DIFFICULTIES IN HEALTH RISK ASSESSMENT AND MANAGEMENT RESULTING FROM EXPOSURES TO ENVIRONMENTAL AGENTS

Soedjajadi Keman

ABSTRACT

The environmental health risk assessment process provides a format to eliminate and evaluate human health risks in relation to environmental agents such as chemical, biological, physical or even psychological agent. The process consists of four steps namely hazards identification, exposure-response assessment, exposure assessment, and risk characterization. While environmental health risk management is process of weighting policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data as well as social, economic and political concerns to reach a decision. Most environmental health risk assessments are associated with a high degree of difficulty, which can be grouped into two major categories: difficulty resulting from the lack of scientific understanding to interpret the available data, and from the lack of available and appropriate information and data. In order to deal with difficulty in environmental health risk assessment studies, often default assumptions have been used. Risk assessment is generally seen, as an objective and scientific process with values are elements that influence the management process. Whereas the type of management decision frequently affects the type and details of the risk assessment. It is recognized that these two processes are related and complementary. Quantitative risk assessment is an important aspect. However, it is only one element in formulating regulatory decisions. Decision makers must also consider other important factors such as social, economical, political and technical factors before they decide whether actions are needed to protect human health.

Keywords: environmental health, risk assessment, risk management

INTRODUCTION

Public concern on the potential health effects resulting from exposure to environmental agents through air, food, and soil leads to demand for protection against environmental health risk. Risk can be defined as degree of severity of health effect due to environmental health hazard factors. Degree of severity of health effect risk can be assessed by measure frequency and degree of severity of health risk. Furthermore, the environmental health chain and the environmental health risk assessment provide clues to estimate and evaluate human health risk in relation to dangerous environmental agents. The following paragraphs discuss environmental health chain, environmental health risk assessment and environmental risk management that are summarized from some related journals and textbooks.

The environmental health chain represents a sequence of events starting from a toxicant release into the environment, entering to the human body and finally to the related health effects. While the environmental health risk assessment process provides a format for estimating the likelihood of adverse health effects of human exposure to an environmental toxicant. The process in general consists of four steps: (1) hazards identification; (2) exposure-response assessment; (3) exposure assessment; and (4) risk characterization. The human health risk can be estimated using by a combination of exposure-response assessment and exposure assessment. The results of the risk assessment together with social, economic, culture and political information are used for environmental risk management decisions on measures to be taken in order to protect public health.

Most of environmental health risk assessments are associated with a high degree of difficulty, especially in the step of risk characterization. Difficulty can be described as “the lack of knowledge as to what the truth is whether qualitative or quantitative” (National Academy of Sciences / National Research Council (NAS/NRC), 1994). Different sources of difficulty play a role in many risk assessments. They mostly refer to (1) the limitation of the scientific understanding for interpretation the available data and to (2) the lack of available and appropriate data and information. Because of these uncertainties, environmental health risk assessment has to be based on default assumptions (based on general knowledge if specific knowledge is not available) and professional judgements. Consistency and predictability are major advantages of default assumption. However, an important disadvantage is that most default assumptions appear to be conservative (Albering, 1998).

Data on toxic chemicals usually come from laboratory experiments on animals’ not epidemiological studies of humans. Moreover, many are inferences based on
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bacterial and/or human cells. Both of these sources of data cause problems because (a) an animal or cell is not a human being; (b) most animal toxicity data is short-term; (c) relatively high exposures are used experimentally, to cause statistically significant effects. Many species are homogenous (purposely to limit variability in response), by contrast, humans are diverse in their response to chemicals due to genetic make up, age, body weight, habits, occupation, health status, diet, etc., that contribute difficulty in the risk assessment. Some argue that extrapolations from animals to humans are more reliable than epidemiological studies due to (a) small study populations (lack of statistical significance); (b) confounding variables; (c) lack of exposure data; and (d) differences between study populations and the population to be protected. Furthermore, when no effect is seen in laboratory animals, is there negligible risk to humans exposed at such a level? A one percent incidence of any disease would be impossible to detect in a study of 25 animals, but would be represent more than two million cases if the entire Indonesia population were exposed. How do we answer this question? In risk assessment, it is assumed that (a) for cancer: there is no safe dose; (b) at low doses, the relationship between exposure (dose) - effect is directly proportional (linear); (c) for other health effects there is a safe dose.

Scientific research is needed to reduce difficulty and replace default assumptions. It forms the basis for the assessment framework and by different authors feedback loops have been postulated interrelating research, environmental health risk assessment and risk management. The output of the risk assessment also identifies the uncertainties and thereby directs the research needs. Specifically, mechanistically oriented research which provides insight into the source-exposure-effect continuum has to be improved, and the results should be effectively incorporated into the environmental health risk assessment process. In the following paragraphs, the environmental health chain and the risk assessment framework will be described as well as the risk management process.

