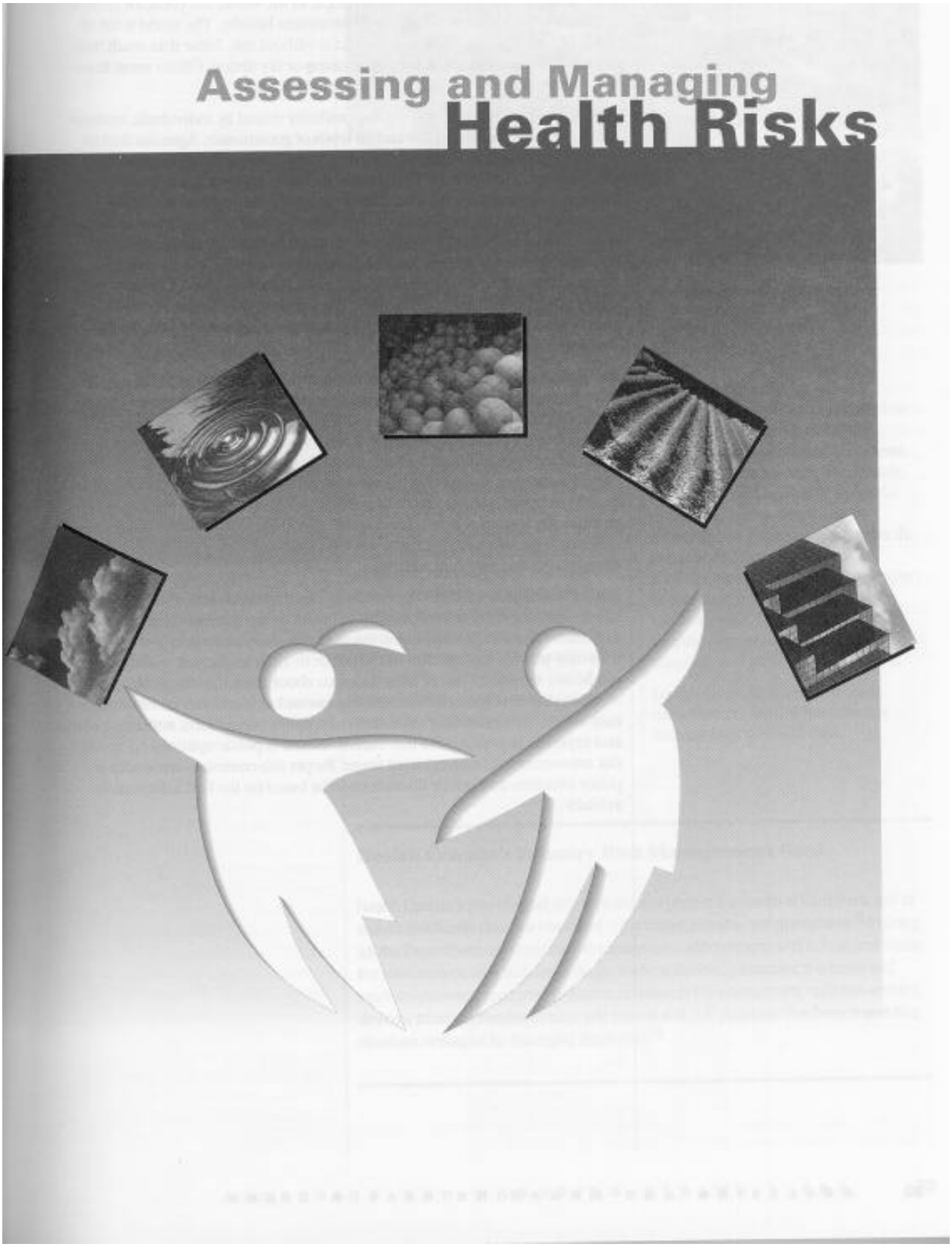
# Assessing and Managing Health Risks



## Chapter Highlights:

Canadians are among the healthiest people in the world, but constant effort is required to keep ourselves and our environment healthy. The world is full of risks, and no activity, process or product is without risk. Some risks result from personal choice, such as mountain climbing or sky diving. Others result from substances, processes or products in the environment.

