

Chapter 3

What Is Risk Assessment, Anyway?

Introduction

Figure 3.1 shows the basic methodology for hazard and risk assessment used by the New South Wales Department of Planning to assess the risk to a surrounding population from an industrial accident (Department of Planning, 1994). It comprises four elements:

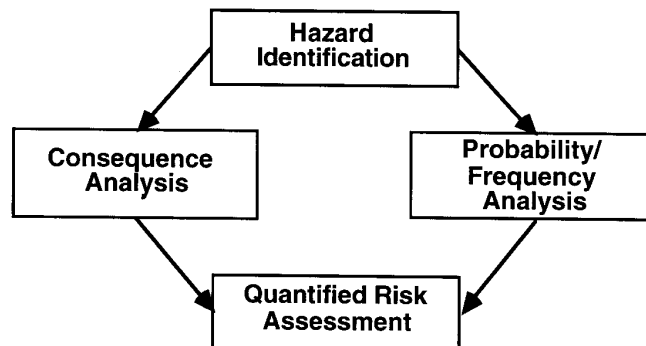
Hazard Identification consists of systematically identifying hazardous events, their potential causes and their consequences — in qualitative terms.

Consequence analysis consists of estimates of the effects of potentially hazardous incidents. This step relies on mathematical models and computerised tools. The outcome of a consequence analysis will be a quantitative estimate of the hazard.

Probability/Frequency Analysis consists of estimates of the likelihood of incidents occurring and the likelihood of particular outcomes (or effects) should those events occur.

Quantified Risk Assessment refers to the combination of the likelihood and the consequences. Risk results are most commonly expressed in terms of human fatality when industrial accidents and chemicals are considered. Other terms can be used such as levels of injury, property damage or environmental damage.

Figure 3.1 Basic Methodology for Hazard Analysis (From Dept of Planning, NSW, 1994)



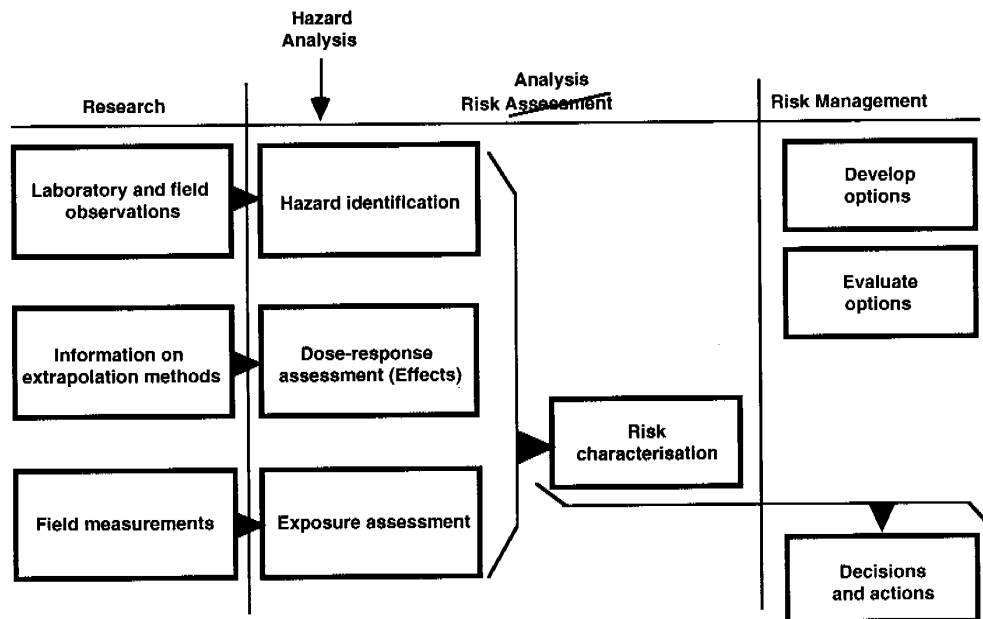
Analysis, assessment and management of risk

Environmental risk analysis considers the risks to human health, welfare and ecosystems that are the result of adverse developmental impacts on the natural environment. When the risk analysis is built into a framework that allows one to identify and characterise potential adverse effects of exposure to environmental hazards then the term risk assessment is used. Because so much has been done, especially in the United States, on risks to human health from hazardous chemicals used or produced in industrial projects the concepts from this area have driven much of the thinking about environmental risk assessment.

