

AN INTEGRATED FRAMEWORK FOR HUMAN HEALTH RISK ASSESSMENT- A REVIEW

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ABSTRACT

A health risk assessment (also referred to as a health risk appraisal and health & well-being assessment) is a questionnaire about a person's medical history, demographic characteristics and lifestyle. It is one of the most widely used screening tools in the field of health promotion and is often the first step in multi-component health promotion programs. Human Health Risk Assessment (HHRA) has five components which include Identify hazards, assess the risks, control the risks, record your findings, review the controls. Ultimately, the insights produced through scientific risk assessment can only guide us in defining the options and making appropriate risk decisions. Comprehensive and sound principles are critical to providing structure and integrity to risk management frameworks. Guiding principles provide an ethical grounding for considering the many factors involved in risk management decision making. However, the application of these principles will require both flexibility and practical judgement. The study is based on critical review of existing literatures from the global perspective.

Keywords: Risk Assessment Framework, Human Health, Risk Analysis, Hazard, Exposure Assessment

INTRODUCTION

Risk is a concept that denotes potential negative impacts to some characteristic of value that may arise from a future event (Rampal et. al., 1999). The ability of humankind to intuitively assess and manage risks has been fundamental for human survival and evolution. Those who were adept at recognizing risk and learning from danger survived to reproduce, whereas those who could not inevitably perished from avoidable environmental hazards (Thomas & Hrudey, 1997). Although dealing with “risk” is an age-old practice, the concept of “risk assessment and management” is relatively new, having only been formally acknowledged and practiced using this terminology for the last 20–30 years. During this period, as risk issues became more complex and relevant scientific knowledge became more detailed, the need for guidelines to provide a framework for risk assessment and risk management became more apparent.

Many international, national, and provincial/state agencies are currently employing various approaches to risk assessment, risk management, and risk communication (Sadhra & Rampal, 1999). These

approaches are used to systematically analyze, apply, and communicate complex and diverse information on human health risks posed by environmental contaminants or circumstances. However, the approaches used vary greatly between and even within the various agencies that advocate for their use. As a result, when dealing with cross-cutting issues such as communication, the application of technical assessment criteria, and the selection and implementation of risk management strategies, there is a lack of consistency. Such inconsistencies result in ineffective risk decisions, communication breakdowns, and inefficient use of resources intended to address human health risks. Furthermore, risk management frameworks are frequently used as a set procedure to deal with problems individually rather than strategically.

Several mechanisms were used to conduct an initial survey of agencies. Internet searches yielded a wealth of information on agency mandates and risk assessment and risk management processes. Many of the key documents could be downloaded directly. Emails and phone calls were also sent to appropriate agency personnel to request information directly. Finally, a one-page questionnaire was sent to agencies for which no other information was available. This questionnaire requested brief summaries of (1) agency-wide approaches to environmental, human health, and occupational health risks; (2) approaches used within agency-specific programs; (3) current status of approaches and programs (i.e., currently in use, under development, about to be implemented); and (4) names and contact information of people who could be contacted for follow-up.

The data was used to provide an overview of risk assessment, risk management, and risk communication approaches, both general and specific to human health, environmental, and occupational risk. The summary data was used to determine which agencies and advisory councils currently have specific and well-defined approaches to environmental, human health, and occupational health risks that should be thoroughly reviewed. Some frameworks were analyzed and compared based on the following criteria: (1) approach basis/limitations; (2) strengths and weaknesses; (3) experience with use; and (4) specific issues addressed. This data was used to identify the elements that should be included in a comprehensive approach.

This article provides a comprehensive analytical review of key national, provincial/state, territorial, and international risk assessment, risk management, and risk communication approaches currently being implemented. The information gathered for review is used to identify differences, similarities, strengths, and weaknesses among the various approaches, as well as elements that should be included in an effective current and comprehensive approach to environmental, human health, and occupational health risks. These elements are supplemented by a set of guiding principles that are recommended to provide an ethical foundation for considering the many factors involved in risk management decision making.

This review was motivated by an increasing interest in Bangladesh to better understand human health risk assessment framework and proper mechanisms to address it. Risk assessment and risk management are vast and ever-changing fields of study and practice. This review would be impossible to include all possible frameworks. The intention, however, was to include both the most important frameworks and a variety of general and specific application frameworks. It is also difficult to stay current in this ever-changing field. While every effort has been made to present the most recent versions of all principles and frameworks, it is recognized that some will have been updated by the time of publication. Instead, consider this review a "snapshot" in time of the state of the art.

Terminology, framework elements, and underlying principles for a common approach were all recommended. The University of Waterloo's NERAM (Network for Environmental Risk Assessment and Risk Management) group collaborated to create a preliminary benchmark framework that can be used as a reference to provide screening and organizational assistance to the review process. This framework is provided as part of the recommendations for a comprehensive and common approach and provides guidance on the implementation of risk management approaches.

APPROACH AND METHODOLOGY

Research Background and Data Collection

The risk-assessment and risk-management literature is extensive, reflecting both the growing importance of risk issues and the field's interdisciplinary scope. The brief background presented below considers some key milestones in the evolution of risk assessment and risk management, but it is not intended to be a comprehensive review of the literature in this field.

For this current review, the major basis of information was collected from published online journals, Google scholar, ResearchGate, ScienceDirect, conference papers, electronic books, Government sites, Web links, Springer Link and Policy documents. Moreover, more than 40 articles were reviewed and 26 published articles chosen for citation. By giving scientifically valuable information on the human health risk assessment framework, these findings will help policymakers, academics, government and non-governmental organizations globally.

