SECTION I. CONCEPTS, PRINCIPLES AND USES

Introduction

This first section of the book provides information on the general aspects of environmental risk assessment and management; the core concepts, definitions and terminology, its use and application, its limitations and the scientific uncertainty involved.

It is comprised of four phases:

i. An introduction to the concept of risk, risk assessment and risk management and how these concepts, in combination, can be used as an effective tool in environmental management and protection.
ii. Specific uses of environmental risk assessment such as regulatory and policy design and decision-making, and site-specific decision-making, and the good and bad points of the techniques.
iii. A typology of use.
iv. An attempt to draw together common principles underlying all environmental risk assessments and produce a generic model, using a practical example, to clarify and illustrate the stages of the environmental risk assessment process.

Chapter 1 provides an introduction to environmental risk assessment. It assumes the reader does not have a detailed knowledge of risk assessment but understands the basic concepts of science. It covers the definitions used in environmental risk assessment and "sets the scene" for the rest of the book.

Chapter 2 looks specifically at the use of risk assessment as an environmental management tool. The chapter aims to outline the major ways in which risk assessment is used and gives specific examples of such use in Europe. This allows the reader to see how the concepts discussed in Chapter 1 are applied in practical situations, from the regulation of chemicals, to the dumping of the Brent Spar. The chapter also points out the advantages of the techniques and the criticisms.

Chapter 3 is designed to illustrate the wide variety of uses of environmental risk assessment. For each use, the specific methodology may vary but the core principles and the stages in the process are fundamentally the same. Recognising this variation in applied methodology, **Chapter 4** identifies the common thread and runs through the environmental risk assessment process, step by step, using a site-specific example of the siting of a new refuse incinerator. It describes a generic environmental risk assessment methodology which includes the steps required in all types of risk assessment.

This section of the book is targeted at a wide audience, from those with little or no knowledge of environmental risk assessment to those who are familiar with it in their own professional field, but are interested in approaches used in other areas. It is educational, but familiar in style, and is pitched at a level which should provide interesting reading to anyone who needs, or wants, to find out about measures in place or used to protect the environment, from an international to a local scale.

1. INTRODUCTION TO RISK ASSESSMENT CONCEPTS

This chapter is a general introduction to environmental risk assessment and examines its basic concepts - hazard, risk, risk assessment, risk management, risk perception and risk communication.

The technique of risk assessment is used in a wide range of professions and academic subjects. Engineers "risk assess" bridges to determine the likelihood and effect of failure of components, and social welfare workers "risk assess" their clients to determine the likelihood of the reoccurrence of anti-social behaviour. Risk assessment has become a commonly used approach in examining environmental problems. It is used to examine risks of very different natures. For instance, the approach is used to assess the environmental risks posed by Genetically Modified Organisms (GMOs), chemicals, ionising radiation and specific industrial plants. Definitions in risk assessment are all-important because of the wide range of uses of the approach, and different meanings of terms used by different groups of experts and practitioners.

In this introductory chapter some basic definitions are necessary.

There has been a gradual move in environmental policy and regulation from hazard-based to risk-based approaches. A risk-based approach attempts to examine the actual risks imposed by an environmental issue rather than the potential hazards that may, or may not arise. An example can be drawn from the approaches used in dealing with land contaminated by toxic agents. A hazard approach would be to identify the toxic agents in the soil and require remediation measures that reduced the toxic concentration to agreed standards. A risk-based approach to soil contamination would begin with an identification of the toxic agents. The level of clean-up required would depend on the likelihood of people being exposed to the toxic agents and the likely effects of that level of exposure. The level of clean-up would depend heavily on how the land is to be used and the risk posed by this land-use.

This move to risk-based approaches is partly in recognition that, for many environmental issues, there can never be a solution that results in zero risk, and that in some instances aiming for complete "safety" will impose heavy compliance costs when attempting to reach a standard which may not be necessary

Box 1.1

Hazard is commonly defined as "the potential to cause harm". A hazard can be defined as "a property or situation that in particular circumstances could lead to harm" (Royal Society, 1992). Risk is a more difficult concept to define. The term risk is used in everyday language to mean "chance of disaster". When used in the process of risk assessment it has specific definitions, the most commonly accepted being "The combination of the probability, or frequency, of occurrence of a defined hazard and the magnitude of the consequences of the occurrence" (Royal Society, 1992).

A large number of chemicals have hazardous properties. Acids may be corrosive or irritant to human beings for example. This is the hazard associated with the chemical. The risk of the acid causing skin irritation or having a corrosive effect will be determined by the likelihood that, in specific circumstances, it will cause a specific degree of harm. If the person is only going to come into contact with the acid after it has been heavily diluted, the risk of skin irritation will be minimal but the hazardous property of the chemical will be unchanged. This illustrates a fundamental concept, underpinning the theory of risk assessment; the nature of the hazard remains the same, but exposure dictates whether harm will actually occur.

to protect humans and the environment. For agents that are assumed to have no threshold of action, such as genotoxic carcinogens like benzene, there is no level at which they can be regulated for "safety" or zero risk. Policy makers and regulators have to develop strategies for dealing with such agents, strategies that present an "acceptable" risk. Opponents to this view advocate the precautionary principle, minimising exposure to levels lower than those considered "acceptable" in the risk-based approach, and removing or substituting those agents considered to have no threshold of action.

Box 1.2

Risk assessment is the procedure in which the risks posed by inherent hazards involved in processes or situations are estimated either quantitatively or qualitatively. In the life cycle of a chemical for instance, risks can arise during manufacture, distribution, in use, or the disposal process. Risk assessment of the chemical involves the identification of the inherent hazards at every stage and an estimation of the risks posed by these hazards. Risk is estimated by incorporating a measure of the likelihood of the hazard actually causing harm and a measure of the severity of harm in terms of the consequences to people or the environment.

The scope and range of risk assessments vary widely. Some look at single risks in a range of exposure scenarios, an example is the Environmental Health Criteria Document series produced by the International Programme on Chemical Safety. Others are site-specific and look at the range of risks posed by a particular installation. An individual agent in a particular environmental media can be examined, such as a particular air or water pollutant. Some assessments go as far as to attempt to examine all the environmental risks posed to a town or city.

The foundations for risk assessment methodologies have traditionally been based on the examination of effects to human health but much more emphasis is now being placed on all environmental damage. Methodologies to examine the threats to ecosystems from environmental risks are now being developed and used. In comparison to human health risk assessment, which is in itself a relatively new field, risk assessment for ecological effects is very much in its infancy and the field is constantly developing.

Box 1.3

In this report, environmental risk assessment (ERA) is the examination of risks resulting from technology that threaten ecosystems, animals and people. It includes human health risk assessments, ecological or ecotoxicological risk assessments, and specific industrial applications of risk assessment that examine end-points in people, biota or ecosystems.

In recent years there has been considerable activity in the field of environmental risk assessment. A large number of international organisations, such as the Organisation of Economic Co-operation and Development (OECD), the World Health Organization (WHO) and the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), have been important in the development of methodologies, particularly for the assessment of chemical risks (van Leeuwen et al., 1996). The Commission of the European Communities has used risk assessment as a major approach to environmental issues. The regulation of GMOs, ionising radiation and chemicals are important examples. Because of the wide range of organisations involved in the development of risk assessment, there are differences in approaches to risk assessment. This has lead to calls for harmonisation. In the field of chemical safety, the International

Programme on Chemical Safety (IPCS) is leading a project that aims to develop an understanding of the methods and principles used by countries and organisations. The development of a willingness to work towards convergence of these approaches is seen as a long-term goal. IPCS are also working with OECD on a harmonisation of hazard/risk assessment terminology (van Leeuwen et al., 1996).

