ASSESSMENT OF STANDARDS

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Contents

Summary

This chapter is about making our decisions based on evaluating risks and benefits that a particular activity or avoidance would bring us. This subject is to improve our analytical techniques in evaluating dangers and develop skills in confronting them. Chemical risk assessment is generally divided into four parts and is approached in the following sequence: 1. Hazard identification, 2. Dose-response relationships, 3. Exposure

assessment, and 4. Risk characterization.

There are two principal sources of information on health effects of humans and animals resulting from exposure to chemicals that can be used in deriving guideline values. Hazard identification, dose-response assessment and risk characterization are reviewed form sources of information on health effect and classification of possibility of carcinogenicity. Two approaches to the derivation of criteria or standard values on judgment of non- or carcinogen are used: one for "threshold chemicals" (non-carcinogen and non-genotoxic carcinogen) and the other for "non-threshold chemicals" (mostly genotoxic carcinogens). Criteria are based mostly on animal studies, and risk analysis methods deal with extrapolations from animals to humans, from short-range to long-range exposures, and with similar scientific issues that require expert judgments and cannot be neatly put into a formula.

1. Introduction

Most chemicals arising in drinking-water are of health concern only after extended exposure of years, rather than months. Typically, changes in water quality occur progressively, except for those substances that are discharged or leach intermittently to flowing surface waters or groundwater supplies from, for example, contaminated landfill sites. A number of chemical contaminants have been shown to cause adverse health effects in humans as a consequence of prolonged exposure through drinking-water from various sources. The substances considered here have been assessed for possible heath effects, and criteria or standard on each countries have been proposed only on the basis of health concerns.

2. Categorization of Source of Chemical Constituents

Chemical contaminants in natural water may be categorized in various ways. Water quality targets are established for individual drinking-water constituents that represent a health risk from long-term exposure and where fluctuations in concentration are small or occur over long periods. They are typically expressed as criteria or standard values (concentrations) of the substances or chemicals of concern.

In the guidelines by World Health Organization (WHO), chemicals contaminating in freshwater are therefore divided into six major source groups, as shown in Table 1. Categories may not always be clear-cut. The group of naturally occurring contaminants, for example, includes many inorganic chemicals that are found in drinking-water as a consequence of release from rocks and soils by rainfall, some of which may become problematical where there is environmental disturbance, such as in mining areas. Chemicals intend for chemical hazards in freshwater are included substances from significant contributor and those form materials and chemicals used in the production and distribution of drinking-water.

Source of chemical constituents	**Examples of sources**
Naturally occurring	Rocks, soils and the effects of the geological setting and climate
Industrial sources and human dwellings	Mining(extractive industries) and manufacturing and processing industries, sewage, solid waters, urban runoff,

	fuel leakages
Agricultural activities	Manures, fertilizers, intensive animal practices and pesticides
Pesticides used in water for public health	Larvicides used in the control of insect vectors of disease
Water treatment or materials in contact with drinking-water	Coagulants, Disinfectant byproducts, piping materials
Cyanobacteria	Eutrophic lakes

Table 1. Categorization of source of chemical constituents

3. Conceptual Development of Risk Assessment

3.1. Definition of Risk Assessment

This section can define risk analysis as a body of knowledge (methodology) that evaluates and derives a probability of an adverse effect of an agent (chemical, physical, or other), industrial process, technology, or natural process. Definition of an "adverse effect" is a value judgment. It could be defined as death or disease (in most cases of human health risk analysis); it could be a failure of a nuclear power plant, or a chemical plant accident, or a loss of invested money. In some recent cases of risk analysis, even vaguely defined terms such as "quality of life" or "sense of community" have been evaluated using risk analysis. Traditionally, most risk assessments (risk analysis applied in a particular situation) deal with health effects or, more recently, with the ecological health or economic well-being (in case of business risk analysis). (Figure 1)