American English and Australian English reverse the meanings of the words risk assessment and risk analysis. In the United States, risk assessment refers to the component of the overall process that is devoted to the calculations, whereas risk analysis is the overall process which includes risk assessment, risk management, risk perception and risk communication. In Australia, risk analysis is widely used to describe the component that is devoted to calculations, whereas risk assessment is understood to be the overall process.

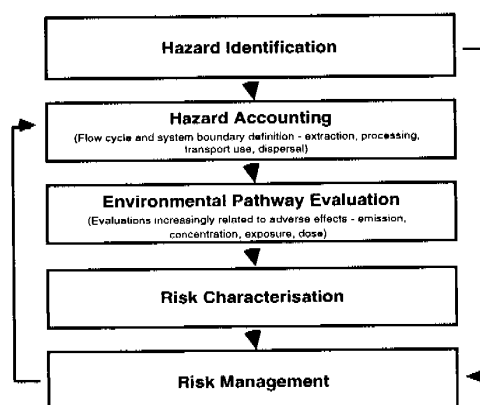
The most frequently cited risk assessment framework (in the US meaning of the term) is that of the National Research Council (1983) which is reproduced in Fig. 3.2. This framework is used by the US EPA for the health effects of chemicals, which they refer to as human-health risk assessment. This framework is based on a belief that most risk assessment problems are similar to those concerning food additives. The framework does not apply equally well to toxics in the environment.

Figure 3.2 Risk Assessment US (1983) Framework (From National Research Council, 1983)



Other criticisms (Office of the Environment, 1991) are that it fails to note the critical importance of carefully and systematically describing the relevant aspects of the project in question, including setting boundaries in space and time. This step is considered necessary to identify the important points where chemical and other hazards may exist. The Asian Development Bank (Office of the Environment, 1991) considers that the National Research Council framework essentially represents the results of such a determination only for a particular set of conditions and management questions. It therefore suggests that the framework of Smith et al. (1988), as shown in Fig. 3.3, is more appropriate. In fact, the US EPA when developing their guidelines for ecological risk assessment (US EPA, 1992) also felt that the framework of Fig. 3.2 was not the most appropriate one and used an alternative (Fig. 7.1) to be discussed in Chapter 7.

Figure 3.3 Recommended risk assessment framework (Smith et al. 1988:23)



It is noteworthy that Fig. 3.2 considers risk management to be separate from risk assessment, whereas Fig. 3.3 integrates risk management into the risk assessment framework. The concept of separation, strongly espoused by ex-US EPA administrator Ruckelshaus (1985), sees regulators (such as the US EPA) who, in striving to support the continued improvement of the science that underpins the risk assessment process, must keep this process separate from risk management, which considers risks in the light of related socio-economic factors. They share a vision of decision making in this process being accomplished at the local level, within broad bounds set at higher government levels.

Paustenbach (1993) also considers the separation of risk assessment from risk management to be the most significant accomplishment of the report of the National Research Council (1983). The purpose of this separation is to ensure that the risk assessment process remains one that is objective. According to Paustenbach (1993), many of the early assessments were so laden with value judgments and the subjective views of the risk assessors that the risk manager was unable to separate the scientific interpretation (the risk analysis, within the terminology that we are using), from the wishes of the risk scientist.

This issue of the separation of management and analysis tasks is related to the ethos of the organisation. If an organisation considers itself to be composed of technicians and regulators, then the US orientation is appropriate. If the organisation sees its role as management and policy analysis, then it is not necessarily appropriate to insist on a clear separation between the analysis and management functions.

Risk communication

Following the favourable reception of the 1983 report of the National Research Council (1983), the emphasis in the United States turned from risk assessment to risk communication (Plough & Krinsky, 1987). A National Research Council (1989) report emphasises that risk communication is more than one-way communication of risk messages from experts to non-experts. Risk communication is an interactive process of exchange of information and opinion among individuals, groups and institutions.

