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Precaution and the Precautionary Principle: two Australian case studies

Staff Working Paper

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Abbreviations and explanations

Abbreviations

AAT	Administrative Appeals Tribunal (also abbreviated as AATA)
ACRE	Advisory Committee on Releases to the Environment
AFMA	Australian Fisheries Management Authority
BRS	Bureau of Rural Sciences
CCAMLR	Convention for the Conservation of Antarctic Living Marine Resources
CSIRO	Commonwealth Scientific and Industrial Research Organisation
EC	European Commission
EPBC Act	*Environment Protection and Biodiversity Conservation Act 1999*
EBFM	Ecosystem based fisheries management
ERA	Ecological risk assessment
ERM	Ecological risk management
ESD	Ecologically sustainable development
EU	European Union
FAA	*Fisheries Administration Act 1991 (Cth)*
FAO	Food and Agriculture Organization
FCA	Federal Court of Australia
FMA	*Fisheries Management Act 1991 (Cth)*

FSANZ	Food Standards Australia New Zealand
GM	Genetically modified
GMO	Genetically modified organism
GTA	Gene Technology Act
IGAE	Inter-Governmental Agreement on the Environment
IOTC	Indian Ocean Tuna Commission
ITQ	Individual transferable quota
MAC	Management advisory committee
MAFRI	Marine and Freshwater Resources Institute
OECD	Organization for Economic Cooperation and Development
OGTR	Office of the Gene Technology Regulator
RAF	Risk analysis framework
RAG	Resource assessment group
RARMP	Risk assessment and risk management plan
SPF	Small Pelagic Fisheries
TAC	Total allowable catch
UN	United Nations
WTO	World Trade Organization

Glossary

Biomass	Total weight of a stock or component of a stock.
Bioremediation	Bioremediation is any process that uses micro-organisms, fungi, plants or their enzymes to reverse damage to the environment by contaminants such as chemicals.
By-catch (fisheries)	All living and non-living material, except for the target species, which is caught while fishing. Includes by-product, discards thrown back into the sea, and any part of the catch that does not reach the deck but is affected by interactions with the fishing gear.
By-product (fisheries)	The part of the by-catch that is kept or sold by the fisher.
Exploitation rate	Fraction of animal (usually fish) deaths caused by fishing, usually expressed as an annual value. Also defined as the proportion of a population caught during the year.
Fishing permit	A right to fish granted under s.32 of the *Fisheries Management Act 1991* to a person which authorises the use of a specified Australian boat by that person, or a person acting on that person's behalf, for fishing in a specified area of the Australian Fishing Zone or in a specified fishery for specified species using specified equipment.
Gene technology	Gene technology involves modifying organisms by directly incorporating, deleting or altering one or more genes or genetic sequences to introduce or alter a specific characteristic or characteristics Organisms that have been modified using gene technology. .
Genetically modified organisms (GMOs)	Organisms that have been modified using gene technology.

Genetically modified (GM) product	Things derived or produced from GMOs.
Individual transferable quotas (ITQs)	ITQs are individual shares of a TAC which allow the holder to catch that portion of the TAC each season. Each season the amount of fish (in weight) permitted to be caught under an ITQ will vary in proportion to changes in the TAC set for that species. ITQs are fully tradeable and can be sold or leased to other persons.
Input controls (fisheries)	Restrictions placed on the amount of effort input into a fishery eg by restricting types and size of fishing gear and boats and the amount of fishing time.
Liability	The obligation of a person or company under the applicable law to provide compensation for damage resulting from an action for which that person or company is deemed to be responsible.
Limited entry (fisheries)	Management arrangements whereby only a fixed number of operators are allowed to fish in a particular fishery. New operators may only gain access to the fishery by purchasing an existing right.
Management plan (fisheries)	An explicit arrangement between a fishery management authority and interested parties that: identifies the interested parties and clarifies their roles, rights and responsibilities; details the agreed objectives for the fishery; specifies the management rules and regulations; and provides other details about the fishery relevant to the management authority, including monitoring, enforcement and consultation arrangements.
Maximum sustainable yield (fisheries)	The maximum catch that can be taken from a fishery on a continuing basis without causing the stocks to be depleted.
Output controls (fisheries)	Restrictions imposed on the quantity of fish that can be taken from a fishery within a specified period of time.
Non-target fish species	Any part of the catch, except the target species.

Pelagic fish	Fish that are normally caught on the sea surface or in the water column.
Sustainable fishing yield	See ‘maximum sustainable yield’.
Total allowable catch (TAC)	The amount of fish of a particular species permitted to be taken from a fishery in prescribed period. TACs are set for fish species managed through ITQs.
Trigger catch limit (TCL)	A catch level that triggers some form of management action in the fishery.

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1 Precaution and the Precautionary Principle

> … not only known risks, but also potential risks to the environment and human health may need to be addressed; when there is a rational basis for concern, when their nature or magnitude is uncertain, and when a causal link with a certain action or process is not fully established … This notion of precaution is based upon the assumption that in certain cases, scientific certainty, to the extent that it is obtainable with regard to environmental issues, may be achieved too late to provide effective responses to environmental threats. (OECD 2002, p. 6)

Many policy issues, particularly in environmental and natural resource management areas, are subject to significant uncertainties. Information about the nature, magnitude and likelihood of adverse consequences from particular activities may be uncertain and/or incomplete. In addition, there may be uncertainty about the expected effects of policy responses intended to mitigate possible threats to the environment and human health. In such circumstances, policymakers may adopt a cautious approach to decision making. Precautionary measures may be implemented to address potential, but uncertain, threats.

Applying precaution often raises questions about application of the Precautionary Principle. The Principle was conceived as a response to the inherent difficulties faced by decision makers confronted with uncertain potential outcomes. Its purpose is to remove uncertainty as an obstacle to addressing potential environmental and health hazards. However, much confusion surrounds the Principle and its role in decision making under uncertainty.

This paper examines two Australian case studies where precaution has been an important element in decision making — fisheries management and licensing of genetically modified organisms (GMOs). It considers three key issues:

- the basis for precautionary decision making
- how precaution has been applied in practice
- whether (and how) the Precautionary Principle contributed to precautionary decision making.

This chapter provides background information on three main categories of Precautionary Principle definitions, their interpretation and their impact on decision making. The

difference between applying precaution and invoking the Precautionary Principle is highlighted. A brief discussion of the most important Australian definitions follows.

Chapter 2 discusses how precaution has been applied in Australian fisheries management. The case study describes the legislative objectives of fisheries management and the definition of the Precautionary Principle included in fisheries legislation. It examines the ecological risk management framework developed by the Australian Fisheries Management Authority (AFMA) to take account of uncertainties and to apply precaution in fisheries management. The chapter then analyses a number of recent legal challenges to AFMA's precautionary decisions.

Chapter 3 investigates how precaution is implemented in the licensing process for the intentional release of GMOs into the environment. The legislative objectives of the regulatory system, and its provisions for precaution, are described. The risk analysis framework for GMO licence applications is examined, with a focus on how uncertainties and potential hazards are taken into account in licensing decisions.

Chapter 4 draws some broader implications for environmental and natural resource management where decision makers must deal with significant uncertainties.

1.1 Applying precaution

Precaution involves being alert to possible future dangers and exercising an appropriate level of caution or prudence to safeguard against, or ward off, possible harm in advance of danger. (The Macquarie Dictionary defines precaution as 'prudent foresight'.)

Precaution is a response to the inherent difficulties faced by decision makers confronted with uncertainty — as distinct from risk — about potential outcomes. The differences between risk and uncertainty are important for decision making. Risk is amenable to conventional cost–benefit analysis and risk assessment and management. In contrast, cost–benefit comparisons, and formulation of risk management strategies, are problematic in the presence of uncertainty because much of the information required for such analyses is not available or is inconclusive. Four types of decision problems and their implications for risk management approaches are identified in box 1.1.

Box 1.1 **Types of decision problems and implications for decision making**

Four types of decision problems, and their implications for applying risk management approaches, can be identified:

1. Decision making with certainty — The outcome of each decision is known in advance. Cost–benefit analysis will identify the costs and benefits of each outcome.
2. Decision making with risk — The range of possible outcomes, and their associated probabilities, are known for each decision. Cost–benefit analysis can identify the risk-weighted costs and benefits of each outcome. Standard risk management techniques can be applied.
3. Decision making with uncertainty — The range of possible outcomes is known for each decision but objective probabilities cannot be determined for each outcome. Standard cost–benefit analysis cannot be used because weights cannot be assigned to each possible outcome. Conventional risk management is hindered by the absence of quantitative (objective) risks.
4. Decision making with ignorance — The full range of outcomes and their associated probabilities are not known. There is insufficient information to permit standard cost–benefit analysis and risk management is difficult.

Source: COMEST 2005.

Uncertainty is pervasive in environmental and natural resource management. Decision makers may be unable to predict with confidence the long-term consequences and intergenerational impacts of activities undertaken (or forgone) now. In addition, there may be uncertainty regarding the preferences of future generations, and of future resource endowments, products and technologies (see, for example, Cooney 2005; Stewart 2002; Wills 1997). Further, the full effects of regulatory measures may not be predictable with certainty.

That said, decision makers with responsibility for managing environmental resources or safeguarding human health have little practical alternative but to deal with uncertainty within some form of risk management framework. Various approaches may be adopted to take account of uncertainties in determining regulatory and policy responses. These approaches include:

- attaching subjective probabilities to various outcomes based on the best available expert advice, thereby converting uncertainty into (subjective) risk
- adopting ‘worst case’ scenarios in designing risk management measures
- applying sensitivity analysis to a selection of potential outcomes — perhaps those subjectively assessed as being most likely to occur or alternatively chosen to include

extreme, ‘worst case’ events — to ensure policy responses will be effective under a range of circumstances.

Conversion of uncertainties into subjective or qualitative ‘risks’, and sensitivity analyses, rest on assumptions that may be incorrect. For example, a sensitivity analysis may exclude outcomes that later occur, because such scenarios were either not anticipated or were mistakenly judged to have negligible probabilities attached. Similarly, ‘worst case’ assumptions may be either too conservative or too pessimistic. Options valuation (see, for example, Farrow 2004; Gollier and Treich 2003) provides an alternative approach that is particularly applicable where the choice is between undertaking a particular activity or not allowing it. However, in practice, there may be few feasible alternatives to using subjective or qualitative ‘risks’, sensitivity analyses and ‘worst case’ assumptions, and these measures are widely used.

Various methods of addressing uncertainty within risk management frameworks may incorporate a degree of precaution. Precaution might be built into frameworks by, for example, making conservative estimates of subjective probabilities or placing relatively high weights on ‘worst case’ outcomes.

There are many options for implementing precaution. Since the nature of the uncertainties and potential hazards vary case-by-case, the appropriate response to the hazards will also vary depending on the circumstances (OECD 2002; Peel 2005; Raffensperger et al. 2000). The range of possible precautionary measures includes:

- research to reduce uncertainties and improve information for decision making
- incorporating ‘safety margins’ or ‘uncertainty factors’ in risk assessments
- adopting measures that are robust to a range of possible circumstances, based on sensitivity analysis
- adaptive management to respond to new information
- regulating new products, processes or technologies to reduce the potential for adverse impacts
- banning (either temporarily or permanently) potentially hazardous activities.

Options may be combined — for example, temporary prohibition while conducting research. The course of action will depend on the circumstances of each case, which include:

- the extent and significance of the information gaps and uncertainties
- the prospects and potential costs and benefits of obtaining better information in the future

- the incidence of damage, for example, whether those likely to be most seriously affected are children (where larger safety margins are often applied), whether adverse effects are concentrated on future generations, or whether environmental impacts will have large flow-on effects through ecological systems
- the possibility of catastrophic events and society's degree of risk aversion
- the capacity, and ease or difficulty, of altering policies in the future, which may depend on whether policy measures would require, or generate incentives for, long-lived investments
- the potential costs and benefits to society of each alternative course of action (Peterson 2006).

1.2 Precautionary Principle definitions

Since the 1990s, versions of the Precautionary Principle have been widely incorporated into international agreements, as well as domestic statutes and policies in many countries, including Australia. Despite widespread reference to 'the' Precautionary Principle, there are, in fact, many versions of the Principle. Most seek to ensure that an absence of scientific certainty about the nature and likelihood of potential serious or irreversible hazards does not lead to a default position that such threats are ignored. However, the multitude of definitions, and their often vague or complicated wording, have led to considerable debate about what the Principle is and what it means for decision making.

The most widely quoted statement of the Precautionary Principle was formulated at the 1992 United Nations (UN) Conference on Environment and Development (also known as the Rio definition):

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. (United Nations 1992, Principle 15)

The Rio definition is not universally accepted, as evidenced by the many alternative definitions. The differences between various definitions can have significant implications for decision making.

Three categories of definition

Various ways of categorising the various definitions of the Principle have been suggested (for example, Cooney 2005; Hansson et al. 2002; Peterson 2006; Stewart 2002; Wiener 2002). This paper uses the classifications 'flexible', 'semi-prescriptive' and

'prescriptive' (adapted from Cooney's (2005) categories of 'weak', 'moderate' and 'strong'). These categories reflect how much each definition constrains decision makers' capacity to respond to a full range of considerations before determining what, if any, precautionary action to take. In brief, the key differences include:

- *Flexible* formulations remove uncertainty as a justification for delaying actions until those uncertainties have been resolved. But there is no mandatory requirement to take action and any precautionary action may have to be 'cost-effective'.[1] The Rio definition is an example.
- *Semi-prescriptive* versions generally require action where there are threats of damage to the environment or to human health. Decision makers have less scope to consider whether the magnitude of potential harm, and cost–benefit comparisons, warrant precautionary action. An example is contained in the Ministerial Declaration from the Third International Conference on the Protection of the North Sea held in 1990:

  > The participants … will continue to apply the precautionary principle, that is to take action to avoid potentially damaging impacts of substances that are persistent, toxic, and liable to bioaccumulate even where there is no scientific evidence to prove a causal link between emissions and effects.

- *Prescriptive* versions typically have a low threshold (or trigger) and stringent obligations for action in response to uncertainty, regardless of the magnitude of the potential threat or of the costs and benefits of action. An example was formulated by Earth Charter in 2000:

  > Prevent harm as the best method of environmental protection and, when knowledge is limited, apply a precautionary approach. Take action to avoid the possibility of serious or irreversible environmental harm even when scientific knowledge is incomplete or inconclusive. Place the burden of proof on those who argue that a proposed activity will not cause significant harm, and make the responsible parties liable for environmental harm. (Article 6)

The major differences between the three categories are summarised in table 1.1. (See Cooney 2005 and Peterson 2006 for a fuller discussion of the differences between definitional categories.)

[1] Cost effectiveness is commonly used to assess actions where benefits are identifiable but difficult to measure or value, or where governments have set an environmental or health goal (such as a pollution target) (OECD 1995). Cost effectiveness may be defined in several ways, such as: achieving a stated objective using the minimum level of inputs; maximising the level of output for a given level of inputs or cost; or maximising the ratio of outcomes (such as lives saved) to the level of inputs used or their cost (COAG 2004; OECD 1995; SCRGSP 2006).

Table 1.1 **A comparison of Precautionary Principle definitions**

	Flexible	*Semi-prescriptive*	*Prescriptive*
Is there a threshold of threat for triggering application of the Principle? [a]	Yes, for example, 'significant', 'irreversible', 'serious' harm	Sometimes	No
Is an assessment of the costs and benefits of alternative actions required?	Usually. Cost effectiveness may be required	Not usually	No
Is precautionary action required?	No	Yes, either required or 'justified'	Yes
Is the burden of proof assigned? [b]	No. Depends on other regulations	No. Depends on other regulations	Yes. Developer/ producer bears the burden of proof
Is liability for harm assigned? [c]	No	No	Usually. Developer/ producer bears liability

[a] Failure to satisfy the threshold test prevents the Principle being invoked but does not preclude precautionary action. [b] The standard of proof is crucial in determining the practical effects of assigning liability. [c] Liability is the legal obligation to provide compensation for damage resulting from an action for which the liable party is held responsible.

Many of the most widely-cited and influential international definitions — namely those contained in the Rio Declaration and other UN agreements — fall into the flexible category. The purpose of flexible versions of the Principle is very specific — to act as a 'rebuttal to the mistaken claim that uncertainty warrants inaction' (Wiener 2002, p. 1520).

To invoke flexible versions of the Principle, there must be plausible, albeit uncertain, evidence relating to both likelihood of occurrence and severity of consequences. Scientific uncertainty alone or the possibility of minor or trivial environmental damage (that is, below the threshold level) will not satisfy the threshold test for triggering application of the Principle. Once the Principle has been invoked, it may be used to rebut objections to precautionary measures based solely on the existence of uncertainty.

Satisfying the threshold test does not, however, oblige decision makers to take precautionary action. Nor does a failure to satisfy the test prevent decision makers from taking precautionary action — applying precaution in decision making and implementing precautionary measures do not rely on invoking the Principle (this is the case for all three categories of definition). Often proponents and critics alike fail to recognise this point.

Under flexible definitions, the justification for precautionary measures rests on whether such measures are expected to pursue society's objectives and improve social welfare. Ecologically sustainable development (ESD), for example, is a common goal of natural resource management — precautionary measures to avoid or mitigate potential environmental hazards may be warranted in pursuit of this objective. The legal basis for precautionary measures is not the Precautionary Principle but the objectives of the relevant

legislation. Neither the Precautionary Principle nor precaution are, of themselves, objectives — they are means to assist decision makers to pursue society's objectives.

Flexible versions permit decision makers to select the most effective and efficient option for pursuing society's goals. In some circumstances, the best option will be to take no action because all feasible options for addressing potential hazards are anticipated to generate costs in excess of benefits.

In contrast, the two more prescriptive categories of definition limit decision makers' capacity to take account of all relevant information, such as economic or social considerations, in deciding whether, or what type of, precautionary action is warranted. By requiring action, they exclude the option of no action when possible threats are trivial or when the expected costs of all feasible alternatives outweigh their expected benefits. Such definitions may distort decision making and lead to perverse consequences where precautionary actions generate greater net environmental or health damage than the potential hazards they were designed to avoid (box 1.2). Flexible definitions are least likely to generate outcomes where the costs of precautionary measures exceed their benefits — policymakers therefore often prefer such versions to more prescriptive definitions (Peterson 2006).

The purpose of flexible definitions

Flexible definitions of the Principle are sometimes seen as being too 'weak' because they do not require decision makers to adopt precautionary measures. Another proposition is that flexible versions offer little practical guidance to decision making (see, for example, Dovers and Handmer 1999; Fisher and Harding 2001; HCSTC 2006).

Sometimes, such comments may reflect a misunderstanding of the purpose of flexible versions of the Principle — that is, to rebut objections to precautionary measures based solely on uncertainty as a rationale for inaction. Many commentators have identified examples where uncertainty was given as a reason for delaying action to address environmental and health dangers. Examples include fishery collapses, asbestos-related diseases, damage to the ozone layer, 'mad cow' disease, birth defects from prescribed medications, environmental damage from 'acid rain', and North Sea pollution (see, for example, Cooney 2004; Hanson 2003; Harremoës et al. 2001; OECD 2002; Weiss 2006). These experiences demonstrated to policymakers that waiting for definitive evidence of harm often meant that it was too late for effective policy responses, particularly when damage was irreversible (OECD 2002).