In Canada, health protection is a responsibility shared by individuals, communities, commercial enterprises and all levels of government. Agencies that are involved in health protection often use a formalized approach for assessing and managing health risks. This process generally involves identifying specific hazards, estimating the associated level of risk, developing and analysing potential options for managing the risk, selecting and implementing a specific risk management strategy and monitoring and evaluating the impact of this strategy. These steps may be taken formally or informally, and to varying degrees, depending on the situation and participants involved. In recent years, government agencies have recognized the importance of involving those people who are most affected by risk management decisions directly in the decision-making process.

*Risk perception* refers to the way in which individuals intuitively see and judge risks. Perceptions can affect behaviour and the decisions people make about controlling risks. Risk perception is influenced by many factors, including age, gender, level of education, geographic region, values and previous exposure to information on the hazard through the news media or other sources. Perceptions may change over time as new information becomes available. Risk management decisions should take into account public perception of risk, as the public may perceive the level of risk associated with a specific health hazard as being different from (often higher than) the level calculated through scientific experiments and statistical analyses.

*Risk communication* involves the exchange of information about the existence, nature, form, severity or acceptability of health or environmental risks. Regulatory agencies practise many forms of risk communication. For example, they may provide information to the public to assist in decision making, alert the public to a significant risk or calm concerns about a risk that the public perceives as serious but that has been scientifically assessed as small. Risk communication may also involve obtaining information on public perceptions, attitudes, beliefs and experiences with a particular hazard, as well as public opinions on specific risk assessment and management issues. Proper risk communication allows policy decisions and public discussions to be based on the best information available.

# ASSESSING AND MANAGING HEALTH RISKS

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## Introduction

Canadians are among the healthiest people in the world, but constant effort is required to keep ourselves and our environment healthy.[30] The world is full of risks, and no activity, process or product is without risk.[31] Some risks result from personal choice, such as mountain climbing or sky diving—or even not looking both ways before crossing the street. Others result from substances, processes or products in the environment. The responsibility for protecting our health is shared by individuals, communities, commercial enterprises and all levels of government.

Protection of health, at either a personal or societal level, is complex. It generally involves identifying specific hazards, estimating the level of risk associated with these hazards, developing and analysing potential options for managing the risks, selecting and implementing a specific risk management strategy and monitoring and evaluating the impact of this strategy. These steps may be taken formally or informally, and to varying degrees, depending on the situation and participants involved.

Health protection agencies often use a formal method for assessing and managing health risks.

### Health Canada's Primary Risk Management Goal

Health Canada's primary goal is to improve and protect the health of Canadians and to ensure that health risks are minimized to the extent possible and practicable.[32] In doing so, the Department assesses the risks associated with contaminants in food and water; the manufacture, sale and use of drugs; medical devices; pesticides; the home and work environment; consumer products; radiation in the environment; radiation-emitting devices; tobacco; disease threats; and natural and civil disasters. The Department also develops strategies for managing these risks.[33]

## Why Use a Framework?

Frameworks for risk assessment and risk management provide structured, analytical guidelines for decision making, yet offer enough flexibility to address specific health hazards in the manner required. Use of a framework helps to ensure a consistent approach to risk assessment and risk management, not only within a particular agency, but also among agencies with similar mandates. For example, to ensure consistency with national and international agencies involved in food inspection, the Food Directorate of Health Canada uses a framework that has been harmonized with those developed by the World Health Organization/Food and Agriculture Organization of the United Nations[36] and the Codex Alimentarius Commission.[37] Frameworks can also improve relationships with stakeholders by involving them in each step of the risk assessment and risk management process.

Frameworks for risk assessment and risk management should be reviewed periodically and updated as needed to take into account new considerations, changing priorities, experience gained during their use and work performed by other national and international organizations.

The U.S. government recently developed a comprehensive framework for the assessment and management of risks to human health and ecosystems.[38] This framework is designed for use by all types of risk managers, including government officials, businesses and individuals. The framework defines health and environmental problems broadly to help identify the potential impact of individual risk management decisions on public health or the environment. In addition, it encourages the active participation of stakeholders and is flexible enough to permit the review of previous steps in the process as new information or perspectives emerge.

