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RISK ASSESSMENT AND ITS USE IN MANAGEMENT - A STATE-OF-ART REVIEW

by
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One of the major environmental issues at present is the control of risks due to the formulation, manufacture, use, and disposal of chemicals. Control measures of various kinds are being designed and implemented in many countries, as well as through international organizations. The extent and type of controls are based upon assessments of the risks - as well as the benefits - of the chemicals.

The purpose of this review is to outline current methods of risk assessment and examine how these are, or could be, applied to the management of toxic chemicals. Thus, the coverage of this review extends to risk management, which attempts to incorporate both scientific analysis and political judgement. Within this framework, the main methods available, their status and limitations, and the major issues involved will be identified.

In setting such a broad task, the coverage is - of necessity - fairly general, with illustrative examples included where appropriate. The review is largely aimed at the users rather than the producers of risk assessments, even though the latter probably do not exist as a clearly identified group. The term "user" means the decision-maker or risk manager at international, national and local levels. The review addresses assessment of direct risk to human health; impacts on nonhuman targets are not considered.

Scope of Risk Assessment and Management

Coping with risk has always been a feature of life in all societies. A variety of means have emerged for human beings to deal with environmental risks, and these coping actions can either be classified as adaptations or adjustments (1). Adaptation usually occurs through gradual, long-term responses, both natural (e.g. selection processes) and cultural (e.g. societal taboos, norms). Adjustments tend to be shorter term, conscious responses including the regulation of risky activities.

Explicit recognition of manmade risks was first documented, not surprisingly, in the workplace. The mining and smelting of, and commerce in, gold, silver, iron, copper and lead gave rise to the first publication on occupational disease in 1472 entitled, "On the poisonous, evil vapours and fumes of metals" (see ref 2). In the Middle Ages, formal evaluation of risk and the associated level of uncertainty also arose with the provision of insurance for cargo loss in maritime commerce. These early risk assessments were simple, straightforward and based directly on a large body of real data. These data, obtained from empirical records of past losses, were used to make quantitative estimates of expected cargo loss (3).

The recent rapid rise of risk assessment and its use in risk management can be linked to two events. The first is World War II, which led to the development of statistical techniques for predicting failure and reliability of aircraft, radar and other components. The techniques developed became known as "operations research". The second event was the growth of the environmental movement in the 1960s and 1970s. Books such as Silent spring (4) painted an evocative - if not totally objective - picture of the possible impacts of pesticides. "Pollution" as an issue was treated on an equal footing with overpopulation, food shortages and natural resource depletion in The limits to growth (5).

Since the early 1960s, public concern in the environment has focused on more specific events and consequences. Foremost are the risks of nuclear power, industrial accidents, such as the explosion at Flixborough, and acute pollution incidents at Seveso (dioxin), Minemata Bay (mercury), London (smog) and Michigan (PBB). The possible consequence of environmental risk that has caused the greatest public concern is cancer, and this fear has been the major driving force in devising and implementing controls on potentially toxic chemicals.

In parallel with rapid growth of environmental concern, the art and science of risk assessment has developed rapidly, leading to a number of major overviews and conferences which have summerized and systematized current thinking. The overviews include those of Lowrence (6), Rowe (7), Kates (1), Burton, Kates & White (8) and Kasperon (2).

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Definition of risk assessment

One major source of confusion is the lack of consensus on definitions of the major terms used in risk assessment, the term, in fact, which has probably given rise to the greatest confusion.

In strictly scientific terms, risk is a statistical concept. It has been defined by the Preparatory Committee of the United Nations Conference on the Human Environment (9) as the expected frequency of undesirable effects arising from exposure to a pollutant. In this way, estimates of risk may be expressed in absolute or in relative terms. The relative risk is the ratio between the risk in the exposed population and the risk in the unexposed population. The absolute risk is the excess risk due to exposure (10). Some workers use the term "environmental risk" to mean the likelihood of adverse consequences for which the probability of occurrence may be highly uncertain (11).

Within the above definition, risk assessment for chemical pollution is the estimation of the nature and likelihood of an adverse effect at various levels of exposure. During the course of decision-making in risk management, however, risks are clearly not only assessed from the statistical but also from the economic, social and political points of view, and these very different considerations are synthesized during the management process. This recognition has led to a much broader definition of risk assessment which includes not only the probability and consequences of certain events but also how societies evaluate them (12).

Since this review addresses risk assessment and its use in decision-making, the latter, broad definition is adopted here. Indeed, the incorporation of both scientific analysis and political judgement is probably the most difficult aspect of the risk management process.

Hazard is an event or act which holds adverse consequences: for chemicals, it is the likelihood that the substance will cause adverse effects at various expected exposure levels.

Impact is an event with consequences that have occurred or are very likely to occur; it differs from risk in that the probability and uncertainty aspects are far less important than for risk.

Components of risk assessment and management

In general terms, risk assessment consists of identification (risk identification), estimation of the likelihood of the risk and the magnitude of its occurrence (risk estimation), measurement of risk acceptance, acceptable levels of risk and alternatives to risk (risk evaluation). Management makes use of risk assessments for the purposes of control.

Risk (or hazard) identification is the process of recognizing hazardous activities, events or substances or their consequences. In the sequence of risk assessment, this process probably constitutes the most important but least studied element (1). According to O'Riordan (13), one feature of the increasing interest in risk assessment is that all kinds of potentially adverse effects, hitherto unexpected, have been uncovered. To a large extent, this increase is a result of improved measurement capability. For example, concentrations of substances in parts per billion or trillion can sometimes be detected. The danger does exist that the mere presence of chemicals will be interpreted as evidence of their hazard; in this way, the whole process of risk assessment would be swamped.

Risk estimation attempts to predict or determine the probability and nature of the likely consequences, including their distribution in space and time. This prediction is generally a very difficult task and, for the case of environmental risks, involves considerable understanding of environmental processes.

