



Australian Government

Department of Health and Ageing
Office of the Gene Technology Regulator

Risk Analysis Framework 2013



The background of the page is a light gray with a repeating pattern of abstract molecular structures. These structures consist of small gray circles (atoms) connected by thin gray lines (bonds). Some of these molecular clusters are enclosed within larger, thin gray circles. The overall aesthetic is clean and scientific.

Risk Analysis Framework 2013

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A MESSAGE FROM THE REGULATOR



It is with great pride that I present to you this fifth update of the *Risk Analysis Framework* (RAF). The RAF outlines the OGTR's approach to conducting risk assessment and preparing risk management plans and licence conditions. Importantly, it also outlines how we communicate with stakeholders about risk analysis. It is this latter purpose that has been the major focus for this revision of the RAF.

Effective communication of our activities is integral to maintaining and building stakeholder trust and confidence in and understanding of the regulatory system. The field of gene technology is a complex and rapidly advancing area of science and this is reflected in the increasingly complicated nature of the work being conducted with genetically modified organisms (GMOs). These factors present some risk communication challenges for all agencies involved in the regulation of GMOs. In addition, an ever expanding range of communication tools and technologies is becoming available. It is therefore timely that we have focused this revision of the RAF on the subject of risk communication.

The development of this edition of the RAF has benefited from advice from both the Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee. Apart from the many discussions within the office on the subject of risk communication, a number of staff have given valuable input to enhancements in other areas, reflecting our practical experiences in conducting regulatory risk analyses for GMOs. I would like to thank the risk analysis experts and others who provided constructive feedback that helped us to produce a better document. I would particularly like to thank Paul Keese for his commitment to the highest standards of risk analysis and for leading our periodic reviews of the RAF. Significant contributions were also made by Peter Thygesen, Robyn Cleland, Andrea Robold, Rebecca Newton, Will Tucker, Vidya Jagadish and others too numerous to mention. The product of these collaborations is a document that I believe keeps us at the forefront of international best practice for regulatory risk analysis of GMOs.

I commend the 2013 *Risk Analysis Framework* to you and welcome your feedback.

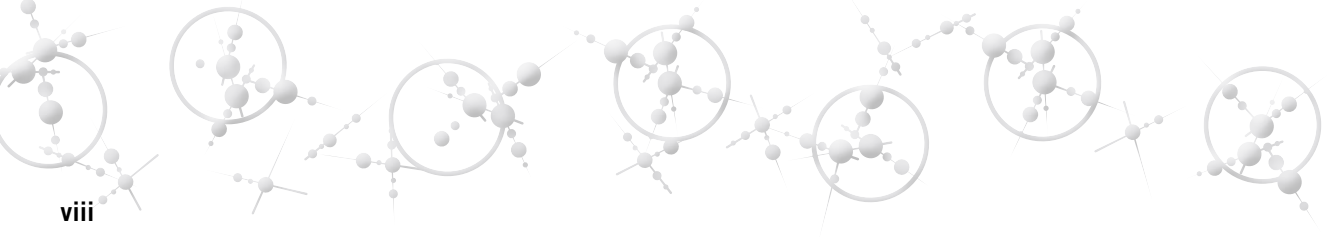
A handwritten signature in black ink, reading "R J Smith".

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 basis for using risk analysis to regulate activities with genetically modified organisms (GMO) in Australia. In particular, the Act mandates preparation of a risk assessment and risk management plan before issuing a licence.

Licences are required for release of a GMO into the environment or for specified GMOs in containment facilities. 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.

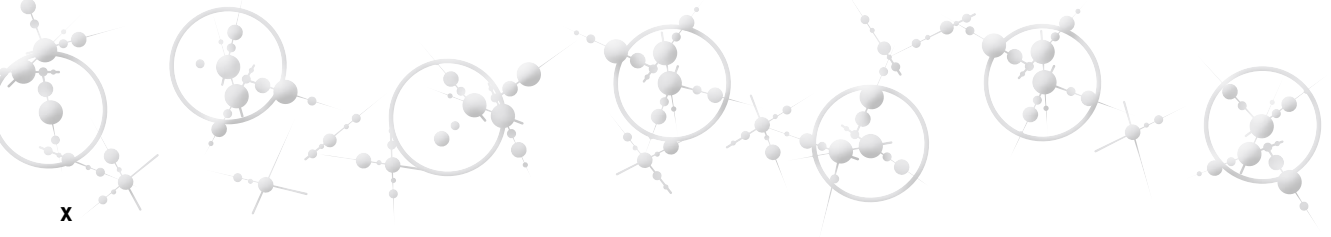
The *Risk Analysis Framework* provides guidance on how the Regulator, together with staff under the Regulator's direction in the Office of the Gene Technology Regulator (OGTR), implements risk analysis of GMOs in accordance with the Act and the Regulations.

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

- provide a guide to the current rationale and approach to risk analysis
- enable a consistent and rigorous risk analysis approach to evaluating licence applications
- provide transparency on the use of risk analysis for decision making.

This version of the *Risk Analysis Framework* incorporates recent advances in risk analysis, increased scientific knowledge, and 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 from gene technology, characterises the risks on the basis of seriousness and chance of harm, and evaluates the need for controls. Risk management 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 method used for risk analysis is based on the Australian Standard/New Zealand Standard ISO 31000:2009, *Risk Management—Principles and guidelines*.

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 defines the scope and boundaries, sets the criteria against which risk will be evaluated, and describes the structures and processes for the analysis. This includes setting criteria for what is considered as harm to people or the environment. The risk context is established within the framework of the legislative requirements of the Act and Regulations.

Decisions on licence applications require case-by-case assessment, including 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.

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

Risk assessment is a structured, reasoned approach for considering the chance of harm from certain activities with a GMO, based on scientific/technical evidence. The aim is to identify, characterise and evaluate 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

(consequences) and how likely it is that harm could occur within the context specified in the application. The level of risk is then evaluated by integrating consequences and likelihood, and the need for measures to reduce risk is considered where pertinent.

There is a focus on scientific/technical evidence in the risk assessment, taking into account any information received from consultation with experts and other stakeholders. This includes scientific/technical advice from the Gene Technology Technical Advisory Committee. In addition, there is consideration of knowledge gaps and other forms of uncertainty.

The risk assessment initially considers a wide range of potential pathways whereby harm might occur. Those pathways that describe substantive risks are considered in more detail and the level of risk evaluated.

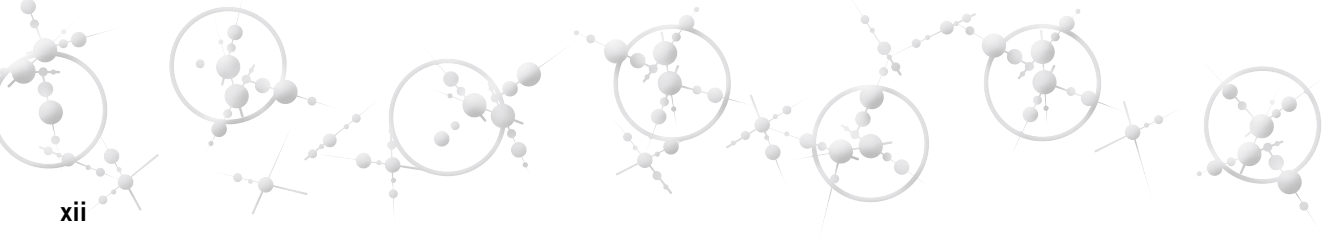
Risk assessment identifies substantive risks and evaluates the level of risk based on a combination of the likelihood and consequences of potential harm.

Risk management protects the health and safety of people and the environment by controlling or mitigating risk. Risk management may be described as answering the following questions: Does anything need to be done about the risk? What can be done about it? What should be done about it? Risk management involves judgments about the choice and application of treatment measures to support decisions about whether certain activities with GMOs should be permitted.

Risk management includes preparation of a risk management plan as well as monitoring and reviewing to provide feedback on all steps in the risk analysis. The risk management plan includes licence conditions that stipulate measures to control or reduce risk. Monitoring and reviewing ensure that decisions remain valid and can be adjusted in response to changes in circumstances or new information.

The risk assessment and risk management plan forms the basis upon which the Regulator decides whether to issue or refuse a licence, and what conditions to impose if a licence is issued. 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 determines appropriate control measures to manage risk and applies these through proposed licence conditions.



Risk communication is integral to the processes of risk analysis and involves an interactive dialogue between the Regulator and stakeholders to build trust in the regulatory system by discussing issues and addressing concerns relating to protecting the health and safety of people and the environment.

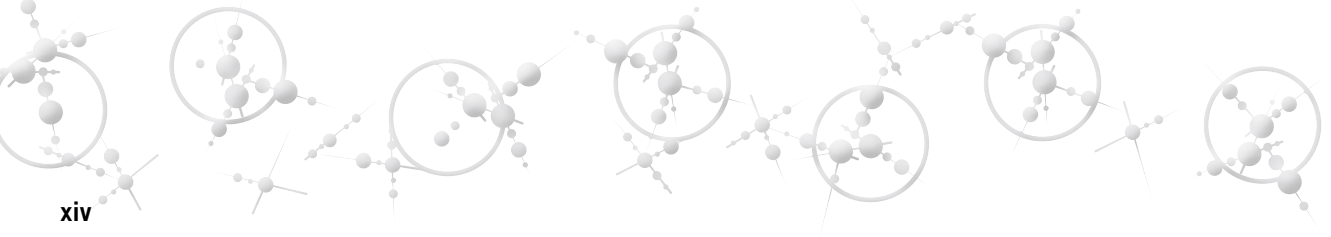
The Regulator undertakes extensive consultation with a diverse range of expert groups and authorities and key stakeholders, including the public, before deciding whether to issue a licence for the release of a GMO into the environment. Differing perceptions of risk can influence the approach of stakeholders to particular issues, and in such instances the Regulator can seek advice on ethical and social issues raised by gene technology from the Gene Technology Ethics and Community Consultative Committee.

The Regulator provides accessible information to interested parties on applications, risk assessment and risk management plans, dealings with GMOs, trial sites and the processes of risk assessment, risk management, and monitoring and compliance activities. The *Risk Analysis Framework* is part of the Regulator’s commitment to clarity, transparency and accountability of decision-making processes.

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
AS/NZS	Australian Standard/New Zealand Standard
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DAFF	Department of Agriculture, Fisheries and Forestry
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
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
IPPC	International Plant Protection Convention
LGFGT	Legislative and Governance Forum on Gene Technology
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NLRD	notifiable low-risk dealing
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
EPA	United States Environmental Protection Agency
WHO	World Health Organization

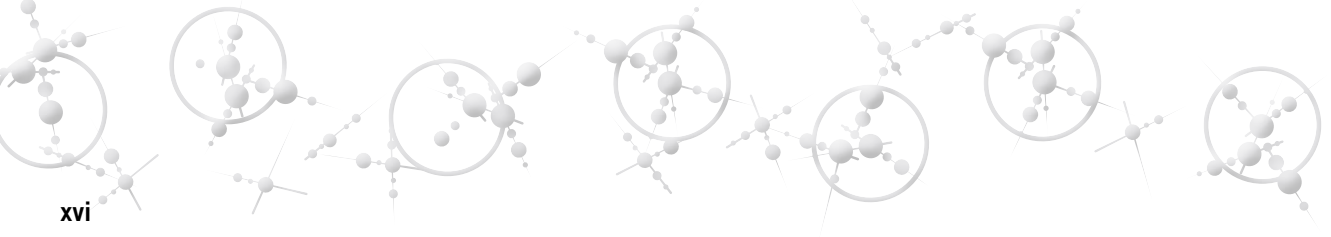


Glossary

Notes: Terms marked with an asterisk* are defined by the *Gene Technology Act 2000*; risk-related terms are based on AS/NZS ISO 31000:2009 *Risk Management—Principles and guidelines*. See also enHealth (2012).

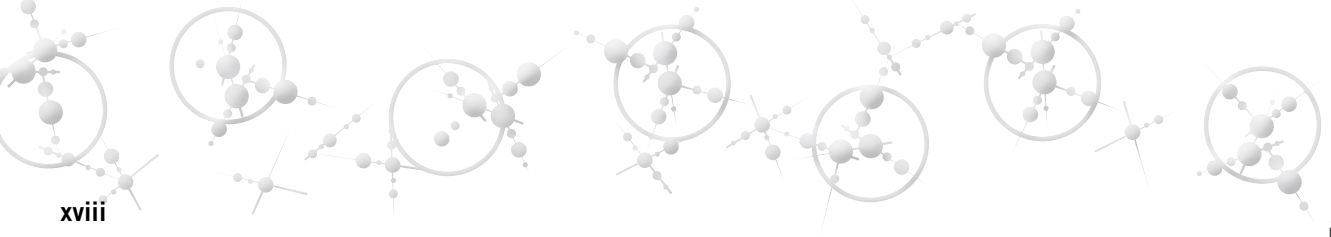
consequence	<p>Harm to protection goals from an activity.</p> <p>NOTE 1: Protection goals are the health and safety of people and the environment.</p> <p>NOTE 2: A consequence assessment determines the degree of seriousness of harm ranging from marginal to major.</p> <p>NOTE 3: An activity can lead to a range of consequences.</p> <p>NOTE 4: Initial consequences can escalate through knock-on effects.</p>
deal with*	<p>In relation to a GMO, means:</p> <ul style="list-style-type: none">a) conduct experiments with the GMOb) make, develop, produce or manufacture the GMOc) breed the GMOd) propagate the GMOe) use the GMO in the course of manufacture of a thing that is not the GMOf) grow, raise or culture the GMOg) import the GMOh) transport the GMOi) dispose of the GMO <p>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).</p> <p>NOTE 1: ‘Deal with’ defines those activities with a GMO that are subject to regulation.</p>
environment*	<p>Includes:</p> <ul style="list-style-type: none">a) ecosystems and their constituent parts; andb) natural and physical resources; andc) the qualities and characteristics of locations, places and areas.

gene technology*	<p>Any technique for the modification of genes or other genetic material, but does not include:</p> <ul style="list-style-type: none"> a) sexual reproduction; or b) homologous recombination; or c) any other technique specified in the Regulations for the purposes of this paragraph.
genetically modified organism*	<ul style="list-style-type: none"> 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, <p>but does not include:</p> <ul style="list-style-type: none"> 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	<p>Adverse outcome or impact.</p> <p>NOTE 1: Harm refers to damage or injury to the health and safety of people or to the environment. This may include change in the morphology, physiology, growth, development, reproduction or life span of an organism or group of organisms that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences. Many biological changes are not considered inherently adverse.</p>
likelihood	<p>Chance.</p> <p>NOTE 1: Likelihood is a general description of the probability, frequency or possibility of causal links in a postulated pathway to harm.</p> <p>NOTE 2: A likelihood assessment determines the chance that harm may occur, ranging from highly unlikely to highly likely.</p>



monitoring	<p>Ongoing checking, supervising, critically observing or determining the status in order to identify change from the performance level required or expected.</p> <p>NOTE 1: A primary role is monitoring for compliance with licence conditions to ensure that the risk management plan is adhered to.</p>
post-release review	<p>Ongoing oversight of general/commercial releases, focused on verifying the findings of the risk assessment and risk management plan and providing feedback into risk analysis.</p>
protection goals	<p>The health and safety of people and the environment.</p>
review	<p>Activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve protection goals.</p>
risk	<p>Potential for harm from an activity.</p> <p>NOTE 1: In the context of the <i>Gene Technology Act 2000</i>, 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.</p> <p>NOTE 2: Risk includes the effect of uncertainty on protection goals.</p> <p>NOTE 3: The level of risk is evaluated according to the degree of seriousness and chance of harm occurring.</p>
risk analysis	<p>Overall process of risk assessment, risk management and risk communication.</p> <p>NOTE 1: Synonymous with 'risk management' as used in AS/NZS ISO 31000:2009 <i>Risk Management—Principles and guidelines</i>.</p>
risk analysis framework	<p>Guidance on the systematic application of legislation, policies, procedures and practices to risk analysis.</p>
risk assessment	<p>Process of risk identification, risk characterisation and risk evaluation.</p> <p>NOTE 1: Risk assessment is a specific requirement of the <i>Gene Technology Act 2000</i>.</p> <p>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.</p>

risk characterisation	<p>Process to comprehend the nature of risk in terms of consequences and likelihood.</p> <p>NOTE 1: Synonymous with ‘risk analysis’ as used in AS/NZS ISO 31000:2009 <i>Risk Management—Principles and guidelines</i>.</p>
risk communication	<p>Continual and iterative process to provide, share or obtain information and to engage in dialogue with stakeholders regarding the analysis of risk.</p>
risk context	<p>Parameters to be taken into account when analysing risk, including the scope and risk criteria.</p>
risk criteria	<p>Terms of reference against which the significance of risk is evaluated.</p>
risk evaluation	<p>Process of comparing the results of risk characterisation with risk criteria to determine if the risk requires risk treatment.</p> <p>NOTE 1: Risk evaluation combines the consequences and likelihood assessments to determine the level of risk and whether risk treatment is required to reduce the level of risk.</p>
risk identification	<p>Process of finding, recognising and describing risks.</p> <p>NOTE 1: Risk identification involves the postulation of risk scenarios that may represent risks greater than negligible and therefore warrant detailed risk characterisation.</p>
risk management	<p>Process to control and mitigate risk.</p> <p>NOTE 1: The purpose of risk management is to protect the health and safety of people and to protect the environment.</p> <p>NOTE 2: Components of risk management include preparation of a risk management plan and ongoing oversight through monitoring and reviewing.</p>
risk management plan	<p>Scheme for managing risk posed by dealings with a GMO.</p> <p>NOTE 1: The risk management plan refers to a specific requirement of the <i>Gene Technology Act 2000</i>.</p> <p>NOTE 2: The risk management plan is implemented through licence conditions that address both risk treatment and general risk management measures.</p>



risk scenario	<p>A set of conditions or circumstances that may occur and result in harm from a risk source.</p> <p>NOTE 1: A risk scenario describes a credible causal pathway through which activities with a GMO could lead to harm due to exposure to a changed attribute of the GMO or of its products, or to the introduced genetic material.</p> <p>NOTE 2: Risk scenario encompasses the term ‘event’ as defined in AS/NZS ISO 31000:2009 <i>Risk Management—Principles and guidelines</i>.</p>
risk source	<p>Element which alone or in combination has the intrinsic potential to give rise to risk.</p> <p>NOTE 1: The risk source relates to changed attributes of the GMO or of its products that are due to gene technology.</p>
risk treatment	<p>Process of selection and implementation of measures to reduce risk.</p>
Stakeholders	<p>Those people and organisations that may affect, be affected by, or perceive themselves to be affected by a decision, activity or risk.</p>
States	<p>Includes all State governments, the Australian Capital Territory and the Northern Territory governments.</p>
Uncertainty	<p>Imperfect ability to assign a character state.</p> <p>NOTE 1: ‘Character state’ includes reference to properties such as time, number, occurrences, dimensions, scale, location, magnitude, quality, nature, causality or the like.</p> <p>NOTE 2: Different types of uncertainty include uncertainty of facts (eg knowledge or variability) or ideas (eg perception or descriptions).</p> <p>NOTE 3: In relation to risk, there can be uncertainty about the level of risk, including identifying the risk source, the causal linkage to harm, the type and degree of harm, or the chance of harm occurring. In relation to risk management, there can be uncertainty about the effectiveness, efficiency and practicality of controls.</p>

The background features a teal-colored lower half and a white upper half, separated by a diagonal line. The teal section is decorated with faint, stylized molecular structures. The white section contains two interlocking puzzle pieces and more molecular diagrams. The text 'CHAPTER 1: INTRODUCTION' is positioned in the white area, above the puzzle pieces.

