (Regulation 16)
Certification	90 working days (Regulation 14)

Notes: DIR = dealings involving intentional release; DNIR = dealings not involving intentional release.

Dealings involving minimal risks

The **GMO Register**[2] is a mechanism provided by the Act (Part 6, Division 3) for authorisation of dealings with GMOs that have a history of safe use. The Regulator may make a determination to include dealings with a GMO on the GMO Register only if the dealings have previously been authorised by a GMO licence, and the Regulator must be satisfied that risks posed by the specific dealings are minimal and that it is not necessary for anyone conducting the dealings to be covered by a licence in order to protect the health and safety of people or to the environment (sections 78 and 79 of the Act). The principles of risk analysis set out in this framework are applicable to determine whether a GMO should be included on the GMO Register. After inclusion on the Register, the dealings no longer require authorisation by a licence but may still have conditions attached to their registration. A determination to include dealings with a GMO on the GMO Register is a disallowable instrument, meaning that the determination is subject to scrutiny, and may be disallowed by the Australian Parliament.

At April 2009, there was only one GMO dealing on the GMO Register.

Exempt dealings are dealings with GMOs that have been assessed over time as posing negligible[3] risks to people or to the environment, and are therefore exempt from licensing and do not require a case-by-case risk assessment. The types of dealings that are exempt are specified in the Regulations (Schedule 2). These dealings comprise basic molecular biology techniques and activities that have been conducted extensively in laboratories worldwide. Exempt dealings do not require a specified level of containment but must not involve intentional release of a GMO into the environment. Guidance on appropriate containment measures for exempt dealings is provided on the OGTR website. Examples of exempt dealings include dealings with:

- an animal into which GM somatic cells have been introduced, where the introduced somatic cells do not produce infectious agents
- small volumes (<10L) of an approved host/vector system into which low risk genetic material has been introduced (for example, the gene must not be uncharacterised, it must not be derived from a pathogenic organism, nor code for a toxin).

Notifiable low risk dealings (NLRDs) are dealings with GMOs that have been assessed over time as posing negligible risks provided certain management

2 It is important to note the difference between the GMO Register and the GMO Record. Inclusion of a dealing with a GMO on the GMO Register authorises that dealing, which therefore no longer requires a licence. The GMO Record provides a listing of authorised dealings with GMOs, including licensed dealings, NLRDs, EDDs and dealings on the GMO Register, as well as dealings with GM products.

3 The term negligible is defined in Chapter 4 and is used here for consistency.

conditions are met. The types of dealings that may be conducted as NLRDs are specified in the Regulations (Schedule 3). Before a type of dealing is listed in Schedule 3, the Regulator must have considered whether the GMOs involved are biologically contained, whether the dealings involve minimal risks to people and the environment, and whether no or minimal conditions would be needed to manage any such risks (section 74 of the Act). NLRDs must not involve intentional release of a GMO into the environment.

NLRDs may only be undertaken in a facility meeting appropriate technical guidelines issued by the Regulator (usually PC1 or PC2 certified facilities). Before being conducted, the dealings must be assessed by an IBC as meeting the NLRD classification in Schedule 3. Details of all new NLRDs that have been assessed by an IBC must be reported to the Regulator annually. NLRDs are included on the Record of GMO and GM Product Dealings but do not require case-by-case risk assessment.

An example of NLRD which may be conducted in PC1 facilities include dealings with:

- GM mice/rats

Examples of NLRDs that may be conducted in PC2 facilities include dealings with:

- a genetically modified animal (other than a mouse or rat) including invertebrates
- a genetically modified plant, provided the dealing occurs in a facility designed to prevent release of its pollen and seed
- an approved host/vector system into which a gene that may pose a higher level of risk has been introduced (for example, the gene may encode a pathogenic determinant or uncharacterised gene from a pathogen).

Licensed dealings

Any dealing not exempt, an NLRD, on the GMO Register, or specified in an EDD must not be conducted unless licensed.

The Regulator considers licence applications on a case-by-case basis, based on whether the risks posed by the dealing can be managed to protect human health and safety and the environment. The Regulator must decide whether to issue a licence for that dealing, and the management conditions to be imposed to manage any risks (if a licence is issued).

The legislation sets out a series of actions the Regulator must take in relation to applications for licences, both for intentional releases (DIRs) and contained releases (DNIRs). The Act details the steps the Regulator must take when assessing the application; while the application forms detail the information the applicant must provide.