Difficulties in using many environmental management tools include the availability and treatment of the basic scientific data on toxicity, ecotoxicity, fate and transport models, and exposure models. In approaches that are dependent upon estimates of risk as their basis, this area becomes crucial. The basic data, if available, are often loaded with uncertainty. When faced with using data fraught with scientific uncertainty, two approaches are possible. Some people would choose to assume that substances or agents are harmless until proved (by science) to have harmful effects. Others would assume that agents are harmful until proved to be "safe". The precautionary principle is fundamental in the European Union's approach to environmental issues. At the Bergen conference in 1990, ministers declared that "Environmental measures must anticipate, prevent, and attack the cause of environmental degradation. Where there are threats of serious and irreversible environmental damage, lack of scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation" (O'Riordan and Cameron, 1994). In the use of risk assessment as part of a risk-based approach, complex methodologies have been developed to attempt to deal with uncertainty. These are used so that uncertain data can still be used in assessments and decisions can be based on those assessments. Where causation between the agent and an effect are not proved, the data are unlikely to be used. Many see this as in opposition to the precautionary principle (Gee, 1997). A precautionary approach would be to do as much as possible to reduce the emission of the agent potentially causing a serious environmental threat before science has proved or disproved causation. An approach based on risk would be to do as much as is necessary to achieve "acceptable" risk based on the results of the risk assessment. The results of these two approaches could lead to very different outcomes.

The risk assessment may include an evaluation of what the risks mean in practice to those affected. This will depend heavily upon how the risk being assessed is perceived. For example, the risks from hazards that are borne voluntarily will be evaluated differently to those that are imposed. Risk evaluation is fundamentally subjective and for this reason some practitioners prefer to separate this stage from the more 'scientific' estimation of risk. This traditional view of a risk assessment being a wholly scientific process has been challenged in recent years and there is a growing acceptance that judgement and values form an integral part of any risk estimation and assessment. In the US, this issue has been recognised by the National Research Council who are influential in developing risk assessment methodology (NRC, 1994). A recent NRC report actually recognises that for successful risk assessment, the characterisation of the risk must be undertaken at the outset in a way which addresses the divergent value judgements of different interested parties and groups (NRC, 1996).

An issue that has been important in risk assessment, especially for those who are trying to examine the decisions arising from it, is the

Box 1.4

Risk management is the decision-making process through which choices can be made between a range of options that achieve the "required outcome". The "required outcome" may be specified by legislation by way of environmental standards, may be determined by a formalised risk-cost-benefit analysis or may be determined by another process for instance "industry norms" or "good practice". It should result in risks being reduced to an "acceptable" level within the constraints of the available resources.

Risk perception involves people's beliefs, attitudes, judgements and feelings, as well as the wider social or cultural values that people adopt towards hazards and their benefits. The way in which people perceive risk is vital in the process of assessing and managing risk. Risk perception will be a major determinant in whether a risk is deemed to be "acceptable" and whether the risk management measures imposed are seen to resolve the problem.

Risk communication is an increasingly important area of risk management. Risk communication is concerned with the way in which information relating to risks is communicated and is closely linked to risk perception. Risk communication can be a one-way transmission of information, imparting safety propaganda for instance, through to a two-way exchange of views on the risk between the "expert" assessor and the "public".

separation of risk assessment and risk management. In the United States this has been a major issue as recommendations for the separation of the "scientific" process of risk assessment and the policy process of risk management were made by the National Research Council and others (NRC, 1983; Carnegie Commission, 1993), and this has been the approach of regulatory bodies, such as the US Environmental Protection Agency. A recognition of the difficulties in attempting to separate science from policy has also occurred in the US and there has been a move away from this view. This issue is less relevant in Europe where there has always been recognition of the blurred dividing line between assessment and policy. In Europe more emphasis tends to be put on stating defined decision criteria and recognising the influence of societal values on the conduct of environmental policy (McCarty and Power, 1996).

Risk can be managed in many ways:

- The risk can be eliminated. A total ban on the use or marketing of a hazardous chemical is an example of risk elimination. However, risk elimination is often not possible as other chemicals will be used to replace the one banned. In this case, one risk had been substituted for another.
- The risk can be transferred to other bodies, for instance industry may transfer the risk of environmental liability to insurance companies.
- The risk can be retained by a company or government. This can be done knowingly, for instance where a company assesses the risk and makes provision to cover the costs of any harm that may arise. Risks are more often retained without knowledge, for instance where assessments have not been carried out or the hazards have not been identified.
- The risk can be reduced. In most policy and regulatory decisions, risk reduction is the most common approach to risk management. Although risk reduction is usually associated with regulation, there are may other ways in which it can be achieved. Examples are voluntary industry agreements and the provision of good risk information to consumers who can then choose lower risk products.

Risk reduction choices are based on much wider issues than the results of the assessment alone. Factors, such as the health and environmental goals of the industry and government, the economic, political and social importance of the industry and the agent that is creating the risk, the influence of consumer, environmental and worker organisations and their perception of the risk, and the availability of substitutes for the agents creating the risk, are all important. The level of risk remaining after risk reduction has been implemented will be decided upon by industry and governments, taking into account the views of the stakeholders. Economic, social, political and cultural factors all need to be considered, which may vary from country to country. This often means that achieving international consensus on risk reduction is very difficult.

It is important to note that although risk assessment is used extensively in environmental policy and regulation, it is not without controversy. Although it provides the scientific foundation for much legislation and environmental policy, the results of risk assessments are often not universally accepted. The major contentious areas include the availability and quality of data used in risk assessment, the interpretation of the data and results of the assessment, the basis and motivations behind the judgements that are fundamental in the assessment of risk, and the treatment of uncertainty. Risk management is also hugely controversial and issues such as the inequitable distribution of the costs and benefits of risk, the methods and validity of valuing costs and benefits, and the incorporation of people's values and perceptions into decision-making are all important. These issues are discussed in Chapter 8.

2. THE ROLE OF RISK ASSESSMENT IN ENVIRONMENTAL MANAGEMENT

This chapter examines the role of risk assessment and management in environmental management. The use of risk assessment by governments and regulators in policy and regulatory decisions is discussed, as is the use of the tool by European industry. The chapter aims to outline the major ways in which risk assessment is used and gives specific examples of such use in Europe. The examples highlight some of the difficulties involved in the use of risk assessment and the subtle differences that arise in different EU states.

More discussion of the benefits of, and pitfalls associated with the use of risk assessment and management as an environmental management tool is contained in Chapter 9.

2.1 The use of risk assessment and management techniques in policy and regulatory decisions

In recent years, risk assessment and management approaches to environmental issues have become increasingly important. At a global level, for instance, risk assessment is the major approach to controlling chemical risks in Agenda 21 of the United Nations Conference on Environment and Development (UNEP, 1992). A risk-based approach to environmental problems is also becoming common in European environmental legislation and policy.

Risk assessment and management techniques are used as decision-making tools in regulation. The range of applications is wide and includes:

- the design of regulation, for instance in determining societally "acceptable" risk levels which may form the basis of environmental standards;
- providing a basis for site-specific decisions, for instance in land-use planning or siting of hazardous installations;
- prioritisation of environmental risks, for instance in the determination of which chemicals to regulate first;
- comparison of risks, for instance to enable comparisons to be made between the resources being allocated to the control of different types of risk, or to allow risk substitution decisions to be made.