Decision-making frameworks have been developed for this purpose by several organizations in Canada and internationally. Although frameworks tend to be based on similar principles, they may differ in scope, terminology, presentation of the steps involved, level of detail and the role of such factors as risk communication and the involvement of stakeholders (i.e. parties who are concerned about or affected by the issue) in the overall process.[34,35]

Although there is no formal *Canadian* approach, the Canadian Standards Association[39,40] has developed two voluntary standards for assessing and managing health risks. The more recent of these standards provides a framework for the process of risk assessment and risk management and incorporates common elements from a number of other frameworks. It has been offered as a Canadian standard applicable across a number of risk management disciplines.[40]

This chapter describes the general process used to assess and manage health risks and includes the framework developed by the Health Protection Branch of Health Canada as an example.[32] The chapter also describes the importance of considering risk perception and undertaking risk communication within the risk assessment and risk management process, and it provides a few examples of broad risk management strategies used by Health Canada.

## The Risk Assessment and Risk Management Process

### Identifying Hazards

*Hazard*: The adverse impact on health that can result from exposure to a substance, process or product.[41]

*Hazard identification* involves recognizing that a particular substance, process or product (i.e. an agent) may cause specific adverse health effects. In the past, hazard identification studies have focussed on physical health effects; more recently, emotional and mental health effects have also been considered.

Scientists use a variety of approaches for the identification of health hazards. The two main sources of information on environmental contaminants—including chemicals, radiation and microbiological hazards—are epidemiological studies of human populations and toxicological studies, which usually involve animals in research laboratories.[32] Other useful information sources include reports of adverse effects in individuals, clinical studies involving human volunteers and discussions with affected communities. Hazards involving consumer products and medical devices are often identified through evaluation of product specifications, product testing and forensic investigations. Hazards involving diseases are often identified through ongoing surveillance.

#### *Using Epidemiology to Identify Hazards*

*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.[42] Epidemiology is concerned with both the frequencies and types of illnesses and deaths in particular groups of people and with the factors that influence their distribution.[43]

## Monitoring Diseases Through the Public Health Intelligence Network

The Laboratory Centre for Disease Control (LCDC) is Canada's only national public health and disease control agency. It carries out disease surveillance, risk assessment and control of diseases of national and international importance through well-established public health networks. The system in place to monitor, investigate, prevent and control health risks is referred to as Public Health Intelligence (PHI).

National networks have been built upon existing provincial infrastructure and in collaboration with over 7000 health partners across Canada, including epidemiologists, physicians, public health professionals and laboratory scientists. Through the networks, health intelligence is gathered that permits LCDC to target national population health interventions, to provide early warning needed to mobilize cost-effective national responses and to collect sound scientific information that provides the basis for health policies.

LCDC also collaborates closely with international health agencies and participates in international surveillance activities that enable Canada to address disease control issues on a global scale.

Epidemiological studies provide information about health hazards in humans. Historically, these studies focussed on outbreaks of communicable (or infectious) diseases. More recently, they have also been used to investigate diseases or injuries caused by chemicals, radiation, consumer products and other environmental hazards.[30]

To determine whether a hazard actually caused death, disease or injury, scientists must first rule out other possible explanations. For example, the association may result from chance, bias (the tendency of the study design or the characteristics of the group being studied to influence the results) or confounding (the influence of factors other than the hazard). If these are unlikely explanations, then scientists try to determine whether there is a cause and effect relationship (causality). Criteria for examining causality include strength of the association, whether the result is biologically plausible, consistency of the findings compared with those of other studies, whether exposure precedes the effect and the dose–response relationship (whether increasing exposure to the hazard increases the effect). When a *statistically significant* association is found between exposure to a hazard and death, disease or injury, then the cause can be investigated.

### *Using Toxicology to Identify Hazards*

*Toxicology*, the *science of poisons*, is the study of the adverse effects of agents on living organisms, including humans.[30] Toxicological studies may involve individuals or groups.

When data are not available from epidemiological studies, hazards may be identified using toxicology. Although toxicological studies may involve humans, such as in clinical toxicology (the study of poisoning victims), they more typically involve laboratory animals, tissues or cells.[44]

A variety of highly sensitive animal toxicology tests exist. Some tests examine the effects of one-time exposure, usually to a high level of an agent, whereas others examine the effects of long-term exposure to an agent, usually at a lower level. Toxicology tests examine a variety of adverse health effects, including cancer and other effects involving reproduction and development, the immune system, the nervous system, genetic material and behaviour. Scientists can identify potential adverse effects in humans by extrapolating the results from animal toxicology studies.