RESULTS AND DISCUSSION

Terminology

At the time of writing, two major international efforts were made to standardize risk terminology. The first was run by the ISO (International Organization for Standardization) and the IEC (International Electrochemical Commission) as part of the ISO/TMB Working Group on Risk Management Terminology. This group created a Working Draft of Risk Management Terminology (International Organization for Standardization, 2000).

Before entering into the deep of human health risk assessment framework, introduce with some terminology is very important which include risk, risk analysis, risk perception, uncertainty, hazard, modes and causes of hazard, accident and incident are most important.

Risk: Risk is an event or condition that may occur, and whose occurrence, if it does take place, has a harmful or negative effect. The term risk can be traced back to the Greek word rizikon (Greek, riza). The term risicum was used in highly specific contexts related to sea trade and its legal problems of loss and damage in the Middle Ages. In the 16th century, the words rischio and riezgo were used, both terms derived from the Arabic word " ريزك rizk", meaning 'to seek prosperity'. This was introduced to continental Europe through interactions with Arab traders from the Middle East and North Africa. The term risk first appeared in the English language in the 17th century, and it appears to have been imported from continental Europe. According to Bertrand Russell risk is "“When one admits that nothing is certain one must also admit that some things are much more nearly certain than others.” Risk is three types,

- Perceived through science (e.g., cholera: need a microscope to see it and a scientific training to understand)
- Perceived directly (Scientists don't know or cannot agree e.g., BSE/vCJD global warming low-level radiation, pesticide residues, HRT, mobile phones, passive smoking, stock market etc).
- Virtual risk (e.g., climbing a tree, riding a bike, driving car)

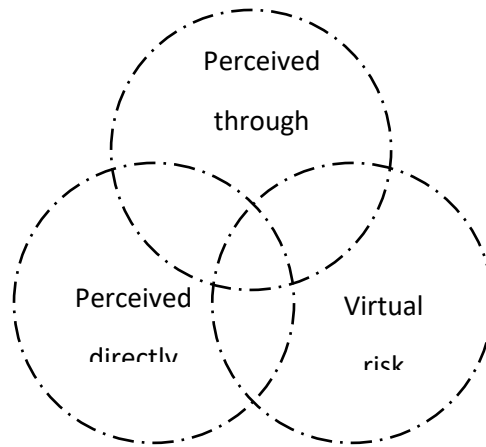


Figure 1: Three types of risks

In engineering, the risk of an accident defined as:

$$\text{Risk} = \text{Probability of an accident} \times \text{Losses per accident} \dots\dots\dots(1)$$

$$\text{Risk} = \text{Likelihood of occurrence} \times \text{Consequences of occurrence} \dots\dots\dots(2)$$

Table 2: various source of risks and annual risk of mortality

Source	Annual risk of mortality
Heart disease	1 in 397 (0.0025)
Cancer	1 in 511 (0.002)
Accidents	1 in 3,014 (0.0003)
Alcohol	1 in 6,210 (0.00016)
Suicide	1 in 12,091 (0.000083)
Homicide	1 in 15,440 (0.000065)
Fire	1 in 82,977 (0.0000012)
Bioterrorism	1 in 56,424,800 (0.00000002)
Food poisoning	1 in 56,424 (0.00002)

Risk Analysis: To quantify the potential detriment and evaluate the effectiveness of proposed remediation risk analysis is important. Risk analysis is the systematic use of available information to determine how often specified events may occur and the magnitude of their consequences. Risk assessment questions three things;

- What can go wrong?
- What is the likelihood that it will go wrong?
- What are the consequences?

Whereas risk management also asks three questions which include;

- What can be done?
- What options are available and what are the associated tradeoffs in terms of cost, risks, and benefits?
- What are the impacts of current management decisions on future options?

Characteristics of Risk: A risk is characterized based on the following;

- Probability of an adverse outcome
- Type and severity of adverse outcome
- Timing of adverse outcomes
- Distribution of adverse outcomes
- Size of the exposed population or the environment

- Certainty of risk estimates

Uncertainty: Uncertainty is a state of having limited knowledge in which it is impossible to precisely describe the current state or the future outcome. In other words, uncertainty is the presence of more than one possible outcome. Human health risk estimates are highly uncertain due to:

- Extrapolation of dose-response curve
- Non-availability of data for exposure assessment

Hazard: A hazard is any source of potential damage, harm or adverse health effects on something or someone under certain conditions at work. A hazard is usually used to describe a potentially harmful situation. There are a number of modes for a hazard that includes:

Dormant:

- The situation has the potential to be hazardous
- No people, property or an environment is currently affected by this. For instance, a hillside may be unstable, with the potential for a landslide, but there is nothing below or on the hillside which could be affected.

Potential or Armed:

- This is a situation where the hazard is in the position to affect persons, property or environment.
- This type of hazard is likely to require further risk assessment.

Active:

- The hazard is certain to cause harm as no intervention is possible before the incident.

Mitigated:

- A potential hazard has been identified
- Actions have been taken in order to ensure it does not become an incident
- This may not be an absolute guarantee of no risk, but action has likely been undertaken to significantly reduce the danger.