2.1.1 Risk assessment and management in regulatory design

Risk assessment can be used as a decision-making tool at national and regional level in the design of regulation. When assessment of risk is used as part of a risk management approach:

- targets for regulation can be selected;
- societally "acceptable" risk levels can be determined;
- decisions can be made on the appropriate level of risk reduction.

Risk assessment and management approaches attempt to provide a formalised framework within which decision-makers can compare the harm caused by the risk with the benefits associated with it and choose appropriate risk reduction measures.

For instance, when examining the risks posed by chemical use, the overriding aim of a risk assessment and management approach is to enable objective decisions to be made on whether the risks posed by a chemical, at a certain dose, outweigh the benefits proffered by its use. Risk assessment and management techniques offer regulators (both national and regional) of chemical risks a methodology to evaluate both the beneficial and negative impacts of a chemical on society. A fundamental, and ultimately political decision, has to be made by regulators in weighing up the costs and benefits. Numerous approaches are used to determine "acceptable" risk levels. These are discussed in more detail in Chapter 8. It is clear, however, that a political decision has to be taken as to what extent the costs of the chemical have to exceed the benefits of its use before risk reduction measures are required.

By using risk assessment and management techniques, the risks of defined health or ecological end-points occurring can be explicitly estimated using scientific techniques within the limits of the available data. Various options to reduce the risk can then be examined by using criteria such as; the cost required for achieving a certain reduction in risk, the feasibility and practicality in reducing the risk and the social impact of reducing the risk.

One very common approach used in defining a level of risk that is "acceptable" and to assist in choosing between risk reduction options is the concept of ALARP (as low as is reasonably practicable). ALARP compares the costs of the risk existing with the costs that will be imposed by trying to reduce the risk. The risk needs to be reduced to as low as it is reasonably practicable. This is fundamental in the regulatory framework of the United Kingdom where legal case law and policy exists defining ALARP in the realm of occupational health and safety. ALARP is also enshrined in Dutch policy on environmental risk (see Box 2.1).

A very important step in the use of risk assessment in regulatory design came with the approach taken by the EC legislation relating to new and existing hazardous substances. The risks from new and existing substances are assessed and risk management decisions taken on the basis of the results. This will be considered in more detail in Chapters 5 and 6 where the EU approach to risk assessment of chemicals is examined.

Box 2.1 The use of risk assessment and management in environmental regulation in the Netherlands

In the Netherlands, risk management approaches were first introduced in the 1986-1990 Programme for Environmental Management of the Dutch Government. This concept of risk management recognised the importance of an "effects-oriented approach" (e.g., environmental quality standards and effects standards) in addition to a "source-orientated approach" (e.g., emission standards based on the best available techniques not entailing excessive cost (BATNEEC)). The risk management policy sets out criteria for judging risks of technological hazards based on the following concepts:

- That a maximum acceptable level of risk can be identified which should not be exceeded irrespective of the economic or social benefit that could result from the activity under consideration.
- That a negligible risk level can be identified at which it not sensible to try to reduce the risk further.
- That between these two levels the risk should be reduced to as low as is reasonably practicable (ALARP).

The risk criteria deriving from such a policy are laid out explicitly in 'Premises for Risk Management' which is part of the National Environmental Plan (Ministry of Housing, Physical Planning and Environment, 1991).

The use of risk assessment and management at regional or international levels can cause difficulties due to the varying social, economic and environmental conditions in different nations. See Box 2.2.

Harmonisation of national approaches to risk assessment and management within the regulatory framework can be restricted because of the differences in the policy objectives of the nations concerned. This is illustrated by the differences in approach and outcome of risk assessments on GMOs between different states. See Box 2.3.

Box 2.2 OECD's risk reduction programme - difficulties of agreeing international risk reduction measures

The OECD programme on chemical risk reduction set up in 1990 attempts to agree substantive international action. In the pilot stage five chemicals - lead, brominated flame retardants, cadmium, mercury and methylene chloride - were selected for examination. Agreements were reached on cadmium, lead and brominated flame retardants.

The agreement reached on lead falls short of the prescriptive action called for by the USA and EC under the Council Acts. The Declaration on lead "recognises the differing needs and circumstances of the Member countries which call for flexible national risk reduction strategies and time frames." Denmark was particularly unhappy about the lead declaration and wished to see all OECD countries follow a principle of minimisation of risks and substitution of the metal.

On cadmium, the OECD has stated that "because of the variance in the nature of exposures and in environmental conditions in OECD member countries, it was accepted that direct action to reduce risk from exposure to cadmium is most appropriately taken at the local, national or regional level." Scandinavian countries, backed by the Dutch, Swiss and Germans led a push for international controls on cadmium use, citing the transboundary impacts of exports of food, fertilisers and other products such as batteries. The International Cadmium Association backed by the UK, Australia, Canada and the US has argued for action based on national needs. Sweden and other Nordic countries have already imposed stringent controls and phase-outs to control exposure to cadmium. The variation in national views on cadmium highlight differences in the interpretation of the precautionary principle in Europe.

The agreement of brominated flame retardants involves a weak voluntary committment to control the manufacture of certain retardants.

The pilot scheme indicates clearly the huge difficulties in agreeing international action on chemical risk reduction where variations in risk exist in different states (due to different patterns of use, exposure and environmental conditions) and the proposed action has different socio-economic implications in different states.

The risk reduction programmes of the OECD will take a new approach of focusing on methodologies rather than specific chemicals. In addition the OECD is to hold workshops to examine the value of non-regulatory initiatives.

2.1.2 Risk assessment and management in site-specific or regional decisions

An example of the incorporation of risk assessment in regulation for site-specific problems is the 'Seveso' Directive (EEC, 1982). This requires operators of relevant industrial sites to provide evidence that the potential major accident hazards for the site have been identified, and that adequate steps have been taken, both to prevent such accidents and to limit their possible consequences to persons and the environment. This legislation requires a form of site-specific ERA. See Box 2.4.

Site-specific problems such as a geographically distinct area of contaminated water or land can be dealt with by ERA. This characterises the health and ecological risks, posed by the site and identifies risk reduction options. Using defined criteria, the most appropriate risk reduction measures are chosen that reduce the risks to an "acceptable" level at an "acceptable"

Box 2.3 Disharmony between GMO risk assessment approaches

Because of several difficulties discovered in the implementation of the 1990 Directive on Deliberate Releases of Genetically Modified Organisms into the Environment, the Directive has been under review. The Directive specifies the data which member states must obtain from companies and assess to decide whether to approve experimental or commercial releases. However, it appears that they have approached assessments with different objectives in mind, resulting in a "lack of harmonisation". Guidelines are currently being drawn up by the European Commission in an attempt to address this problem (ENDS, 1996).

Box 2.4 The Seveso Directive - an example of regulation requiring site-specific risk assessment

Member States have developed guidance for industrial sources to help with compliance with the national legislation enacted in response to the 'Seveso' Directive.

The Dutch government sponsored the development of methods to quantify risks. The SAFETI package has been developed for use in site-specific decision making. Risk assessment in the Netherlands has been applied to the siting and land use zoning of hazardous installations. In response to the 'Seveso' Directive, three government reports lay out a well- defined and standard methodology for quantified risk assessment (Ministry of Social Affairs and Employment, 1988, 1989, 1991). The UK Government has produced guidance on the effects on the environment that would constitute a major accident. It is attempting, with industrial collaboration, to relate these effects to the amount of chemical in the environment that would cause this amount of damage. A major difficulty that has been experienced is the determination of the significance of the damage. Work is being carried out to develop a semi-quantitative ranking system for environmental damage based on a compilation of all criteria used to value the environment (DoE, 1991).

cost. ERA is thus useful in land-use planning or siting decisions. A difficulty in such decision-making is that the risks and benefits generated by new hazardous installations are never distributed equitably. The question of "acceptable to whom" always arises.

