ENVIRONMENTAL RISK MANAGEMENT AUTHORITY

ERMA New Zealand

NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

APPROACH TO RISK

POSITION PAPER ON THE APPROACH TO RISK, METHODOLOGIES FOR DEALING WITH THIS AND THE TECHNICAL AND COMMUNITY INFORMATION REQUIRED FOR IMPLEMENTATION

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PREFACE

The HSNO Act requires the Environmental Risk Management Authority (the Authority) to consider the need for caution where there is scientific and technical uncertainty. In addition the HSNO Methodology (the Methodology) refers to the approach to risk that the Authority should adopt in evaluating applications where there is risk and uncertainty. In practice the Authority has considered uncertainty in a wider context than just scientific and technical information.

To assist in developing its position on risk, the Authority requires credible information on generic scientific and other issues and on the way in which the community views certain types of risk. As a precursor to investing in obtaining this information and as a means of detailing the type of information required, it is appropriate to review the Authority's approach to decision making. This paper provides a background to the concepts of attitude to risk and uncertainty, a summary of current thinking in developing approaches to risk, and an overview of existing data sources in New Zealand. It is intended to provide a basis for the review of the approach to risk within the decision-making framework, and a structure for obtaining the required further information to support the implementation of this.

This paper was peer reviewed and circulated as a consultation draft in conjunction with the review of the ERMA Methodology in March 2002. This version incorporates all comments.

It is anticipated that the paper on 'approach to risk' will be the basis for an ongoing work programme aimed at:

- further exploring key issues; and
- developing relevant databases so that theory can be turned into practice.

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1. INTRODUCTION

In making decisions under the HSNO Act, the Authority is required to balance adverse and positive effects. Many effects that are required to be considered by the Authority are not certain for a variety of reasons and the quality of information may vary between the alternative actions. The notion of decision making under uncertainty requires the Authority to consider the criteria it will apply in making decisions and its attitude to uncertainty. Decision making may also be influenced by risk characteristics (other than the probability and magnitude of consequences) and guidelines are necessary for dealing with this.

One way of looking at how attitude to risk is given effect in decision making is to examine the decision support mechanisms and the type of criteria used by decision makers. A limited list of approaches or decision support mechanisms used in environmental management includes:

- risk assessment;
- cost benefit analysis; and
- minimum standards.

Within risk assessment and cost-benefit analysis there are two major themes associated with attitude to risk:

- the notion of willingness to accept/reject risk, i.e. risk averseness; and
- the notion of caution, or how to act in face of uncertainty.

1.1 What is 'approach to risk'?

Decision makers are often faced with comparing risks when considering the outcomes of alternative actions where these outcomes are not certain. In most cases the outcomes will be a complex mixture of positive and negative elements, and part of the decision process will involve weighing up these effects to reach a decision.

Risk-based decision making is concerned with the decision-maker deciding whether the estimated levels of risk are deemed to be 'acceptable'[1] or not. The criteria that the decision maker uses to decide whether risks are acceptable or not reflect the decision maker's approach to risk. The context in which the decision is being made also determines acceptability. Decision makers are acting on behalf of the whole of society but within this there are inevitably different societal groups, and therefore it is important that they understand and take account of the factors that affect the attitudes towards risk of these different groups.

There are two common ways of looking at 'approach to risk'. In formal decision analysis a decision maker may adopt an approach to risk based on the calculation of expected values and a weighing up of risks (costs) and benefits. This concept of an approach to risk depends

[1] In some jurisdictions the concept of 'tolerable risk' is used in preference to 'acceptable' risk on the grounds that risks are not 'acceptable' but may be tolerated under certain circumstances or for certain period of time with the expectation of particular counterbalancing benefits. In the ERMA context the phrase 'acceptable risk' is aligned with 'tolerable risk' since the decision process requires weighing up of risks and benefits.

on putting different weights on the adverse and beneficial effects depending on how much risk of an adverse outcome the decision maker is prepared to accept.

Risk neutral decision makers are simply concerned with minimising costs or maximising benefits and will therefore make decisions based on the expected value of each alternative action (defined in economic terms). Decision makers may also be:

- *risk averse*: willing to accept only a low likelihood of adverse outcomes, irrespective of level of potential benefit (minimising the loss irrespective of the potential benefit); or
- *risk prone*: willing to accept a relatively high likelihood of adverse outcomes in the expectation of a greater benefit (maximising the benefit irrespective of the potential loss)

This way of looking at 'approach to risk' does not specifically consider uncertainty, and assumes that the information available to the decision maker about the likelihood and magnitude of effects is statistically sound. Uncertainty may be addressed by calculating standard deviations (where the major issue is sampling error), or in other ways constructing a range of values. These ranges may be applied to estimates of both likelihood and magnitude, and these may be combined, to estimate bounds on the level of risk.

A second way of looking at 'approach to risk' addresses uncertainty explicitly, and considers how the decision maker should address risk in the face of uncertainty. There are many circumstances, particularly in environmental decision making, where there may be very little information available, or the information may be recognised as being statistically unreliable. In these circumstances the decision maker may choose to be cautious or adopt 'precaution'.

Both ways of looking at the approach to risk need to take account of the other factors impacting on the decision, including:

- who is at risk and who bears the benefits;
- the characteristics of the particular risks;
- the administrative basis for the decision; and
- how the 'acceptable level' of risk is determined (criteria).

In addition the decision maker needs to be explicit about how the attitudes of the stakeholders and interested parties are included or not in the decision-making process.

1.2 Why the Authority needs to adopt an 'approach to risk'

The Authority effectively makes decisions on behalf of the New Zealand public and the New Zealand environment, although the way in which it does this is, in large, prescribed by the HSNO Act. This paper is concerned with the approach to risk that the Authority adopts during the decision-making process.

The purpose of the HSNO Act is to *"protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms*". While the emphasis is on managing adverse effects, in making specific decisions under the Act the Authority is required to *"consistently apply"* the

Methodology[2] which includes requirements to balance the risks, costs and benefits of applications for new organisms and hazardous substances.

Section 7 of the Act, entitled 'Precautionary Approach', further requires *"all persons exercising functions, powers, and duties under this Act"*.. to *"take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects*". Caution[3] is defined in the dictionary as 'attention to safety, prudence, or carefulness', while precaution is defined[3] as 'an action taken beforehand to avoid risk or ensure a good result'. The notion of precaution includes reference to actions taken beforehand and 'risk', while the definition of caution carries an ongoing imperative, and refers to 'safety'. This paper refers to both caution and precaution because the distinction does not pertain within the HSNO context, as the Authority makes decisions at a point in time and cannot revisit that particular decision, without recourse to reassessment of the organism or substance[4].

The wording in the Act is very permissive, such that the Authority would be acting lawfully in deciding that caution was not warranted, provided it explained why. In practice, the Authority has generally exercised caution.

The Methodology is more explicit about what to do when there is significant uncertainty about risks (including likelihood and magnitude of effect). Clause 29, entitled *"Uncertainty"* states that:

> *"Where the Authority encounters scientific and technical uncertainty relating to the potential adverse effects of a substance or organism, or where there is disputed scientific or technical information the Authority:*
>
> *(a) Shall determine the materiality and significance to the application of the uncertainty or dispute taking into account the extent of agreement on the scope and meaning of the scientific evidence; and*
>
> *(b) May, where the uncertainty or dispute is material or significant, facilitate discussion between the parties concerned to clarify the uncertainty or dispute."*

However, this does not give any guidance as to how the Authority will treat unresolved uncertainty within its decision processes. Clause 12 states that:

> *"In evaluating assessments of risks associated with an application the Authority shall take into account:*
>
> *(a) the nature of the adverse effects;*
>
> *(b) the probability of occurrence and the magnitude of each adverse effect;*
>
> *(c) the risk assessed as a combination of the magnitude of the adverse effect and the probability of its occurrence;*
>
> *(d) the options and proposals for managing the risks identified; and*
>
> *(e) the uncertainty bounds on the information contained in the assessment expressed quantitatively where possible but otherwise through narrative statements."*

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[2] - required by the Act to include "an assessment of monetary and non-monetary costs and benefits".
[3] The Concise Oxford Dictionary, 8th Edition. © Oxford University Press.
[4] The process for reassessment is such that it requires a new application and approval process.

The reference to 'uncertainty' in (e) reflects uncertainty in measurements and variability, rather than unresolved uncertainty or lack of knowledge. Clause 33 lists the factors that will affect the Authority's 'approach to risk':

> *"In considering how cautious or risk averse to be when considering applications, the Authority shall have regard to the extent to which the following risk characteristics exist:*
>
> *(a) Exposure to the risk is involuntary;*
>
> *(b) The risk will persist over time:*
>
> *(c) The risk is subject to uncontrollable spread and is likely to extend its effects beyond the immediate location of incidence:*
>
> *(d) The potential adverse effects are irreversible:*
>
> *(e) The risk is not known or understood by society and there is little experience or understanding of possible measures for managing the potential adverse effects."*

Thus, clause 33 of the Methodology provides a link to section 7 of the Act by linking 'caution' and being 'risk averse', and also through subsection (e), introduces uncertainty with respect to managing potential adverse effects.