## Estimating Risks

*Risk:* A measure of both the hazard to health from exposure to a substance, process or product and the probability of the hazard occurring.[41]

Once a hazard is identified, the associated risk can be estimated. *Risk estimation* involves determining the likelihood that a particular adverse health effect will occur following exposure to an agent. For environmental contaminants, risks are usually estimated through epidemiological or toxicological studies. As scientific data are often incomplete or not available, however, such estimations must often be supplemented with more qualitative approximations.

It is important to assess the amount of exposure to the person, group or area being monitored in order to estimate the risk from any substance. *Exposure assessment* can be done by directly measuring the exposure as it occurs, predicting exposure from various media (air, water, food, soil) using monitoring data and computer modelling and reconstructing historical exposure patterns.

### Polluted Recreational Waters and Gastrointestinal Illness

Polluted beaches and other polluted recreational waters are responsible for some gastrointestinal, respiratory and skin infections. An epidemiological study involving several Ontario beaches showed that swimmers were 2.3 times more likely than non-swimmers to develop an infection.[47,48] The swimmers experienced respiratory illnesses most often, followed by gastrointestinal and other illnesses.

Another epidemiological study, conducted on the St. Lawrence River near Quebec City, compared the incidence of illness among competitors and observers at a windsurfing event in an area known to be contaminated with sewage.[49] The study found that the windsurfers were 5.5 times as likely as the observers to suffer gastrointestinal illnesses and 2.9 times as likely to develop ear, eye and skin infections.

### *Using Epidemiology to Estimate Risks*

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.[45] Incidence rates are used to calculate important measures of risk, such as *relative risk*.[46]

*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.[30]

Although epidemiological studies provide a good source of information, they have many limitations. For example, they can be costly and difficult to conduct, because many factors can influence health; they frequently take years to complete; and they may not account for small changes in health status.[50] These limitations often mean that toxicological studies are the principal tools for risk estimation, although they too have limitations.

### *Using Toxicology to Estimate Risks*

When human data are not available, animal toxicology studies are frequently used to estimate risk. Animal toxicology studies provide the main source of data for chemical risk estimations.

Risk estimates are usually obtained by conducting *dose–response assessment* studies involving laboratory animals. The animals are given a range of doses of an agent, and the resulting health effects are monitored over time. When properly designed and conducted, these experiments allow a *dose–response curve* to be calculated (see Figure 4). If appropriate data are available, an exposure assessment in humans can also be performed.[35]

A primary objective of toxicological studies is to determine levels of exposure to specific substances, such as agricultural chemicals, food additives or contaminants, that present little or no risk to humans. For some types of substances, it is assumed that there is a probability of harm at any level of exposure (in other words, it is assumed that there is *no threshold* for effects). Examples include *genotoxic*

## Estimating the Risks of Ionizing Radiation

Ionizing radiation can cause both *threshold* and *non-threshold* health effects. In the case of threshold health effects, there is a generally accepted minimum dose (or threshold) below which no health effects occur. This threshold is typically hundreds of times higher than the doses associated with natural background radiation or normal exposures from regulated practices, such as nuclear facilities.

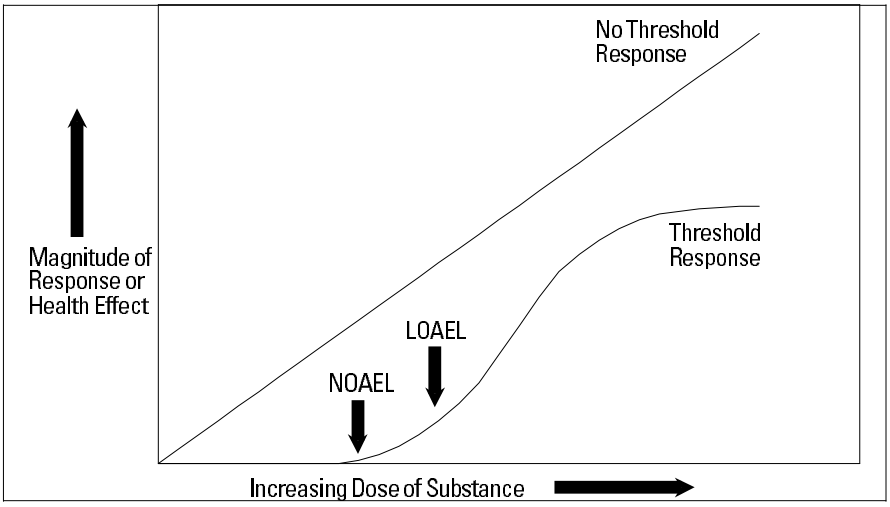
Non-threshold effects, by comparison, are those that can occur at any level of exposure —although they may not show up for years after the exposure has occurred. Radiation protection authorities generally assume that there is no risk-free level of exposure and that the probability of non-threshold effects is directly proportional to the size of the dose. The most significant non-threshold effect associated with human exposure to ionizing radiation is an increased incidence of cancer. There is also a risk of genetic (i.e. hereditary) effects being transmitted to future generations.