ENVIRONMENTAL HEALTH CHAIN

When a toxicant is released from industrial source for example to the environment, it may be transported by water, air, soil or food to the immediate environment of humans. Through mechanism of ingestion, inhalation, absorption or its combination the toxicant enters the human body (internal dose). The toxicant undergoes biotransformation (metabolism and excretion), and interacts with target molecules, cells, tissues or organs by which it may produce adverse health effects. For relating internal dose to altered structure and or physiological function or adverse health effects, sequence in between namely the target dose and the biologically effective dose are important parameters. The target dose represents the part of the internal dose that reaches the tissue of interest. The biologically effective dose is the dose of a toxicant or its metabolite that reaches the site of toxic action and induces an altered structure and or physiological function (Environmental Protection Agency, 1992; Keman, 1997).

Environmental health risks in relation to environmentally exposure are frequently expressed as a product of the emission or the effluent term, the exposure function, the cell or tissue or organ dose and the adverse health effect associated with the delivered dose or toxic potency factor. This suggests that the

Figure 1. Environmental health chain
health risks of an environmental toxicant mainly are a
d function of events from an emission source into the
environment to the ultimate adverse health effect
represented by the environmental health chain as
illustrated in Figure 1 can be used as a framework to
evaluate and estimate environmental health risk
(McKone and Bogen, 1991; 1992; Sexton, 1993;
Sampson et al., 1994; Keman, 1997).

The environmental health chain is successive in
composition, which means that the input into the next
module is the result from the previous module. The lack
of scientific information on any part of the chain
influences the assessment of health risk related to
environmental exposure. This chain from emission
source of exposure to health effect is a simplified
representation. Important information on for example
transport, fate, metabolism and bioavailability is
required for a good understanding of the risk chain.
Furthermore, environmental exposure will vary over
time, and health effects vary in term of frequency and
severity. Moreover, there might be a time delay between
exposure and adverse health effect (Covello and
Merkhofer, 1993).

Although each element of the environmental health
chain is important in order to determine the risk for
general public associated with environmental pollution,
much attention has been paid to the last part of the
chain. Many studies have related environmental
exposure to dose to effects in animals and humans.
Frequently, actual exposure in relation to environmental
toxicant has not been determined. Up to the 1990s
exposure assessment has been primarily based on
measurements or on model predictions of concentration
in the environment of humans generally exposed
through single exposure pathway (Gillen, 1996). An
example of this is the measurement of human exposure
to air agents or pollutants by air monitoring stations.
However, most of human exposures to environmental
agents, for example pesticides, dioxins, polychlorinated
biphenyls (PCBs), cadmium, polycyclic aromatic
hydrocarbons (PAHs) and benzene seem to follow
multiple environmental pathways (water, air, soil or
food) and multiple routes (ingestion, inhalation and skin
absorption). Nowadays, much attention is directed to the
assessment of total exposure of environmental agents by
multiple exposure pathways (Sexton et al., 1995).

Another method to evaluate health risk in relation to
environmental agents is the effect approach namely
epidemiological approach which is in contrast with
toxicological approach as described above (Albering,
1998). As alternative to the analysis of the
environmental health chain, the environmental health
risk assessment framework can be used to evaluate
health risk in relation to environmental toxicant
exposure.

ENVIRONMENTAL HEALTH RISK
ASSESSMENT

Environmental health risk assessment is the process of
describing the likelihood that potentially adverse health
effects are caused by a chemical, biological, or physical
agent. Risk assessment is a relatively young area and
still developed in environmental health science, and risk
assessment process has not already been developed.
There are some discussions on the term of “risk
assessment” and “risk management”. There are some
disagreements on how to make the distinction between
risk assessment and risk management. Some authors use
term risk assessment for entire the risk management
process, whereas others use risk management only as a
part of the risk management process, and some use risk
assessment to characterize threats to human health from
environmental exposure as a part of the regulatory
decision making process (Sexton, 1995; van Leeuwen
and Hermens, 1995). Generally, risk assessors estimate
risk while risk managers determine a safe level or
whether risks are unacceptable and what do about these
risks (Sexton et al., 1993). The concept of risk plays
important role in the evaluation of health effects in
relation to exposure to environmental agents.

The type of the risk management decision frequently
affects the type and detail of the risk assessment. Since
research provides inputs for both risk assessment and
risk management, risk assessment can be seen as a
function to link between science and decision (Patton,
1993; van Leeuwen and Hermens, 1995). Therefore,
risk assessment and risk management are connected, be
it by different methods, different objectives, information
and results as described in the following paragraph.