CHAPTER 1: INTRODUCTION

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 this technology. However, prior to 2000, activities with GMOs were overseen by a voluntary system that lacked monitoring and enforcement powers. 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 laws¹, replaced a voluntary scheme administered by the Genetic Manipulation Advisory Committee. A summary of the gene technology regulatory system and certain legislative requirements relevant to risk analysis is provided in 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. Risk analysis is used to support the decision-making process.

This *Risk Analysis Framework* is a key document for providing guidance about the Regulator's approach to applying risk analysis. It is the primary risk analysis reference for Office of the Gene Technology Regulator (OGTR) staff and may also be useful to a range of stakeholders including:

- licence applicants and the community that is subject to regulation
- government agencies involved in regulating GMOs or GM products
- stakeholders who provide advice to the Regulator on licence applications
- regulators of GMOs from other international jurisdictions
- individuals and groups interested in the regulation of GMOs in Australia.

The Regulator will revise this document as experience, scientific consensus and regulatory practice evolve.

¹ In 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.

Purpose of the *Risk Analysis Framework*

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

- provide guidance on the current rationale and approach to risk analysis
- enable a consistent and rigorous risk analysis approach to evaluating applications for licences and making decisions about other classes of GMO dealings
- provide transparency on the use of risk analysis to support decision making.

The *Risk Analysis Framework* seeks to:

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

The method used for risk analysis is based on the AS/NZS ISO 31000:2009 *Risk Management—Principles and guidelines* (Standards Australia 2009) (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 Regulator is responsible for regulating certain activities (dealings) with GMOs to protect people and the environment. GMOs include organisms that have been modified by gene technology or have inherited a trait that occurred as a result of gene technology.

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 dealings² 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.

There are two categories of GMO licence.

1. Dealings that involve intentional release of a GMO into the environment (DIR). This includes limited and controlled releases, such as field trials for experimental purposes and general/commercial releases.
2. Dealings that do not involve intentional release of a GMO into the environment (DNIR). This mostly includes GMOs in containment facilities that are usually certified to a specified level of physical containment (PC).

Before issuing a licence, the Regulator must prepare an RARMP in relation to the proposed dealings (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* is primarily intended to inform consideration of applications for DIR and DNIR licences.

When the Regulator conducts risk assessments for other classes of dealings (eg notifiable low-risk dealing, exempt dealing, placing a GMO on the Register or an emergency dealing determination), the same approach to risk analysis described here will be applied.

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

Identifying and managing risks

Risk is defined³ as the 'potential for harm from an activity'. This includes the effect of uncertainty on protection goals, namely the health and safety of people and the environment. The level of risk is evaluated according to the degree of seriousness and chance of harm that can be attributed to gene technology. Regulation is triggered by gene technology, rather than by a novel trait per se.

Processes other than gene technology may 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 also be generated by chemical or radiation mutagenesis, wide crosses, or by conventional breeding practices. Similarly, alterations in virulence or pathogenicity of a micro-organism can occur by chemical or radiation mutagenesis, or natural recombination. Experience with organisms that have similar traits generated without use of gene technology provides useful information for considering potential risks from a GMO.

Where possible, risks are identified using a comparative risk assessment, such that risk from dealing with a GMO is considered relative to the parent organism within the environment where the GMO is expected to be present, including standard management practices. The focus of the assessment is whether traits modified by 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.

Managing risk is achieved by imposing licence conditions that place controls and limits on certain activities with the GMO. For example, conditions might be imposed to restrict 1) spread and persistence of the GMO, its progeny or the introduced genes, and 2) exposure of people and the environment to the GMO or its products.

Protection

Protective measures are applied at all stages in the regulation of gene technology.

Protective measures before authorisation of a dealing with a GMO are achieved by:

- prohibiting dealings with GMOs unless authorised under the Act
- having provisions in the Act allowing the Regulator to refuse a licence

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

- conducting risk assessments that rely on credible evidence and consideration of uncertainty in preparation of RARMPs
- identifying risk management controls that are effective
- using scientific and regulatory expertise within and outside the OGTR
- consulting with Australian Government agencies, State governments, the Australian Government Environment Minister and the public
- having 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.

The Regulator must not issue a licence unless satisfied that risks can be managed (section 56(1)).

Protective measures after authorisation of a dealing with a GMO are achieved by:

- applying specific licence conditions to manage risk
- applying licence conditions that limit and control dealings and ensure important parameters of the risk context remain appropriate
- having statutory licence conditions such as reporting of additional information about risks to people or to the environment, contravention of a licence, or unintended effects (section 65)
- requiring compliance with licence conditions
- having provisions in the Act that allow the Regulator to suspend, vary or cancel a licence
- requiring the applicant to provide sufficient information regarding the identity of each GMO and the locations of facilities used to contain the GMO, the exact coordinates of limited and controlled releases, and the amounts of the GMO for general/commercial releases
- monitoring of facilities and release sites by the OGTR
- having post-release review for general/commercial releases of the GMO
- maintaining awareness of new scientific findings and adverse events reporting
- requiring contingency/emergency plans.

Protective measures address the development process for a GMO intended to be released into the environment, which typically follow a stepwise approach involving:

- initial laboratory-based research in physical containment
- small-scale experimental releases (such as field trials) with conditions to limit and control the release in space and time
- general/commercial releases, with or without specific limits or 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, as well as international experience of the same GMO. This enables a body of evidence to be assembled about risks, while ensuring that human health and safety and the environment are protected.

There are also GMOs that are not intended to be released into the environment but are the subject of ongoing research in containment facilities. In these cases, protection is largely focused on the level of containment, which in the case of a micro-organism is often informed by the level of risk of the parent organism (Standards Australia 2010a).

Although protective measures are intended to minimise harm, all activities and decisions involve some level of risk. Therefore, protective measures should be commensurate with the level of risk.

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

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

Assessment of risk to the health and safety of people includes consideration of the occupational health and safety of people dealing with a GMO, as well as the general public who may come into contact with the GMO or material derived from the GMO. The risk depends on the effects of the genetic modification and exposure of people to the GMO, and the introduced genetic material and/or its products. In particular, there is consideration of potential for increased toxicity, allergenicity, disease or injury as a result of the possible production of a novel product or by altered production of an endogenous product.

Harm to the health of people may also occur through production of other types of compounds (eg anti-nutrients that interfere directly with absorption of vitamins, minerals and other nutrients); reduced production of key nutrients or other compounds that promote good health (such as antioxidants); endocrine disruptors; and/or factors that induce autoimmunity or tumour formation.

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.

This definition of *environment* in the Act differs from the definition in the *Environmental Protection and Biodiversity Conservation Act 1999*, which also includes reference to heritage values of places and social, economic and cultural aspects.

Assessment of risk to the environment includes consideration of effects on biotic and abiotic components of the environment. Harm to the environment may result from:

- impaired health of organisms due to toxicity or disease
- reduced quality of biotic components (eg reduced biodiversity)
- reduced quality of abiotic components (eg soil, water or air)
- disruption of ecosystem processes (eg altered nutrient levels or fire regimes).

Different risks may be identified for different land uses and areas. For example, the potential weediness of a GMO may differ between agricultural and undisturbed environments. In addition, risks may be dependent upon the availability of hosts for infectious agents, symbionts or parasites, or food and shelter for pest animals.

Regulatory framework to achieve the object of the Act

The legislation provides that the object of the Act is to be achieved through a regulatory framework (section 4), which:

- (aa) provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation

- (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 reduce risk 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 are acquired to provide confidence in their 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) or lack a plausible causal pathway to indicate threats of serious or irreversible environmental damage from a GMO (Patterson & Gray 2012). In addition, precautionary approaches that require controls in excess to the level of risk may stifle research and development, and delay implementation of beneficial technologies.

The aim of providing an efficient and effective system of regulation for the application of gene technology, as described in section 4(a), is supported by other sections of the legislation. These include:

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

The latter also supports section 4(b), which requires the regulatory system to operate in a consistent way with existing Australian and State government regulation relevant to GMOs and GM products (see Appendix A).

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

- Australian Pesticides and Veterinary Medicines Authority (APVMA), which regulates pesticides and veterinary medicines containing GMOs or GM products, including evaluation of human health and safety, product efficacy, environmental safety and effects on trade from residues
- Food Standards Australia New Zealand (FSANZ), which is responsible for developing and administering the Australia New Zealand Food Standards Code, which lists requirements for foods such as additives, food safety, labelling and GM foods
- Therapeutic Goods Administration (TGA), which regulates the quality, safety and efficacy of therapeutic products, including human medicines that contain GMOs or GM products
- National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which covers evaluation of industrial chemicals, including relevant GM products, for occupational health and safety and environmental safety
- Department of Agriculture, Fisheries and Forestry (DAFF), which has responsibility for managing the potential quarantine risks associated with imported goods. Imported GMOs must meet relevant import conditions as well as those required by the Regulator.

In addition, the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) administers the *Environment Protection and Biodiversity Conservation Act 1999*, which provides for the protection of the environment, with emphasis on matters of national environmental significance.

CHAPTER 2: RISK ANALYSIS APPROACH USED BY THE OGTR

CHAPTER 2: RISK ANALYSIS APPROACH USED BY THE OGTR

This chapter describes the risk analysis approach used by the OGTR and the national and international sources that informed development of this approach. In addition, the role of uncertainty in risk analysis is discussed, and the principles guiding the Regulator's use of risk analysis are outlined.

Models of risk analysis

The AS/NZS ISO 31000:2009 *Risk Management—Principles and guidelines* (Standards Australia 2009) has been developed to guide organisations that deal with risk. According to AS/NZS ISO 31000:2009, 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 2004), the International Plant Protection Convention (IPPC), and the Codex Alimentarius Commission (Codex Alimentarius Commission 2003) provide standards and guidance for risk analysis in the specific areas of animal, plant and human health risks.

The first comprehensive guidance on risk analysis of GMOs was published by the Organisation for Economic Co-operation and Development (OECD 1986; Bergmans 2006) based on the logic and rationale for health and environmental risk assessments in a 1983 report from the US Academy of Sciences National Research Council (Jardine et al. 2003; National Research Council 1983; National Research Council 2008).

National guidance material on risk analysis of human health and environmental risks from biological organisms, such as that developed for plants (Standards Australia 2006) and micro-organisms (Standards Australia 2010a), also provides useful models for risk analysis of GMOs. Other useful national guidance is provided by the risk assessment model for environmental health (enHealth 2012).

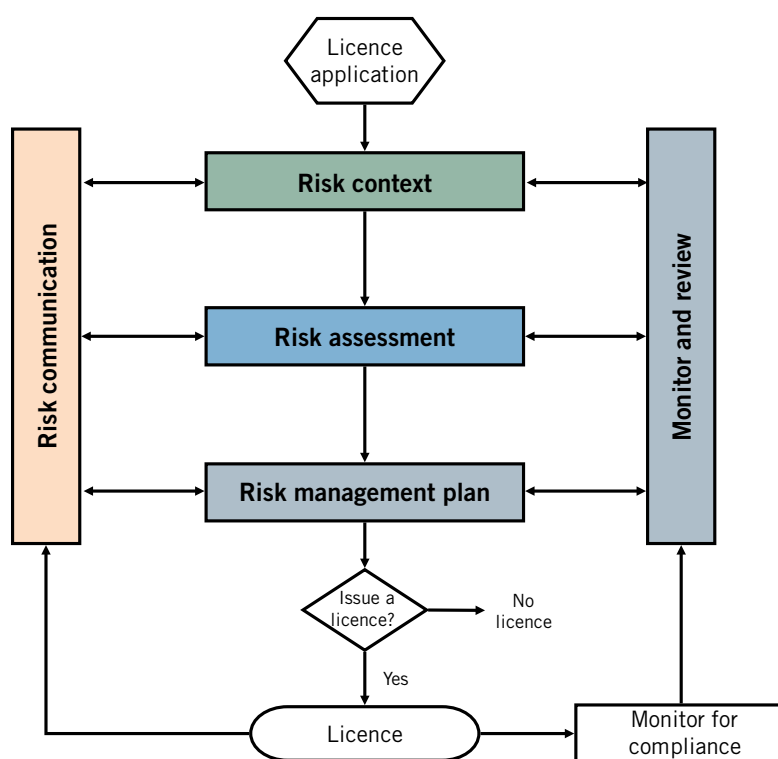
Annex III of the United Nations Cartagena Protocol on Biosafety (Secretariat of the Convention on Biological Diversity 2000) also provides guidance for risk assessments of GMOs, but does not detail how to perform the assessments.

This version of the *Risk Analysis Framework* is most closely aligned with AS/NZS ISO 31000:2009; however, all of these models were considered in its preparation.

OGTR risk analysis method

The risk analysis method the Regulator uses for GMO licence applications (Figure 2.1) is based on AS/NZS ISO 31000:2009 *Risk Management—Principles and guidelines* (Standards Australia 2009). However, this process is not necessarily linear as there is significant iteration of each step during the preparation of an RARMP for each licence application.

Figure 2.1: Risk analysis method for GMO licence applications



Components in risk analysis

Risk context

Establishing the risk context (see Chapter 3) is the preparatory step that defines the scope and boundaries, sets the criteria against which risk will be evaluated, and describes the structures and processes for the analysis. This includes setting criteria for what is considered as damage or injury to people or the environment. The risk context is established within the framework of the legislative requirements of the Act and Regulations.

Decisions on licence applications require case-by-case assessment, including preparation of an RARMP. Details of the GMO and the proposed activities, including any proposed controls, limits or containment measures, form the specific context for the RARMP. Details of the parent organism and the environment where activities with the GMO will occur form the comparative baselines.

Risk assessment

Risk assessment (see Chapter 4) is a structured, reasoned approach to consider the potential for harm from certain activities with a GMO, based on scientific/technical evidence and consideration of uncertainty. The aim is to identify, characterise and evaluate 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 initially considers a wide range of potential pathways whereby harm might occur. Those pathways that identify substantive risks are considered in more detail by characterising how serious the harm could be (consequences) and how likely it is that harm could occur. The level of risk is then evaluated to determine whether measures to reduce risk are required.

Identifying and characterising risk relies on scientific/technical evidence, involving consultation with experts and other stakeholders, as well as consideration of knowledge gaps and other forms of uncertainty.

Risk management

Risk management (see Chapter 5) may be described as answering the following questions: Does anything need to be done about the risk? What can be done about it? What should be done about it? Risk management involves judgments about the choice and application of treatment measures to support decisions about whether certain activities with GMOs should be permitted.

Risk management includes the preparation of a risk management plan and monitoring and reviewing to provide feedback on all steps in the risk analysis. The risk management plan

includes licence conditions that stipulate measures to control or reduce risk. Monitoring and reviewing ensure that decisions remain valid and that decisions can be adjusted to account for changes in circumstances or new information.

The RARMP forms the basis upon which the Regulator decides whether to issue or refuse a licence, and what conditions to impose if a licence is issued. To issue a licence the Regulator must be satisfied that risks posed by proposed dealings with a GMO can be managed to protect human health and safety and the environment. If the Regulator considers that risks cannot be managed, a licence must be refused.

Risk communication

Risk communication (see Chapter 6) engages in dialogue about the risks to human health and the environment posed by certain dealings with a GMO. It includes extensive consultation with experts and specified stakeholders during preparation of RARMPs for DIR applications. This includes people who may be affected by risks from the GMO or the proposed controls. The Regulator may also consult with experts on DNIR applications.

Risk communication is integral to the processes of risk assessment and risk management. It involves an interactive dialogue between the Regulator and stakeholders to build trust in the regulatory system by discussing issues and addressing concerns.

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 for the release of a GMO into the environment. In many instances, differing perceptions of risk can influence the approach of stakeholders to particular issues.