The application forms issued by the Regulator for both DIRs and DNIRs 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 support the application.

Preparing a RARMP

For DIRs and DNIRs, the Act specifies to take into account 'the risks posed by the dealings proposed to be authorised by the licence' (sections 47(2) and 51 (1a)) and 'the means of managing any risks posed by those dealings in such a way as to protect: (i) the health and safety of people; and (ii) the environment (sections 47(3) and 51 (2a)) as well as advice from any consultation and any matter prescribed by the regulations.

Requirements for the RARMPs of all DIR applications are specified in section 51 of the Act as well as in Regulations 9A and 10.

The Regulator must take into account the risks posed by the proposed dealings, including any risks to the health and safety of people or risks to the environment as prescribed by the Regulations. Regulation 9A prescribes that the Regulator, when preparing a risk assessment, must have regard to:

- the properties of the organism to which dealings proposed to be authorised by a licence relate before it became, or will become, a GMO
- the effect or the expected effect, of the genetic modification, that has occurred, or will occur, on the properties of the organism
- provisions for limiting dissemination or persistence of the GMO or its genetic material in the environment
- the potential for spread or persistence of the GMO or its genetic material in the environment
- the extent or scale of the proposed dealings
- any likely impacts of the proposed dealings on the health and safety of people.

Regulation 10(1) requires the Regulator to consider:

- any previous assessment by a regulatory authority, in Australia or overseas, in relation to allowing or approving dealings with the GMO

and the potential of the GMO concerned to:

- be harmful to other organisms
- adversely affect any ecosystems
- transfer genetic material to another organism
- spread, or persist in the environment
- be toxic allergenic or pathogenic to other organisms.

In taking into account any risk or potential capacity mentioned above, the Regulator must consider both the short term and the long term (Regulation 10(2)).

Information required under Regulations 9A and 10 provide essential parameters for the risk context and serves as terms of reference for the entire risk analysis process. The first two considerations of Regulation 9A, in combination with the object of the Act, form the basis for using comparative risk assessment.

Consulting on the RARMP

The Regulator may consult, on any aspect of a DNIR application, with:

- the states
- Gene Technology Technical Advisory Committee (GTTAC)
- relevant Commonwealth authorities or agencies
- any local council the Regulator considers appropriate
- any other person the Regulator considers appropriate (section 47(4)).

When preparing a risk assessment and risk management plan (RARMP) (section 50(3)) for a DIR, the Regulator must, unless satisfied that it is a limited and controlled release application under section 50A, seek advice from:

- the states
- GTTAC
- each Commonwealth authority or agency prescribed by the regulations
- the Environment Minister
- any local council the Regulator considers appropriate.

In addition, the public must be consulted after preparing a RARMP and before making a decision whether to issue a licence (section 52). Regulation 9 specifies the Commonwealth authorities and agencies that must be consulted.

Considering whether to issue a licence

Applicant suitability is an important consideration in the Regulator's consideration whether to issue a licence. Section 58 specifies the particulars to assess applicant suitability. In addition, certification of facilities and accreditation of organisations, as specified in Part 7 of the Act, will form part of the risk context. The statutory licence conditions set out in sections 63, 64 and 65 of the Act provide context for both risk assessment and risk management. In addition, the Regulator may prescribe or impose additional conditions on the licence to manage risk to a tolerable level.

Deciding whether to issue a licence and notifying the decision

Section 56(1) specifies that the Regulator must not issue a licence unless 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 the health and safety of people and the environment. When the Regulator has made a decision whether to issue a licence, he or she must notify the applicant or licence holder (section 180).

After a licence has been issued

Once a licence is issued, the licence holder must comply with the conditions of the licence. A substantive part of the legislation (including Parts 10 and 11 of the Act) concerns the topics 'enforcement' and 'powers of inspection'. The Act also specifies that the Regulator may suspend, cancel or vary existing licences (sections 68 and 71).

In addition, the Act provides for substantive penalties for undertaking unlawful dealings (for an outline, see section 31) and for interference with authorised dealings with a GMO (section 192A).

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 outlines how these risks can be managed.

The requirements of the legislation have been framed to place greater scrutiny on dealings that involve release into the environment (DIRs). The Regulator may impose conditions on all licences. Measures will be imposed to restrict the persistence and spread of the GMO and its genetic material in the environment for all DIRs determined to be limited and controlled releases. Non-compliance with conditions placed on licences issued under the Act is a criminal offence.

