SECTION III. RISK MANAGEMENT AND NEW DIRECTIONS

Introduction

This final section of the book provides information on risk management and discusses the issues surrounding the use of environmental risk assessment and management as environmental management tools, and initiatives to make them more effective.

Chapter 8 introduces the important concepts in risk management and the tools and techniques which make up the process. The importance of risk evaluation and perception is emphasised, including the significance of the principles of cultural theory which is illustrated by using the greenhouse effect as an example. The three approaches to reaching "acceptable" risk decisions are explained; professional judgement, bootstrapping, and formal analyses such as cost-benefit analysis. Risk reduction techniques and measures are also outlined.

Chapter 9 looks at some of the major issues in environmental risk assessment and management such as data deficiencies and gaps, the need for harmonisation internationally, and the acceleration of the practical process. It also identifies initiatives being taken to address some of the problems.

The section is targeted towards decision-makers contemplating risk-based decisions and requiring a knowledge of the principles of risk management and also the general audience of industry, interest groups and the general public interested in the risk management decision-making process and the concepts which underpin it, and the problems and uncertainties surrounding the use of risk assessment and risk management as environmental management tools.

8. EVALUATION OF RISK AND RISK MANAGEMENT

In this chapter, the complex process of determining the significance or value of the identified hazards and estimated risks to those concerned, or affected, is examined. The evaluation of risk is concerned with issues relating to how those affected by risks perceive them, the value issues underlying the perceived problem, and the trade-off between the perceived risks and benefits. The controversy surrounding BSE is used as an example of where risk evaluation has proved hugely important in the implementation of decisions arising from risk assessment. This chapter will look at the factors involved in risk perception and risk acceptance.

This chapter also examines the advantages and disadvantages of the major approaches used in making risk management decisions - bootstrapping, formalised methods such as cost-risk-benefit analysis, and professional judgement. Examples of the use of these approaches in environmental management are discussed.

8.1 The importance of risk evaluation and perception

This book is primarily concerned with Environmental Risk Assessment (ERA). Assessment of risk is seen by some as a wholly scientific process but the limits of this view have already been discussed. Complex social and value issues are often part of a risk assessment, either explicitly where risk evaluation is seen as a part of the assessment process, or implicitly where they mould problem formulation, the first step of most assessments in practice.

ERA provides information on which decisions can be made. Risk management attempts to enable choices to be made on the best course of action in any situation. A report on ERA without a discussion of risk management would not be complete.

Risk evaluation attempts to define what the estimated risk actually means to people concerned with, or affected by, the risk. A large part of this evaluation will be the consideration of how people perceive risks.

Different risks are perceived in different ways. A large body of psychological research on risk has identified factors that are important in risk perception. Table 8.1 outlines the major factors identified. Familiar, understandable events that we have control over and affect only ourselves (drug-taking or hand-gliding for instance) are perceived as being less risky than unknown, catastrophic events that are out of our control and affect our children and family (nuclear explosions for instance). Cultural theorists have developed cultural views on risk that have been gaining more authority in recent years. The psychometric approach in psychological research concentrating on the different attributes of an individual's risk perception, and the cultural approach are fundamentally different and explore risk perception from different starting points and within different frameworks.
There has been considerable criticism of the

Table 8.1: General (negative) attributes of hazards that influence risk perception and acceptance

1. Involuntary exposure to a risk.
2. Lack of personal control over outcomes.
3. Uncertainty about probabilities or consequences of exposure.
4. Lack of personal experience with the risk (fear of unknown).
5. Difficulty in imagining risk exposure.
6. Effects of exposure delayed in time.
7. Genetic effects of exposure (threatens future generations).
8. Infrequent but catastrophic accidents ('Kill Size').
9. Benefits not highly visible.
10. Benefits go to others (inequity).

Source: Royal Society, 1992

psychometric approach to risk perception, not only of the way in which the method may affect the results but, more generally of how the research only gives the perceived risk characteristics of hazards rather than the underlying psychological processes which generate them. The empirical evidence from psychometric studies tends to support the theory that the dread (or fear) associated with a hazard, the lack of knowledge concerning a hazard, and the number of people exposed to a hazard, all affect its perception. Experts' perceptions of risks tend to be less affected by these qualitative aspects (Slovic, 1987), although the same underlying factors do exist (Fischhoff, 1990).

An important point for environmental risk management was raised in early work carried out by Vlek and Stallen in the Netherlands (Vlek and Stallen, 1980). They analysed hazards using two main dimensions. Firstly, they looked at the size of a potential accident and, not surprisingly, found a high degree of agreement between respondents that the greater the size, the greater the perceived risk. The second dimension was "degree of organised safety". The response to this was split. For approximately half the respondents, activities with a high degree of organisation for safety, e.g., a chemical plant in a residential area, are seen to be the most risky. For the other half of the respondents, activities with a low degree of organised safety, e.g., smoking in bed, are seen to be the most risky. Vlek and Stallen point out that the dimensions on which people disagree are those which involve socially controversial issues. This has been further looked at by sociologists, such as Brian Wynne, who argue that these dimensions are precisely the ones with contested institutional or political implications. For instance, looking at the "degree of organised safety", the perception of the risk being higher if there is a large degree of organised safety indicates lack of trust and satisfaction with existing risk management structures, e.g., government and regulators.

Wynne has carried out a lot of work on the social framing of risk assessments. This is important not only in the examination of the judgements that always form a part of a risk assessment, but also in looking at the underlying frameworks for the models of risk assessment. These arguments are used by those who refute the concept that risk assessment is a scientific process. Wynne examined the proposal for the proposed oxide fuels reprocessing plant at Sellafield in the UK. He found that the experts and the public had different frames of reference for the problem. In particular, expert definitions incorporated implicit assumptions about the social and institutional processes of risk management. By reducing risk to purely technical matters, the expert view "accepted existing decision making organisations as trustworthy, natural, impartial and open-minded about the future" (Wynne, 1992). The public objecting to the plant, however, placed far less credibility in government organisations and had a different frame of reference for the problem. This has clear implications on those who attempt to use risk assessment as an attempt to legitimise decisions on the basis that decisions are being based on "sound science". It seems that more often than not science is not the problem. The proposed dumping of the Brent Spar described in Chapter 2 is an example of this.