Photo: Graham Burns, Environmental Images

Contaminated land sites are an example where risk-based regulation is being used in Europe. In the UK and Sweden, the risks posed by contaminated land sites are assessed in relation to the land's proposed use and remediation measures are required based on a risk management approach.

Decisions on the best approach to be taken in respect of sectors of industry or distinct regions can be taken after considering the risks posed by either the specific industry sector or the industrial sources within a region. See Box 2.5.

2.1.3 Risk assessment as a tool for prioritisation of agents for risk reduction

Risk assessment can enable comparisons to be made between different risks. This is useful in the prioritisation of chemicals and in evaluating the basis of regulatory action for different risks. See Box 2.6.

Risk assessment incorporates both available hazard and exposure data. It thus enables priorities for action to be made on the basis of the actual risk posed rather than potential hazard. In its most complete form, the results of a risk assessment will give detailed information on the effects of the risk, the likely actual exposure to the chemical in a range of exposure scenarios, and estimates of likelihood of the chemical

Box 2.5 Integrated regional risk assessment

A four-year collaborative research programme in Switzerland has been carried out to support a plan to provide a "co-ordinated strategy for risk reduction and safety/hazard management in a spatially defined region across a broad range of hazard sources that includes synergistic effects" (Gheorghe and Nicolet-Monnier, 1995). The project addresses the risks from both routine releases from industry and accidental releases. This method of regional risk assessment could prove a useful tool for risk managers and regional planners. It may assist in the determination of "acceptable" levels of risk to the public and environment in the face of the increasing complexity of technological risks and the increasing density of hazard sources such as industrial developments and road transport.

An example of an integrated regional risk assessment, the Chester Risk Assessment Project, incorporates not only industrial risks but those posed by transportation and natural sources in the city of Chester, USA (http://www.envirolink.org/orgs/pen/crcql/index.html).

Box 2.6 Priority Setting in Regulation 793/93 (The Evaluation and Control of Existing Substances)

Regulation 793/93 on existing substances includes the requirement to prioritise chemicals for action. At the moment, over 100,000 substances are present on the European Inventory of Existing Commercial Substances (EINECS). Article 8 of the Regulation states that the Commission will regularly draw up lists of priority substances that require immediate attention because of their potential effects on people or the environment.

The Commission will use the following steps in prioritisation:

Part I: Consolidate and distribute The International Uniform Chemical Information Database (IUCLID) held at the Joint Research Centre in Ispra.
Part II: Rank the IUCLID substances using an automated ranking method. This method - Informal Priority Setting uses criteria such as physico-chemical properties, environmental fate and pathways data, toxicity and ecotoxicity data;
Part III: Distribute the ranking and underlying data used to Member States and Industry;
Part IV: Introduce expert judgement into the ranking by Member States and Industry and finalise ranking;
Part V: Produce a proposal for a priority list.

The priority setting stage will use data available from IUCLID and will be similar to the final risk assessment. However the priority ranking is concerned with relative concern between all IUCLID substances and can be based on much less data than the risk assessment (CEC/ECB, 1993).

The major difficulty in the use of such an assessment system is the availability of the basic data. The development of the IUCLID database is in progress but it only includes those few thousand chemicals that are marketed and sold in amounts exceeding 1000 tons per year. Before 1998, producers and importers will have to submit (limited) documentation on substances marketed in amounts above 10 tons per year if the data is already available. The huge data deficiencies are highlighted in a report from the Danish Board of Technology that states "The vast majority of the chemicals on the EINECS list have not been assessed for hazards or risks to man and the environment, or they may be short of data for proper assessments" (Danish Board of Technology, 1996).

having the effects identified at the exposures estimated. On this basis it is possible to rank chemical risks. The ability to provide detailed risk assessments for chemicals is dependent on the availability of good quality toxicological data. This is a major problem in use of risk assessment as an environmental management tool, as complete data are available for very few chemicals.

Risks are very rarely ranked purely on their negative impacts. Regulators can choose to incorporate the following issues:

- the social, economic and political impact of the risk reduction measures for each of the chemicals
- the practicality of risk reduction and
- the constraints of existing national policy and legislation that define how certain risks have to be dealt with.

2.1.4 Risk assessment as a tool for comparisons to be made between risks

A risk assessment may point to inadequacies in existing action on controlling risks by contrasting the resources that are devoted to comparatively lower risk agents to those with higher risks. This enables regions and nations to select targets for regulation. The aim is to ensure that the most severe risks are dealt with first and that the costs imposed on industry to achieve a societally agreed level of control is appropriate to the degree of risk. Risk assessment and management approaches are therefore an important tool for environmental management in a climate of limited resources (see Box 2.7).

The ultimate use of this type of risk comparison has occurred in the United States. Government studies have examined the effectiveness and basis of environmental regulation by calculating the

Box 2.7 The use of risk assessment and management in the UK regulatory system

In the UK, risk assessment and management are being increasingly used in regulation. The Department of Trade and Industry (DTI) for instance, sees risk assessment as a technique for enabling decisions about regulation to be in proportion to the risk. Risk assessment of regulatory proposals is required to ensure that regulation is justified on a formal risk benefit basis as part of the UK Government's deregulation initiative (DTI, 1993, 1994).

cost of each life saved by environmental legislation regulating specific risks (US EPA, 1987). Recent US legislation also requires risk assessment and risk-benefit analysis for all new regulation (Risk Assessment and Cost-Benefit Act 1995 available on the internet at http://www.thomas.loc.gov).

The use of such risk comparisons is justifiable from the viewpoint of the efficient management of enforcement resources. A question should be raised as to whether all environmental risks need to be dealt with in the same way. Why should the amount of money it costs to save a life through regulation be the basis of whether, and how, risks are controlled by Governments? This approach does not take into account how environmental risks are perceived and the priorities of the public, which should be a fundamental consideration in any legislative framework. An example can be drawn from risks in food. The health risks posed by eating barbecued foods are assessed scientifically as being greater than those posed by pesticide residues in food. Should the fact that the majority of the public would not wish to see the barbecuing of food controlled by legislation have any effect on the regulation of pesticide residues?

The use of risk comparisons does illuminate many areas where the decisions on controlling the risk are dominated by factors other than the science involved. The difficult decisions have to be made once the comparisons are made.

Comparative risk is a relatively new field in Europe. Risk comparisons are becoming enshrined in environmental legislation, however, and their use is likely to increase. See Box 2.8 and Box 2.9.

Box 2.8 The Proposed EC Biocides Directive - a contentious use of risk comparisons

The draft Directive on biocides sets up a harmonised system of control over the placing on the EC market of a wide range of products - from household detergents to industrial rodenticides and anti-fouling agents - based on an assessment of the risks they pose to human health and the environment. A revised proposal incorporates an annex containing a framework of common principles upon which member states can base decisions to authorise products (EC, 1995).

One proposal in the Directive that has provoked intense opposition is "comparative assessment". The debate is significant because the Biocides Directive would be the first to enshrine this concept. The Directive would allow the inclusion of an active ingredient to be refused "if there is another active substance ... for the same product type or another method of control exists, which in the light of scientific or technical knowledge presents significantly less risk to health or the environment." The principle of substitution based on comparative analysis has long been supported by the Scandinavian States. At the Environment Council in December 1994, seven Member States - Belgium, Denmark, Germany, Austria, the Netherlands, Finland and Sweden - entered a statement in the minutes asserting their belief that "by comparative assessment as proposed in the Commission proposal ... it is possible to reach a high level of protection of the environment and health respecting the economic and practical consequences for the user." The French and the UK oppose such comparative assessment.