The Regulator provides accessible information to interested parties on applications, licences, dealings with GMOs, trial sites, and the processes of risk assessment, risk management, monitoring and compliance activities undertaken by the OGTR. The *Risk Analysis Framework* is part of the Regulator's commitment to clarity, transparency and accountability for decision-making processes.

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; Standards Australia 2009; USEPA 1998; Wolt et al. 2010). The main risk analysis terms used in this framework are described in Table 2.1, which also provides alternative terms used in other frameworks to describe components of risk with similar functions.

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

Terms used here	Related terms described in other risk frameworks
RISK ANALYSIS	RISK MANAGEMENT
Risk context	Planning, Preparation, Problem formulation
Risk assessment	
Risk identification	Problem formulation, Risk hypothesis, Hazard identification, Conceptual model
Risk characterisation	Risk analysis
Risk evaluation	Risk profile, Risk estimate
Risk management	
Risk treatment	Risk control, Risk reduction, Risk mitigation
Monitoring and review	
Risk communication	

Sources: FAO & WHO 2006; Hill 2005; National Research Council 1983; OIE 2004; Raybould 2006; Standards Australia 2009; USEPA 1998; Wolt et al. 2010

Risk characterisation relates to assessment of the chance and seriousness of harm. According to AS/NZS ISO 31000:2009 *Risk Management—Principles and guidelines*, this is described by the terms ‘Likelihood’ and ‘Consequences’, which are used here. However, many other terms are used in the literature depending on the source of risk (Table 2.2).

Table 2.2: Alternative terms to Consequences and Likelihood

RISK CHARACTERISATION			
Risk source	Type of concern	Consequences	Likelihood
Physical	Hazard ⁴	Hazard	Exposure
Chemical	Toxicity	Hazard, Dose response	Exposure
Plant/Animal	Weed/Pest	Impact	Invasiveness
Micro-organism	Pathogenicity, Disease	Symptoms, Virulence	Infectivity

⁴ Hazard is also considered as a source of potential harm that is equivalent to ‘risk source’ (see Glossary).

Uncertainty

Uncertainty is an intrinsic part of risk analysis. There can be uncertainty about identifying the risk source, the causal linkage to harm, the type and degree of harm, or the chance of harm occurring, or the level of risk. In relation to risk management, there can be uncertainty about the effectiveness, efficiency and practicality of controls.

Risk analysis can be considered as part of a first tier uncertainty analysis, namely a structured, transparent process to analyse and address uncertainty when identifying, characterising and evaluating risk. However, there is always some residual uncertainty that remains. If the residual uncertainty is important and critical to decision making, then this residual uncertainty may be subjected to further analysis (= second tier uncertainty analysis), such as building 'worst case' scenarios, or by using meta-analysis where results from several studies are combined.

There are several types of uncertainty in risk analysis (Bammer & Smithson 2008; Clark & Brinkley 2001; Hayes 2004). These include:

- uncertainty about facts
 - knowledge—data gaps, errors, small sample size, use of surrogate data
 - variability—inherent fluctuations or differences over time, space or group, associated with diversity and heterogeneity
- uncertainty about ideas
 - description—expression of ideas with symbols, language or models can be subject to vagueness, ambiguity, context dependence, indeterminacy or under-specificity
 - perception—processing and interpreting risk is shaped by our mental processes and social/cultural circumstances, which vary between individuals and over time.

Some typical approaches to addressing uncertainty in the risk analysis include:

- establishing parameters for data quality
- obtaining additional data
- identifying and correcting errors
- applying conservative estimates
- using upper and lower bounds of estimates
- seeking expert opinion (eg GTTAC) or independent review

- providing clear definitions of key words
- prioritising by re-evaluation against objectives, scope and risk criteria
- applying additional controls/containment to manage risk
- applying second tier uncertainty analysis.

Explicit consideration of uncertainty in risk analysis facilitates:

- increased clarity, consistency, credibility, repeatability and transparency in the decision-making process
- highlighting of areas where more effort is needed to improve conclusions
- clearer distinction of the values and facts used in decision making
- addressing issues and concerns of stakeholders
- more effective communication about risk.

Analysis and treatment of uncertainty are conducted on a case-by-case basis according to the type of uncertainty, proportionality to the level of risk and importance in the decision-making process.

Guiding principles of risk analysis

For risk analysis to be effective, a number of principles are followed to ensure the goals of the gene technology regulatory scheme are achieved. These guiding principles are adapted from AS/NZS ISO 31000:2009 *Risk Management—Principles and guidelines*. They are also consistent with those described by the Australian Government Department of Health and Ageing for environmental health risk assessment (enHealth 2012). They are:

- a) Risk analysis creates and protects value.**
Risk analysis contributes to the demonstrable achievement of objectives to protect the health and safety of people, and to protect the environment.
- b) Risk analysis is an integral part of all organisational processes.**
Risk analysis is not a stand-alone activity that is separate from the main activities and processes of the organisation, but integral to the whole regulatory process.

- c) **Risk analysis is part of decision making.**
Risk analysis helps the Regulator make informed choices, prioritise actions and distinguish among alternative courses of action.
- d) **Risk analysis explicitly addresses uncertainty.**
Risk analysis explicitly takes account of uncertainty, the nature of that uncertainty, and how it can be addressed.
- e) **Risk analysis is systematic, structured and timely.**
A systematic, timely and structured approach to risk analysis contributes to efficiency and to consistent, comparable and reliable results.
- f) **Risk analysis is based on the best available information.**
The inputs to analysing risk are based on information sources such as scientific evidence, historical data, experience, stakeholder feedback, observation, forecasts and expert judgment. This takes into account any limitations of the evidence or the possibility of divergence among experts.
- g) **Risk analysis is tailored.**
Risk analysis is aligned with the regulatory context and risks to the health and safety of people and to the environment.
- h) **Risk analysis takes human and cultural factors into account.**
Risk analysis, in particular risk communication, recognises the capabilities, perceptions and intentions of OGTR staff and external people who can facilitate or hinder achievement of the regulatory objectives.
- i) **Risk analysis is transparent and inclusive.**
Appropriate and timely involvement of stakeholders and, in particular, the Regulator and OGTR staff ensures that risk analysis remains relevant and up to date. Involvement also allows stakeholders to be properly represented and to have their views taken into account in determining risk criteria.
- j) **Risk analysis is dynamic, iterative and responsive to change.**
Risk analysis continually senses and responds to change. As external and internal events occur, context and knowledge change, monitoring and review of risks take place, and new risks emerge, change or disappear.
- k) **Risk analysis facilitates continual improvement.**
Strategies are developed and implemented to improve risk analysis expertise.

In addition to these general principles, the Regulator supports the ethical application of gene technology by researchers and users. The *National Framework of Ethical Principles in Gene Technology 2012* issued by the Gene Technology Ethics and Community Consultative Committee (GTECCC) provides 10 key ethical principles relating to gene technology, and to genetically modified organisms (GMOs):

Principle 1—Acting with integrity

Act with integrity in the search for and application of knowledge and benefits in gene technology research, both in the design of the research and by having appropriate scientific qualifications to undertake the work and follow relevant codes of best scientific practice.

Principle 2—Avoiding conflicts of interest

Declare and properly manage any conflicts of interest under the terms of the Australian Code for the Responsible Conduct of Research or other relevant requirements.

Principle 3—Maintaining records of scientific data

According to best scientific practices, maintain accurate and comprehensive records of all relevant facts and data in dealings with gene technology to the standards required by regulatory authorities, including records of all negative as well as positive results.

Principle 4—Caring for the environment and sustainability

Conduct dealings with gene technology so as to protect the environment, including genetic diversity, organisms, species and natural ecosystems, and to promote improvements in human health and sustainable agriculture and industry.

Principle 5—Avoiding harm to humans and animals

Minimise risks of harm or discomfort to humans and animals likely to be adversely affected by gene technology research by ensuring compliance with the gene technology legislation.

Principle 6—Assessing long-term impacts

Conduct dealings with gene technology with regard to the impact on present and future generations, including assessment of the long-term side-effects of applications of gene technology.

Principle 7—Sharing knowledge and benefits

Respect intellectual property rights, endeavour to promote access to scientific developments and share knowledge, and ensure that the Australian community benefits from gene technology.

Principle 8—Promoting benevolent purposes

Conduct dealings with gene technology that promote their benevolent application and discontinue dealings that involve risk outside the relevant authorisation requirements.

Principle 9—Ensuring transparency

Conduct dealings with gene technology in a manner that ensures transparency and public scrutiny of the processes and that allows community consultation with those with a direct or potential interest.

Principle 10—Considering responsibility beyond national borders

Ensure that dealings with gene technology do not cause damage to the environment in Australia or beyond the limits of the national jurisdiction.



The background features a light gray field with faint, stylized molecular structures. These structures consist of small circles connected by thin lines, with some larger circles enclosed within thin circular borders. The bottom half of the image is a solid dark green area, which is separated from the light gray area by a jagged, puzzle-piece-like border.

CHAPTER 3: RISK CONTEXT

CHAPTER 3: RISK CONTEXT

This chapter describes the role of the context in risk analysis and how it is applied in the preparation of an RARMP for licence applications.

Important parameters for establishing the risk context include the scope and boundaries; the criteria for determining harm, including its seriousness and likelihood; and the method for assessing, managing and communicating risk. Defining these parameters are 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 for risk analysis of applications for DIR and DNIR licences in relation to the:

- subject of regulation—dealings with a GMO
- trigger for regulation—use of gene technology
- means for classifying classes of dealings—such as licences, NLRDs, exempt
- protection goals—health and safety of people, the environment
- method to achieve protection goals—identifying and managing risks
- matters to consider when preparing RARMPs
- 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 of monitoring and types of enforcement powers
- definition of key terms—such as deal with, environment, gene technology, GMO.

Greater detail is provided in Chapter 1 and Appendix A. The Explanatory Memorandum to the Gene Technology Bill 2000 provides additional contextual explanation.

Policy principles, policy guidelines and codes of practice issued by the Gene Technology Ministerial Council (now the Legislative and Governance Forum on Gene Technology) (sections 21–24) may also determine elements of the scope and boundaries for risk analysis.

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

The boundaries for risk analysis of DIRs and DNIRs are determined, in part, by the requirements of any law of the Commonwealth, including 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 are the responsibility of another agency. For example, the APVMA is responsible for regulating all pesticide use for agricultural and domestic purposes, including the use of GMOs as pesticides. 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 use of a therapeutic agent would be imposed by the TGA. Appendix A contains detailed information about the interaction between the Regulator and other agencies.

Establishing risk criteria

The legislation specifies matters the Regulator must consider in preparing the risk assessment (section 51(1)(a) and regulations 9A and 10), including consideration of both the short- and long-term effects from the proposed dealings with a GMO. These matters include:

- the properties of the parent organism
- the effect of the genetic modification on the parent organism
- provisions for limiting the dissemination of the GMO in the environment
- the extent of scale of the proposed dealings
- the likely impacts of the proposed dealings on the health and safety of people
- previous assessments
- the potential of the GMO to be harmful to humans and other organisms
- the potential of the GMO to adversely affect any ecosystem
- the potential of the GMO to transfer genetic material to another organism
- the potential of the GMO to spread or persist 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.

These matters provide the basis for establishing risk criteria as part of the risk context, including:

- the nature and types of consequences that may occur and how they will be measured
- how consequence is defined in the consequence assessment
- how likelihood is defined in the likelihood assessment
- how the level of risk is evaluated.

Establishing risk consequence criteria

Defining the nature of harm and the level of harm is the central element in establishing the risk consequence criteria. Consequence criteria are derived from the protection goals. In risk assessment, the consequences are expressed in terms of potential harm to human health and safety and the environment.

Harm to the health and safety of people includes:

- toxicity or allergenicity
- disease
- illness or injury.

Harm to the environment includes:

- toxicity to desirable (valued) organisms that should be protected
- loss of biodiversity, including loss of species diversity or genetic diversity within a species
- adverse impacts of a new or more serious weed, pest or pathogen
- disruption of biotic communities
- degradation of the abiotic environment.

Harm reflects an undesirable condition involving damage or injury. This includes change in the morphology, physiology, growth, development, reproduction or life span of an organism or group of organisms that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences.

The perception of harm can vary between people. It can also change over time and differ according to other factors such as variations in the vulnerability of individuals or type of land use. For example, a cold medication may be considered harmful if it causes severe side-effects. However, if a cancer drug causes the same type of side-effects, it may not be considered harmful. Similarly, a plant producing large amounts of biomass in a pasture may be considered desirable whereas the same plant may be considered harmful (weedy) in a nature conservation area as it may end up displacing a native species. In addition, one harmful outcome can sometimes give rise to further downstream harms. For example, increased harms from weeds, pests or pathogens can lead to loss of biodiversity.

International standards such as those of the IPPC and OIE, and national health and environmental legislation, can provide guidance on the values to be protected from harm. In addition, the Regulator adopts values such as the risk categorisation of pathogens (Standards Australia 2010a) or those associated with good agricultural management practices for managing weeds, pests or diseases. These considerations are used to develop generic consequence criteria that are applicable to all types of GMOs (Table 3.1).

Table 3.1: Generic consequence assessment criteria for the degree of harm to the health and safety of people or the environment (adapted from Standards Australia 2010a)

Level of harm	Health	Environment
Marginal	Ailment not requiring medical treatment	Minimal disruption to a biotic community that is reversible and limited in time and space
Minor	Minor illness/injury requiring medical treatment	Limited damage that is reversible and limited in time and space or in the numbers affected
Intermediate	Serious illness/injuries usually requiring hospitalisation; treatment is usually available; prevention may be available	Damage that is widespread but reversible or of minor severity
Major	Deaths or life-threatening illness/injuries; treatment or prevention is not usually available	Extensive damage to whole ecosystems, communities or entire species that persists over time

Notes: The criteria listed in this table are illustrative and will depend on the circumstances of the specific case. These may be used to establish baselines for parent organisms as well as to assess the potential harm (degree of change) due to gene technology.

The criteria for harm are used to establish the baseline for assessing risk for the parent organism and to specify the types of change due to gene technology that would be considered significant in terms of potential harm from the GMO. Potential harm from

gene technology may be associated with intended traits introduced into the GMO or with unintended changes.

More specific consequence criteria are based on harms caused by undesirable organisms (Department of Sustainability, Environment, Water, Population and Communities 2011a, b; Standards Australia 2006, 2010a; Thorp & Lynch 2000). For example, undesirable plants that cause economic, social or environmental harm, or harm to human/animal health, are called weeds.⁵ Similarly, animals that cause harm are known as pests and harmful micro-organisms may be pathogens. Therefore, harms from non-GM weeds, pests and pathogens establish the criteria for potential harm from GMOs, depending on the nature of the modified trait and the type of GMO under consideration.

For example, potential harms proposed for GM plants are based on those established for weeds, including potential harm from sexually compatible relatives that may receive the introduced genetic material from the GM plant. However, the potential harm from a GM plant is expected to require detailed consideration of only a subset of harms caused by weeds.

Risk assessment context

The Act requires case-by-case decision making for applications for DIR (section 50) and DNIR (section 47(1)) licences. Establishing the risk assessment context includes consideration of the following:

- the GMO—details of the genetic modification and trait changes
- the proposed dealings—proposed activities with the GMO, proposed controls and limits (for DIRs) or containment measures (for DNIRs)
- the parent organism—details of the comparator (eg origin and taxonomy, production and uses, biological characterisation, ecology)
- the receiving environment—baseline information (eg environmental conditions, production or work practices, presence of organisms that the GMO can exchange DNA with through sexual reproduction, presence of similar genes)
- previous releases—previous risk assessment or experience gained with a particular GMO in the course of prior dealings in Australia or overseas.

5 A weed is 'a plant that requires some form of action to reduce its harmful effects on the economy, the environment, human health and amenity' (Natural Resource Management Ministerial Council 2006). Similarly, weeds are 'naturalised plants that cause negative impacts' (Standards Australia 2006).

Information on the GMO, including the nature of the genetic modification and any novel or altered phenotypic properties (intended or unintended), forms an essential part of the risk assessment context. This includes information on the following three components:

1. Invasiveness (infectivity). This is the ability of the GMO to spread and persist in the environment. This includes properties that affect the ability to survive, establish, colonise, infect or parasitise, reproduce and disperse over long distances or between hosts.
2. Capacity for harm. This includes properties of the GMO that may cause damage, toxicity, disease or injury to people or desirable components of the environment.
3. Capacity for gene transfer. This includes potential transfer of the introduced/modified genetic material to sexually compatible relatives of a plant or animal; or by horizontal gene transfer to humans, plants, animals, micro-organisms or viruses.

The proposed dealings with the GMO and the receiving environment provide the starting point for identifying risks. The receiving environment includes the type of land use/containment facility where the GMO is expected to be present and the vulnerability of people or desirable components of the environment exposed to the GMO. This includes changes over time due to changes in land use or from climate change.

In addition, any proposed controls or containment measures to restrict 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 products. In the case of DIR field trials, proposed controls may include physical barriers, isolation distances and modified work practices, as well as limits on the access, scale, locations, duration and types of activities. For DNIRs controls will include the level of containment, standard work/clinical practices, and availability of treatments/vaccines. The risk assessment assumes that the proposed controls will be effective to restrict the proposed release to the limits the applicant has proposed. Their suitability to do so is evaluated in the risk management plan.

The parent organism and receiving environment form part of the baseline for a comparative risk assessment. This includes standard management practices applied to the parent organism. Information on the parent species includes consideration of uses, taxonomy, origin, means of production, morphology, development, biochemistry, abiotic and biotic interactions with the environment, harm due to impacts if a weed, pest or pathogen, and the potential for gene transfer to other organisms present in Australia. Relevant information from studies undertaken in Australia and overseas is considered and biology documents

on a number of parent species have been developed by the OGTR.⁶ Typically, the parent organism used as a comparator is considered at the taxonomic level of species. The use of a higher or lower taxonomic level should be supported by a scientifically sound rationale.