For both DNIR and DIR applications the applicant must provide information specified in the application forms 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 to the environment and an assessment of the applicant's capacity to manage any risks posed by the proposed dealings.

Dealings not involving intentional releases

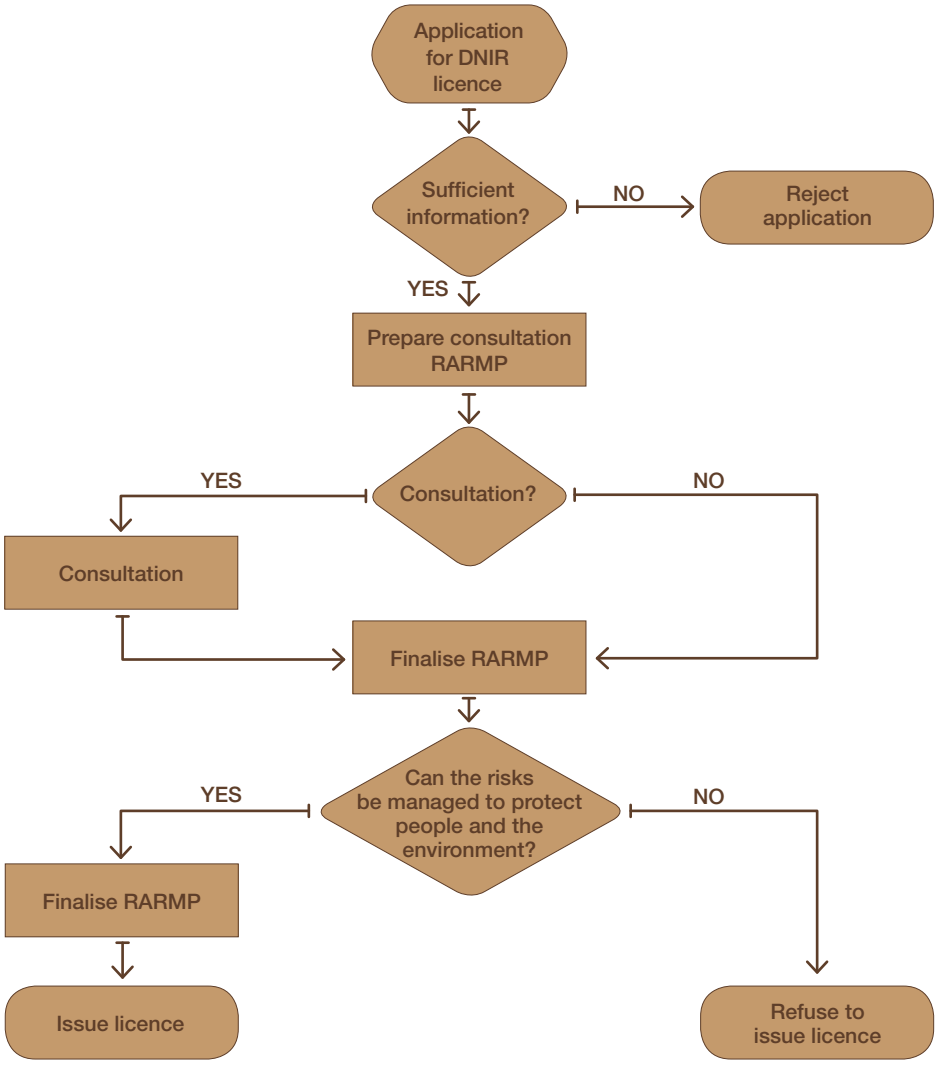
DNIRs usually take place under specified physical containment conditions in certified facilities, which minimise risks to the environment. The Act requires preparation of a RARMP for DNIR applications (section 47). The application form specifies the information the Regulator requires.

The legislation provides that in relation to DNIR licences the Regulator may consult GTTAC, the states, relevant Australian Government agencies, and any other person the Regulator considers appropriate.

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

As a guide to the legislative requirements, the process required in respect of DNIR applications is described in Figure A2.

Figure A2: DNIR assessment process



Dealings involving intentional release

The application form is the same for all DIRs (including limited and controlled releases) and the Regulator will use information submitted by the applicant (as specified in the application form) to determine which consultation process will apply and the timeframe allowed under the Act for processing the application, on a case-by-case basis.