The Swedish Experience

In Sweden a review of all biocides on the market was initiated in 1990. Products for particular applications are assessed simultaneously, enabling regulators to take a holistic view on the comparative risks of substances and their impact of their withdrawal from the market. Sweden recognises the limitations of comparative assessment. The differences in risk must be significant to make a comparison justified, and comparative assessment cannot be used where a substance poses less risk in one area but the alternatives pose less risk in others. The Swedish recognise that the economic and practical costs to the user must be considered.

Box 2.9 Control on off-shore use of chemicals - Oslo and Paris Commission (OSPAR)

At the OSPAR meeting in Oslo in June 1996, member countries agreed a Decision to introduce a mandatory notification and screening system for chemicals used by the off-shore oil and gas industry. The scheme will run for a trial period of 2 years.

All applications made to the national authorities for the use and discharge of chemicals will have to include standardised toxicity data in the form of a "harmonised off-shore chemical notification format" (HOCNF). In the case of currently permitted chemicals, HOCNF data will be required on a priority basis. Chemicals will be run through a pre-screening process to enable national authorities to decide whether they should be authorised or substituted. As a basis for such decisions, chemicals will be subject to a risk assessment and ranked according to the risks they pose. Risk will be measured using a methodology known as CHARM - chemical hazard assessment and risk management. This bases risk on a quotient between the predicted environmental concentration (PEC) and the no-effect concentration (NEC) in a standardised discharge scenario. If an operator decides to replace a chemical for an economic or performance reasons, the preferred chemical's PEC/NEC ratio must not be higher than that of the substance currently in use. National authorities "shall when taking regulatory action ensure that over time a shift is realised towards lower relative PEC/NEC ratios".

2.2 The use of risk assessment and management techniques in industry

ERA has traditionally been a function of policy and regulatory agencies and most development has taken place in these fields. ERA is becoming more common in industry partly as a result of the use of ERA in regulation.

2.2.1 Compliance with legislation

In recent years, the focus of much European regulation of chemicals and ionising radiation has been risk assessment. Many industries have been at the forefront of the development of ERA techniques but now the approach is being imposed on industry by environmental regulation.

The 'Seveso'(EEC, 1982) and COMAH directives (CEC, 1994) require major hazard industries to produce "safety cases" which include health and environmental risk assessments. The COMAH directive extends the 'Seveso' directive by placing emphasis on safety management systems, and extended public information requirement on operators, and gives new rights to the public on siting and land use. These extensions to the 'Seveso' directive relating to public involvement and information mean that major hazard industries will need to concentrate on how the public perceive risk. This will become important within the regulatory framework (the way consumers perceive risk has always been important for commercial purposes, now residents of local communities will have a legal role in environmental decisions).

2.2.2 Product safety

The new and existing substances legislation on chemicals requires that manufacturers of chemicals assess environmental risks. This is examined in more detail in Chapter 5.

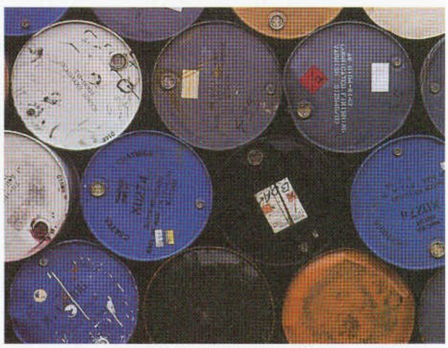


Photo: Graham Burns, Environmental Images

Manufacturers of products carry out ERAs. Procter and Gamble, for instance, have examined the fate of hypochlorite bleach used domestically (Schowanek et al., 1996). This type of research is fundamental to good ERA.

2.2.3 Financial planning

Environmental risk assessment can be an important tool in financial planning for companies. As the methodology allows for the quantification of risk, this can be valued and financial appraisal based on monetary values performed. The risk assessment can form the basis for evaluating the costs to the company of different options for risk reduction, for instance in deciding how far risk reduction measures should go. The risks posed by different processes or operations can be evaluated, for instance in deciding whether to transport hazardous materials by road or rail. From the point of view of the company, the valuation of environmental damage and life will be different from that carried out to reflect values at societal level. At a company level, environmental valuation is likely to include only those aspects that directly effect them - insurance costs, compliance costs with legislation, costs incurred from contravention of legal liabilities - and as such may exclude externalities. The risk of the costs of externalities being imposed on the company is often insured against which may become a part of the environmental valuation by the company.

2.2.4 Site-specific decision making - choosing between risk management options

Companies use ERA to determine the levels of risk that exist in a certain process or plant to enable effective decisions to be made on how to deal with the risk.

For instance, the risks posed by a particular process can be examined. The assessment of risk estimates the level of risk and an evaluation may be carried out to determine the significance of the presence of the risk. Based upon this information, decisions can be made as to whether the risk is retained, reduced to an "acceptable, tolerable or desired" level or transferred to an insurance company.

2.2.5 Prioritisation and evaluation of risk reduction measures

Risk assessment and management can be important decision-making tools in evaluating risk reduction measures in industry. The decision by a company to reduce the risk may be prompted by legislation, by financial considerations such as potential reduction in insurance premiums, by environmental or humanitarian considerations or by other commercial factors. Risk assessment and management can be used to determine how far the risk has to be reduced. This will usually be in the absence of regulatory standards or where the company wishes to set their own internal "acceptability" or "tolerability" standards.

The techniques can be used to examine the implications of risk reduction measures. Risk assessment and management in this context is not a finite process. All risk reduction measures can be examined and the new situation, post reduction, should be analysed. An important role for risk assessment and management is to determine when to commence and importantly (for commercial organisations) cease risk reduction measures. An example of this approach is the guidance produced by CONCAWE, the petrochemical industry group on risk reduction measures to be used in the petrochemical industry (CONCAWE, 1996) or that produced by the UK Petroleum Institute for petrol filling stations.

2.3 What risk assessment can and cannot do

Although risk assessment and management have, and will, continued to become increasingly important environmental management tools, it is important to look at what the techniques can actually achieve and equally as importantly, what they cannot.

2.3.1 What is good about environmental risk assessment and management techniques?

They can be successful:

- where a technique is necessary to weigh up information that is basically in different "languages". Risk assessment and management are often used in public policy decision-making which demands that science and social, economic and political information is taken into account. Risk management techniques attempt to provide a bridge between the scientific and the social.
- as a mechanism to aid decision-making especially the choice between options for action, e.g., risk reduction options. Once you have determined the criteria on which choices are to be made then risk assessment and management methods will aid decision-making.
- as a means of comparison between risks to determine whether there is equity of action or that the action is proportionate to the risk.
- as they can break down complex systems and identify areas of processes or plant where risk reduction options can be most effective.
- as a basis for effective risk communication. Risk assessment can give a risk communicator the effective base for communication. However, the limitations are clear. If the communicator wishes to convince a sceptical public or other interest group, they will have to address the value issues that underlie the perception of the risk.
- as a method for highlighting and prioritising research needs.

2.3.2 What are the pitfalls of environmental risk assessment and management techniques?

The techniques have been criticised for a number of reasons, some of which are not real criticisms of the techniques but are related to the philosophical basis of carrying out such assessments in the first place. The dumping of the Brent Spar is one such example. See Box 2.10.