These bland words hide the fact that environmental priorities need to reflect the risks perceived by the community. Experts primarily interested in risk communication have suggested that this can be expressed by using a definition for risk based on community perception as follows:

$$\text{RISK} = \text{HAZARD} \times \text{OUTRAGE}$$

Health risk assessment , ecological risk assessment, and comparative risk assessment

The literature on environmental risk assessment is divided into three major areas: health risk assessment (Paustenbach, 1995), which deals with the effects of chemicals on the human population, the recent notions of ecological risk assessment (US EPA, 1992; Suter et al., 1993) and, more recently, comparative risk assessment (Davies, 1995).

Much of the development of health risk assessment is the result of work done outside environmental agencies. Ecological risk assessment, by contrast, is a more recent activity that integrates numerous techniques from ecology, environmental systems analysis and traditional engineering risk analysis to use them in a risk assessment framework. This approach has produced some useful advances in that attention is directed to the common elements of the disciplines in the search for a synergistic approach that combines the best elements of both.

The United States EPA was also a major motivating force in the use of risk assessment as a tool with which to determine environmental priorities (Davies, 1995). This has already been mentioned in Chapter 1. The issue of comparative risk analysis rose to the top of the environmental policy agenda in the 1990s because the budgetary squeeze at all levels of government made it obvious that not every environmental problem

could be addressed — somehow priorities had to be set. One of the strengths of the comparative risk assessment process is that it encourages people to take a much broader look at the environment than they would if they focused only on a single agency's existing programs, as typically happens in the budget process (Minard, 1995).

The United States experience

An overview of the United States approach to science-based environmental management, and its strong reliance on risk assessment to provide quantitative answers, may be found in a special issue of *Technology: Journal of the Franklin Institute* (Moghissi and Tise, 1994) devoted to this topic.

Health Risk Assessment

The United States experience with risk assessment, primarily health risk assessment, is dealt with by the National Research Council (1983, 1989). The use of risk assessment in regulatory decision-making necessitates a decision on which substance to regulate. This depends in part on the degree of hazard, so risk assessment has been used (either explicitly or implicitly) to set priorities. The United States experience was that risk assessment for priority setting (i.e. choosing from amongst the range of substances to regulate) was more informal, less systematic and less visible than those for establishing regulatory controls.

Agenda setting involves decisions about which substances to select, and in what order, for more intense formal regulatory review. In this phase there must be some assessment, however informal, that indicates reason for concern. Chemicals that are judged to present appreciable risks to health are candidates for regulatory action and an agency will begin to develop options for regulatory exposures. An important point here is that priority setting and regulatory option determination place different requirements on risk assessors. A risk assessment to establish testing priorities may incorporate many worst-case assumptions if there are data gaps because research should be directed at substances with the most critical gaps. But such assumptions may be inappropriate for analysing regulatory controls, particularly if the regulator must try to ensure that controls are acceptable and comprise 'good law' to the extent that they are, by and large, complied with and can be enforced. In establishing regulatory priorities, the same inference options should be chosen for all chemicals, because the main point of the analysis is to make useful risk comparisons so that agency resources will be used rationally.

Ecological risk assessment

The US EPA (1992) published a framework for ecological risk assessment and followed this up with policy guidance for managers that have to deal with ecological risk (Troyer & Brody, 1994). The framework constitutes an interim product to be refined at a later stage with the production of formal risk assessment guidelines. The report (US EPA, 1992) defines ecological risk assessment as 'a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors'. A stressor includes any chemical, physical or biological entity that can induce adverse effects on individuals, populations, communities or ecosystems. The term stressor is a deliberate attempt to replace the term 'dose-response' and steer conventional views in risk assessment to include risks due to elements other than chemicals. The framework for ecological risk is similar in concept to the human health risk guidelines (National Research Council, 1983), but there are three areas of difference:

- i) it considers effects beyond individuals of a species and examines populations, communities or ecosystems as appropriate;
- ii) there is no single set of ecological values to be protected that can be generally applied; and

iii) non-chemical, as well as chemical, stressors are considered.

The United States attitude towards risk assessment has, in many cases, flowed from legislative initiatives. For example, the 'Delaney clause' of the Food Additive Amendments of 1958 stipulated that no additive that was found to be carcinogenic could be allowed in the food supply, on the grounds that it was not possible to specify a safe human exposure to such an agent. Quantitative risk assessment is seen as attractive because, at least ideally, it allows decision-makers and the public to discriminate between important and trivial threats — thus going beyond qualitative findings that there is some risk, however small. The Clean Air Act, and the 1990 Clean Air Act Amendments, required the EPA to enter into a contract with the National Research Council (NRC) to create a committee to report on risk assessment of hazardous air pollutants (National Research Council, 1994).