However, selecting the appropriate comparator is not always straightforward. In some cases, the parent organism may also be a GMO which has undergone a new modification, and therefore a risk assessment is required for the new modification. A range of other factors influence selection of the appropriate comparator, such as:

- information on the parent species is lacking or the parent species is not present in the Australian environment
- parent organisms have been highly modified compared to the original parent species, such as many viral vectors and vaccines
- the GMO proposed for release has undergone several generations of conventional breeding with genotypes distinct from the parent organism
- chimeric organisms, such as some viruses or products of synthetic biology, lack an easily definable parent species
- the GMO has developed through hybridisation between different species.

The environment into which the GMO is released is also relevant for intentional releases. For example, for a GM crop plant, the development of a baseline for the risk assessment would include consideration of information on current growing and management practices applied to the non-GM crop; presence of related, sexually compatible species; presence of relevant pests and diseases; and background presence of gene(s) used in the genetic modification.

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.

Similarly for intentional release of a GMO that is a human vaccine, baseline considerations of the receiving environment would include the geographic regions where the release would occur; the intended clinical practices; other relevant GMOs already released; presence of related species; abundance of gene(s) used in the genetic modification already present naturally in the environment; and any particularly vulnerable or susceptible entities that may be specifically affected by the proposed release.

6 Biology documents prepared by the OGTR are available at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

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 or clinical practices, or changes in land use. For example, normal agricultural practice for cotton prior to release of GM insecticidal cotton included intensive pesticide use with multiple applications per growing season. Subsequently, there has been a significant reduction (85%) in the amount of insecticide active ingredient applied to Bollgard II GM cotton (Fitt 2008). Reduced chemical application has also led to reports of changes in the abundance of non-target insects in cotton-growing areas (Cattaneo et al. 2006; Romeis et al. 2008; Whitehouse et al. 2005). Such 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 prescribed in the legislation, including advice from stakeholders (sections 47(3), 47(4), 51(2), 52 of the Act; regulation 10)
- decision-making processes to decide whether to issue or refuse a licence (sections 55, 56, 58)
- the types and nature of licence conditions that may be prescribed or imposed (section 62(2)), informing people of their obligations (section 63), monitoring and audits (section 64), and additional information related to adverse findings (section 65).

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

Risk assessment identifies risks from gene technology. These risks are considered in the context of the biology of the whole organism and its environment. All organisms have intrinsic potential to cause harm to a varying degree. Management of risks inherent to parent species provides an important context for managing risks of GM species. For example, while a particular genetic modification of a pathogenic risk group 3 organism (Standards Australia 2010a) may be assessed as posing insubstantial risk, the resultant GM organism is likely to still require containment in a PC3 facility and PC3 work practices because of the risks inherent to the parent RG3 organism. The management requirements that typically apply to the parent species provide an important context for managing risk from the GMO.



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

- the certification of facilities to specified physical containment levels
- the Regulator's function to issue technical and procedural guidelines (section 27)
- 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.

For example, the Act empowers the Regulator to issue technical and procedural guidelines in relation to GMOs (sections 27(d), 90, 98). This includes guidelines for transport, storage and disposal 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 the policy on post-harvest crops).

Risk communication context

The risk communication context provides details of who is consulted, when, in what capacity (eg 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 mandatory consultation with the stakeholders proscribed in the Act (eg sections 44, 47(4), 50(3), 51, 52, 53, 71(5), 72B(2), 72E(3)) and Regulations, the Regulator can seek advice from other appropriate people or organisations. There are greater provisions for consultation on licence applications to release a GMO into the environment (DIRs) than for activities with GMOs in containment (DNIRs).

The background of the page is a light gray with a pattern of abstract molecular structures. These structures consist of small circles (nodes) connected by thin lines (edges). Some nodes are larger than others, and some are enclosed within larger circles. The pattern is more dense in the upper half of the page. A horizontal line divides the page into two main sections. The upper section is white, and the lower section is a solid blue color. The transition between the two sections is a smooth gradient. The title 'CHAPTER 4: RISK ASSESSMENT' is positioned in the upper white section, centered horizontally. The text is in a bold, sans-serif font, with 'CHAPTER 4:' in blue and 'RISK ASSESSMENT' in black.

CHAPTER 4: RISK ASSESSMENT

CHAPTER 4: RISK ASSESSMENT

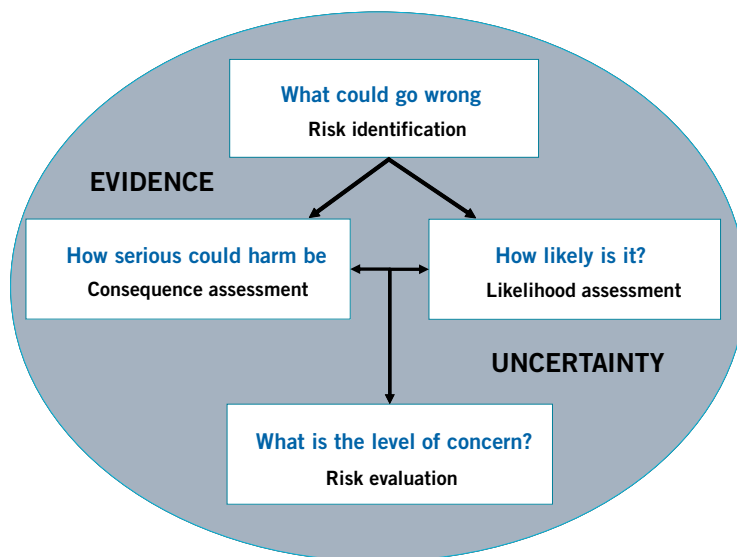
This chapter explains the risk assessment method the Regulator uses to consider applications for DIR and DNIR licences. This method is also applied to consideration of other matters, for example preparing advice on the classification of GMO dealings as exempt or notifiable low-risk dealings (sections 74, 75 and 140–143 of the Act), on an emergency dealing determination (section 72B(2)(c)) or on the GMO Register (section 79). 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? (Risk identification) Initially, a broad range of circumstances is considered, whereby the proposed dealings with a GMO are postulated to give rise to harm to people or the environment (risk scenarios). Each risk scenario describes a plausible causal linkage between the GMO and harm.
- How serious could the harm be? (Risk characterisation—consequence assessment) An identified risk is subjected to 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 the 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 concern? (Risk evaluation) The level of risk is evaluated as negligible, low, moderate or high by considering a combination of the seriousness of harm and the likelihood of it occurring. Risk evaluation determines whether or not mitigation measures to reduce risk are required.

Scientific and technical information is used to answer the first three questions. In addition, consideration of uncertainty, in particular knowledge gaps, occurs throughout consideration of all of these questions.

Figure 4.1: Considerations for risk assessment



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

- as a result of ongoing accumulation of information (such as data requested from the applicant, expert advice, consultation, or literature searches)
- as a result of development of more specific consequence criteria when substantive risks are identified and considered in more detail
- as a result of consideration of potential interactions between postulated risk scenarios, or
- in response to the monitoring 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 evaluation of the level of an identified risk. The scientific advisory body to the Regulator, GTTAC, in particular, has an important function in providing scientific and technical advice on assessment of 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).

Risk identification

Risk identification considers what could go wrong from activities with a GMO. It is the 'process of finding, recognising and describing risk'. Risks are identified within the context established for the risk assessment (see Chapter 3), taking into account the proposed dealings with the GMOs, 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.

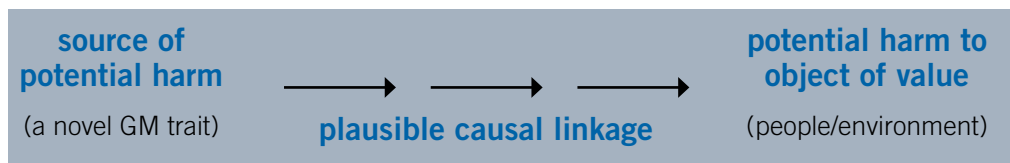
Postulating risk scenarios

Initially, risk identification considers a wide range of circumstances where potential harm to people or the environment could be credibly linked to exposure to the GMO or GM product, or the introduced genetic material (risk scenarios).

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. It is an hypothesis constructed from three essential components (Figure 4.2).

1. A risk source. A new or altered property/trait of the GMO.
2. A potential harm to people or the environment.
3. A plausible causal linkage between components 1 and 2.

Figure 4.2: Components of a risk scenario



However, the relevance or importance of a risk scenario will depend on the context. The effects of a novel GM trait need to be considered in the context of the whole organism. Also, the plausibility of a causal linkage to harm will depend on a broad range of external factors such as the type of containment or confinement, availability of sexually compatible relatives, likely environmental conditions or the nature of nearby land use/functions.

Many possible risk scenarios can be formulated, but only those risks that may be greater than negligible are considered in detail in the risk assessment. For example, Hayes et al. (2004) proposed almost 200 risk scenarios for the commercial release of a hypothetical herbicide-tolerant GM canola. However, only four risk scenarios were considered substantive for two commercial releases of herbicide-tolerant canola (OGTR 2003a; OGTR 2003b).

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
- additive effects may occur when different scenarios lead to the same adverse outcome, which could increase the negative impact
- antagonistic effects may occur when the introduced trait alters the characteristics of the organism in opposing ways.

Risk scenarios often require multiple steps and sets of circumstances to occur before harm is realised. 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, a risk scenario involving 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. Similarly, as a result of recombination, the transfer of genetic material from GM viral vaccine to a compatible virus species may result in increased pathogenicity or altered host range in the recipient species.

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 handbook that accompanies ISO 31000:2009 (Standards Australia 2012) and Hayes (2004) contains 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 genotype and phenotype 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 that is toxic or allergenic to humans
- production of a substance that is toxic to other organisms
- 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
- expression of an introduced gene that may alter the infectivity or pathogenicity, host range, transmissibility, pathogen load or vector specificity of a disease agent
- interaction of introduced genes or products related to pathogenicity 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)
- altered production (such as farming) practices
- alteration to the physical environment, including biogeochemical cycles that partition chemical elements and compounds between the living and non-living parts of the ecosystem
- unauthorised activities, including vandalism and terrorism.

The legislation (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 in 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 over-emphasising 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 should not 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 be considered further.
- Is the risk substantive? After an initial consideration of the chance and seriousness of harm, does the risk scenario warrant more detailed consideration?

Risk identification aims to include all risks that may require risk mitigation or reduction. However, in the absence of extensive experience with impacts from a particular GMO, identifying all substantive risks having a level of risk that 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. Therefore, the Regulator takes a cautious approach, 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.

The approach the Regulator uses also includes consulting a number of people with relevant expertise in the risk assessment process and by extensive internal review, and in the case of DIRs, external review of the risk assessment.

Risk characterisation

Risk characterisation determines the seriousness of harm (consequence assessment) and the chance of harm (likelihood assessment) from a GMO. The likelihood and consequence assessments are based on inferences from the available scientific and technical information, and include consideration of uncertainty. In the process of more detailed characterisation of identified risks, the generic criteria for the nature and types of consequences described in Chapter 2 are continually updated and become more clearly elaborated to allow evidence-based characterisation of a specific risk scenario.

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 as 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 used 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 (eg 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 system 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 use relative descriptions of likelihood and consequences, and can combine data derived from various sources, including quantitative data, if available. By using qualitative assessments, the maximum amount of information can be used in describing likelihood and consequence.

Use of qualitative or quantitative approaches depends on the amount, type and quality of available data; the complexity of the risk scenario 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 (Hart 2001).

Table 4.1: Relative merits of qualitative and quantitative risk assessments

TYPE OF ASSESSMENT		
	Qualitative	Quantitative
Strengths	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • High objectivity • Typically repeatable and testable • Greater consistency between assessors • Compatible with statistical interrogation • Allows formal incorporation of some types of uncertainty
Weaknesses	<ul style="list-style-type: none"> • Subject to greater linguistic uncertainty due to ambiguity, vagueness and under-specificity • Estimates are more subject to variation between assessors • More prone to heuristics and biases of inputs such as expert opinion • More difficult to formally treat uncertainty • Validation is difficult 	<ul style="list-style-type: none"> • Use of numbers can lead to overconfidence • More complex • No established criteria for interpreting the outputs • Difficult to communicate to stakeholders • Accuracy may be illusory if effects are serious, but there is little direct evidence • Can give misleading results due to poor data, over-simplification or complexity • Some methods require more data

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

- there may be limited long-term experience with particular organisms and/or introduced genes/traits
- there is an absence of demonstrated harm
- potential harm relating to human health and safety and the environment is highly varied
- environmental effects manifest within highly complex systems that have many incompletely understood variables
- harm may occur in the long term through indirect routes, for example through interaction with impacts from climate change, and is 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. The use of common language rather than numbers makes qualitative assessments more accessible for risk communication.

The weaknesses of qualitative assessments described in Table 4.1 can be controlled and minimised in several ways, including the use of different terms for the various levels of likelihood, consequences and risk to reduce ambiguity. Potential variations between assessors can be reduced through quality control measures such as internal and external review and sourcing of expert advice. Differing viewpoints, perspectives and biases can be reduced through stakeholder input via effective consultation. Validation of findings can be supported by the monitoring and review processes.

Nevertheless, there is a requirement for testable and repeatable scientific evidence to support qualitative estimates of likelihood and consequences according to measurable, observable criteria of harm to human health and safety or to the environment. For example, toxicological or epidemiological data may be used in cases where harm is postulated to arise from the presence of toxins, allergens or other chemicals, such as enzyme inhibitors or anti-nutrients.

Consequence assessment

Consequence is 'harm to protection goals from an activity'; in particular, harm to people or to the environment. A consequence assessment determines the potential degree of seriousness of harm (see Table 4.2). The seriousness of harm is dependent on the scale at which impacts are considered. Harm to humans is usually considered significant at the level of an individual, whereas harm to the environment is usually considered significant at the level of species, communities or ecosystems.

The presence of vulnerable, including rare or endangered, 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 to people or to the environment may include consideration of:

- What is the magnitude of each potential adverse impact: does it cause a large change over baseline conditions?
- What is the spatial extent or scale of the potential adverse impact?
- What is the temporal occurrence of the impact, namely, the duration and frequency? Does it cause a rapid rate of change? Is it likely to occur in the short or long term? What is the duration (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 so, how often? Will it disappear?
- Can the adverse impact be reversed and, if so, how long will this take?
- Is the exposed species rare or endangered?

The presence of sexually compatible GMOs is also considered with respect to whether potential interactions or combined effects might alter the consequences.

Table 4.2 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 so as to be applicable to the wide range of possible licence applications and potential risks. The variety of potential risks may be affected by different factors (magnitude, scale, time, reversibility) that may contribute to the significance of adverse outcomes. For specific risks, these descriptors may be defined in more detail.

Table 4.2: Consequence assessment scale

Consequence assessment	Degree of potential harm to the health of people and the environment due to gene technology relative to the parent organism
Marginal	Minimal or no increase in illness/injury to people. Minimal or no increase in harm to desirable components of the environment.
Minor	Minor increase in illness/injury to people that is readily treatable. Minor increase in damage to desirable components of the environment that is reversible and limited in time and space or numbers affected.
Intermediate	Significant increase in illness/injury to people that requires specialised treatment. Significant increase in damage to desirable components of the environment that is widespread but reversible or of limited severity.
Major	Significant increase in severity of illness/injury to people, or large numbers of people affected, and generally not treatable. Major increase in damage to desirable components of the environment, with extensive biological or physical disruption to whole ecosystems, communities or an entire species, which persists over time.

In some cases, these qualitative descriptors may be supported by quantitative descriptors for certain harms. For example, the adverse impact of a GMO to reduce the establishment of desirable vegetation would be considered marginal, if the GMO does not affect the germination and seedling survival of desired plants (eg regenerating pasture, sown crops, planted trees, regenerating native vegetation); minor, if the GMO stops the establishment of less than 10% of desired plants; intermediate, if the GMO stops the establishment of between 10% and 50% of desired plants; and major, if the GMO stops the establishment of more than 50% of desired plants.

Desirable organisms or components of the environment that should be protected (or undesirable counterparts that should be controlled) are determined by legislation, government policies, national and international guidance material, and widely accepted community norms.

The consequences are assessed with respect to the impact of gene technology. Where there is no appropriate comparator parent organism, such as may be the case for some products of synthetic biology, then the generic consequence assessment scale (Table 3.1) can be used.

Likelihood assessment

The likelihood assessment determines the chance that harm will occur, and is expressed as highly likely, likely, unlikely or highly unlikely (see Table 4.3). If the chance of harm is close to zero, then risk is considered minimal and needs no further analysis. However, care needs to be exercised when considering the remote possibility of risks that may have extreme adverse impacts.

Table 4.3: Likelihood assessment scale

Likelihood of harm from gene technology	
Highly unlikely	Harm may occur only in very rare circumstances
Unlikely	Harm could occur in some limited circumstances
Likely	Harm could occur in many circumstances
Highly likely	Harm is expected to occur in most circumstances

Factors that are important in considering the likelihood of harm occurring are those related to plausible linkages between a dealing with a GMO and potential harm to people or susceptible entities in the environment from exposure to the GMO, the introduced gene(s) or products of the introduced gene(s).

Identifying all steps in a causal pathway leading to harm is important for deriving an overall assessment of the chance that harm may occur. For example, a causal pathway leading to increased harm (eg weediness or pathogenicity) may involve many steps, including transfer of the introduced genetic material from the GMO into a sexually compatible relative; survival and increased fitness of the recipient species; followed by spread and persistence of the recipient species, which then results in harm (eg 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 (eg the co-occurrence of a sexually compatible relative is not expected due to incompatible climate requirements between the GMO and its relative), resulting in a very low overall probability even if all other steps have a reasonable chance of occurring.