Environmental health risk assessments have been
carried out many decades before general consensus on
the process had been achieved in the mid 1970s that risk
assessment reorganized as a way to evaluate potential
hazard from exposure to environmental agents (Ziegler,
1993). Lawrence provided the first conceptual
framework of environmental health risk assessment in
1975 (Ozonoff, 1994). The framework includes (1) an
identification of the condition of exposure to a toxicant;
(2) the adverse health effect of the toxicant; (3) a
determination of a quantitative relationship between
exposure and adverse health effect; and finally, (4) an
estimation of the health risk by a combination of the
condition of exposure to the agent and the exposure
dose – response relationship.
The estimated risks are used for policy making and management decision with considering other aspects such as social, economic, culture and political factors (Ozonoff, 1994). The US National Research Council Committee of the National Academy of Science (NAS/NRC) published the book entitled “Risk Assessment in The Federal Government” in 1983 popularly quoted as “The Red Book”. This publication emphasised the problem of increasing cancer risk due to environmental exposure to toxic chemicals. In the committee’s view, the basic shortcoming of risk assessment is the difficulty and lack of scientific knowledge of the health hazards (Albering, 1998). It codifies what has become a common view, that risk assessment as “estimating the magnitude, likelihood and uncertainties of environmentally induced health effects (Albering, 1998). The risk assessment process is as shown in Figure 2. includes one or all of the following steps: (1) hazard identification; (2) dose-response assessment; (3) exposure assessment; and (4) risk characterization. This framework provides a conceptual understanding that leads to enhance the uniformity and clarity of human health risk assessment (Patton, 1993; Barnthouse, 1994).

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### Research
- Laboratory and field observation of adverse health effects and exposures to particular toxicant
- Information on extrapolation methods for high to low, animal to human
- Field measurements estimated exposures characterization of populations

### Risk Assessment
- **Hazard identification**
  - Does the toxicant cause the adverse health effects
- **Exposure (dose) – response assessment**
  - What is the relationship between exposure (dose) and incidence in human
- **Exposure assessment**
  - What exposures are currently experienced or anticipated under different conditions
- **Risk characterization**
  - What is the estimated incidence of the adverse health effects in a given population?

### Risk Management
- Development of regulatory options
- Evaluation of public health, economic, social, and political consequence of regulatory options
- Agency decisions and actions

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**Figure 2.** Environmental health risk assessment proposed by ‘The US National Research Council Committee of the National Academy of Science (NAS/NRC)’. 
The step of hazard identification aims to determine whether the available scientific data describe a causal relationship between exposure to a toxicant in the environment and the toxic health effects that toxicant produces as well as the level of exposure at which this occur. Information on the toxicant responsible for the effects may come from animal bioassays, mutagenicity assays, and epidemiological studies.

The goal of the step of dose-response is to establish a quantitative relationship between exposure (dose) and adverse health effects that have been observed. The dose-response assessment is based mainly on two important extrapolations: (1) from high to low dose; and (2) from animals to humans.

The step of exposure assessment is designed in focusing on measuring and estimating the magnitude, frequency and duration of human exposures to an environmental toxicant, or on estimating future exposure of agents to be introduced into the environment (Barnthouse, 1994). Generally, there are three approaches for the quantification of exposure which each approach has different shortcomings and strengths: (1) the direct approach measures actual exposure at the surrounding human body such as personal dust sampler; (2) the reconstructive approach estimates past exposure levels based on reconstruction of the internal dose observed in human tissues, for instance exposure biomarkers; and (3) the predictive approach estimates exposure by using different mathematical models and is the most commonly used approach in the quantification of exposure (Sampson et al., 1994; Sexton et al., 1995; Albering, 1998).

![Risk Assessment Diagram](image-url)

Figure 3. Risk assessment formulated by Covello dan Merkhofer (1993)
The final step in environmental health risk assessment is risk characterization. It deals with estimating the incidence of a health effect under various circumstances of human exposure. It is a combination of both exposure and dose-response assessment, in which uncertainties with regard to the exposure and dose-response assessments, and the overall uncertainties in the final step are described. Within this respect, risk characterization represents the interface between the risk assessor (the scientist) and the risk manager (the decision maker). The known uncertainties from the first three steps are clearly expressed in order to assist the decision maker and are furthermore a guide for the scientist to plan new research in order to decrease those levels of uncertainties (Albering, 1998).

Over the last decades, several frameworks for environmental health risk assessment have become available. These frameworks clarify the main elements in risk assessment and risk management. The basic of four elements of the framework has been improved. Covello and Merkhofer (1993) have formulated an alternative model as shown in Figure 3. The authors have decided that hazard identification, as the first step in the NAS/NRC model is an essential step before the assessment process equal to the quantitative process of risk assessment. Furthermore, release assessment has been included as the first step in the risk assessment process. It is designed to establish a quantification of the possibility of an environmental source, for example industrial accidents or technological failure, to release agents into the environment. Exposure assessment is similar as formulated by the NAS/NRC model, but it is conducted before dose-response assessment, which has been described as consequence assessment. Moreover, ecological and human consequences have been included into this assessment.