There are many criticisms that are focused on the use of the techniques. These include:

- That the use of scientific techniques such as risk assessment encourages an over-reliance on and over-confidence in the results. This is particularly focused at risk areas where there are great uncertainties and conservative approaches and safety factors are common. Those who query the certainty of the science will often claim that reliance on risk assessments based upon uncertain science is ill-judged.
- Risk assessment focuses on parts of a problem rather than the whole. The most commonly performed risk assessments concentrate on single chemicals. Site-specific risk assessments may examine a number of risks but each will be done in isolation as the scientific data are not available for looking at mixtures of agents yet.
- In the United States risk assessment is generally disliked by trade unionists, environmentalists and consumerists due in part to the valuation of life and environmental quality involved in many risk management procedures.
- The relationship between risk assessment and management and the precautionary principle is somewhat awkward - how precautionary do

Box 2.10 Dumping of the Brent Spar

In April 1995, Greenpeace activists boarded the Brent Spar, a decommissioned oil storage buoy which Shell Expro, its owners, intended to dump in the deep sea north-west of the Hebrides. Greenpeace argued that the dumped Brent Spar would damage deep-sea ecosystems, possibly harm humans and in any case it was wrong to use the deep ocean as a rubbish dump. After world-wide media coverage and public pressure, Shell abandoned their disposal plan in June 1995. This was after they had been granted a deep-sea disposal license on the basis of the Best Practicable Environmental Option (BPEO) study, based on scientific evidence.

The arguments about whether the Spar should have been dumped or not seemed to concern two issues. Firstly there was a lot of confusion as to the make-up and contents of the Brent Spar and the second issue concerned the arguments in the BPEO study. The first issue was cleared in November 1995 when Det Norske Veritas published its independent inventory of the Spar's contents confirming the figures provided by Shell and correcting the Greenpeace estimates, especially on hydrocarbons. The second issue, on the BPEO is more contentious.


Photo: David Simm, Environmental Images

The BPEO documents produced by consultants for Shell contained a number of errors which lead to criticism within the scientific community. This lead to the UK government asking the UK Natural Environment Research Council to set up an independent expert group to "examine the scientific evidence in relation to the potential environmental impacts of large off-shore structures, using the Brent Spar as an example". The outcome of the inquiry was a call for more open, independent decision-making but they did not comment on deep-sea dumping.

The point crucial to environmental risk assessment and management is that most of the public argument on the dumping concerned the contents of the Brent Spar and the amount of damage to the deep-sea ecosystems that this would cause. These public arguments concerned the technical and scientific aspects of the risk assessment. The values of the environmentalists and those opposing the dumping meant that they believed that nothing should be dumped in the sea. No amount of scientific discussion and argument would have counteracted this belief. It was, however, these scientific and technical issues on which the decision-making was based. It can be seen that the technical assessors and those opposing the dumping were actually arguing from different viewpoints and answering different questions. To those opposing the dumping, a fundamental issue was not the actual level of damage the Brent Spar would cause but the whole policy of allowing dumping at sea. The recommendation of the UK NERC for more open decision making can be seen as an attempt to address this problem. Controversial environmental decisions such as that taken in relation to the Brent Spar need to be made in as transparent a way as possible. The questions that the decision-makers were attempting to answer needed to be clearly defined at the beginning of the assessment process. The role of the wider policy issues such as the application of the precautionary principle needed to be defined at the initial stages of the assessment.

Ultimately the decision by Shell not to dump in the deep-sea was based not on the scientific evidence but on commercial reality - they realised the potential commercial damage of going ahead and dumping. This indicates that values and other factors were just as vital in Shell's decision-making as they were in Shell's opponents.

you have to be? Global warming is an example of an issue where the science surrounding an issue is very uncertain but the consequences of inaction are huge. Doubt exists as to whether a technique such as risk assessment can be applied. A totally precautionary stance would be that as we are not sure, then all action to prevent the consequences that have been hypothesised, should be taken. In the real world where the action required for preventing global warming has enormous social, political and economic repercussions this may not be possible. A technique such as risk assessment and management that is able to incorporate such issues will look attractive but how precautionary do we need to be in the assessment to take account of the uncertainty? The need of development work addressing these problems are described in section III

3. A TYPOLOGY OF RISK ASSESSMENT AND MANAGEMENT METHODS

As seen in Chapter 2, the uses of risk assessments are wide and varied. The risks examined in the assessment can be physical such as radiation, biological such as a genetically modified organism or pathogen, or chemical such as an immuno-toxic substance. The target/receptor to be examined in the risk assessment can vary. Human beings are the species most extensively considered in risk assessments - human health risk assessments - but other single species risk assessments are common. Many ecological risk assessments can be considered single species, since only a few types of representative organisms are selected as assessment end-points (Landis et al., 1995). The end-points examined in the risk assessment are varied. They can be mortality or morbidity in human health assessments or other single species assessments. For some ecological risk assessments, end-points may be extinction or total catch. Some ecological risk assessments use end-points that indicate biodiversity or disturbance to ecological systems.

In this Chapter, a typology of risk assessment methods in use or development will be outlined. The typology is shown in Figure 3.1 and breaks environmental risk assessment into:

- Human Health Risk Assessment
- Ecological Risk Assessment
- Applied Industrial Risk Assessment

The basis of the human health/ecological split is that although the two processes are conceptually similar (in fact ecological risk assessment has developed from human health risk assessment), the two have a differing historical development and regulatory and policy imperatives. Applied industrial applications have been separated as many of these assessments do not look in isolation at people or ecological systems. They look at real situations and tend not to be as "pure" as the first two categories. They are likely to include engineering risk assessments as part of the overall environmental risk assessments and may take an integrated approach to human and environmental risks. They are likely to lay much more importance to ensuring that the risk assessment can be used in risk management decisions as the objective is more clear-cut - to make a risk management decision intended to protect humans and the environment (and the company) within defined spatial boundaries.

It will be noted that the human health typology and the industrial use typology are more detailed than that for ecological risk assessment. This is because these are the areas in which the methodology is most developed.

The typology does not outline all the possible types of risk assessment. In the area of ecological risk assessment, there are many developing techniques and much research is being carried out to define suitable end-points. The typology of ecological risk assessment shown, is that currently practised, or that in an advanced state of development in government or industry.

The typology for industrial application for risk assessment is based on use of the method rather than the type of method.

