CANADIAN HANDBOOK ON HEALTH IMPACT ASSESSMENT

Volume 3

Roles for the Health Practitioner

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DECEMBER 1999

The Risk Management Decision Making Process

Chapter B Contents

Introduction

The purpose of risk management is to identify potential sources of harm and make decisions about appropriate actions concerning those sources. Proposed development projects may have a number of potential hazards. What are the risks and what needs to be done about them? Decisions concerning these issues are more workable if they are based on science, people and feasibility. The scientific evidence needs to be gathered making sure that people's concerns are being addressed and that the decisions are feasible in terms of available resources, technology, etc. Examples of decisions that can be made are: the type of advice to provide; how to communicate risks; mitigation strategies; and setting standards.

A formal risk assessment and risk management process helps risk managers focus their efforts on finding solutions and strategies for mitigating problems such as health hazards. A number of formal, structured processes often referred to as frameworks have been developed by organizations. Examples include the Risk Determination Framework developed by the Health Protection Branch (HPB) in the early 1990's, the Q850 standard developed by the Canadian Standards Association (CSA, 1997) and CODEX Alimentarious. The former focusses on making decisions concerning health risks while Q850 is designed to address a broader range of issues including health hazards, injury, property damage, and harm to the environment.

The HPB Risk Determination Framework is based on the following steps (Figure 1). Hazards are first identified, then risks estimated in the step called risk analysis. Then options for mitigating the risk are developed and analysed in the option evaluation phase. All of this is considered to be the risk assessment portion of the process. Subsequently, the risk management portion begins where the decision is made and

implemented. Monitoring and evaluation of the strategy conducted and the entire process reviewed as new information comes to light.

There are several benefits in following risk decision making processes. They provide a systematic approach to decision making, help identify important considerations and fosters transparency and consequently accountability to the risk management decision making process. It also provides a common basis on which to address risks which is important in ensuring the fairness of the risk management decision making process across all projects and in facilitating collaboration, communication and negotiation among partners.

While there are a number of significant advantages, there are also some limitations to their utility. Data may be unavailable or limited yet decisions are required despite the uncertainty. Information may change with time. For example, mechanistic information about health impacts may come available after the EA had been completed and the project accepted. The framework is not meant to supply an automatic decision. Thus, subjective judgement still plays an important role. Rigorously adhering to a framework also does not automatically lead to consensus among stakeholders.

The HPB risk determination process is being revised into a new updated risk management framework. The new framework will provide greater emphasis on consultation and communication, explicitly address the benefits characterization and expand the context of risk to include social, cultural, economic and ethical considerations as well as determinants of health. Once the new framework has been finalized it will be accessible on the Health Canada website: http://www.hc-sc.gc.ca .

In this chapter, no particular framework will be presented. Rather the main concepts in risk assessment and risk management will be described.

Components of the Risk Management Process

The key components of the risk management process are: Communication, identifying the issues, characterizing risks and benefits, developing and assessing options, making and implementing decisions, and following up the results including monitoring.

Communication

Communication: The act of exchanging and sharing information, ideas and beliefs.

The consultation and communication process is becoming more widely recognized as an important component of the risk management process. Such efforts range from providing and obtaining information to total public involvement. Information exchange is useful for informing affected parties about risks and risk management decisions and to acquire scientific knowledge as well as to find out more about the concerns of affected parties. More active consultations can take place in which views are exchanged, an understanding reached on those views and even decisions made. The ultimate in participation by affected parties is total involvement from the beginning of the risk management process right through to making decisions, implementation, evaluation and follow-up monitoring. Here participants share in the responsibility and accountability for the risk management decisions. Chapter XXX in this handbook provides a more detailed description of the issues surrounding communication and methods for practising communications.

Benefits to relevant and quality communication strategies are building trust and improving confidence in risk management decision makers, learning about concerns, needs and attitudes, gathering information about the broader context of the risk and increasing acceptance and understanding of the risk management decisions. This is particularly relevant to the environmental assessment process which is to be done in a

public and participatory manner. There is a need to involve those that are impacted since their perspectives and concerns may be different than those undertaking the science. Acknowledging these concerns can initiate ways of addressing the concerns.