Risk evaluation is the process whereby the importance of the estimated risk is evaluated by society. Such judgements may be made in relation to the risk itself, in comparison with other risks, by balancing the risk with the benefits (of the product/activity) or by considering the costs of avoidance.

Risk control is the implementive phase of risk management. It involves decisions relating to the appropriate type and level of regulatory control, its implementation, enforcement and (ideally) re-evaluation of its effectiveness at regular intervals.

O'Riordan (14) considers that both risk identification and estimation have advanced spectacularly as a result of the great current interest in risk assessment. While this result has been generally beneficial, it has often produced anxiety among the public, which is uncertain of the implications of these findings. This concern has placed great strains on the traditional procedures of evaluation and regulation; that is, risk evaluation and control are lagging behind the technically sophisticated phases of identification and estimation.

Types of risk

Environmental risks may be variously classified: type of activity (e.g. explosion, continuous discharge); exposure (e.g. instantaneous, chronic); probability of occurrence; severity; reversibility; visibility; duration; and ubiquity of effect. Burton & Whyte (12) have categorized environmental risks in the context of governmental management, as follows: public health, natural resources, planned economic development, natural disasters and introduction of new products. These domains and the risks inherent in them are, of course, interrelated; availability of natural resources puts certain limits on economic development, and the rate and direction of economic development are major factors in the introduction of new products.

Panorama of risks

Only a few attempts have been made to establish the overall risk from broad societal activities. Harriss et al. (15) have attempted to determine the present burden of technological hazard. For example, they analysed mortality data in the United States between 1900 and 1975, and divided them into acute and chronic causes of death. Harriss et al. noted that chronic causes of death account for about 85% of mortality in the United States and that male life expectancy has not increased since 1950. They conclude that mortality due to technological hazard is not currently rising. In this century, a significant reduction of deaths from acute causes - particularly natural hazards - has occurred. However, chronic causes of death have increased, a finding that Harris et al. state is rooted significantly in technology.

According to O'Riordan (14), "There is now some justification to the assertion that it may no longer be possible to reduce total environmental risk. Efforts to combat risk in some sectors may well produce new hazards in other sectors, probably affecting different groups of people." O'Riordan hypothesizes that "we may be reaching some level of 'environmental steady state' in which extremely costly efforts to reduce risk merely stop the whole penumbra from getting worse".

The absence of an adequate risk panorama means that some emphasis is on methods of comparing risks with the relevant benefits. However, frequent controversies erupt concerning the basis for such comparison. For example, risks can be compared as follows: risks which increase the chance of death by, say, 1×10^{-6}; risks of death by occupation and location; risks from natural and corresponding man-made events (e.g. radiation); or natural and man-made events (e.g. risk from hurricanes versus risk from component failure in a nuclear power plant). The risk assessments may be made on the basis of the worst possible scenario or of the most probable events.

Levels of risk assessment

Risks from individual activities or substances must be considered in the larger context. Individual and isolated management decisions, while reducing risks for the problem in question, may actually increase the total risk or adversely change the distribution of risks and benefits. Although difficult, the assessment of risks at progressively higher levels of decision-making is becoming necessary. In environmental impact assessment of major development projects, not only the advantages and disadvantages of the particular project need to be evaluated, but also the policies within which the proposal was conceived (13).

Assessing the risk of policies and plans which may have environmental consequences offers a number of advantages: it is anticipatory, allowing time for effective preventive action or the examination of alternatives, and it brings environmental factors into the minds of high-level decision-makers. While large uncertainties may exist in risk assessments at that level, they are probably comparable to uncertainties in economic, technological and social factors. Environmental risk and impact assessment of sectoral policies and plans are slowly becoming features of national environmental management systems. In Sweden, for example, the environmental risks arising from alternative energy policies are being assessed (16). A major challenge for risk management will be to provide effective ties between assessments and consequent decisions at the various levels.

Toxic Chemicals Problem

Technological development and economic growth have brought about a rapid increase in the use of natural substances, such as minerals and oils, and developments in chemistry have made possible the synthesis of large numbers of chemicals for use in industry, agriculture and in the home. With the growth of the environmental movement in the 1960s, certain chemicals came under strong attack by the media - and subsequently in many cases by the public - as a result of their unforseen side effects. The main types of chemical under fire were pesticides (in particular DDT), foodstuffs (e.g. cyclamates, mercury in tuna) and pharmaceuticals (mainly as a result of the thalidomide tragedy). Public concern was often translated into regulatory action. In many countries, for example, pesticides are now subject to detailed environmental assessment prior to use. Case histories of individual events of this nature are discussed in Technology and social shock (17), probably the only comparative study of risk management in practice.

However, the main attention of the public, media, pressure groups and government was turned on the evident deterioration in air and water quality in many places throughout the world. In most countries, the main priorities were urban air pollution (e.g. by sulfur dioxide, suspended particulates, nitrogen oxides, carbon monoxide, hydrocarbons and photochemical oxidants, lead, asbestos), freshwater pollution (e.g. biochemical oxygen demand, suspended solids, nitrates, cadmium, mercury, flourides), noise and pollution by pesticides (e.g. DDT).

The precise characteristics of these problems vary from one location to another. However, they are generally "hot spot" problems, arising from a limited number of sources, with sources and targets fairly clearly linked, and with elevated emissions usually resulting in immediate and visible (acute) effects.

In general, these "traditional" pollution problems have been managed through reactive rather than anticipatory measures and institutions. As Krier & Ursin (18) have demonstrated in a case study of the Los Angeles smoke problem, these measures often consist of a policy of "least steps" or "least cost steps". According to Page (11), this reactive approach can be viewed as largely self-correcting for the traditional pollutants.

Pollution control legislation has undoubtedly slowed down and, in some cases, reversed the growth of traditional pollution problems. In the United Kingdom, for example, the reduction of sulfur dioxide (SO_2) and smoke levels in London and the clean-up of the Thames River are visible proof; many other countries have similar success stories.