Clause 33 states that the Authority *"shall have regard to.."*. This does not mean that the Authority will necessarily be more cautious in all cases where these characteristics apply, but that consideration should be given to these factors.

The ERMA New Zealand Annotated Methodology (the Annotated Methodology) provides more explicit guidance as to the way the Authority will address uncertainty in its decision making by defining two further concepts – 'attitude to risk' and 'degree of caution'. 'Attitude to risk' is defined as how the Authority will value uncertain outcomes vis-à-vis certain outcomes, for different risk types and characteristics, and 'degree of caution' as how conservative the Authority will be in the assumptions it uses in its analysis and determinations. While this definition of 'attitude to risk' only refers to the consequence aspect of risk, implicit within the terminology is that uncertainty in terms of uncertainty around estimates of likelihood or probability will also affect the attitude to risk adopted. The implication of the definition of 'attitude to risk' is that the Authority will place different weights on different risks according to the certainty of information and the relevant factors.

To summarise, the requirement for the Authority to adopt an 'approach to risk' is based on:

1. the HSNO Act, which refers to being cautious in the face of scientific and technical uncertainty;
2. the Methodology, which refers to procedural matters in terms of dealing with uncertainty, and also specifies the factors associated with the risks that the Authority will consider in developing an approach to risk or a particular application; and
3. the Annotated Methodology, which defines 'degree of caution' and 'attitude to risk'.

2. CURRENT PRACTICE: RISK ANALYSIS AND DECISION MAKING

2.1 Decision analysis and approach to risk

Classical decision theory is an axiomatic theory used for making choices in uncertain conditions. Decision theory is also prescriptive, which means that if the decision maker accepts the axioms of the theory, the 'correct' choice will be made. However, because decision theory is concerned with uncertainty, making the 'correct' choice does not necessarily lead to a 'good' outcome.

Decision analysis is the practical application of decision theory and uses tools from economics, operations research, and management science. Early emphasis in decision analysis was on the use of dollar values and a number of different decision rules were developed of which the most common (neutral) one was the maximisation of expected values[5]. Two lines were subsequently explored: cost-benefit analysis concentrating on quantification in dollar terms, and multi-attribute utility theory, which concentrated on eliciting and combining the preferences or utilities of decision makers. Both of these lines of approach depend on putting different weights on the adverse and beneficial effects according to how much risk of an adverse outcome the decision maker is prepared to accept.

The classical model of rational decision making depends on the assumptions that decision makers are able to:

- agree on the goals that govern a given decision;
- identify all alternative courses of action (options) that are relevant to their goals;
- identify all relevant consequences of each alternative[6]; and
- compare the sets of consequences and decide on the optimum alternative, using some appropriate calculus.

In addition, the model assumes a known preference function and perfect information. Logically, these conditions cannot be met, and in practice varying approximations are made that reflect the (often gross) lack of perfect information.

Decision analysis provides a simple framework illustrating the elements of risk and the economic approach to differentiating between risk and uncertainty. This framework uses different decision rules to choose a preferred option. The particular decision rule used will depend on whether the decision maker is risk averse or risk prone. In this context, a risk averse decision maker will seek to minimise the maximum loss and will choose the action for which the maximum loss is the least.

A key assumption of the decision analysis approach is that all the possible outcomes of an action are known, which means that the probabilities for the various outcomes for each action should sum to 1.0. The approach also depends on the existence of a common 'value' for all the outcomes. While this is usually a 'dollar' value or imputed dollar value, it is possible, though not common, to use other units.

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[5] As noted earlier, the attitude of the decision maker to risk will result in different criteria being applied.

[6] Since risk analysis is concerned with what may happen in the future, "all relevant consequences" are not known, and therefore classical decision analysis is seldom appropriate for analysing risk.

In this context risk attitude is based on whether the decision maker is willing to take more or less risk given the context of the decision and the value of the expected outcome, which is usually estimated in terms of net loss or net benefit. Where the outcomes are not known, or it is not possible to estimate the probabilities of the outcomes then a decision analyst will say that there is uncertainty rather than risk. Traditional decision analysis is primarily concerned with risk rather than uncertainty, and uncertainty is addressed by sensitivity analysis through varying the parameters[7].

2.2 Uncertainty and Precaution

2.2.1 Uncertainty and variability

Decisions concerning the environment need to take into account:

- the potential time lag between action and impact;
- the irreversibility aspect of many environmental risks;
- complexity;
- cumulative effects;
- considerable uncertainty associated with poor quality or sparse data; and
- simple non-understanding or ignorance of what may happen.

Environmental decision making may also require weighing up of short-term benefit and long-term uncertain cost (risk), or short-term cost (risk) and long-term uncertain benefit. By their nature short-term effects are easier to estimate than long-term effects.

In the past uncertainty has been addressed as a single concept, although different uncertainties such as strategic (problem related) and tactical uncertainty were acknowledged in decision analysis. More recently, the existence of different types of uncertainty or levels of ignorance, have been recognised. These distinctions are particularly important for environmental issues. As some uncertainties have been reduced by science, others have been shown to be less tractable to scientific investigations and greater knowledge has not significantly reduced the uncertainty, for example, climate change issues.

Some of this was recognised in 1937 by Keynes, who noted:

> *"By 'uncertain' knowledge, let me explain, I do not mean merely to distinguish what is known for certain from what is only probable. The game of roulette is not subject, in this sense, to uncertainty... The sense in which I am using the term is that in which the prospect of a European war is uncertain, or the price of copper and the rate of interest twenty years hence...About these matters there is no scientific basis on which to form any calculable probability whatever. We simply do not know……..[8]".*

[7] In this context sensitivity analysis is the process of varying the values of input parameters and repeating the analysis. By examining the differences (range) of the outputs, the most sensitive parameters and their effect can be determined.

[8] John Maynard Keynes, "General Theory of Employment", Quarterly Journal of Economics, 1937.

Having acknowledged uncertainty, Keynes goes on to say that decision makers need to proceed as if probabilities existed, introducing the notion of subjective probabilities. The validity of subjective probabilities remains a matter of considerable debate today.

In the early 1990s Brian Wynne described four types of risk/uncertainty:

- risk - where we know the odds (probability or likelihood);
- uncertainty - where we don't know the odds but may know the main parameters;
- ignorance - where we 'don't know what we don't know'; and
- indeterminacy - where causal chains or networks are open (spans uncertainty and ignorance).

These categories can be presented on a spectrum in the following way.

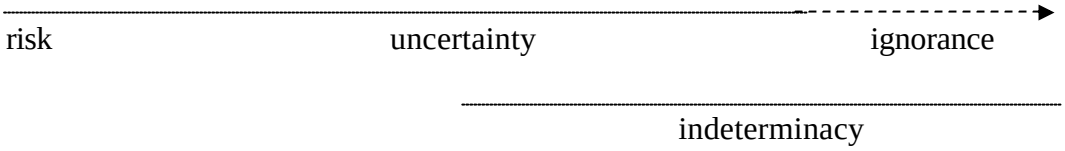

Figure 1: Risk spectrum

Wynne later stated that decisions affecting the natural and social environment are characterised by a combination of scientific uncertainty and ignorance, where scientific uncertainty is associated with random processes, measurement uncertainty, and the interpretation of measurements. Wider uncertainties relate to ignorance including problem identification and whether or not appropriate models and parameters have been used.

O'Riordan and Cox[9] introduce a two dimensional representation shown below that describes four levels of 'incertitude'.

		KNOWLEDGE ABOUT OUTCOMES	
		Well-defined outcomes	Poorly defined outcomes
KNOWLEDGE ABOUT LIKELIHOODS	Some basis for probabilities	**risk**	**ambiguity**
		"**INCERTITUDE**"	
	No basis for probabilities	**uncertainty**	**ignorance**

Figure 2: Incertitude

[9] O'Riordan, T, and Cox, P. 2001. Science, Risk, Uncertainty and Precaution. *Senior Executive's Seminar – HRH The Prince of Wales's Business and the Environment Programme.* University of Cambridge.

In Figure 2, 'uncertainty' applies where there is no firm basis for probabilities, but some reasonably clear idea as to outcomes. 'Ambiguity' applies where the outcomes are not clear. 'Ignorance' exists where there is no history of cause and effect that can be used to predict outcomes. Thus science (by its own rules) cannot predict either likelihood or outcome. Examples of ignorance defined in this way occur when there is innovative technology, or a new product or substance.