Box 1.2 **Decision making distortions under prescriptive and semi-prescriptive definitions of the Precautionary Principle**

The main types of potential decision making distortions under prescriptive and semi-prescriptive definitions include:

Distorting regulatory priorities — The more prescriptive versions of the Principle may distort regulatory priorities, by causing a loss of focus on the most dangerous hazards, and redirecting regulatory attention from 'known or plausible hazards to speculative and ill-founded ones' (Graham 2004, p. 1). Such an outcome may impose significant costs on society and may even increase the overall amount of environmental or health damage.

Stifling development and technological innovation — Excessive application of precaution may stifle technological innovation and paralyse development. The impact of prescriptive versions will depend on how precaution is implemented, and most importantly, what standard of proof of safety is required. Requiring zero (or close to zero) risk 'can be relied on to block action indefinitely, with all the associated costs' (Cooney 2004, p. 36) while a less stringent standard of proof, such as 'reasonable proof of safety' will be less restrictive of development and innovation.

Perverse consequences — Prescriptive definitions, which mandate action regardless of cost effectiveness, may generate perverse consequences, where the costs of precautionary measures exceed the costs of waiting until the anticipated risks are proven. Where precautionary measures are costly but ultimately revealed to be ineffective, due to uncertainty about hazards and how to address them, 'a risk-averse society could make things worse' (Wills 1997, p. 58).

The possibility of perverse outcomes from precautionary measures results from a failure to recognise that regulatory measures have costs, as well as benefits, and may themselves give rise to (known or uncertain) risks. According to Bodansky, the 'precautionary principle seems to suggest that the choice is between risk and caution, but often the choice is between one risk and another' (1991, p. 43). For example, regulations designed to reduce the risk of aeroplane crashes may increase the price of air travel, leading more people to drive between destinations, resulting in more road accidents.

Sources: Bodansky 1991; Cooney 2004; Goldstein and Carruth 2003; Graham 2004; Hahn and Sunstein 2005; Majone 2002; OIRA 2003; Wiener 2002; Wills 1997.

Flexible versions of the Precautionary Principle support the application of precautionary measures by rebutting objections based on the existence of uncertainty. In addition, the existence of a legal foundation for the application of precaution provides decision makers with the authority and incentives to take such precautionary measures. Flexible formulations provide further indirect support for good decision making by flagging uncertainty and the potential for serious consequences. In doing so, decision makers are reminded to take account of uncertainties, information gaps and potential hazards. Flexible

versions of the Principle may therefore help to avoid a default position where such hazards are ignored because of the uncertainties attached to them.

Criticisms of flexible versions may reflect a subjective preference for prescriptive versions. Proponents of strong precautionary action — regardless of the social, economic and environmental costs — usually object to flexible formulations. Official statements of the Principle do not generally fall within the prescriptive category.

1.3 Australian provisions for precaution

The Precautionary Principle is well established in Australian environmental and natural resource management legislation. As well as being incorporated into a number of international treaties and agreements[2] to which Australia is party, the Principle has been incorporated into domestic policies and statutes. Various statements of the Principle are included in more than 120 Australian and state statutes and hundreds of non-binding policies (Dovers 2002). (Peel 2005, Appendix A, lists some of the main Australian legislative provisions for precautionary approaches.)

Definitions of the Principle included in Australian and state legislation and policies are generally similar. Most definitions are modelled on, or refer directly to, the definition included in the Inter-Governmental Agreement on the Environment (IGAE). The most influential Australian definitions are those included in the IGAE, the *National Strategy for Ecologically Sustainable Development*, and the *Environment Protection and Biodiversity Conservation Act 1999*, all of which are modelled on the Rio definition. Most Australian definitions of the Principle, therefore, fall into the flexible category.

The IGAE provides an overarching framework for environmental and natural resource management in Australia. The Precautionary Principle definition included in the IGAE is closely based on the second (and most important) sentence in the Rio definition. The IGAE definition states:

> Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.
>
> In the application of the precautionary principle, public and private decisions should be guided by: (i) careful evaluation to avoid, wherever practicable, serious or irreversible damage to the environment; and (ii) an assessment of the risk-weighted consequences of various options. (Australian Government 1992, para. 3.5.1)

[2] Including, for example, the Convention on International Trade in Endangered Species (CITES), the UN Convention on Biodiversity, and the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures.

While the IGAE definition excludes the Rio definition's reference to 'cost-effective' measures, its requirement for an assessment of 'risk-weighted consequences' includes the costs, benefits and risks of alternative measures. In addition, the IGAE includes three other ESD principles relating to: (i) intergenerational equity, (ii) conservation of biological diversity and ecological integrity, and (iii) improved valuation, pricing and incentive mechanisms. The third of these additional principles requires that 'environmental goals, having been established, should be pursued in the most cost effective way' (Australian Government 1992, para. 3.5.1). Cost effectiveness is further supported by a statement that 'measures adopted should be cost effective and not be disproportionate to the significance of the environmental problems being addressed' (Australian Government 1992, para. 3.4).

A statement of the Precautionary Principle is one of the seven guiding ESD principles included in the *National Strategy for Ecologically Sustainable Development* (ESD Steering Committee 1992). The version in the Strategy is identical to the first part of the IGAE definition:

> … where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation. (ESD Steering Committee 1992)

The other guiding principles in the Strategy, which all have equal weight, provide that decision makers must incorporate economic, environmental, social and equity considerations, and ensure the adoption of cost-effective and flexible policy instruments. Other important considerations are the promotion of international competitiveness and broad community involvement in decision making.

The Precautionary Principle is a key component of the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act), a significant piece of legislation with broad applicability to environmental, natural resource management, and conservation activities. The definition of the Principle is effectively identical to the first part of the IGAE definition:

> The precautionary principle is that lack of full scientific certainty should not be used as a reason for postponing a measure to prevent degradation of the environment where there are threats of serious or irreversible environmental damage. (*Environment Protection and Biodiversity Conservation Act 1999*, s. 391)

The EPBC Act requires the Minister to 'take account of the precautionary principle in making a decision … to the extent he or she can do so consistently with the other provisions' of the Act (EPBC Act, s. 391).

Many other pieces of legislation, including state environmental legislation and legislation relating to specific industries, include reference to a version of the Precautionary Principle (see Peterson 2006 for a discussion of Australian legislation). The references included in

fisheries legislation and the Gene Technology Act, and their relevance for decision making, are discussed in the following chapters.

1.4 Two Australian case studies of precaution

The two case studies analysed in chapters 2 and 3 examine precautionary decision making, and the influence of a flexible definition of the Precautionary Principle, within two quite different legislative and policy contexts. In both cases, a risk management framework was adopted to address risks and uncertainties, including potential, highly adverse events, such as a fish stock collapse or a 'runaway rogue' gene. But the basis for decision making — particularly the types of risks and uncertainties to be considered, and the decision making process — differs significantly in each case. These differences reflect objectives, and underlying methodologies, specific to the area under management.

In the fisheries case study, the underlying foundation for decision making is primarily sustainable resource management, focused on achieving environmental goals in conjunction with economic efficiency, social and industry objectives. Fisheries management is conducted within the context of a long history, involving experience with different management regimes and their environmental, economic and other impacts (including, in some fisheries, severe environmental damage and several fish stock collapses). Awareness of the potential serious environmental consequences of inadequate fishery regulation has prompted a cautious approach. Fishery managers seek to balance competing objectives (and interests) through an adaptive management approach that utilises improvements in knowledge about fish stocks and the impacts of fishing. Legal challenges by industry participants dissatisfied with the financial impacts of regulatory decisions are not unexpected in such circumstances.

In the GMO case study, decision makers operate within a different model — one that, in contrast to fisheries, focuses primarily on scientific matters to the exclusion of economic and social considerations. The nature of the risks and uncertainties involved also differs. Because of the relatively short history of gene technology use and the rapidly evolving nature of gene technology, knowledge about the potential adverse consequences (and their probabilities) of gene manipulation is limited. The management approach has therefore been to implement controls designed to minimise possible negative health and environmental impacts while undertaking research to improve scientific knowledge, with much less concern about expected economic, social and environmental benefits from gene technology use.

As noted at the beginning of this chapter, inferences can be drawn from the case studies about the basis for precautionary decision making, the practical application of precaution, and the influence of the flexible version of the Precautionary Principle adopted in Australia.

2 Precaution in fisheries management

Fisheries management is subject to considerable uncertainties. Collapses in overseas and Australian fisheries, and indications of overfishing in other fisheries, generated concerns in recent decades that fishery management arrangements did not take sufficient account of uncertain, but possible, threats to fish stocks and marine environments. These concerns prompted governments to incorporate the Precautionary Principle into decision making frameworks. Since the Principle was incorporated into Australian fisheries legislation in 1997, a series of legal challenges have disputed the degree of precaution applied in regulatory decisions in Commonwealth-managed fisheries.

Section 2.1 explains why precautionary approaches may be necessary in fisheries management and outlines international guidance for applying precaution. In sections 2.2 and 2.3, Australian approaches to applying precaution are described and the Australian Fisheries Management Authority's (AFMA) ecological risk management framework is examined. The study then considers Australian administrative reviews of AFMA's precautionary decision making in section 2.4 and identifies some implications of those decisions in section 2.5. Finally, section 2.6 summarises the key findings.

2.1 Uncertainty and precaution in fisheries management

This section summarises the rationale for applying precaution in fisheries management and describes the approach developed by the United Nations Food and Agriculture Organization (FAO) to guide fisheries managers in applying precaution.

Reasons for precaution in fisheries management

Concerns over the sustainability of fishing practices and fisheries management began to arise in the latter half of the nineteenth century (Harremoës et al. 2001). Collapses of major fisheries demonstrated the serious, and in some cases irreversible, environmental effects of overfishing and the severe economic consequences for fishing industries. Significant uncertainty — about fish stocks, the marine environment, and impacts from fishing — hindered the development of appropriate management arrangements and contributed to fishery collapses. The Canadian Northwest Atlantic Cod fishery, for example, collapsed in

1992 (Harremoës et al. 2001; other examples are also documented). In 1997, the FAO noted:

> … a large proportion of the world's exploited fish stocks are fully exploited, over-exploited, depleted or in need of recovery … Major ecological damage, which may not always be reversible, and economic waste are already evident in many cases. (FAO 1997, p. 6)

In Australia, the Bureau of Rural Sciences (BRS) prepares independent overviews of trends in the biological status of fish stocks managed under Commonwealth management arrangements. Out of a total of 83 stocks, 24 were classified in 2005 as 'overfished' or subject to overfishing (and therefore at risk of becoming overfished), up from four in 1997 (McLoughlin 2006, p. 5) (table 2.1).[1] The increase in the number of overfished stocks reflects, in part, better biological and ecological information for some stocks previously assessed as 'uncertain' (or 'not classified') (Rayns 2007, p. 596). It also reflects the long time periods, sometimes decades, required for recovery of overfished stocks. Only 5 overfished stocks continued to be subject to overfishing (down from 6 in 2004) and stocks are expected to recover over time. Nineteen stocks were classified as 'not overfished'.

Table 2.1 **Stock status of Commonwealth-managed fisheries**

	1992	*1997*	*2001–02*	*2002–03*	*2004*	*2005*
Not overfished	17	20	19	20	17	19
Overfished and/or subject to overfishing	5	4	11	16	17	24
Uncertain	9	31	34	34	40	40
Not classified	52	28	19	13	9	0
Total	***83***	***83***	***83***	***83***	***83***	***83***

Source: McLoughlin 2006, p. 5.

Forty of the 83 stocks — almost half — were classified as 'uncertain' (down from a total of 59 in the 'uncertain' and 'not classified' categories in 1997). Often uncertainty reflects insufficient research. McLoughlin stated:

> The continued high proportion of stocks classified uncertain is cause for concern … these stocks require assessments that establish their status more reliably … Uncertainty is often linked to low-value fisheries where there is a lack of funding to conduct research. (2006, p. 5)

The status of many by-product and other by-catch species was not reviewed 'because of a lack of data' (Caton and McLoughlin 2005, p. 1).

[1] While the BRS's 2005 stock status report (McLoughlin 2006) is the latest available, the classifications are based on data which in many cases was collected in 2003–04.

However, even with more research, some uncertainty would remain due to the complexity of marine ecosystems, and time lags and difficulties in obtaining relevant scientific information. For example, AFMA noted:

> It is important to recognise that the ability of research to resolve key knowledge gaps in relation to the biology and management of Small Pelagic Fisheries (SPF) species is limited. This is due largely to the complexity of environmental influences on stock abundance and availability, as well as the migratory, and low value nature of small pelagic fisheries like the SPF. (*Green and Australian Fisheries Management Authority* [2004] AATA 426 (29 April 2004), para. 52)

Lack of relevant scientific knowledge, combined with the potential for serious or irreversible environmental damage, suggests that precaution may be warranted. The FAO concluded that 'most problems affecting the [fisheries] sector result from insufficiency of precaution in management regimes when faced with high levels of uncertainty' (1996, p. 3). Precautionary provisions were incorporated into international fisheries agreements and policies from the mid-1990s and into Australian fisheries legislation in 1997.

International approaches to uncertainty and precaution in fisheries management

Support for a precautionary approach in fisheries management has been led by the FAO (for example, FAO 1995, 1996). A precautionary approach was adopted by the United Nations (1995) in its *Agreement on the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks*, which came into force in December 2001. The UN Fish Stocks Agreement states that signatories 'shall apply the precautionary approach widely to conservation, management and exploitation of straddling fish stocks and highly migratory fish stocks' (Article 6) and specifies actions to be taken, including research, monitoring, establishment of precautionary reference points and other management measures (Article 6 and Annex II). The Agreement extends to the management approach taken to these stocks in national waters and management of fish species through regional fisheries management organisations.

The FAO has drawn up guidelines for the development of fishery management frameworks (box 2.1). Detailed advice is provided on how to conduct fishery management and research in the context of uncertainty. Specific guidelines identify ways to address uncertainty and apply precaution, such as the identification of possible scenarios and development of contingency plans and decision rules for responding to unexpected or unpredictable events.

Box 2.1 **FAO guidelines for fishery management**

- Identification of broad management objectives, expressed as measurable management targets.
- Assessment of benefits and costs (including social, health and safety, economic, and biological/environmental).
- Transparency in the assessment and analysis process.
- Research to reduce critical uncertainties and to formulate biological objectives, targets and constraints.
- Periodic re-assessment of the level of precaution incorporated in plans, and use of the most up-to-date scientific information.
- Explicit consideration of undesirable and potentially unacceptable outcomes, and the development of contingency plans and other plans to avoid or mitigate such outcomes.
- Regular monitoring of outcomes and evaluation of the reliability and feasibility of management options, including periodic, independent, objective and in-depth peer review.
- Built-in flexibility involving regular small adjustments to management measures to maintain an acceptably low probability that constraints will be violated, and the establishment of decision rules for responding to unexpected or unpredictable events with minimum delay.

Source: FAO 1996.

The guidelines are consistent with the characteristics of good regulatory practice (described in Argy and Johnson 2003; see also OBPR 2006), specifically:

- the focus on setting objectives (or a desired level of risk)
- a firm foundation of scientific information for decision making
- cost–benefit analysis
- regular monitoring and review
- the adoption of adaptive management practices to ensure regulatory measures are adjusted to take account of new information.

The FAO recommends that precaution be applied at all four stages of the management process: planning, implementation, enforcement and monitoring, and evaluation. In the planning stage, for example, objectives would include restricting environmental impacts of fishing to acceptable levels, such as by limiting by-catch and some types of fishing gear, and management plans would specify monitoring and information collection arrangements, decision rules for responding to unexpected environmental impacts, and contingency plans.

FAO guidelines for the implementation stage list specific measures to achieve fisheries management objectives. These measures include:

- entry and effort controls
- permit and/or quota arrangements that provide sufficient flexibility to reduce excess capacity as necessary
- information collection arrangements, including research and monitoring
- establishment of contingency plans, decision rules and trigger points to guide management responses to unforeseen events.

The extent to which these measures are precautionary will depend on how they are implemented and the degree of precaution incorporated into fishery management objectives. For example, entry and effort controls will only be precautionary if they are based on stock exploitation and environmental impact targets that have been set at precautionary levels. Likewise, the degree of precaution built into tools like decision rules and trigger points will determine how precautionary they are in practice.

The FAO advocates the use of broad information relevant to the fishery, to supplement the best scientific information available, as part of a precautionary approach. Such information includes the substantial knowledge and experience of fishers and other industry participants, relevant economic and social factors, and 'a history of experience with the effects of fishing, in the fishery under consideration and/or similar fisheries from which possible consequences of fishing can be identified and used to guide future precautionary management' (FAO 1996, p. 18). It also recommends extensive consultation in the development of management plans. The FAO considers broad stakeholder involvement essential, to not only improve the regulator's information base, but also to promote compliance with the management regime — voluntary compliance is particularly important when uncertainties make monitoring more costly and difficult (FAO 1996).

The FAO recommends that precautionary decision making includes 'development of an understanding of the sources of uncertainty … and collection of sufficient information to quantify this uncertainty' (FAO 1996, p. 17). The amount and nature of the information collected would be determined in the context of the expected costs and benefits (which would, in turn, be influenced by the value of the fishery). Without such information, 'a precautionary approach to fishery management would implicitly account for the unknown uncertainty by being more conservative' (FAO 1996, p. 18). Fisheries managers should attempt to identify knowledge gaps and formulate a range of reasonable scenarios 'about underlying biological, economic and social processes' (FAO 1996, p. 19), based on available information and an examination of the consequences of proposed management actions under each scenario. Management plan options should be evaluated for their feasibility and reliability and be robust to both risk and incomplete knowledge (FAO 1996).

2.2 Australian fisheries objectives

Management of Australian fisheries has been shared between the Commonwealth and state and territory governments since the 1950s when the Commonwealth Government introduced the *Fisheries Act 1952*. The Offshore Constitutional Settlement sets out a formal agreement between the Commonwealth and state and territory governments sharing jurisdictional responsibility for marine areas within the Australian Fishing Zone.[2] AFMA is responsible for Commonwealth-managed fisheries.[3] Since the key legal cases involving the Precautionary Principle relate to AFMA decisions, this case study focuses on Commonwealth management arrangements.[4]

The basis for precautionary fisheries management is provided by the objectives set out in fisheries legislation. The main Commonwealth fisheries acts are the *Fisheries Management Act 1991* (FM Act), which sets out the objectives and regulatory framework for sustainable fisheries management, and the *Fisheries Administration Act 1991* (FA Act), which establishes AFMA and lists its objectives, functions and powers.[5] Guidance on implementing fisheries objectives may be obtained from the legislation itself, from policy documents, and from international agreements to which Australia is a party.

Australia is, for example, a party to the UN Fish Stocks Agreement (section 2.1) and has actively supported voluntary agreements developed under the auspices of the FAO. Australia is also a signatory to the 1982 Law of the Sea Convention which requires action to restore depleted fish populations to levels above those at which maximum productivity occurs (FAO 1997). Australia has taken an active and sometimes leading role in regional fisheries bodies, such as the Commission for the Conservation of Southern Bluefin Tuna, the Convention for the Conservation of Antarctic Living Marine Resources (CCAMLR), and the Indian Ocean Tuna Commission (IOTC). These bodies assess regional fish stocks and the impacts of fishing on target stocks and the broader marine environment, set total

2 Generally, in waters within the three nautical mile limit, management control remains with the states and territories while fisheries outside this limit are managed under Commonwealth arrangements, except where joint or alternative management arrangements have been negotiated.