This *Risk Analysis Framework* outlines the approach taken to risk analysis and to preparation of RARMPs. As a guide to the legislative and administrative requirements, the eight-stage process adopted in respect of DIR applications is shown in Figure A3 and is described below.

Stage 1 – The applicant must prepare comprehensive information about the proposed dealings with the GMO, possible hazards and consequent risks posed by the dealings and proposed ways that each risk would be managed. The Regulator's information requirements are set out in detail on the application form. The applicant must ensure 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 to support applications for dealings involving intentional releases of GMOs.

Stage 2 – The IBC reviews the application and appends an evaluation report setting out its advice as to the completeness of the application form. The IBC's role is to ensure the quality of applications submitted to the Regulator.

Stage 3 – Section 50A of the Act allows the Regulator to make a determination on the application as to whether it is for a limited and controlled release which would follow a shorter process.

Section 50A(1) of the Act specifies limited and controlled release applications as applying, if the Regulator is satisfied that:

a the principal purpose of the application is to enable the licence holder, and persons covered by the licence to conduct experiments

b the application proposes, in relation to any GMO in respect of which dealings are proposed to be authorised:
   i. controls to restrict dissemination or persistence of the GMO and its genetic material in the environment
   ii. limits on the proposed release of the GMO

c the Regulator is satisfied that the controls and limits are of such a kind that it is appropriate for the Regulator not to seek the advice referred to in subsection 50(3).

Section 50A(2) of the Act describes the term 'controls' as including:

a methods to restrict the dissemination or persistence of the GMO or its genetic material into the environment
b methods for disposal of the GMO or its genetic material
c data collection, including studies to be conducted about the GMO or its genetic material
d the geographic area in which the proposed dealings with the GMO or its genetic material may occur
e compliance, in relation to dealings with the GMO or its genetic material, with:
    i. a code of practice issued under section 24, or
    ii. a technical or procedural guideline issued under section 27.

Section 50A(3) describes the term 'limits' as including:

a the scope of the dealings with the GMO
b the scale of the dealings with the GMO
c the locations of the dealings with the GMO
d the duration of the dealings with the GMO
e the persons who are to be permitted to conduct the dealings with the GMO.

Stage 4 – A 'Notification of Application' is sent out for all DIR applications to those on the OGTR mailing list and placed on the website advising when the consultation RARMP is expected to be released for comment. This is not a requirement of the Act but increases the transparency of the regulatory system and aims to increase participation in the consultation process.

The Regulator must provide a copy of the application (excluding any information that the Regulator has declared to be, or is under consideration as, confidential commercial information) to anyone that requests a copy (section 54 of the Act).

Stage 5 – The Regulator must seek advice on the application regarding matters relevant to preparation of the RARMP, under section 50 of the Act, from GTTAC, the states, prescribed Australian Government agencies, the Environment Minister, and appropriate local government authorities. The Regulator usually consults with local government authorities where the release is proposed to occur. In addition, the Regulator also routinely seeks advice from other relevant Australian Government agencies such as the Department of Agriculture, Fisheries and Forestry and the Department of Foreign Affairs and Trade. If the application is for a limited and controlled release, this consultation step is not required.

Stage 6 – Section 51 of the Act requires the Regulator to prepare a RARMP (consultation version), and to take account of submissions received during any consultation on the application under section 50 of the Act.

The actual risk assessment process is, to some extent, shaped by the data requirements set out in the DIR application form; 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, and the advice of any person or group. The Regulator may also request more information from the applicant or hold a public hearing.

Preparation of the risk assessment involves developing risk scenarios that describe how risks that may be posed by the dealings with the GMO could result in harm, identifying risks that require more detailed characterisation and estimating the level of risk based on the likelihood of the event occurring and the likely consequences of that occurrence. Risks are then evaluated to determine which require treatment in order to protect people and the environment.

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

Stage 7 – Once the consultation version of the RARMP is prepared for a DIR application, the Regulator must determine if any of the proposed dealings pose a significant risk to the health and safety of people or to the environment. The minimum consultation period specified in the Act is 50 days if the Regulator is satisfied that the dealings may pose a significant risk to the health and safety of people or to the environment. If the Regulator considers that the proposed dealings do not pose significant risks, a minimum 30-day consultation period is specified (section 52(2)).