The Wynne and O'Riordan approaches are reasonably consistent, with the O'Riordan two-dimensional approach providing a useful way of categorising situations or activities. Wynne's definition of 'ignorance' as being 'don't know what we don't know' is arguably broader than O'Riordan's, since in the O'Riordan model 'ignorance' relates to situations where there may be some information. This paper adopts the O'Riordan categorisation with the addition of Wynne's concept of 'indeterminacy.'

All individual uncertainties (related to specific probabilities or identified outcomes) can, in principle, be reduced by the provision of appropriate information, however, increased knowledge may increase total uncertainty, as new uncertainties are revealed. This introduces the notion of the usefulness of knowledge, where useful knowledge is knowledge that can be used to improve the decision process, and useless knowledge, which cannot be used (that is, is irrelevant to the decision). An example of useless knowledge is increased accuracy for estimates in one area that is overwhelmed by uncertainty in other areas.

Scientific experiments can be used to seek to reduce uncertainty. If some ranking of 'importance' can be given to different types of uncertainty and ignorance for particular problems and at the same time judgement can be used to assess the *usefulness* of the information likely to be obtained from particular experiments, then it may be possible to prioritise efforts to reduce uncertainty for maximum gain. An example might be in relation to a group of hazardous substances that have been well studied in the laboratory but for which there are few data on human exposures (and effects). In this instance, licensing agencies may choose to place a greater premium on adding to the human studies than extending the animal work, since greater gains are likely to be made by reducing uncertainties in the former category.

Variability differs from uncertainty. It arises from differences in the nature and extent of exposure and variations in susceptibility (heterogeneity). Sometimes probability or frequency distributions can be used to analyse variability. More often, sensitivity analysis can put bounds around the impact of variability.

2.2.2 Precaution

Section 7 of the Act requires the Authority to be cautious where there is scientific and technical uncertainty, and this is referred to as a 'precautionary approach'. The term 'precautionary' has been used in environmental decision making since the early 1990s to reflect an approach to environmental management that takes account of lack of knowledge about long-term outcomes where cause-effect relationships are not fully established. A precautionary approach can be seen as part of a spectrum of approaches to environmental management, including reactive, proactive, and precautionary approaches.

The term 'precaution' is used in two senses: in the context of the Precautionary Principle, and in the less formal context of 'being cautious' (precautionary approach). The formal Precautionary Principle[10] has been adopted by the Economic Union and the United Kingdom as a guiding principle of environmental policy[11]. It is used when information suggests cause and effect but cannot prove it, or when the possible undesirable consequences are so great that a 'business as usual' approach cannot be chanced. Justification for its use is on grounds of either complexity or uncertainty and ignorance. Complexity is the inability to unambiguously identify all cause-effect relationships, while uncertainty and ignorance exist where there is limited or no previous knowledge on which to base the prediction of impacts (both what those impacts might be, and the likelihood of their occurrence).

In Australia the 1992 Intergovernmental Agreement on the Environment (IGAE) defined the Precautionary Principle as:

> *"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, private and public 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"*

In other words, scientific uncertainty (or lack of established cause-effect relationships) is not a reason for not taking measures to prevent environmental degradation, but rather a signal to put appropriate measures in place in advance of more certain scientific evidence.

Some of the issues to be addressed in applying this form of the Precautionary Principle are:

- what is the potential for threats of environmental damage?
- are the threats serious or irreversible?
- are precautionary measures required?
- what precautionary measures *can be* applied?
- how much precaution is warranted?
- what precautionary measures *should be* applied? [12]

The Canadian Environmental Protection Act (1999) specifically incorporates the Precautionary Principle in the same form as the Rio Declaration, i.e. that "*lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation*". As in the Rio declaration, the French version of the

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[10] The Precautionary Principle as laid down in principle 15 of the Rio declaration requires that "action be taken to prevent environmental damage even if there is uncertainty regarding its cause and possible extent" (commonly interpreted as the environment should not be left to show harm before protective action is taken, and scientific uncertainty should not be used as a justification to delay measures which protect the environment).

[11] This paper does not attempt to review the literature on the Precautionary approach, but simply provides a brief introduction. Additional reading is given in the Bibliography.

[12] Deville, A. and Harding, R. 1997. Applying the Precautionary Principle. The Federation Press. Sydney, Australia., and Fisher, E., and Harding, R. The Precautionary Principle in Australia: from aspiration to practice. In: O'Riordan, T., Cameron, J., and Jordan, A. 2001. Reinterpreting the Precautionary Principle. Cameron May.

Canadian Act refers to "*effective measures*" while the English version refers to "*cost-effective measures*".

The essence of the precautionary principle is that rather than await certainty policy makers should act in anticipation of any adverse effect, to prevent it. Most current applications of the precautionary principle require policy makers to act judiciously when there is adequate evidence and where action can be *justified* on the grounds of cost effectiveness and where inaction could lead to potential irreversible outcomes or serious harm to future generations.

In New Zealand, the Precautionary Principle is articulated most fully in the Government's *Environment 2010 Strategy* where it is given prominence as one of eleven key principles for integrating, environment, society, and economy[13]. The Precautionary Principle embodies fundamental values related to society's expectations for environmental management and the concept of sustainability. However, because precaution has costs, the Precautionary Principle can be very difficult to implement in practice.

In most New Zealand legislation and practice, the emphasis has been on the notion of adopting a 'precautionary approach', as being a practical way of giving effect to the concept of precaution. Section 7 of the HSNO Act requires decision makers to consider the need to be cautious where there is scientific or technical uncertainty. Thus the adoption of a precautionary approach is linked to the existence of uncertainty. Uncertainty is not defined in the HSNO Act, but it can be assumed that it includes the full range of uncertainty, ambiguity and ignorance as outlined by O'Riordan.

The adoption of a precautionary approach is often seen as a pragmatic way of dealing with uncertainty and ignorance. There are significant issues associated with the lack of a common interpretation of the meaning of the formal Precautionary Principle (as promoted at the Rio Conference), and a lack of commonly accepted application. While adopting a precautionary approach may appear to be a means of achieving the same purpose without the formal 'baggage' associated with the Precautionary Principle, it is important that decision makers should endeavour to apply systematic and consistent criteria, or at the least follow a transparent and reasoned process.

2.3 Attitudes to risk

Perceptions of risk affect the level of risk that individuals and communities consider acceptable, and also affect the way that people respond to risk issues. The term 'risk perceptions' (or perceived risk) derives from psychological research and refers to subjective judgements made either by experts or lay people. Perceptions are based on inferential rules known as heuristics. In applying these heuristics people use a wide range of contextual and scientific information from many sources. While risk assessment uses scientific information, it also necessitates the construction of scenarios (for example, the use of decision trees), which require experts to use these same heuristics.

[13] "*...precautionary principle should be applied to resource management practice, where there is limited knowledge or understanding about the potential for adverse environmental effects or the risk of serious or irreversible environmental damage.*"

Clause 33 of the Methodology lists the factors that the Authority is currently required to take into account in establishing an approach to risk. These derive from the factors that risk perception research has identified as affecting the way people perceive risk.

Attitudes are based on beliefs and evaluations of those beliefs. Thus attitudes are formed by perceptions and perceptions are shaped by pre-existing beliefs and expectations. Risk perception research seeks to develop a better understanding of the links between an individual's perceptions of risk and their response to risk. One way of looking at this is to say that the characteristics of particular risks affect individual's attitudes to risk and this attitude in turn may affect the way people respond (behaviour). Thus the way individuals and communities perceive risk affects the way that they respond to situations that they perceive as risky and consequently the level of risk that they are prepared to accept (or tolerate) in any particular circumstance.

Some researchers have found that risk analysts tend to consider only two components of risk – the likelihood of the event occurring, and the size of the event should it occur[14]. The lay public, however, tends to consider risks within a much broader context, and takes into account a wide range of factors. Research over the past 20 years has identified the following factors as being important:

- whether the risk is voluntary or involuntary;
- the degree of control over the risk the subject has;
- whether the subject is familiar or unfamiliar with the risk, whether it is a `new' risk, or whether it has been previously experienced (not necessarily directly);
- whether the risk is known to science or not;
- the severity of the effects of consequences and whether they are likely to be immediate or delayed; chronic, cumulative or catastrophic in nature; common or dread;
- the size of the group exposed to the risk;
- the distribution of the risk (socially, over time, and geographically);
- the necessity of exposure;
- the effect on future generations;
- the global catastrophic nature of the risk;
- whether there is seen to be any easy way of reducing the risk;
- whether there are any alternative actions that would reduce the risk;
- the degree of personal exposure;
- whether the hazard is encountered occupationally;
- whether the risk affects `average' people;
- whether there is likely to be misuse (e.g. of a substance); and
- whether the consequences are reversible.