Assessing likelihood is more difficult for complex pathways. For instance, horizontal gene transfer from a GM plant or animal to a pathogenic micro-organism 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 micro-organism to survive, replicate, display a selective advantage over the parent organism and give rise to some identifiable harm, such as increased virulence. In such

cases, the overall likelihood of an adverse outcome occurring will be substantially lower than the likelihood of any 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, usually allow 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.

For 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 term than in the longer term.

In the case of DNIRs with pathogens in containment, the first step in developing plausible causal pathways to potential harm involves activities with the GMO that could give rise to infection of a laboratory worker or release from the containment facility, leading to spread and/or persistence of the GMO in the environment. This first step is considered to have only a small chance of occurring for GMOs in PC2 facilities due to the containment and some work practice requirements, and only a rare chance for GMOs in PC3 or PC4 facilities due to even greater requirements for protection that apply to these facilities.

Quality of evidence

Evidence used in risk identification and risk characterisation is obtained by a thorough review of the relevant scientific literature and from information supplied by the licence applicant. In addition, evidence is obtained in the form of advice from GTTAC and other prescribed agencies in the case of DIR licence applications and certain DNIR licence applications. The Regulator may also consult other relevant experts to gain information.

An applicant must supply information as prescribed by the Regulations (if any) and as specified in writing by the Regulator (section 40) (eg 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.

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, available, reproducible and capable of independent verification
- 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—whether 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 from 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 can be placed on each piece of evidence.

Figure 4.3 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 4.3: Some types of information and their relative value 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.
	Opinion of an expert familiar with the GMO, parent organism, modified traits, ecology.	Experimental data on related surrogate systems.
	General biological principles.	
	Other technical reports, specialist literature, government reports, etc.	
	Experience of no reports of 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, enabling 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 evaluation of risk, including consideration of residual uncertainty. Collection and assessment of unnecessary or excessive data is an inefficient use of resources for applicants and the Regulator.

Where another Australian regulatory agency or a regulatory agency of another country has made an assessment of the same or a similar GMO, their findings are taken into account 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 a GMO are unavailable, inconsistent or incomplete, the significance of that absence, inconsistency or incompleteness will be considered in the risk assessment process.

Risk evaluation

Risk is evaluated against the objective of protecting the health and safety of people and the environment to determine the level of concern and, subsequently, the need for controls to mitigate or reduce risk. Risk evaluation may also aid consideration of whether the proposed dealings should be authorised, need further assessment, or require collection of additional information.

Factors used to determine which risks need treatment may include:

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

Risk evaluation combines the consequence and likelihood assessments, using a risk matrix (Figure 4.4), to determine the level of risk and whether risk treatment is required to reduce the level of risk (Table 4.4). This includes consideration of uncertainty and its impact on decision making. The Regulator may, where appropriate, consider interactions between potential risks. In most cases, the combination of effects is not expected to be significant when the associated risks are estimated to be negligible.

Figure 4.4: Risk matrix used to estimate the level of risk

		LEVEL OF RISK			
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					

Table 4.4: Evaluation of the level of risk

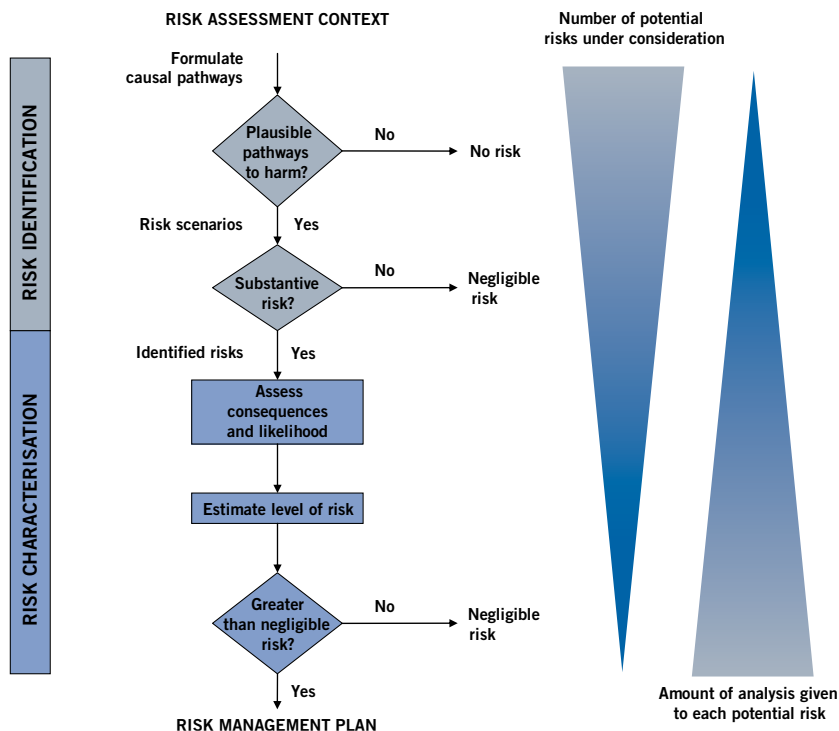
Level of risk	Risk evaluation definitions
Negligible	Risk is of no discernible concern and there is no present need to invoke actions for mitigation.
Low	Risk is of minimal concern, but may invoke actions for mitigation beyond standard practices.
Moderate	Risk is of marked concern and will necessitate actions for mitigation that need to be demonstrated as effective.
High	Risk is of considerable concern that is unacceptable unless actions for mitigation are highly feasible and effective.

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 the risk matrix should be reduced (Cox 2008).

The Regulator applies a set of distinct descriptors to the consequence assessment (Table 4.2), likelihood assessment (Table 4.3) and level of risk (Table 4.4) 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.

Typically, the method used for preparing a risk assessment in relation to 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 (see Figure 4.5). Many potential risks are considered initially, but most of these will be insubstantial. Therefore, fewer risks will remain that require a more detailed assessment and even fewer risks that will warrant consideration for risk treatment.

Figure 4.5: Summary of approach used for preparing a risk assessment for DIRs and DNIRs



Significant risk

In the case of DIRs, after preparing the risk assessment 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, a longer period of consultation is mandated.

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.



The background features a light gray field with faint, stylized molecular or network diagrams consisting of circles and connecting lines. A large, solid green shape, resembling a puzzle piece, is positioned on the left and bottom, with a white, irregularly shaped cutout in the upper right area. The text 'Chapter 5: Risk management' is located within this white cutout.

Chapter 5: Risk management

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—including treating risk, general risk management measures, and draft 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 or refuse a licence and, if issued, what conditions are included in the 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 a 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:

- What are the outcomes of the risk evaluation?
- What measures are available for managing risk?
- How effective are the risk management measures?
- How feasible, practical or compatible are the risk management measures?
- Which treatment measure(s) provide the optimum and/or desired level of management for the proposed dealing?

- Do the risk management 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 would be focused on preventing the risk being realised rather than on reducing or repairing the resultant harm.

The risk assessment includes consideration of the causal pathway(s) necessary for any given risk to be realised. This understanding of how dealings with a 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 points in the chain where treatment may be most easily and/or effectively applied.

While the focus of risk management of moderate and high risks is on treatment measures to prevent risks being realised, attention is also 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?’ In considering possible management conditions for dealings that involve moderate or high-risk estimates, it is important to establish if the harm or damage that might result could be reversed, and to identify curative or ameliorative actions as well as preventative measures. 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 link in a causal pathway, increase the effectiveness of risk management. 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 were breached and seed spilled, it would be unlikely that the weediness risk would be realised, because clean-up measures would be invoked.

Nevertheless, in some cases, the measures proposed by the applicant may be evaluated as excessive or not required to protect the health and safety of people or the environment. In addition, a measure to manage one risk may introduce a new risk or increase the level

of risk. For example, additional personal protective equipment such as a chainmail glove to prevent injury from scalpels or needles reduces dexterity and may lead to increased chance of spills of a GMO in containment.

Risk treatment

When a risk is evaluated as requiring treatment, options to reduce, mitigate or avoid the risk are identified and assessed, and selected management measures are implemented through licence conditions. This includes consideration of options to reduce exposure to the GMO or its products, and to restrict opportunities for the spread and persistence of the GMO, its progeny or the introduced genes.

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

- proposed dealings
- controls and limits proposed by the applicant
- nature and properties of the organism
- trait (the characteristics of the GMO conferred by gene technology)
- properties, number and location of the introduced genes
- location of the dealings, including proposed type and level of containment (DNIRs), or environmental conditions at the release site (DIRs)
- 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 effectively in practice
- meet currently accepted requirements for best practice (eg good agricultural practice, good laboratory practice, good clinical practice, good manufacturing practice)
- manage the risks to the level required for the duration of the dealings and period of the licence
- be able to be monitored.

The selection of risk management measures is made according to their efficacy, efficiency and practicality, commensurate with the level of risk. If risk treatment measures are selected for an identified risk, they should reduce risk 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 then 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 will be managed by the draft options before a licence can be issued. This may include options that manage the risks most comprehensively and/or those 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 pathways to harm (eg due to climate change) or 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 observed during 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 field trial of a GM plant would be based on data of the overall distribution of pollen, and not just on the median distance pollen might travel.

In the case of limited and controlled DIRs and some DNIRs, the Regulator assists 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 if this is considered appropriate to manage risk. 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.

General risk management measures

Proposed controls and limits for DIRs and proposed containment measures for DNIRs provide important elements of the risk context against which risks are assessed. In the case of DIRs with GM plants, these containment measures may include specifying physical controls (such as fences), isolation distances, monitoring zones, pollen traps, post-release clean-up and specific monitoring requirements (such as removal of sexually compatible species from the release site). In the case of DNIRs, this includes the level of physical containment and work practices.

The risk management plan considers the adequacy and appropriateness of these proposed measures to restrict the spread and persistence of the GMO such that risks can be managed.

This is particularly relevant to limited and controlled DIRs and DNIRs where these measures are intended to compensate for uncertainty or inexperience with the GMO. Therefore, the risk management plan considers whether these measures will be sufficient to contain or restrict the spread and persistence of the GMO. However, these measures are also considered in terms of suitability, necessity and the possibility of introducing additional risks.

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

- suitability of the applicant
- identification of the persons or classes of persons proposed to be covered by the licence
- 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 corporates, 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 applicant to meet the conditions of the licence (section 58 of the Act).

The Regulator requires DNIR and limited and controlled release licence holders to have contingency plans in place in case the GMOs are spilled or found where they are not intended. The nature of such plans will vary depending on the licence and nature of the dealings. This includes informing the Regulator 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 relevant changes in circumstances, unintended effects, new risks or contravention of conditions.

If new or increased 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, the Regulator may instigate an investigation to determine the nature and extent of non-compliance (OGTR 2007). If proven, a range of remedies are 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 the environment could result. However, the Regulator seeks to achieve cooperative compliance wherever possible.

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 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, 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 that preventative and/or ameliorative treatment measures can be applied with confidence. The requirement to provide the Regulator with a reliable method to detect the GMO and its modified genes is included in all risk management plans for DIRs.

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 the outcomes remain valid in the light of changes in circumstances or new information. A number of both internal and external feedback mechanisms can be used to maintain the effectiveness and efficiency of risk assessment and risk management, while considering the concerns of all interested and affected stakeholders.

Internal processes of monitoring and review include:

- standard operating procedures for specific administrative processes
- internal peer review of DIR and DNIR RARMPs

- merit-based selection processes for OGTR staff
- conflict of interest declarations and procedures for OGTR staff.

External processes of monitoring and review include:

- expert scrutiny by GTTAC of certain licence applications and RARMPs
- 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 RARMPs
- oversight by the Legislative and Governance Forum on Gene Technology
- external, independent selection of the Regulator and Advisory Committee members, and Legislative and Governance Forum on Gene Technology 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 relevant events (eg conferences, seminars, workshops and in-house training), and monitoring the determinations, experience and policy developments of agencies regulating GMOs in other countries.

Monitoring and reviewing contribute to identifying situations where treatment measures are not adequately managing the risks, either as a result of control measures not maintaining the effectiveness of the limits imposed or non-compliance, or because of changed circumstances and/or unexpected or unintended effects. They also facilitate 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.

Ongoing oversight provisions

Some general/commercial release DIR licences, particularly those requesting unrestricted release, 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 release.⁷ This provides a mechanism for ‘closing the loop(s)’ in the risk analysis process, or for verifying findings of the RARMP, 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 occur where the risk estimate is greater than negligible, or there is relevant uncertainty (eg lack of consensus among expert advisers).

A second component of post-release review is to collect information on 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 RARMPs at any time after the licence is issued. Such reviews take into account any relevant new information, or may be triggered by findings from either of the other components of the post-release review. The purpose of a review would be to ensure the findings of the RARMP remain current. If the review findings justify either an increase or a decrease in the initial risk estimate(s), or identify new risks to people or to the environment that need managing, this could lead to review of the risk management plan and changes to the licence conditions.

Decision making

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 issuing licences to authorise dealings with GMOs, which includes imposition of licence conditions. The Regulator also decides on suspending, cancelling, transferring or varying licences. Each of these decisions is based on whether the Regulator is satisfied that any

⁷ Such conditions would be additional to the notification requirements imposed on licence holders under section 65 of the Act (see ‘General risk management measures’).

risks posed by the dealings can be managed in such a way as to protect the health and safety of people and the environment.

Although the risk analysis framework described applies to the consideration of all licence applications, there is no one-size-fits-all solution. 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 be satisfied that the applicant is a suitable person to hold the licence and must seek advice from the GTTAC and a wide range of agencies and authorities (see Figure A1). In addition, the Regulator can seek advice from the GTECCC, and the Legislative and Governance Forum on Gene Technology 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 the GTTAC, the States, relevant Australian Government agencies, and anyone else the Regulator thinks appropriate.

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

The key factors in making these decisions 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 will 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.

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

- routine monitoring of limited and controlled environmental releases and contained dealings
- unscheduled monitoring of limited and controlled environmental releases and contained dealings (spot checks)
- profiling of dealings to aid strategic planning of monitoring activities
- 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
- performing incident reviews in response to 'self reported' non-compliance
- conducting investigations in response to allegations of non-compliance with conditions or breaches 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 occur at any time irrespective of non-compliance.

In the case of limited and controlled DIRs for GM plants, post-harvest monitoring continues until the GMOs resulting from the authorised dealings have been removed from the release sites to the Regulator's satisfaction.



The background features a white upper half and a green lower half separated by a wavy, torn-paper-like line. Faint, light gray molecular structures, consisting of circles and connecting lines, are scattered across the white background. The green lower half also contains faint, darker green molecular structures.

CHAPTER 6: RISK COMMUNICATION

CHAPTER 6: RISK COMMUNICATION

This chapter presents the main objectives of risk communication and the approach that the Regulator takes to fulfil these objectives. It also includes a discussion of some theoretical elements of risk communication and risk perception.

In practice, 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
- communicate the reasoning behind licence decisions in an open and objective manner in clear language
- listen and respond, in a timely manner, to relevant concerns of stakeholders
- periodically review communication strategies and practices of the OGTR to ensure effective, appropriately targeted and efficient communication with stakeholders.

What is risk communication?

Risk communication is a 'continual and iterative process to provide, share or obtain information and to engage in dialogue with stakeholders regarding the analysis of risk', within the context of the legislation.

Risk communication is a two-way process, not an attempt to change basic values and beliefs (Gough 1991). The Regulator recognises and accepts that the community holds a wide range of views on gene technology and considers all issues and concerns raised that are within the scope of gene technology legislation.

The Regulator exchanges information and views with stakeholders and the general community about potential risks from gene technology. Risk communication provides the Regulator with access to the relevant factual information and analyses, as well as awareness of the needs, values and concerns of stakeholders. The Regulator also communicates the reasons underpinning decisions based on risk assessment.

The primary guidance used in the *Risk Analysis Framework* is based on the Handbook for Communicating and Consulting about Risk (Standards Australia 2010b), which is a companion to the Australian/New Zealand Risk Management Standard (Standards Australia 2009). Useful guidance on risk communication is also provided by enHealth (2012).

Why do risk communication?

Effective risk communication is central to effective risk analysis. The goals of risk communication relevant to regulation can be categorised as follows:

- *Engagement*—to involve internal and external stakeholders (Table 6.1) in the regulation of risk through dialogue.
- *Informing*—to foster understanding of the risks amongst different constituencies (eg licence holders and others from the regulated community, as well as researchers, farmers, health workers, industry, consumers, interest groups and the general community). The information can relate to the existence, nature, form, likelihood, significance, evaluation, control measures and monitoring of the risks, including the quality of the evidence, inherent uncertainty and compliance with licence conditions.
- *Building trust*—to promote trust and credibility in the ability of the Regulator and the OGTR to effectively regulate gene technology.

Stakeholders

Release of GMOs into the Australian environment is of interest to a wide spectrum of the community, including State and local governments, non-government organisations, community groups, businesses and individuals. Some of the major stakeholder groups are shown in Table 6.1.