Challenges faced in developing communication strategies are perceptions of risk, apathy and reactiveness. Distrust and low confidence hinder communication efforts. Establishing the right involvement including choosing representatives of key affected parties can be difficult. As well, well designed communication strategies can be costly and time consuming to implement.

Perception of Risk

Individuals' perceptions of risk are the results of their personal evaluation of the information they have about the risk. The public's perceptions of risk rarely reflects the estimated risk based on scientific evidence which can be disconcerting since perceptions can and have been known to drive government agendas and action. Perceived risk is not only based on the individual's knowledge of the science, but has been shown to also reflect the individual's values, beliefs and how much they dread the hazard. Trying to force perceived risk to resemble observed risk can be a futile task since the two measures of risk actually measure different things. Instead, perceived risk needs to be viewed as useful information in the risk management decision making process. By trying to understand the basis of perceptions; communication, education, and consultation will become more fruitful.

Communication is important throughout the risk management decision making process and will be highlighted throughout the following sections.

Identifying the Issues

Hazard: The adverse impact on health which can result from exposure to a substance. (Health Canada, 1997)

At the initial stage of the risk management process, problems are identified and a decision is made whether or not to proceed through the risk assessment/risk management process. Problems include substances, products and processes which have the potential for adversely affecting our health. More specific examples include pesticides, gases, radiation, air pollution, food additives, soil contamination, and water pollution. Health impacts include cancer, malformations, neurotoxicity, endocrine disruption, and respiratory illness.

Many methods are available for identifying hazards including:

- Measuring contaminant levels
- Reports of cases of adverse health effects
- Epidemiological and toxicological studies

Hazards do not only include bio-physical hazards but social, economic hazards as well. A population health approach includes all aspects of well-being, not just health and safety concerns. Recognizing that there are interactions among individual characteristics, social and economic factors and the physical environment, strategies for improving health must focus on the spectrum of influences called the determinants of health. These include employment and working conditions, income level and social status, education, social support networks, childhood care and experience, physical environment, personal health practices, individual capacity and coping skills, health services, gender and culture (Health Canada, 1997).

In addition to potential hazards there may also be potential benefits associated with the

issue. For example, a development project may bring relative prosperity to an area with economic spin off benefits to its residents. Since decisions are often made by weighing risks and benefits, these benefits also need to be identified through a consultative process with affected parties.

Before proceeding in assessing and managing the risk, the problem should be put into context so that the problem is not considered in isolation of other effects and considerations which may play a role in decision making. Those who are affected may have concerns about lifestyle changes, changes in their standard of living and quality of life. The array of possible concerns is vast and thus it is important to focus in on those concerns of importance by consulting with the affected parties at the issue identification stage. In describing the context, special sub-populations at risk, eg., children, the aged, men and women should also be identified.

Once the context is described, a specific plan should then be developed for assessing and managing the risk following the broad guidance of the steps to be described in the following sections. The plan should include outlining the risk management goals, selecting the risk management team, beginning the development of a consultation and communication plan and a documentation plan. In particular, the scope of the decisions that are to be made should be determined to ensure that all subsequent analysis are relevant to the decisions to be made. This ensures an effective though efficient process is followed throughout. Again, participation of all affected and interested parties will aid in determining the scope of the decisions.

Risk: A measure of both the hazard to health from exposure to a substance, process or product and the probability of the hazard occurring. (Health Canada, 1997)

Characterizing Risks and Benefits

Characterizing risks and benefits takes a broad view of potential impacts which includes social, economic, ethical impacts as well as health and safety. Not only are risks described and analysed but potential benefits associated with the problem are analysed as well. For example, breast milk may contain potentially harmful contaminants but also has well documented benefits for developing infants.

The risk characterization process includes establishing risk based on health and safety, social, economic and other considerations, identifying affected populations, assessing exposure and estimating risk. Uncertainties in the available information need to be described and assessed. Affected parties are consulted as appropriate. It is particularly important that the risk and benefit characterization be focussed on the decisions to be made. Otherwise, more information may be collected than is required for making the decision, thus making the process unwieldy and unduly expensive.

This section will focus on the scientific characterization of risk.