People's values, or judgments of what is valuable or important in life, also affect attitudes towards risk. Some values are shared by social groups, but these same groups may also

[14] This is a slightly simplistic interpretation since risk analysts know that risks that arise in significantly different contexts cannot be compared. For example, the probability of being killed in a car accident should not be compared with the risk of being killed in a workplace related accident.

exhibit a range of values that not necessarily shared. Attitudes towards environmental risks can often be separated into those motivated by self-interest and those motivated by underlying values or ethical judgements. Underlying values will affect the emphasis that individuals place on the factors listed above.

Where decision makers are acting on behalf of society they need to be aware of these factors, how they help form the attitudes towards risk of individuals and communities, and the underlying values that also influence these attitudes. Public perceptions of risk may be formed using different information to technical estimates of risk. Information about perceptions can be used to supplement technical information and to help prioritise the management of risks.

In 1988, Schmeidler and Sandman[15] explored the issue of 'trust' in relation to risk, concentrating on the perception of trust, the importance of trust and operational definitions of trust, including consideration of trust between parties involved in disputes and communication processes, and trust of the process itself. Subsequent risk perception and risk communication literature, has demonstrated that the issue of trust is very important in public decision-making processes. Trust can be eroded, lost by incompetence, the withholding of information, denial of vested interest, the use or suspicion of influence, and a refusal or inability to involve the public in risk decision making. In making environmental decisions in the public interest, risk regulators, analysts and promoters need to promote ways of building and maintaining trust by demonstrating that risks have been fully examined and reduced to as low a level as possible (practicable), that the benefits occurring to the process are in the public interest and that appropriate emergency response procedures have been established and are operational.

The crucial message is that unless trust can be established between all parties involved it is unlikely that an enforceable solution will be reached.

2.4 The Precautionary Principle, the precautionary approach and risk analysis

Risk assessment and risk management are proactive tools that can be used to make decisions before harm occurs. The Precautionary Principle is an additional tool that is invoked when risks cannot be properly identified and assessed. A precautionary approach is a way of including caution explicitly within the decision process.

Most risk assessment techniques are based on variations of decision analysis, and are therefore most appropriate when there is good (high quality) information about the probability or likelihood of specific outcomes and their magnitude if they do occur. This does not mean that quantitative information is necessary. There are good techniques that can be used to make qualitative estimates of the level of risk, but such estimates must be used

[15] Schmeidler, E., and Sandman, P.M. 1988. Getting to maybe: decisions on the road to negotiation in Hazardous waste facility siting. Environmental Communication Research Programme, Rutgers University, New Jersey, January 1988.

cautiously. Analysts should be careful about comparing different types of risks when using qualitative assessments.

Risk assessment is also appropriate where there is variability in estimates, and in cases of measurement uncertainty. In both of these circumstances it is usually possible to place bounds on estimates or to use sensitivity analysis to (a) limit the variations, or (b) ascertain which parameters are the most sensitive.

The Precautionary Principle has a connotation of inflexibility and the lack of a consistent interpretation. In addition, from a legal perspective it is considered to be difficult to implement partly because it does not specify 'how much' caution should be taken. Other (international) legal views consider it to be a 'general approach to environmental management' (and useful from that perspective). Many scientists also mistrust it as an 'environmental philosophy', rather than a scientific approach. However, Stirling (1999[16]) concludes that the key elements of adopting a precautionary approach are entirely consistent with sound scientific practice in responding to intractable problems in risk assessment. If risk assessment is carried out in an open and consistent manner then the framing assumptions can be tested and validated against the wider socio-political factors, inherent in environmental risk decisions.

While risk assessment requires the parallel consideration of benefits, the Precautionary Principle does not consider compensating benefits. This can be argued to be a potentially serious flaw. Thus if the benefit to be derived from actions (carrying risk) is the mitigation of existing environmental damage, then exercising precaution in relation to not mitigating that risk would seem to be as valid as considering the uncertainty associated with new measures which might have associated with them a separate set of risks. In these circumstances, decision makers might seek to achieve the same result by avoiding the risk if possible, delaying while further information is sought, or seeking some sort of middle ground. However, delay is simply a form of decision and carries connotations of uncertainty and consequences as well.

For example, consider the proposed introduction of a new chemical for possum control. The new chemical is known to be highly effective in killing possums, but there is a suspicion that it might cause adverse health effects in humans that have long-term chronic exposure to small quantities of the substance. There is little evidence of these effects, and mitigation procedures would ensure that handlers used appropriate protective equipment and clothing. The adoption of a precautionary approach without consideration of benefits would favour not introducing the substance, whereas if existing environmental damage and the potential for future damage were considered then precaution might well favour introduction.

Precautionary approaches deal with situations where there is much less knowledge or information about the possible outcomes and their full implications. Risk assessment and the adoption of a precautionary approach are not mutually exclusive. In practice it is often sensible to adopt a precautionary approach within risk assessment. This can be done at two levels: by being cautious when making estimates of likelihood and magnitude of effect, and by being cautious in making decisions based on risk estimates.

[16] Stirling, A. 1999. ESRC Global Environmental Change Programme: Science and Precaution in the Management of Technological Risk – synthesis report. May 1999.

Two useful tools that can be used are the adoption of a worst-case scenario, and the calculation of bounds to risk. Adopting a worst-case scenario involves setting all parameters at a level reflecting the worst thing that could happen, and calculating the risks on this basis. This is a valid approach when there is significant uncertainty, however if not used carefully it can produce meaningless results, and it should not be used as a way of avoiding making judgements.

Alternatively, it may be possible to put ranges on all the parameters, and use these to calculate upper and lower bounds to the risks. This latter approach can also be used as a means of conducting a sensitivity analysis to see which parameters are the most sensitive, and thus where more information can reduce uncertainty.

While these approaches are specifically directed towards demonstrating how to apply a precautionary approach it should be noted that scenario analysis is a common tool in risk analysis, and that typically it is applied by using 'plausible' values or ranges for parameters

Another approach that has been used by the International panel on Climate Change (IPPC) is to frame the sensitivity analysis in terms of the limits of adaptation, thus shifting the focus of the analysis to questions such as what level of risk would constitute serious damage, and where would this damage occur. In this instance, the challenge facing the Panel is to define what constitutes a 'dangerous' disturbance in the planet's climate. The conventional approach has been to base predictions on observations of past climate effects, however there are enormous uncertainties associated with extrapolation from current data to conditions in a future warmer world. As a result, some have argued that a better application of the precautionary approach is to define dangerous climate change in terms of the rate of change that physical, natural and social systems can cope with, or to which they can adapt.

3. RISK CHARACTERISTICS AND UNCERTAINTY - OTHER RELEVANT JURISDICTIONS IN NEW ZEALAND

The HSNO Act has arguably the most developed legislative framework in New Zealand for dealing with risk and uncertainty. However, these concepts are included in other legislation, including the Resource Management Act (RMA), the Biosecurity Act, and the Fisheries Act.

As noted in section 2.2, in New Zealand, the precautionary principle is articulated most fully in the Government's E*nvironment 2010 Strategy*. The *Strategy* states that the "*...precautionary principle should be applied to resource management practice, where there is limited knowledge or understanding about the potential for adverse environmental effects or the risk of serious or irreversible environmental damage*."

The Resource Management Act (RMA) is viewed by some as a precautionary statute[17] (Board of Inquiry 1995). Although the precautionary principle is not explicitly mentioned in the Act, the articulation of sustainable management has been viewed as representing a precautionary approach to environmental problems. The definition of adverse effects in the RMA includes any potential effect of high or low probability that has a high potential impact (thus 'effect' includes the notion of 'risk'). Dealing with adverse effects, while meeting the reasonably foreseeable needs of future generations, and safeguarding the life-supporting capacity of the environment can be seen as requiring the adoption of a precautionary approach.

The RMA does not include mention of the word caution, and while there is one reference to uncertainty, it is not relevant to the consideration of effects. Thus any guidance on how the processes under the RMA reflect risk and uncertainty has to be drawn from case law.

The Biosecurity Act (1993) does not include mention of either uncertainty, or caution, but does refer to 'precaution' in the Purpose of the Act (section 42), which states that –

> *The purpose of this Part of this Act is to provide for the continuous monitoring of New Zealand's status in regard to pests and unwanted organisms-*
>
> *(a) To facilitate the provision of assurances and certificates in relation to exports of organisms and their products; and*
>
> *(b) As a basis for the proper administration of this Act, including the institution of* ***precautionary*** *actions, emergency and exigency arrangements, and pest management strategies; and*
>
> *(c) To monitor the effect of pest management strategies; and*
>
> *(d) Otherwise to enable any of New Zealand's international reporting obligations and trading requirements to be met.*

However, no guidance is given as to what sort of actions would constitute 'precautionary' actions, or how they should be implemented.