This improvement is formally documented in the Organisation for Economic Co-operation and Development (OECD) State of Environment Report (19), which surveys trends in pollution problems common to many OECD countries. This report indicates that, from 1965 to 1975, a general decrease has occurred in emissions of SO_2 and particulates, in the levels of suspended solids and biochemical oxygen demand (BOD) in rivers and in the concentrations of DDT, PCB and mercury in wildlife. Upward trends are noted in emissions of nitrogen oxides and in the levels of nitrates in rivers and oil pollution at sea.

Emerging environmental concerns

However, the OECD report also notes that a wider range of substances is being identified as potentially hazardous. Emissions from diffuse sources have generally increased, and concern is growing about chronic exposure to substances which may result in genetic changes and cancer.

Characteristics of toxic chemicals

We are slowly becoming aware of a new and serious threat to human health arising from exposure to certain toxic substances in the home, at work and at play. This awareness has undoubtedly been accelerated by the fact that some of the chemicals are linked to cancer (20). If traditional pollutants have been reasonably well controlled by existing procedures and institutions, can these institutions cope equally well with potentially toxic chemicals and what is the magnitude of the threat?

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Table 1 compares the general characteristics of toxic chemicals with traditional pollution problems.

Table 1. Comparison of general characteristics of toxic chemicals with traditional pollution problems

Category	Traditional pollutants	Toxic chemicals
Numbers	Relatively few (40-50)	ca. 30,000 (71 tn per year
Substance character-istics	Urban and industrial wastes, often in gaseous form	Mainly synthesized products; no counterparts in nature; often persistent
Sources/ emissions	Local, distinct sources or area sources - usually primary	Diffuse sources often through product dissipation
Pathways	Usually fairly direct	Complex; through the environment, through use or both
Exposure of concern	Usually acute: distinct gradients of exposure with distance from source	Highly variable from one person to the next, both in time and space
Effect	Usually visible, immediate and generally reversible	Latent (delayed) subtle effects
	Threshold of response generally accepted	Possibility of dose-response with no threshold

Page (11) considered the characteristics common to toxic chemicals from the point of view of uncertainty and institutional management. He defined nine characteristics:

- ignorance of mechanism;
- potential for catastrophic costs;
- relatively modest benefits;
- low subjective probability of catastrophic costs;
- internal transfer of benefits (i.e. transferred through markets and reflected in the product prices);
- external transfer of costs (i.e. the market mechanism has failed to internalize costs: hence the need for regulation)
- collective risk (i.e. borne by several people simultaneously);
- latency of effect; and
- irreversibility.

Numbers and quantities

During the last decade, about 4 million chemicals have been discovered or synthesized. However, estimates vary as to the number in common use. According to one set of estimates, about 30 000 are made in quantities greater than one metric tonne per annum (21). About 1500 are produced in excess of 500 tons and 100 in excess of 50 000 tons per annum (22). However, according to the Chemical Abstracts Service of the American Chemical Society, 33 000 chemicals were in common use as of November 1977. Environmental Protection Agency (EPA) estimates at about the same time indicate 50 000 excluding pesticides and food additives, for which the estimated numbers are 1500 (EPA estimate) and 7500 (Federal Drug Administration (FDA) estimate) respectively (23). In 1950, the total world production of organic chemicals was 7 million tons, which by 1970 had climbed to 63 million tons, of which about 20 million tons were estimated to be released into the general environment. The expected production figure for 1985 is 250 million tons.

Miller et al. (24) have calculated the global implications of the present quantity of chemicals along the following lines. The surface of the earth is about $500 \times 10^{12} m^2$. Releasing 500 tons per year is, therefore, exactly equivalent to producing enough of a substance to contribute one microgram to every square metre of the earth's surface. If these are concentrated by a factor of 10^3 in rivers and streams, for example, (which account for about 0.1% of the earth's surface), this calculation would mean that producing 500 tons per year could contribute 1 mg per square metre of river surface. At the present time, about 1000 substances are produced in sufficient quantities to have the potential of pollution on this scale. Relatively few substances are toxic at this level, but those that are persistent and are being produced in large quantities could be hazardous. Assuming a continuing annual increase of 2% in chemical production, the amount of chemicals will increase by a factor of 624 during the next hundred years. In addition, large numbers of chemicals also increase the possibility of synergistic or antagonistic effects.

Sources, pathways and exposures

Whereas traditional pollutants are usually emitted through identifiable point sources, chemicals often find their way into the environment after use, for example, discarded products such as batteries, plastics, car components or cans. Thus, chemicals can reach man through occupational exposure, consumer habits and/or through environmental pathways. Through the last means, substances which are persistent, mobile and produced in significant quantities may reach targets which are a long distance from the contributing sources. Some environmental chemicals, sometimes referred to as multimedia pollutants, reach targets through several types of sources and pathways. Perhaps the best known examples are lead and cadmium. For example, lead exposure of any particular individual may depend upon the nearby vehicle traffic (lead in petrol), industrial sources (lead smelters), drinking-water (lead pipes, hard or soft water), type of food eaten (tinned or fresh, local or imported) as well as the products used (lead in paint, cosmetics, batteries, etc.). Although lead has been recognized as a high priority pollutant, the sheer complexity of possible sources, pathways and exposure patterns makes its effective control very difficult.

Effects

Perhaps the most significant difference between traditional pollutants and toxic chemicals is in the nature of the harmful effects. Apart from occasional acute poisonings, the current concern over toxic chemicals relates to their effects following long-term, relatively low-level exposure. These effects are difficult to identify or control for two main reasons. The first reason is uncertainty: we do not know which substances are toxic, by what routes they reach their targets and who will be exposed to them. The second reason is latency of effect: the harmful effect may occur many years after the onset of exposure. These periods are thought to range between 10 years and 40 years. Latent effects are often the most feared and include carcinogenicity, mutagenicity and teratogenicity.