Risk managers may wish to scientifically assess risk and then use formalised risk management procedures to choose the most satisfactory course of action in response to that risk. This normally means reducing risk to an "acceptable" level at an "acceptable" cost. If the result of the risk management process is not accepted by the public, they are often viewed as irrational and the solution is seen as giving them more information in a way that they can understand. If it is understood that risk perception is affected by factors such as "degree of organised safety" which involve socially controversial issues, it becomes clear that decisions on acceptability are unlikely to be fundamentally affected by attempts to educate the public on scientific risk assessment. Refer to Box 8.1.

The cultural theorists have added fuel to these arguments. Cultural theorists argue that risk

Box 8.1 BSE – A difficult risk to manage

BSE (Bovine Spongiform Encephalopathy) is a disease of cattle which was first identified in 1986. It causes microscopic holes in the brains of affected animals. These animals become uncoordinated, nervous and eventually die. CJD (Creutzfeldt Jakob Disease) is a very rare human disease. It affects about one person in a million each year. There is no conclusive scientific proof of a connection between BSE and CJD. In March 1996, a new variant of the disease was identified. This differs from the usual sporadic form, because it affects younger people (this may change with time) but primarily because the clinical features and pathological changes in the brain were unique. As at 1 November 1996, 14 such cases had been identified in the UK and one in France.

Since 1986, extensive scientific research has been sponsored by the UK Government, based on the advice from several scientific committees with remits of animal and human health. Fifty-seven pieces of legislation have been enacted in the UK since 1988. The European Commission has also legislated on BSE since 1989.

The UK Government has made risk management decisions based on the scientific consensus at the time. Ultimately, the decisions were made within a framework that considered the implications for the UK beef industry and farmers' interests. Scientific disagreement over the extent of the BSE infection, transmission routes of BSE infection and the reality of the threat to human health fuelled the controversy in the media.

The crisis came to a head when the EU banned the importation of British beef in response to evidence of a possible link between BSE and CJD. Action in the UK was based on the scientific advisory group's advice at that stage, based on the scientific evidence and the crisis in consumer confidence. This included a ban on the sale of cattle over 30 months old and a slaughter programme.

The UK Government characterised the European decision as being taken on non-scientific grounds. The lack of scientific certainty and "proof" have coloured public perception of risk. The BSE crisis in the UK demonstrates that whether experts and policy makers believe that the public have an irrational view of risk, irrational or not, it cannot be ignored. The consuming public had taken a view on the BSE issue. Beef sales in the UK and Europe fell dramatically. The case of BSE highlights the immense difficulties in attempting to make public policy decisions using immature scientific data. Such decisions still have to be made, however, in the absence of hard evidence, and at that point it is the translation of science, policy and perceived risk into public statements that need careful consideration.

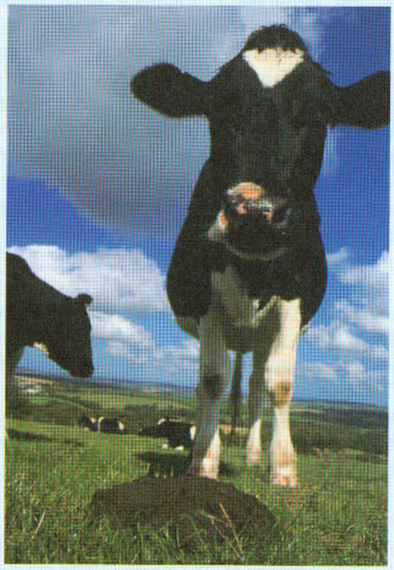
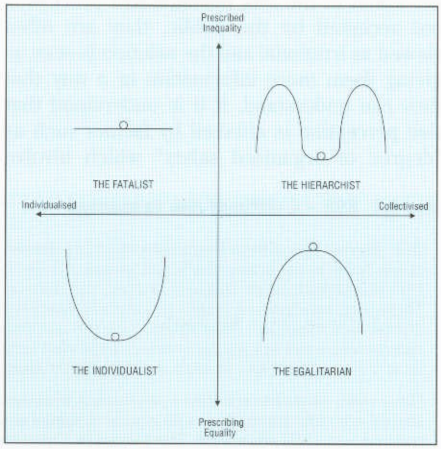


Photo: Chris Martin, Environmental Images is "culturally constructed" (Douglas and Wildavsky, 1983). Cultural theory develops an inquiry into the origins of the beliefs about nature that guide risk-taking decisions and discern patterns. The essence of these cultural patterns has been distilled into a fourfold typology illustrated in Figure 8.1. Individualists are enterprising self-made people, relatively free from control by others, who strive to exert control over their environment and the people in it. Hierarchists inhabit a world with strong group boundaries and binding prescriptions. Social relationships in this world are hierarchical, with every one knowing their place. Egalitarians have strong group loyalties but little respect for externally imposed rules, other than those imposed by nature. Group decisions are arrived at democratically and leaders rule by force of personality and persuasion. Fatalists have minimal control over their lives. They belong to no groups responsible for the decisions that rule their lives. These four distinctive views of the world are the basis of four different rationalities. Disputes about risk in which the participants charge each other with "irrationality" or "vested interests" are usually seen upon examination as arguments where the participants are arguing from different premises and different views of the world.

Figure 8.1: The four rationalities



Source: Adams, 1995

An example of how these different world views affect our understanding of environmental risks is taken from 'Risk' by Adams (1995). The approach of cultural theory suggests not that some are rational and others irrational, but that the participants are arguing rationally from different premises. Refer to Box 8.2.