[17] E.g. see Board of Inquiry (1995) "Proposed Taranaki Power Station - Air Discharge Effects" Report and Recommendation of the Board of Enquiry pursuant to Section 148 of the Resource Management Act 1991.

The Fisheries Act (1996) also addresses uncertainty explicitly. The Purpose of the Act is "*to provide for the utilisation of fisheries resources while ensuring sustainability*". Section 10 of the Act states that –

> *"All persons exercising or performing functions, duties, or powers under this Act, in relation to the utilisation of fisheries resources or ensuring sustainability, shall take into account the following information principles:*
>
> *(a) Decisions should be based on the best available information:*
>
> *(b) Decision makers should consider any uncertainty in the information available in any case:*
>
> *(c) Decision makers should be cautious when information is uncertain, unreliable, or inadequate:*
>
> *(d) The absence of, or any uncertainty in, any information should not used as a reason for postponing or failing to take any measure to achieve the purpose of this Act.*"

The Fisheries Act clearly differentiates between uncertain information and unreliable information, and requires decision makers to be cautious when information is unavailable, of poor quality, or uncertain. While (d), is directly linked to the phraseology of the Precautionary Principle, it is notable that it is linked to 'ensuring sustainability', rather than mitigating or preventing adverse effects, thus allowing for the possibility of considering compensating benefits.

4. THE ERMA NEW ZEALAND APPROACH TO RISK

4.1 Introduction

The two aspects of adopting an 'approach to risk' can be summarised as:

- the degree of willingness to accept risk, i.e. degree of risk averseness; and
- the need for caution in the face of uncertainty, i.e. reaction to uncertainty.

The first of these primarily relates to the characteristics of risk, and the second to the information available about risk. Section 1.2 shows how both aspects are captured in the HSNO Act and the present Methodology, with Clause 33 of the Methodology providing the link to section 7 of the Act. The Annotated Methodology[18] is more explicit than the Order-in-Council, and introduces definitions of 'attitude to risk' and 'degree of caution'.

The sections below describe the general approach to risk currently used by ERMA New Zealand, discuss whether it can (should) be used in the future or not, and propose enhancements.

4.2 Establishing an enhanced 'approach to risk' based on risk characteristics

A decision maker's attitude must be informed by the context in which the decision is being made, and the legislative requirements of the decision process.

Clause 33 of the Methodology provides the formal requirements that direct the Authority's application of an approach to risk, and lists the factors that should make the Authority more or less risk averse in making decisions. That is, whether:

- exposure to the risk is involuntary;
- the risk will persist over time;
- the risk is subject to uncontrollable spread and is likely to extend its effects beyond the immediate location of incidence;
- the potential effects are irreversible;
- the risk is not known or understood by society and there is little experience or understanding of possible measures for managing the potential adverse effects.

These factors are a combination of the characteristics of environmental risk, and the factors that individuals are known to take into account when making their own personal evaluations of risk. The questions that arise are whether this general approach in Clause 33 is satisfactory, whether the list of factors is sufficient and how they should be applied. The question of how they should be applied is dealt with separately in section 4.4 because the application needs to be considered in an integrated way such that uncertainty and risk characteristics are addressed together.

[18] The Annotated Methodology does not have any legal status. It has been published by ERMA as an information paper providing further explanation as to the application of the Methodology.

ERMA contends that the general approach as outlined in Clause 33 of the Methodology is sound and should be endorsed. The use of the approach has not led to unsatisfactory (to the Authority) decisions, and formal and informal responses received by ERMA indicate that the signals it gives have been found to be appropriate. However, ERMA proposes that the approach could usefully be extended by including other risk characteristics in the list requiring consideration, and by looking at the issue of 'weighting', or deciding how much weight to give to which factors, under which circumstances.

4.2.1 Additional risk characteristics[19]

One additional factor to consider is the distribution of risks, costs and benefits. Clause 13 of the Methodology refers to the distribution of costs and benefits. It states that in evaluating assessments of costs and benefits associated with an application the Authority shall take distributional effects over time, space, and groups in the community into account. While the distribution of risks is not addressed explicitly, there is an implicit assumption (through the definition of risks and costs) that the distribution of risks is also pertinent to the Authority's decision processes.

The key factors are (a) the extent to which costs (risks) are distributed differently to benefits, and (b) the extent to which risks themselves are unequally distributed within the population. It is argued that in both cases there should be a disposition toward being risk averse in decision making. For example, if the benefits and risks accrue to the same group, then a decision to approve is more likely than if the benefit accrues to one group and risks are borne by another. An example of the second case is where one particular sector of the population is known to be more at risk from a substance or organism than the general population, such that if only the 'average' risk is considered, this group might be severely disadvantaged. If risks, costs, and benefits are all considered as effects where effects may be either positive or negative and have both a likelihood of occurrence and a magnitude of effect, then an appropriate addition to the list of factors in Clause 33 might be:

- the distribution of effects over time, space and groups in the community

Social scientists have shown that citizens in general judge the tolerability (or acceptability) of risk on two key dimensions – voluntariness and catastrophic potential. Communities are known to be less accepting of risks having particularly serious consequences, than would be suggested by combining consequence and probability. That is, where the adverse outcome has the potential to affect a large number of people, greater weight is placed on the consequence element of the risk equation. Thus a further appropriate addition to the list of factors in Clause 33 might be:

- the extent to which the magnitude of an effect is sufficiently serious to override a low probability (likelihood) of occurrence.

There are other factors (drawing from those in section 2.3 of this paper) that might be added, but these two are suggested to be the key additional factors.

[19] This section is concerned primarily with equity in terms of risk. It is noted that equity is addressed primarily in Clause 13 of the Methodology. An inequitable distribution of risks may in some cases lead the Authority to be more risk averse, but when costs and benefits are also considered, the Authority may chose to be less risk averse, e.g. is a particular drug is known to adversely effect a small sector of the population, but has large scale benefits to other sectors.

A question to explore further is whether a measure reflecting the extent to which particular risks are acceptable (from a moral, ethical or cultural point of view) should be included as an additional factor. Concerns of this nature do not fit comfortably into the existing main effects-based process, and at this stage there is limited information available in New Zealand to provide a basis for making judgements on the moral, ethical and cultural aspects of particular types of application to ERMA. The public notification and submission process undertaken by ERMA for specific applications provides valuable information in these particular cases. However, in general the area requires further research. This paper does not at present take a position on that question, and simply notes that the issue is relevant.

4.2.2 Weighting of risks to account for the approach to risk

While it is possible to identify factors that might lead to risk averseness, it is more difficult to determine how far these factors should influence decision making, or how they should be used to weight risks. There is no evident theoretical basis for tackling this problem. There is thus no option but to deal with it empirically, most probably by collecting information on the 'strength of feeling' people have for the various factors and feeding this into the analysis.

In the absence of empirical data, the alternative is to rely on the informed judgement of the decision-makers. Effectively this can be considered as a sample of the views of the wider population. However, if this course of action is taken, the judgement should be made explicitly. That is, each of the significant risks of an application should be evaluated against each of the factors, and this should be made explicit in the decision[20]. Amongst other things, separation of such judgements from the determination of the level of risk would enable the 'risk attitude' of the Authority to be identified. While the Authority might have reservations about that degree of disclosure, it is information that stakeholders might legitimately wish to have.

4.2.3 Weighting of benefits

The notion of 'risk averseness' most often applies to adverse effects, and thus the result will be to weight adverse effects higher than positive effects. However, where an application has benefits that are directed towards achieving the purpose of the Act by, for example, mitigating an environmental risk, the decision maker may choose to place greater weight on the benefits side when weighing-up risks (and costs) and benefits. An example of where the logic may lie in increasing the weight of the benefit might be the introduction of a biocontrol agent. These kinds of situations need to be recognised when they occur, and again, where this approach is incorporated in the decision process it should be explicitly acknowledged.

4.3 Enhancing ERMA's approach to addressing different types of uncertainty

The Act and the Methodology both require the Authority to be cautious in the face of scientific and technical uncertainty, or to adopt a precautionary approach to decision making. While international discussions about the application of the Precautionary Principle have highlighted some formal ways of implementing this, there is nothing fundamentally new in adopting a precautionary approach, and decision makers are often cautious in the face of uncertainty.

[20] This is likely to be in a qualitative sense rather than the application of formal quantitative weights.

The current Methodology focuses very much on a mechanistic approach to uncertainty, i.e. how it should be measured, and the fact that it should be considered, but does not define the mechanics about how it should be considered.

4.3.1 Distinguishing between different types of uncertainty

Risk decision making requires predicting the future, using information available from the past. The probability element of risk, i.e. the probability associated with different levels of a particular consequence[21] can be conveniently referred to as inherent uncertainty. In this instance, while much may be known about the probability distribution of the specific consequence, there is uncertainty about the occurrence of consequences, or what will happen, in particular cases.