These long latencies and the nature of the effects mean that once the effect has become manifest, the possibility for control action is gone. Even after the effects have appeared in a number of people, the cause seldom becomes clear: the people affected will have lived in various locations, will have worked on a number of jobs and will have had different and changing dietary and consumer habits. Also important to remember is that each individual in a population may have a different susceptibility to a chemical. The only significant exception may be effects which occur upon occupational exposure to a particular chemical or group of chemicals. In this case, the affected group may be relatively easy to identify, and retrospective epidemiological studies can often pinpoint the causal agent(s).

Health burden

Our understanding of the overall risks or health burdens from the manufacture, use and disposal of chemicals is certainly no better, and probably worse, than that for other types of risk.

Although cancer is the second highest cause of death in many countries, our understanding of the possible link between cancer and toxic chemicals is elementary. For example, a Royal Society study group (25) stated the following:

> "A high proportion of cancers, perhaps 85%, were thought to be environmentally determined in the sense that, given different environments, the incidence of most types of cancer would vary. Many specific hazards of cancer had been traced to occupational exposure to chemicals in industry, though such hazards were not likely to account for more than about 1% of all cancers now occurring in the UK. A few other cases could be attributed to pollution by

industrial products or industrial waste
(e.g. respiratory cancer attributable to
asbestos dust)."

This figure for the incidence of cancers attributed to occupational exposure can be contrasted to a report which appeared in the United States at about the same time under the auspices of the National Cancer Institute (NCI), the National Institute of Environmental Health Sciences (NIEHS) and the National Institute for Occupational Safety and Health (NIOSH) (26). The summary of this report stated that "... projections suggest that occupationally related cancers may comprise as much as 20% or more of total cancer mortality in forthcoming decades".

Comment upon these statements is outside the scope of this report and the expertise of the author. However, the discrepancy is an indication of the difficulty of gauging the dangers of chemicals - even in the occupational environment, which is certainly less difficult to assess than is the general environment. If the Royal Society estimate is correct, cancer resulting from occupational exposure accounts for 0.3% of all male deaths in the United Kingdom; if the NCI estimate is more realistic, the relevant figure rises to about 5% of all deaths (27).

Main chemical groups

Chemicals may be classified in various ways: no ideal classification exists, and each approach has its advantages and disadvantages. The value of classification is to organize the required information in an orderly fashion.

Holdgate (28) has shown some alternative systems for classifying pollutant substances. Holdgate's main categories are by nature, properties, sectors of the environment, source, patterns of use, and target and effects. This system is broadly applicable to chemicals in general. The main addition to the Holdgate list would be consumer articles.

Perhaps the simplest classification is according to the main divisions of regulatory control, which are generally according to chemical use and life cycle stage. The main use categories are: chemicals used in industry; chemicals used in household/consumer products; chemicals in agriculture; chemicals as food and feed additives; and toxic/hazardous waste. For each of these categories, all or several of the following life stages may result in some risk and, therefore, need control: development, manufacture, packaging, labelling, storage, transport, marketing, import/export, use/applications, disposal, and emission/discharges.

Risk Assessment of Toxic Chemicals

The preceding sections illustrate the general nature of the toxic chemicals problem and the main factors involved in risk assessment methodology. In this section the current methods, problems, issues and status of risk assessment of toxic chemicals will be considered. The three components of risk assessment - identification, estimation and evaluation - will be considered separately because the data, expertise and methods are very different in each case. The section on risk management is intended to clarify how these components are interconnected in practice.

A number of illustrative and highly idealized schemes have been proposed for environmental health decision-making (28-30). Table 2 attempts to synthesize these schemes and relate them to the main components of risk management.

Hazard identification

Identification of the existence of a hazard is probably the most important but least studied component of risk assessment (1). Identification can occur at various stages along the chemical life cycle (Table 3).

In broad terms, identification may be of a new chemical (or its effect), of changes in the sources, pathway and exposure to existing chemicals or of additional scientific information which may throw some new light on a problem. Identification occurs by means of anticipation or discovery. Anticipation implies the use of some predesigned detection system whereas discovery is often a random event.

Table 2. Synthesized scheme for environmental health decision-making as related to components of risk management

Scheme	Components of risk management
1. Identify the hazardous agent and the broad nature of the hazard	Identification
2. Determine the level of priority in relation to other chemicals	Estimation
3. Define conditions of exposure levels, target groups, trends in time	
4. Establish dose-effect and dose-response relationships for the chemical	
5. Relate exposure (3) to likelihood and nature of effect (4)	
6. Evaluate the costs, risk and benefits of the chemical and/or activity	Evaluation
7. Evaluate the acceptable level of risk to the various targets	
8. Specify the type and level of control required to achieve acceptable risk	Control
9. Implement and enforce controls	
10. Review actual risk levels and effectiveness of the controls applied	

Table 3. Hazard identification at various stages of chemical life cycle

Stage	Method	Type
Predevelopment	Forecasting	Anticipation
Premanufacture	Screening	Anticipation
Emission Pathways to targets (by environment or use) Exposure	Monitoring	Anticipation or discovery
Effect/response	Diagnosis	Discovery

The methods of identification are forecasting, screening and monitoring. Forecasting is the systematic identification (analysis and evaluation) of the potential effects of technological developments on human health (31). Screening is a standardized procedure applied to classify products, processes, phenomena or persons for their hazard potential (1). Particularly for new chemicals, screening is carried out through notification and approval procedures. Monitoring is the process of multiple observation for defined purposes of one or more elements of the environment (32). Most important, monitoring should be carried out for specific purposes or objectives, and these objectives are generally to be seen in the context of environmental management. Monitoring is a particularly useful technique for the identification of existing chemicals in the environment. It is also a particularly useful technique for the identification and assessment of symptoms or effects in relation to their possible causes.