3 AFMA is a statutory authority established to undertake the day-to-day management of Commonwealth fisheries. It is situated under the Department of Agriculture, Fisheries and Forestry and responsible to its Minister.

4 The Principle has not, to date, been raised in legal challenges to fisheries management decisions at state level, although it has been referred to in challenges to decisions on aquaculture-related development applications (for example, *Port Stephens Pearls Pty Ltd v Minister for Infrastructure and Planning* [2005] NSWLEC 426 (15 August 2005) and *Tuna Boat Owners Association of SA v Development Assessment Commission and Conservation Council of SA* [2000] SASC 238 (2 August 2000)). The Principle has also been raised in challenges to other development decisions (see, for example, Gullett 2006).

5 The Act also establishes the Fishing Industry Council, which advises the Minister on industry-related matters based on broad consultation.

allowable catches for target stocks, and allocate fishing quotas among members with the aim of promoting sustainable fishing.

Legislative objectives

Section 3(1) of the FM Act sets out five fisheries management objectives that 'must be pursued' by the Minister and AFMA:[6]

> (a) implementing efficient and cost-effective fisheries management on behalf of the Commonwealth; and
>
> (b) ensuring that the exploitation of fisheries resources and the carrying on of any related activities are conducted in a manner consistent with the principles of ecologically sustainable development (which include the exercise of the precautionary principle), in particular the need to have regard to the impact of fishing activities on non-target species and the long term sustainability of the marine environment; and
>
> (c) maximising the net economic returns to the Australian community from the management of Australian fisheries; and
>
> (d) ensuring accountability to the fishing industry and to the Australian community in AFMA's management of fisheries resources; and
>
> (e) achieving government targets in relation to the recovery of the costs of AFMA.

The objectives included in the FA Act, which AFMA 'must pursue', are essentially the same as those provided in s. 3(1) of the FM Act, with the addition that AFMA must ensure compliance with Australia's international fisheries obligations. In addition to the primary fisheries objectives listed in s. 3(1) of the FM Act, the Minister and AFMA 'are to have regard to' further objectives listed in s. 3(2) of the Act. These supplementary objectives encompass optimal sustainable use of marine resources (including preventing overexploitation), conservation and protection of whales, and compliance with Australia's obligations under international fisheries agreements.

Section 3A of the FM Act (also included as s. 6A of the FA Act) defines ecologically sustainable development (ESD) principles to guide the Minister and AFMA in their pursuit of ESD under s. 3(1)(b):

> (a) decision-making processes should effectively integrate both long-term and short-term economic, environmental, social and equity considerations;
>
> (b) if there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation;

6 The legislative objectives have been modified since the FM Act commenced in 1991. These changes need to be borne in mind when considering AFMA's performance over time against its objectives and the basis for past legal challenges to fishery management decisions.

(c) the principle of inter-generational equity — that the present generation should ensure that the health, diversity and productivity of the environment is maintained or enhanced for the benefit of future generations;

(d) the conservation of biological diversity and ecological integrity should be a fundamental consideration in decision-making;

(e) improved valuation, pricing and incentive mechanisms should be promoted.

The ESD principles included in the fisheries acts are based on the principles for environmental policy contained in the Inter-Governmental Agreement on the Environment (IGAE) (chapter 1). A definition of the Precautionary Principle is included at s. 3A(b) of the Act — the wording is the same as the first part of the IGAE definition of the Precautionary Principle. The definition is closely based on the Rio definition (chapter 1), except that the FM Act emphasises that the serious or irreversible damage referred to is 'environmental'. In addition, the Rio definition's proviso that measures be 'cost-effective' has been excluded. However, s. 4(1) of the FM Act provides that the Principle has the same meaning as in clause 3.5.1 of the IGAE. This provision effectively extends the FM Act definition so that, in applying the Principle, decisions should be guided by 'careful evaluation to avoid, wherever practicable, serious or irreversible damage to the environment; and an assessment of the risk-weighted consequences of various options' (Australian Government 1992, clause 3.5.1).

The IGAE's more expansive statement of the fourth principle for environmental policy (stated at s. 3A(e) of the FM Act) requires that 'measures adopted should be cost-effective and not be disproportionate to the significance of the environmental problems being addressed' (Australian Government 1992, para. 3.4).

The requirement for an assessment of risk-weighted consequences in applying the Principle, combined with the requirement for cost effectiveness under the fourth ESD principle in the IGAE, suggests that fisheries managers may have good legal grounds for assessing the cost effectiveness of precautionary measures in their decision making processes. Although not specifically mentioned, the definition of the Principle does not exclude cost–benefit analyses.

The definition of the Precautionary Principle included in Commonwealth fisheries legislation is therefore a flexible version of the Principle (as defined in chapter 1). The purpose of the Principle's inclusion in the legislation is to remove scientific uncertainty as a justification for inaction to address potential environmental hazards to fisheries and the broader marine environment. The Principle does not *require* any particular type of precautionary action. Any precautionary measures adopted by fisheries managers must pursue the objectives listed in the fisheries acts.

The *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act) is also relevant to fisheries management, providing for the strategic assessment of Commonwealth

fisheries (Part 10), accreditation of management plans or regimes and the creation of offences in relation to listed threatened species and ecological communities (Part 13), and assessment of the sustainability of native fish species before they can be exported (Part 13A). Current assessments are based on the Guidelines for the Ecologically Sustainable Management of Fisheries developed by the former Department of Environment and Heritage (now the Department of Environment and Water Resources) (see below). The Act provides for the 'listing' of threatened species, including fish species, which may trigger action to reduce the threat. Under the EPBC Act, the Precautionary Principle is one of the relevant considerations that the Minister 'must take account of' in regard to exports of native fish (Part 13A).

Policy guidelines

The Guidelines for the Ecological Sustainability of Fisheries set out two main principles — to avoid or reverse the environmental effects of overfishing and to minimise adverse ecosystem effects of fishing operations — and associated objectives 'to satisfy the Australian Government requirements for a demonstrably ecologically sustainable fishery' (DEH 2001). The guidelines were developed after consultation with industry, state and territory governments and environment groups, and were refined following experience in selected fisheries. Policies adopted must have a high chance of achieving the objectives, 'considering uncertainties in the assessment and precautionary management actions' (DEH 2001).

The guidelines, which are consistent with those developed by the FAO, have a number of desirable features, including:

- transparency
- broad consultation
- clear objectives and performance measurement criteria
- enforceability
- periodic review
- compliance with international and regional management regimes.

In regard to uncertainty and precautionary decision making, the criteria identified for applying the guidelines state that decisions on ecologically viable stock levels should 'provide margins of safety for error and uncertainty', 'reliable information' should be collected, and a 'risk analysis, appropriate to the scale of the fishery and its potential impacts' should be conducted into the susceptibility of a number of specified ecosystem components (DEH 2001).

2.3 Australian fisheries management framework

This section describes the basis for precautionary decision making and explains how precaution has been applied in fisheries management. Management arrangements in Commonwealth managed fisheries, including AFMA's ecological risk management framework, are described. The main precautionary management approaches adopted by AFMA are then compared with the FAO guidelines for applying precaution in fisheries management.

Australian fisheries management arrangements

Initially, the main management methods used in Australian fisheries were input controls, such as entry, area and gear restrictions. Input controls attempt to limit the quantity of fish caught by restricting industry capacity and effort. Despite these controls, many major fisheries experienced declining stock levels, industry overcapitalisation and concerns about overfishing. These problems led to Commonwealth legislative reform in 1991 to implement stricter management controls, with further amendment in 1997 when the Precautionary Principle was added to the FM and FA Acts.

The FM Act requires AFMA to develop management plans for each major fishery. Management plans generally shift the focus of management arrangements from input controls to more economically efficient and effective output controls, in particular total allowable catches (TACs) and individual tradeable quotas (ITQs) (DAFF 2003). Plans establish processes for determining total catch limits and capacity in the fishery and allocate statutory fishing rights, such as permits and quotas. Formulation of plans requires a wide-ranging process of consultation with industry stakeholders and the general community, who have ongoing input into fishery management through management advisory committees (MACs).

Substantial delays have characterised the development and implementation of management plans. AFMA has stated that the main causes of delay are the extensive consultation requirements and serious information deficiencies.[7] To determine the output or TAC of the fishery in a season, fisheries managers must be able to estimate, with reasonable certainty, the 'maximum sustainable yield' of the fishery. This requires detailed scientific information on the biological characteristics of target species; the status of fish stocks; the impact of fishing activities on target species, non-target species (by-catch) and the marine environment; and, for migratory species, the relationship between stocks in the local fishery and those in the adjacent high seas or in other countries' fisheries. In addition,

[7] See, for example, the cases of *Justice and Australian Fisheries Management Authority and Department of Fisheries Western Australia* [2002] AATA 49 (30 January 2002) and *Green and Australian Fisheries Management Authority* [2004] AATA 426 (29 April 2004).

allocation and enforcement of quotas require industry, economic and social information, including data on industry capacity, capitalisation, and actual and latent (that is, existing but not activated) effort. In many fisheries, much of this information is either unavailable or unreliable, particularly information relating to by-catch and broader environmental impacts (Caton and McLoughlin 2005).

As an interim measure, while undertaking scientific research and consulting with stakeholders to finalise management plans, AFMA implemented input controls to protect fish stocks and prevent industry overcapitalisation. AFMA acknowledged in response to legal challenges that some of its interim measures were 'economically inefficient', but argued that they were necessary to maintain the environmental status quo until data were available to allow the implementation of more suitable management arrangements (section 2.4). However, as noted in section 2.1, recent BRS assessments have classified an increasing number of stocks under Commonwealth management arrangements as overfished or subject to overfishing (due, in part, to better information about some stocks; see table 2.1).

Reflecting increasing concern about the sustainability of fish stocks and the viability of the Australian fishing industry, the then Australian Minister for Fisheries, Forestry and Conservation issued a formal Direction to AFMA in December 2005: [8]

> The Australian Government considers that decisive action is needed immediately to halt overfishing and to create the conditions that will give overfished stocks a chance to recover to an acceptable level in the near future. (AFMA 2006a, p. 2)

The Minister's Direction requires AFMA to 'take a more strategic, science-based approach to setting total allowable catch and/or effort levels' (MacDonald 2005b, p. 1). The Direction also requires AFMA to implement output controls in the form of ITQs in most fisheries by 2010 and to undertake a cost–benefit analysis of input controls to determine whether they should be phased out by 2010. AFMA is currently implementing a new Harvest Strategy Framework that sets agreed target and limit reference points and clear decision rules for each fishery species. Measures under the Strategy include ecological risk assessments for all fisheries,[9] increased monitoring, higher penalties for non-compliance, closures of some fisheries, tighter discard controls, and buybacks of fishing licences.

[8] The Australian Government also announced a $220 million *Securing Our Fishing Future* package of measures, including Marine Protected Areas in the South East Marine Region, a structural adjustment package (including licence buybacks), and improved compliance measures and data collection. (AFMA 2006d; MacDonald 2005a, 2005b)

[9] Ecological risk assessments were in development at the time the Direction was issued.

AFMA's ecological risk assessment and management framework

AFMA is pursuing an Ecosystem Based Fisheries Management (EBFM) approach that considers the impact of fishing on all aspects of the marine environment, including target species, by-catch species, protected species, habitats and communities. Key elements of this approach include implementing a broad Ecological Risk Management (ERM) framework, the new harvest strategies, and a number of other initiatives (such as by-catch reduction incentives, greater protection of threatened species, improved data collection, and expanded communication and consultation measures) (AFMA 2007).

The Ecological Risk Management (ERM) framework

The ERM framework will draw together a range of ongoing and new initiatives to ensure that appropriate management responses are implemented for the various components of the marine environment. For example, the ERM framework will tie together management responses already underway to address by-catch issues (through By-catch Action Plans developed under the Commonwealth By-catch Policy) and new additional initiatives being implemented through a major by-catch and discarding project developed by AFMA to achieve by-catch reduction targets (established in response to the 2005 Ministerial Direction). The ERM framework will also contribute directly, in terms of managing target and by-product species, to implementing the Australian Government's new Harvest Strategy Policy.

Development of the ERM framework commenced in 2001 with a significant investment by AFMA and CSIRO (with additional funding from the BRS and the Marine and Freshwater Resources Institute (MAFRI)) in a major project to explicitly assess the ecological risks in all key AFMA-managed fisheries. The first stage of the Ecological Risk Assessment (ERA) project, comprising a qualitative assessment of potential ecological risks in most Commonwealth fisheries, was finalised in 2004.[10] The second stage, which commenced in October 2004, involves a semi-quantitative assessment of all major fisheries using biological, catch and fishery research data (AFMA 2006b). Results from the second stage of the ERAs will be used to ensure that a comprehensive package of appropriate management responses are in place to address the high potential risks identified for each major fishery. The assessments and corresponding management responses are key elements of the ERM framework.

10 The National ESD Reporting Framework for Australian Fisheries contains a risk assessment approach that is similar to the ERA's Level 1 risk assessment (Hobday et al. 2004). The National Oceans Office is developing approaches to ecological risk assessment for use in regional marine planning, including consideration of the impacts of fishing.

Ecological Risk Assessments (ERAs)

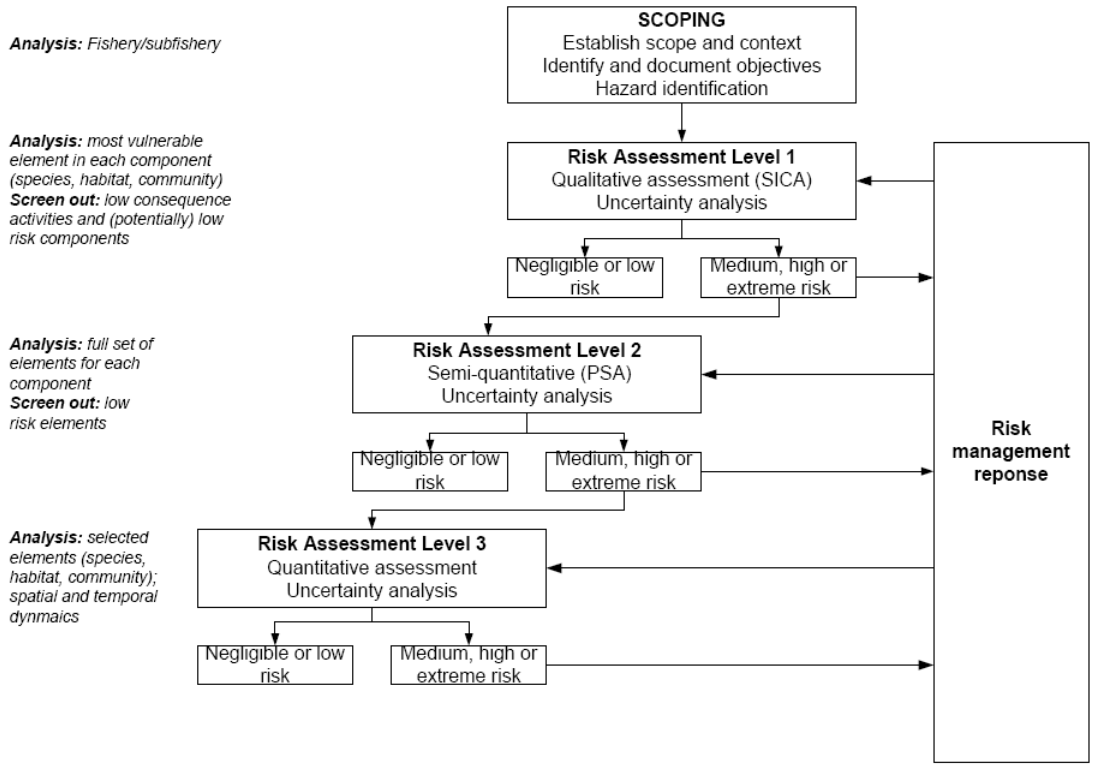
ERAs form a major component of the basis for precautionary decision making in fisheries management. The ERA framework developed for fisheries adapts conventional risk assessment methods to deal with the greater complexities and uncertainties inherent in ecological systems and the significant resource constraints (such as time and data limitations) affecting many fisheries (Hobday et al. 2004). A hierarchical approach — comprising a scoping level and three risk assessment levels — has been adopted in an effort to ensure that the process is comprehensive and rigorous 'but also realistic with regard to the time and resources available … and the amount of data, information, and expertise available to address specific impacts and issues' (Hobday et al. 2004, p. 1). An overview of the framework is shown in box 2.2.

ERAs assess the direct and indirect impacts of fishing on five key components of the marine ecosystem — target species, by-product and by-catch species, protected species, habitats, and communities. The assessments categorise the five components into low, medium or high risk. At each level of the risk assessment process, activities identified as low risk are screened out.

There are four steps in the ERA process:

- At the scoping stage, the species, habitats and communities that could be affected by fishing are identified. In addition, there is 'explicit consideration of impacts due to natural variability and sources of human impact other than fishing' (Hobday et al. 2004, p. 1), in order to identify all relevant impacts and reduce uncertainties. Management targets for each of the five ecological components are identified, where possible, including through stakeholder input and AFMA management decisions. Where targets cannot be identified, implicit targets are provided at Level 1.

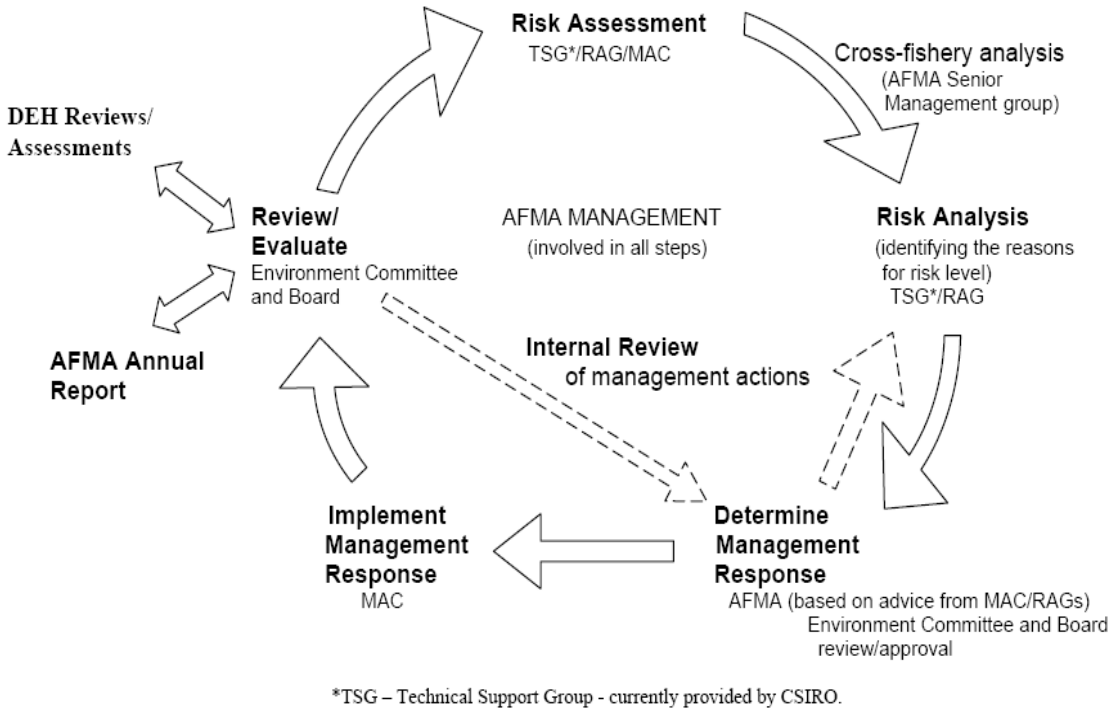
Box 2.2 **AFMA ecological risk assessment framework**



Source: Hobday et al. 2004, p. 14.