Estimates of radiation risk are based primarily on epidemiological studies of humans exposed to high doses of radiation. The main source of information on the risk of radiation-induced cancer is studies on the Japanese atomic bomb survivors. Other sources include studies of workers exposed to high levels of radiation and case reports of patients treated with radiation for various medical conditions. Additional data have been derived from studies involving laboratory animals. Information on hereditary effects also comes from studies involving laboratory animals, as no hereditary effects have been observed in humans, including children of the Japanese bomb survivors.

*carcinogens*, such as ionizing radiation and certain types of chemicals, which cause cancer by damaging DNA. For other substances, including chemicals that cause cancer but do not damage DNA (*non-genotoxic carcinogens*) and chemicals that do not cause cancer (*non-carcinogens*), it is assumed that there is a *threshold* dose below which adverse effects are unlikely to occur.

An example of a subthreshold dose is the *no-observed-adverse-effect level* or NOAEL (in theory, the threshold should be higher than the NOAEL). In risk estimation, these doses are usually divided by *uncertainty factors* (sometimes called *safety factors*) to establish an acceptable level of exposure for humans. This acceptable level is called the *reference dose* (RfD), *tolerable daily intake* (TDI) or *acceptable* (or *admissible*) *daily intake* (ADI). Uncertainty factors compensate for differences in sensitivity between species or among humans as well as other uncertainties, such as the quality of the experimental data, the adequacy of the study, the nature and severity of the effect and the possibility of interactions with other substances. If it is not possible to determine a NOAEL, a *lowest-observed-adverse-effect level* (LOAEL) may be used instead. In these cases, an additional uncertainty factor is generally applied.

**Figure 4**
**Dose–Response Relationship**




*Source:* ***Investigating Human Exposure to Contaminants in the Environment: A Handbook for Exposure Calculations,*** *Draft, Health Canada, 1994, p. 8.*

For non-threshold substances, the determination of acceptability is not as straightforward. For these substances, it is assumed that there is risk associated with any amount of exposure, no matter how small. Often it is not possible to eliminate exposure completely, and thus risk managers try to minimize exposure to the extent possible, taking into consideration feasibility, societal factors and economic factors. Risk can be estimated by developing exposure–response relationships based on epidemiological or toxicological studies.

### *Uncertainty and Risk Estimation*

Although epidemiology and toxicology are useful for estimating risk, both have limitations that can result in uncertainty. For example, results from studies of people exposed to particular contaminants in the workplace may not apply to people exposed in other settings, because the health effects observed at high levels of exposure may not occur at lower levels. For effects such as cancer, it is often difficult to estimate exposure or demonstrate cause and effect in the general population, because cancer takes a long time to develop and multiple factors may be involved in its onset. Similarly, when human risks are estimated using animal toxicology, some uncertainty is introduced from the extrapolation of effects seen at the high doses used in laboratory studies to potential effects at the lower exposure levels experienced by humans in everyday life.[52]

The uncertainty of risk estimates has increasingly led to the use of a range or distribution of risk estimates rather than a single value. This distribution indicates the likely maximum and minimum risks for different individuals and the relative likelihood of intermediate risks between these extremes.[52]

## Developing Options for Risk Management

Once risks have been estimated, options are developed for preventing, eliminating, minimizing or reducing the risks. Options may be regulatory or non-regulatory in nature, depending on such factors as the mandate of the organization involved, program objectives and policies, the current regulatory environment and the availability of non-regulatory alternatives.