Comparative risk assessment

During 1995 the Republican party introduced a number of bills in Congress dealing with risk assessment requirements. The first of these, known colloquially as the 'risk bill' (Title III of H.R.9), requires federal agencies to conduct comprehensive risk assessments before issuing any new regulation. It also mandates cost-benefit analyses for any proposed rule for which compliance would cost industry more than \$25 million, with the results of such analyses determining whether the rule would be issued. This bill and HR1022, which is the Risk Assessment and Cost/Benefit Act of 1995, have been supported by industry but denounced by environmental groups and the EPA. An official statement by the US EPA administrator, Carol M. Browner, in early February 1995 says:

"The risk bill purports to be an application of sound science; in truth, it perverts not just science but also common sense. It mandates a costly, procedural maze that will delay or stop the public-health protections traditionally enjoyed by all Americans. Under the provisions of the bill recently marked up by the House, EPA could not have banned lead from gasoline or dangerous pesticides like DDT. The House Committee actions to date dictate new, costly procedures that would supersede all existing laws. This means 20 years of protections for our children and our air, our land and our water are being rolled back in the dead of night without even a thoughtful debate in Congress. Risk analysis is an important tool that is already used to assure all major rules are scientifically justified. Requiring it for every single action is neither fair, effective nor affordable. We strongly urge Congress to rethink this hastily drafted and potentially detrimental measure."

A subsequent statement on HR1022 indicated that the EPA would be working with the Senate to oppose these bills.

In discussing this matter during a visit to the United States the view was expressed that the present congressional interest in risk assessment arose from concerns of industry and state governments that they had to spend considerable sums to comply with EPA requirements. Risk assessment was perceived as the only tool with which to fight Federal requirements. Until two years ago no congressman had heard of risk assessment, which was then merely a decision-making tool within the EPA. Environmental groups have strongly opposed risk assessment, most probably because risk assessment expertise lies within industry and they feel correspondingly disadvantaged.

Much of the value in comparative risk assessment is in the process itself. It forces people to think systematically about the issues and determine their priorities. At the moment it appears that the US may require risk assessments and cost-benefit analyses to be done, but there is no enforcement mechanism.

The judicial reviews of regulations that occur in the US as a result of court actions are an important driving force for risk assessment. Courts, in determining truth (as opposed to accepted truth) need to know how to make determinations. These events have led policy makers to see risk as the most probable estimate of the risk, not the upper bound estimate of risk which has, in the past, been advocated on the grounds of environmental conservatism.

The US EPA wants national environmental protection that is informed by risk assessment, but not dictated by risk assessment.

Superfund

The Comprehensive Environmental Response, Compensation and Liability Act (CERCLA, better known as Superfund) provides the legislative framework (and authorises the funding) for the US Department of Defense clean-ups at its military bases, the Department of Energy's clean-ups at the nuclear weapons plants and for the US EPA to clean up sites that pose serious health and ecological risks.

Superfund provides a mechanism to rank such sites. The most troublesome are placed on the National Priorities List. Towards the end of 1994 there were 1 286 such sites on the list. (Portney & Probst, 1994). The law also established a process for determining the appropriate clean-up approach. It created several new federal taxes to fund a trust fund that is used on an emergency basis to finance clean-ups, or on a long-term basis to finance clean-up at sites where no responsible party can be found and made to clean up the site. Further, the Superfund law created a mechanism to enable the EPA to identify responsible parties and require them to pay for clean-up.

Section 121 of Superfund calls for a clean-up that "utilizes permanent solutions and alternative treatment technologies..to the maximum extent practicable" at each site. This innocuous wording appears to rule out a risk based approach to remediation --- in which the extent of the clean-up depends on the seriousness of the current health risks that a site poses. Portney & Probst (1994) give the example of a site near a residential area. The site was once an industrial dump but is now fenced off and currently vacant. The soil at the site is contaminated but is not contributing to the contamination of the groundwater. In view of the low risk presently posed by the site some people claim that it would be appropriate to cap the site to contain the contamination, build a stronger fence and continue to monitor.