- Level 1 involves a comprehensive but largely qualitative analysis of risks. The expected consequences of fishing activities are ranked, using 'worst case' scenarios focused on the 'component thought to be most vulnerable to that fishing activity' (Hobday et al. 2004, p. 15). The degree of confidence (low or high) in the conclusion is recorded, based on the level of uncertainty associated with the assessment.
- Level 2 applies a semi-quantitative assessment to the subset of medium and high risk activities identified at Level 1 to calculate, for each ecological component, its exposure to fishing and its capacity to recover from damage. Where information is not available for a particular component, a 'worst case' value is assumed. The level of uncertainty associated with each assessed risk score is calculated. Level 2 assessments are currently being finalised.
- Level 3 applies a full quantitative 'model-based' assessment method to the smaller subset of activities identified as medium and high risk in Level 2. Level 3 methods are still under development.

Box 2.3 **Ecological risk assessment framework**



Source: AFMA 2006b, p. 4.

The ERA framework links into existing fishery processes and structures to facilitate implementation (box 2.3). Fishery Resource Assessment Groups (RAGs)[11] and MACs[12], which may include representatives from the fishing industry, environmental agencies, fishery managers and technical experts, will draw on the ERAs to develop recommended management responses. Hobday et al. (2004) highlighted the importance of stakeholder

[11] Resource Assessment Groups (RAGs) comprising scientists, fishers, fishery economists, and other stakeholders (such as conservation groups, recreational fishers, and the states) have been established for each major fishery group or individual species under management (AFMA 2006c). The RAGs undertake fishery assessments in each fishery and make recommendations to the AFMA Board (through individual fishery MACs) on the setting of harvest strategies, total allowable catches (TACs), stock rebuilding targets, biological trigger points, and other management issues. As well as scientific information on fish stocks, RAGs use industry knowledge and management strategies, market prices and harvesting costs in their assessments.

[12] Management advisory committees (MACs) provide a forum for discussing fishery management issues, promoting communication among stakeholders, and advising the AFMA Board. The AFMA Board appoints the members of each MAC in consultation with industry, state and territory fisheries agencies, environmental and conservation organisations, research institutions, recreational fishing bodies (where applicable) and other appropriate stakeholders.

involvement to improving regulatory decision making and confidence in management decisions.

Harvest Strategy Policy

A draft Commonwealth Fisheries Harvest Strategy Policy was released for consultation in March 2007 (DAFF 2007a). The Policy aims to provide a consistent, predictable and transparent framework for 'applying an evidence-based, precautionary approach to setting harvest levels on a fishery by fishery basis' (DAFF 2007a, p. i). Harvest strategies developed under the Policy will set out management actions needed to achieve defined biological and economic objectives in a given fishery. Key elements of these strategies are processes for monitoring and assessing biological and economic conditions in the fishery, and decision rules (or control rules) that control the intensity of fishing activity to achieve sustainable reference points for fish stocks (expressed in terms of the fishing mortality rate and biomass).[13]

Control rules will be fishery-specific as they will depend, for each fishery, on the management tools used and on biological and economic conditions. For fisheries employing output controls, control rules will specify the level of catch or quota for any given level of stock. Where input controls are used, the control rules will specify input levels, such as effort levels, size limits, and season length, for a given stock status. The Draft Guidelines, issued in March 2007, noted:

> Control rules should specify unambiguous management responses, and not simply call for unspecified changes in catch or effort, or further review of the situation. (DAFF 2007b, p. 10)

The methodology for calculating target and limit biomass reference points for each fishery was specified in the 2005 Ministerial Direction to ensure consistency across fisheries (as far as possible). The reference points clearly define acceptable levels of risk in fisheries management and clarify when management action is required. Rayns observed:

[13] The target biomass reference point (b_{TARG}) is equal to or greater than the stock size required to produce maximum economic yield (b_{MEY}). (For most practical discount rates and fishing costs, maximum economic yield generally implies a larger equilibrium stock of fish than that derived from the maximum ecologically sustainable yield.) If a stock falls below the target, the harvest strategy requires corrective action to rebuild biomass to or above the target level. The limit reference point (b_{LIM}) is the biomass level where stock is considered 'overfished' and the risk to the sustainability of the stock is regarded as unacceptably high. Fish stocks may not fall below the limit reference point with a likelihood of more than 10 per cent (within a timeframe set at the average lifespan for the particular stock) (DAFF 2007a, 2007b; Rayns 2007).

> This public articulation of acceptable risk by government in the use of public resources at a national level has filled the gap between broad legislative objectives and fishery-specific management arrangements. (2007, p. 597)

Harvest strategies must be 'robust to the uncertainty inherent in the assessment and management of fisheries' (DAFF 2007b, p. 20), which may involve sensitivity analysis. Information from ERA outcomes may assist in developing harvest strategies (DAFF 2007b). For some stocks, insufficient data may prevent good estimates of maximum economic and maximum sustainable yields, and thus create difficulties for determining target and limit reference points. The Draft Guidelines noted that greater precaution will be applied as uncertainty increases and stated:

> … the Policy advocates a risk management approach, whereby exploitation levels reduce as uncertainty around stock status increases. This will ensure fisheries are managed at an acceptable level of risk to the Australian Government irrespective of our level of knowledge. (DAFF 2007b, p. 7)

Harvest strategies are to be developed for each stock or fishery by the relevant RAG, working group or project team, with critical evaluation of draft strategies by the RAG and MAC. Selection of an appropriate strategy should involve careful assessment of the costs and benefits (including management costs) of alternative strategies (DAFF 2007b), to ensure that AFMA's legislative objective of cost-effective and efficient fisheries management is met. Harvest strategies are to be implemented for all Commonwealth-managed fisheries by 1 January 2008.[14]

AFMA's approach to uncertainty and precaution

AFMA's procedures for dealing with uncertainty and applying precaution in its management of Australian fisheries are based, in large part, on internationally accepted guidelines for fisheries management. The input and output controls adopted in management plans are consistent with the precautionary approach recommended in the FAO guidelines (section 2.1).

AFMA employs a modified risk management approach to deal with the environmental risks and uncertainties associated with fishing. Processes have been established to identify sources of uncertainty, formulate alternative scenarios, establish confidence levels for fishery assessments, assess the risks of management options, and establish biological

[14] Stocks that are expected to be below the adult biomass limit reference point (b_{LIM}) as at 1 January 2008 will be subject to transitional arrangements: 'Targeted fishing for any of these stocks, not currently subject to zero catch, need not be reduced immediately to zero, however, management actions shall be directed to rapid rebuilding of these stocks. These transitional arrangements will apply for no more than one year and the Policy will apply to all stocks in full from 31 December 2008.' (DAFF 2007a, p. 4)

reference (or trigger) points. The ERM framework and Harvest Strategy Policy expand these processes.

The ERM framework, and particularly the ERAs, explicitly recognise uncertainty and attempt to improve fishery information, identify potential hazards and their associated risks and uncertainties, and highlight the degree of confidence warranted in the assessments. ERAs take a precautionary approach by making 'worst case' assumptions and assigning the highest level of qualitative 'risk' where information gaps prevent estimation of quantitative risk levels (AFMA 2006b; Hobday et al. 2004). Where sufficient information exists, uncertainties may be converted into subjective risks to make them amenable to standard risk management techniques. In other cases, sensitivity analyses are undertaken to ensure that management measures (in ERAs and harvest strategies) will be effective under a range of alternative scenarios.[15] The Harvest Strategy Policy (and Ministerial Direction) determine the degree of precaution to be implemented in fisheries management by defining acceptable levels of risk, including subjective (uncertain) risks, through establishing reference points and decision rules for AFMA-managed fisheries. Greater precaution is to be applied as uncertainty increases.

AFMA's decision making processes incorporate public consultation to ascertain industry and broader stakeholder knowledge and views, particularly through the RAGs and MACs. In addition, there may be scope for broader public involvement; for example, the MACs seek public comment on draft fishery plans. AFMA's broad consultation processes and use of relevant economic, social, and industry knowledge, as well as the available scientific evidence, are consistent with the FAO guidelines as well as with the ESD provisions in the Fisheries Acts (s. 3A of the FM Act and s. 6A of the FA Act, which require decision making processes to integrate economic, environmental, social and equity considerations).

The Minister's 2005 Direction requires AFMA to strengthen its precautionary approach to fisheries management. As discussed in the next section, AFMA's precautionary management decisions have been subject to a series of legal challenges, questioning the degree of precaution applied. The Direction may provide AFMA with stronger legal authority for implementing precaution by clarifying how its legislative objectives are to be pursued. Further, the development of the ERM framework, and Harvest Strategy Policy, could be expected to clarify and improve industry and public understanding of AFMA's

15 As noted in chapter 1, conversion of uncertainties into subjective or qualitative 'risks', and sensitivity analyses, rest on assumptions that may be incorrect. For example, a sensitivity analysis may exclude outcomes that later occur, because such scenarios were either not anticipated or were mistakenly judged to have negligible probabilities of occurrence. Similarly, 'worst case' assumptions may be either too conservative or too pessimistic. An alternative approach is options valuation (see, for example, Gollier and Treich 2003), which is particularly applicable where the choice is between undertaking a particular activity or not allowing it (for example, fishing a particular stock). However, in practice, there may be few feasible alternatives to using subjective or qualitative 'risks', sensitivity analyses and 'worst case' assumptions. When applying these measures, therefore, their shortcomings should be recognised.

risk management processes. In addition, the expanded scope for stakeholder involvement could enhance understanding and acceptance of AFMA's precautionary decisions.

2.4 Legal challenges to fisheries management decisions

One means of gaining some insight into the application of precautionary measures — and the contribution of the Precautionary Principle to decision making — is to examine the extent of legal challenges to AFMA's decisions. Such an investigation reveals that application of precautionary measures has been subject to extensive legal debate. The Precautionary Principle has provided a focus for legal challenge, which has proved expensive and time-consuming not just for the applicants (who were unsuccessful in all the major cases involving the Principle), but also for the courts/tribunals and for AFMA itself. The legal challenges to AFMA's decisions reveal dissatisfaction on the part of some sections of the Australian fishing industry. Not surprisingly, much of the dissatisfaction appears largely to derive from the financial consequences of decisions for aggrieved fishers.

In the fisheries area, most legal challenges involving the Precautionary Principle have been merits review appeals to the Commonwealth Administrative Appeals Tribunal (AAT)[16] regarding AFMA decisions on quota allocations, granting of permits, and imposition of gear or area restrictions. The AAT has had to decide whether the Principle is applicable, what information is relevant to decision making, whether precautionary measures are justified, and how precaution should be balanced against AFMA's other objectives, as well as case-specific matters.

As noted in section 2.2, the fisheries acts define the version of the Precautionary Principle applicable in fisheries management. The reference to 'threats of serious or irreversible environmental damage' (s. 3A(b) in the FM Act) sets a threshold test for determining whether the Principle is relevant to any particular decision. Credible evidence of such threats is required to satisfy the threshold test for invoking the Principle. The evidence for such threats, and whether the threshold test was satisfied, formed a major element in many legal challenges. Some litigants argued that precautionary measures could not be adopted *unless* the threshold test was satisfied.

16 The AAT is a quasi-judicial body that examines the merits of the appealed decision, including its consistency with the relevant legislation and policy. It considers the reasonableness of the weights placed on various objectives (where there are multiple objectives), the circumstances of each case, and compliance with decision making processes. It places itself 'in the shoes' of the original decision maker and can substitute a new decision that it considers 'preferable' on the evidence.

Decisions on whether the Principle applied fall into two main groups. In the first group of cases, the AAT did not give detailed consideration to the Principle or its threshold test. In the second group, the AAT considered whether the threshold test was satisfied and whether a failure to satisfy the threshold test prevented AFMA from exercising precaution in decision making. In all cases, AFMA's decisions were upheld regardless of a failure to satisfy the threshold test. This outcome is not surprising, given the flexible formulation of the Principle, since the adoption of precautionary measures relies on the legislative objectives of fisheries management, not on invoking the Precautionary Principle (chapter 1). Examination of legal reasoning in the major cases involving the Principle suggests that the Principle's purpose and relevance is frequently misunderstood by industry participants, giving rise to legal challenges that are unlikely to be successful.

These cases pre-date the development of the Harvest Strategy Policy and full implementation of the ERM framework (section 2.3). Both these initiatives (and the precedents set by tribunal and court decisions to date) may reduce the future incidence of legal challenge. More research into the ecological impacts of fishing may place management measures on a more scientifically informed footing. By identifying more clearly the sources and magnitude of uncertainties and the possible hazards related to them, ERAs may provide a clearer basis for the application of precaution. The reference points and decision rules established in the Harvest Strategy Policy indicate more clearly the degree of precaution considered appropriate in fisheries management. Increased transparency and opportunities for stakeholder participation at most stages of the decision and implementation process may further contribute to improving stakeholder confidence in AFMA's assessments and management decisions, potentially reducing the incidence of legal challenges.

First group — no consideration of the threshold test

In these decisions, the AAT accepted that uncertainty justified the adoption of precautionary measures without considering whether the threshold test had been met. These decisions reflect the nature of the Principle — as highlighted in chapter 1, a failure to satisfy the threshold test does not preclude the adoption of precautionary measures (under any version of the Principle) that are warranted by legislative objectives. Several examples are discussed below.

In the **Bolding** case (*Bolding and Australian Fisheries Management Authority* [2001] AATA 235 (23 March 2001)), the applicant challenged AFMA's decision not to remove gear restrictions in the South East Non-Trawl and Southern Shark Fisheries following the introduction of ITQs. AFMA had maintained the gear restrictions as an interim measure while structural adjustment occurred in response to the major management changes in the fisheries, and a comprehensive review of input controls and their alternatives was undertaken. In addition, AFMA and the Tasmanian and Victorian fisheries departments

had concerns about the potential effect of removing gear restrictions on by-catch and non-quota species, especially in the absence of monitoring and control systems for non-quota species. AFMA argued that a precautionary approach required it to avoid dramatic changes in policy when the consequences were not well understood. The AAT concluded:

> … it is apparent that AFMA has been struggling for more than a decade to adjust its policies [towards sustainable development], while trying to maintain the viability and economic efficiency of the Australian fishing industry. This has involved some awkward choices and tradeoffs … AFMA has generally adopted a step-wise approach, attempting to identify implications before taking action and evaluating outcomes before proceeding further. (*Bolding and AFMA* 2001, para. 66)

The tribunal accepted that AFMA's adoption of precautionary measures pursued its objectives, and was consistent with the Precautionary Principle, in the context of 'insufficient scientific evidence' to currently define by-catch limits for all non-quota species.

The applicant in the **Green** case (*Green and Australian Fisheries Management Authority* [2004] AATA 426 (29 April 2004)) challenged AFMA's refusal to grant a fishing permit to fish for a number of small pelagic fish species in Zone B of the Jack Mackerel Fishery under its limited entry policy. In the context of a paucity of scientific knowledge about the target fish stocks and the impacts of fishing, some evidence of overfishing in Zone A of the fishery, an increase in commercial fishing effort and potential for activation of latent effort in the fishery, AFMA adopted an adaptive management approach involving 'step-wise development with impact monitoring', early effort limitations to avoid overcapitalisation, and 'the design of institutional or financial "brakes" to avoid "explosive" development' (*Green and AFMA* 2004, para. 41). The AAT found the limited entry policy to be consistent with the Precautionary Principle and not inconsistent with the pursuit of any fishery objective.

In the **Rhodes** case (*Rhodes and Australian Fisheries Management Authority* [2005] AATA 707 (27 July 2005)), the applicant sought a review of AFMA's decision to cancel a fishing permit. AFMA justified the decision, in part, by reference to the Precautionary Principle, based on scientific evidence of low shark stocks. The AAT accepted AFMA's view that 'where any doubt existed it was preferable to act in the interests of sustainability of the species rather than increase pressure on the stock' (*Rhodes and AFMA* 2005, para. 89) and upheld AFMA's precautionary decision.

The **Fischer** case (*Fischer and Anor and Australian Fisheries Management Authority* [2005] AATA 936 (27 September 2005)) involved a challenge to quota allocations for gummy and school shark in the Gillnet Hook and Trap Fishery on the grounds that the TAC, on which the quota allocations were based, relied on conflicting and uncertain scientific evidence on shark stock levels. In effect, the applicant objected to AFMA's precautionary approach to determining the TAC (and therefore individual allocations) on

the basis of scientific uncertainty. The AAT rejected the applicant's argument that the inadequacy of the data — that is, scientific uncertainty — required a review of the TAC:

> The argument [of the applicants] was simply that the total allowable catch was so flawed that it must be abandoned. Ultimately the basis for the flaw was said to be the absence of satisfactory evidence of the biomass of gummy and school shark. Arguments such as these create problems for the Tribunal. Had I decided that the material upon which AFMA acted was flawed what could be done? The Tribunal could not commission an assessment of the reserves. That is not its role. It does not have the resources available to it. The Tribunal must do the best it can with the material before it … The Tribunal would also need to act cautiously before it sought to require AFMA to conduct research involving substantial expenditure … the Tribunal will approach with caution large and complex issues with which the agency making the reviewable decision is especially well equipped to deal. (*Fischer and Anor and AFMA* 2005, paras. 105–07)

The tribunal upheld AFMA's decision. While the Precautionary Principle was not explicitly referred to, the decision indicates how the flexible version of the Principle could be used to rebut claims that uncertainty is a valid objection to precautionary measures.

The **Humane Society** case (*Humane Society International and Minister for the Environment and Heritage* [2006] AATA 298 (3 April 2006)) differs from the previous cases in being brought by a conservation group, rather than by an aggrieved fisher. The challenge asserted that the Minister's decision to declare fishing operations in the Southern Bluefin Tuna Fishery an approved wildlife trading operation (and approve the fishery management plan) under the EPBC Act was premature given uncertainties about whether or not the fish is an endangered species. The applicant argued for greater precaution.

While recognising the existence of some biological and ecological uncertainties, the AAT did not consider these sufficient to justify revision of AFMA's management plan, which had been determined in accordance with its objectives. The tribunal's conclusion was similar to that in the Fischer case in finding that the Minister and the tribunal were entitled to rely on the 'evidence and opinions of skilled scientists and others intimately involved in the particular field' where the issues are 'highly specialised and equally highly uncertain' (*Humane Society and Minister for the Environment and Heritage* 2006, para. 59).