In this first type of uncertainty, the shape and width of the probability curve (where this can be constructed) may influence decision making, i.e. whether the probability curve is symmetrical or asymmetrical, and the size of the standard deviation. If the standard deviation is small, there may be a greater willingness to use expected values in decision making.

The second source of uncertainty is that relating to the extent and quality of the data available. Uncertainty of this type may arise from lack of accuracy or precision in measurement, or simply lack of data. Lack of data or information, on both probabilities and outcomes, is particularly common (almost inevitable) in looking at the long-term effects of new technologies, and this is sufficient to warrant special attention in decision making. Following O'Riordan and Cox (Figure 2), this aspect of uncertainty links to the concept of ignorance. These issues are discussed further in the final section of the paper.

A third source of uncertainty is that arising from the relationship between the circumstances under which data are obtained, and 'real world' circumstances. A classic example is the use of data obtained from experiments on animals to predict toxic impacts on humans. A new organism example is the extrapolation of laboratory experiments on horizontal gene transfer to predict the significance of this mechanism in the open environment.

A fourth source of uncertainty is that relating to the strength of an hypothesis (derived from real world or experimental observations) in acting as a general predictor of real world situations. Fairly obviously, hypotheses which are based on a large amount of data or which have a record of reliable prediction, carry a lower degree of uncertainty. Sometimes this is called model uncertainty.

The third and fourth sources of uncertainty discussed here link to known problems with extrapolation and the notion of variability.

A fifth source of uncertainty is that of unknown or even unknowable uncertainty (referred to as 'ignorance' in the Wynne spectrum in Figure 1), and that is briefly discussed in the next sub-section of the paper (4.3.2).

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[21] In this instance probability refers to the probability of different levels of a particular outcome. For example, an outcome might be damage to a particular species of fish, where there is a known probability distribution relating different levels of damage.

Ideally all aspects of uncertainty should be identified, characterised according to their source, and some measure of the extent to which they are likely to affect the estimation of risk should be given. However, in environmental risk decision making particularly, characterisation will rarely be quantitative – it is more likely to be qualitative and subjective. There is often a temptation to resort to 'pseudo quantification', including the application of safety factors, the use of indices, or the allocation of representative numbers to levels of probability and magnitude. While such approaches have value in specific circumstances these endeavours to quantify should be recognised for what they are – a reflection of qualitative judgements.

4.3.2 Hypothetical or unknown uncertainly

A central issue in applying the precautionary approach is that of dealing with hypothetical uncertainties, where an adverse outcome is hypothesised, but there is no evidence for or against a cause-effect relationship. An extreme approach to this is the view that 'if it can be hypothesised then it must be allowed to influence decision making', i.e. we cannot chance it turning out to be true. The flaw in this approach is that the ability to hypothesise is limited only by human imagination. The test of reasonableness has to apply, i.e. that the hypothesis has some reasonable basis, whether that basis is scientific, anecdotal and so on. A challenging question is 'who should apply the test'? Should it be applied by people who have legitimate experience and/or expertise in the area (the use of experts), or should the test of reasonableness lie in the views of informed lay people?

Comparisons of estimates made by lay people and by experts operating beyond their area of expertise are quite similar. Therefore, where expert judgements are used it is important to ensure that the experts are working within their own area.

While it is accepted that 'absence of evidence is not evidence of absence', and such hypotheses should be acknowledged, in many cases consideration of the factors listed in Clause 33 as affecting 'approach to risk' will be adequate to ensure effective decision making.

4.3.3 Reducing uncertainty with information

An aspect of uncertainty that has also been discussed is the use of information to reduce uncertainty. Further information can reduce measurement uncertainty and some aspects of lack of knowledge (ignorance). Clause 8 of the Methodology takes account of the value of information by stating that:

> *The information used by the Authority in considering an application shall be that which is relevant and appropriate in the context of the scale and significance of the risks, costs, and benefits associated with the substance or organism.*

However, while new information may reduce uncertainty, the cost of obtaining that information as well as the scale of the activity needs to be considered. Sensitivity analysis and the calculation of upper and lower bounds may be used to help decide the value of information.

At times additional information may introduce further uncertainties or risk. As further knowledge is gained about an environmental problem, contingencies that were not considered previously may also become apparent.

4.3.4 Disputes between experts

It is a well-established convention that decision-makers are expected to rely on expert advice, but this depends on validation of the available expertise. Experts may disagree, often for good reasons. Some of the reasons for disagreement may be that experts have used different models for prediction, or that they have made different assumptions. They may have framed the problem differently. Analysing the reasons for the disagreement may assist in deciding how to proceed. If disagreement occurs it is important to understand these reasons and then make a judgement about the degree of uncertainty introduced. Simply looking for a third expert to resolve an impasse without proper understanding of why the differences have arisen is not likely to be profitable.

4.3.5 Characterising uncertainty

In principle, the uncertainty from separate sources ought to be described, to ensure that all the relevant uncertainty is considered. In practice (especially in environmental risk management), that is often impracticable because of the lack of data. In these circumstances, an integrated statement is more likely to be developed.

Any description of uncertainty should contain the following elements:

- the source of the uncertainty, e.g. lack of data? credibility of hypothesis? lack of appropriate models, complexity, etc.;
- the nature of the uncertainty, e.g. does it apply to type or scale of the consequences? to the probability of occurrence? etc.;
- whether further information is likely to resolve the uncertainty, and if so, a statement as to why this information has not been sought/obtained; and
- the uncertainty bounds, preferably described quantitatively, but more often qualitatively.

If data are lacking, a common approach is to qualitatively describe best and worst cases. This should not be done without indicating how likely the best and worst cases are. If uncertainty is high then the best and worst cases may be too extreme to be helpful.

4.4 Application of the enhanced 'approach to risk'

When it comes to practical implementation, risk averseness (the response to risk characteristics) and uncertainty are closely linked. Thus, all things being equal, if a risk averse approach is indicated, then more caution will be exercised in dealing with uncertainty. However, risk averseness may also influence decision making if there is no uncertainty.

There are several ways that the Authority could reflect its position on risk.

4.4.1 Containment applications

For containment applications, the Authority can usually implement a risk averse position by strengthening the controls it imposes thus reducing the residual risk, usually to a negligible level. Under the se circumstances, risk characteristics are usually no longer relevant to the decision. The one exception (and it is one reason for including it in the list of factors) is where consequences of the risk are so great, that the reduction in likelihood or probability of occurrence through containment is no longer sufficient in itself, to reflect a risk averse position.

Containment situations recognised by HSNO apply to both new organisms and hazardous substances.

With a release application, however, the option of risk mitigation by containment is not so available, and the further discussion below relates to release situations.

4.4.2 Release applications

It is convenient to think of risks as falling into one of three zones:

- the zone of negligible risk;
- the zone of unacceptable risk; and
- the middle zone of risk that might or might not be acceptable.

The middle zone is that of most interest under HSNO decision making.

One approach to risk adverseness is to move the boundaries between the various risk zones closer to the origin, as shown below. This can have the effect of moving a risk from one zone to another, e.g., the zone of potentially acceptable risks to the zone of unacceptable risks.

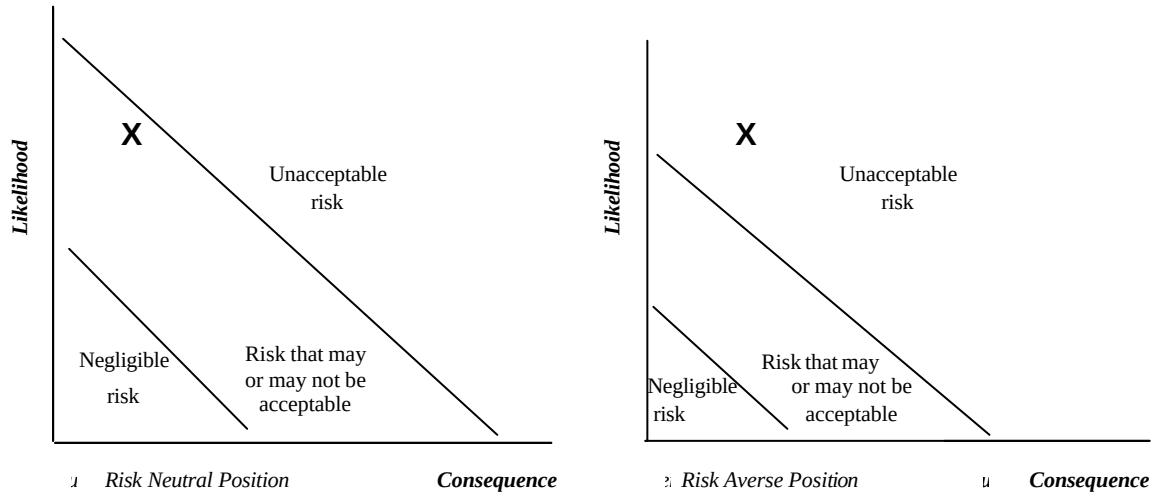

Figure 3: Risk boundaries

This approach is very blunt, i.e. it simply moves 'propositions' either inside or outside the negligible and unacceptable boundaries. The structure of the HSNO Act only partially

accommodates this approach; the 'unacceptability boundary' is represented by the Minimum Standards in Section 36 for New Organism releases, but there is no equivalent for hazardous substances. Conversely the 'negligible risk boundary' is represented by the thresholds in the hazardous substance regulations, but no boundary exists for new organisms.