Causes of Hazards: There are many causes, but they can broadly be termed into:

- Natural Hazards: These include anything which is caused by a natural process (e.g., Volcanoes, earthquakes)
- Man-Made Hazards: They resulted from human's activities (e.g., Global warming, pollution)

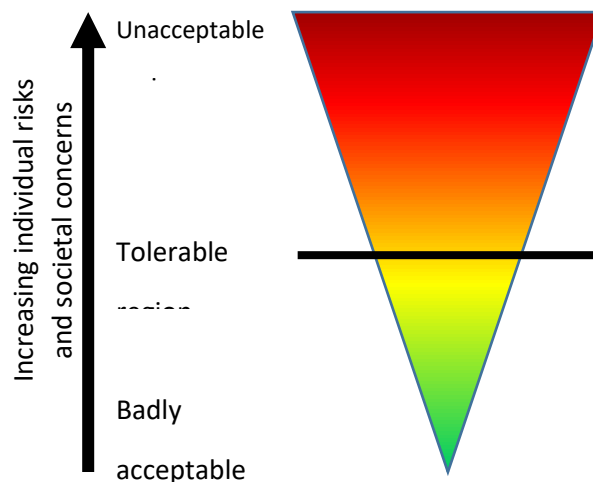


Figure 2 ALARP graph. Adapted from (risktec.tuv-knowledge, 2022)

ALARP: ALARP (as low as reasonably practicable) is a term often used in the milieu of safety-critical and safety involved systems, shown in above figure 2. The ALARP principle states that the residual risk should be as low as reasonably practicable. It has particular connotations as a route to reduce risks to SFARP (so far as is reasonably practicable, i.e., safe and without risks to health) in UK Health and Safety law.

Human Health Risk Assessment (HHRA)

A human health risk assessment is the process to estimate the nature and probability of adverse health effects in humans who may be exposed to chemicals in contaminated. HHRA estimates the probability that exposure of number of people to some chemicals that will cause some adverse response such as:

- Cancer
- Reproductive failure
- Neurological damage
- Developmental problems or
- Birth defects

Various definitions for selected risk assessment terms were extracted from key documents and sources. Through several means, including the Internet, interested people were being asked to:

- Identify or provide their preferred definition for each term
- Identify terms considered as synonyms
- Indicate whether any important key documents/sources have been omitted.

These efforts at standardization reflect the problems that have arisen with different definitions and understanding of some of the fundamental terms associated with this field. For the purposes of this review, the following definitions of the fundamental terms are used:

Risk assessment: "An organized process used to describe and estimate the likelihood of adverse health outcomes from environmental exposures to chemicals. Hazard identification, dose-response assessment, exposure assessment, and risk characterization are the four steps" (U.S. Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997).

Risk management: "The process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and ecosystems. The goal of risk management is to reduce or prevent risks while taking into account social, cultural, ethical, political, and legal considerations (U.S. Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997).

Risk communication: "An interactive process of exchange of information among individuals, groups, and institutions (that) raises the level of understanding of relevant issues or actions for those involved and satisfies them that they are adequately informed within the limits of available knowledge" (U.S. National Research Council, 1989).

Overview of Principles

A Human Health Risk Assessment (HHRA) is a process to determine if contaminants detected at a site are of concern to human health and the environment. The HHRA falls under the evaluation step of the voluntary agreement process, and involves using environmental data to estimate the nature, magnitude, and probability of adverse health effects on people who may be exposed to the contaminated environmental media (e.g., soil, soil gas, groundwater, surface water), now and in the future. Voluntary agreement projects use the HHRA to make decisions about allowable use or reuse of the property, and to facilitate an effective assessment and cleanup strategy to ensure safe end use. DTSC's Human and Ecological Risk Office (HERO) should be involved in the scoping meeting for new voluntary agreements in order to provide feedback and guidance on the HHRA process.

Comprehensive and sound principles are critical to providing structure and integrity to risk management frameworks. Several sets of underlying principles and foundations for risk management were examined

in the course of this review. The breadth and comprehensive nature of these various principles provides an invaluable basis for determining those concepts that should be included in an overall set of principles for environmental, human health, and occupational health risk approaches. A brief description of each set of principles is provided here. According to, New Brunswick Department of the Environment. (1999), assigns four steps to risk assessment which include;

- I. Hazard Identification
- II. Toxicity Assessment
- III. Risk Characterization
- IV. Exposure Assessment