8.2 How safe is safe enough?

A question that is fundamental when talking about risk issues is "How safe is safe enough?" An ERA will characterise the risk posed by a situation and then the process of risk management will eventually lead to a choice of action that will achieve the desired level of "safety". The determination of this "acceptable" or "tolerable" level of risk may have been prescribed before the risk assessment process begins - through societally determined acceptable levels of risk in the form of legislative environmental quality standards for instance, or industry derived "norms". In this case, risk management attempts to analyse which options for action based on the results of the risk assessment will produce these pre-determined risk levels. Where no acceptable risk standards exist, the risk management process will attempt to derive "acceptable" or tolerable risk on a case-by-case basis. This will always raise the question of "Acceptable to whom?" When risk assessment and management procedures are carried out by regulators or government, the aim is to produce societally

Box 8.2 The Greenhouse Effect

Global warming is a hugely contentious scientific issue with the potential, if the theory is correct, to impose huge damage on the world's environment. Global warming is a classic environmental risk problem. The science is uncertain but the implications of ignoring it are mammoth.

"The greenhouse debate turns out to be yet another case of people arguing in the dark. Again the participants in the debate turn out to exhibit the biases characteristic of the stereotypes of cultural theory. The scientific disagreement about the nature of the processes at work and how to model them, and the inability of scientists to settle their arguments by appeal to empirical data, provide a fertile environment for the development of biases. Biases, like mushrooms, flourish in the dark." *Source; Adams J, 1995, Risk, UCL Press*

The fatalist is amused by the exertions of those trying to make sense of an unpredictable universe. Many scientists studying environment change are rendered fatalistic by their apparent insignificance in the face of the magnitude of the processes under investigation.

The egalitarian uses his view of nature as something fragile and precarious to search for data that confirm his view. Egalitarians support the precautionary principle and so the uncertainty in the debate becomes a driving force for the call for urgent action.

Individualists who have a view of nature as robust and benign can explain the climate variation in the last century as "natural variability". Where egalitarians present uncertainty as grounds for precautionary action, individualists find the limits on the present understanding of climate change as grounds for optimism.

Hierarchists look at the climate record and see cause for concern but not panic. They bring the same scientific/managerial approach to the threat of global warming that they bring to all risks. Hierarchists favour a constrained version of the precautionary principle and more research to devise effective management strategies.

Photo: Steve Morgan, Environmental Images

acceptable risk levels. When an individual company carries out a risk assessment, in the absence of societally determined standards, risk levels will be determined which are acceptable to the company. These may have reference to societally acceptable levels or may be based on a formal risk-cost-benefit approach as advocated by some software packages on risk reduction.

Decision making to determine "acceptable" or "tolerable" risk uses a number of approaches. The three major approaches to acceptable risk decisions are professional judgement where technical experts devise solutions, bootstrapping where historical precedent guides decision making, and formal analyses where theory-based procedures for modelling problems and calculating the best decision are used.

Acceptable risk decisions require a choice of alternative courses of action. Decision making in risk management aims to select the best option, this defines the most "acceptable" risk level. There are no universally acceptable options however. The choice of an option and its associated risks, costs and benefits, depends upon the set of options, consequences, values and facts examined in the decision-making process. In different situations, different options, values and information may be relevant. Fischhoff et al. (1981) refer to "acceptable risk problems" describing a kind of decision problem instead of "acceptable risk".

8.2.1 Professional judgement

Professional judgement is extensively used to determine acceptability. Technical experts, most knowledgeable in their fields, examine the risks and make conclusions based on "best judgement". In making their decisions, formal analyses may be used but they are not bound by their conclusions. In ERA, technical and professional judgement is the most common approach in the determination of acceptability. Because of the often, complex scientific nature of environmental risk, technical experts are often seen as the only people able to make such judgements. For instance in the BSE case, the scientific committee advising the UK Government examines the options for reducing the BSE risks and makes recommendations. These recommended options aim to ensure that the risks from BSE are "acceptable" and are based on professional judgement.

When professionals attempt to address risk questions they often restrict the question to one that fits in to their own understanding and training. Professionals often accept narrow problem definitions. They do this when "they restrict themselves to the consequences that interest their immediate client (perhaps ignoring broader societal concerns), or to solutions within their areas of professional competence (rather than pointing their client elsewhere), or to alternative versions of the proposed technology (without seriously considering the no-go option)" (Fischoff et al, 1981). This is important in the public acceptance of risk management decisions because the problem may be defined differently by the professionals and the public. Many decisions taken by professionals are reached by judgmental processes that are very difficult to explain and articulate to those without their professional training. For instance some professional approaches to dealing with uncertain data can leave people without the same professional training confused. Professional judgement however is seen to "work". Professional judgement produces answers to risk questions and its decisions are formulated in a way which allows their implementation. This is one of the major advantages of the approach to making acceptable risk decisions. Professional judgement also fits current institutional arrangements. Professionals accommodate themselves to the bureaucracies within which their decisions are made. Unlike scientists, whose cautionary norms may keep them from making statements definitive enough to allow bureaucrats to do their jobs, professionals are willing to make a "best guess".

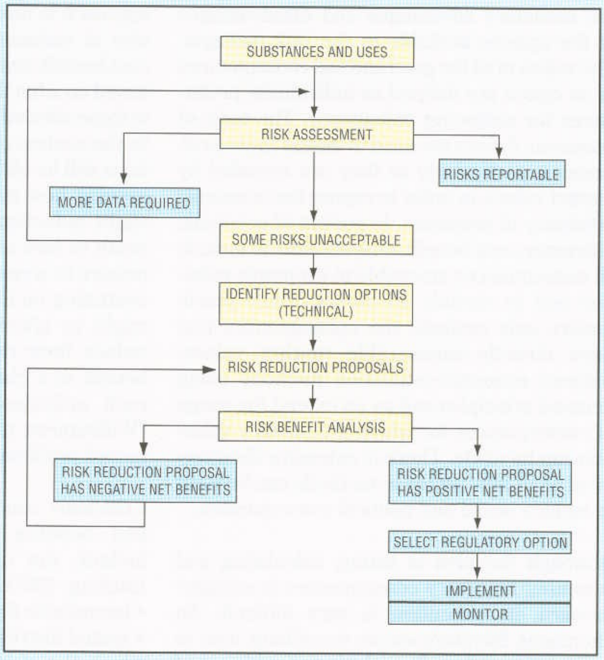
8.2.2 Formal analysis

Cost benefit, cost-risk-benefit and decision analysis, are the most common of formal