The statutory timeframe allowed for consideration of a DIR application, except for a limited and controlled release application, is 255 days. For a limited and controlled release application this timeframe is either 170 days (for dealings that may pose a significant risk) or 150 days (dealings that do not pose a significant risk).

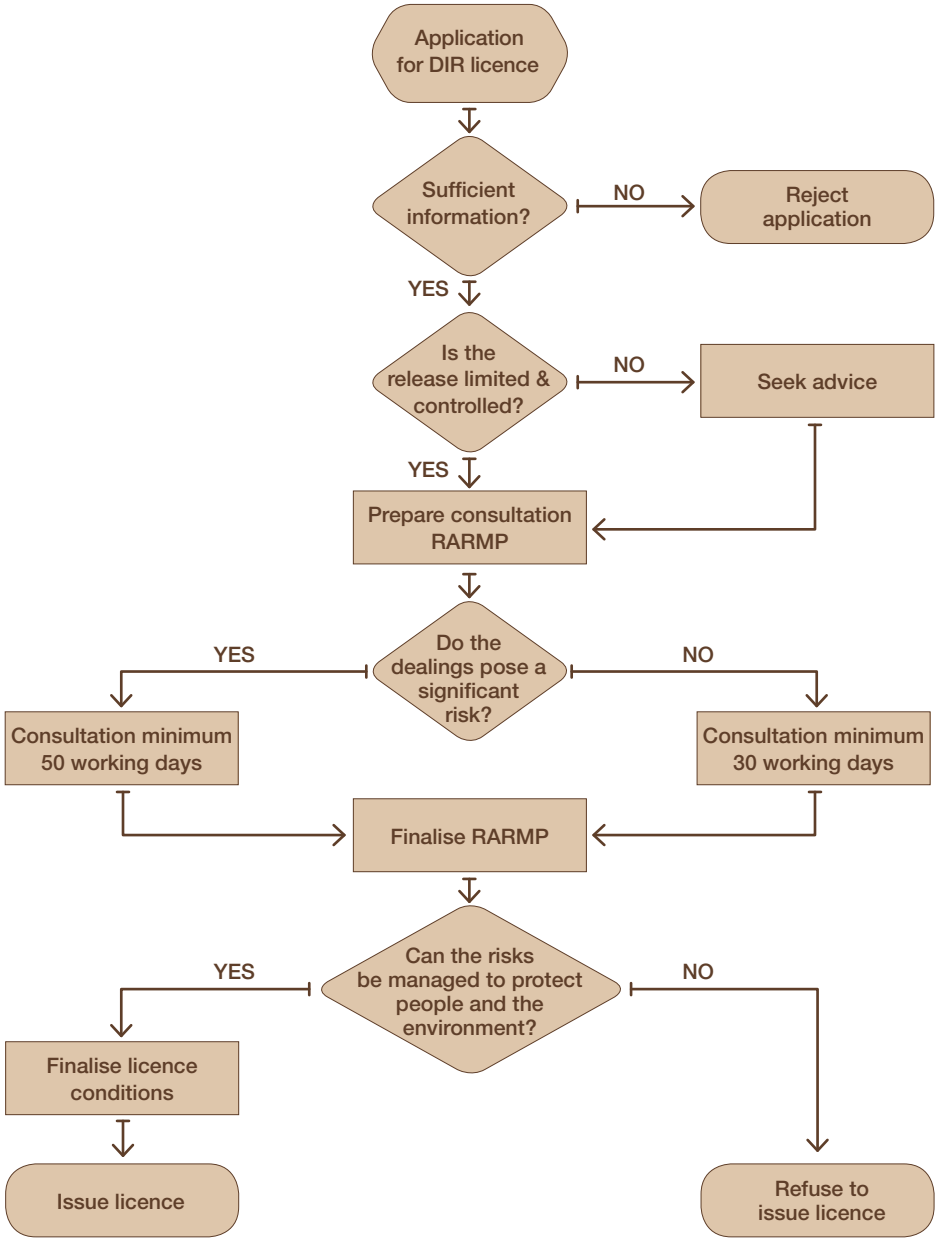
The Regulator is required to seek public comment on the consultation RARMP via advertisements in a national newspaper, in the Australian Government Gazette and place notices on the Regulator's website. In practice the Regulator advertises more broadly, including metropolitan and regional newspapers and specialist interest press and will advise by mail

or email all persons and organisations that have registered their interest in receiving such information on the OGTR mailing lists. Under section 52(3) of the Act the Regulator must also seek advice on the RARMP from the expert groups, agencies and authorities mentioned above (for consultation on the application).