However, decision-makers seldom address risk in the absence of the benefit. A more sophisticated approach is for the Authority to exhibit a more risk averse position by requiring a greater level of benefits to justify a given set of risks, that is, to give risks and costs a higher weighting than benefits in the weighing up process.

The figure below illustrates diagrammatically how this weighing up approach might be applied.

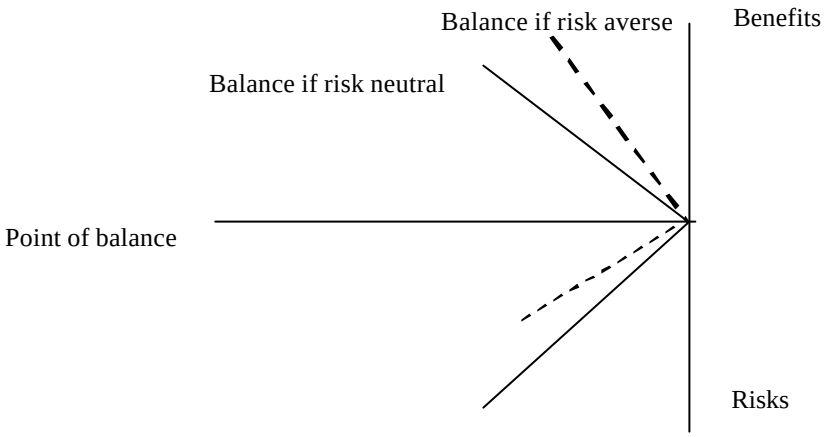

Figure 4: Weighting of risks and benefits in the weighing up process

In practice a combined approach is likely to apply and this is entirely consistent with the HSNO framework, i.e.

- the first step is to consider whether any weighing is required at all, i.e. can it be quickly concluded that the risk is either negligible or unacceptable;
- if the application remains in contention after the first step, a judgement must be made about how far to weight the risks before weighing them against benefits.

4.4.3 Addressing uncertainty

There are two situations that can be distinguished in dealing with uncertainty *per sé*. The first is where there is some knowledge about the degree and type of uncertainty, and the second is where there is little or no knowledge about the degree of uncertainty, i.e. it is apparently unbounded. The latter situation is not only more difficult to deal with, but is often associated with difficult or controversial areas of decision making.

The first question that should be addressed by decision makers is always that of whether the uncertainty is sufficiently significant to potentially influence the decision on the application. If information on uncertainty bounds of the parameters is available, then it is logical to look

at worst-case circumstances in addressing the question. If that information is not available (usually the case for hypothetical or unknown unknowns), then a judgement must be made. As indicated previously, the only guidance that can be given is that the judgement is reasonable (and consistent) given all of the circumstances.

The second question to pose (if questions remain) is that of whether additional information, which might usefully reduce uncertainty, could be feasibly and cost-effectively obtained.

There are a number of aspects to this:

- if significant time and cost is involved, then this must be balanced against the cost of delay; and
- there must be some assurance that extra information can be feasibly obtained and will materially assist in making a decision. In many cases it may be better to approve or decline an application to give a certain result reasonably quickly.

Thirdly, it needs to be considered whether the decision can be framed in a way that reduces the impact of uncertainty. This is a very powerful issue for containment decisions, since containment may reduce residual risk to a negligible level despite uncertainty (as has been discussed in 4.4.1). However, it has force as well for hazardous substance releases because of the ability to set controls. The Authority has indeed already adopted an explicit policy of considering the strengthening of controls to counter uncertainty, although the policy has yet to be tested because no substantial hazardous substance release decisions have yet been made.

If the option of 'conditional release' is eventually legislated for, the setting of conditions will also become an option for dealing with uncertainty in new organism release. The impact is likely to be most marked for the first tier of GMO releases, because (*ipso facto*) there will be no release history available and little information on long-term effects. Conditions can considerably mitigate the uncertainty arising from this by (for example):

- limiting the scope of release until more information is available; and/or
- requiring monitoring so that information is generated as a part of the release process.

Finally, uncertainty must be taken into account in the making of a 'yes/no' decision on an application.

If information is available on uncertainty bounds, then the logical approach is to reflect uncertainty in the 'values' that are ascribed to risks and benefits in the weighing up of costs, risks and benefits. In practical effect this is no different to allowing risk characteristics to influence the weighing process. Either way, the process is as diagrammatically represented on Figures 3 and 4. However, it is important to consider carefully how far uncertainty should be reflected, e.g. it may not be reasonable to use a worst case scenario, if the likelihood is very low or if the scenario is judged to be unrealistic.

If information is not available on uncertainty bounds, then the approach is the same as indicated above, i.e. a reasonable judgement must be made. However, at this final stage the judgement is not about the significance of the risk, it is about whether an application should be approved or declined.

5. INFORMATION REQUIREMENTS: APPLYING THE 'APPROACH TO RISK' IN PRACTICE

This paper has provided an overview of the basic principles of adopting an 'approach to risk' and some more detail on the way in which ERMA has applied the processes laid out in the ERMA Methodology. In order to reflect risk characteristics in risk averseness, it is necessary to have up-to-date information available about societal attitudes and values relating to those characteristics. This will include both New Zealand information, current overseas information, and information about trends.

Similarly, to decide when a precautionary approach is warranted, ERMA needs to identify areas of generic uncertainty (such as the significance of cross-pollination for plants), and to determine the parameters that are going to have the most influence on risks, costs and benefits. In addition, it would be appropriate to gain an understanding of the current thinking on different aspects of uncertainty in relation to environmental management in general, as well as specific to hazardous substances and new organisms in particular.

Most applications to ERMA can be grouped into classes, and basic information requirements for each of these identified. In addition to scientific information (human health and ecological), there will be 'class related' or generic aspects of social and cultural information. For example, surveys have been conducted on the public's attitude towards biotechnology that can provide a baseline for discussion of the specific issues raised by submitters on a particular application.

Undertaking the major literature and research reviews required to inform an approach to risk is beyond the scope of this paper. However, a brief literature search of New Zealand studies is included as Appendix A. It concentrates on studies of public perceptions of risk, primarily in the area of biotechnology, with some comparison between different types of risk.

6. GAPS AND UNRESOLVED ISSUES

Following on from the previous section, and recognising the particular areas that are relevant to the Authority's decision processes, it is evident that further investigation is required to:

- compare community attitudes towards the risks associated with hazardous substances, new organisms of different types, and genetic modification; and
- compare attitudes towards these types of risks and attitudes toward other risks.

While the general factors that influence attitudes are known, there have been few attempts to link attitudes and particular 'quantums' of caution that might apply.

Obtaining the basic information for establishing this link will require:

- review of current literature in New Zealand overseas of public perceptions and attitudes towards different types of risk including risks;
- review of current literature on aspects of uncertainty; and
- review of current approaches to determining acceptable and tolerable levels of risk in the particular areas relevant to the Authority.

A brief literature search was undertaken in the preparation of this paper. It is clear, however, that a more detailed literature search is necessary and is likely to indicate that further research is required, including surveys. The work undertaken to date indicates that different sectors within the community exhibit different tolerances to different types of risk. Therefore, the Authority will need to determine whether there are particular groups in society whose views will be given greater weight or if some kind of 'average' can be struck.

Following on from this there is the need to develop practical tools for translating levels of risk averseness into procedures for decision making. The Methodology provides the principles that will apply, but does not specify the way in which they will be applied. Policies and procedures will need to be developed that give clear guidance as to how the Authority will apply the approaches described in 4.4.2.

Professional judgement will remain a feature of the weighing up process, but over time, a body of experience will enable the Authority to establish criteria that will be able to be applied.

7. CONCLUSIONS

Based on the work done to date, and the criteria of practicality and effectiveness, it is concluded that the general approach to risk adopted by the Authority is reasonable. It rests on a coherent theoretical model of risk and uncertainty, and attempts to take account of the practical considerations that are important for the Agency's effectiveness.