The longest time-scale of anticipation is provided by technological forecasting. A number of techniques are available which can be divided into these groups:

intuitive (brainstorming); exploratory (trend extrapolation, precursive events and scenario writing); and normative (33). The development of these techniques depends on the establishment of the relationships between production, use and disposal of chemicals on the one hand, and factors such as industrial and economic growth and changes, population growth, urbanization, technological advances and societal patterns on the other. Even if forecasts are developed, their proper use is not easy to ensure; governments rarely have great interest in looking ahead to the next 10 to 20 years.

Perhaps the best-known forecast was Limits to growth (5). Here, certain functional relationships were assumed between economic growth, population growth, pollution generation, resource extraction and food production. The most detailed technological forecast at the global level was produced by Leontieff et al. (34). This forecast was a general purpose input-output economic model constructed to study development in relation to environmental issues. The world was divided into 15 regions and 45 economic sectors. The model forecast for 1980, 1990 and 2000 included levels of emissions of airborne particulates, biological oxygen demand, nitrogen nutrients, phosphates, suspended and dissolved solids, solid wastes and pesticides and assumed four different levels of pollution.

At the national level, realization is growing of the need to identify and assess the long-term consequences of sectoral policies and plans. In Sweden, for example, a governmental commission assessed the long-term risk to public health from the use of fossil fuels and nuclear power (16). In the United Kingdom the Royal Commission on Environmental Pollution examined the relationships between possible agricultural developments to the year 2000 and agricultural pollution (35).

Both cases deal with relatively few, reasonably well-known pollutants. The growth in the quantity, numbers and types of chemicals used in industry and agriculture and by consumers and the consequent implications for health have not been forecast. However, a simple trend extrapolation of the growth in the volume of organic chemicals was made by Korte (22).

Forecasting at the level of particular technologies or processes can also be useful. For example, the health effects of changes in raw materials, process conditions, methods of release and disposal can be used to estimate trends in overall risk from specific industrial processes. This type of forecast is very similar to the requirements of environmental impact assessment. Identification and estimation of risk on a process-by-process basis is being carried out through the WHO/EURO programme entitled "Priority problems in toxic chemicals control in Europe".

Screening has become particularly important as a method of risk identification and estimation as a result of the introduction of mandatory notification procedures for new chemicals. Countries which have enacted toxic substances controls along these lines include the United States, Member States of the European Economic Community (Belgium, Denmark, France, Luxemburg, Federal Republic of Germany, Ireland, Italy, Netherlands and the United Kingdom) as well as Canada, Japan, Norway, Sweden and Switzerland. Some member countries of the Committee for Mutual Economic Assistance (CMEA) have also implemented such legislation. We shall return to the subject of notification in the section on management. For the purposes of identification, compulsory notification of new chemicals significantly enhances the process of identification. However, the danger exists that the identification of chemicals by other means may be somewhat neglected because notification is apparently effective. This situation would pose a problem for existing chemicals, for the by-products, breakdown products, etc., of new chemicals which cannot be notified and for notified new chemicals which have a significantly different impact from the predictions of premarket testing.

The establishment of notification requirements has been an important factor in the growth of data banks on chemicals. They provide a valuable service in extracting relevant information from the published literature. This service helps regulatory agencies, industry and public interest groups to identify chemicals or chemical "families" which may pose various types of risk to humans and the environment.

At the international level, two major chemical data banks have been established: UNEP's International Register of Potentially Toxic Chemicals (IRPTC) and EEC's European Chemical Date Information Network (ECDIN). IRPTC, for example, has information on about 30 000 chemicals (36). When complete, a data set in each substance will include, as far as possible: chemical and physical properties; production and use; movement, distribution and transformation in the environment; concentrations in air, water and food; effects on humans; effects on the environment, including sampling, analysis and spills; and relevant national and international controls.

While premarket screening by notification procedures is a major development in the identification of new chemicals, the very large number and quantity of chemicals already in use and in the environment will continue to pose the greatest problems in the foreseeable future. For the latter group, monitoring is perhaps the most important tool of identification.

Monitoring systems can be divided into those that measure any changes in the distribution and performance of targets (target monitoring) and those that measure factors which may cause changes in the environment (factor monitoring) (37).

Identification of hazards can occur at various stages in the chemical life cycle and through various types of monitoring, such as emission monitoring, trend surveillance, historical monitoring, ecological monitoring, speculative and proxy monitoring, exposure monitoring and biological monitoring. Other types of monitoring (e.g. pathway monitoring and monitoring in epidemiology) are possible but are more relevant to risk estimation than to identification.

Pollutants may be emitted from point or area sources which are stationary or mobile. Point sources can be monitored relatively easily. Emissions from area sources (e.g. domestic or agricultural) and mobile sources (e.g. motor vehicles) are more difficult to measure directly, and emissions are usually estimated from inventories or from data on input materials and process conditions.

The measurement and statistical evaluation of trends are important tools in identifying pollution build-up. Trend surveillance systems acquire particular importance in the absence of statutory ambient standards or objectives as, for example, in the United Kingdom. A significant proportion of the monitoring effort at the national level is tied up in two major surveillance networks: the National Survey of Air Pollution and the River Pollution

Survey. The former includes measurement of SO_2 and smoke levels at about 1100 urban and 200 rural sites: additional pollutants are now also measured at some of the sites. The River Pollution Survey is a periodic assessment and classification of the quality of some 39 000 km of rivers and canals in the United Kingdom according to four classes, ranging from clean to grossly polluted. The category assigned depends upon parameters such as BOD, suspended solids, toxic substances content and number of complaints.