Many in the environmental community and Congress do not believe that the above approach would be a permanent remedy, believing that a permanent remedy is one that goes well beyond containment, extending perhaps to the excavation and incineration of contaminated soils or the pumping and treatment of groundwater. They would balk at a remedy that would reduce exposure to contamination without removing the contamination itself.

The Department of Energy, faced with similar problems in relation to its nuclear weapons complexes, requested the National Academy of Sciences to assess whether a risk based approach to evaluating the consequences of alternative remedial actions is feasible and desirable (National Research Council, 1994b). The conclusion was that it was both feasible and desirable for the Department of Energy to undertake the necessary, credible, scientifically-based risk assessment program to define, on a major site-by-site basis, in a meaningful way, the major long-term product and health and environmental risks at their sites.

Major contractors to the Department of Energy, such as Battelle or Argonne National Laboratory (MacDonnell et al, 1994), already use integrated risk management in their program of managing contaminated sites. Figure 3.4 provides a schematic of the integrated risk management approach used by Battelle to determine risk management strategies.

Canada

Toft & Meek (1993) note that the concept of identifying and evaluating potential risks associated with industrial chemicals before they are manufactured or imported has been incorporated into the new Canadian Environmental Protection Act of 1988. Canada uses a three step process of health risk assessment and risk management:

1. Hazard identification
2. Risk estimation
3. Option evaluation

Figure 3.4 Integrated Risk Management



The first two of these refer to risk assessment whereas the third deals with risk management. The new substances program deals with chemicals, polymers and the products of biotechnology. It aims to ensure that no new substances are introduced that are harmful.

The Canadian Act also deals with existing chemicals by requiring establishment of a priority substances list (PSL). The definition of toxic chemicals is on the basis of either: (a) immediate or long term harmful effect on the environment; (b) danger to the environment on which human health depends; or (c) danger in Canada to human life or health. In this activity, the Canadians use a definition of risk as ENTRY-EXPOSURE-EFFECTS to obtain a risk definition based on the letter 'E'. In determining the priority substance list (PSL) there are flowcharts to assist with evaluation of each of the three components of the risk.

Environment Canada is presently extending PSL from a list based on human health effects to a second list based on ecological effects (e.g. effects of hexachlorobenzene on mink on the St. Claire River).

Canada has recently produced a framework for ecological risk assessment (Gaudet, 1994) as part of the national contaminated sites remediation program. As may be expected, the framework considers receptors and ecological effects to populations rather than to individuals in the species. It also accepts that each site is unique and sets no single level of protection for ecological systems.

The unique feature of the Canadian framework is its three tier approach which allows the ecological risk assessment to be tailored to the level of complexity of the problem. The first tier (level one) is a simple, qualitative comparison based on previous data and literature — often descriptive in form. The second tier (level two) is semi-quantitative with emphasis on standard environmental methods and models. The third tier (level three) uses site-specific data to undertake predictive modelling, using quantitative information on complex ecosystem responses.

There is a separate agency — Pest Management Regulatory Agency — set up on 1 April 1995 that deals with pesticides. This agency favours field trials to test the toxicity of chemicals.