Regulatory options generally rely on the government's authority to enforce compliance and may include direct

## Assessing the Health Risks of Food-borne Contaminants[51]

Under the *Food and Drugs Act and Regulations*, Health Canada is responsible for assessing the human health risks of food-borne chemical and radiological contaminants (as well as agricultural chemicals and food additives). The assessment of each chemical is a scientific, multistage process involving the following steps:

**Step One: Determining the Tolerable Daily Intake (TDI)**

The toxicity of a chemical substance—i.e. its capacity to cause harm—is usually determined from studies involving laboratory animals, unless sufficient human data are available. Scientists establish a tolerable daily intake (TDI) by estimating the maximum quantity of the substance that is considered safe for human consumption each day, over an entire lifetime. (For substances that are intentionally added to foods, scientists establish an acceptable daily intake, or ADI, based on all of the available toxicological data as well as human feeding trials, where appropriate.)

**Step Two: Determining Probable Daily Intake (PDI)**

Scientists first identify foods that may contain the chemical. Using data on food consumption patterns in different population groups, they estimate the probable daily intake (PDI) of the chemical for different age groups in the general population and, where possible, for high-risk subgroups.

**Step Three: Comparison of TDI and PDI**

If the PDI exceeds the TDI, a variety of risk management options are considered, including:

- establishing guidelines or specific regulations controlling the chemical substance;
- restricting the sale or distribution of food produced in areas that may have been identified as the source of contamination; and
- recommending changes in dietary habits.

Unlike chemical contaminants, the risks associated with radiation hazards are based primarily on human data and are assessed by international organizations, such as the United Nations Scientific Committee on the Effects of Atomic Radiation. Recommended limits for the ingestion of radionuclides are based on the risk of health effects as determined by these studies. These limits are usually specified as annual limits rather than daily limits, as radiation effects are assumed to be cumulative. The *total* dose from all radionuclides must be less than the limited value.

## Broadening the Risk Estimation Process

Risk estimations involving chemical, radiation and microbiological hazards have traditionally relied heavily on the use of toxicological, clinical and epidemiological data. Although not applicable to all situations, there is a growing trend that involves greater participation of affected parties as well as the incorporation of non-scientific information into the risk estimation process.

One example of this approach is within the Effects on Aboriginals from the Great Lakes Environment (EAGLE) Project, a partnership between the Assembly of First Nations, First Nations communities in the Great Lakes basin and Health Canada. The risk estimations carried out under the EAGLE Project take into account both scientific data and the traditional knowledge held by Aboriginal Peoples. Although primary risks to health are a key concern, indirect risks and impacts are also emphasized. Physical health effects are considered, such as the occurrence of disease, as well as psychological, social, economic and spiritual health. The approach relies on partnerships involving government representatives, community members, scientific experts, the private sector and others. Partners are encouraged to express their concerns and needs actively during the risk estimation process, in order to ensure a well-balanced solution to specific problems.

regulation, self-regulation and the issuing of permits or approvals. Direct regulation involves the enforcement of requirements stated in legislation. Self-regulation involves allowing the affected parties to create mechanisms to ensure that regulated processes or products will not harm humans or the environment and that these will conform to the legislated rules. Permits and approvals require the individual or organization that creates the risk to obtain written permission from government before undertaking a specific risk-producing activity.[53]

Non-regulatory options include advisory, economic and technological measures. Advisory approaches may involve providing risk producers with information that encourages them to reduce risk or that will help affected individuals make more informed decisions. Economic approaches use financial incentives or disincentives to limit risk and may include financial assistance to developers of risk-reducing technologies and penalties for polluters. Technological approaches involve the development of new risk-reducing methods or the application of existing methods by risk producers.[53]

Health Canada uses a combination of direct regulation, advisory and technological approaches to manage health risks within its mandate. Consumer advisories and voluntary compliance by manufacturers are used to reduce the risks associated with consumer products. A recent example of voluntary compliance in Canada was the removal of lead-containing window shades (miniblinds) from stores in 1996 in response to a health advisory issued in the United States. Technological approaches may also be used, as in the development of childproof cigarette lighters. In this case, the action was taken under the Canadian *Hazardous Products Act*.