Box 8.3 Example of possible use of formal analysis

The Existing Substances Regulation (No. 793/93) requires that after risk assessment, the substance under examination shall be evaluated and necessary control measures recommended. It states that "Where such control measures include recommendations for restrictions on the marketing, or use of the substance in question, the rapporteur shall submit an analysis of the advantages and drawback of the substance and the availability of replacement substances." The implication of this article is that benefits as well as risks should be taken into account when developing control measures for existing substances. The UK Government/Industry Group has identified risk-benefit analysis as a means of aiding such decisions. This would "identify the costs and benefits associated with different technical options for controls, weighing up the costs and benefits associated with different technical options and identifying the preferred control option" (UK Government Industry Working Group, 1995). The proposed method is shown in Figure 8.2.

Figure 8.2: The steps in risk benefit analysis required by the Existing Substances Regulation 793/93. The six steps referred to in the text are the ones in the centre blocks



Source: UK Government Industry Working Group, 1995

analysis techniques for alternative risk management options. These share a number of features. They require a choice among alternative courses of action. For instance, cost-benefit analysis attempts to identify the option with the greatest benefits compared to costs. Complex problems are broken down into manageable components that can be studied individually and then combined to make an overall assessment. Strongly prescriptive decision rules are used. The components are combined according to formalised procedures. Finally, there has to be a common unit (monetary value for cost-benefit analysis, worth or utility for decision analysis) to compare different consequences and make trade-offs between conflicting objectives.

Cost-benefit analysis goes by many names including risk-cost-benefit analysis and risk-benefit analysis. Cost-benefit analysis is used to describe techniques that explicitly consider the monetary advantages and disadvantages of the options available to the risk manager. The values of all the good and bad consequences of an option are defined as individuals' preferences (or subjective valuations). The tools of economic theory are used to assess these preferences, particularly as they are revealed by market values, in order to expose the economic efficiency of proposals. In pursuit of economic efficiency, cost-benefit analysis aims to include all consequences amenable to economic valuation and to exclude all others. Many practitioners only evaluate the consequences that have directly measurable market values. Indirect economic-evaluation methods using demand principles and so on extend the range of consequences for which a monetary valuation can be made. There is extensive disagreement as to how far these methods can be used to include social and political consequences.

Although the idea of listing, calculating and summing monetary consequences is straightforward, its execution is very difficult. An enormous literature exists describing how to carry out cost-benefit analysis and critiques of the process. One major area of criticism concerns the ways in which monetary valuations are placed on individuals' preferences. In some cases it is difficult to obtain data on which to measure people's valuation. For some factors, it is impossible to provide cash quantification.

For some time, the most commonly used basis of valuation was the "human capital" or "foregone earnings" approach. This considers a person's earnings and treats the present value of those earnings as the economic value of a person. The implication of this is that there is no value to those who do not work. To avoid this implication some add an allowance for pain and suffering for the cost calculated from foregone earnings. The human capital approach is morally repugnant to some and is also at variance with the usual approach in cost-benefit analysis. For these, valuations are based on what the goods or services are worth to those affected directly or indirectly by options. In the context of most risk issues, these valuations will be obtained by asking questions concerning how much people will pay for a very slight reduction in their chance of premature death or how much compensation they would require to accept a slightly higher risk. By concentrating on the total sum that all those who might be affected would be willing to pay to reduce their risk, it is possible to value the benefit of a change in risk which only alters each individual's risk by a small amount. "Willingness to avoid" figures are used for hazard problems that involve involuntary risks.

Criticisms concerning the valuation of costs and benefits of environmental problems include the difficulties in accounting for (Stirling, 1997):

- inequitable distribution of costs and benefits;
- spatial distribution of risks;
- how the risks and benefits affect existing patterns of privilege and social injustice;
- intergenerational equity;
- the valuation of impacts to ecosystems or non-human organisms;
- the immediacy, gravity and severity of the effects;
- controllability, familiarity of the risk .

It is clear that the use of cost-benefit analysis in ERA has major difficulties. Valuation of human life is difficult and controversial. Willingness to pay valuation studies are fraught with methodological problems but the questions can be asked and have some meaning to the respondents. For instance they could be asked how much they would pay to not suffer upper respiratory tract irritation from air pollution. Valuation of the damage to ecosystems or the loss of a plant species is obviously much more difficult, if not impossible. For cost-benefit analysis to be used in ecological risk assessment, valuations must be placed on the costs and benefits. How meaningful these are is open to question. A classic example of the problems of valuing environmental goods is from the UK road building programme. A value has to be put on the land the road will potentially go through. If the road is to go through an area protected from development by law due to its exceptional ecosystem, the valuation of the land will be very low. This is because there is legislation preventing development which severely restricts the market value of the land. The results of the cost-benefit analysis would therefore favour road building through land where ecosystems are protected by law than other land open to development.

Decision analysis is an axiomatic theory for making choices in uncertain conditions. Decision analysis involves:

- Identification of the decision problem by identifying the relevant options, consequences and alternatives.
- Uncertainties about the present and future states of the world are quantified as probabilities. Decision analysis, views probabilities as expressions of an individual's beliefs and are elicited as judgements.
- Subjective value judgements (utilities) are used to assess principles. Soft considerations such as aesthetics can be included easily (unlike in cost-benefit analysis).
- The attractiveness of each alternative is summarised by its expected utility, which is the sum of the utilities of each possible outcome, weighed by their respective probabilities of occurrence.
- Sensitivity analysis is carried out.