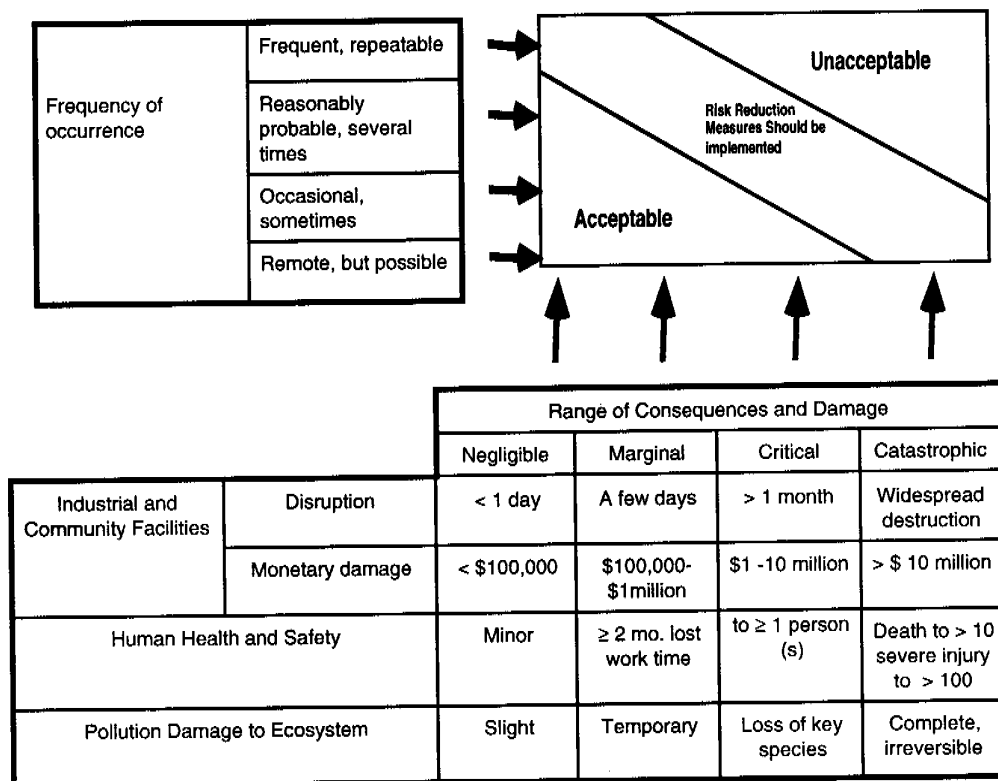
Asian Development Bank

The Asian Development Bank (ADB) has published a lengthy report (Office of Environment, 1991) dealing with environmental risk assessment. The report is divided into three parts:

- Part 1 Review of the state of the art of environmental risk assessment;
- Part 2 Guidelines for environmental risk;
- Part 3 Case examples

The guidelines for Part 2 consist of methods by which one may determine whether a risk analysis needs to be done, rather than guidelines for doing the risk analysis. The guidelines are designed to enable an analyst to categorise a development project on the basis of the frequency of occurrence of risks and the severity of consequences or damage. A full risk assessment is undertaken only when a project falls outside the region marked as acceptable in Fig. 3.5. The case examples of Part 3 then deal with case studies in determining where a proposed project lies on Fig.3.5. The location on the figure indicates whether a full risk assessment needs to take place.

Figure 3.5 Risk Assessment - Asian Development Bank Evaluation Matrix



Netherlands

The Dutch National Environment Protection Policy (Directorate General for Environmental Protection, 1988) aims to protect the structure (the species) of an ecosystem and by doing so also protecting the function (the qualitative and quantitative distribution of species) of the ecosystem. The Netherlands has recently published risk limits of chemical substances in soil, air and water (Directorate for Chemicals, External Safety and Radiation Protection, 1994).

Criteria in the form of risk limits are set such that exposure of a listed substance at a concentration below the limit should not result in adverse effects to humans or ecosystems. Three risk limits are considered:

- i) Serious contamination risk concentration. This occurs when 50 percent of the species potentially present in an ecosystem experience hazardous effects as a consequence of one or more substances present in concentrations above the no observed effect concentration of these species.
- ii) Maximum permissible risk concentration (also known as maximum tolerable risk). This is the concentration above which the risk of adverse effects is unacceptable. It is set to protect 95 percent of the species, and is derived from an extrapolation model. For human health, this is set at 10^{-6} per year for non-carcinogens and non-genotoxic carcinogens, and is set at 10^{-4} per lifetime for genotoxic carcinogens, based on the no observed effect level (NOEL).
- iii) The negligible risk concentration. This is set at 100 times below the maximum permissible risk concentration.

Until recently, assessment of substances in The Netherlands differed for the various categories of chemicals using different methods and criteria. The need to harmonise the various hazard and risk assessment systems gradually became evident, resulting in the development of the Uniform System for the Evaluation of Substances (USES 1.0) which was launched in April 1994 in support of the Netherlands National Environment Policy Plan.

USES is a decision-support instrument for use by relevant authorities which enables them to make rapid and efficient assessments of the general risks posed by substances, including new substances, existing substances, agricultural pesticides and biocides. It is not designed for comprehensive assessments, but merely allows initial (screening) and more refined assessments to be made. USES 1.0 is available as a user-friendly computer program and we have acquired a copy.