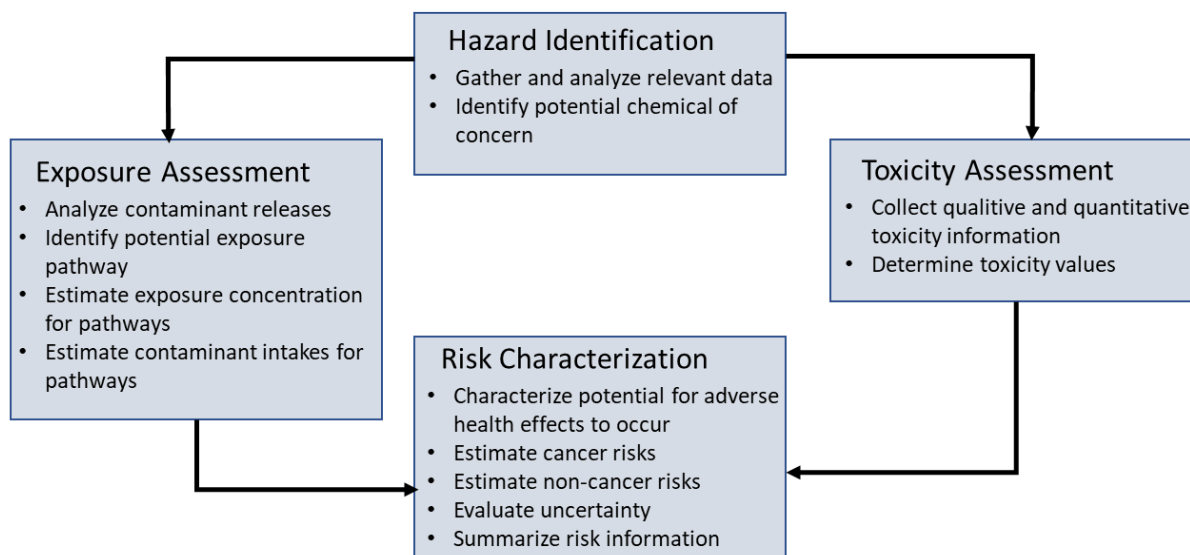


Figure 3: various source of risks and annual risk of mortality

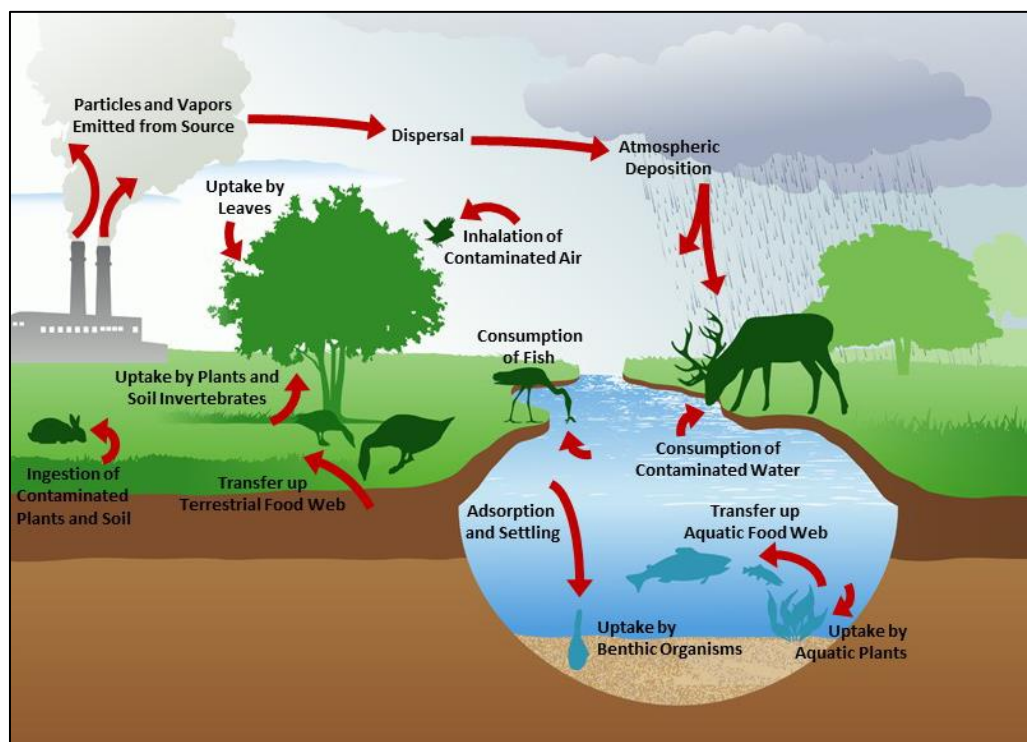


Figure 4: Visual representation of exposure assessment pathway. Adapted from: Multimedia Fate and Transport Modeling – General

Hazard Identification: Hazard identification is the process of determining whether or not a given chemical is linked to a particular health effect. Data collected at a site are used to determine what chemicals are present and whether they can cause effects (both cancerous and non-cancerous) harmful to people who may come in contact with the contaminated media. Examines data on contaminants detected during monitoring and emphasizes those of concern.

- This step verifies that if the activity in question occurs (such as exposure to a chemical)
 - can it cause any adverse effects on the environment?
 - If yes, what are those effects?
- Requires knowledge of source of contamination, concentration of contaminants and transport mechanisms, i.e., how they reach to the receptor