The Regulator is required to consult with the Australian Government Environment Minister on DIR licence applications.

Stage 8 – 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 RARMP, having regard to any policy principles issued by the 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 OGTR website, advises all experts, agencies and authorities that were consulted and people or organisations that made submissions, and notifies registered recipients on the OGTR mailing list.

Figure A3: DIR assessment process



Inadvertent dealings

The Act (Part 5) allows the Regulator to grant a temporary licence (no longer than 12 months) to a person inadvertently dealing with an unlicensed GMO. The licence may be issued to the person for the purposes of disposing of the GMO. There is no requirement to prepare a RARMP or consult in relation to inadvertent dealing applications but the Regulator must not issue a licence unless satisfied that the risks posed by the dealings are able to be managed in such as way as to protect the health and safety of people and the environment.

Emergency dealing determinations

The EDD provision in the Act (section 72A–E) provides the relevant minister with the power to expedite an approval of a dealing with a GMO in an emergency. This recognises that situations may arise in which a rapid assessment of a proposed dealing with a GMO may be required. An EDD can only be made for a limited period (up to six months) but may be extended by the minister. Before making an EDD, the minister must be satisfied that:

- there is an actual or imminent threat to the health and safety of people or to the environment
- the dealings proposed to be specified in the EDD would, or would be likely to, adequately address the threat
- any risks posed by the dealings proposed to be specified in the EDD are able to be managed in such a way as to protect the health and safety of people and the environment.

The minister must receive advice in relation to the threat and addressing the threat from the Commonwealth Chief Medical Officer; the Commonwealth Chief Veterinary Officer; or the Commonwealth Chief Plant Protection Officer; and in relation to managing those risks from the Gene Technology Regulator. The states must also be consulted.

In developing the risk assessment advice for the minister, the Regulator will apply the principles embodied in the *Risk Analysis Framework* but is not required to follow the consultation processes that apply to DIR applications.

GMO Record

The Act requires the Regulator to maintain a record of approved GMOs and GM product dealings (the GMO Record, section 138). Details of licences issued (DNIR, DIR, inadvertent dealings), information about NLRDs, GMO dealings included on the GMO Register, EDDs and information about GM products approved by other regulatory authorities, are included on the GMO Record.

The GMO Record[4] is currently divided into separate sections for recording:

- GM products – those used in food processing, therapeutics, and pesticides and veterinary medicines
- notifiable low risk dealings – NLRDs
- contained dealings – DNIR licences
- intentional releases – DIR licences
- inadvertent dealing licences
- GMO Register
- emergency dealing determinations – EDDs.

Gene Technology Ministerial Council

The Gene Technology Ministerial Council (GTMC) oversees implementation of the legislation and the role of the Regulator. The GTMC was established by the *Gene Technology Agreement 2001* between the Australian Government and the governments of all states. The Agreement also commits state governments to enacting corresponding state legislation.

The role of the GTMC is to provide policy input into implementing and operating the regulatory scheme. In addition the GTMC 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.

The Act provides for the GTMC to issue policy principles on ethical issues relating to GMOs and 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). 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 Advisory Committees

The legislation creates two committees to provide advice to the Regulator and the GTMC: the GTTAC and GTECCC. Membership of the committees consists of persons with expertise in one or more scientific fields[5] – GTTAC – or with skills and experience in areas relevant to gene technology as specified in the Act.

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

5 Categories of expertise include molecular biology; ecology; plant, microbial, animal or human genetics; virology; entomology; agricultural or aquacultural systems; biosafety engineering; public health; occupational health and safety; risk assessment; clinical medicine; biochemistry; pharmacology; plant or animal pathology; botany; microbiology; animal biology; immunology; and toxicology.

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
- the need for and content of policy principles, policy guidelines, codes of practice and technical and procedural guidelines.

GTECCC – 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 ethics in respect of conducting dealings with GMOs
- the need for, and content of, policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons
- the need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products and the content of such principles, guidelines and codes
- community consultation in respect of the process for applications for licences covering dealings that involve the intentional release of a GMO into the environment
- risk communication matters in relation to dealings that involve the intentional release of a GMO into the environment
- matters of general concern identified by the Regulator in relation to applications made under this Act
- matters of general concern in relation to GMOs.