Table 6.1: Stakeholders with interests in gene technology regulation

Group	Stakeholders
Regulated community	Licence holders, accredited organisations, IBCs
Advisory bodies	Gene Technology Technical Advisory Committee, Gene Technology Ethics and Community Consultative Committee, Human Genetics Advisory Committee, Australian Health Ethics Committee
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, Research and Tertiary Education, Department of Health and Ageing, National Health and Medical Research Council
Health workers	Medical officers, clinicians, toxicologists, epidemiologists
Industry/Commerce	Food, medical, agricultural, biotechnology, veterinary, human medicines industries and retailers
Interest groups	Environmental groups (eg Australian Conservation Foundation, World Wildlife Fund, Friends of the Earth, Greenpeace), consumer groups (eg Australian Consumers Association, Consumers Health Forum), health professionals, lobbyists, consultants, regulatory affairs advisors, specialist professional societies (eg Australasian Gene Therapy Society, International Society for Biosafety Research)
Prescribed agencies under the Act	FSANZ, DAFF Biosecurity, NICNAS, APVMA, TGA (see Appendix A)
Primary producers and related groups	National and State farmers' federations, peak farming organisations, individual producers, seed suppliers, traders, handlers
Research	University Pro/Vice Chancellors for R&D, CEOs/Directors of research institutes, CSIRO, Cooperative Research Centres, research and development corporations, other researchers
The public	

Notes: APVMA = Australian Pesticides and Veterinary Medicines Authority; DAFF = Department of Agriculture, Fisheries and Forestry; FSANZ = Food Standards Australia New Zealand; NICNAS = National Industrial Chemicals Notification and Assessment Scheme; TGA = Therapeutic Goods Administration.

Risk communication processes

Risk communication processes consider the following questions (AS/NZS HB327:2010).

- What are the objectives of the specific communication?
- Who will be involved?
- What is to be communicated?
- How will the information be communicated?
- How will consultation be conducted?

The role of risk communication in the risk analysis process

Risk communication is integral to all other steps in risk analysis (Standards Australia 2010b; Figure 2.1), including the risk context, to ensure that the scope and boundaries are clearly elaborated, the criteria used to make decisions about risk are clearly defined, stakeholder interests are considered and feedback is provided.

When establishing the risk context, risk communication requires:

- identifying key stakeholders
- specifying the purpose of the process, information requirements and the means of meeting them
- specifying who is to be consulted, and when and how the process will occur, including feedback and evaluation
- identifying information that may have restricted access for commercial or security reasons.

Risk communication also supports development of the RARMP. Risk assessment is supported by broad communication and consultation on DIRs with stakeholders to help avoid overlooking important risks. In addition, risk assessment includes the use of the risk matrix (Figure 4.4) to communicate the level of risk. Another important aspect is acknowledgement and analysis of uncertainty. This is particularly relevant for qualitative risk assessments conducted by the Regulator, where clarity of the language can help to reduce the overall uncertainty.

The risk management plan provides the analysis and rationale for proposed controls or restrictions, which are communicated to the applicant and others through the licence conditions. Licence conditions should explicitly and clearly describe the obligations to the licence holder to ensure risk is managed. In addition, consultation may be required during monitoring and review, including post-release review.

Engagement

Fischhoff (1995) argued that effective risk communication involves presenting the facts, communicating and explaining the facts, demonstrating that similar risks have been accepted in the past, and bringing stakeholders on board as partners. Therefore, provision of information is not sufficient. Stakeholders' views should be sought as they provide a valid input into risk assessment and risk management (Fiorino 1990).

Successful engagement depends upon providing suitable platforms and procedures for dialogue (Renn 2009). Processes for engagement range from simple surveys to forms of deliberative democracy, which provide the highest level of public involvement (McComas et al. 2009). Three broad categories of engagement are described in Table 6.2.

Between 1998 and 2001 there were public forums and extensive consultation on the development of Australia's regulatory scheme for gene technology, including a consensus conference on gene technology in the food chain (Lay Panel Report 1999). A citizens' panel of 14 members engaged with experts and opinion leaders on issues related to risk and regulation of GMOs. These processes informed the development of the legislation that gave effect to the regulatory scheme.

The Act legislates for a single, independent decision maker (the Regulator) and specifies processes for input from a broad range of stakeholders and the public. The Regulator can also consult with any expert or interest group considered useful for decision making.

The Regulator establishes dialogue with stakeholders and the community through:

- consultation with stakeholders and the community on RARMPs prepared for licence applications for the proposed environmental releases of a GMO
- communication with licence applicants on data requirements and with licence holders on implementation of licence conditions
- requests for advice or submissions from experts and interested parties on specific guidance documents
- communication with other regulators (eg Regulators' Forums), academics, industry representatives, risk analysts and interest groups at public meetings, workshops and conferences on risk assessment and regulation of GMOs
- communication with government policy groups

- involvement in specific focus group meetings, workshops and collaborations (eg IBC Forums, consensus documents produced by the OECD Working Group on Harmonisation of Regulatory Oversight of Biotechnology, the National Post-Border Weed Risk Management Forum)
- exchange of information with regulatory agencies and experts from other countries on approaches to risk analysis and regulation of GMOs.

Table 6.2: Different levels of engagement

Mode of engagement	Basis for dialogue	Examples	Strengths	Weaknesses
Passive	Knowledge and expertise	<ul style="list-style-type: none"> • Notification of decisions • Surveys 	<ul style="list-style-type: none"> • Efficient when non-controversial 	<ul style="list-style-type: none"> • Processes tend to be opaque • Ineffective where there is controversy or significant uncertainty
Consultative	Experience and competence that is reliant on evidence	<ul style="list-style-type: none"> • Written comments on draft material • Workshops and meetings • Advisory bodies • Public hearings 	<ul style="list-style-type: none"> • Allows input from a broad range of individuals and interest groups • Supports transparency of decision making • Supports more informed decisions where moderate conflict is present 	<ul style="list-style-type: none"> • May favour formality and elitism • May poorly resolve high-intensity conflict
Participatory	World views and values	<ul style="list-style-type: none"> • Public discussion events • Deliberative democracy 	<ul style="list-style-type: none"> • Useful for high-intensity conflict • Supports shared decision making 	<ul style="list-style-type: none"> • Costly in time and resources • Difficult to achieve true representativeness • Can be influenced by better organised interest groups • Does not necessarily lead to better decisions than simpler modes of communication

Informing

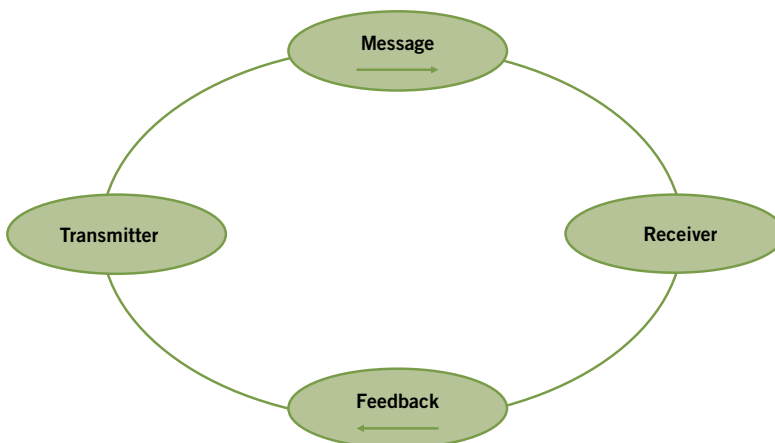
One of the functions of the Regulator under the Act is to provide information and advice to the public about the regulation of GMOs.

Informing serves several purposes, including:

- increasing community awareness of the technology and of the regulatory scheme
- clarifying obligations and requirements of stakeholders such as licence applicants, licence holders and Institutional Biosafety Committees (IBCs)
- assisting coordination of different government agencies with a role in the regulation of GMOs or GM products
- informing the Regulator of stakeholder perceptions of risks relating to GMOs
- informing the community of decisions and the reasons for those decisions
- maintaining links with international organisations and agencies associated with the regulation of GMOs.

The standard model of information transmission has three components (Australia Standards 2010b, Figure 6.1). The messages are put in a form that can be transmitted by the transmitter. Secondly, the message is transmitted through a communication channel (eg newspaper, website, email, telephone, letter etc). Thirdly, the message is received and interpreted. The message should be comprehensible to the receiver and consistent with the meaning intended by the transmitter. In turn, the receiver may inform the transmitter in terms of feedback.

Figure 6.1: Transmission of information (adapted from Standards Australia 2010b)



However, many factors influence the effectiveness of information transmission (Standards Australia 2010b). Some of these include:

- the degree of concern or conflict present
- the social and cultural background of the transmitter and receiver
- demographic variation such as gender, age, education, income and personal circumstances
- uncertainty of the meaning of words, models and other descriptive forms
- psychological biases
- the complexity of the language and concepts in the message
- the timeliness in sending the message
- the appropriateness of the communication channel and its impact on the clarity of the message
- knowledge or understanding of the receiver
- the motivation, readiness and interest of the receiver to process the message.

Many of these factors are characteristics of individual receivers. The Regulator and the OGTR seek to maximise effective transmission of information by taking a structured, consistent approach to risk analysis and using consistent language when communicating about risk.

The absence of information can also influence risk debates. Lyytimäki et al. (2011) describe how ‘potentially relevant information may be downplayed or omitted and less relevant overemphasized when actors with varying interests, knowledge bases, and risk frames interact’. Some information may be intentionally restricted for privacy reasons or because it is confidential commercial information, whereas other information may be inadvertently absent or may be assumed.

Building trust

Another important goal of risk communication is building trust. People rely on trust in all transactions. Likewise, effective regulation is reliant on trust. Regulation should be seen in both words and actions as even-handed and independent of any particular interest group.

Trust is considered to involve the confident expectation of certain behaviours. These include (based on Covello 2009):

- Competence—having appropriate expertise, knowledge and experience, and applying sound judgment
- Integrity—operating in a manner that is objective, fair, consistent and honest, and with goodwill
- Respect—recognising and valuing individuality and differences, and demonstrating listening, compassion, empathy and caring, particularly in a crisis.

Important factors intended to address trust in the regulation of GMOs include:

- Governance—primarily achieved by establishing a mandatory regulatory system, namely, the *Gene Technology Act 2000*. Aspects of trust are also enshrined in other legislation (eg *Public Service Act*, *Privacy Act*, *Freedom of Information Act* and provisions for confidential commercial information) and administrative procedures (eg the Australian Public Service Values and Code of Conduct, and conflict of interest policies).
- Openness—being accessible and available; encouraging listening, debate and deliberation of concerns; acknowledging errors and uncertainty; and showing capacity to learn.
- Transparency—providing insight and clarity into how regulation works in practice, including:
 - ‘doing the right things’—(quality assurance, validation) effectiveness of the process to achieve the protection goals
 - ‘doing things right’—(quality control, verification) the ability of the steps in risk analysis to correctly fulfil their specified function
 - ‘saying what you do’—matching words with actual practices, together with interpretations, definitions and reasons
 - ‘doing what you say’—providing accountability and responsiveness through action
 - ‘saying it clearly’—simplifying the message without being inaccurate, limiting the use of technical terms, and satisfying the interests and needs of the target audience (OECD 2002).

However, trust in regulation of GMOs is also dependent on the motivations of members in different sectors of the community. Although the Act is intended to provide people with

confidence that any approved releases of GMOs are managed appropriately so that they are not harmful to them or the environment, other factors can be significant in influencing confidence in governmental regulatory oversight (Jaffe 2004). For members of the general public, these factors may include concerns about the technology; uncertainty about the rigour of the regulatory scheme; scientific uncertainty; concerns over long-term safety; and distrust of industry or government more generally. Other stakeholders, such as industry, on the other hand, may be concerned about other matters, such as consistency, reliable processes and clear pathways to commercialise products.

Loss of trust in the Regulator and the OGTR diminishes the effectiveness of regulation. It may result in loss of confidence by the community, reduced compliance with legislation or licence conditions, or reduced numbers of licence applications.

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.

Risk perception

Risk communication is also affected by how people understand or perceive things as a risk. The traditional approach has been to view risk within rational decision theory. It assigns probabilities, or degrees of belief, to future outcomes that may be beneficial or adverse (Kaplan & Garrick 1981; Keynes 1921). This analytical approach is widely applied in economics, auditing, engineering, gambling, and activities that use evidence-based decision making. This includes regulation of GMOs, which uses scientific/technical information as the basis of risk decisions. According to Kahneman (2011), this is the product of a slower, more deliberative thought process that is analytical in nature.

However, factors other than assignment of probabilities also influence perception of risk (Slovic 1987). Perception of risk varies considerably between individuals, depending on each person's unique proximity and susceptibility to any given risk (Finkel 2008). Perception and understanding of risk can also be influenced by personal experiences, knowledge, beliefs, values and attitudes.

Understanding how risks may be perceived can be important in ensuring effective transmission and receipt of risk communication messages. It also provides risk evaluators and decision makers insights into psychological and social factors that may affect their perception of risk as well as that of different stakeholders, thereby influencing the risk communication process.

Several conceptual frameworks have been established to explain our diverse understanding of and responses to risk. Some frameworks include:

- Psychometric model—describes recurring mental and emotive ‘rules of thumb’ (heuristics) (Kahneman 2011; Kahneman & Tversky 1996; Tom et al. 2007) that result in responses to risk that depart systematically from rational decision theory.
- Social/cultural theory—emphasises that risk takes place in a social context in which people’s attitudes to particular risks are shaped by the social context of family and friends, as well as interest groups for which we feel sympathy or opposition. Furthermore, people are affected differently by risks, know different things about those risks and have different views about them (Australian Standards 2010b; Beck 1992; Douglas & Wildavsky 1982; Giddens 1990).
- Evolutionary anthropology model—postulates that current responses to risk are fashioned from adaptation to threats that dominated human evolution, namely, disease, incorrect assignment of paternity, accidents, intergroup competition (warfare), subsistence failure and cooperation failure (Tucker & Ferson 2008).

These considerations of engagement, informing, building trust and how risk is perceived provide a useful background in informing the practice of risk communication.

Risk communication in practice

Consultation on applications

During development of the Act it became apparent that openness and transparency in decision making was important to the community and that there should be opportunities for public input as part of the decision-making process.

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 advising receipt of the application and when the consultation RARMP is expected to be released for comment is sent to those on the OGTR mailing list and placed on the OGTR website. This notification also provides summary information about the application. The consultation process is slightly different for the two types of DIR applications, with one round of consultation for limited and controlled releases and two rounds for general/commercial releases.

The Regulator consults on DIR licence applications for commercial releases with State and local governments in the area in which the GMO(s) are expected to occur, prescribed Australian Government agencies and the Environment Minister, and the GTTAC. This is to ensure expert input is obtained on matters to be considered in the preparation of the RARMP. Once the RARMP is prepared, a second round of consultation occurs, which includes these stakeholders and the public. The Regulator also consults the GTTAC on RARMPs prepared for certain DNIR applications.

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 may lead the Regulator to seek further information from the applicant. In addition, the Act gives the Regulator wide powers to seek further information 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, usually more diverse than required by the Act, as well as by notification on the OGTR website and by writing directly to interested parties. Publications include national, metropolitan, regional and rural newspapers and the Australian Government Gazette.

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 appropriately addressed. If deficiencies, such as new risks, inaccurate assessments, or better risk management strategies are identified through the consultation process, the RARMP, and where necessary proposed licence conditions, are amended to address them.

Comments provided by stakeholders to date have covered widely diverse issues, including raising 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 RARMP) readily available.

Some issues stakeholders have raised (such as economic, food labelling, marketing or marketability questions and concerns) are outside the scope of assessments required by the Act; some may fall within the jurisdiction of State governments (eg trade and marketing issues) or other regulatory agencies. For instance, FSANZ is responsible for food safety and the APVMA regulates pesticide use. Where complementary regulatory responsibility exists, there may be some discussion of this in the RARMP.

In the development of the Act, in relation to dealings with GMOs undertaken in containment (DNIRs), stakeholders were less concerned about having direct input into the decision-making process. The Regulator may consult State and local governments, prescribed Australian Government agencies, the GTTAC or any other person the Regulator considers appropriate. The Regulator routinely consults the government of the State in which the dealings are proposed to occur and the GTTAC on certain DNIR applications. The Regulator also provides information on the dealings (including the aims, a description of the project, and the date of issue and expiry of the licence) to stakeholders through the GMO Record.

Social and ethical issues

As a relatively new area, gene technology generates 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 and the Ministerial Council (now the Legislative and Governance Forum on Gene Technology) on ethical issues and issues of concern to the community (sections 106, 107). The committee comprises up to 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). The committee does not comment on individual applications.

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 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 (confidential commercial information and information about 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/email 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/email and RARMP summary (copy of consultation RARMP if requested)
Notify the applicant of the decision and review rights (sections 59, 108)	Letter/email and licence (if issued)
Maintain GMO Record (information on authorised GMO dealings and GM product approvals), including conditions of licence and location of trial sites (section 138)	GMO Record on website
Quarterly and annual reports (sections 136, 136A and 137)	Publication as a booklet; tabled in the Parliament, website, copy of annual report sent to States

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

Additional communication undertaken by the OGTR	Form of communication
Notifications of receipt of applications and publication of consultation DIR RARMPs	Client register, advertisements in State, regional and/or local newspapers and specialist publications
Questions and answers, biology and ecology documents and summaries of DIR RARMPs	Website (hardcopies available on request)
Consult additional stakeholders (such as the Department of Agriculture, Fisheries and Forestry) on DIR applications	Letter, email, face-to-face meeting
Notify stakeholders of licence decisions	Letter/email to States, prescribed Australian Government agencies and Environment Minister, appropriate local councils, public submitters, client register, website
Requirement for annual reporting by accredited organisations	Form on the website
Monitoring and compliance activities	Protocols on website, site visits, spot checks, audits and practice reviews, discussions with licence holders
Consult widely on related matters (eg this document)	Letter, briefing, presentation, face-to-face meeting
Ministerial correspondences, briefs	Letter, email
Establish cooperative relationships with other Australian Government regulatory agencies	Memoranda of understanding, informal consultation, brief, meeting
1800 telephone number	Verbal queries
Email address	Email queries
Adverse event reporting required in licences	Email/phone
Advise/update regulated organisations	IBC training nationally, dedicated section on website with relevant information
Conferences, forums, public addresses, workshops	Oral and written presentations by Regulator and OGTR staff
Quarterly and annual reports	Publication notified and posted on OGTR website, copies of quarterly reports sent to States, copies of Annual Report circulated to prescribed stakeholders and accredited organisations/IBCs

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 (see Table 6.5). 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.