The current approach is based on:

- deciding how risk averse to be in the light of a set of general risk characteristics;
- deciding how to respond to uncertainty through the application of caution.

It is concluded that the existing list of risk characteristics should however be extended to include:

- the distribution of effects over time, space and groups in the community; and
- the extent to which the magnitude of an effect is sufficiently serious to override a low probability (likelihood) of occurrence.

In addition it is recognised that the general approach would be enhanced by further development of the tools used to apply it, to ensure that the decision process is transparent and consistent. While this paper has not addressed the issue of institutional trust, research has demonstrated how trust and credibility can influence attitudes towards risk.

An issue for further discussion is that of whether community attitudes to specific risks (whether these are morally, ethically or culturally based) should be included in the list of risk characteristics.

It is not sufficient to identify key risk characteristics. There must be some basis for deciding what weight they should be given in the weighing up process, and this might be deduced from community surveys, or (in the absence of such data) left to the judgement of the decision-makers.

In addressing uncertainty, it is important to characterise it as far as possible. Characterisation will very often be qualitative rather than quantitative, but should ideally include the source and nature of the uncertainty and the bounds of uncertainty.

A particular challenge, and a source of vigorous debate in regard to the precautionary approach, is that of dealing with hypothetical or unknown uncertainties, sometimes referred to as ignorance or indeterminacy. In the HSNO context it is contended that the principle of reasonableness must apply, i.e. for an hypothesised cause-effect relationship to be taken into account, it must have a reasonable basis. The test of 'reasonableness' will be assessed on the basis of expert advice and professional judgement.

In general terms both risk characteristics and uncertainty can be taken account of in the same way, by 'weighting' adverse effects in the decision-making process, so they have correspondingly more or less influence in the weighing up of adverse and beneficial effects.

In the extreme, the weighting may be sufficient to make the risk unacceptable under any terms, in which case the application is simply declined.

Within this general paradigm, there are some prior steps that should be taken in assessing uncertainty. These include characterisation of the uncertainty, making a judgement on the significance of uncertainty,(should it influence the decision), and specifying a rationale for reducing uncertainty by generating additional information.

APPENDIX A NEW ZEALAND RESOURCE MATERIAL ON PERCEPTIONS OF SCIENCE AND RISK

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Key findings

Rohrmann, 1996

The 'technical/qualitative' approach to risk analysis is inadequate to reflect the complex pattern of individual risk evaluations. How people think about the magnitude and acceptability of risks and how they make their respective judgements and decisions is influenced by knowledge, values and feelings.

Conclusions

- Competent knowledge about universal and culture-specific factors of risk perception and evaluation is crucial for risk management.
- Risk judgements e.g. the magnitude of risk, and risk acceptance are influenced by subjective aspects such as health concerns, or feelings of anxiety, and particularly ecological attitudes.
- Group differences in evaluating risk are considerable, with the 'technologically-orientated' or 'monetarian' groups showing less negative judgements than 'ecologists' or 'feminists'. In general, these effects are larger that country-related variances.
- Attitudes towards environmental issues, impacts of technology and social values, have considerable influence on both risk magnitudes and risk acceptance. People with an 'ecological orientation' evaluate risks more critically than those with a 'technological orientation'. There are, however, exceptions. Engineers and students express more concern about smoking than environmentalists or psychology students in the study. The highest acceptance of risky private activities, e.g. skiing or smoking is found in 'feminists'.
- Risk perceptions and attitudes differ with employment status – e.g. professionals and students have different attitudes.

Gregory et al, 1997

- perceptions of hazards by the general public often differ significantly from expert predictions and perceptions of the same hazard.

Conner, A., 1997.

The study tends to under-rate public concerns about risk. For example: "While surveys show that there is a significant level of perceived risk, they show that it cannot be interpreted as opposition to genetic technology".

Couchman, P., and Fink-Jensen,K. 1990.

The results are from a survey of over 2000 New Zealanders in 1990.

Asked if they would believe a statement by a government scientist about the safety of a research project, just over one third of the public (36%) agreed, while the largest proportion neither agreed nor disagreed.

One third (34%) said that they would not usually believe private company statements; 28% of farmers, 56% of scientists and 59% of teachers would not usually believe private company statements about the safety of research or products.

Of those who had heard about genetic engineering, 56% of the public, 46% of farmers, 84% of scientists, and 88% of teachers said they had concerns about this area.

On the whole, research in genetic engineering is more acceptable to scientists and teachers than to the general public, particularly with the manipulation of animal cells, where nearly half of the public (44%), but less than a quarter of scientists (22%) and teachers (18%) find it unacceptable.

The public and farmers perceive most hazards arising from the manipulation of human cells (74% and 76% respectively). A smaller proportion of both scientists (57%) and teachers (44%) perceived hazards in that area.

The manipulation of plant genes was considered least hazardous by the public (42% perceived hazards), farmers (33%) and scientists (39%).

Consuming of genetically-modified foods; public concerns varied: meat(48% concerned); dairy products (43%); vegetables (38%); and medicines (34%).

Acceptability of genetic engineering varied by age, region and interest in science and technology.

Of those who had concerns about using genetically-engineered products, a higher percentage were women (49%) than men (37%).

Macer, D.R.J., & Bezar, H.J. 1995.

The paper reports on a 1993 survey conducted in 10 countries.

- The survey found stronger negative attitudes towards genetic engineering among Australians and New Zealanders. The perception of risk ('very concerned') was higher in New Zealand (39% 'very concerned') and Australia (34%) than in Japan (15%) or Thailand (7%).
- There were variations in attitudes to different uses of genetic engineering. For example, highest levels of support were for bacteria to clean up oil spills, and for disease-resistant crops. There was less support for genetic engineering of cows to produce more milk, and a very low level of support for genetic engineering to produce larger sporting fish.
- In all countries surveyed, the highest levels of support were for plant-plant gene transfers, and lowest support for animal-plant and human-animal gene transfers.

Sheppard R & Urquhart L. 1991.

The paper reports a 1990 survey of 1000 New Zealanders.

- The three most serious pests identified were: rabbits (by 93%); posssums (90%); and wasps (80%).
- Trapping (acceptable to 83%) and shooting (65%) were the most acceptable control methods. Only 51% supported the use of RCD; the lowest acceptance of RCD was among women and young people.

Hannah, M. L., 2001

The survey examined the health risk perceptions of staff (n=190) working at central, regional and local government levels in New Zealand.

Respondents ranked the most important hazard categories relative to each other for New Zealanders' health to be in order from

- contaminated drinking water;
- air pollution;
- ozone depletion of atmosphere/ultraviolet exposure;
- second-hand smoke;
- pollution of rivers and oceans;
- waste disposal, solid and liquid;
- pesticide/herbicide use; and,
- chemical use other than pesticides.

There were significant differences in perceptions when results were analysed by gender, sector and level of government. Women's risk perceptions on levels of risk were often significantly higher than men's. Respondents defining themselves as working in the health sector were also more likely to perceive higher health risks. Central government staff tended to rate health risks higher than staff at a regional level. The results suggest that risk perceptions are shaped by the social context of gender, work sector and the level of government.

Report of the Royal Commission on Genetic Modification. 2001.

- There was general agreement among the supporters of genetic modification that risk assessment should be based on scientific principles.
- Several submissions, such as that from New Zealand Dairy Board (IP67), suggested that non-scientific factors should not be allowed to impinge upon or distort the objective process of risk assessment.
- Submissions from other proponents of genetic modification, however, considered that a decision on the use of genetic modification could not be based solely on an objective scientific approach to risk because a scientific assessment could not take into account the cultural, social, political and economic factors that influenced perceptions of risk.
- Although science might be able to identify and determine the benefits of the use of the technology in relation to the size and probability of risk, it could not determine whether the level of risk associated with the use would be acceptable to the community. Any use of genetic modification without community acceptance would be unethical and, possibly, unwise.
- Submissions advocating a risk assessment process based, at least partially, on scientific principles were confident that the behaviour of the technology could be predicted and that the current knowledge and understanding of the technology was sufficient to identify the risks and to assess the probability of harm occurring.
- Submissions from the opponents of genetic modification, however, emphasised that the technology was unpredictable; therefore, the risks and potential harm were also unpredictable and could neither be assessed nor be managed.
- Several of the submissions stated that the risks of genetic modification were "unknown and unknowable" and any assessment of risk would, therefore, be based on conjecture.

- Some submissions, such as that from Bio Dynamic Farming and Gardening Association in New Zealand (IP61), called for the assessment of the risks of genetic modification to be empirical and based principally on observation of behaviour.
- Other submissions, particularly those from Maori organisations, called for an inclusive risk management assessment that would take into account the range of factors that influence perspectives on the use of genetic modification. An inclusive assessment process would ensure that genetic modification, genetically modified organisms and products were not released into the community until after an accepted level of risk had been determined.

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