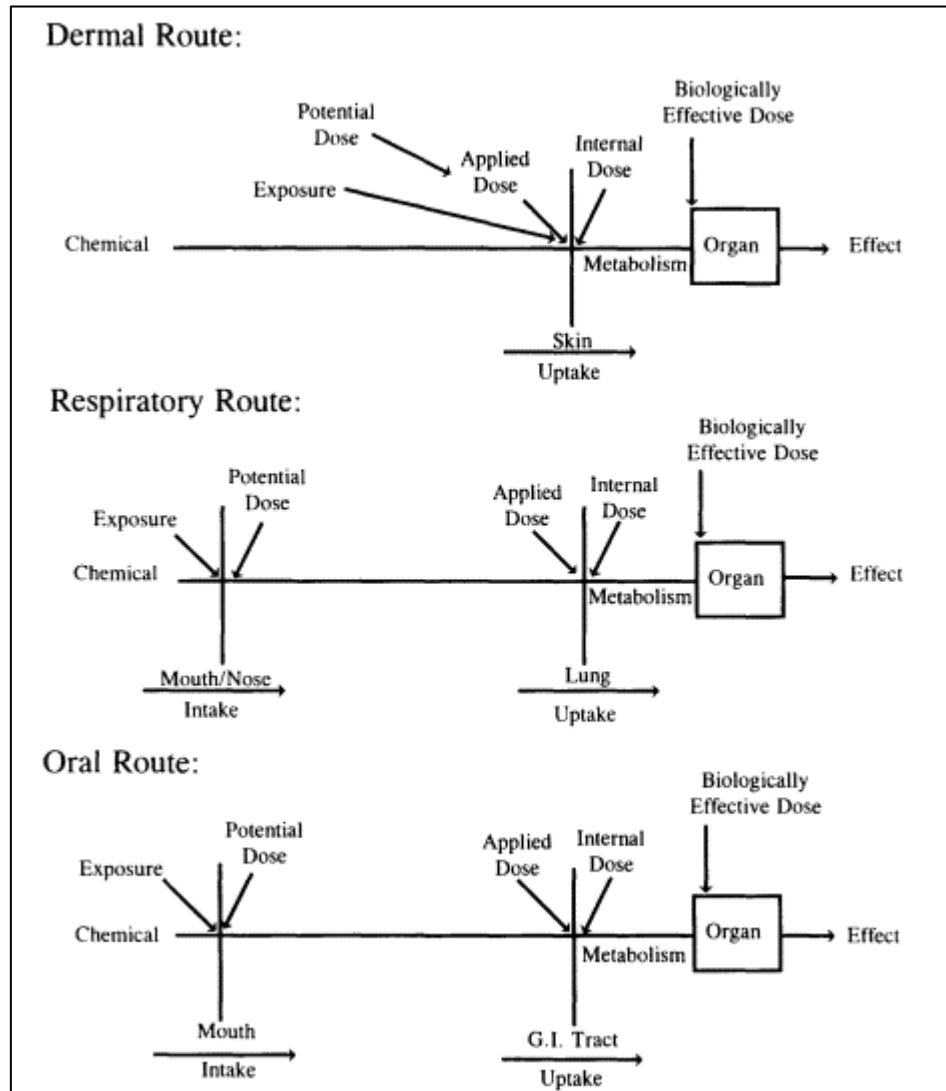


Fig 5: Schematic of dose and exposure. Adapted from: (*Environmental Epidemiology, Volume 2, n.d.*)

Exposure Assessment: This step identifies current and potential future populations who may come in contact with the site's contaminants; the various media that may have been affected by the contamination; pathways of exposures for potentially exposed populations (through ingestion, inhalation, or absorption through the skin); and estimated contaminant concentrations (intake rates) that may be taken up via the various exposure pathways. Schematic of figure 5 shows the interrelation between dose and exposure.

Exposure assessment asks following questions:

- How much toxic is the involved chemical?
- How likely is it to get exposed to the chemical?
- How the toxic chemical can be transported from the source to the point of contact with receptor (pathways)?
- What are the exposure routes?
- What are the possible consequences of exposure to the chemical?

An exposure assessment is a three-step process:

- I. The pathways for the toxic agents must be determined
- II. The concentration of toxicants in the air, soil, water, and food at a particular exposure point must be determined
- III. The human contact (exposure routes) with these toxicants must be established.

Exposure assessment considers the following:

- size and nature of the population that has been exposed to the toxicant
- length of the time of exposure
- frequency of exposure, and
- toxicant concentration to which the people have been exposed.

Exposure may occur in three different ways:

- inhalation
- dermal contact
- skin
- eye
- oral ingestion
 - drinking polluted water
 - eating polluted food (and soil)

Toxicity Assessment: This step incorporates toxicity information about the chemicals into the HHRA. This information is typically available on the U.S. Environmental Protection Agency and/or the California Environmental Protection Agency websites, including DTSC's HHRA Note 3.

Risk Characterization: This step combines information from the previous steps to evaluate cumulative cancer risks and non-cancer hazards the site poses to potentially exposed human populations. This information is used to determine whether the site is safe or contaminants are present at levels posing unacceptable risks to people and the environment, requiring remediation of contaminated media. Risk management decisions are developed based on the results of cumulative cancer risk and non-cancer hazard estimates for the site.

In risk characterization two models are very popular;

One-Hit Model: One-hit model is the most common and the simplest model that provides a biological process carcinogenesis. In a one-hit model, the relationship between dose (d) and life time cancer risk (P) is given by:

$$P = 1 - e^{-(q_0 + q_1 d)} \dots\dots\dots(3)$$

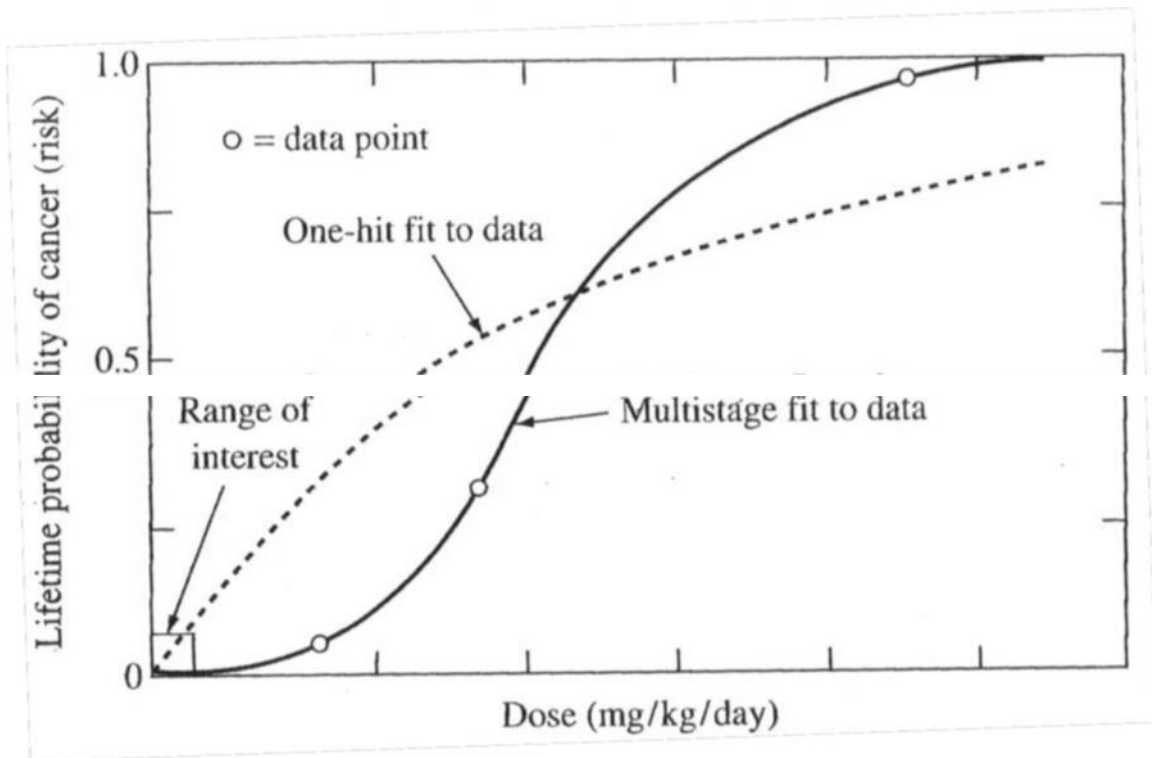


Fig 6: Schematic diagram of One-Hit model

At low dosage (where the dose-response curve is assumed linear) the slope of the curve is called potency factor (PF):

$$PF = (\text{Incremental Lifetime Cancer Risk} / \text{Chronic Daily Intake}) \dots\dots\dots (4)$$

If a carcinogenic chemical is present in drinking water, the chronic daily intake (CDI) is defined as the dose of the contaminant averaged over an entire lifetime where the intake rate is the amount of contaminated water ingested every day.

$$CDI = (\text{Concentration} \times \text{Intake Rate}) / \text{Body Weight} \dots\dots\dots (5)$$

If a carcinogen is present in drinking water but not for the entire lifetime, then the chronic daily intake (CDI) of the contaminant is calculated as:

$$CDI = (\text{Concentration} \times \text{Intake Rate} \times \text{Exposure}) / (\text{Body Weight} \times 70 \times 365) \dots\dots (6)$$

Multistage Model: A more general model is called multistage model. When we use the animal toxicity data to humans, a safety factor is applied to calculate the threshold limit for human. The human threshold is called reference dose (RfD).

$$RfD = \text{Safety Factor} \times \text{Animal Threshold (e.g., NOAEL)} \dots\dots\dots (7)$$

The exposure is compared with RfD to see whether the dose estimated based on exposure is safe. The measure is called hazard quotient (HQ) and is defined as:

$$HQ = \text{Average Daily Dose During Exposure Period} / RfD \dots\dots\dots (8)$$

According to the definition

- If $HQ < 1$, there is no significant non-cancer risk
- If $HQ > 1$, there is a potential non-cancer risk

Overview of Frameworks

Frameworks for assessment, management, and communication of environmental health risks (including human health, ecological, and occupational risks) have been developed by a variety of governmental, standard-setting and other agencies. Some of these frameworks are general in nature, while others target specific applications of risk assessment, such as contaminated sites, standard setting, or food safety. The documents assembled in this study reflect the broad range of frameworks available provincially, nationally, and internationally.

Table 2 Overview of General Frameworks for Human Health, Occupational Health, and Ecological Risk Assessment and Management, and Their Key Features

Framework	Description and key features
Framework for Risk Management (U.S. Presidential/ Congressional Commission on Risk Assessment and Risk Management, 1997)	Perhaps the most influential framework. Considered to reflect the international "state of the art" in risk management
Decision-Making Framework for Identifying, Assessing and Managing Health Risks (Health Canada, 2000)	Based on the Framework for Risk Management, replacing the 1990 framework
Health Risk Determination: The Challenge of Health Protection (Health and Welfare Canada, 1990)	Used as the model for health risk assessment and management by the federal government until 2000
CSA-Q850 Risk Management: Guidelines for Decision-Makers (Canadian Standards Association, 1997)	Provides generic guidance to government and industry for many types of risk
CSA-Z763 Introduction to Environmental Risk Assessment Studies (Canadian Standards Association, 1996)	Published as a companion to CSA-Q850, and based on CSA-Q634–91; stresses that environmental risk assessment is part of good corporate environmental policy
CSA-Q634–91 Risk Analysis Requirements and Guidelines (Canadian Standards Association, 1991)	Developed primarily to address the occupational risk from exposure to hazardous materials or processes
Integrated Framework for Population Health Risk Management (Birkwood & Hogan, 1999)	One of the few frameworks for population health risk assessment and management; includes key aspects from the fields of health promotion
Integrated Risk Management Framework (Treasury Board of Canada Secretariat, 2001)	Designed to provide guidance to advance the use of a more corporate and systematic approach to risk management, and to assist public service employees in their decision making
Risk Assessment in the Federal Government: Managing the Process (U.S. National Research Council, 1983)	Represents the first formalized effort to describe the health risk assessment and management process in a structured way consolidates earlier efforts at developing a comprehensive framework, and has since been widely endorsed throughout the world it has been the most influential framework in risk assessment
Science and Judgement in Risk Assessment in (U.S. National Research Council, 1994)	Expert panel publication characterizing the scope of judgement and uncertainty involved in risk assessment
Understanding Risk: Informing Decisions in	Based on an "analytic–deliberative process" for risk characterization

