

# **Setting environmental standards**

## **Guidelines for decision-making**

**Edited by  
H. W. de Koning**



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**WORLD HEALTH ORGANIZATION – GENEVA**

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## GUIDELINES FOR DECISION-MAKING

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H. W. de Koning

*Division of Environmental Health  
World Health Organization  
Geneva, Switzerland*



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## Preface

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Awareness about environmental pollution has increased during recent years so that there is now widespread appreciation of the serious health risks and the need for preventive measures. Such measures, implemented voluntarily or through legislation, have many technical and economic ramifications, as well as social and public health implications.

The various aspects of the decision-making process for the development of environmental standards are discussed in this publication from the standpoint of health. Several sections deal with the definition of appropriate health objectives or norms while other sections discuss the strategies and legislative instruments available to achieve these norms. In practice, of course, the decision-making process must be adapted to the overall economic, social, public health, and planning policies of each country. An attempt has been made throughout the text to provide examples and illustrations of how individual countries have done this.

Various procedures related to the decision-making process are described to provide the reader with an insight into and an understanding of what is involved and what uncertainties may surround the information that is being used. More detailed information on these procedures can be obtained from the references cited.

Many experts in different fields have contributed to the preparation of this publication. Some have prepared whole sections, while others have provided comments and suggestions for improvement, participated in meetings or acted as consultants. A list of contributors is given on pp. vi-vii and the contribution of all those involved is gratefully acknowledged. Special mention should be made of the work of Dr W. Muir, Hampshire Research Associates Inc., Alexandria, VA, USA, who, particularly in the early stages of the project, played a significant role in its coordination.

This book is the result of cooperation between the World Health Organization (WHO) and the Environmental Law Centre, which is located in Bonn, Federal Republic of Germany, and forms part of the Secretariat of the International Union for Conservation of Nature and Natural Resources (IUCN). The Centre provided support in the preparation of this publication and technical advice throughout the project. The United Nations Environment Programme provided financial support for the publication of this book.

Comments and queries regarding this publication should be addressed to the Division of Environmental Health, World Health Organization, 1211 Geneva 27, Switzerland.

The views expressed in this book should not be construed as representing either decisions or policies of the International Union for Conservation of Nature and Natural Resources, the United Nations Environment Programme, or the World Health Organization.

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# Introduction

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For this publication, environmental pollution is defined as energy or waste materials that are discharged into the environment where they can cause damage to human health (Holdgate, 1979). This definition excludes potentially hazardous materials used by individuals on themselves, for example, cosmetics, food additives, pharmaceuticals, or tobacco. The toxicity of environmental pollutants depends on their formulation and concentration. For example, the organic combinations of mercury, especially methylmercury, pose a greater hazard than the inorganic mercury salts. Similarly, high concentrations of sulfur dioxide ( $\text{SO}_2$ ) in urban areas can undoubtedly harm both plants and people, even though sulfur is an essential component of all living organisms.

Pollutants may reach man through different pathways, e.g., via water, air, food, or consumer products, but one source usually contributes the major proportion of the pollutant. This pathway is called the "critical pathway". If the environmental health effects of a substance are to be monitored and controlled in the most efficient and economic way, this critical pathway must be identified. If this is not possible, the quality and quantity of total exposure via multiple pathways must be carefully assessed. The absence of such knowledge is one of the principal obstacles to the control or prevention of the adverse health effects associated with environmental pollutants. For example, a child suffering from lead poisoning may have been ingesting lead in drinking-water that flows through lead pipes, in paint or soil containing lead, or in food contaminated by lead through the air, water, soil, or via the food chain. When setting ambient air standards or permissible industrial effluent standards for lead, therefore, it is necessary to consider whether the amounts of lead reaching the child from all other sources should be taken into account.

An additional problem is that some pollutants are chemically very stable and degrade only very slowly. This stability means that the pollutant persists in the environment resulting in its gradual accumulation, for example, in the soil. A well known example of this type of pollutant is the insecticide DDT, but there are many other examples.

For some years there has been a considerable development of environmental policies at the national, regional, and international levels (Schaefer, 1981). The scope of these policies includes both the reduction of pollution and the preservation of natural resources, as well

as the promotion of an improved quality of life. The control of environmental pollution, and in particular the setting of standards, raises difficult problems for governments, because different people, or groups of people, have different views of the extent to which a government should protect its citizens from risk and at what cost. Often it is a question of distribution: who is bearing the risk<sup>1</sup> and who the cost? (Technical Information Project, 1979).