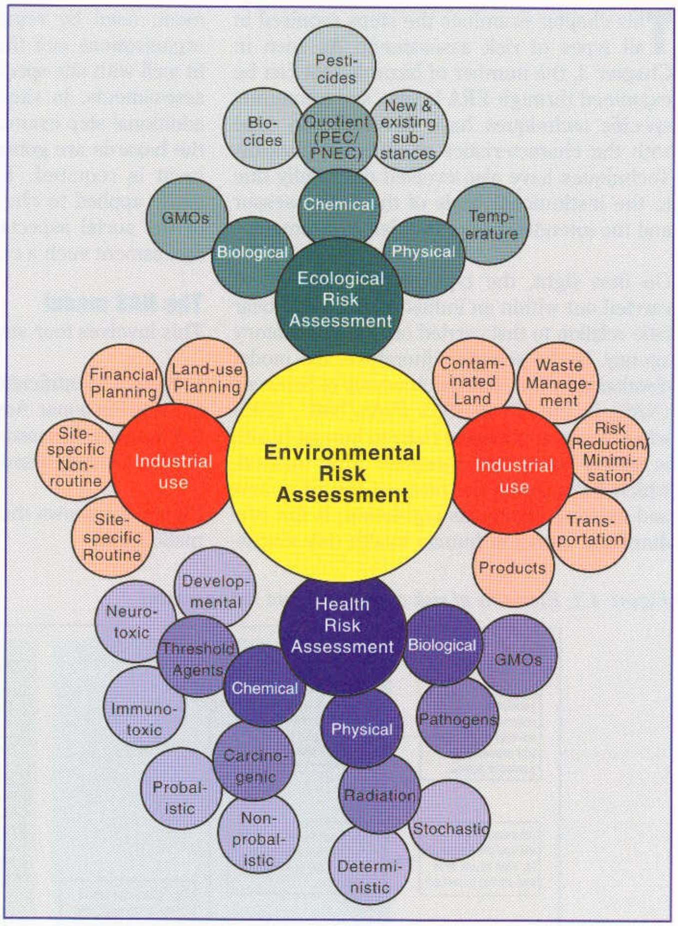


Figure 3.1: A typology of risk assessment

Source: Fairman and Mead, 1996

4. OVERVIEW OF RISK ASSESSMENT METHODS

This chapter examines the steps required in all types of risk assessment. As seen in Chapter 3, the number of hazards that can be examined through ERA is vast, and numerous specific techniques have developed to cope with the characteristics of different hazards. Techniques have also evolved differently due to the institutional basis of the risk assessor and the intended use of the risk assessment.

On first sight, the type of risk assessment carried out within an industrial plant will bear little relation to that carried out by a regulatory agency. In the scientific literature, the model developed by the National Academy of Sciences (NAS) in the US in 1983 (NAS/NRC, 1983) which looks at chemical risks to human health is widely used and accepted. This method, which has formed the basis of the EU's new and existing chemicals legislation, is the predominant model in human health risk assessment, used by regulatory or policy-making organisations and the methodology does not fit well with site-specific or process/plant risk assessments. In site-specific assessments, an additional step examining how, why and when the hazards are going to get into the environment is required. The NAS model is most easily applied to chemicals and excludes any of the social aspects of risk that make risk assessment such a complex task.

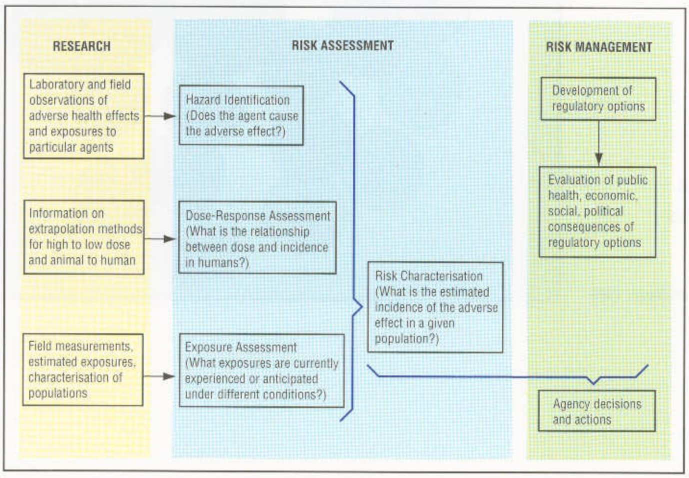
The NAS model

This involves four steps:

1. Hazard Identification
2. Dose-Response Assessment
3. Exposure Assessment
4. Risk Characterisation

Figure 4.1 shows the NAS model in diagrammatic form.

Figure 4.1: Elements of risk assessment and management



Source: NAS/NRC, 1983

This model was developed for human health risk assessment and has formed the basis of ecological models of risk assessment used in the US. Because of the widespread use of this model in regulatory and policy terms for human health protection, Chapter 5 on human health risk assessment will examine these elements in more detail.

The NAS model is very important but does not encompass all the types of ERA that are in use. There are a number of unifying principles underlying all risk assessments. These underlying principles are developed from those laid down by Covello and Merkhofer (Covello and Merkhofer, 1993).

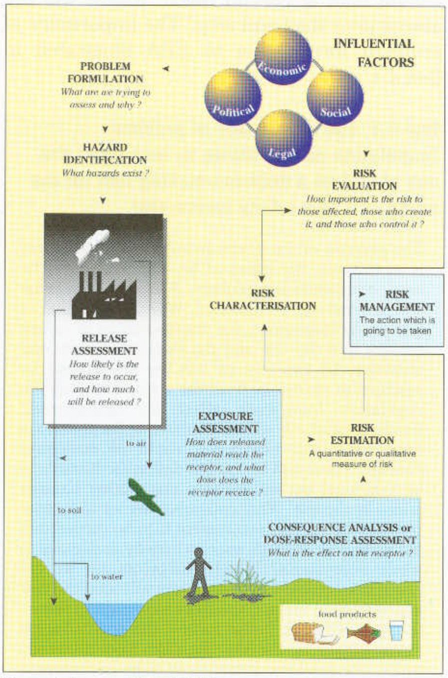
ERA will include a number of steps:

- Problem Formulation
- Hazard Identification
- Release Assessment
- Exposure Assessment
- Consequence Assessment
- Risk Estimation

Environmental risk assessment is also likely to include a step specifically excluded from the NAS model, that of risk evaluation. This step has been laid down in the European legislation on new and existing substances.

A diagrammatic representation of this model is shown in Figure 4.2.

Figure 4.2: The elements of risk assessment



Source: Fairman and Mead, 1996

Problem formulation is fundamental in environmental risk assessment. Initially the problem has to be defined and certain issues must be clear before the assessment starts, such as what are we actually attempting to assess? What is the risk source? Is it a single chemical, an industrial plant or a process such as transportation? Are we concerned with the production, use or disposal of the hazard? The risk source will create hazards that may be released to air, water or ground. The hazards may be physical, chemical or biological in nature.

Why are we carrying out the risk assessment? This will affect the hazards that we examine. What hazards are we to include in the assessment? Are we using regulatory standards as a guide to determine "acceptable" risk? Are we using regulatory and policy frameworks to determine which end-points are significant?

Does the legal framework determine how we should look at certain risks? Where will the assessment start and stop? The importance of problem formulation to ERA illustrated in Box 4.1.

Box 4.1 The importance of problem formulation can be shown by looking at the use of ERA as a decision-making tool for the siting of a new refuse incinerator

The purpose of the environmental risk assessment is to examine the effect of the incinerator on the local inhabitants and ecology. A fundamental issue will be what will be assessed. Will the operation of the whole incinerator, the transportation of refuse coming into the site and the removal of non-combustibles, be assessed or will the assessment be confined to emissions from the stack? How will the regulatory framework affect the assessment? Existing standards will no doubt exist for emissions to air for human health and maybe for ecological damage. These will be used to define the hazards to be examined but will exclude many other hazards posed by the site. What end-points are we to assess? If an ecological risk assessment is to be carried out, are we to look at single species toxicity or damage to whole ecosystems? Which end-points are we not going to examine? Local residents will want the risk assessment to include the risks important to them - the risk of falling house values, the psychological stress caused by the site, the risks from increased traffic, the aesthetic intrusion in their environment and the perceived reduction in their quality of life. It is likely that a risk assessment will only include the likely consequences of accidental or routine releases from the site in terms of specific health and ecological end-points. By limiting the definition of the problem to these issues and excluding those of equal importance to the local community, the whole assessment process may become unacceptable to those affected by it. Ideally those affected by the incinerator should be involved in an open process of problem formulation alongside the "experts" who are going to carry out the technical assessment.