In all of these cases, AFMA's decisions were upheld — AFMA's broad ESD goal (under which the Precautionary Principle is listed) was found to provide sufficient legal support for its management decisions. The AAT approved AFMA's cautious 'step-wise' approach — in other words, adaptive management of the fisheries — in the context of scientific uncertainty and possible, but unproven, risks to fish stocks. The uncertainty was sufficient to justify precautionary measures taken in pursuit of AFMA's legislative objectives.

Second group — consideration of the threshold test

In the second group of cases, the AAT considered in detail whether the threshold test for the Precautionary Principle had been satisfied in each case under consideration. In each of the examples discussed below, the AAT decided that there was insufficient scientific evidence to satisfy the threshold test so the Principle was not relevant to AFMA's decision making processes in these cases. Nevertheless, the AAT upheld all of AFMA's precautionary decisions as pursuing its objectives, especially its broader ESD objectives and its objective of promoting longer term fisheries viability (this objective has since been replaced with the objective of maximising economic returns from fisheries exploitation). These decisions are consistent with the wording of the Principle adopted in fisheries legislation. Precautionary measures are not justified by the Principle itself; they must be warranted by the pursuit of fishery objectives in uncertain circumstances.

In the **Dixon** case (*Dixon and Australian Fisheries Management Authority and Executive Director of Fisheries WA and Northern Territory of Australia* [2000] AATA 442 (5 June 2000)), the applicant appealed the imposition on his fishing permit of a geographic restriction limiting his fishing operations to the southern area of the Southern and Western Tuna and Billfish Fishery (below latitude 34°S). Conflicting scientific information was presented about stock levels of the main target species. AFMA argued that scientific information about the target species, the links between local and global stocks of the species, and effects of fishing on by-catch species was inadequate, and that the existence of significant uncertainty justified a precautionary management approach. However, scientific evidence was presented to the AAT, suggesting that stocks of the main target species were abundant with no indication of localised depletion and that catch rates in the local fishery were unlikely to impact on the sustainability of regional fisheries.

The AAT decided that the threshold test had not been satisfied given '[t]he lack of evidence pointing to any serious or irreversible threat to the marine environment' (*Dixon and AFMA and Executive Director of Fisheries WA and Northern Territory of Australia* 2000, para. 203). However, it decided that failure to meet the threshold did not preclude AFMA from applying precautionary measures in pursuit of its ESD objective, provided these measures were consistent with its other objectives.

The applicant argued that the restriction was inefficient and in conflict with AFMA's economic efficiency objective (since modified in the legislation). While AFMA acknowledged the inefficiency of the restriction, AFMA and the Western Australian and Northern Territory fisheries authorities argued that the restriction was necessary to curb the activation of additional fishing effort and investment in the fishery, pending the development of a management plan and the implementation of more efficient and effective management controls. The AAT accepted this argument and found that, in weighing up its objectives, AFMA had not given 'undue paramountcy' (or weight) to its ESD objective

because ‘a cautious management approach’ could legitimately be seen as furthering its objective of ensuring the long-term viability of the fishery. In this context, the AAT referred to experience in other Australian fisheries which had faced significant difficulties in implementing controls once the need to restrain effort was recognised, with the result that some fisheries collapsed and others required costly adjustment programs to remove excess capacity. The restriction was also seen as supporting Australia’s international obligations, given international concerns (by the IOTC) about target fish stocks.

The **Justice** case (*Justice and Australian Fisheries Management Authority and Department of Fisheries Western Australia* [2002] AATA 49 (30 January 2002)) also challenged the imposition of the 34°S area restriction in the same fishery as in the Dixon case. Again, conflicting scientific evidence was produced, and concerns were raised about the impact of commercial fishing on recreational fishing and the sustainability of fish stocks in Western Australian state waters. While the AAT accepted that there was no evidence of ‘significant or irreversible damage’ in the fishery, it noted the distinction (drawn by a CSIRO scientist) between a strict scientific test of whether the threshold had been satisfied, which would necessitate urgent and severe fishing restrictions, and a precautionary management approach aimed at avoiding the need for severe restrictions (*Justice and AFMA and Department of Fisheries WA* 2002, para. 77). The tribunal concluded that precautionary measures could be adopted even though the threshold test for the Precautionary Principle had not been satisfied.

In making its decision, the AAT noted that the area restriction reduced the risk of overcapitalisation in the fishery (by reducing the risk of overfishing) and supported AFMA’s objectives relating to efficient, cost-effective and sustainable fisheries management (since modified). In response to arguments that the restriction was inefficient, the AAT stated that pursuit of ESD was an ‘equally important statutory objective’ (*Justice and AFMA and Department of Fisheries WA* 2002, para. 77) as ensuring economic efficiency. It also contended that ‘an assessment of the risk-weighted consequences of various options’ (a requirement under the IGAE) justified retention of the restriction as an interim measure. The tribunal strongly recommended ‘urgent establishment of a management plan’ (*Justice and AFMA and Department of Fisheries WA* 2002, para. 95), as it had done in the Dixon decision.

The **Latitude Fisheries** case (*Latitude Fisheries Pty Ltd and Anor and Australian Fisheries Management Authority* [2000] AATA 1025 (22 November 2000)) involved a challenge to AFMA’s refusal to grant a permit for tuna fishing under its limited entry policy. Scientific evidence about the sustainability of the fishery was very limited. AFMA had no concerns about overexploitation of the target species or about the proposed fishing method, although it noted concerns expressed by the IOTC about regional stocks. Instead, AFMA justified the policy as maintaining the level of investment and effort in the fishery at a sustainable level.

The AAT ruled that the threshold test for the Precautionary Principle was not satisfied 'since there is not before the tribunal sufficient scientific evidence of a serious threat to ecological sustainability' (*Latitude Fisheries and Anor and AFMA* 2000, para. 174). Nevertheless, the tribunal supported AFMA's interim input controls, including its limited entry policy, as providing 'a cautious and responsible approach to managing' the fishery, which reduced the threat of serious environmental damage. It therefore upheld AFMA's refusal to grant a permit to the applicants.

The applicants appealed to the Federal Court (*Latitude Fisheries Pty Ltd v Australian Fisheries Management Authority* [2002] FCA 416 (10 April 2002)), arguing that the limited entry policy did not pursue AFMA's statutory objectives, in particular its (then) economic efficiency objective. The Court dismissed the appeal on the basis that AFMA's decision was consistent with both its ESD objective and the objective of maximising the long-term economic returns from the fishery as a whole.

In the **Ajka** case (*Ajka Pty Ltd and Australian Fisheries Management Authority* [2001] AATA 258 (30 March 2001)), the applicant appealed AFMA's limited entry policy and its refusal to grant permits to fish for a new target species (skipjack tuna) in the Eastern and South/West Tuna and Billfish Fisheries. Scientific evidence (presented by the applicant and accepted by AFMA) suggested that the species was an abundant and under-utilised resource in the fishery. However, AFMA argued for a cautious approach due to uncertainty about the species' biology and fishing impacts, some international concern about stocks, and consequent concerns about the long-term viability of the fishery.

The AAT concluded that, although the threshold test could not be satisfied due to lack of evidence, 'risk cannot be denied if the necessary meaningful scientific knowledge as to the status of the stock is absent' (*Ajka and AFMA* 2001, para. 85.6). The tribunal accepted that uncertainty alone was sufficient to justify the application of precautionary measures, stating: 'whilst the necessary scientific evidence as to the state of the fish stocks in the fisheries remains, to say the least uncertain, there is, accordingly, a risk of serious environmental damage' (*Ajka and AFMA* 2001, para. 86).

AFMA's limited entry policy was upheld by the tribunal as a 'step' towards the pursuit of its ESD objectives. The AAT concluded that, given the degree of uncertainty in that particular fishery, pursuit of ESD and precautionary objectives was 'paramount and transcends the pursuit of other objectives' (*Ajka and AFMA* 2001, para. 87). The Federal Court subsequently dismissed an appeal challenging the tribunal's decision that the Precautionary Principle and ESD had greater weight than AFMA's other objectives.

The **De Brett** case (*De Brett Investments Pty Ltd and Anor and Australian Fisheries Management Authority and Anor* [2004] AATA 704 (30 June 2004)) involved a challenge to the shark 'finning' by-catch condition imposed on tuna fishers. The condition required the entire carcass to be returned to shore, stopping the practice of removing the fin and

discarding the carcass back into the water. AFMA intended the condition to be an interim measure to facilitate compliance with existing shark by-catch limits by encouraging fishers to release sharks alive. In addition, by facilitating identification of by-catch shark species, the measure was expected to improve knowledge about tuna fishing's impacts, which would contribute to shark conservation efforts and meeting Australia's international shark conservation obligations. Scientific evidence on shark stocks was 'patchy and inadequate' (*De Brett and Anor and AFMA and Anor* 2004, para. 168). Conflicting scientific views were presented about the impact of shark by-catch on shark stocks. The AAT concluded:

> … we are unable to form a view as to the consequences of imposing, or not imposing, a finning condition. We cannot assess the consequences that are likely to follow either course or the risk of their doing so for we simply do not have the information. That means that we cannot assess whether there is a threat of serious or irreversible environmental damage within the meaning of the precautionary principle. (*De Brett and Anor and AFMA and Anor* 2004, para. 170)

While the tribunal decided that uncertainties in the available scientific evidence did not satisfy the threshold test for the Principle, it found that the finning condition supported the achievement of by-catch limits by improving information needed to determine the status of shark stocks and the impacts of tuna fishing. This information was essential if AFMA was to achieve its objectives of maximising economic efficiency and meeting ESD principles.

The decisions in these cases highlight that a failure to satisfy the threshold test for the Precautionary Principle is no barrier to the implementation of precautionary measures, if those measures can be warranted by AFMA's fishery objectives. As noted in chapter 1, invoking the Principle and applying precautionary measures are two separate issues — precaution may be warranted even though the version of the Principle included in fisheries legislation is not relevant to, and cannot therefore justify, a particular fishery management decision.

2.5 Implications of the legal rulings

The purpose of flexible versions of the Precautionary Principle, such as that included in fisheries legislation, is to rebut objections to precautionary measures based solely on uncertainty as a rationale for not addressing potential environmental hazards. Only one of the legal challenges to AFMA's fisheries management decisions (the Fischer case) argued that AFMA's precautionary measures should be abandoned pending resolution of scientific uncertainties. In contrast, many applicants argued that there were no significant uncertainties and that AFMA's actions were therefore too precautionary. Others opposed AFMA's decisions on the grounds that AFMA's economic objectives had been given insufficient weight relative to its sustainability objective, to which the Precautionary Principle relates.

Overall, the decisions confirm that the Precautionary Principle, of itself, is not required to underpin the implementation of precautionary measures. By its nature, the Principle provides little guidance for precautionary decision making, above that which is provided by addressing uncertainty while pursuing fisheries objectives. This conclusion does not imply that the Principle has been, or is, irrelevant to policymaking — the existence of the Principle in fisheries legislation may have strengthened AFMA's legal authority to adopt a precautionary approach in addressing uncertainties in the pursuit of its legislative ESD objectives.

The significance of the Precautionary Principle

In reviewing fisheries management decisions, the AAT and Federal Court have accepted that uncertainty is sufficient to justify the adoption of precautionary measures that are warranted by the pursuit of AFMA's legislative objectives. As long as legislative support for precautionary measures is provided by fishery objectives, such measures can be adopted without reference to the Precautionary Principle. In the fisheries cases, legislative support has been found in broader ESD objectives and the economic and cost-effective management objectives. The objective of compliance with international fisheries obligations may also provide legislative backing for precautionary measures, although it has not been decisive in legal cases to date.

However, most of the litigants in the fisheries cases considered here have mistakenly argued that the Precautionary Principle must be invoked in order to justify precautionary measures. They have asserted that an absence of evidence of potential serious or irreversible environmental damage means that the threshold test for invoking the Principle cannot be met.[17] Failure to satisfy the threshold test has been the basis for much of the legal argument brought by applicants against AFMA's precautionary measures.

This confusion about the meaning and relevance of the Principle has created perceptions among some industry participants of a lack of transparency and consistency in decision making and, in particular, concerns about arbitrary application of the Principle. Sant noted in relation to fisheries management: 'Overall, the public expressions of what the precautionary principle implies confuse rather than clarify.' (2005, p. 108) The Department of Agriculture, Fisheries and Forestry noted, in its 2003 review of fisheries policy, industry pressures for improved accountability and transparency in the implementation of precaution (DAFF 2003). Misunderstandings about the rationale for AFMA's precautionary measures have, in turn, engendered a lack of confidence in decision making processes and prompted legal challenges to regulatory decisions.

[17] An absence of evidence does not necessarily imply that adverse effects are not possible. Lack of evidence may reflect information gaps and substantial uncertainty.

The Harvest Strategy Policy and ERA process — with their scope for stakeholder participation, clearer identification of the sources and extent of uncertainties and acceptable degree of risk, and improved documentation of the decision making process — may elucidate the rationale for precautionary decisions and thus improve public and industry understanding of management decisions. In addition, the Minister's 2005 Direction clarifies AFMA's policy objectives by stating more detailed management goals and requiring the adoption of precautionary measures in pursuit of these goals. These measures may improve the accountability and transparency of fisheries decision making.[18] More effective fisheries management in pursuit of environmental and economic objectives will also promote greater confidence in AFMA's management.[19]

Balancing of objectives

The FM and FA Acts list multiple objectives for fisheries management. This creates challenges for AFMA in appropriately balancing these statutory objectives in its decision making. This balancing is particularly important where apparent conflict exists between the pursuit of various objectives, specifically biodiversity/conservation and the more traditional fisheries objective of maximising economic returns from resource utilisation. The relative priorities given by AFMA to its different objectives has been an important factor in a number of legal challenges to AFMA decisions. It is important to remember that precaution, and the Precautionary Principle, are not objectives in themselves but provide guidance to fisheries managers in implementing ESD.

AFMA has significant discretion in balancing its various objectives. The tribunal has accepted AFMA's determination of the weight to be placed on any one objective in the context of the particular decision and accepted that 'tradeoffs are inevitable in AFMA's decision-making' (*Rhodes and AFMA* 2005, para. 52). Interim controls acknowledged to be inefficient have been validated by the AAT, despite conflicting with AFMA's former economic efficiency objective, because they were seen as pursuing other objectives, namely cost-effective fisheries management, ESD, and the long-term viability of the

18 Improved accountability, transparency and clarity would not prevent further legal challenges to AFMA's decisions. Appeals processes provide an important check on the legitimacy and validity of decisions.

19 An AFMA executive has noted: 'AFMA was generally slow [from the late 1990s] to adapt to changing government and stakeholder demands. Consequently, government and industry lost confidence in the Board's ability to manage fisheries successfully, eventually leading to a change in membership and a substantial shift in direction. Driven by the new Board, consultation and advice were improved by a Board member attending every MAC meeting and a wider range of participants being involved in decision making. However, a solution to the problems of overfished stocks and poor economic performance of the industry was still lacking.' (Rayns 2007, p. 597)

industry.[20] The tribunal's willingness to accept this trade-off resulted in part from its acceptance that the inefficient measures were only temporary and would soon be replaced by more efficient output-based controls when management plans were finalised (despite very lengthy delays in finalising plans), such as in the Dixon and Justice cases.

Fishers and other industry participants have questioned AFMA's decisions on balancing objectives. Disagreements over the application of precaution have been significant in concerns about the balancing of objectives (implying concern about the perceived priority given to environmental objectives over economic objectives). The Department of Agriculture, Fisheries and Forestry's review of fisheries policy noted that public consultations had identified AFMA's application of precaution as an issue for concern:

> Stakeholders seek more effective implementation and accountability by AFMA against the basic principles of the legislative objectives of the FM Act, especially the precautionary principle in decision making and carrying out the economic efficiency objective. (DAFF 2003, p. 6)

Against this background, the review indicated that:

> AFMA is obliged to consider the full suite of management objectives in its management of Commonwealth fisheries. However, it may be necessary to give additional emphasis to some objectives, in order to ensure the long-term biological sustainability of Commonwealth fishery resources … (DAFF 2003, p. 22)

The review recommended clarifying the application of precaution by amending the fisheries legislation to incorporate the ESD definition contained in the EPBC Act. The EPBC Act definition was added as s. 3A of the FM Act and s. 6A of the FA Act in 2006. The Minister's December 2005 Direction to AFMA provides support for placing greater weight on environmental objectives, at least in some over-fished fisheries.

2.6 Summary of key points

This chapter addressed key issues (outlined in chapter 1) concerning the application of precaution in Australian fisheries management. The main findings are:

- Precautionary decision making in fisheries management is based on:
  - substantial uncertainties about fish stocks and the environmental impacts of fishing, lack of relevant scientific knowledge, and potential for serious or irreversible environmental damage
  - the objectives set out in Australian fisheries legislation, in particular ecological sustainability

[20] AFMA's legislative objectives have been modified since these cases were brought before the AAT.

  - international agreements and guidelines, including FAO guidelines for fishery management, Australian policy guidelines and the Minister's 2005 Direction.
- Precaution is applied through a regulatory framework managed by AFMA, specifically:
  - an ecological risk management framework, which explicitly recognises uncertainty and takes a precautionary approach by making 'worst case' assumptions and assigning the highest level of qualitative 'risk' where information gaps are significant
  - the Australian Government's new Harvest Strategy Policy
  - broad consultation processes and use of relevant economic, social and industry knowledge
  - fishery management plans that, among other things, set total allowable catches and individual quotas
  - input controls, such as entry, area and gear restrictions.
- The Precautionary Principle's contribution to decision making in fisheries management has been limited:
  - precautionary measures are justified by the pursuit of the legislative objectives of fisheries management, particularly ESD objectives, not by reference to the Principle
  - the purpose of the version of the Principle included in fisheries legislation is to rebut objections to precautionary measures based solely on uncertainty
  - legislative reference to the Principle may strengthen AFMA's legal authority to adopt a precautionary approach in pursuit of its ESD objectives
  - a failure to satisfy the threshold test for invoking the Principle does not preclude the adoption of precautionary measures, where they are warranted by legislative objectives
  - the Principle itself provides little guidance for precautionary decision making.

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3 Precaution in GMO risk analysis

This case study examines how Australia's Gene Technology Regulator applies precaution when assessing licence applications for dealings involving the intentional release of genetically modified organisms (GMOs) into the environment (hereafter referred to as 'intentional releases').[1] It explains why a precautionary approach may be appropriate when introducing new gene technologies into the environment (section 3.1), describes Australia's legislative scheme for regulating gene technology (sections 3.2 and 3.3), and analyses how a focus on science-based evidence influences the way the Regulator assesses licence applications (section 3.4). Section 3.5 discusses the implications of the Precautionary Principle for decision making in GMO licensing. Section 3.6 provides a summary of key findings.

3.1 Gene technology

Gene technology involves modifying organisms by incorporating, deleting or altering one or more genes or genetic sequences to introduce or alter a specific characteristic(s). GMOs are organisms that have been modified using gene technology and GM products are goods derived or produced from GMOs. Gene technology has potential applications in agriculture, medical research, therapeutics, the industrial sector and bioremediation (GTR 2005).