For example, the people living near a waste dump are more likely to suffer the consequences of an accident at the site than people from another area who use its services as a treatment or disposal facility. On the other hand, the immediate neighbours of a chemical manufacturing plant may not oppose its installation, even if the risk involved in the factory siting is similar to that of the waste dump, because they will benefit economically from its presence through the creation of jobs.

It is particularly important to encourage broad participation in the decision-making process since the risk involved is often not evenly distributed; different groups may be particularly affected by environmental pollution for various reasons such as age or nutritional status, as well as for geographical reasons. In addition, the way in which people balance costs and benefits will differ. A major challenge of environmental standard-setting for governments and citizens is learning to communicate with each other about risks and to make decisions on the basis of information that is often incomplete.

Toxicity is the capacity of a substance to cause injury to a living organism. Hazard refers to the potential of a pollutant to induce harm (World Health Organization, 1977). The purpose of environmental health standards is to reduce or eliminate health or environmental hazards.

The assessment of the pollution hazard should be a strictly scientific process—a matter of evaluating probabilities using the best available information about the dispersion of a pollutant and the associated effect on the health of man or other targets. Once the likelihood of a particular level of effect under particular circumstances of emission and dispersal has been determined, value judgements become important; the effects on the socioeconomic system must be considered. The socioeconomic system in turn determines the types of effect that are acceptable, and the measures that may be taken to control the pollution. In practical terms, this control will involve limitation of effluents or emissions of pollutants, of radiation to the environment, or of the exposure of individuals. Another important consideration is prevention of hazard; this is a fundamental factor in the organization of a system of protection for man.

It is becoming increasingly evident that both prevention and control of environmental pollution involve a number of complex societal

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<sup>1</sup> Risk is the probability of unfavourable or undesirable effects appearing as a result of a given exposure.

systems and must be analysed within a framework that is sufficiently broad to include all intrinsic and extrinsic factors that might affect human health and other targets (Davos & Nienberg, 1980). Each society will have a particular legal and procedural framework for making decisions about control measures and for determining whether these should be advisory or mandatory.

The main steps in the formulation of public policy decisions to protect health and welfare from environmental hazards usually occur in two stages, as follows.

## 1. Scientific stage

- (a) *Knowledge of the hazard*—involves identification and characterization.
- (b) *Evaluation of the risk*—establishes the probability and severity of potential adverse effects on health and safety.
- (c) *Assessment of hazard*—determines routes of exposure and estimates the number of people exposed.

At the conclusion of this stage it should be possible to determine the levels of pollutants that do not produce adverse effects and to establish necessary safety margins, thus establishing goals or norms for national environmental pollution prevention and control programmes.

## 2. Political and administrative stage

- (a) *Determination of acceptable risk*—views problem not as a scientific matter, but rather one of opinion.
- (b) *Determination of public to be protected*—considers not only healthy individuals but also population groups whose particular physiological make-up or state of health need to be taken into account.
- (c) *Consideration of human ecology*—sees man in balance with his environment.
- (d) *Choice of control technology*—requires both formulation of strategy and selection of appropriate control techniques.
- (e) *Legislation/standards*—considers existing national legal framework and identifies necessary legal strategies.
- (f) *Economics*—strikes a balance between costs and benefits.

This stage requires knowledge of the technical, social, financial, legal, and institutional implications of the solutions to be adopted. This knowledge promotes the examination of links between environmental problems, the solutions, and society (Rodricks & Tardiff, 1984; Males, 1985). At this stage, consideration is given to the means of achieving the environmental health goals.

The framework outlined above is somewhat schematic and in most cases it will only be followed in a generalized way. It puts forward a logical progression in decision-making that, in "real life" situations, might not always be followed. Also, it proposes a decision-making process that is "science-driven". In practice, the decision-maker might have to find solutions for existing environmental problems, in which case the process might work in reverse: from the political to the scientific stage (see also Chapter 2). Lastly, although the process outlined above is linear, in practice it is cyclical, as constant improvements in information are likely to result in adjustments and changes being made to strategies, standards, and methods. However, no matter how the process operates, the elements described remain valid; they are discussed further in the other chapters of this book.

This approach to decision-making is not without its critics. Criticisms stem in part from the inadequacy of the data on which the assessment is based. For example, uncertainties concerning the effects of chronic exposure to environmental pollution make it almost impossible to quantify the associated risks. Further criticism stems from the concept of risk acceptability—acceptable to whom?

Faced with such uncertainties some would suggest that it might be better to take all practicable steps to eliminate avoidable risk, irrespective of precise quantification. However, the prevailing approach to pollution control is based on the principle that with scarce resources, attempts should be made to relate the control imposed to the hazards of exposure, and this approach is followed in this publication.