The hazards that we choose to take into account will have been defined by the problem formulation. Hazard identification is an enormous task and some argue that the

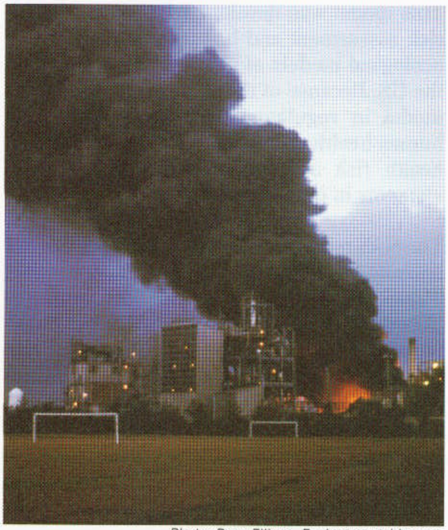


Photo: Dave Ellison, Environmental Images

process should be distinct from risk assessment. Obviously for the risk assessment of a single chemical or agent for regulatory or decision-making purposes, hazard identification will be a clear and distinct step. However, in complex processes, plant and sites, hazard identification can involve large numbers of disparate hazards and, in practice, the identification of hazards that cause harm to the receptor will not be the initial defined step in the risk assessment process. The assessment may need to identify process hazards that lead to the receptor being exposed to an agent. Geological hazards, such as fault-lines, may be important, for instance in the siting of hazardous installations.

Hazard identification in an ERA involves the establishment of those agents that could possibly cause harm to the receptor of interest - usually people, a specified organism or an

Box 4.2 Example of release assessment for the refuse incinerator

A release assessment is the examination of the routine operation of the incinerator to determine the potential for releases of hazardous materials into the environment. The release assessment should include both the operation of the plant and the moving of refuse into the plant and waste out of the plant. Emission from the chimney stack and loading and unloading of waste into and out of the site should be considered. In addition to routine operations, an examination of what could possibly go wrong to cause non-routine releases, how likely this is, what the releases would be, and in what quantity, would form part of the release assessment. Techniques for release assessment could be modelling techniques such as HAZOP studies or event trees, which are engineering techniques to predict failures and possible events in plants. On the basis of such techniques, likely emissions can be predicted and modelled. Actual air monitoring data from the incinerator stack and local environment would, of course, be better but they are unlikely to be available in the case of a planning decision. Data from other similar plants and performance tests would be useful in confirming how realistic your modelling has been.

Photo: Alan Greig

ecosystem. Their identification may involve the establishment of those agents that may cause harm and working backwards to identify how this harm could occur. Alternatively, in the assessment of plant or processes, hazard identification may arise from examining all possible outcomes of routine operation and identifying the consequences of deviations from normal operation.

It can be seen that hazard identification can be intimately linked with the other steps of risk assessment such as the release analysis. It may not be a distinct and separate step but part of a more iterative process. Methods by which hazards are identified are determined by the nature of the hazard and include toxicological testing, examination of failure and accident rates and epidemiological studies.

A **Release Assessment** involves the identification of the potential of the risk source to introduce hazardous agents into the environment. This may be descriptive or involve the quantification of the release.

A release assessment will include a description of the types, amounts, timings and probabilities of the release of hazards into the environment and a description of how these attributes might change as a result of various actions or events. See Box 4.2.

An **Exposure Assessment** consists of describing and quantifying the relevant conditions and characteristics of human and environmental exposures to hazards produced or released by a particular risk source. Exposure assessments will include a description of the intensity, frequency and duration of exposure through the various exposure media; routes of exposure; and the nature of the population exposed. See Box 4.3.

Box 4.3 Example of an exposure assessment for the incinerator

Exposure Assessment includes modelling the fate and transport of the pollutants released by the incinerator operations through the air, surface and ground water, and soil, examining the possible routes of exposure for people and the ecological system of interest. A question of up-most importance is whose exposure are we going to examine? This will be defined by the problem formulation, which in turn will be shaped by the purpose of the assessment. As the assessment is to be used for land-use planning, the exposure assessment will concentrate on the local community. It is important for realistic estimates of the local population's exposure to be produced. In order to do this it will be necessary to determine what kinds of people make up the local population, how long they spend in the vicinity of the plant, how long in their homes, and what kind of activities they perform there. Any groups sensitive to the pollutants likely to be emitted by the incinerator will have to be examined. It may be necessary to look at food chain models if the pollutants released are persistent and likely to enter the food chain. Exposure-route modelling is likely to be carried out to convert the results of fate and transport models for the pollutants into doses received by the local population. In situations where plants are already in existence, monitoring could be carried out for chemicals present in the environmental media or biological monitoring such as monitoring doses of the chemicals or metabolites in receptors.

A **Consequence Assessment** will examine the consequences of the release or production of the hazards, to the specified population and the quantification of the relationship between specified exposures to the hazard and the health and environmental consequences of those exposures. The consequences examined for human health are usually mortality or morbidity. The consequences examined in ecological systems are much more varied and few defined end-points exist at present. The data for consequence assessment will be based on toxicity and ecotoxicity testing, epidemiology and modelling such as dose-response models.

Risk Estimation consists of integrating the results from the release assessment, exposure assessment and the consequence assessment to produce measures of environmental and health risks. This may include an estimate of the numbers of people experiencing health effects over time or measures indicating environmental damage, and the uncertainty involved in these estimates. See Box 4.4.

Risk Evaluation is the examination of what the risk assessment actually means in practice. This will include acknowledgement of the public perception of the risk and the influence that this will have on the acceptability of risk and risk decisions. The risk evaluation may take account of perceived risks and benefits and incorporate these issues in the final risk assessment. See Box 4.5.

Risk Characterisation is the integration of risk evaluation and risk estimation. In some assessments, risk evaluation may be excluded due to its "non-scientific" nature, although the flaws in this argument have already been discussed.

Box 4.4 Example of risk estimation related to the incinerator

For each of the identified hazards:

- an assessment of the range of doses of the hazard that the local population will receive through air, water and soil, and
- an assessment of the effects of the hazard at a range of doses will be obtained. The data deficiencies and uncertainties in the effects and exposure data will be identified.

The risk estimate may identify the numbers of people in the local population that will experience a certain health effect or it may be a ratio of exposure doses to doses that could cause a harmful effect.

Box 4.5 Example of risk evaluation for the incinerator

The evaluation of the risks posed by the incinerator will be determined by many factors including:

- the environmental values of the local population. If the local population oppose the incineration of refuse on environmental grounds, this will have a negative impact on risk evaluation.
- the perception of the risk by the local community. The perception of the risks posed by the incinerator will vary in the community. If, however, the risks are perceived as great, this will, again, cause the risk to be evaluated negatively.
- Whether the risks estimated by the assessment equate with the risks perceived in the community. If there are great variations between the risk as assessed by the regulator or incinerator operator and that perceived by the local community, there is likely to be an element of mistrust between the assessor and the community. This will have a negative impact on the risk evaluation.
- the benefits gained by the local community. The benefits (if any) provided by the incinerator will affect the risk evaluation. If for instance, employment is provided by the incinerator, the risk may be evaluated more favourably. The distribution of the benefits amongst the community will obviously be important.

These underlying principles apply to all risk assessment. For some assessments, such as those examining the risks posed by particular sites or installations, all steps will be carried out explicitly. In many assessments, the risk is examined in hypothetical scenarios. Regulators for instance wishing to assess societal risk will not carry out release assessments but will measure or model exposure of society or a section of society.

In a generic risk assessment of a single chemical, a release assessment is not required. However, to ensure the credibility of the result, it is important that elements such as the exposure assessment are realistic. A mass-balance check or examination of release conditions can confirm whether the hypothesised exposure is reasonable.