Risk Characterization Methods

Epidemiology is the study of the distribution and determinants of health-related states or events in specified human populations and the application of this study to the control of health problems. (Health Canada, 1997)

Many methods are available for assessing health and safety risks. Human studies provide the most relevant information about human health risks. However limitations often preclude establishing cause and effect relationships. Cause and effect is best investigated using experiments in which the risk factor under study is the only factor changed in exposed and unexposed subjects. All other factors which could have potential impact on health are kept the same. In human studies, this is almost always impossible to accomplish due to the diversity in the human population. For example, an apparent

effect could actually be due to another factor that is correlated with the factor under study, called a confounding factor. Clinical trials in which drug, surgical procedures or minor health effects are the closest to providing cause and effect information. However, these trials are unethical to use in determining many effects, such as toxic chemicals on humans.

Cause can only definitely be determined in a randomized experiment. Most epidemiology is observational. Thus a case for causality must be built up through the strength of the evidence, biological plausibility, consistency over a number of studies, by following subjects before and after exposure and by establishing a dose-response relationship.

Types of epidemiological studies include cohort studies in which a sample of subjects are followed over time with exposures measured and disease outcome recorded. Another common epidemiological study is the case-control study in which subjects with the disease outcome (cases) have exposure histories compared to those free of the disease (controls). Other types of epidemiological studies include cross-sectional and ecological studies. Epidemiological studies and their analysis are discussed in more detail in Chapter D on epidemiology.

Not all potential human health hazards are amenable to epidemiological investigation. For example, small increases in risk can be difficult to identify and the time involved in assessing chronic risks would be many years in a prospective study. Thus animal toxicology studies are often used as a surrogate.

Animal studies allow for testing of substances using mammalian models. Testing can be done before the chemical is available for humans. Studies can be done in a controlled environment in which only the factor under study is changed. However,

rodents and other animals do not always have the same biological response mechanisms as humans since metabolism and pharmacokinetics could differ between species.

There are a number of types of animal bioassays. Acute studies expose subjects to high concentrations for short periods of time. Subchronic studies expose subjects daily for a portion of a lifetime, for example 90 days for mice and rats. In chronic studies, subjects are exposed daily for a lifetime (two years for mice and rats).

Other studies include metabolic and pharmacokinetic studies used to investigate absorption, distribution and elimination of the study compound. Teratology studies are used to study potential birth defects and reproductive studies are used to investigate reproductive effects possibly over a number of generations. There are also tests for genetic effects using bacteria, fungi, plant, insect and cultured mammalian cells and studies to investigate effects on the central and peripheral nervous systems.

In many programs such as under the Canadian Environmental Protection Act (CEPA): CEPA priority substances; CEPA new substances; and, the drinking water guideline program, the evaluation of risk evidence is based on the weight-of-evidence for carcinogenicity. For example under the weight-of-evidence scales for CEPA Priority Substances, substances are classified as carcinogenic to humans (Group I) if there is a causal carcinogenic relationship shown in human studies. Probably carcinogenic to humans (Group II), if there is significant evidence of carcinogenicity shown in animal studies but the epidemiological evidence is inadequate to establish causality; possible carcinogenic to humans (Group III) if the carcinogenic evidence is limited in both epidemiological and toxicological studies. Groups IV and V are likely not carcinogenic to humans and Group VI is unclassifiable with respect to carcinogenicity due to inadequate data.

Risk estimation

Risk is established quantitatively by estimating the exposure-response relationship then estimating exposure to determine if exposure is sufficient to present a risk.

Exposure assessment is the study of the amount of a substance that comes into contact with a living system. Sources of exposure to chemical and physical agents includes occupations, drinking water, consumer products, food, transport and waste disposal. Major pathways of human exposure are air, water, soil and food.