As the key elements in a decision analysis are subjective, they must come from someone. In societal decisions there is rarely one person who is the final arbiter. Although formal analysis can help in producing agreement, it can also polarise views. The act of publicly specifying one's views may harden one's commitment to them and discourage compromise. Constituent groups can gain experience of decision analysis and exaggerate their positions in order to bias the analysis. When the parties cannot agree on the relative attractiveness of the alternatives, other procedures will be needed to obtain a decision. Although decision analysis has problems, bodies such as the International Commission on Radiological Protection are moving away from cost-benefit analysis to multi attribute decision analysis in assessing risk reduction options.

Formal analysis has strong prescriptive rules for decision making. A strong selling point for formal analysis is that it is open not only to evaluation but to sensitivity analysis. However, such analyses are difficult to scrutinise when, as with other techniques, value-laden assumptions are included in the problem definition. Formal analysis is widely used by regulatory and policy making bodies. The great strengths of formal analysis are its openness and soundness. Formal analysis appeals to some because it appears to give a value-free aid to decision making. However formal analyses mix issues of fact and values in complex and often hidden ways. As with other techniques, the openness that formal analysis promises is rarely achieved. Formal analyses rarely undergo peer review as would a scientific risk assessment and, in the event that they do, reviewers may not have the financial or technical resources needed to probe into the analysis. Fischhoff (1981) surmises that "Cost-benefit analysis and decision analysis were not developed for the problems of acceptable risk decisions. Cost-benefit is suited to private decisions in areas with responsive markets, immediate consequences and well informed consumers. Decision analysis presumes the existence of an entity empowered to speak on behalf of society."

8.2.3 Bootstrapping

Bootstrapping approaches identify and continue policies that have evolved over time. It is argued that society achieves a reasonable balance between risks and benefits only through experience. The safety levels achieved with old risks provide the best guide as to how to manage new risks. Examples of bootstrapping approaches are risk compendiums and comparison charts, revealed preferences and implied preferences.

Risk compendiums attempt to quantify different risks in common terms. These are aggregated into compendiums to allow decision makers to make comparisons between risks. Examples of the use of risk comparisons are detailed in Chapter 2, as are some of the flaws in their use. Comparative risk has become widely used in the US and is becoming increasingly common in Europe. The arguments on the validity of comparing widely disparate risks are based on the fact that all that is being compared is a statistical estimation of harm without incorporating public perceptions and evaluations, and the benefits attached to the risks.

The revealed preference approach was outlined by Starr in his ground-breaking paper in 1969 (Starr, 1969). This technique improves upon simple consideration of risk by considering benefits attached to risks. It assumes that society has already reached an essentially optimum balance between risks and benefits of existing technologies. A new technology's risks are deemed acceptable if they do not exceed the level of risk associated with ongoing technologies that have similar benefit.

This technique is used extensively to provide industry acceptable risk levels. For instance the levels of risk that are acceptable in the "best" sectors of heavy industry, are used by nuclear regulators to determine acceptability or tolerability in the nuclear industry. This technique is heavily criticised, however, because of attempts to elucidate preferences across industry sectors where the risks are publicly perceived in different ways.

Implied preferences use existing laws, court precedents and regulatory actions to reflect the compromise between what people want and what political and economic arrangements allow them. It may be possible to identify the implicit risk-benefit trade-offs and apply it as a standard for the acceptability of other hazards. An example of an implied preference is the concept of ALARP (as low as is reasonably practicable) embodied in European occupational health and safety legislation and used widely in the UK and Holland in occupational and environmental policy. In the UK, ALARP is defined by legal case law. Proponents of implied preferences make no claims that existing rulings are perfect. They are thought to represent society's best attempt to accommodate people's desires. Laws and policies are however sometimes badly written, applied to situations they were never intended and reflect the political and public concerns at the time they were written. Implied preferences can often produce decisions that lack coherence.

Bootstrapping approaches offer incomplete problem definitions. Although they consider some fact and value issues in detail, they ignore the question of what other options are available. Relying on descriptions of the past for guidance as to future risk decisions presumes that past decisions were correct. With revealed and implied preferences, the economic, political and social relations that existed at the time of the original decision will be enshrined in the current decision. Many will find this unacceptable as situations change over time. Like cost-benefit analysis, revealed-preference analysis fail to consider the equity involved in who receives the benefits and who bears the costs.

8.3 Risk management action

As was discussed in Chapter 1 of the book, environmental risk can be:

- transferred to another body such as an insurance company,
- retained by a company or nation,
- eliminated by removal of the risk agent, or
- reduced.

In most environmental risk management conducted by nations on behalf of society, risk reduction will be the risk management option chosen. For individuals or companies, risk transfer is a common approach. This may be required by legislation, especially for infrequent catastrophic events. Risk elimination is often very difficult because of all the social and economic effects the removal of an agent can create. For instance the elimination of a pesticide may have implications on the socio-economic conditions in a region.

Risk reduction for environmental risks can involve many techniques. For chemicals they are discussed in the draft European technical guidance document (CEC/ECB, 1996b). Generally there are a range of approaches to risk reduction. These include:

- Substitution. Can the agent be substituted by another, less risky agent? For instance, can a chemical pesticide be substituted by a biological method? What are the risks of the new agent being introduced into the scenario? Is the new agent as effective?
- Information. Providing information about the safe use and disposal of agents will try to ensure that the risks assessed are the same as what actually occur in practice.
- Education and information may also allow the public and users to choose lower risk options and force the manufacturers into the production of less risky agents.
- Limit the availability of the agent by marketing bans or limits on the production or importation of the agent. Such a risk reduction technique has severe implications politically and economically and can often be controversial. Such decisions are taken at a national or regional level and at an international level such agreements are difficult to obtain.

8.4 Some concluding remarks

ERA is a process by which environmental risks can be examined and a qualitative or quantitative measure of risk derived. The process can never be wholly scientific, but uses scientific data to arrive at a measure of the risk that has been chosen to be examined. Many social factors, such as those discussed in this chapter, will heavily influence how environmental problems are formulated and therefore exactly what the ERA will examine. The result of the ERA may be a quantitative scientific estimate. It is important to recognise, however, that social factors will affect this risk estimate and are fundamental in the decisions that are made as a result of the ERA. ERA takes time, resources and energy. The answers provided by ERA will be crucial in decision-making. It may be wise for those who wish to use ERA to take heed of the handling of BSE and the Brent Spar, and recognise that often the social issues involved in environmental risk decisions will be just as important as the scientific assessments.