USES considers the expected emissions of a substance and the effects of those emissions, and establishes the hazard quotient, which is the ratio of the potential exposure to the substance and the level at which no adverse effects are expected. Where possible, USES also quantifies the uncertainties in the hazard quotient so that it constitutes a genuine risk assessment. In this way USES determines hazard quotients for several groups at risk: humans; micro-organisms in sewage treatment plants; aquatic ecosystems; terrestrial ecosystems; and top predators.

The hazard quotient for these groups can be determined on both a local and regional scale based on a standardised environment (i.e. USES has not been developed for the assessment of site specific risks). To keep underestimation and overestimation of the risks to a minimum, USES takes a realistic worst case approach, whereby average values are taken, wherever possible, for parameters and variables while the exposure scenario is a conservative estimate.

USES 1.0 is the first version of this system and further development will focus on its current limitations, the main ones being:

- it currently can be applied only to organic substances and is not yet suitable for the assessment of inorganic chemicals, surfactants or ionised substances;
- the uncertainty analysis is still very limited, both for exposure and effects assessment;
- model analysis, including validation, needs further work; and
- hazards such as global warming, ozone depletion, acidification, eutrophication, calamities etc. are not considered.

Acceptance of USES is being pursued amongst European Community (EC) member states and it is hoped formal adoption will occur towards the end of 1996.

A procedure for the assessment of contaminated sites, comparable to USES, has also been developed.

New Zealand

New Zealand has substantial activity underway involving risk assessment. The Hazardous Substances and New Organisms (HSNO) reform, being undertaken by the Ministry for the Environment, seeks to evaluate the risks from introducing hazardous substances or new organisms (including genetically modified organisms) in the New Zealand environment. There are plans to set up an Environmental and Risk Management Agency in June 1996 to oversee this reform.

The Ministry of Health and Ministry for the Environment (1993) recently proposed draft health and environmental guidelines for selected timber treatment chemicals. The risk assessment part of the guidelines follows the US EPA methods.

United Kingdom

The United Kingdom follows a scheme for the assessment of new chemicals that is based on recent work from the OECD that has been harmonised for use throughout the European Community. New chemicals assessment for eco-toxicity is based very strongly on laboratory work, especially aquatic risk characterisation using daphnia, algae and fish. The OECD classification is given in Table 3.1.

The European Community (Official Journal of the European Community, No L 110A/68, 1993) has a system with a number of classes for substances with eco-toxic properties. These classes are divided into those that affect aquatic environments (R50-53, from very toxic to harmful) shown in Fig. 3.6 and those that affect non-aquatic environments (R54-59), e.g. toxic to flora, fauna, soil organisms or bees.

Figure 3.6 Aquatic Environmental Classification EEC Directive

Classification	Risk Phrase	Criteria
Very Toxic (carries symbol)	R50 & R53	a) L(E) C50 \leq 1 mg/l and not readily biodegradable or log P > 3
	R50	b) L(E) C50 \leq 1 mg/l
Toxic (carries symbol)	R51 & R53	L(E) C50 $1 > \leq$ 10mg/l and not readily biodegradable or log P > 3
Harmful	R52 & R53	L(E) C50 > 10mg/l \leq 100mg/l and not readily biodegradable Other evidence allowed on degradability and toxicity may lead to non-classification
Safety Clause	R52 &/or R53	Substances not satisfying above may be considered as being hazardous eg. Poor water solubility

The European Community issued a directive in September 1993 (Directive 93/67/EEC) that requires new chemicals to be subject to detailed risk assessment. This directive fits in with the overall EU scheme as illustrated in Fig. 3.7. The risk assessment decision scheme for substances affecting aquatic environments (Fig. 3.8) is based on determining the ratio between the predicted environmental concentration and the predicted no effect concentration (based partly on the laboratory studies mentioned above). If the exposure exceeds the no effect level, then the substance is considered to have the potential to cause adverse effects and requires refined assessment. One possibility for such refined assessment is that of computer modelling, and the Department of Environment is working with the Dutch on USES, a computer model to deal with the air, soil and water compartments.