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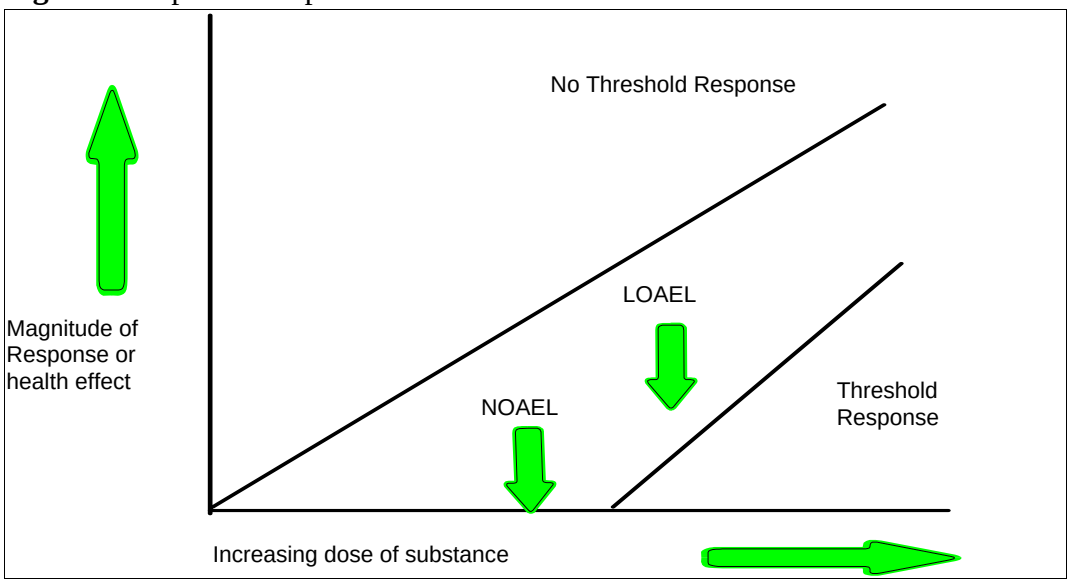
In assessing exposure, the monitored group should be as representative of the population being studied as possible. If animal studies are being used to assess risk than the exposure route should match the human exposure routes. Assessments are conducted on a case by case basis and need to be tailored to the needs of the risk assessment.

Methodologies for assessing exposure include directly measuring levels while contact is occurring, predicting exposure using monitoring data and computer modelling and reconstructing past exposure using surveys, tissue biomarkers and other tools. Environmental monitoring measures amounts in an area or situation such as water and air, and personal monitoring helps establish levels that are individual experiences.

Figure 1: Exposure-response for threshold and non-threshold substances



To estimate risk, chemical agents are classified into one of two categories. For threshold substances, there is a level of exposure below which there is no risk. A reference dose, tolerable daily intake or acceptable daily intake is calculated and compared to typical exposure levels to determine risk. For non-threshold substances, any exposure no matter how small leads to an increase in risk. Examples of non-threshold type substances are genotoxic carcinogens such as ionizing radiation and certain types of chemicals, which cause cancer by damaging DNA and mutagens.

Risk estimates based on epidemiological data are often expressed as *disease incidence* or *mortality rates*—in other words, the number of new cases of disease or deaths in a population at risk during a specified time. One measure of disease incidence is the *cancer incidence rate*, the number of new cases of cancer that occur in a given period. For example, the estimated incidence rate of lung cancer in 1995 was

20 000 in the entire population of Canada, or about 1 in 1500. Incidence rates are used to calculate important measures of risk, such as *relative risk*.

Relative risk compares the incidence rate of disease or death in a group exposed to a specific agent with the corresponding rate in an unexposed group. In other words, it shows the likelihood of an exposed population contracting the disease or dying compared with the likelihood in an unexposed population.

Reference doses (or concentrations) for threshold substances are traditionally calculated by dividing a no observed adverse effect level (NOAEL) established in an animal bioassay by uncertainty factors to take into account uncertainties associated with the animal toxicology studies. Common default values are 10 for the animal to human extrapolation and 10 for susceptible human sub-populations. Other factors may cover using a LOAEL (lower observed adverse effect level) in place of a NOAEL, using subchronic studies in place of chronic studies, inadequacies in the database and developmental effects.

Reference Dose

$$RfD = \frac{NOAEL}{u_1 * u_2 * u_3}$$

where u_1, u_2 and u_3 are uncertainty factors

Limitations to the NOAEL approach are that the selection of the NOAEL depends on a statistical test which depends on the sample size of the dose groups. In addition, there are a limited number of dose groups so that the NOAEL may in fact be much lower than the actual threshold. A dose-response modelling approach has been proposed as an alternative from which the dose yielding an increase risk of 5% or 10% over background is used in place of the NOAEL. This approach is not used widely.