Most of this book has focused on the techniques used in ERA. The approaches to risk management discussed in this chapter are as important, in terms of the influence they have on the decision-making outcome, as the ERA itself. Risk management techniques are less transparent than those developed for ERA and the influence of different criteria on decision making is often difficult to unravel. Formal analysis can be more easily "opened up" to scrutiny by others but exactly the same criticisms used against ERA can be levelled at it (availability of data, the interpretation and uncertainty). The focus of attention in ERA in recent years has been moved to "tighten up" and increase formality within ERA. Environmental risk management needs to undergo the same process.

9. NEW DIRECTIONS

This final chapter of the book looks at the issues that need to be addressed for ERA to become a more effective environmental management tool. Many problems with ERA have been raised in the text and a number of international and national programmes are aimed at addressing these. The focus of these international programmes is chemical risk assessment, but it is clear that the major problems that beset chemical risk assessment apply to the assessment of biological and radiation risks to a greater or lesser extent.

The major issues in environmental risk assessment (ERA) and environmental risk management will be dealt with separately, with recognition that this is a somewhat artificial distinction.

9.1 Major issues in environmental risk assessment

9.1.1 Harmonisation of risk assessment methods

Large numbers of international, national and regional bodies are involved in producing and using risk assessments. This is particularly true for chemical risks.

Chapter 19 of Agenda 21 has provided the framework within which chemical risks are dealt. In Chapter 19, UNCED called for co-operation between the bodies involved in risk assessment. In this context, IPCS is seen as the nucleus for international co-operation on environmentally sound management of chemicals. There is a need for the multiplicity of organisations currently carrying out risk assessment not only to harmonise their programmes of work which, to some extent, is already occurring (McCutcheon, 1996), but to harmonise the methodologies they are using.

IPCS is already leading a project on the harmonisation of approaches used in chemical risk assessment with IPCS looking at human health risk assessment and OECD looking at ecological risk assessment. Harmonisation of procedures does not have to be a standardisation but is defined as "an understanding of the methods and practices used in various countries and organisations so as to develop confidence in, and acceptance of, assessments that use different approaches" (van Leeuwen et al., 1996).

With radiation risks, there are relatively few bodies involved in assessment and the problem of differing methodologies is not a major issue. Biological risk assessment is a relatively new field with few international bodies involved in assessments at this time. A Joint FAO/WHO Expert Consultation in 1995 recommended that "scientific risk assessment should be the basis of (so called) Codex risk management decisions involving health and safety of food standards" (FAO/WHO, 1995). It is conceivable that problems with a growing number of methodologies and definitions may become an issue as risk assessment is increasingly used.

A harmonisation of risk assessment methods and definitions will have many advantages:

- risk assessments produced by one organisation would be able to be used by others;
- accelerating the huge task of risk assessing all priority agents by distributing the assessments amongst agencies;
- increasing the understanding and scientific basis of risk assessment;
- enabling easier communication between different risk assessors;
- enabling easier communication between assessors and managers.

The task is a very difficult one however. A harmonisation of risk assessment procedures would ultimately mean harmonising the terminology and use of "safety factors", "uncertainty factors" and "application factors". It would mean that where the assessor has used professional judgement in the risk assessment, this would have to be made explicit. If this is not done, the results of an assessment using the harmonised methods may become unacceptable to others using the same method. As it is generally accepted that risk assessment is not a wholly scientific process, this issue could become important. A standardised risk assessment procedure would require the use of definitive decision rules and default values to make explicit judgements. The approach of the IPCS/OECD is not standardisation but harmonisation. Even so, difficult issues involving the use of judgement and what that means in practice will need to be addressed.

9.1.2 Data deficiencies and gaps

A major outcome of any examination into risk assessment and management is always the need for further research to attempt to fill the gaps in our basic knowledge about the hazards themselves and exposure, uptake and effects. Considerable data gaps exist in chemical and biological risk assessment.

Whilst it is acknowledged that there are approximately 10–15 million chemicals known to exist, only about one per cent of these are commercially marketed and distributed. The EU has registered just over 100,000 chemicals. About 1,500 account for in excess of 95 per cent of total chemical production. There are huge data deficiencies even for this group. Table 9.1 shows the amount of data available for the High Production Volume Chemicals present on the EINECs list. For most chemicals, even base set data are incomplete. This can only allow an initial or preliminary assessment of risk. Such data gaps will force the assessor to use default values (derived from QSAR or worst case scenarios) which has obvious implications for the quality of the assessment. The gaps in data could also mean that hazards are not identified at all so that the risk assessment is completely inadequate. Data are inadequate in all other areas of risk assessment, apart from the hazard and effects stages. Data on how the agent acts in the environment as well as how it reaches the human or ecosystem target are also lacking (Danish Board of Technology, 1996).

Table 9.1: The amount of presently available effect-data for approximately 2,500 HPVC chemicals on the EINECS list[1]

Effect	Available data (IPS - estimate, 1992)	Renewed estimate (ECB, 1996)
Acute toxicity	90%	90%
Sub-acute toxicity	30%	53%
Carcinogenicity	10%	
Mutagenicity	50%	62%
Fertility	10%	20%
Teratogenicity	30%	30%
Acute ecotoxicity (fish or daphnia)	50%	55%
Short-time ecotoxicity (algae)	5%	20-30%
Toxicity on terrestrial organism(s)	≤ 5%	5%

1 The two estimates both arise from information given by the European Chemical Bureau (ECB), Ispra - via the IPS working group in 1992, and updated directly from ECB in March 1996. Differences are due to the fact that the EU Commission in the intervening period of time has called for submissions of unpublished information from the European chemical industry.