Table 6.5: Forms of communication with stakeholders

Stakeholders	Form of communication
Applicant	Application form Informal/formal discussion Confidential Commercial Information application RARMP—consultation and final version Licence—reporting requirements, ongoing monitoring and compliance
IBCs	Informal/formal discussion Letter/email requesting advice or notification National IBC Forums
Experts	Meeting, informal discussion Letter requesting advice
Prescribed agencies	Memoranda of understanding Informal/formal discussion Letter/email requesting advice or notification
Local councils	Letter/email requesting advice
Government	Memoranda of understanding Informal/formal discussion Letter/email requesting advice
Public	1800 telephone number Advertisements Website Email/letter Client register

The website provides extensive information on the operation of the OGTR, including various application forms, 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 express particular concerns.

The Regulator's quarterly and annual reports provide details on applications considered, monitoring and compliance 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 consultancy contracts managed.

In addition, the OGTR provides regular training for 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 strict penalties under the Act for non-compliance.

The Regulator also engages with other international organisations regulating GMOs and is involved with harmonisation of regulation of biotechnology through the OECD.

Adapting risk communication to changing conditions

In an environment of rapidly changing forms of communication, the OGTR seeks to continually improve its risk communication processes. This involves monitoring submissions on consultation documents, reviewing the type and form of information made available to stakeholders and interested parties, and improving collaboration and coordination with other government agencies on risk communication. In addition, the advisory committees, GTTAC and GTECCC, provide important input.

Initiatives to adapt risk communication to changing circumstances include:

- using a variety of graphical tools and new electronic forms of transmitting information to communicate risk-based decisions and consultation processes (including making better use of existing tools, i.e. the OGTR website)
- using modern web-based tools (Department of Finance and Deregulation 2010) to enhance engagement with a broader range of people in the community
- increasing the use of clear language, including minimising scientific/technical jargon and complex bureaucratic language.

Conclusions

The Regulator undertakes a wide range of risk communication activities, exchanging information with stakeholders and the general community about potential risks from gene technology. To summarise:

- Risk communication is crucial to all aspects of risk analysis.
- Risk communication seeks to engage, inform and build trust with stakeholders and the community.
- Consultation with stakeholders, interest groups and the community is an important component for establishing engagement.
- The community varies considerably in their attitudes, interests, beliefs and risk biases, which requires matching with different types, amounts and channels of communication.



The background of the page is a light gray with a pattern of faint, stylized molecular structures. These structures consist of circles of various sizes connected by thin lines, resembling a network or a chemical structure. The top half of the page is white, and the bottom half is a solid teal color. A large, white puzzle piece shape is cut out from the top half, overlapping the teal area. The word "REFERENCES" is printed in a bold, black, sans-serif font in the upper right corner of the white area.

REFERENCES

REFERENCES

- Bammer, G., Smithson, M. (2008). *Uncertainty and risk*. Earthscan, London.
- Beck, U. (1992). *Risk society: Towards a new modernity*. Sage, New Delhi.
- Bennet, P.G. (2000). Applying the precautionary principle: A conceptual framework. *Foresight and Precaution* **1**: 223–227.
- Bergmans, H. (2006). Basic framework for risk assessment for transgenic plants developed by the OECD: 20 years after the OECD 'Blue Book'. *Environmental Biosafety Research* **5**: 213–218.
- Cattaneo, M.G., Yafuso, C., Schmidt, C., Huang, C-Y., Rahman, M., Olson, C., Ellers-Kirk, C., Orr, B.J., Marsh, S.E., Antilla, L., Dutilleul, P., Carrière, Y. (2006). Farm-scale evaluation of the impacts of transgenic cotton on biodiversity, pesticide use, and yield. *Proceedings of the National Academy of Sciences USA* **103**: 7571–7576.
- Clark, A.J., Brinkley, T. (2001). *Risk management: for climate, agriculture and policy*. Commonwealth of Australia, Canberra.
- Codex Alimentarius Commission (2003). Working principles for risk analysis for application in the framework of the Codex Alimentarius. In: *Codex Alimentarius Commission Procedural Manual*, ed. 13, Joint FAO/WHO Food Standards Programme. Rome. Available at <http://www.codexalimentarius.net/download/standards/10007/CXG_044e.pdf>.
- Covello, V.T. (2009). Strategies for overcoming challenges to effective risk communication. In: R.L. Heath, H.D. O'Hair, eds, *Handbook of risk and crisis communication*. Routledge, Hoboken, pp. 143–167.
- Cox, L.A. Jr (2008). What's wrong with risk matrices? *Risk Analysis* **28**: 497–512.
- Department of Finance and Deregulation (2010). *Engage: Getting on with Government 2.0*. Available at <<http://www.finance.gov.au/publications/gov20taskforcereport/index.html>>.
- Department of Sustainability, Environment, Water, Population and Communities (2011a). *Biodiversity action plans*. Available at <<http://www.environment.gov.au/biodiversity/threatened/publications/action/>>.
- Department of Sustainability, Environment, Water, Population and Communities (2011b). *Threat abatement plans*. Available at <<http://www.environment.gov.au/biodiversity/threatened/tap.html>>.

- Douglas, M., Wildavsky, A. (1982). *Risk and culture*. University of California Press, Berkeley.
- enHealth (2012). *Environmental health risk assessment: Guidelines for assessing human health risks from environmental hazards*. Australian Government Department of Health and Ageing, Canberra. Available at <[http://www.health.gov.au/internet/main/publishing.nsf/content/804F8795BABFB1C7CA256F1900045479/\\$File/DoHA-EHRA-120910.pdf](http://www.health.gov.au/internet/main/publishing.nsf/content/804F8795BABFB1C7CA256F1900045479/$File/DoHA-EHRA-120910.pdf)>.
- FAO, WHO (2006). *Food safety risk analysis: A guide for national food safety authorities*. FAO Food and Nutrition Paper 87. Rome.
- Finkel, A.M. (2008). Perceiving others' perceptions of risk: Still a task for Sisyphus. *Annals New York Academy of Science* **1125**: 121–137.
- Fiorino, D.J. (1990). Citizen participation and environmental risk: A survey of institutional mechanisms. *Science, Technology and Human Values* **15**: 226–243.
- Fischhoff, B. (1995). Risk perception and communication unplugged: Twenty years of process. *Risk Analysis* **15**: 137–145.
- Fitt, G.P. (2008). Have Bt crops led to changes in insecticide use patterns and impacted IPM? In: J. Romeis, T.M. Shelton, G. Kennedy, eds, *Integration of insect-resistant GM crops within IPM programs: Progress in Biological Control Series*, Springer-Verlag, Berlin, Heidelberg, Germany, pp. 303–328.
- Giddens, A. (1990). *Consequences of modernity*. Polity Press, Cambridge.
- Gough, J.D. (1991). *Risk communication: The implications for risk management*. Information Paper No. 33. Centre for Resource Management, Lincoln University, Canterbury, New Zealand.
- GTECCC (2012). *National framework for the development of ethical principles in gene technology*. Gene Technology Ethics and Community Consultative Committee, Canberra. Available at <[http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gtecccpapers-1/\\$FILE/gtecccethicalprinciples2012.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gtecccpapers-1/$FILE/gtecccethicalprinciples2012.pdf)>.
- Hart (2001). *Probabilistic risk assessment for pesticides in Europe: implementation & research needs*. Report of the European workshop on probabilistic risk assessment for the environmental impacts of plant protection products (EUPRA). Available at <<http://www.fera.defra.gov.uk/events/pastConferences/documents/eupraReport.pdf>>.
- Hayes, K.R. (2004). *Ecological implications of GMOs: Robust methodologies for ecological risk assessment. Best practice and current practice in ecological risk assessment for genetically modified organisms*. Department of the Environment, Water, Heritage and the Arts. Available at <<http://www.environment.gov.au/settlements/biotechnology/publications/pubs/bestpractice-summary.pdf>>.

- Hayes, K.R., Gregg, P.C., Gupta, V.V.S.R., Jessop, R., Lonsdale, M., Sindel, B., Stanley, J. Williams, C.K. (2004). Identifying hazards in complex ecological systems. Part 3: Hierarchical Holographic Model for oilseed rape. *Environmental Biosafety Research* **3**: 109–128.
- Hill, R.A. (2005). Conceptualizing risk assessment methodology for genetically modified organisms. *Environmental Biosafety Research* **4**: 67–70.
- Jaffe, G. (2004). Regulating transgenic crops: A comparative analysis of different regulatory processes. *Transgenic Research* **13**: 5–19.
- Jardine, C., Hrudey, S., Shortreed, J., Craig, L., Krewski, D., Furgal, C., McColl, S. (2003). Risk management frameworks for human health and environmental risks. *Journal of Toxicology and Environmental Health Part B: Critical Reviews* **6**: 569–718.
- Kahneman, D. (2011). *Thinking, fast and slow*. Farrar, Straus and Giroux, New York.
- Kahneman, D., Tversky, A. (1996). On the reality of cognitive illusions. *Psychology Review*, **103**: 582–591.
- Kaplan, S., Garrick, B. (1981). On the quantitative definition of risk. *Risk Analysis* **1**: 11–27.
- Keynes, J.M. (1921). *A treatise on probability*. Macmillan and Co., London.
- Klinke, A., Renn, O. (2002). A new approach to risk evaluation and management: Risk-based, precaution-based, and discourse-based strategies. *Risk Analysis* **22**: 1071–1094.
- Lay Panel Report (1999). First Australian consensus conference: Gene technology in the food chain. Available at <<http://www.greencrossaustralia.org/media/40073/layreport.pdf>>.
- Lyytimäki, J., Assmuth, T., Hildén, M. (2011). Unrecognized, concealed, or forgotten—the case of absent information in risk communication. *Journal of Risk Research* **14**: 757–773.
- McComas, K.A., Arvai, J., Besley, J.C. (2009). Linking public participation and decision making through risk communication. In: R.L. Heath, H.D. O'Hair, eds, *Handbook of risk and crisis communication*. Routledge, Hoboken, pp. 364–385.
- National Research Council (1983). *Risk assessment in the Federal Government: Managing the process*. National Academy Press, Washington, D.C.
- National Research Council (2008). *Science and decisions: Advancing risk assessment*. National Academy Press, Washington, D.C.
- Natural Resource Management Ministerial Council (2006). *Australian Weeds Strategy—A national strategy for weed management in Australia*. Australian Government Department of the Environment and Water Resources, Canberra ACT.
- OECD (1986). Recombinant DNA safety considerations. Available at <<http://www.oecd.org/science/biotechnologypolicies/40986855.pdf>>.

- OECD (2002). Guidance document on risk communication for chemical risk management. Available at <[http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono\(2002\)18&doclanguage=en](http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2002)18&doclanguage=en)>.
- OGTR (2003a). General release of Roundup Ready® canola (*Brassica napus*) in Australia (DIR 020/2002). Available at <[http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir020-3/\\$FILE/dir020finalrarmp.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir020-3/$FILE/dir020finalrarmp.pdf)>.
- OGTR (2003b). Commercial release of InVigor® hybrid canola (*Brassica napus*) for use in the Australian cropping system (DIR 021/2002). Available at <[http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir021-3/\\$FILE/dir021finalrarmp2.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir021-3/$FILE/dir021finalrarmp2.pdf)>.
- OGTR (2007). Monitoring and compliance risk analysis protocol. Available at <[http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mcother-3/\\$FILE/riskprotocolJuly07.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/mcother-3/$FILE/riskprotocolJuly07.pdf)>.
- OIE (2004). *Handbook on import risk analysis for animals and animal products: Introduction and qualitative risk analysis*. Report No. 1. Office International des Epizooties (World Organisation for Animal Health), Paris.
- Patterson, A., Gray, T. (2012). Unprincipled? The British government's pragmatic approach to the precautionary principle. *Environmental Politics* **21**: 432–450.
- Raybould, A. (2006). Problem formulation and hypothesis testing for environmental risk assessments of genetically modified crops. *Environmental Biosafety Research* **5**: 119–126.
- Renn, O. (2009). Risk communication: Insights and requirements for designing successful communication programs on health and environmental hazards. In: R.L. Heath, H.D. O'Hair, eds, *Handbook of Risk and Crisis Communication*. Routledge, Hoboken, pp. 80–98.
- Renn, O., Dreyer, M., Klinke, A., Losert, C., Stirling, A., van Zwanenberg, P., Muller-Herold, U., Morosini, M., Fisher E. (2003). *The application of the precautionary principle in the European Union. Final document of the EU project 'Regulatory Strategies and Research Needs to Compose and Specify a European Policy on the Application of the Precautionary Principle' (PrecauPri)*. Centre of Technology Assessment in Baden-Wuerttemberg, Stuttgart, Germany.
- Romeis, J., Bartsch, D., Bigler, F., Candolfi, M.P., Gielkens, M.M.C., Hartley, S.E., Hellmich, R.L., Huesing, J.E., Jepson, P.C., Layton, R., Quemada, H., Raybould, A., Rose, R.I., Schiemann, J., Sears, M.K., Shelton, A.M., Sweet, J., Vaituzis, Z., Wolt, J.D. (2008). Assessment of risk of insect-resistant transgenic crops to non-target arthropods. *Nature Biotechnology* **26**: 203–208.
- Sandin, P., Peterson, M., Hansson, S.O., Rudén, C., Juthe, A. (2002). Five charges against the precautionary principle. *Journal of Risk Research* **5**: 287–299.
- Secretariat of the Convention on Biological Diversity (2000). *Cartagena protocol on biosafety to the Convention on Biological Diversity*. Secretariat of the Convention on Biological Diversity, Montreal.

- Slovic, P. (1987). Perception of risk. *Science* **236**: 280–285.
- Standards Australia (2006). *HB 294:2006 National Post-Border Weed Risk Management Protocol*, Standards Australia/Standards New Zealand, Sydney and Wellington.
- Standards Australia (2009). *AS/NZS ISO 31000:2009 Risk Management—Principles and guidelines*. Standards Australia/Standards New Zealand, Sydney and Wellington.
- Standards Australia (2010a). *AS/NZS 2243.3:2010 Safety in laboratories Part 3: Microbiological safety and containment*. Standards Australia/Standards New Zealand, Sydney and Wellington.
- Standards Australia (2010b). *HB 327:2010 Communicating and consulting about risk*. Standards Australia/Standards New Zealand, Sydney and Wellington.
- Standards Australia (2012). *HB 89–2012 Risk management—guidelines on risk assessment techniques*. Standards Australia/Standards New Zealand, Sydney and Wellington.
- Thorp, J.R., Lynch, R. (2000). *The determination of weeds of national significance*. National Weeds Strategy Executive Committee, Launceston.
- Tom, S.B., Fox, C.R., Trepel, C., Poldrak, R.A. (2007). The neural basis of loss aversion in decision-making under risk. *Science* **315**: 280–285.
- Tucker, W.T., Ferson, S. (2008). Evolved altruism, strong reciprocity, and perception of risk. *Annals New York Academy of Science* **1125**: 111–120.
- USEPA (1998). *Guidelines for ecological risk assessment*. EPA/630/R-95-002F. US Environmental Protection Agency, Risk Assessment Forum, Washington, D.C.
- van den Belt, H. (2003). Debating the precautionary principle: ‘guilty until proven innocent’ or ‘innocent until proven guilty’? *Plant Physiology* **132**: 1122–1126.
- van der Sluijs, J.P., Craye, M., Funtowicz, S.O., Klopogge, P., Ravetz, J.R., Risbey, J.S. (2005). Combining quantitative and qualitative measures of uncertainty in model based environmental assessment: The NUSAP System. *Risk Analysis* **25**: 481–492.
- Whitehouse, M.E.A., Wilson, L.J., Fitt, G.P. (2005). A comparison of arthropod communities in transgenic Bt and conventional cotton in Australia. *Environmental Entomology* **34**: 1224–1241.
- WHO (2008). *Uncertainty and data quality in exposure assessment*. World Health Organization, pp. 1–175. Available at <http://www.who.int/ipcs/publications/methods/harmonization/exposure_assessment.pdf>.
- Wolt, J.D., Keese, P., Raybould, A., Fitzpatrick, J.W., Burachik, M., Gray, A., Olin, S.S., Schiemann, J., Sears, M., Wu, F. (2010). Problem formulation in the environmental risk assessment for genetically modified plants. *Transgenic Research* **19**: 425–436.

The background of the page is a light gray color. It is decorated with several faint, stylized molecular structures. These structures consist of small gray circles (representing atoms) connected by thin gray lines (representing bonds). Some of these structures are enclosed within larger, thin gray circles. A prominent green wavy line runs horizontally across the middle of the page, separating the light gray upper section from a solid green lower section. The text "Appendix 1" is located in the upper right area, above the green line.

Appendix 1

APPENDIX A: GENE TECHNOLOGY REGULATORY SYSTEM

The purpose of this Appendix is to:

- provide background to the 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, which 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 who 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 on the 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, which commits the States to pass corresponding laws.

Reviews of legislation

In 2005–06, as required by section 194 of the Act, the Gene Technology Ministerial Council (now the Legislative and Governance Forum on Gene Technology [LGFGT]) 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 introducing limited and controlled release provisions
- licence variations—providing clarification on the circumstances in which licence variations can be made
- a new provision—Emergency Dealing Determination (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 LGFGT 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.