### Analysing Options for Risk Management

In order to select a suitable risk management strategy, potential options may be evaluated in light of different factors. These include the nature of the health hazard and the likelihood of its occurrence, uncertainties in risk estimation, health benefits related to 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.[32]

***Did you know?***

*Economic analysis may be used to compare risks and benefits. Cost-effective analysis compares the costs of different ways of achieving a specified goal in terms of reduced exposure or improved health status. Cost–benefit analysis enumerates all benefits and costs by assigning a dollar value to each. Risk–benefit analysis enumerates health risks and health benefits without expressing these effects in economic terms.*[41]

Decisions made by regulatory bodies are generally based on more than just consideration of the risk, although there may be exceptions, such as where no level of risk is considered safe. In Canada, for example, when a substance is suspected to cause cancer in humans, it is not permitted for use as a food additive in any amount. This is the case for potassium bromate, which was dropped from the food additive tables of the *Food and Drugs Act and Regulations* in March 1994,[58] even though residue levels in foods tend to be very low.

| Some 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.<br><br>For example, when examining smoking and the risk of lung cancer, one might consider the following information: approximately one-third of Canadians smoke[54]; there is a synergistic effect between smoking and exposure to radon gas (i.e. the combined effect is greater than the sum of their separate effects)[55]; and 85% of lung cancers are directly related to smoking, of which about 90% are fatal.[56] |
| 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.[41] 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.[57] |
| 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.[41] |
| 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.[31] For example, although automobile seat belts have reduced traffic fatalities, some people have died from injuries caused by seat belts during traffic accidents. |

The acceptability of risk, from both an individual and social perspective, is influenced by risk perception, values, judgments and other factors, such as the trade-offs people make between potential hazards and related benefits. Although the public may hold opinions about what is acceptable, there are often no objective measures for determining acceptability. This is true for many regulated health hazards, including chemicals, radiation and microbiological agents.

For regulated substances, the level of acceptability may vary with the specific application and substance being considered. Not only the risk, but also the benefits and technological, economic and social factors, including perceptions, must be acknowledged. In such instances, the aim of risk management is to ensure that basic exposure limits are not exceeded and to further reduce the level of risk to "as low as reasonably achievable," given social and economic considerations.

## Making and Implementing a Decision

Following option analysis, a risk management option is selected and an implementation strategy is developed. Responsibility for decision making in the protection of human health generally rests with a regulatory agency, such as Health Canada. Risk management decisions are often made in consultation with stakeholders, with emphasis on the effective communication of information and consideration of the viewpoint of affected parties. Health protection strategies also tend to be implemented in consultation with stakeholders. Consultation is particularly important for strategies involving partnerships and community action programs.

In recent years, there has been a growing recognition that the perspectives and concerns of all affected parties must be considered during the risk management process. Different parties can provide valuable, relevant information that might not otherwise be available. Decisions made through consensus may be implemented differently from those not involving consensus, and often more effectively, as they allow stakeholders a sense of ownership in the decision. The broader scope gained by involving individuals who represent many viewpoints can lead to more practical and effective implementation strategies. However, as consensus building may take more time and effort than traditional risk management approaches, it may not be feasible in certain situations, particularly emergencies.

## Monitoring and Evaluating the Strategy

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.[32]

### Risk Management for Ionizing Radiation

In Canada, radiation protection is the responsibility of the federal government and the provinces. The Atomic Energy Control Board (AECB) regulates nuclear facilities and the use of radioactive materials. Health Canada provides health advice to the AECB and, in consultation with the provinces, manages the risks associated with unregulated exposures, such as radioactivity in food and water and radiation-emitting devices. Radiation protection in Canada is carried out in accordance with the data and principles established by national and international agencies, such as the International Commission on Radiological Protection (ICRP), the United Nations Scientific Committee on the Effects of Atomic Radiation, the World Health Organization and the U.S. National Council on Radiation Protection and Measurements.

The first priority of radiation protection is to prevent the occurrence of threshold health effects associated with exposure to ionizing radiation from regulated practices, in both workers and the general public. The second priority is to minimize the long-term, non-threshold health effects resulting from exposure to low levels of radiation. The ICRP has recommended dose limits for occupational exposures and public exposures arising from radioactivity released into the environment from regulated activities. These limits are regarded as maximum tolerable levels that must not be exceeded under normal circumstances. Radiation doses are kept below the limit by ensuring that exposures are "as low as reasonably achievable," taking into account economic and social considerations.

## Reviewing the Process

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. One example is Health Canada's recent review of the 1989 *Tobacco Products Control Act*, prompted by a Supreme Court decision that struck down key sections of the legislation, which resulted in *Bill C-71*, the new *Canadian Tobacco Act*.