In some cases, environmental variability in space and time is such that the "signal" can only be separated from the "noise" if sufficiently long-time series data are available as, for example, in the study of climatic change in which several cycles of various "wavelengths" are working: seasonal, annual, sunspot, magnetic, etc. "Change" is difficult to separate from "variability". In other cases, current pollution problems need to be seen in a historical perspective to evaluate their significance. This situation is particularly relevant for priority pollutants, such as lead, which have both natural and anthropogenic cycles. In most of these situations, environmental monitoring has not been carried out for a sufficient length of time. Then indirect methods may be possible, including chemical analysis of tree rings, museum specimens and sediment profiles. Such methods are sometimes referred to as historical monitoring. For example, analysis of snow profiles in Greenland has revealed that lead levels there have increased fivefold since 1850 and 100-fold since 800 BC (38). This kind of information helps to put current pollution levels and future trends into perspective.

Ecological monitoring may be useful in two ways: for synoptic measurements of pollution levels and for measurements of the bio-accumulative properties of certain substances. When a pollution problem has been identified, a synoptic picture of the scale and nature of the problem is often useful. These synoptic measurements can then indicate where more specific and precise monitoring is required. Such initial surveys may need to be carried out as quickly and as cheaply as possible. In these cases biological materials may be useful. For example, certain mosses have been extensively used to study the regional patterns of metal deposition from the atmosphere. Studies have shown that "moss bags" made from the mosses provide quantitative and reproducible results. Moss bags are inexpensive to make, do not need electrical power and can therefore be exposed cheaply to cover a number of sites over a large area.

Certain organisms accumulate chemical substances from the air, water, soil, etc., and biomagnification factors of 10^5 are not uncommon. Normally, toxic substances occur in the environment in such small concentrations that precise measurements may not be possible or only so with highly sophisticated analytical equipment. In such cases measurements of the levels in biota may be more convenient and informative. An added advantage of such organisms is that they tend to reflect integrated rather than instantaneous exposure. A practical example of this is the Mussel Watch project (39). Pollutants in the marine environment are often in parts per million (or even per billion) concentrations and are difficult to measure. Molluscs (e.g. mussels) have been collected from a large number of central sites around the United States, and the levels of selected heavy metals, pesticides, hydrocarbons and radionuclides have been measured. These measurements provide a very useful comparative picture of pollution over a very large area.

Many substances may be emitted into the environment without the knowledge of the regulatory agencies. Alternatively, some substances transform in the environment, and the transformation products may not be known. In other instances, remobilization of a pollutant may occur. Therefore, with the ever-increasing number and quantity of chemicals in the environment, systematic monitoring for discovery will take on added importance. One approach might be to undertake, at a few carefully selected sites, periodic sampling for as wide a range of substances as possible and using the best techniques available. Such a system may help to discover unknown substances particularly in the atmosphere or reveal unexpected levels of known chemicals. Such an approach might be termed speculative monitoring. In some cases, detection of a particular pollutant in the environment raises the likelihood of certain others being there, as for example, on the grounds of geochemical affinity (e.g. zinc and cadmium). This approach is sometimes termed proxy monitoring.

The routes of chemical exposure to humans are through ingestion (mainly food and water), inhalation (air) and skin contact. However, substantial variations in dietary habits and contact with products may occur among individuals. For the purposes of identification, the monitoring of air, water and food can be useful in recognizing the main groups at risk from particular chemicals as well as overall trends in exposure. A further difficulty arises in the case of pollutants which can reach targets through more than one of these routes. The coordination of the data from individual exposure pathways in such a way that total exposures can be estimated has proven extremely difficult.

Monitoring of various foods for a relatively few trace contaminants, such as lead, cadmium, mercury, arsenic, tin, mycotoxins and the "drins", is carried out in many countries on a regular basis. The information is incorporated into dietary surveys, with representative diets being defined by using questionnaires and other survey techniques. Selective studies on individual foodstuffs which may contain particularly high levels of certain toxins are also carried out. One problem with dietary surveys is the difficulty of considering intake from locally grown food products which are occasionally contaminated from nearby emission sources or from contaminated land.

Drinking-water surveillance has long been practised in most countries of Europe. However, some suspicion has been raised regarding a positive correlation between the softness of water and the incidence of heart disease.

Intake through inhalation can be measured indirectly by monitoring the concentration of the substances in the air. However, Munn (private communication, 1980) has confirmed that the relationship between measured concentrations and actual exposures is rather complex, depending on a number of factors such as surroundings, time spent indoors/outdoors, type of activity undertaken and breathing pattern.

Dermal contact is usually through the use of products, etc. Thus, it varies from one individual to another, and monitoring is of limited applicability. Rather, exposure is predicted or estimated by identifying exposed groups of workers, users, etc., and the extent of their exposure.

A valuable approach in indicating or determining human exposure is biological monitoring, which often provides a more direct indication of total exposure than the measurement of levels in air, water, food or soil. Samples can sometimes be taken from the organ where the earliest detectable effect occurs (e.g. cadmium in the kidney), but more accessible indicators of dose, such as blood, urine, hair or teeth, are more commonly used. Some biological monitoring reflects recent exposure (e.g. lead in blood) while other tissues reflect integrated exposure (e.g. lead in teeth).

The control of the occupational environment is a priority task of all countries, and extensive legislation exists to limit occupational exposure to toxic substances. However, occupational experience can also be quite valuable in identifying and assessing the risks arising from exposure by the general population to lower levels of pollution. This approach is called target monitoring for occupational exposure.

In addition, monitoring of nonhuman targets can sometimes provide early warning of pollution risks to human targets. Monitoring of the effects of pollution on biota may occur at several levels: measurement of biochemical, physiological and behavioural changes in individual organisms; measurement of changes in population parameters; measurement of changes in the distribution and abundance of species; and measurement of community changes.

A number of examples can be cited of the use of ecological surveillance. Aldrin, dieldrin and DDT have sometimes been found to cause reproductive failure in birds: the methylmercury problem was recognized in Sweden from observation of dying birds. Increased SO_2 levels have been detected by the disappearance of lichens. In this case, lichens act as so-called indicator species. Such species may provide useful early warning because they are either sensitive to (or thrive on) the presence of specific pollutants.