Accreditation and certification

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

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.

IBCs provide on-site scrutiny of low risk contained 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 applicants submit 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 at <http://www.ogtr.gov.au>.

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 trained and competent staff carry out those procedures and practices . Guidelines for certification of each type of facility (laboratory, plant house, aquaria, etc.) to physical containment (PC) levels 1, 2, 3 or 4, have been 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.

Coordination with other regulatory agencies

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 to the environment relating to 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.

During development of the gene technology legislation 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 legislation, relating to mutual consultation and exchange of information regarding their assessments and approvals.

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.

Situations arise where approval of particular dealings with a GMO requires approval by both the Regulator and another regulatory body; the respective roles of these agencies are listed, along with relevant legislation, in Table A3.

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

Similarly, while the Regulator must approve the environmental release of GM insecticidal or herbicide tolerant plants into the environment, the APVMA, which is responsible for regulating agricultural chemicals, must register the insecticidal gene product or approve application of the herbicide to which the GM plants are tolerant.

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 as 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.

An example of where this cannot apply is when 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.

Table A3: 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 and OGTR	Health and Ageing	OGTR provides a national scheme for the regulation of GMOs in Australia, in order to protect human health and 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 and tissues	TGA Therapeutic Goods Administration	Health and Ageing	TGA administers legislation that provides a national framework for the regulation of medicines, medical devices, blood and tissues in Australia, including GM and GM-derived therapeutic products, and ensures their quality, safety and efficacy.	*Therapeutic Goods Act 1989*
Food	FSANZ Food Standards Australia and New Zealand	Health and 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*
Agricultural and Veterinary Chemicals	APVMA Australian Pesticides and Veterinary Medicines Authority	Agriculture, Fisheries and Forestry	APVMA operates the national system that evaluates, registers and 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 and Veterinary Chemicals (Code) Act 1994;* *Agricultural and Veterinary Chemicals Administration Act 1994*

GMO/GM products	Agency	Portfolio	Scope	Relevant legislation
Industrial Chemicals	NICNAS/OCS National Industrial Chemicals Notification and Assessment Scheme/ Office of Chemical Safety	Health and Ageing	NICNAS provides a national notification and assessment scheme to protect the health of the public, workers and the environment from the harmful effects of industrial chemicals.	*Industrial Chemicals (Notification and Assessment) Act 1989*
Quarantine	AQIS Australian Quarantine and Inspection Service	Agriculture, Fisheries and Forestry	AQIS regulates the importation into Australia of all animal, plant and biological products that may pose a quarantine pest and/or disease risk. Import permit applications must indicate the presence of a GMO and the OGTR authorisation.	*Quarantine Act 1908;* *Imported Food Control Act 1992*

Notes: Further details of the Australian gene technology regulatory system are available on the OGTR website at <http://www.ogtr.gov.au>. Specific queries can be addressed to the OGTR freecall number (1800 181 030) or the OGTR email inbox (ogtr@health.gov.au).

APPENDIX B

Appendix B Risk analysis for a release of a GMO into the Australian environment

Legislation	
What is the primary legislation that covers the release of a GMO into the environment?	*Gene Technology Act 2000,* see <http://www.ogtr.gov.au/pubform/legislation.htm>
What is the purpose/object of the legislation with respect to GMOs?	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.
Is GMO defined?	Yes, section 10 of the Act
Which agency(ies) is responsible for the primary legislation?	Office of the Gene Technology Regulator (OGTR) see <http://www.ogtr.gov.au>
Who is the decision-maker(s)? What is their status?	Gene Technology Regulator (Regulator) Statutory office holder, accountable to Australian Parliament
What processes does the Agency follow to support the decision maker(s)?	OGTR staff prepare a draft of the risk assessment and risk management plan for the Regulator on each application. The Gene Technology Technical Advisory Committee provides expert advice to the Regulator on the application and draft risk assessment and risk management plan.
What is the trigger for regulation?	Process based, use of gene technology
What are the types of approvals granted? (for example, licence, notification, permit) Mandatory or voluntary?	Licences for DIRs (dealings involving intentional release of a GMO into the environment) and GMO Register (section 76) Mandatory system
What are the timeframes for the assessment process and do the approvals have a lifespan?	150 or 170 working days for limited and controlled releases 255 working days for general/commercial releases Licences for limited and controlled releases are time limited. Licences for general/commercial releases are usually not time limited.
Are all organisms covered? (for example, plants, animals, microbes, viruses, humans)	Yes, except humans that have undergone somatic cell therapy are not included in the definition of a GMO.
Does the system distinguish between different types of environmental release? (such as confined field trials and commercial releases)	Yes. Environmental releases are divided into two classes, namely: 'limited and controlled' (typically field trials) all others (typically commercial or general releases)
Are GM products covered?	GM products are regulated by other agencies, according to their use (for example, Food by FSANZ; agricultural products by APVMA; medical products by TGA; industrial chemicals by NICNAS)
Is the applicant required to pay fees for the regulatory process?	No
What other legislation and agencies regulate the use of GMOs?	Food Standards Australia New Zealand (FSANZ) see <http://www.foodstandards.gov.au> Australian Pesticides and Veterinary Medicines Authority (APVMA) see <http://www.apvma.gov.au> Therapeutic Goods Administration (TGA) see <http://www.tga.gov.au> National Industrial Chemicals Notification and Assessment Scheme (NICNAS) see <http://www.nicnas.gov.au>