a Democratic Society (U.S. National Research Council, 1996)	
Guidelines for Ecological Risk Assessment (U.S. EPA, 1998b)	Designed to provide a consistent approach in the application of U.S. EPA environmental laws
Guidelines for Carcinogenic Risk Assessment (U.S. EPA, 1986)	Designed to set forth principles and procedures to guide U.S. EPA scientists in the conduct of cancer risk assessments, and to inform U.S. EPA decision makers and the public about these procedures
Proposed Guidelines for Carcinogenic Risk Assessment (U.S. EPA, 1996)	Designed to replace 1986 guidelines; underwent revision in 1999; still considered draft after several years of feedback
Risk Characterization Handbook (U.S. EPA, 2000)	Based on the premise that, to be effective, risk characterization must be transparent, clear, consistent, and reasonable (TCCR)
U.S. DOE Risk Integration Framework (2000)	Recognized that the integration of risk information and issues into decision-making and the integration of program activities across various projects and sites are critical to the credibility and accountability of their Environmental Management Program
Australian/New Zealand Risk Management Standard (AS/NZS 4360) (1999)	Jointly developed by Standards Australia and Standards New Zealand, the standard is intended to provide a “generic guide for the establishment and implementation of the risk management process involving establishing the context and the identification, analysis, evaluation, treatment, communication and ongoing monitoring of risks”
Australian Environmental Health Risk Assessment: Guidelines for Assessing Human Health Risks from Environmental Hazards (2002)	An Australian national approach to environmental health risk assessment; brings together the standard risk assessment components of issues of identification, hazard assessment, exposure assessment, risk characterization, and risk management; engagement of stakeholders, risk communication, and community consultation is seen to “envelope” the process
Health Council of the Netherlands: Environmental Risk Management Approach (1996)	Conceptual framework for evaluating and deciding about risks in the Netherlands
United Kingdom Framework for Environmental Risk Assessment and Risk Management (2000)	Based on a tiered approach to environmental risk assessment and risk management where the level of effort put into assessing each risk is proportionate to its priority (in relation to other

	risks) and its complexity (in relation to an understanding of the likely impacts)
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Occupational Health Risk Assessment and Risk Management

The UK Health and Safety Executive (HSE) is charged with the mission “to ensure that risks to people’s health and safety from work activities are properly controlled.” The HSE has set out Five Steps to Risk Assessment (1998) to help employers and self-employed people assess risks in the workplace (aimed at firms in the commercial, service, and light industrial sectors). The five steps are:

1. Look for hazards.
2. Decide who might be harmed and how.
3. Evaluate the risks and decide whether the existing precautions are adequate or whether more should be done.
4. Record your findings.
5. Review your assessment and revise it if necessary.

Additionally, NIOSH also funds research to improve occupational health risk methods and policy development through its National Occupational Research Agenda (NORA) program. The Risk Assessment Methods (RAM) Team has identified five priority research areas to promote improvement in the methodologies used for risk assessment:

- Sources of human variability in susceptibility among workers exposed to toxic substances.
- Evaluation of toxicological risk assessment models using epidemiologic data.
- Utilizing biomarkers of disease in development risk of assessment models for predicting the risk of chronic diseases.
- The impact of errors in exposure assessments on epidemiologic risk assessments.
- The influence of pattern of exposures in determining occupational health risks.

Frameworks for Specific Applications

Many frameworks have been developed for specific application of risk assessment. These include, but are not limited to, frameworks for (1) contaminated sites; (2) northern contaminants; (3) priority substances; (4) standards development; (5) food safety; (6) medical devices; (7) prescription drug use; (8) emergency response; (9) transportation; and (10) risk communication.

Checklist for Risk Management

Based on this comprehensive approach to risk management, we propose the following as a “checklist” to ensure a good risk management decision:

- Make sure you’re solving the right problem.
- Consider the problem and the risk within the full context of the situation, using a broad perspective.
- Acknowledge, incorporate, and balance the multiple dimensions of risk.
- Ensure the highest degree of reliability for all components of the risk management process.
- Involve interested and affected parties from the outset of the process.
- Commit to honest and open communication between all parties.
- Employ continuous evaluation throughout the process (formative, process, and outcome evaluation), and be prepared to change the decision if new information becomes available

Decision-Making Principles

These principles are intended to be aspirational, rather than prescriptive— their application requires flexibility and practical judgement. Risk management is inherently a process in search of balance among competing interests and concerns. Each risk management decision will be a “balancing act” of competing priorities, and trade-offs may sometimes have to be made between seemingly conflicting principles.

1. **Do more good than harm (beneficence, nonmalificence).** This principal stems from the prima facie ethical principles of beneficence (do good) and nonmalificence (do no harm). It is

adapted from the original “do no harm” of the Hippocratic Oath: I will prescribe regimen for the good of my patients according to my ability and my judgement and never do harm to anyone.