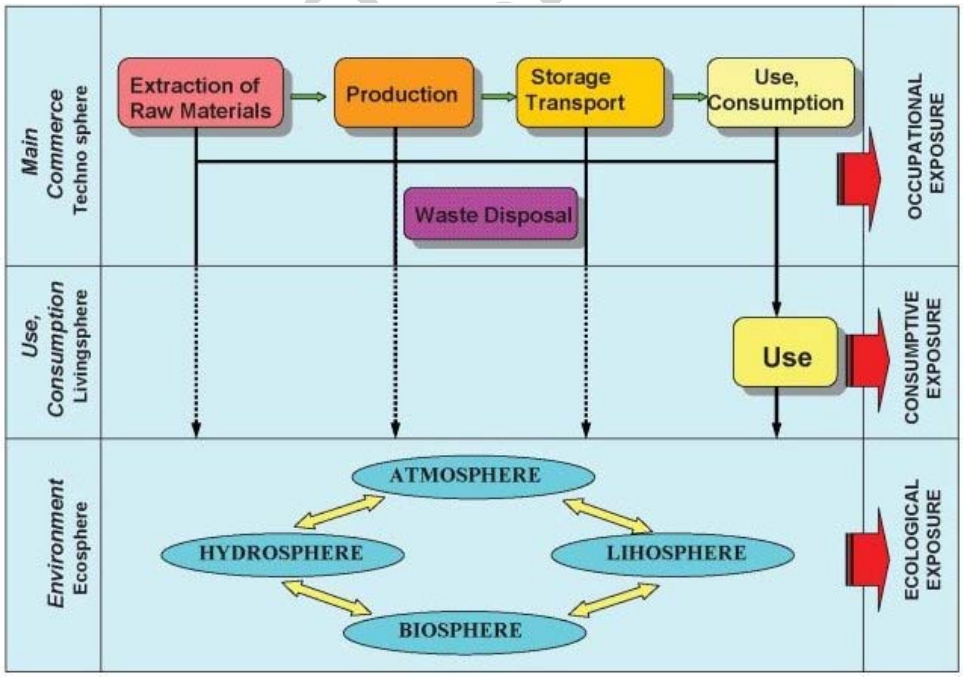

Figure 1. Among the three compartments of exposure system

3.2. Historical Overview of Risk Analysis

Historical perspective on risk analysis applications in society was given by Covello and Mumpower (1985). Modern risk analysis has roots in probability theory and the development of scientific methods for identifying causal links between adverse health effects and different types of hazardous activities. Conceptual development of risk analysis in the united States and other industrially developed countries started from two directions: (1) with the development of nuclear power plants and concerns about their safety (this problem led to the development of the classical probabilistic risk analysis) (Upton, 1983) and (2) with the establishment of the U.S. Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), National Institute for Occupational Safety and Health (NIOSH), and equivalent governmental agencies in developed countries. Modern industrial society underwent changes that must be factored into risk analysis and management associated with industrial development.

4. Risk Assessment Process

4.1. Health Outcome Targets

Health outcome targets may be the basis for evaluation of results through quantitative risk assessment models. In these cases, health outcomes are estimated based on information concerning exposure and dose-response relationship. Health outcome targets based on information on the impact of tested interventions on the health of real populations are ideal but rarely available. More common are or fractions of total disease burden, preferably based on epidemiological evidence or, alternatively, risk assessment studies.

4.2. Approaches to Risk Analysis

Chemical risk analysis is generally divided into four parts (NAS 1983). Formal risk assessment can be organized into Figure 2.

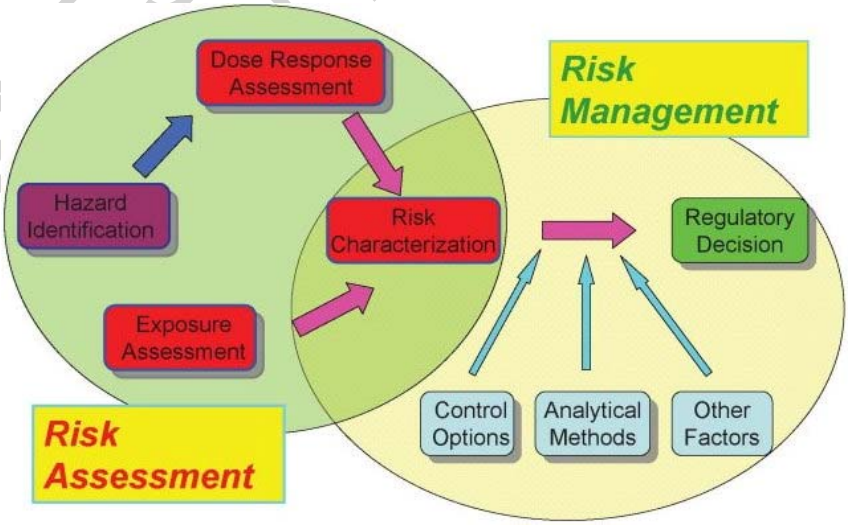

Figure 2. Procedure of regulatory science for environmental chemicals

1. Hazard identification — identifying potentially toxic chemicals (agent).

2. Dose-response relationships — determining toxic effects depending on amounts ingested, inhaled, or otherwise entering the human organism. These are usually determined from animal studies. Different "end points" of toxicity are observed, depending on the target organ of a chemical. Severity of a particular effect is a function of dose. (How is quantity, intensity, or concentration of a hazard related to adverse effect?)

3. Exposure assessment — determining the fate of the chemical in the environment and its consumption by humans. Ideally, by performing environmental fate and transport of chemicals, and by evaluating food intakes, inhalation, and possible dermal contacts, one can asses total quantities of toxic chemicals in an exposed individual or population, which may cause adverse health effects. In criteria derivation, one uses either worse case exposure scenario or most probable exposure scenario and point values for various human parameters. Monte Carlo modeling uses real-world distribution data for those parameters. (Who is exposed? to what and how much? how long? other exposures?)

4. Risk characterization. If an actual exposure to environmental pollutant (or pollutants) exceeds limits set by the criteria, efforts should be made to decrease the concentrations of pollutant. The magnitude of risk can be estimated by comparing the particular exposure to derived criteria or reference doses. (consists of evaluating and combining data all of the previous items 2, 3 and makes calculations based on data, with all the assumptions clearly stated; often the conclusion is that more data and/or improvement in methodology is needed and that no numerical risk number can be derived to express accurately the magnitude of risk. For establishing criteria and standards, assumptions are made about "average exposures," and the criteria are set at the concentration at which it is believed that no harm would occur.)

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Biographical Sketch

Masanori Ando is with the Faculty of Pharmaceutical Sciences of Musashino University as professor, where he has been in his present post since 2004. He obtained a Bachelor's Degree in Meiji Pharmaceutical College in 1970. He worked for National Institute of Health Sciences until 2004. In the meantime, he obtained a Ph.D in Pharmaceutical Sciences from Tokyo University. He has written and edited books on risk assessment, management and analytical standard methods of drinking water, indoor air chemicals, air toxicants and cosmetic strategy. He has been the author or co-author of approximately 120 research articles. He is member of Japan Society on Water Environment, Pharmaceutical Society of Japan, Japan Society for Environmental Chemistry, Japan Society of Endocrine Disrupters Research, Japan Water Works Association, Society of Indoor Environment Japan, The Japanese Society of Toxicology.