Methodology	
Is there a guidance document publicly available on the risk analysis methodology and terminology?	Yes, *Risk Analysis Framework*, see <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>
What type of assessment methodology is used? (such as risk, safety, impact or effect assessments)	Case-specific, science-based risk assessment is required before approval.
What is the subject of the assessment?	Dealings with GMOs, which include: conduct experiments with; make, develop, produce or manufacture; breed; propagate; use in the course of manufacture of a thing that is not the GMO; grow, raise or culture; import; transport; dispose; and includes the possession, supply or use of the GMO for the purposes of the above activities.
Who does the assessment?	The Gene Technology Regulator with support from OGTR staff based on information supplied by the applicant, literature searches and expert advice.
What are the scope and boundaries of the assessment?	Health and safety of people and the environment (within the Australian territory) but excludes consideration of social, cultural or ethical values, or economic impacts.
What national/international standards and guidelines are used for the assessment?	Australian New Zealand Risk Management Standards (AS/NZS 4360:2004) OECD consensus documents WHO/FAO guidelines are used for guidance
Is a cost–benefit analysis performed?	No
Are qualitative or quantitative assessments used?	Qualitative, but using quantitative data where available.
Are data requirements and assessment endpoints specified?	Partially, the Act specifies issues that must be considered for the risk assessment and the Risk Analysis Framework provides additional guidance.
Are baseline comparisons used in the assessment?	Yes, comparison of GMO to non-GM parent and other baselines such as receiving environment
Is hazard identification performed as part of the assessment?	Yes, in the form of risk scenarios that postulate plausible causal or exposure pathways from dealings with a GMO to potential harm for people or a desirable environmental entity
Is there a risk calculation?	Yes, based on a combination of likelihood and consequences assessments.
Does the assessment include consideration of uncertainty?	Yes, uncertainty and its effect on the estimate of the level of risk and possible control measures are discussed.
Is there monitoring of compliance with conditions of the release?	Yes, a minimum of 20% of all sites is monitored each calendar year.
Are there provisions for regulatory oversight of the environmental release after the approval is granted?	Yes, including case-specific surveillance of an identified risk of commercial releases, verification of the assessment, reporting adverse experience/effects, and reviews.

Communication/consultation	
Are decisions publicly available?	Yes, available in the GMO record at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmorec-index-1>
Are applications publicly available?	Yes, upon specific request
Are assessments publicly available?	Yes, available as part of the GMO record at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmorec-index-1>
Is there consultation before approval of the release?	Yes, the legislation requires extensive consultation with the public, other regulators, state and local governments and a scientific advisory committee on the application and/or draft risk assessment.
Are advisory committees or groups consulted?	Yes, the Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee.
Are external experts consulted?	Yes, if required.
Are other government agencies consulted?	Yes. The Minister for the Environment; other federal regulatory agencies involved in regulating GMOs or GM products; designated state government agencies; and relevant local governments according to the location of the proposed release.
Is there an ability to hold a public forum on applications?	Yes, but not mandatory
Are there any provisions for 'in-confidence' material	Yes, see <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/cci>
Are the locations of field trial sites publicly available? (including environmental releases that are experimental, limited or contained)	Yes, see <http://www.maps.ogtr.gov.au/jsp/index.jsp>