2. **Fair process of decision-making (fairness, natural justice).** Risk management must involve a fair process for all parties. It must be just, equitable, impartial, unbiased, dispassionate, and objective as far as possible given the circumstances of each situation. Achieving a fair process will thus require seeking a proper balance of conflicting needs, rights, and demands.
3. **Ensure an equitable distribution of risk (equity).** An equitable process of risk management will help achieve a fair outcome and equal treatment of all concerned through an equal distribution of benefits and burdens. This principle includes the concept of distributive justice, that is, equal opportunities for all individuals.
4. **Seek optimal use of limited risk management resources (utility).** All agencies recognize that the resources available to them (including intellectual, tangible, and financial resources) for achieving effective risk management are limited. Optimal risk management demands using limited resources where they will achieve the most risk reduction or overall benefit.
5. **Promise no more risk management than can be delivered (honesty).** Creating expectations for risk management that cannot be met will inevitably generate conflict. This is readily avoided with honest and candid public accounting of what we know and don't know, and what we can and can't do using risk assessment and risk management. Failure to acknowledge and understand the limitations to our knowledge impairs our ability to make difficult decisions under uncertainty. Misguided confidence in risk assessment (by both the risk agency and the public) creates a major problem for risk management and risk communication.
6. **Impose no more risk than you would tolerate yourself (the Golden Rule).** The Golden Rule is a rule of ethical conduct first referred to in the Bible (Mt 7:12 and Lk 6:31) and stating that you should do unto others as you would have others do unto you. The Golden Rule has served society extremely well as a beacon for guiding civilized human behavior.
7. **Be cautious in the face of uncertainty (“better safe than sorry”).** Uncertainty is inherent in all aspects of determining potential human health, ecological, or occupational risk. Making appropriate decisions in the face of this uncertainty is a major challenge of risk management. Dealing with uncertainty depends on many factors, including the potential adverse consequences of the hazard, and public concerns about the inherent risk. Risk management must adopt a cautious approach when faced with a potentially serious or irreversible risk, even if the scientific evidence is uncertain. Prudent action may be taken without having to await scientific certainty.
8. **Foster informed risk decision making for all stakeholders (autonomy).** People and communities have the right to be involved in decisions that affect their lives and those of the people they care about. These principles honor both the right for self-determination and informed decision making. Fostering autonomous decision making involves both providing people with the opportunity to participate and full and honest disclosure of all the information required for informed decisions.
9. **Risk management processes must be flexible and evolutionary to be open to new knowledge and understanding (evolution, evaluation, iterative process).** Committing to use the best evidence means that the risk management process must be able to accommodate new evidence and evolve with new understanding of the problem. The incorporation of new evidence requires that risk management be a flexible, evolutionary, and iterative process. It also entails employing evaluation throughout the process to ensure that the problem and approach are appropriate, that the process is proceeding successfully, and that the risk management measures are effective.

10. **The complete elimination of risk is not possible (life is not risk free).** Risk is pervasive in our society. Despite the desire expressed by some people for “zero risk” in their environment, we know this to be fundamentally unachievable. No activity, process, or product is without risk (Health Canada, 2000). Furthermore, the undertaking of some risk is necessary for us to learn, grow, progress and evolve in our world.

Implementation

Some key features to consider with regard to implementing a framework for risk management are the time horizons and functional levels within an organization. Time horizons can range from long-range issues dealing with strategic risks, medium-term issues that relate to tactical risks, and short-term issues that relate to operational risks. The functional levels within the organization will normally include decision making, policy analysis, supervision and monitoring, and operations. Effective implementation of a risk management framework requires a process that allows effective transfer of information from the top down for deciding on what issues need to be addressed and from the bottom up to ensure that sufficient detail is understood by decision makers and that they understand the external environment and the internal performance of the organization in response.

The benchmark framework for risk management incorporates risk management functions at three levels: senior management, policy and program planning, and operations. The functions that need to be performed, the criteria that are used to measure performance, and the capacity requirements to perform these functions are outlined. Finally, the proposed functions of the benchmark framework are validated against three well-established risk management frameworks.

SUMMARY AND CONCLUSIONS

Various approaches to risk assessment, risk management and risk communication have been developed by many international, national, and provincial/ state agencies over the last 20 years. As evidenced in this overview, these approaches have tended to vary considerably as each agency attempted to develop their own process. However, with increasing experience in the application of these approaches, we are evolving to a common understanding of the key elements required for successful risk assessment, risk management and risk communication. We now understand that risk is a multidimensional concept that must also include the perspectives of those affected. Risk assessment informs risk management, but is only one of many inputs to the process. Risk management also involves social, cultural, ethical, political, and legal considerations. A good risk management decision emerges from a decision-making process that elicits the views of those affected by the decision, so that differing technical assessments, public values, knowledge, and perceptions are considered. Ultimately, the insights produced through scientific risk assessment can only guide us in defining the options and making appropriate risk decisions. Comprehensive and sound principles are critical to providing structure and integrity to risk management frameworks. Guiding principles provide an ethical grounding for considering the many factors involved in risk management decision making. However, the application of these principles will require both flexibility and practical judgement. Risk management is inherently a process in search of balance among competing interests and concerns. Each risk management decision will be a “balancing act” of competing priorities, and trade-offs may sometimes have to be made between seemingly conflicting principles.

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