For non-threshold substances, the traditional approach is to estimate an exposure-response curve, than estimate the risk at typical environmental exposures. However, in most cases, exposure at small levels usually encountered in the environment are not

observed in animal bioassay studies nor in occupational epidemiological studies. Thus, the portion of the dose-response curve, at the low environmental levels is unknown, making extrapolating to low doses highly uncertain. Various methods have been proposed to estimate risk at low levels including the linearized multistage model and model free extrapolation.

Uncertainty

In characterizing risks and benefits, the uncertainties and assumptions should be described and quantified where possible. Uncertainties in extrapolating from animal toxicology studies include high doses in animal studies versus low human exposures and differences among species. Using a different route of exposure instead of the target route leads to uncertainty as well as using subchronic studies for examining chronic effects.

Uncertainties in human epidemiological studies are found in historical exposure estimation when measuring technology has changed over time or reliable historical levels are unavailable. Even exposure estimation for prospective studies can be uncertain when collecting the information requiring a high degree of cooperation from subjects or when the measurement instruments are complex, eg., dietary surveys. In addition, disease may have diagnostic errors. Human epidemiology studies are often based on occupational groups who are exposed to higher levels than the general population and susceptibility, exposure patterns and demographics vary among individuals.

Uncertainty is dealt with by invoking conservative assumptions. Some typical assumption made are that humans are as sensitive as the most sensitive animals, that

the dose-response curve for DNA reactive toxicants is linear in low dose regions, that there is no threshold for genotoxicity, consideration is given to high exposure groups, risk estimates for non-threshold toxicants usually incorporate upper confidence limits, and uncertainty factors are used in establishing guidelines for threshold effects.

Uncertainty is quantified for risk and exposure estimates using probabilistic assessment. Distributions are developed using data or subjective information for each input parameter. Input distributions are sampled using Monte Carlo techniques and the results entered into the exposure or risk equation to obtain one simulated point. This procedure is repeated a large number of times, perhaps 5,000 or more until a risk or exposure distribution is built up.

Probabilistic assessment yields more comprehensive information about the risk or exposure estimate, which are traditionally presented as a single point estimate. The resulting range of estimates allows risk managers to: put the point estimates into better perspective by displaying other characteristics of the distribution such a percentiles, modes and medians; to identify the impact of uncertainties in each of the input factors; and enable more realistic comparisons among several exposures or risks. However, there are limitations as well. Input distributions are often highly subjective and complicated to interpret. Training may be required to conduct the analysis as well as to educate others in its interpretation. This analysis does not eliminate the need for professional judgement and carries a potential for errors in assumption. It is also important to distinguish between variability, that is the inherent variability associated with a factor such as body weight, and true uncertainty which refers to lack of knowledge.

Developing and Assessing Options

A number of broad classes of options are available for managing risks and can be regulatory or non-regulatory in nature. Non-regulatory options include: advisories where information is provided to promote risk avoidance; new technologies developed to reduce risk, for example child proof lighters; and, economic where financial incentives and disincentives are used to reduce risk. Voluntary compliance strategies and guidelines are also non-regulatory options.

Considerations for evaluating options include hazards and the risks involved, uncertainties in the risk estimation, health benefits associated with the hazard, public perception of risk, acceptability of the risk, characteristics of the option (including technical feasibility, potential effectiveness and environmental, economic and social impacts) and the viewpoint involved (e.g. individual or societal). Viewpoint is particularly important when those who bear the risks do not obtain the benefits.

A simple strategy for evaluating options would be to choose the one which leads to the greatest reduction in risk. Another strategy is to select the technology which leads to the greatest reduction in risk. However, there are often a number of other factors which impact on the decision so that more complex methods are desirable. For example costs of mitigation often play a role. Cost-effectiveness analyses compare costs of reducing exposure by one unit. Benefit-cost analyses compare costs of mitigation versus benefits incurred. There are limitations and uncertainties associated with this procedure. For example, costs are often easier to predict than assessing intangible benefits such as health and the quality of life.