Figure 3.7 Decision Making for Controls in the EU

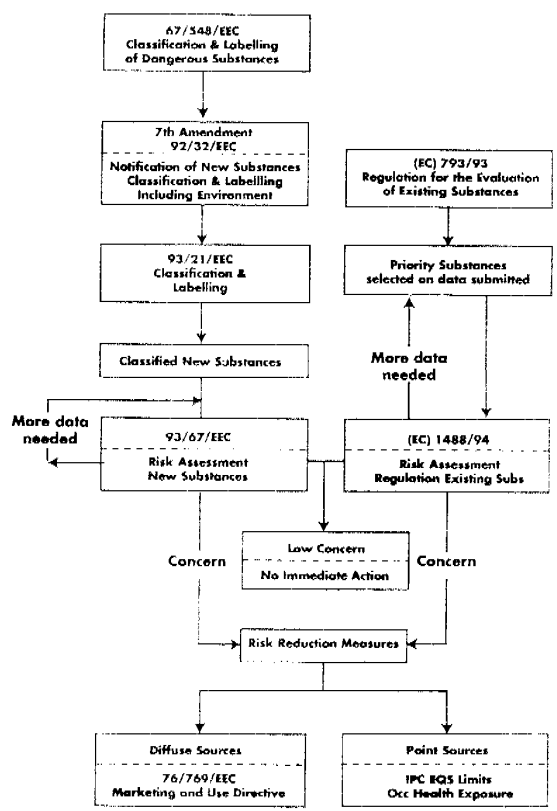


Figure 3.8 Aquatic Risk Characterisation Decision Scheme for Further Testing

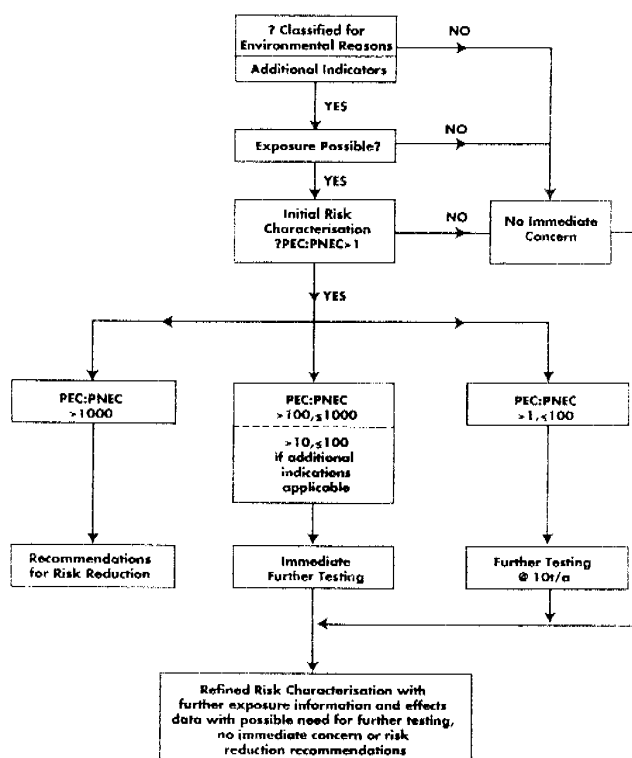


Table 3.1 OECD Threshold Values

Aquatic Acute Toxicity Test			
	Criteria		
	Very Toxic	Toxic	Harmful
96h LC50 fish	≤ 1.0 mg/l	≤10 mg/l	≤ 100 mg/l
or			
48h EC50 Daphnia	≤ 1.0 mg/l	≤10 mg/l	≤ 100 mg/l
or			
72h EC50 algae	≤ 1.0 mg/l	≤10 mg/l	≤100 mg/l
<i>Bioaccumulation</i>			
Kow > 1000 unless Biological Concentration Factor is less than 100			
<i>Bio-degradability</i>			
BOD ₅ /COD ratio < 0.5			

Source: Ministry for the Environment (1994)

Her Majesty's Inspectorate of Pollution (HMIP) in association with the consulting firm Technica-DNV has established CIERA (Centre for Integrated Environmental Risk Assessment) as a joint initiative to focus on four priority areas:

- corporate risk management for setting HMIP national priorities;
- regional risk management for regional priorities;
- site risk management for local site priorities; and
- inspection and monitoring prioritisation using risk technology.

CIERA is in place until the UK establishes a new Environmental Agency which is expected to occur probably in 1996. This will combine HMIP, the River Authorities and the Waste Authority.

CIERA is expected to deal with both top and tail issues.

Top issues: Risk identification, hazard identification setting boundaries and objectives for studies.

Tail issues: Decision making, risk reduction measures and strategies, cost-benefit analysis, risk communication, monitoring and feedback.

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