Benefits, risks and uncertainties associated with gene technology

Gene technology has a range of potential advantages over 'conventional' technologies. Proponents of gene technology argue, for example, that gene technology promises to 'be more precise, produce results more quickly and cost effectively, and introduce traits not possible through conventional techniques' (SCAC 2000, p. 14). Potential benefits include:

- improved crop yields and produce that is better adapted to customers' needs

[1] Other agencies in Australia with responsibility for regulating GM products include the Therapeutic Goods Administration, the Australian Quarantine and Inspection Service and Food Standards Australia New Zealand (FSANZ). The OGTR's *Risk Analysis Framework* (2005) identifies the various regulatory agencies in Australia with a role in regulating gene technology, including their scope and relevant legislation.

- reduced labour and energy costs in crop production
- quicker adaptation of crops to environmental and climatic factors, such as by reducing water use or increasing salt resistance or drought tolerance
- foods with enhanced health benefits such as a higher expression of vitamins or anti-cancer proteins and fewer allergy-causing substances
- improved efficacy, availability and cheaper production of medical products
- reduced use of conventional chemicals and pesticides resulting in environmental benefits, such as reduced groundwater and soil contamination
- improved cost-effectiveness of 'environmentally friendly' products, such as biodegradable plastics and bio-diesel (SCAC 2000).

Gene technology also has potential risks and uncertain hazards. These include:

- introduction of unidentified allergens into GM food
- contamination of traditional or organic crops by neighbouring GM crops
- the inability to eliminate a GM crop once it is released and found to have an adverse impact
- increased environmental competitiveness of GMOs, creating weeds in the case of plants, or pests in the case of animals
- insect-resistant crops adversely affecting non-target insects
- the transfer of herbicide-resistant genes from GM crops to related species resulting in herbicide-resistant weeds (SCAC 2000).

Reasons for precaution in gene technology regulation

The relatively short history of gene technology use and the complexity of the environment into which gene technology is released have created uncertainty about potential hazards associated with intentional releases of GMOs (OGTR 2005). This uncertainty has generated public concern and led to calls for policymakers to provide better assurances that gene technologies are safe before releasing them into the environment. In response to public concerns, Australia's regulatory framework for gene technology incorporates several precautionary provisions consistent with regulation in other developed countries (box 3.1).

Box 3.1 **GMO regulation and precaution — overseas examples**

A number of countries have incorporated the concept of precaution into GMO risk assessment. For example:

- The preamble to the European Community's Directive 2001/18/EC on deliberate release of GMOs into the environment states that the Precautionary Principle has been taken into account in the drafting of the Directive and that it must be taken into account when implementing it (clause 8). The Directive states that environmental risk assessments should be consistent with the Precautionary Principle.
- In New Zealand, the *Hazardous Substances and New Organisms Act* (HSNO Act) — which covers the field testing and release of new organisms (including GMOs) — states that anyone performing duties under the Act must take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects (s. 7).
- In Canada, the *Canadian Environment Protection Act 1999* is one of several pieces of legislation governing the deliberate release of GMOs into the environment. The preamble to the Act states that 'the Government of Canada is committed to implementing the precautionary principle that, where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation'. The Act established a national advisory committee that can provide both technical and policy advice to the Minister. In giving advice and recommendations to the Minister, the National Advisory Committee must apply the Principle (s. 6 (1.1)).

Source: IRP 2006.

3.2 Objectives of gene technology regulation

The development of Australia's current regulatory framework for GMOs in the late 1990s was largely in response to public concerns about the uncertainties and potential hazards associated with gene technology. Factors that prompted calls for a formal regulatory system to replace the previous voluntary system included:

- a rapid increase in GMO releases for field trials and commercial purposes
- perceptions that the system was not sufficiently open, transparent and enforceable
- concerns that industry would not be rigorous enough in evaluating risk and implementing management strategies
- the need to expand regulatory coverage to include activities that did not fall within the mandate of other Australian legislation (GTR 2005).

Legislative objectives

The *Gene Technology Act 2000* (GTA) and Gene Technology Regulations 2001 came into effect in June 2001, establishing a national legislative scheme for the regulation of GMOs and providing the basis for corresponding state and territory laws. The object of the GTA 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. (s. 3)

The GTA defines 'the environment' as ecosystems and their constituent parts; natural and physical resources; and the qualities and characteristics of locations, places and areas. This definition contrasts with the broader definition of the environment in the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act), which includes social, economic and cultural aspects. Economic and social impacts were omitted from the scope of the GTA to reflect the view — gained from public consultation during the development of the legislation — that the regulatory system should focus on human health and the environment and be 'science-based' (OGTR 2005).

Section 4 of the GTA states that the GTA's object is to be achieved through a regulatory framework that:

> 4 (aa) provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation; and
>
> (a) provides an efficient and effective system for the application of gene technologies; and
>
> (b) operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products.

Section 4(aa) of the GTA incorporates the definition of the Precautionary Principle stated in Principle 15 of the Rio Declaration on the Environment and Development (see section 1.2), with an added emphasis that threats refer to 'environmental' damage. Legislators added this statement of the Principle in the later stages of the legislation's development to reflect a desire to implement a 'precautionary approach' in regulating gene technology (OGTR 2005, p. 9).

The three 'pillars'[2] of the regulatory scheme outlined in s. 4 of the GTA are similar to the more expansive list of 'recitals' to the Intergovernmental Gene Technology Agreement that set out an understanding among the Commonwealth, state and territory governments regarding the establishment of a nationally consistent regulatory system for gene

[2] The OGTR's Risk Analysis Framework uses this term when referring to the three parts of s. 4 of the GTA.

technology (box 3.2). The recitals do not, however, include explicit reference to the Precautionary Principle.

Box 3.2 **Recitals to the Gene Technology Agreement**

In 2001, the Commonwealth, state and territory governments, established an intergovernmental agreement as a basis for the establishment of a nationally consistent regulatory system for gene technology. The parties agreed that:

A. there is a need for a co-operative national legislative scheme 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 genetically modified organisms; and

B. the Scheme should:

(a) provide an efficient and effective regulatory system for the application of gene technologies;

(b) operate in a seamless manner in conjunction with existing Commonwealth and State regulatory schemes relevant to genetically modified organisms and products derived from such organisms (for example, the schemes that regulate food, therapeutic goods, agricultural and veterinary chemicals and industrial chemicals);

(c) be nationally consistent, drawing on power conferred by the Commonwealth, State and Territory Parliaments;

(d) be based on a scientific assessment of risks undertaken by an independent regulator, whose decisions must be consistent with policy principles issued by a Council of Ministers concerning social, cultural, ethical and other non-scientific matters ([these] principles must not derogate from the health and safety of people or the environment);

(e) ensure that the regulatory burden is commensurate with the risks and consistent with achieving the objectives referred to in Recital A;

(f) be characterised by decision-making that is transparent, and that incorporates extensive stakeholder and community involvement;

(g) be able to be amended to respond to the development of gene technologies and their uses; and

(h) be consistent with Australia's relevant international treaty obligations.

Source: Gene Technology Agreement 2001.

The Precautionary Principle in gene technology legislation

Enacting the GTA involved extensive debate about the role of precaution and the relevance of the Precautionary Principle. The Commonwealth, state and territory governments agreed that it was best to avoid explicit reference to the Precautionary Principle because of potential for uncertainty about its interpretation. Governments decided that debate on the proposed legislation should focus on the adequacy of the risk assessment and management process rather than on arguments about the meaning of the Precautionary Principle (Interim OGTR in SCAC 2000).

A Senate Committee inquiring into the Gene Technology Bill (SCAC 2000) did not support including the Precautionary Principle as a specific test in the licensing provisions of the GTA in a similar fashion to requirements in s. 391 of the EPBC Act (which requires the Minister to consider the Precautionary Principle in making a range of decisions). It considered the EPBC Act approach too stringent for the gene technology legislation (SCAC 2000).

After much debate, the Rio formulation of the Principle was introduced into the legislation (GTA, s. 4(aa)), but the term Precautionary Principle is not mentioned.[3] The Rio formulation is included as one of the three pillars underpinning the gene technology regulatory framework. Each pillar of the regulatory framework is given equal weight and must be balanced in implementing the Act (OGTR 2005).

Peel notes that the way the GTA incorporates precaution is equivocal: 'it is not a mandatory consideration in the decision making process of risk assessment and risk management, but nor is it clearly a discretionary matter for the Regulator given its place as a "pillar" of the Act's regulatory framework' (2005, p. 173). Further, unlike the EPBC Act, precaution in the GTA does not explicitly incorporate the concepts of ecologically sustainable development (ESD) and therefore lacks the broader context provided by the overarching goals of ESD (Peel 2005).

An Independent Review into the operation of the GTA revisited the issue of precaution in 2005-06. Several submissions expressed dissatisfaction with the Regulator's application of precaution and argued for more rigorous implementation (IRP 2006). One participant suggested that the reference to precaution in the GTA was an empty gesture, stating s. 4(aa) was the result of 'a last minute compromise, which has not worked' (GeneEthics Network 2005, p. 3). Other participants pointed out that the inclusion of cost effectiveness in the Rio formulation of the Precautionary Principle was inconsistent with the narrower scope of the GTA, which excludes social and economic considerations (GTEC 2005). As discussed in section 3.4, much of the debate surrounding precaution in gene technology regulation stems from fundamental disagreement among stakeholders regarding the role that non-scientific factors, such as economic and social impacts, should play in the traditionally science-based domain.

Although the Review concluded that the current provision for applying precaution (under s. 4(aa) of the GTA) is still appropriate, it did not elaborate on why it came to this conclusion, nor did it assess the effectiveness and consistency of the Regulator's implementation of precaution to date. It simply noted that the Regulator adopted a cautionary approach to licence decisions that, 'if applied effectively and consistently, would preclude the release of any GMO that might present "threats of serious or

[3] The Rio Declaration is a flexible version of the Precautionary Principle (see chapter 1).

irreversible environmental damage" without adequate risk mitigation measures as part of the licence conditions' (IRP 2006, p. 37).

3.3 Australia's regulatory framework

The GTA established an independent statutory office holder, the Gene Technology Regulator[4], who is responsible for administering the Act (OGTR 2005). The Office of the Gene Technology Regulator (OGTR) assists the Regulator and the Regulator may seek advice on matters relating to gene technology from specialist committees established under the Act (the Gene Technology Technical Advisory Committee, the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee)[5]. The Gene Technology Ministerial Council (GTMC), which comprises Commonwealth and state and territory ministers from a range of portfolios including health, agriculture and environment, oversees the implementation of the GTA. Among other things, the Ministerial Council may issue policy principles, policy guidelines and codes of practice to underpin the activities of the Regulator.

The GTA prevents all dealings[6] with GMOs unless they are either designated as posing negligible risk or licensed by the Regulator. Dealings involving routine laboratory techniques that have been used safely for many years or that have been assessed over time to pose minimal risk when performed in contained facilities are not directly scrutinised by the Regulator and do not need a licence (OGTR 2005). Dealings that have not yet been shown to be low risk — including those undertaken under specified containment conditions in certified facilities and those involving intentional release of GMOs into the environment — require a licence. Intentional releases receive the most scrutiny because of their greater potential to spread GMOs and their genetic material. Intentional releases vary in scope from limited field trials to commercial releases.

The Regulator has the power to place specific conditions on licences, including the duration and location of a dealing, to ensure adequate management of any risks posed by the dealing. The Regulator acknowledges, however, that while protective measures should be sufficient to minimise exposure to harm, those measures should be commensurate with

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4 The Gene Technology Regulator is appointed by the Governor-General with the agreement of the majority of all jurisdictions (OGTR nd). The Gene Technology Regulator is Dr Sue Meek.

5 The *Gene Technology Amendment Act 2007* includes provisions to combine the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee into the Gene Technology Ethics and Community Consultative Committee. The start date is 1 January 2008 unless an earlier date is fixed by proclamation.

6 To deal with a GMO means to experiment with, manufacture, breed, propagate, grow, culture, import, possess, supply, use, transport, or dispose of a GMO.

the potential harm (OGTR 2005). Proportionality of measures to protect against potential harm is a feature of good regulatory practice (Argy and Johnson 2003).

The GTA's licensing system uses a 'risk analysis' process (comprising risk assessment, risk management and risk communication procedures), which is based on scientific evidence and stakeholder consultation (OGTR 2005). The OGTR emphasises that its approach to risk analysis is science-based. The Regulator examines applications for licensed dealings on a case-by-case basis and prepares a Risk Assessment and Risk Management Plan (RARMP) for each application.

The Regulator's approach to applying precaution

The Regulator has interpreted s. 4(aa) of the GTA as an obligation to take 'protective measures as a prudent and sound response in the face of a lack of full scientific certainty' (OGTR 2005, p. 9). In practice, this involves:

- either postponing a GMO dealing or approving it subject to additional protective measures, where there is a credible, but unproven, threat. The level of protection applied in each case will depend on the magnitude of the risks and uncertainty involved. A step-by-step approach to approving dealings is often used so that more information can be acquired to reduce uncertainty
- adopting a cautious approach to estimating and managing risks when there is uncertainty about either the likelihood of a dealing resulting in adverse consequences or the magnitude of those consequences
- addressing other sources of uncertainty that may affect either the Regulator's ability to make well-informed decisions or the public's confidence in and understanding of the Regulator's decisions.

The last of these is very broad in scope and applies to all stages in the decision making process for allowing GMO dealings, including collecting, analysing, interpreting and communicating information about risks and designing management responses.

Process for assessing licence applications for dealings involving intentional release of GMOs into the environment[7]

Before the Regulator assesses an application for intentional release, the applicant must prepare detailed information about the proposed dealing, including potential risks and proposed methods for managing those risks. Information provided by the applicant must be supported by relevant data and references (Gene Technology Regulations, reg. 7(3)). A bio-safety committee then reviews the application for completeness.[8]

On receiving an intentional release application, the Regulator undertakes an initial assessment of risks to human health and safety or the environment, having regard to:

- the properties of the organism
- the effect, or expected effect, of the genetic modification
- provisions for limiting the dissemination or persistence of the GMO
- the potential for spread or persistence of the GMO
- the extent or scale of the proposed dealing
- any likely impacts of the proposed dealings on the health or safety of people (GTA, s. 49(2)).

If the Regulator deems that an application involves a dealing that is likely to pose a significant risk, a notice of the application must be published inviting submissions on whether the Regulator should issue a licence. If the Regulator does not identify significant risks from a dealing in the first instance, public consultation can be deferred until the draft RARMP is complete.

The Regulator must prepare a RARMP before issuing any intentional release licence. Risk assessment involves identifying hazards that may be posed by a dealing and then estimating the level of risk posed by such hazards based on the likelihood of the event occurring and the likely consequences of that occurrence (OGTR 2005). The risk management plan evaluates which risks require management and considers what

7 This paper describes the licence application process for intentional releases that applied until 30 June 2007. The *Gene Technology Amendment Act 2007* recently introduced changes to the licensing process for intentional releases. As of 1 July 2007, intentional releases were split into two sub-categories: limited/controlled releases and standard/general releases. Other changes to the Act are indicated in footnotes where relevant. References to sections of gene technology legislation and regulation in this paper relate to the former licensing system.

8 Bio-safety committees are made up of people with a range of relevant GMO expertise and act as the main interface between industry and the OGTR. Bio-safety committees' functions include screening licence applications and overseeing day-to-day research activities. Each bio-safety committee will typically be affiliated with a research organisation.

management measures are appropriate, taking into account a number of prescribed matters (box 3.3).

Before preparing the draft RARMP, the Regulator is obliged to consult on the application with the states, the OGTR's technical advisory committee, the Environment Minister, relevant local councils, and other agencies responsible for regulating gene technology.[9] (The Regulator is not required to consult the gene ethics and community consultative committees.)

Once the draft RARMP is complete, the Regulator must notify the public and invite written submissions and seek further input from the various groups that were consulted on the application. The Regulator then finalises the RARMP and makes a decision on the licence application, having regard to any policy principles issued by the GTMC (OGTR 2005).

An applicant can seek to have a decision reviewed. This may involve an internal review by the Regulator but may also include further merits review by the Administrative Appeals Tribunal (AAT) to affirm or vary the decision or substitute a new decision. Merits review rights are only available to applicants for licences, not third parties affected by GMO dealings (IRP 2006; Kalinko 2001).

The Federal Court can review decisions under the *Administrative Decisions (Judicial Review) Act 1977*, but can only consider matters relating to defects in the decision making process. If the court decides the decision making process is flawed, it can remit the decision to the decision maker for reconsideration (IRP 2006). Any person 'aggrieved' by a decision made under the GTA can apply to the Federal Court for review if they can establish 'standing' or a 'special interest'. Although standing is judged on a case-by-case basis, the general position is that an applicant must be able to show an interest beyond that of ordinary members of the public (OGTR nd). Aggrieved parties may include, for example, conservation groups that have actively campaigned on an issue or individuals who may be directly affected by a decision, such as neighbouring farmers. To date, there have been no legal challenges by third parties (ANEDO 2005).

9 From 1 July 2007, limited and controlled releases (field trials) are required to have one round of consultation only on the RARMP. Consultation is with the states, the Gene Technology Technical Advisory Committee, prescribed agencies, relevant local councils and the public. For the standard/general release category, the consultation is the same as before 1 July. Namely, the Regulator is required to seek advice from the states, the Gene Technology Technical Advisory Committee, prescribed agencies and relevant local councils on the application itself and on the RARMP. The public is consulted on the RARMP. If the Regulator identifies a significant risk when developing the RARMP, the notice announcing public consultation must clearly state this and the minimum consultation period must be 50 days rather than the standard 30 days.

Box 3.3 **Matters to be considered by the Regulator when assessing a licence application for release of GMOs into the environment[10]**

The GTA and Gene Technology Regulations prescribe the matters the Regulator must consider when assessing a licence application for intentional release. These include:

- risks presented by the proposed dealings, including the risks to health and safety of people and the environment, having regard to:

– matters considered by the Regulator in her initial assessment about whether the dealing may pose a significant risk (GTA s. 51(1)(a))

– other matters prescribed in regulations including the potential for the GMO concerned to 'be toxic, allergenic or pathogenic to other organisms', 'adversely affect any ecosystems' and 'have, in comparison to related organisms, selective advantage in the environment' (Gene Technology Regulations 2001, reg. 10(1b))

- the means of managing any risks to protect the health and safety of people and the environment (GTA, s. 52 (2)(a))

- any advice in relation to risk assessments or risk management from the states, Gene Technology Technical Advisory Committee, other government agencies responsible for regulating gene technology in Australia (for example, Australian Quarantine and Inspection Service), the Environment Minister, local council or, where applicable, public submissions (GTA, s. 51(b) to (f) and s. 52(b) to (f))

- any previous assessment, in Australia or overseas, in relation to allowing or approving dealings with the GMO (Gene Technology Regulations 2001, reg. 10(1a))

- the short term and the long term (Gene Technology Regulations 2001, reg. 10(2)).

The GTA provides scope for the Regulator to consider additional information, such as relevant independent research, in managing risks to the health and safety of people and the environment (GTA, s. 51(3)). The Regulator may also take any other actions considered appropriate for deciding the application, including requesting more information from the applicant or holding public hearings (GTA, s. 53). The risk assessment process excludes consideration of benefits that may arise from GMO dealings, as well as any social or economic impacts.

Source: OGTR 2005.