Things to Consider When Analysing Options

Nature of the hazard and the associated risk	Many factors may be considered, such as the level and probability of exposure to the hazard, the nature and size of the population(s) at risk, interactions of the hazard with other hazards and the magnitude of the risk relative to other similar risks.
Benefits associated with the hazard	Hazards may be weighed against associated benefits. For example, although there may be some associated health effects, chlorine is often used to kill microbes in water and in public swimming pools because of its effectiveness.
Public perception of risk	Risk perception refers to the way in which individuals intuitively see and judge risks. For example, people often overestimate the likelihood of unlikely events, such as airplane accidents, and underestimate the likelihood of more common events, such as heart disease or stroke.
Risk acceptability	Acceptable risk is one that is so small, whose consequences are so slight or whose associated benefits (perceived or real) are so great that persons or groups in society are willing to take or be subjected to that risk.
Characteristics of the potential risk management option	Policies and actions intended to reduce risks may result in other risks or potential health, environmental, economic and social impacts. For example, although automobile air bags have reduced traffic fatalities, some people have died from injuries caused by the deployment of the air bag during a traffic accidents.

Source: Health Canada (1997) "Health and Environment - Partners for Life"

When appropriate, it is advisable for the proponent to present a number of options so that comparisons among mitigation strategies can be made. For example, in the recent decision by the Panel reviewing the High Level Nuclear Waste Disposal Concept, the Panel indicated that comparisons with alternative options to the concept of burying the waste are necessary to help the public understand better the issues and relative risk.

Making and Implementing Decisions

In making the decision, responsibility and accountability needs to be established. This should have been done in the planning phase of the risk management process. Decisions can also be made through deliberation with stakeholders, the public and other affected parties. In the latter case, those participating are jointly responsible and accountable for the decisions. Consultation is particularly important for strategies involving partnerships and community action programs.

Once the decision is made, it should be communicated to affected parties and an implementation plan developed. Roles and responsibilities are assigned, the objectives of the strategy formalized, timeliness and milestones established, a consultation and communication plan developed and resources allocated.

The strategy and implementation should be evaluated to be sure that risk is mitigated as expected. Monitoring and surveillance program are designed and implemented, performance indicators measured and quality control and quality assurance systems put in place.

Risk management decisions need to be reviewed regularly. New toxicological or epidemiological evidence could lead to changes in the risk characterization. Monitoring may also indicate unexpected changes in status which may need to be investigated. Review could lead to a revisiting of the risk/benefit characterization, options analysis and decisions.

Following up the Results

Agencies that implement risk management strategies frequently monitor and evaluate them to determine their effectiveness. Although it is desirable to measure different impacts, those related to physical health effects are often easier to measure than those

related to non-physical health effects, such as stress.

Strategies may be evaluated both qualitatively and quantitatively. For example, human exposure to contaminants in water or food may be monitored by analysing concentrations of the contaminant in human tissues or body fluids both before and after the risk management strategy is implemented. Evaluations may also involve epidemiological studies, surveillance (monitoring the incidence of disease, injury, product failure, etc., following implementation of the risk management strategy) and formal and informal gathering of information from stakeholders.

New information may lead to a review of any step in the risk assessment and risk management process. This review may occur at any point in time and is typically undertaken by the organization responsible for risk management. Review may lead to a reconsideration and revision of any previous step in the risk assessment and risk management process.

Difficulties and Challenges

The process needs to be general enough so that it an be applied to a wide range of environmental assessment projects. At the same time, it needs to provide enough guidance to the process so that all the essential elements of the process are addressed. This can be done by having specific guidelines associated with each general step of the framework. For example, guidelines for exposure assessments could be provided in the risk estimation phase.

As the social and regulatory climate changes, different issues must be considered when

assessing and managing risks. Frameworks need to be reviewed to ensure that these considerations are being addressed. As mentioned in Section 3.1, HPB of HC is currently updating their framework to reflect greater emphasis on the participation of stakeholders, partners, and the general public.

Gathering the information and consulting with those impacted in order to satisfy the process requirements may seem time consuming especially since they are designed to span a range of ideas and options. In the end, time put into this structured approach may actually save time since it likely will lead to more complete information and actually reduce the number of times an assessment needs to be revisited before a decision concerning the viability of the project is made.

Conclusions

A structure decision making process can help us structure and systematize the collection of information for environmental assessments. They need to be updated periodically as the social and regulatory climates change. There are limitations to their use but nevertheless has the potential to yield more complete, transparent information on which to base decisions.

Suggested Readings and Resources

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