### Identification of priority pollution issues

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There are generally insufficient resources available to deal with all the pollution problems in a country, and it will be necessary to establish priorities. Two general criteria should be considered in doing so (Whyte & Burton, 1980):

1. The boundaries of the problem must be defined. For example, a decision has to be made as to whether the risk to human health is the sole or major criterion for control. In the past, priority ratings have tended to focus on human health alone but increasingly, hazards to animals, plants, and natural areas have prompted environmental action in their own right.

Within human health and well-being, a hierarchy of effects can be identified from minor temporary ailments through acute illness to chronic diseases. Particular problems arise with chronic diseases, which are often difficult to relate to specific hazards or sources of risk. For others the significance of effects is uncertain. For example, it is known that at levels of less than 100 µg of lead per 100 ml of whole blood, anaemia does not usually occur. However, these low concentrations of lead in the blood affect the activity of an enzyme, *protoporphyrinogen synthase* (EC 4.2.1.24) (see Fig. 1 and 2, pages 18 and 19). Can this be considered to be a significant effect on human health? The question of what constitutes a health effect is discussed further in Chapter 4.

2. The problem in question must be put into a wider context by consideration of other risks and/or benefits. Risks can be evaluated in terms of the additional hazard they present over:

- what occurs naturally in the environment;
- what has been tolerated for long periods of time with no apparent ill effects;
- the level that is accepted as beneficial (e.g., in the case of pesticides).

For example, natural background levels have been used as a yardstick in measuring the risk associated with nuclear power production, the potential risk of adding fluoride to the domestic water supply as a public health measure, and the assessment of elevated noise levels near airports and traffic routes.

The question arises as to how national agencies should choose which pollutants must be controlled from among the thousands introduced into the environment. Traditionally, this decision has been based on a

subjective consideration of a number of factors such as immediate hazard, public concern, feasibility of control, etc.; formal procedures have not generally been used. However, most developed countries and international organizations have now adopted systems for setting priorities in order to provide more rigorous guidance. Five criteria (World Health Organization, 1976) are usually applied in determining the extent to which a pollutant may pose an environmental hazard. These are:

- 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 exposure generally merits a higher priority than isolated or accidental exposure.
- Ubiquity and abundance of the pollutant in the environment. Of special concern are inadvertently produced chemicals and substances 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 transformation or metabolic alterations. Since alterations may produce chemical substances 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 exposure involving a large proportion of the general population, or occupational groups, and to selective exposures of highly vulnerable groups such as pregnant women, newborn children, the infirm or the elderly.

### Selection of pollutants for control

In practice, hazard identification begins with one component of the problem, usually the source of the effect, and does not consider the system as a whole at the outset. Some methods of identification are systematic while others appear to be more or less *ad hoc*. This is a pragmatic response to the different ways in which hazards are discovered. In the following paragraphs the different reasons for which pollutants may be selected for attention by environmental decision-makers are discussed.

### *Systematic evaluations*

In the United States of America, efforts have been made to identify priority chemical pollutants systematically by using a scoring system to rank each substance (Environmental Protection Agency, 1977). Several other efforts in different parts of the world rely upon the knowledge and opinions of groups of experts.

At the international level, the Council for Mutual Economic Assistance (CMEA) and the Organization for Economic Cooperation and Development (OECD) both have programmes on methods of setting priorities for testing of new and existing chemicals. As a result of cooperation among CMEA countries during recent years, a number of documents have been published including a reference book on problems of industrial toxicology (GKNT, 1986). This publication contains guidelines and recommendations for studying various aspects of the biological effects of chemical compounds as well as procedures for establishing sanitary standards in CMEA countries. OECD recently published a guidance document, in two volumes, for the selection for further testing of chemicals on which data are inadequate. The second volume of the report includes nearly 700 citations that are useful in setting priorities (Organization for Economic Cooperation and Development, 1984).

### *Local or foreign public health crises*

Often, national authorities are forced into the decision-making process by the discovery of a major local problem. For example, the Japanese government in the 1960s had to react quickly to deal with the mercury poisonings at Minamata (Katsuma, 1968). After the experience at Minamata, other countries around the world attempted to assess their own local situation with regard to mercury, and to take appropriate action.

Environmental problems are rarely confined to one country and in most instances sooner or later a particular problem will occur in several locations. As a result, the setting of standards and priorities for environmental control in one country may be influenced by the action of others. For example, when scientists in the Netherlands in the early 1970s discovered that certain harmful organic substances were present in drinking-water as a result of chlorination, many countries took appropriate control action.