The LGFGT initiated a second independent review of the Act in June 2011, including inviting public submissions. The report of the 2011 Independent Review of the Gene Technology Act 2000 was made publicly available in December 2011.⁸ The Review investigated emerging trends and international developments in biotechnology and their regulation, the efficiency and effectiveness of the operation of the Act consistently across the national scheme for gene technology regulation in Australia, and the interface between the Act and other regulation. The Review found that the Act was working well and that the OGTR was operating in an effective and efficient manner. The Review considered that the current consultation processes in relation to applications under the Act were working well.

Three sets of amendments to the Regulations have been made: Amendment Regulations 2006 (as a result of the 2004–06 Regulator's review), Amendment Regulations 2007 (consequential amendments due to the review of the *Gene Technology Act 2000*) and Amendment Regulations 2011, which included requirements for transport, storage and disposal of GMOs.

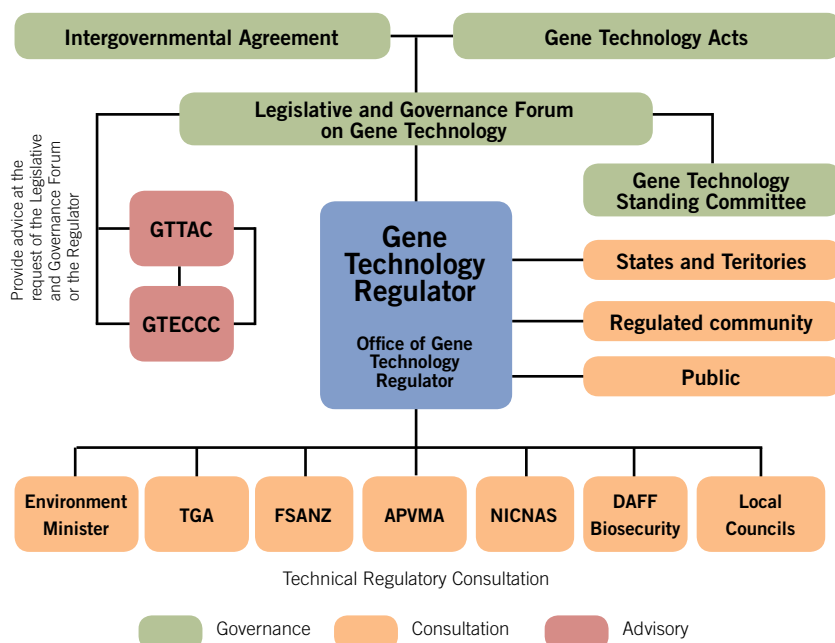
Operation of the regulatory system

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 (the Regulator), who is charged with administering the Act and making decisions about development and use of GMOs under the Act.

8 <<http://www.health.gov.au/internet/main/publishing.nsf/Content/genereview-finalreport>>

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 LGFGT, 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 LGFGT on matters relating to gene technology. These are the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics and Community Consultative Committee (GTECCC).⁹

Figure A1: Governance arrangements for the Gene Technology Regulator



Notes: APVMA = Australian Pesticides and Veterinary Medicines Authority; DAFF = Department of Agriculture, Fisheries and Forestry; FSANZ = Food Standards Australia New Zealand; GTECCC = Gene Technology Ethics and Community Consultative Committee; GTTAC = Gene Technology Technical Advisory Committee; NICNAS = National Industrial Chemicals Notification and Assessment Scheme; TGA = Therapeutic Goods Administration.

⁹ Amendments to the legislation replaced the Gene Technology Ethics Committee and Gene Technology Community Consultative Committee with the GTECCC from 1 January 2008.

Legislative and Governance Forum on Gene Technology

The Legislative and Governance Forum on Gene Technology (LGFGT) oversees implementation of the legislation and the role of the Regulator. The LGFGT was established by the *Gene Technology Agreement 2001* between the Australian Government and the governments of all States. The Agreement commits State governments to enact corresponding State legislation.

The role of the LGFGT is to provide policy input into implementing and operating the regulatory scheme. In addition, the LGFGT 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 LGFGT is supported by the Gene Technology Standing Committee.

The Act provides for the LGFGT 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 LGFGT 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 LGFGT: the GTTAC and the GTECCC. Membership of the committees consists of persons with expertise in one or more scientific fields (GTTAC) or with skills and experience in areas relevant to gene technology as specified in the Act (GTECCC).

GTTAC—provides scientific and technical advice, at the request of the Regulator or the LGFGT, 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 LGFGT, 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 the Act
- matters of general concern in relation to GMOs.

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 an 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 the health and safety of people or 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 reviewed by IBC; RARMP prepared and licence decision by the Regulator	Yes ≥PC2 (usually) and other conditions will apply
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 method described in Chapter 4 that is 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 working 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**¹⁰ 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 the environment (sections 78 and 79 of the Act). The principles of risk analysis set out in this framework are applicable to determining 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.

One GMO dealing has so far been placed on the GMO Register.

Exempt dealings are dealings with GMOs that have been assessed over time as posing negligible¹¹ 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 (<25L) of an approved host/vector system into which low-risk genetic material has been introduced (eg the gene must not be uncharacterised, it must not be derived from a pathogenic organism, nor code for a toxin).

10 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.

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

Notifiable low-risk dealings (NLRDs) are dealings with GMOs that have been assessed over time as posing negligible risks provided certain management conditions are met. The types of dealings that may be conducted as NLRDs are specified in the Regulations (Parts 1 and 2 of Schedule 3). Before a type of dealing is listed in these Parts of 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 an NLRD, in accordance with regulation 13. 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 an 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 (eg the gene may encode a pathogenic determinant or uncharacterised gene from a pathogen).

Licensed dealings

Any dealing that is not exempt, or on the GMO Register or specified in an EDD, or an NLRD, 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 review and support the application.

Preparing an 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 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 provides 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/Territories
- 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/Territories
- 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 an 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 on whether to issue a licence. Section 58 specifies the particulars for assessing applicant suitability. In addition, certification of facilities and accreditation of organisations, as specified in Part 7 of the Act, 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 an RARMP for both DNIR and DIR applications. The risk assessment takes account of any risks to human health and safety or to 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 of GMOs 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 minimises risks to the environment. The Act requires preparation of an RARMP for DNIR applications (section 47). The application form specifies the information the Regulator requires.

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 five-stage process adopted in respect of DNIR applications is shown in Figure A2 and is described below.

Stage 1—The applicant must prepare information about the proposed dealings with the GMO, possible risks posed by the dealings and proposed ways that each risk would be managed. The applicant must ensure all responses to the Regulator's information requirements are supported by appropriate data and literature citations.

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. If there is not sufficient information, the application is rejected.

Stage 3—Section 47 of the *Gene Technology Act 2000* requires the Regulator to prepare a risk assessment and risk management plan (RARMP). The information provided in the application is used to prepare the RARMP in relation to the proposed dealings.

The actual risk assessment process is, to some extent, shaped by the data requirements set out in the DNIR application form; however, the Regulator can require submission of any data required to comprehensively identify 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.

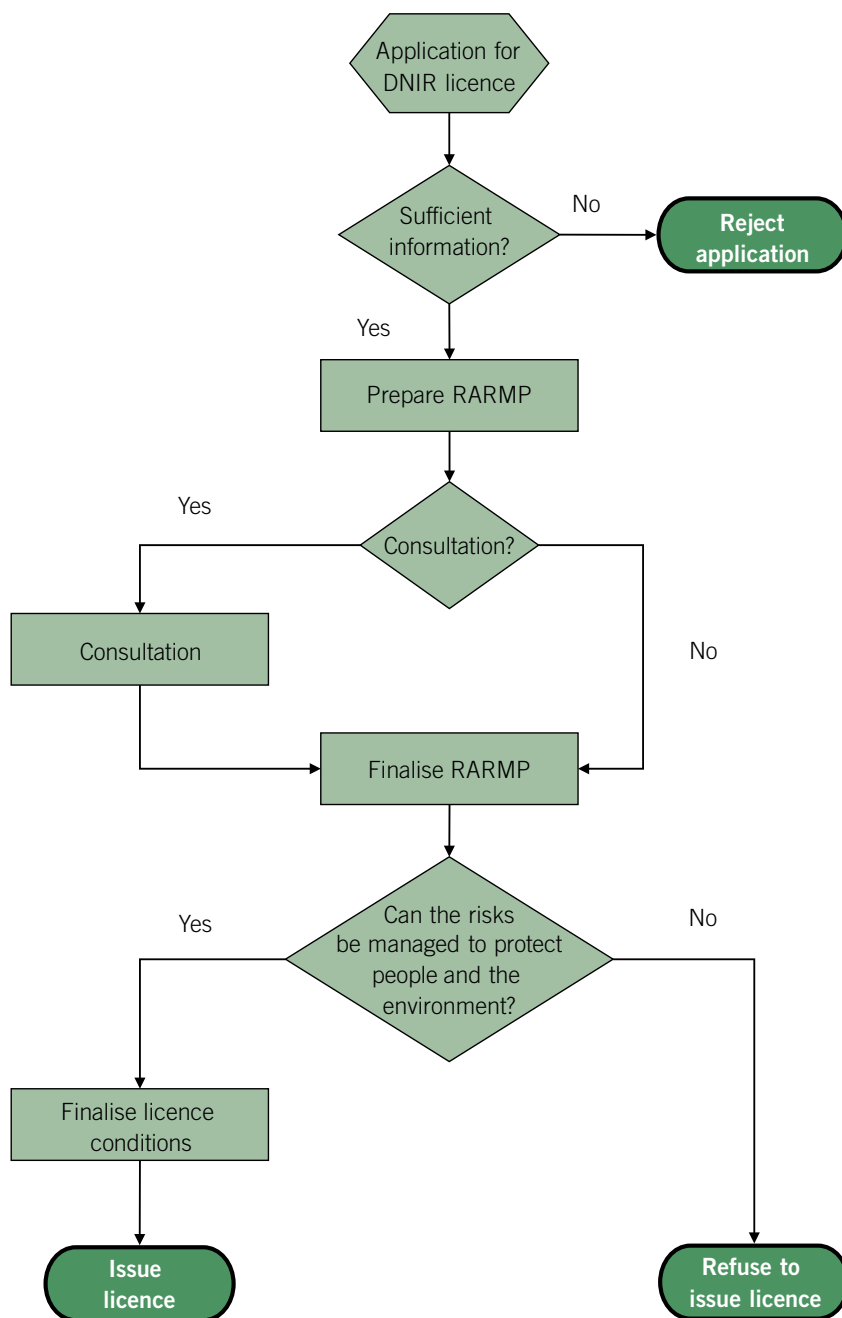
Preparation of the risk assessment involves developing risk scenarios that describe how risks that may be posed by the dealings with the GMO could result in harm, identifying risks that require more detailed characterisation and estimating the level of risk based on the likelihood of the event occurring 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 4—The Regulator may consult experts, agencies or authorities about the RARMP, such as the GTTAC, the States and Territories, prescribed Australian Government agencies, the Environment Minister, and appropriate local government authorities.

Stage 5—The Regulator makes the decision on whether to issue a licence or not, and if agreeing to issue the licence, any conditions to be imposed. This decision is based upon the RARMP, having regard to any policy principles issued by the LGFGT. The Regulator must notify the applicant in writing that a licence decision has been made. The Regulator also advises all experts, agencies and authorities that were consulted.

The statutory timeframe allowed for consideration of a DNIR application is 90 days.

Figure A2: DNIR assessment process

Dealings involving intentional release

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 risks posed by the dealings and proposed ways that each risk will 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, providing quantitative data where appropriate. 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 who 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 the GTTAC, the States, prescribed Australian Government agencies, the Environment Minister, and appropriate local government authorities. The Regulator usually consults with local government authorities on 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 an 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 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)).

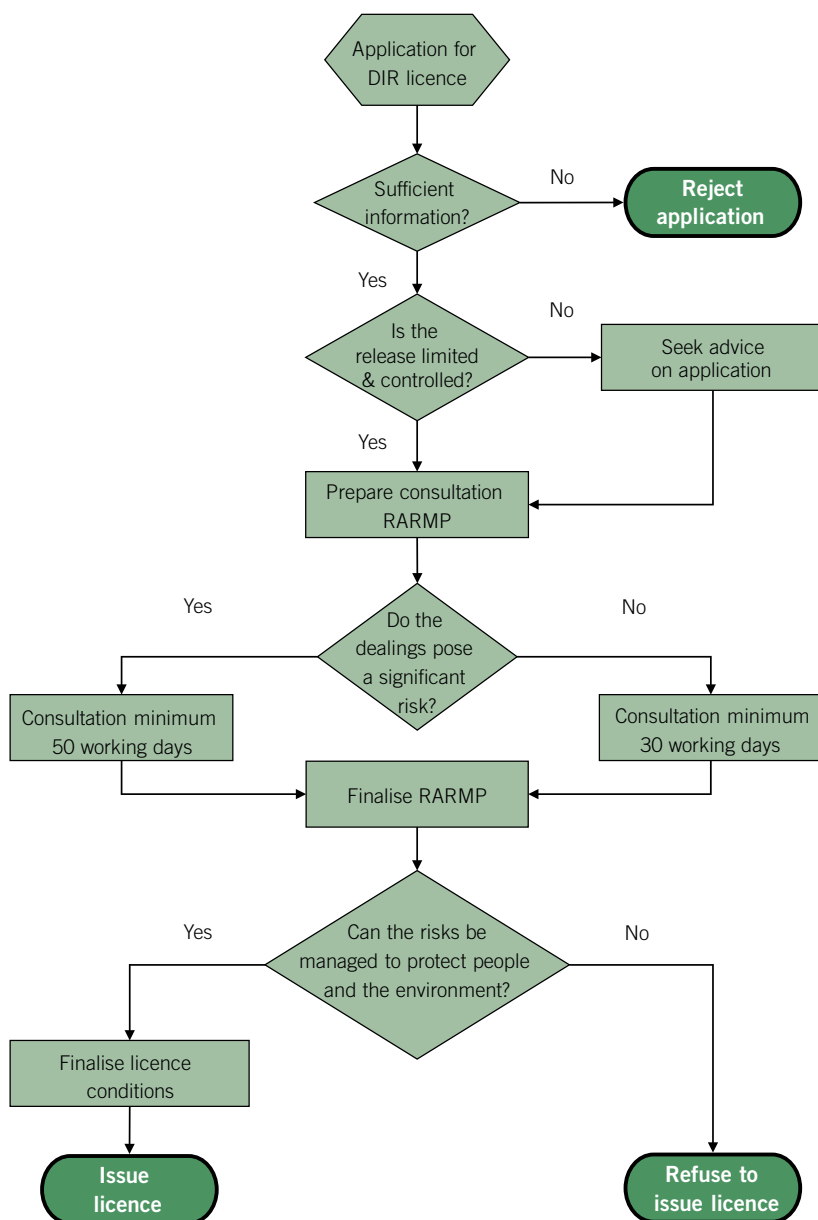
The statutory timeframe allowed for consideration of a DIR application, except for a limited and controlled release application, is 255 days. For a limited and controlled release application this timeframe is either 170 days (for dealings that may pose a significant risk) or 150 days (for dealings that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

The Regulator is required to seek public comment on the consultation RARMP via advertisements in a national newspaper and the Australian Government Gazette and notices placed on the Regulator's website. In practice, the Regulator advertises more broadly, including metropolitan and regional newspapers and special interest press, and advises 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 LGFGT. 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 an 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 a 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 Record¹² is currently divided into separate sections for recording:

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

Accreditation and certification

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

An organisation undertaking licensed 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 evaluation 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*

12 The GMO Record can be accessed through the Regulator's website at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmorec-index-1>>.

accreditation of organisations and the 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 containment 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 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 to 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 license general release of a GMO into the environment that is used as a human therapeutic, 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 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	Scope	Relevant legislation
Office of the Gene Technology Regulator (OGTR) Portfolio of Health and Ageing		
GMO dealings	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.	<i>Gene Technology Act 2000</i>
Therapeutic Goods Administration (TGA) Portfolio of Health and Ageing		
Medicines, medical devices, blood and tissues	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.	<i>Therapeutic Goods Act 1989</i>

GM0/GM products	Scope	Relevant legislation
Food Standards Australia and New Zealand (FSANZ) Portfolio of Health and Ageing		
Food	FSANZ is responsible for the Australia New Zealand Food Standards Code, which prohibits use of food products produced using gene technology in Australia unless there is specific approval for sale of these foods following a safety assessment. The Code also contains provisions for labelling certain GM foods.	<i>Food Standards Australia New Zealand Act 1991</i>
Australian Pesticides and Veterinary Medicines Authority (APVMA) Portfolio of Agriculture, Fisheries and Forestry		
Agricultural and Veterinary Chemicals	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.	<i>Agricultural and Veterinary Chemicals (Code) Act 1994;</i> <i>Agricultural and Veterinary Chemicals Administration Act 1994</i>
National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Portfolio of Health and Ageing		
Industrial Chemicals	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.	<i>Industrial Chemicals (Notification and Assessment) Act 1989</i>
DAFF Biosecurity Portfolio of Agriculture, Fisheries and Forestry		
Quarantine	DAFF Biosecurity regulates importation into Australia of all animal, plant and biological products that may pose a quarantine pest and/or disease risk.	<i>Quarantine Act 1908;</i> <i>Imported Food Control Act 1992</i>

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).



The background is a solid teal color. It features several faint, light-blue molecular structures scattered across the page. These structures consist of circles of varying sizes connected by lines, representing atoms and bonds. Some of these molecular clusters are enclosed within larger, thin-lined circles. In the bottom right corner, there is a circular inset showing a close-up of a person's hand, with fingers slightly curled, resting on a white surface.

www.ogtr.gov.au

All information in this publication is correct as at May 2013

D10223 May 2013