Source: Danish Board of Technology, 1996

Data on human health effects of chemicals may be inadequate, but those for ecotoxicological effects are even worse. Although, most attention has been based on the aquatic environment, even in this area there are huge data deficiencies.

Data gaps are a major block on the use of risk assessment for biological hazards. FAO/WHO recognised that "Codex should encourage the development of risk assessment for biological hazards with the recognition that the scientific understanding and knowledge are not currently adequate to quantitatively assess risk in most instances" (FAO/WHO, 1995). The risk assessment of bacterial hazards in food for instance is hampered by the lack of basic scientific data identifying pathogens, determining dose-response relations and in exposure assessment.

9.1.3 Harmonisation of test protocols for chemicals

A lot of work has already been done on harmonising test protocols. There are areas that need further work, particularly human health reproductive toxicity tests and the development of a test method for the effects of chemicals influencing hormonal processes or functions (van Leeuwen et al., 1996). A development of toxicity testing methods for mixtures of chemicals, such as diesel exhaust gases, have been recommended by a number of reports (NRC, 1996). In the area of biological hazards, FAO/WHO have recommended that more research be carried out to identify and quantify biological hazards. (FAO/WHO, 1995).

9.1.4 Understanding of mixtures or multiple stressors

A lot of criticism is aimed at some ERA due to its essentially reductionist nature. Some ERAs examine single chemicals and biological agents for instance. This causes a number of problems:

- That the effects of mixtures of chemicals are not addressed in most ERAs. Additivity of certain chemicals in the aquatic environment has been shown in the laboratory but examples of synergism or antagonism are much less common. The scientific understanding of mixture toxicity is poor and more work needs to be done looking at mixtures of chemicals (van Leeuwen et al., 1996; NRC, 1996; Danish Board of Technology, 1996).
- That the agent is being examined without addressing the other stressors to which the target receptor is exposed. Exposure to organic solvents for instance, increases the likelihood of noise induced hearing loss with exposure to noise, but these factors are rarely taken into account. (Morata et al, 1993)
- That the ERA is often conducted without regard to many of the other factors which may influence the result (for instance nutritional status of the exposed population).

9.1.5 Improvement of exposure assessment

Exposure models are a fundamental part of many risk assessments, where monitoring data are not available or incomplete. There has been criticism of many exposure models used. For instance, the model currently used in the Technical Guidance on new and existing chemicals has been shown to have clear weaknesses and flaws. Validation of existing exposure models has been recommended and internationally agreed models are needed (van Leeuwen et al., 1996). Current thinking in exposure assessment has moved away from the reliance on the "hypothetical maximum exposed individual" to "a maximum exposed actual person and estimates of the total number of potentially exposed people in the geographical area of interest" or alternatively "high-end" exposure (Baram, 1996b). It should also include consideration of genetic and other host differences in susceptibility and so on. van Leeuwen et al. recommend the use of probability distribution of exposures which can be arrived at using statistical techniques (van Leeuwen et al., 1996).

9.1.6 Internationally harmonised assessment factors

The uncertainties involved in ERA are well recognised and documented. One of the major techniques used to take account of uncertainties in scientific data is the use of uncertainty or assessment factors. Uncertainty factors are used mainly in the dose-response stage on a human health risk assessment or in the effects assessment of an ecological risk assessment. They relate to insufficiencies of experimental investigations and to the transfer of results across species.

Table 9.2 outlines the differences in uncertainty factors applied by a number of agencies in human health risk assessment. ECETOC has suggested that uncertainty factors should be reduced from the usual factors of 10 (ECETOC, 1995b).

Uncertainties in ecological risk assessment have been less well investigated. By far the greatest area of uncertainty is the lack of data and inadequacies in the existing information about ecotoxicological effects. The development of uncertainty factors that cover the major areas of ecotoxicological data is needed. This uncertainty arises from lack of knowledge about interspecies variations, intraspecies variations, life-long effects, and the major problem of lack of basic data. Currently there

Table 9.2: Uncertainty factors applied in the setting of human limit values (modified from ECETOC, 1995[71])

)	Renwick[72]	WHO*, [73]	US EPA[74]	ECETOC[71]
Interspecies	(10)	10	10	
kinetic	*4*	*4*		
dynamic	*2.5*	*2.5*		
oral intake				*4*
inhalation				*1*
Intraspecies	(10)	10	10	
kinetic	*4*	*3.2*		
dynamic	*2.5*	*3.2*		
general population				*3*
workplace environment				*2*
Extrapolation			10	
acute ⇒ subchronic				3
subchronic ⇒ chronic				2-3
Extrapolation LO(A)EL ⇒ NO(A)EL	>1	(1-) 10	10	3
Special effects (e.g., cancer)	1-10	1-10	1-10	
Inadequate data base	1-10	1-10	>1-10	
Residual uncertainties (modifying factor = MF)			<1-10	

* Normally, WHO experts do not accept uncertainty factors totalling above 104.

Source: Danish Board of Technology, 1996 are differences between the factors used by the EU, OECD and US EPA (van Leeuwen et al., 1996). In Denmark, another uncertainty factor is being considered to take account of uncertainties related to complex environmental effects, combination effects and persistence (Danish Board of Technology, 1996).

There is a general recognition of the need for consistent definitions for these factors used to cover uncertainty, not only within each field of risk assessment, but across the areas of human health and ecological risk assessment. The development of clear definitions and classifications of assessment factors is seen by many as being necessary, together with their application in a transparent and harmonised manner. van Leeuwen et al. state that "This should include the combined use of assessment factors and a critical analysis of the related overall multiplication problem of these factors to prevent them from becoming unrealistic" (van Leeuwen et al., 1996).

9.1.7 Speeding up risk assessments

ERA is costly in both time and resources. It is estimated, for instance, that if we consider the first 2,000 high production volume chemicals, if 20 are assessed annually, it will take 100 years to complete the list (van Leeuwen et al., 1996). Complex ERAs such as the one conducted by the US EPA on dioxin can take tens of years to complete. Action is required to speed up the process. Two main approaches are emerging.