### *Research*

In some cases, environmental health issues appear on the decision-making agenda as suspected problems. For example, several countries have taken action since 1975 either to limit their production capacity of chlorofluorocarbons (CFC) or to ban (or severely restrict) their use as aerosol propellants. These actions were taken on the basis of a theory that the release of chlorofluorocarbons into the atmosphere will eventually significantly reduce the amount of ozone in the stratosphere that shields the earth's surface from harmful solar ultraviolet radiation (Council on Environmental Quality, 1975). While supporting evidence for this theory has been presented, the restrictions have been implemented before there has been any direct observation of a decrease in the ozone layer.



### *Outside opinion*

Often, the press or local political figures will focus attention upon an issue to such an extent that priorities for action must be changed. In Canada, for example, press and politicians have drawn attention to the existence of several hundred miles of railroad bed made from asbestos tailings. As a result, environmental health officials have been obliged to consider the associated risks and possible remedial action.

### *Chemical similarity*

Problems may often be suspected on the basis of the chemical similarity between one substance and another that is known to be hazardous. For example, polybrominated biphenyls quickly received regulatory scrutiny around the world after the chemically similar polychlorinated biphenyls were shown to constitute a major environmental hazard.

The factors discussed above may influence local and national authorities in their efforts to set priorities for action. Alternatively, such authorities may wish to devote their full effort to controlling hazards and may therefore rely upon various international programmes to establish priority lists. These lists may be supplemented by local and national surveys to pinpoint specific local problems.

### *Advantages of international cooperation*

The advantages of international cooperation include the availability to decision-makers of expert reviews of information from many countries at low cost. Generally, such reviews provide not only internationally relevant suggestions for priority action but also associated information on evaluation of health effects, suggested safe levels for human, plant, and animal exposure, production or emission data, and concentrations in different environmental media, etc. Further information on relevant documentation produced by different international programmes is given in the following paragraphs.

### *WHO Environmental Health Criteria programme*

Established in 1973, the main objective of this programme is to assess existing information on the relationship between exposure to environmental pollutants, or other physical factors, and human health, as well as to provide guidelines for setting exposure limits that are consistent with health protection. This programme was later in-

corporated into the newly established International Programme on Chemical Safety (IPCS).<sup>1</sup>

In view of the large number of environmental agents and factors that may adversely influence human health, the preparation of criteria documents must be based on clearly defined priorities. Each criteria document comprises an extensive scientific review of a specific environmental pollutant, group of pollutants, or physical factor(s); the information provided ranges from sources and exposure levels to a detailed account of the available evidence concerning effects on human health. Over fifty documents have been published to date. A list of Environmental Health Criteria publications is given in Annex 1.

### *International Register of Potentially Toxic Chemicals*

The International Register of Potentially Toxic Chemicals (IRPTC) is part of the United Nations Environment Programme. The Register serves as an international data bank and information service on possible chemical hazards.<sup>2</sup> Its activities involve the development of data profiles on chemicals, the operation of a query-response service, and the regular publication of the IRPTC bulletin which contains up-to-date information on chemicals. The main objective of this programme is to facilitate access by countries to existing data on the effects of chemicals on man and the environment, and thus to contribute to a more efficient use of national and international resources. The programme also helps to identify the potential hazards of chemicals and pollutants, and to improve awareness of such hazards.

At the present time, the IRPTC has data profiles on more than 500 chemical substances; a list of these is available from IRPTC. Two specific files from the Register have been published separately: the *IRPTC legal file* (also accessible on-line) and *Treatment and disposal methods for waste chemicals*. Examples of pertinent records are given in Annex 2.

### *International Agency for Research on Cancer*

In 1965, the World Health Assembly established the International Agency for Research on Cancer (IARC) in Lyon, France. One major activity of IARC over the last decade has been the publication of monographs evaluating the possible carcinogenic hazards from chemical substances and complex mixtures. Up to September 1986, 38 volumes had been issued, concerning approximately 700 chemicals, groups of chemicals, and industrial processes. Of these, 30 chemical substances, mixtures, or groups of products, and 9 industrial processes

<sup>1</sup> MERCIER, M. *The International Programme on Chemical Safety*. Unpublished WHO document, EHE/80.14, Rev. 1.

<sup>2</sup> *Summary of the Second Meeting of Experts on Listing of Environmentally Dangerous Chemical Substances and Processes of Global Significance, 21-25 November 1983*. Geneva United Nations Environment Programme, 1983.