Licence applications to date

As of June 2007, the OGTR had assessed 71 licence applications for intentional release and was in the process of reviewing another four. Of the 71 assessed applications, there were 57 approvals and 14 withdrawn applications. Among the licensed dealings involving intentional release, 10 involved commercial release. GMOs approved for commercial release include herbicide-tolerant and insect-resistant varieties of cotton and canola, an oral

10 These conditions relate to the licence application process that operated prior to 1 July 2007.

cholera vaccine and novel-coloured carnations (OGTR 2007). To date, none of the Regulator's decisions on licence applications has been legally challenged (OGTR, pers. comm., 20 February 2007).

The Australian National Audit Office (ANAO 2005) suggested that moratoria on GMOs imposed by some state and territory governments have affected the number of intentional release licence applications submitted to the OGTR (box 3.4). Since September 2003, all states and territories except Queensland and the Northern Territory have introduced moratoria legislation. In a review of the GTA, an independent panel expressed concerns about the failure to achieve national consistency in gene technology regulation because of the various state/territory moratoria on growing GM crops and the lack of transparency in dealing with market considerations. Most of these moratoria are due to expire by the end of 2008 or sooner (IRP 2006). (For general discussion of the advantages and disadvantages of applying moratoria to GM products, see Dolling and Peterson 2000.) New South Wales, Victoria and South Australia have initiated reviews of their moratoria on genetically modified canola.

Industry and research groups raised concerns that application periods for intentional releases are too long. In particular, they called for the regulatory process to distinguish between controlled field trials that enable data to be collected and commercial releases. They argued that the lack of distinction delayed licence approvals and imposed additional administrative costs. Governments responded to these concerns by amending the Gene Technology Act to enable the Regulator to differentiate between limited and controlled releases (field trials) and standard/general releases when licensing GMO dealings.

Box 3.4 **State moratoria on GMOs**

The GTA allows the Gene Technology Ministerial Council (GTMC) to issue policy principles for a range of matters relating to GMO dealings. To date, the GTMC has issued only one policy principle, which allows state governments to impose moratoria on the use of GMOs in their jurisdiction to protect the marketability of non-GM crops. This policy principle reflects state governments' responsibility for economic development within their respective jurisdictions.

Moratoria differ significantly between states. Some moratoria prohibit commercial production of any GM crops (not just food), while others allow for the limited and controlled trials of declared GM crops for research purposes.

Source: IRP 2006.

The OGTR's Risk Analysis Framework

Uncertainty is pervasive in risk analysis for gene technology (section 3.1). The OGTR's Risk Analysis Framework (RAF) is a reference document that explains the Regulator's

decision making processes and how the Regulator takes account of uncertainty. The RAF describes several different types of uncertainty that relate to five areas:

- knowledge, its acquisition and validation
- descriptions of risks in the form of words, models, figures, pictures or symbols
- bias and variability in risk perception
- the complex nature of dynamic systems
- the inherent randomness, variability or indeterminacy of a thing, quality or process.

The RAF identifies 'establishing the risk context', 'estimating the level of risk' and 'decision making' as processes in the risk analysis framework that are particularly sensitive to uncertainty. The discussion of uncertainty in the current RAF, published in 2005, is significantly more detailed than the discussion in the previous RAF from 2002. As a broad indication of coverage, the term 'uncertainty' appears over 50 times in the main body of the 2005 RAF compared with just twice in the 2002 RAF.

The RAF emphasises there are no 'one size fits all' solutions to risk assessment and risk management and that the Regulator adopts a case-by-case approach to each application. However, the RAF outlines general strategies used to deal with uncertainty according to the three components of risk analysis — risk assessment, risk management and risk communication.

Risk assessment

The RAF describes risk assessment as a scientific process that deals as far as possible with 'objective' scientific evidence to identify hazards and estimate risks. The RAF notes that the risk assessment process will identify uncertainty with respect to the likelihood and consequence of risks. In most cases, the Regulator must undertake qualitative risk assessments because there are insufficient data to apply quantitative methods. In such cases, risk is expressed using relative descriptions of likelihood and consequences.[11]

[11] As noted in chapter 1, conversion of uncertainties into subjective or qualitative 'risks', and sensitivity analyses, rest on assumptions that may be incorrect. For example, a sensitivity analysis may exclude outcomes that later occur, because such scenarios were either not anticipated or were mistakenly judged to have negligible probabilities of occurrence. Similarly, 'worst case' assumptions may be either too conservative or too pessimistic. Options valuation provides an alternative approach, and is particularly applicable where the choice is between undertaking a particular activity or not allowing it. (See, for example, Farrow (2004) which applies options value to risk assessment for GM corn.) However, in practice, there may be few feasible alternatives to using subjective or qualitative 'risks', sensitivity analyses and 'worst case' assumptions, and these measures are widely used. When applying these measures, therefore, their shortcomings should be recognised.

Although there is an emphasis on providing testable scientific evidence to support qualitative estimates of likelihood and consequence, quantitative methods are often unable to deal adequately with the complexity of the system involved or contribute definitive answers (box 3.5).[12]

The RAF notes, however, that qualitative risk assessments are more susceptible to ambiguity, subjectivity and bias. It therefore outlines steps the Regulator can take to minimise these limitations, including:

- using clearly defined terminology for likelihood, consequences and risk estimates to improve transparency and consistency
- imposing quality control measures, such as internal and external review and employing additional expert advice, to control for subjectivity between assessors and improve consistency
- clearly defining objectives, matters that are relevant to the licensing decision and weights put on different kinds of evidence to increase transparency and consistency
- facilitating broad stakeholder consultation to
  - identify uncertainty that may otherwise lead to information being over- or under-emphasised during the preparation of a RARMP
  - make the regulatory process more transparent to stakeholders.

The RAF states that the Regulator exercises caution in establishing risk estimates by including 'allowance for uncertainty in deriving risk estimates'. However, it is unclear what this means in practice.

12 Adopting more qualitative techniques for risk assessment is common in biological and natural resource disciplines where a lack of basic data is often a limiting factor. Nunn (2001) noted that, while there is a tendency to see quantitative techniques as more 'scientific', a quantitative risk assessment that uses poor data or inappropriate quantitative techniques can be far less scientific than a good semi-quantitative or qualitative assessment.

Box 3.5 **Risk estimate matrix**

The RAF includes a qualitative risk matrix to assist decision makers arrive at a risk estimate. The risk matrix is a guide to thinking about the relationship between the consequences and the likelihood of particular hazards. Uncertainty about either or both of these factors will affect the risk estimate. However, the RAF does not specify how the Regulator does this in practice.

The risk matrix can also assist decision makers consider strategies for managing risks. For example, the RAF includes the following indicative thresholds for different levels of management action:

- negligible — 'risk is insubstantial and there is no present need to invoke actions for mitigation'
- low — 'risk is minimal, but may invoke actions for mitigation beyond normal practices'
- moderate — 'risk is of marked concern that will necessitate actions for mitigation that need to be demonstrated as effective'
- high — 'risk is unacceptable unless actions for mitigation are highly feasible and effective'. (OGTR 2005, p. 47)

The RAF reflects the view that the management response should be proportional to the risk and that measures to prevent damage should not be limited to bans (GTR 2005).

The RAF states that the risk matrix is 'not a prescriptive solution for deciding on the appropriate risk estimate for any given adverse outcome' and it should not be 'used to set predetermined management conditions for a particular risk level' (OGTR 2005, p. 48). Rather its purpose is to inform the risk evaluation process.

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

For example, many risk assessments will have a summary table which lists the event that may give rise to the risk, the consequence assessment (rating and reasons for rating), a likelihood assessment (rating and reasons for rating) and risk estimate (negligible, moderate or high) and the answer to 'does the risk require management?' (yes or no).

Source: GTR 2005; OGTR 2005.

Risk management

All human activity involves some level of risk and it is rarely possible to achieve situations of zero risk. The RAF describes risk management as a process that involves prudential judgements about what should be done about risks posed by GMO dealings (OGTR 2005). It highlights the importance of taking any uncertainty about likelihood or consequence of risks into account when considering what risk management options are appropriate.

In evaluating the risks of a proposed dealing, the Regulator considers the significance of the absence or incompleteness of information. If the risk appears manageable, despite the uncertainty created by incomplete information, then the Regulator may allow the dealing under limited and controlled field conditions. Approval of an intentional release typically involves a staged approach to reduce uncertainty in risk assessments. For example, a new GMO may start in certified facilities but proceed to contained, small-scale field trials once scientists are more familiar with its properties. As more information is gathered and uncertainty is reduced, larger-scale releases may be possible, with reduced containment or commercial release (OGTR 2005). As more information is collected at each stage, the Regulator may vary the conditions of the licence.

Where risk estimates are uncertain — due to insufficient or conflicting data on the likelihood or seriousness of consequences, or lack of experience with using a GMO — risk treatment measures may be more stringent. For example, the performance of a plant grown under ideal conditions, such as a greenhouse, can be a poor predictor of how that plant will perform in the open environment because, among other things, there are many more variables in the open environment. Because of uncertainty about the likelihood or consequence of an undesired event — such as the GM plant cross-pollinating with a nearby, related non-GM species — the Regulator may isolate the GM plant within a geographic buffer zone that is defined by the overall distribution of pollen rather than the median distance pollen might travel (OGTR 2005).[13]

The RAF also deals with uncertainty relating to the efficacy of risk treatment measures. For example, it outlines the importance of using clear, unambiguous language so that the licence holder understands the licence conditions and the Regulator can enforce licence conditions. After a licence is issued, licence holders must notify the Regulator of any new information about the risks posed by a dealing, any non-compliance with a licence, any unintended or adverse consequences from a dealing, or if a GMO is unintentionally

[13] Alternatively, the Regulator may build redundancy into safety procedures (that is, if a series of events must occur for a risk to be realised, the Regulator may implement measures that target multiple stages in the causal pathway). The OGTR noted '[w]here the level of risk is uncertain, but the consequences of the risk being realised would be significant, one might adopt conservative professional judgement in implementing management strategies' (OGTR 2002, p. 20). Risk treatment measures, including limiting the location and duration of licensed dealings, are determined on a case-by-case basis.

released. The Regulator can impose monitoring conditions to ensure compliance with a licence. Licence holders must have contingency plans in case of an unexpected adverse event, which will vary depending on the nature of the dealing. General requirements for quality assurance, including accreditation of organisations undertaking dealings and certification of facilities, also apply. The Regulator has authority to impose additional protective measures on dealings in response to new information or changed circumstances (OGTR 2005).

Risk communication

Risk communication relates to the processes and structures the Regulator uses to communicate with stakeholders about risks posed to human health and safety and the environment by GMO dealings. It provides a means of increasing the transparency and accountability of the Regulator's decisions relating to risk assessment and risk management and acquiring relevant information from stakeholders about risks.

The RAF points out that risk communication can be challenging because stakeholders' views about risks associated with gene technology range across a wide spectrum of positions. Further, the Regulator must ensure stakeholders understand the types of risks associated with gene technology that are material to the decision to issue a licence.

Strategies for addressing uncertainty in risk communication include:

- consulting with, and communicating information to, relevant stakeholders
- requiring more comprehensive consultation requirements for intentional release applications
- allocating greater resources to communication activities where there is a perception of greater risk (such as intentional releases that are commercial)
- seeking advice on social and ethical issues from the Gene Technology Ethics Committee and Gene Technology Community Consultative Committee.

3.4 Implications of the Regulator's focus on science-based evidence

Much of the debate surrounding the use of precaution in gene technology regulation stems from disagreement among stakeholders regarding the role non-scientific factors should play in the traditionally science-based domain.

The Regulator's mandate

The Regulator has a clearly defined mandate in terms of what can and cannot be considered when issuing a licence for the release of GMO technology. Specifically, the scope of deliberations is limited to 'managing risks to human health and safety and the environment that arise from, or as a result of, gene technology' (OGTR 2005, p. 12). This means:

- economic, social and cultural impacts from the release of a GMO are not material to licensing decisions
- benefits from the release of GMOs, including those to human health and the environment, are excluded from licensing decisions
- risks posed by a GMO product are characterised in terms of the additional risks beyond those posed by a non-GMO equivalent.

A potential drawback of only considering some of the impacts from gene technology in licence applications is that it can potentially distort decisions about what level of precaution to set. Acceptability of risk to the community is influenced by the nature and the magnitude of the anticipated risks and the distribution of costs and benefits across a range of factors, including social, economic and environmental. The discovery of new GMO technology with potentially large economic benefits, for example, may influence society's preferences about how much risk it is willing to accept (even when estimates are uncertain). Depending on the size and likelihood of costs and benefits, accepted risk levels may differ from case to case (Binder 2002). Underlying a measure with the highest net benefit to the community as a whole is a level of risk which, if the measure is chosen, the community 'accepts' — zero is only one of a range of accepted risk levels (Binder 2002).

Consideration of a wider range of benefits and costs

Consideration of other areas of risk analysis have identified the importance of considering a broad range of costs and benefits. Examining Australian quarantine policy for bananas, for example, James and Anderson (1998) used empirical analysis to show the importance of considering economic benefits in risk analysis. The study found that while import restrictions mainly focused on import competing producers, a fuller analysis that included consumers showed that the gains to consumers might outweigh the losses to import competing producers from removing a ban on imports. (For further discussion on economic factors in risk analysis, also see Adamson and Cook 2007.)

Some proponents of gene technology have questioned the narrow focus of risk analysis under the GTA. The Grains Research and Development Corporation (2005), for example, argued for greater flexibility in risk analysis to allow consideration of the potential benefits of gene technologies as well as the risks. The Corporation argued that this would promote

more balance in the risk assessment process and support the Australian Government's vision that, consistent with safeguarding human health and ensuring environmental protection, Australia captures the benefits of biotechnology for the Australian community, industry and environment (Australian Government 2000).

Others have argued that not considering a broad set of costs and benefits is inconsistent with the way the GTA and Australian Government policy have incorporated precaution. As discussed earlier, the GTA's inclusion of the Rio formulation of the Precautionary Principle, which refers to cost effectiveness, implies consideration of a broad set of factors — economic, social and environmental — when implementing precautionary measures. Further, Australia's National ESD policy — which provides broad strategic directions and a framework for policy and decision making — advocates an integrated consideration of the broad economic, social and environmental implications of policy decisions, including cost effectiveness, effects on economic growth and international competitiveness, and international environmental impacts of Australian actions (DEH 2005).

Arguments for focussing on science-based evidence

The RAF justifies an exclusive focus on the evaluation of risks to human health and safety and the environment to 'prevent economic considerations (e.g. cost benefit analysis, market access and agricultural trade implications), from compromising the regulatory system's focus upon the scientific evaluation of risk and protection of human health and the environment' (OGTR 2005, p. 13). The GTEC put the same argument in the following terms:

> … one possible negative consequence … under a regime with expansive objects and considerations, [is that] the potential high economic benefits of a new development can outweigh the objective of environmental protection, allowing a decision-maker to permit a development on social and economic grounds even though it might pose considerable environmental harm (GTEC 2005, p. 5).

The potential for the Regulator to favour economic objectives over health and environmental objectives does not necessarily mean that economic objectives should be excluded from the decision making process. An alternative, for example, would be for the GTA, regulations, or RAF, to give health and environmental objectives primacy over other objectives. The advantage of this approach is that it can take other factors (and community views) into account while still maintaining the primary focus on human health and the environment.

Another argument put for omitting economic and other factors from the gene technology licensing process is that other provisions are in place to address these considerations. For example, the exclusion of economic issues reflects the state and territory governments' prime responsibility for economic development issues in their respective jurisdictions

(GTR 2005). In practice, however, the various provisions for addressing the risks and benefits posed by GMO dealings appear to fall short of a comprehensive and integrated assessment of all relevant factors. For example, while there are provisions that allow state and territory governments to implement additional precautionary measures where there are concerns that GMOs may result in economic risks, it is unclear how and when economic benefits from gene technology are taken into account when deciding whether or not to release a GMO. Policy principles issued under s. 21(aa) of the GTA allow for greater caution by recognising areas under state law for the purpose of preserving the identity of GM crops and non-GM crops for marketing purposes. However, there appear to be no provisions for state governments to reverse or reduce the level of caution imposed by the Regulator where the expected economic benefits from doing so are large. Section 21(b) appears to confirm this conclusion when it states that policy principles can be made in relation to matters other than the health and safety of people and the environment, but that they must not derogate from the health and safety of people and the environment.

Some stakeholders within the biotechnology industry have argued that, rather than complementing the OGTR's regulatory functions, state-based moratoria on GMOs have undermined the achievement of a nationally consistent regulatory system agreed to under the Intergovernmental Agreement on Gene Technology (IRP 2006). Some have argued that the existence of state-based moratoria has affected the transparency and consistency of decisions regarding GMO dealings. Monsanto, for example, has noted that '[w]hilst the federal regulatory system is a clear, transparent regulatory system where risks are independently assessed, the disabling legislations enacted by most States do not provide mechanisms for the transparent, independent risk assessment of market and trade issues' (2005, pp. 5-6). Responding to concerns about the impact state-based moratoria are having on the consistency, transparency and effectiveness of regulation under the GTA, an independent review of the GTA recommended that the Commonwealth, state and territory governments develop a 'nationally consistent scheme for gene technology including a nationally consistent transparent approach to market considerations as soon as practicable' (IRP 2006, p. 97). The GTMC agreed to refer the issue of market considerations to the Primary Industries Ministerial Council for advice by the end of 2007 (Agrifoods Awareness Australia 2007).

Challenges when considering non-science-based matters

An implication of expanding the scope of the GTA would be that the Regulator would have to compare different types of costs and benefits, such as economic, social and environmental, from GMO dealings. The Independent Review Panel outlined some of the difficulties with this:

> While some submissions and participants in consultations argued that the Regulator should have regard to benefits as well as risks, most regarded such an extension as impractical or undesirable. It was considered impractical on several grounds. Firstly,

> the existence or scale of many benefits did not become apparent for some years after the GMO was released. Bt cotton [cotton genetically modified to include the Bt toxin derived from soil bacteria, for pest resistance] was cited as an example of where new benefits are still being identified years after commercial release. Secondly, it would be very difficult to construct a calculus for measuring risk and benefit in the same time frame and dimension.
>
> During the consultations, an individual observed that while it might be possible to make sense of risks and benefits in the same aspect of a GMO's impact on health or the environment, trying to compare risks and benefits across different aspects would lead the Regulator up blind allies and be unworkable. (IRP 2006, pp. 31–32)

Although comparing different types of costs and benefits associated with GMO dealings can be technically challenging, basing decisions about the acceptability of risks on a narrow set of factors may lead to suboptimal outcomes — especially where there is limited scope to change those decisions at a later stage based on broader considerations. This is because, as discussed above, the acceptability of risk will be influenced by the nature and the magnitude of the anticipated risks and benefits across a range of factors, including social, economic and environmental. Further, given that the Regulator allows dealings that could potentially pose some risks implies an acknowledgement that there are benefits from GMO dealings that justify the risk of an adverse event, even though the benefits are not explicitly articulated (Lawson 2002; Linacre et al. 2006).