Grouping of chemicals for prioritisation

The "chemical by chemical, medium by medium, risk by risk strategy" has been recognised as an inefficient way to address environmental issues. Often regulatory agencies act in this fashion because of institutional and legislative frameworks but it is often inefficient and conflictual (Baram, 1996b).

The grouping of chemicals by their mode of toxic action is already being carried out to speed up the prioritisation stage of assessments. Grouping in the IPS method for EU existing chemical substances has increased the speed of the process considerably (van Leeuwen et al., 1996). In a report by the Danish Board of Technology, it was recommended that existing chemicals should have to go through an extended notification and regulation system. To speed up assessments and use the existing data in the most productive way, it was recommended "that decisions for aligning all chemicals into chemical groups, blocks or from one chemical to another, from one chemical/ biochemical or structural relationship, etc." and that "the most dangerous chemical in each group shall be the determinant for classification of all the group" (Danish Board of Technology, 1996). This would be an incentive for manufacturers and producers to supply data as all the chemicals within the group would be dealt with in the same manner as the most dangerous one unless there was information to do otherwise.

Step by step tiered assessments

There is a general move within the risk assessment community to the use of tiered risk assessment. This is the approach taken by the EC in their approach to new and existing substances (CEC/ECB, 1996a). This approach is discussed in Chapter 6. Tiered assessments are seen by many as the most resource efficient way of attempting ERA.

9.2 Environmental risk management

9.2.1 Development of explicit methodologies for risk management

As described in Chapter 8, there are multitudes of approaches that are used in risk management. There have recently been calls for a harmonisation in the approaches used in risk management (van Leeuwen et al., 1996). Exactly what this harmonisation would mean in practice is not defined. It is difficult to envisage harmonisation of approaches outside the arena of the formal analyses such as decision and cost-benefit analysis. Harmonisation of bootstrapping approaches or professional judgement does not seem possible because of the lack of definable criteria on which they are based.

Definitions in risk management do need harmonisation. It is important for all stakeholders to understand the same thing by risk-benefit analysis for instance. For other approaches to risk management decision making, a harmonisation of the approach may not be possible but transparency of approach is necessary. As we have seen in Chapter 8, approaches using experts and professionals or bootstrapping are often difficult to make transparent due to their very nature. There is a general trend in risk management towards more formalised and open procedures and an increased transparency in risk management decisions will be part of this (Royal Society, 1992).

9.2.2 Increased transparency of decision-making

The trend towards increased transparency in risk management decision-making is consistent with the principles of participatory democracy. It is also recognised that a transparent process is necessary to foster trust, one of the major factors in whether risks are perceived negatively and whether actions to reduce risks are accepted by the public. van Leeuwen et al. recommend that it is necessary "to increase transparency in the step wise risk management process by providing clear guidance on the determination and weighing of advantages and implications of risk reduction measures" (van Leeuwen et al., 1996). FAO/WHO have recommended "the improvement in transparency of their risk assessment activities by ensuring that decisions be thoroughly documented and that all significant supporting data and other material be archived" (FAO/WHO, 1995).

9.2.3 Peer review of risk management assessments

A major part of the 1996 Commission on Risk Assessment and Management report (NRC 1996) was focused on the use and limitations of cost-benefit analysis in decision making.

The report recognises that economic tools are "legitimate and useful ways to obtain information for the risk management framework and regulatory decisions....but not sole or overriding determinant of regulatory decisions." The report states that where costs and benefits cannot be assigned monetary values, they should be addressed explicitly.

Another very important recommendation of the report is that the economic analysis undergoes peer review. This is in line with the calls for increased transparency in ERA. It is interesting that the risk assessment on which the risk management decisions are made will undergo extensive peer review in the scientific community, but the risk management analysis, which is pivotal in determining action, is often completely hidden.

Enormous attention is focused on the uncertainties in the risk assessment process but uncertainties in risk management are just as important. The CRAM report recommends that the uncertainties in the analysis are made explicit and quantified if possible.

9.2.4 Increased participation in risk management

The Commission on Risk Assessment and Management report has proposed a new framework for risk management that would address each risk problem in its full social context. The framework would integrate public values, perceptions, ethics and other considerations into risk management decisions. A major input would be given to stakeholders and risk managers at local levels to characterise the problem that needs to be addressed. Within the chosen context all sources of the pollutant, all pathways of exposure and socio-economic and cultural factors would be evaluated. This is very different from traditional approaches to ERA where technical experts have defined the problem, usually by reference to hazard data. The analysis of the risks would be primarily technical with an input from stakeholders to allow a combination of social and scientific considerations (NRC, 1996).

This is very similar to the combination of risk estimation and evaluation common in a number of European countries (Royal Society, 1992). The options could then be defined, decisions made, actions implemented and the effects evaluated. This approach is very different from the theoretical risk assessment/management split which, until recently, was accepted and recommended by much of the risk assessment and management community.

Participation in the risk management process would be increased dramatically by such a framework and the proposals have been well received by some in the risk community in the US. However, reservations have been expressed by OSHA and by the members of the National Science Foundation. Some of the comments state that the new framework tries to capture the thinking in risk management over the last 15 years without seriously addressing the core issues (Baram, 1996b) It remains to be seen whether the proposed new framework will be implemented. Simply by its conception and publication, however, it is likely to become influential and indicates that some of the major issues raised in the academic literature will be addressed by policy makers. This will result in increased participation in, and transparency of, risk management decisions. Europe has a very different cultural and political tradition to the US.

The development of risk assessment and management procedures of CRAM of whilst generally following the US (the NAS/NRC model for instance) have retained some uniquely European features. The increasing formalisation of risk assessment and management in Europe is likely to increase transparency of decision making considerably. Increased participation in risk management decisions is ultimately a political decision (with obvious pitfalls) but one which is likely to be necessary to ensure that risk assessment and management decisions are accepted and understood by the communities they affect.