The above section has indicated the main types of monitoring which are potentially useful in identification (although inevitably some of the methods described are equally of relevance to estimation and control). At present, however, monitoring is used predominantly for control. This situation is due to two interrelated factors: pollution management has generally been reactive rather than anticipatory and our relative ignorance of environmental processes makes decisions concerning what, where, when and how to monitor extremely difficult (40). Thus, expectations are perhaps unrealistic that monitoring can provide comprehensive anticipatory systems for individual environmental chemicals, bar those of the highest priority. On the other hand, the scope and methods for discovery monitoring may be improved.

However, some advances can be made, given changes in overall management approach. In this connection, the conclusions of a recent study on EPA monitoring, carried out by the US National Academy of Sciences (41), are relevant. The three major conclusions of the report were as follows:

- inadequate use is made of scientific principles in monitoring;
- monitoring programmes are too fragmented; and
- a need exists to monitor for anticipation and discovery: "EPA's exclusive emphasis on monitoring to control sources of pollution rather than to anticipate and discover environmental problems means that these problems are not detected at a sufficiently early stage".

The problems are by no means unique to the United States; they are common to most countries. In view of the ever-increasing number of chemicals in the environment and the growing realization of the possible risks involved, the conclusions must be taken very seriously.

Diagnosis begins with observation of the abnormal - e.g. illness of the individual. Environmental diagnosis is usually of populations rather than individuals. It relies on epidemiological methods and on comprehensive and reliable health data. WHO has identified various types of data registers which would be helpful in the early diagnosis of adverse health effects. They include disease incidence registers, carrier registers, registers of congenital anomalies and occupational health statistics.

Identification of environmental hazard is, at best, haphazard. In general, institutions have reacted to environmental hazards rather than anticipating them. This approach will become increasingly serious, given the rapid growth in the use of chemicals. Mandatory notification schemes are being introduced in many countries that substantially enhance identification of individual new chemicals. Chemicals already in use and/or in the environment will continue to pose the major problems and recognition of their presence or build-up remains of high priority. Monitoring is an essential tool in this effort, but current monitoring systems are not generally usable for identification, particularly of a wide range of chemicals.

One important purpose of hazard identification is to provide the maximum time for preventive action to be taken. For this reason, identification of environmental hazard at progressively higher levels of decision-making should be encouraged. Forecasting is a useful tool in this regard and is able to deal with whole groups or classes rather than individual chemicals. Although at present the uncertainties in such forecasts may be rather large, they are probably no greater than the forecasts in other factors (e.g. economic, social and political).

Risk estimation

Risk estimation seeks to measure the likelihood of an event occurring and the likelihood and nature of the consequences that follow (1). In other words, the risk and nature of adverse consequencies should be related to the causal activity. The four main tasks of risk estimation are specified under step 2, 3, 4 and 5 of the schematic model of risk management (Table 2). Step 2 helps define the type and detail of the estimation required. Whatever that estimation may be, the actual risk estimate for each chemical consists of three steps: determining the conditions of exposure, establishing the possible adverse effects, and relating the estimated (or measured) exposure to the likelihood and nature of the effect.

Ideally, these relationships should be expressed quantitatively and with a fair degree of confidence. However, our capability of assessing sources, pathways, transformation, accumulations and exposures to a chemical on the one hand and of defining the relevant dose-effect relationships on the other is, in general, insufficient to achieve this ideal. In view of the large number of potentially hazardous environmental chemicals and of the limited resources available, the assessment and control of individual chemicals must be based on a clear set of priorities for research, testing, monitoring and control.

Formal or informal priorities for environmental management have always existed. In general, they have been based on experience with individual pollutants or with hazardous activities. Few of these priorities have been established by the use of formal criteria. Rather, public perception, political judgement and scientific appreciation of risk or impacts have been gradually marged through the decision-making process. This informal approach cannot be applied to the vast range of environmental chemicals, and a noticeable tendency is for regulatory agencies to use more formal methods of setting priorities. Two basic steps are involved in establishing priorities: establish criteria by which priorities are defined and apply criteria to the chemicals of concern.

A fact sometimes forgotten is that different types of criteria are used for different purposes. For example, the criteria for ranking chemicals on the basis of their effects on the environment will be, at least in part, different from ranking criteria for effects on human health. Similarly, the criteria for establishing testing, monitoring or pollution abatement priorities all differ to some extent.

In this review we are concerned with priorities with respect to assessment of chemical effects on human health. Setting such priorities in practice inevitably involves political and economic as well as purely scientific judgements and makes priority setting one of the more difficult tasks of risk estimation. The prime factor which determines the degree (or priority) of concern is the possible effect of the chemical on human health; in particular, the severity, ubiquity, frequency or occurrence, reversibility and duration of the effect. However, questions of risk acceptability are also taken into account at this stage. For example, if children are the potential targets (e.g. lead and intellectual development) or if attention has been raised by the media (e.g. chlorofluorocarbons and the depletion of the stratospheric ozone layer), the priority attached to a problem tends to increase.

However, the above attributes of effect are known only if the risk has already been extensively assessed or if adverse impact has occurred. Thus, the criteria actually used to select priorities are based upon measurable parameters which can be used to predict the likely nature of the effects. As such, their determination, even on a comparative rather than on an absolute basis, constitutes a preliminary assessment. Fairly wide agreement exists on these parameters, and the list of criteria below, established by a WHO scientific group (31), is fairly typical:

"- Severity and frequency of observed or suspected adverse effects on human health. Of importance are irreversible or chronic effects, such as genetic, neurotoxic, carcinogenic and embryotoxic effects including teratogenicity. Continuous or repeated exposures generally merit a higher priority than isolated or accidental exposures.

- Ubiquity and abundance of the agent in man's environment. Of special concern are inadvertently produced agents, the levels of which may be expected to increase rapidly, and agents that add to a natural hazard.