An alternative to changing the scope of the GTA may be to allow for an additional step in the process of approving licences. This may involve a decision maker reviewing the Gene Technology Regulator's decisions in light of broader economic and social considerations. In some cases, the decision maker may choose to override the decisions made by the Gene Technology Regulator based on broader considerations, in which case they would need the authority to do so. As demonstrated by recent experience with the state-based moratoria on GMOs, however, care would be required to integrate effectively new regulations into the current national system.

Undertaking a comprehensive analysis of costs and benefits — either through the OGTR or through an additional stage in the approval process — would facilitate better-informed decision making, make factors that go into the decisions more transparent, and provide an avenue for the public to raise issues that have been so far disregarded as outside the scope of the risk analysis process. As new methods of eliciting people's valuations of non-market factors (such as environmental values) improve, comparisons between different factors may become more feasible. In a submission to the independent review, the Regulator mentioned considerations if such steps were to be undertaken. These included:

- ensuring economic (and social) impact assessments are undertaken by organisations with relevant expertise

- deciding at what stage of development it is reasonable to attempt to conduct such assessments
- ensuring economic, trade and social impact assessment processes are flexible enough to deal with changing circumstances and attitudes
- remaining consistent with Australia's international obligations including World Trade Organization (WTO) obligations, which mandate science-based risk assessment processes (GTR 2005).

Framing of risks

A matter closely related to the GTA's scope is the approach the Regulator uses to frame risks from GMOs. Under the GTA, the Regulator must assess risks posed by a particular GMO relative to the risks posed by the unmodified parental organism in the receiving environment. This is the approach undertaken for risk assessment in other countries, including under EU Directive 2001/18/EC on deliberate release of GMOs. Framing risk from GMOs in this way raises several issues, including whether the risks and benefits that are common to GMOs and their non-GMO equivalents are treated in a consistent manner.

Following farm-scale evaluations of genetically-modified herbicide-tolerant crops at the farm level in the United Kingdom, the Advisory Committee on Releases to the Environment (ACRE) released a report that identified inconsistencies in the regulatory assessment of the environmental impact of GM crops in comparison with other agricultural crops and practices (box 3.6), which may lead to undesirable distortions in technology choices. ACRE (2006) argued for a broader and more consistent regulatory approach to risk assessment.

Box 3.6 **Report of the ACRE Sub-group on Wider Issues Raised by the Farm-Scale Evaluations of Herbicide Tolerant GM Crops**

ACRE (Advisory Committee on Releases to the Environment) is a statutory scientific advisory committee that advises the UK Government on matters relating to the release and marketing of GMOs, including implementing EU Directive 2001/18/EC on the deliberate release of GMOs into the environment. In a report on Wider Issues Raised by the Farm-Scale Evaluations of Herbicide Tolerant GM Crops, ACRE found a number of inconsistencies in the regulatory approaches to GM and non-GM crops. The report found, for example, that:

- Although Directive 2001/18/EC requires an environmental risk assessment of the potential environmental impacts from the specific cultivation, management and harvesting techniques used for GM plants, non-GM crops and other changes to agricultural management do not require similar risk assessments. This is despite evidence that the environmental impact of changes in agricultural management can be at least as significant as those associated with GM crops.
- Directive 2001/18/EC makes no provision for assessing potential environmental benefits from GM crops even though environmental benefits are a major focus in a number of national and EU initiatives. These include:
  - the introduction of a number of other novel crops (such as energy crops) and agricultural management practices
  - EU and national agricultural policy reforms that focus on the multifunctional nature of agricultural systems, and their capacity to contribute to a wide variety of environmental goods and services
  - emerging private markets, in which farmers are paid to produce environmental goods and services (such as flood protection, carbon sequestration, landscape aesthetics, and biodiversity services), as well as to continue to produce food.

Source: ACRE 2006.

Public participation

Despite claims that Australia's regulatory system is 'the most open in the world' (GTR 2005, p. 14) in terms of transparency and accountability provisions, some have observed that public involvement in risk analysis is restricted (see, for example, Lawson 2002; Peel 2005; Wickson 2005). Critics of the gene technology regulatory scheme have argued that implementing precaution involves more than establishing a set of rules to guide decisions under uncertainty. Rather, implementing precaution is a process that involves broadening expertise and including a wide range of views as a means of identifying uncertainties other than those dealt with by the scientific risk assessment process (Oreszczyn 2004). Embedded in these arguments is a belief that science alone cannot (and should not) be used to decide policy, particularly where scientific evidence is inconclusive (Kriebel et al. 2001).

As discussed, the scope of the GTA means that not all community views about a GMO dealing are relevant to the Regulator's decision whether to issue a licence. The Regulator, for example, has noted:

> Despite the incorporation of prominent advice that these cannot be taken into account in the assessment process, many submissions from the public raise issues that are excluded from consideration by the Regulator (eg. issues to do with economic impacts) or are the responsibility of other regulatory agencies (eg. food labelling, and the use of agricultural chemicals). (GTR 2005, p. 15)

Critics of purely science-based approaches to regulating gene technology have argued that implementation of precaution requires broadening the scope of admissible evidence and advice. Barrett and Raffensperger (2002) have advocated applying a 'weight of evidence' standard that admits multiple lines of evidence in reaching conclusions in policies for GM organisms. Wickson (2005) has argued that the Regulator should have to consult with the non-scientific advisory committee(s) in the same way and to the same degree as the committee of scientific experts.

Another aspect of broadening public participation is allowing greater public access to the risk analysis process, particularly risk assessment. Some commentators have noted that despite being characterised as 'a scientific process that does not take political or other non-scientific aspects … into account' (OGTR 2002, p. 12), risk assessment can involve uncertainties of an intractable nature. The potential for an incorrect decision to have serious consequences, it is argued, necessitates social choices about how much uncertainty is acceptable (Peel 2005; see also Goldstein and Carruth 2004). Scientists undertaking environmental risk assessments must make assumptions, choices, and inferences based on professional judgment and standard practices, which if not known by the public or policymakers, may make 'scientific' results appear to be more certain and less value laden than is warranted (Kriebel et al. 2001). Lawson and Hindmarsh (2006), for example, analysed a 2003 licence application for the commercial release of GM canola and identified several areas where the Regulator had made apparently conclusive decisions without acknowledging uncertainty about the data on which the decision was based. (This licence application predates the most recent version of the OGTR's RAF.) Cameron (1999) argued that in order to implement the Precautionary Principle effectively, decision makers need to provide access to the environmental information used to make important subjective determinations (and highlight where there was a lack of relevant information).

Until recently, the Regulator was only obliged to consult with the public prior to the RARMP when it determined that a proposed dealing posed a potentially significant risk.[14]

[14] The provision in the GTA requiring the Regulator to consult with the public prior to the draft RARMP when it determined a dealing posed a potentially significant risk no longer exists. Instead, the Regulator is required to provide a longer public consultation period on the RARMP. (See footnote 9.)

Wickson (2005) has also noted that the Regulator is only required to consult with its committee of scientific experts and not its community-based advisory committee.

However, the Regulator has contended that consultations with the public have not so far identified any additional risks to human health and safety not already identified in the RARMP (GTR 2005). The Regulator also noted that the former provision in the GTA that required consultation with the public for dealings that may involve significant risk before the draft RARMP is prepared did not seem 'optimal'[15]:

> The prescribed consultations on the application with expert groups and authorities and the development of the RARMP enable the Regulator to form a more considered and informed view on whether the application is likely to pose significant risks. As many members of the public are not scientifically or technically trained, it would seem more useful to have access to this information before being asked to make a submission. An important aim of consultations on applications is to inform the assessment process, having the public consultation after the preliminary assessment does not achieve this aim. (GTR 2005, pp. 15–16)

While elements of the RAF promote greater transparency in the OGTR's decision making process, it appears unlikely that the science-based approach adopted by the Regulator can be easily reconciled with broader considerations of precaution without legislative change (see Ahteensuu 2004).

Broadening the scope of public participation in risk analysis may require fundamental changes to the scope of the GTA. The costs and benefits of doing so would need to be carefully considered.

3.5 Implications of the Precautionary Principle

Although the GTA does not explicitly refer to the Precautionary Principle, its reference to precaution adopts wording from the Rio formulation of the Principle. The reference to precaution was included to reflect the view that uncertainties about potential adverse consequences from using gene technology warranted taking precautionary measures.

Unlike other areas of regulation in which precaution is relevant, there has been relatively little debate in the field of gene technology regulation about whether precautionary measures are justified in the face of uncertainty. Rather, debate has centred on how to apply precaution and the degree of precaution required (see SCAC 2000).

Despite drawing attention to the need for precaution, the words in the Rio Declaration offer little in the way of guidance on how to apply precaution. The RAF describes how the

[15] See footnote 14.

Regulator deals with uncertainties that arise during risk assessment, risk management and risk communication.

Although the precautionary measures outlined in the RAF are consistent with the Precautionary Principle in some respects (that is, that uncertainty is not a reason not to implement measures to address potential hazards), implementing precautionary measures under the RAF does not require reference the Precautionary Principle. The Regulator applies protective measures of progressively greater stringency to dealings as potential risk and uncertainty increase.

It is debateable whether the precautionary approach adopted by the Regulator would have been substantially different had the Rio wording not been included in the GTA. On the one hand, one could argue implementing precaution in gene technology regulation is simply good regulatory practice and that including the Precautionary Principle in the GTA makes little practical difference. The RAF, for example, equates the Rio wording with simply taking a 'prudent and sound response in the face of a lack of full scientific certainty'. Hence, one would expect any robust risk analysis framework to follow such an approach as a matter of course. Conversely, some would argue the value of including the Principle in the GTA is that it gives the public certainty that the Regulator will implement precaution. The Australian Conservation Foundation, for example, has remarked:

> I would not like to see someone forget that the precautionary principle applies simply because we have not taken five minutes to draft it into the legislation. (ACF cited in SCAC 2000, p. 37)

Confusion that has surrounded the interpretation of the Precautionary Principle in other contexts (such as fisheries, see chapter 2), and hence detracted from its value, is less evident in gene technology regulation. This may vindicate the legislators' decision to omit the term Precautionary Principle from the GTA for this very reason.

3.6 Summary of key points

This chapter addressed the key issues (outlined in chapter 1) regarding the application of precaution in gene technology regulation. The main findings are:

- Precautionary decision making in gene technology regulation is based on:
  - uncertainty regarding potential hazards to the health and safety of people and the environment due to the relatively short history of gene technology use, limited knowledge about the effects of gene manipulation, the complexity of the environment into which gene technology is released, and the rapidly evolving nature of gene technology

- provisions set out in Australian gene technology legislation, in particular s.4 (aa) which incorporates wording based on the Rio definition of the Precautionary Principle.

- The Gene Technology Regulator, supported by the OGTR, applies precaution through a national regulatory framework for gene technology. Features of this framework include:
  - a RAF, which takes account of uncertainty that arises during risk assessment, risk management and risk communication
  - a licensing system for direct intentional releases which:
    - assesses applications using scientific evidence
    - considers the potential negative effects of gene technology on human health and safety and the environment but does not consider positive effects or economic or social impacts
    - by itself, potentially distorts the level of precaution from what is socially optimal because of its focus on some impacts from GMOs but not others
    - appears to be poorly aligned with policy principles under the GTA that allow the states to increase but not decrease the level of precaution set by the Regulator based on economic considerations (thereby preventing a comprehensive and integrated assessment of the risks and benefits from GMOs).
- The Precautionary Principle's contribution to decision making in gene technology regulation has been limited:
  - debate regarding precaution and gene technology has centred on how precaution should be applied and the degree of precaution required
  - despite drawing attention to the need for precaution, the words in the Rio Declaration offer little in the way of guidance on how to apply precaution
  - detailed guidance on how precaution is applied during the licensing process is provided by the RAF
  - implementing precautionary measures under the RAF does not require reference to the Precautionary Principle.

4 Implications for implementing precaution

The legislative frameworks and the processes established by decision makers in two policy areas subject to significant scientific uncertainty — fisheries management and intentional releases of genetically modified organisms (GMOs) — have been analysed to provide insights into the practical application of precaution and the role and influence of the Precautionary Principle. Drawing on these case studies, this paper set out to examine:

- the basis for precautionary decision making
- how precaution has been applied in practice
- whether and how Australian (flexible) versions of the Precautionary Principle have contributed to precautionary decision making.

This section summarises the findings and draws some broad implications for other natural resource management areas.

4.1 The basis for precautionary decision making

Precaution may be warranted where uncertainty surrounds the consequences of certain activities, with potential for adverse outcomes. Many areas of natural resource management are subject to considerable uncertainties.

Precautionary measures to avoid or mitigate potential environmental hazards may be warranted because they contribute to achieving society's objectives, for example, ecologically sustainable development (ESD) — a common goal of natural resource management. Other precautionary measures may be implemented in pursuit of human health and safety objectives. As noted in chapter 1, neither the Precautionary Principle nor precaution are, of themselves, objectives — they are tools to assist in achieving society's objectives.

Precaution can be applied in decision making under uncertainty without any reference to the Precautionary Principle. In legal reviews of fishery management decisions, precautionary measures were found to be legally valid even though the Principle was not invoked. Sufficient grounds existed in the Australian Fisheries Management Authority's (AFMA's) legislative objectives, particularly those

relating to ecological sustainability, to satisfy the tribunal and court that AFMA's precautionary management decisions were justified. In GMO regulation, the legislative objectives of protecting human health and the environment support the application of precaution in licensing decisions. The Precautionary Principle is not explicitly mentioned in GMO legislation (although a statement of precaution, modelled on the Rio Declaration, is included).

Similarly, precautionary decision making in other natural resource management areas does not require reference to the Principle in legislation. The incorporation in legislation of ESD objectives, or objectives relating to protection of human health or the environment, may provide sufficient legal justification for precautionary decision making. Australia's Intergovernmental Agreement on the Environment (IGAE), which provides an overarching framework for environmental and natural resource management, may provide further legal grounds for the pursuit of ecological sustainability in natural resource management policies, even where ESD is not explicitly mentioned in specific legislation.

4.2 The application of precaution

Effective implementation of precaution requires decision makers to take account of the full range of relevant factors — including the magnitude, nature and severity of potential harm, and economic, social, environmental, and health costs and benefits — in determining the type of precautionary action that may be warranted. Flexible versions of the Precautionary Principle, such as the Rio Declaration and most Australian definitions, are consistent with these requirements for effective implementation of precaution. Not surprisingly, flexible versions are often preferred by policymakers because they do not constrain assessments of costs and benefits and are least likely to generate outcomes where the costs of precautionary measures outweigh their benefits.

Decision making may, however, be constrained in other ways by, for example, legislative objectives. As noted in chapter 3, the Gene Technology Regulator's mandate is limited to managing potential health and environmental threats, to the exclusion of economic and social considerations and potential health or environmental benefits, when assessing licence applications for the intentional release of modified genetic material. As a result, the licensing process does not integrate the full range of factors influencing community views about potential hazards associated with GMOs. While some of these factors are considered separately in state-based processes, a comprehensive and integrated assessment of the full costs and benefits from GMOs is currently lacking. In contrast, the legislative objectives of Australian fisheries management cover economic, environmental, social and equity considerations.

Decision making in the presence of uncertainty requires methods to deal with uncertainties and information gaps and methodologies to determine an appropriate level of precaution.

Decision makers have little practical alternative but to deal with uncertainty within some form of risk management framework. AFMA's Ecological Risk Management (ERM) framework and Harvest Strategy Policy Guidelines and the Gene Technology Regulator's Risk Analysis Framework (RAF) set out detailed processes for dealing with information gaps and uncertainties, such as sensitivity analyses, identification of 'worst case' scenarios, assignment of confidence levels to assessments, and guidelines for using qualitative risk assessment techniques. (As noted in chapters 2 and 3, decision makers need to recognise the inherent shortcomings of these approaches, which are an unavoidable result of information gaps and uncertainties.) The decision frameworks also provide operational guidance on what actions to take when confronted with uncertain threats.

In fisheries management, AFMA's decision making processes incorporate extensive public consultation and the use of relevant economic, social and industry knowledge, as well as the available scientific evidence. The Gene Technology Regulator's assessment processes also provide scope for industry and public input to gene technology licensing decisions, although the Regulator's science-based approach restricts consideration of certain (non-scientific) issues. Both frameworks require documentation and communication of the basis for precautionary decision making, which may clarify the reasons for precautionary decisions, increase transparency and improve public and industry confidence in decision making. There may be benefits to policymakers in other natural resource management areas from developing clear frameworks for dealing with uncertainty.

4.3 The Precautionary Principle's contribution to decision making

As noted in chapter 1, most Australian legislative definitions of the Precautionary Principle fall into the flexible category, being modelled on the Rio Declaration. The definition in fisheries legislation is a flexible version. As such, the Principle has the very specific, narrow purpose of rebutting objections to precautionary measures based on the claim that uncertainty warrants inaction. The reference to applying precaution in gene technology legislation is also based on the Rio Declaration.

That uncertainty is rarely raised these days as an objection to precautionary action may demonstrate that the flexible version of Principle has achieved its purpose. By drawing attention to the fact that uncertainty is not necessarily a reason for inaction to address potential hazards, the Principle may have averted the problem it was designed to solve. That is, the very existence of the Principle may have made the trigger for its application less likely to occur.

Alternatively, experience of the adverse consequences of past failures to act may have convinced policymakers (and the public) that uncertainty does not justify inaction — the

Principle may have thus become virtually redundant. Sufficient examples exist of adverse, sometimes irreversible, consequences from postponing action to address unproven hazards to have demonstrated that waiting until uncertainties are resolved may forgo the opportunity to take effective policy action (chapter 1).

Nevertheless, this does not imply that the Principle has no significance for decision making. Flexible versions of the Principle remind policymakers to take account of uncertainties, information gaps and potential hazards. In addition, the existence of a legal foundation for the application of precaution provides decision makers with the authority and incentives to take precautionary measures.

However, the Principle, by its nature, provides little guidance for precautionary decision making. As noted in chapter 2, it is questionable whether AFMA's precautionary fishery management decisions, or the outcome of legal challenges to those decisions, would have been any different even if no direct reference to the Precautionary Principle was included in fisheries legislation. Likewise, the absence of explicit reference to the Principle in gene technology legislation is unlikely to have restricted the Regulator's application of precaution in decision making (or led to different licensing decisions). This is because, as highlighted in this paper, precautionary approaches are supported by legislative objectives, not the Precautionary Principle. Applying precaution does not rely on invoking the Principle.

Confusion about the meaning and significance of the Principle may, however, have negative implications for precautionary decision making. As seen in fisheries management, uncertainty about when and how precaution will be applied can create perceptions within the affected industry or the public of insufficient transparency, consistency and accountability in precautionary decision making. Unsuccessful legal challenges to fishery decisions have been prompted by misunderstanding of the basis for precautionary decision making, as well as dissatisfaction with the financial impacts of regulatory decisions. These have proven expensive and time-consuming not just for the unsuccessful applicants, but also for the courts/tribunals and for AFMA itself.

Concerns regarding the potential negative impacts of uncertainty about the Principle's interpretation led Australian governments to avoid explicit reference to the Principle in gene technology legislation. Policymakers in other natural resource management areas may wish to consider whether the meaning and policy relevance of the Precautionary Principle should be clarified or whether it would be preferable to omit all reference to it. Regardless of reference to the Principle, continuing to clarify the basis for precautionary decision making, where necessary, would improve decision making processes and enhance public understanding of precautionary measures.