Scientific research provides and forms factual basis for the four step of the risk assessment framework and should reflect the latest scientific understanding. Health risk assessment research is related to many disciplines of science such as environmental health, epidemiology, biology, chemistry, physics, genetics, pathology, pharmacology, toxicology, and statistics. Although scientific is the part of the framework, at that time much attention has been given to the conceptual difference between risk assessment and risk management (Albering, 1998). Feedback loops exists between scientific research, risk assessment and risk management (Sexton et al., 1993; 1995). Scientific data and understandings are important inputs for management decisions, while the output of the risk assessment and risk management processes may generate additional research.

Originally, the NAS/NRC risk assessment framework has been used to evaluate carcinogenic risks from exposure to environmental agents and other health related effects such as reproductive and developmental disorders could be evaluated. Since 1990s, ecological risk assessment has moved to the front to join human health risk assessment in term of usefulness of environmental policy. In 1992, the U.S. Environmental Protection Agency (EPA) has modified the original NAS/NRC framework to evaluate the ecological risks due to chemicals and other stressors in relation to environmental pollution (Barnthouse, 1994). The framework includes the following steps: (1) problem formulation; (2) risk analysis; and (3) risk characterization. In the step of problem formulation, the types and details of the risk assessment are determined according to the state of the arts of the scientific knowledge and to the relevance for the decision making process. Characterizations of exposure and and effects are discussed with the decision maker to make the acceptability of the estimated risks and who afterward has to communicate to the public (Barnthouse, 1994; Albering, 1998).
The committee of Risk Assessment Methodology (CRAM) of the U.S. National Academy of Science has reconciled ecological risk assessments with the original NAS/NRC framework (Figure 4), which serves as a methodological framework for both ecological and health risk assessments in environmental policy (Barnthouse, 1994). The ultimate goal for both models (EPA and CRAM) is to provide a conceptual framework that can increase the merits of ecological risk assessment (Barnthouse, 1994).

The term of dose in dose-response assessment has been replaced with the term of exposure since the concept of dose cannot correctly be applied to non-chemical endpoints and difficulties to measure exactly chemicals dose in the environment. The CRAM committee acknowledges that policy decisions affect the hazard identification. The committee also notes the need to create a relationship between the output of the assessment and the scientific foundation for new risk assessment. An important aspect of understanding the risks, particularly in ecological risk assessment, is effective communication between decision makers and the public (Barnthouse, 1994; Albering, 1998).

ENVIRONMENTAL HEALTH RISK MANAGEMENT

The NAS/NRC committee has defined risk management as “the process of weighting policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic and political concern to reach a decision”. The committee has recommended a separation of risk assessment and risk management due to assumption that decision makers may influence the scientific research outcomes. The committee has also noted that policy choices and scientific judgements have to be made to conduct risk assessment, and it is a part of social, economic and political policy issues. They have used term “risk assessment policy” or “scientific policy” for those since it is lay between facts (science) and values (policy) (Sexton et al., 1993; 1995).

There is some discussion on the conceptual separation between risk assessment and risk management. Risk assessment is generally seen as an objective and scientific process, whereas value is elements influencing the management (van Leeuwen, 1995; Sexton, 1995). However, some authors criticised the objectivity of risk assessment and argue that social justice and public
policy are important aspects that influence the risk assessment (Jasanoff, 1993; Somers, 1995). It was recognized by some authors that those two processes are related and complementary. Type of management decision frequently affects the type and detail of the risk assessment (Patton, 1993; Sexton et al., 1995).

Determination of the acceptability of risks, a selection of the most cost-effective method to prevent or reduce effects from environmental exposure, an evaluation of the success of risk mitigation efforts, regulatory requirements, remediation of environmental pollution, and risk communication are important goals of the risk management process (Patton, 1993; Ziegler, 1993). A variety of options can be taken to achieve those goals, broadly classified as regulatory, economic, advisory or technological issue. In this process, the results of a risk assessment are used to decide whether risks are acceptable or unacceptable. If the risks are unacceptable, what do about these risk. Although quantitative risk estimation is an important aspect, it is only an element in formulating regulatory decision. Decision maker must also consider other important factors such as social, economical, cultural, political and technical factors, before taking actions to protect public health (Sexton et al., 1993). Effective communication between risk assessors and risk managers is important during development of the holistic environmental health risk assessment framework.

REFERENCES