- Persistence in the environment. Pollutants that resist environmental degradation and accumulate, in man, in the environment or in food chains, deserve attention.

- Environmental transformations or metabolic alterations. Since these alterations may lead to the production of chemicals that have greater toxic potential, it may be more important to ascertain the distribution of the derivatives than that of the original pollutant.

- Population exposed. Attention should be paid to exposures involving a large portion of the general population, or occupational groups, and to selective exposures of highly vulnerable groups represented by pregnant women, the newborn, children, the inform or the aged."

Considerable resources are required to obtain a reasonable determination of these parameters. For example, environmental persistence is extremely difficult to estimate by testing, and measurements in the environment are much more preferable. At least partially for this reason, criteria for priorities tend to differ between new and existing chemicals. The other reason is that priority setting is probably less important for new chemicals as long as each is assessed to the required level (i.e. in principle, the point at which the benefits of an increment increase in the precision of the assessment is outweighed by the incremental cost of the additional information).

Thus, for the case of new chemicals, the approach is generally to establish hierarchies or tiers of tests. Tiered testing is very well summarized in Gusman et al. (42).

The tendency is to require a minimum set of data, referred to by the OECD countries as "minimum premarket set of data" (MPD). This set usually includes the following: acute toxicity; local effects on skin and eye; potential for allergic sensitization; short-term tests for mutagenicity (which may also be predictive of carcinogenicity); a short-term repeated dose (subchronic) study; selected physical and chemical information; degradation/accumulation data; and ecotoxicological tests with fish, daphnia and algae. The OECD premarket set of data includes all of these elements as well as chemical identification data, production/use/disposal data, analytical methods, recommended precautions and emergency measures.

Subsequent tiers and types of testing depend upon the indications of toxicity from MPD. Researchers generally agree that increasing flexibility is needed at the higher tiers because professional judgements are unavoidable once interpretation of the base set results is undertaken. The factor which is most frequently used to "trigger" higher tiers of tests is volume of production, which is most readily measured and understood. The EEC's directive on dangerous substances (43) adopts this approach, as outlined by Gusman et al. (42):

> "Additional testing beyond the base set may be required by a government if the quantity of a substance placed on the market by a notifier reaches a level of 10 tons per year or a total of 50 tons. At 100 tons per year, or 500 tons cumulative, the government must require an additional group of tests unless in any particular case an alternative scientific study would be preferable. At 1000 tons per year or 5000 tons cumulative, the government

will draw up a programme of tests to be carried out by the notifier in order to enable the competent authority to evaluate the risk of the substance for man and the environment."

In most countries, the priorities for assessment and control are established and reviewed on the basis of past experience and expert evaluation. The criteria are generally used for guidance rather than as parameters to be quantified. For example, although the United Kingdom does not use a formal set of priorities, the following substances are generally agreed to be of high priority for assessment and control: lead, cadmium, mercury, sulfur dioxide and sulfur compounds, PCBs, "drins", asbestos, oil, nitrogen oxides, nitrates, ozone, carbon monoxide, polycylic aromatic hydrocarbons, smoke and particulates.

Hierarchical approaches to the establishment of priorities resemble hierarchical testing sequences for new chemicals. One such system is the subject of a recent draft report by UNEP (44) which proposes a three-stage approach. During the initial screen, a master file of substances for consideration is compiled from a wide range of data sources. This file should include high production volume and high exposure substances, regardless of known toxicity. Ordering on the basis of exposure may sometimes have to be based on categories of use. About 300-400 substances would pass through the initial screen.

At the second stage, health and environmental effects would be considered. The selection would be carried out by an expert panel which would score each substance on an interim list according to its assessment of each of the following factors: carcinogenicity, mutagenicity, teratogenicity, acute toxicity, bio-accumulation, influence of nutrition and infectious diseases on toxicity and environmental effects. This list would contain about 100 substances. At the third stage, final priorities would be selected from the interim list by examining each substance in detail - as far as possible - on its biological activity.

Considerable effort has been devoted to the development of a quantitative ranking system to compare the risks from various chemicals. One of the earliest such procedures was that of Reiquam (45) who attempted to predict future environmental stresses on the basis of the following formula:

$$U_i = P_i R_i \left(C_{i,E} + C_{i,H} + C_{i,R}\right)$$

where: for chemical i, U_i is its total importance (risk rating), P_i is persistence, R_i is geographical distribution, and $C_{i,E}$; $C_{i,H}$; and $C_{i,R}$ are three "complexity indices" which describe the number of interaction with environmental, human and resource systems, respectively. Table 4 shows the resulting list. If only human health considerations are included, then $C_{i,E}$ and $C_{i,R}$ become zero and some changes in the order will occur.

Miller et al. (24) developed a hazard rating scheme based on the following conceptual model:

Environmental input = Total produced x Fraction applied directly to environment + Losses at various stages x Impossibility of containment

Availability to target = Environmental input x Persistence x Transport & dispersion

Toxic response = Availability to target Σ_i Fraction transformed to species i x Fractional bioaccumulation & intake of species i x Toxicity of species i

This model was applied to 20 chemicals and chemical groups: vinyl chloride (chloroethene), N-nitrosodiethylamine (or diethylnitrosamine), benzene, benzo(a)pyrene, dioxin (2,3,6,7 tetrachlorodibenzidioxin), 2,4-D, 2,4,5-T, polychlorinated biphenyls (in general), tetraethyl lead, organotin compounds, mercuric chloride, methylmercury, lithium carbonate, beryllium oxide, thallium (general), nickel (general), mercury (general), lead (general), cadmium (general), and vanadium (especially the n-oxides). Although most of the substances chosen are relatively familiar, many of the required data were found to be unavailable. In general terms, Miller et al. found persistence the most difficult to quantify. However, they concluded that this kind of hazard rating approach may be worthwhile and feasible to