## Regulatory Decision Making for Pesticides

The Pest Management Regulatory Agency (PMRA) manages the regulation of pesticides at the federal level in Canada. A major component of the federal regulatory system is the premarket evaluation of potential health risks and environmental risks and assurance that the product offers a worthwhile contribution to pest management.

The PMRA requires pesticide manufacturers to provide information that will enable PMRA scientists to assess potential health hazards and estimate probable exposure levels when the product is used as directed. A health risk assessment is then performed in a fashion similar to the steps outlined in the risk assessment and management framework developed by the Health Protection Branch of Health Canada, from the perspective of both occupational and bystander safety, as well as food safety. An environmental risk assessment is also performed, which considers the environmental fate and toxicology of the pesticide to assess risks posed to non-target plants and animals (i.e. those species towards which the pesticide is not intentionally directed), both on land and in water bodies.

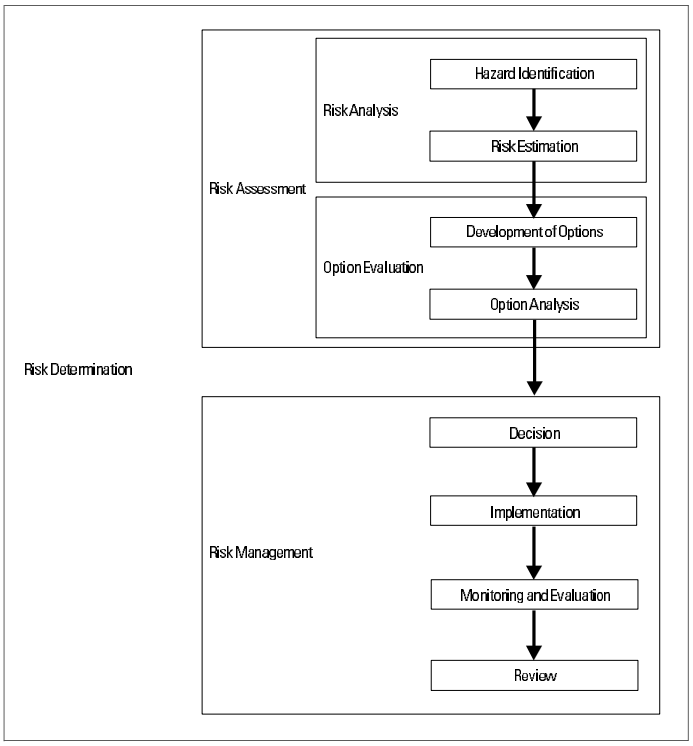
If either the health or environmental risk is not considered acceptable, the applicant may choose to develop measures to reduce the risk. For example, if there is an unacceptable risk to the people who handle, mix or apply the pesticide, the chemical composition of the product may be changed, the containers may be redesigned for safer handling or the applicators may be required to wear full protective clothing. For environmental risks, use restrictions may be considered, such as increased buffer zones around sensitive water areas (i.e. the area between the water and the location where the pesticide is being sprayed) or other measures.

No pest control product may be registered for use if it serves no useful purpose or is ineffective. Thus, the applicant must also prove that the product has value. The value assessment is an important part of the evaluation process, by ensuring that no excess burden is placed on the environment or on our health. In the end, both the risks and the value of the pesticide must be considered acceptable before the pesticide may be registered. The regulatory decision may approve certain proposed uses but deem others unacceptable.

### The Health Protection Branch Model: A Sample Framework

The framework developed by the Health Protection Branch of Health Canada follows the general process described above and consists of two parts: risk assessment and risk management (see Figure 5).[32] Risk assessment includes four steps: hazard identification, risk estimation, development of options and option analysis. Risk management also includes four steps: decision making, implementation (of a specific risk management strategy), monitoring and evaluation (of the impact of the strategy) and review. Although the framework is generally applicable to all health risks, it is best suited to those involving chemicals, radiation and microbiological hazards, which are the primary focus of this report.

**Figure 5**
**Framework Developed by the Health Protection Branch of Health Canada**




*Source:* ***Health Risk Determination: The Challenge of Health Protection,*** *Health Canada, 1993, p. 4.*

## Risk Perception

*Risk perception* refers to the way in which individuals intuitively see and judge risks.[41] Perceptions can affect behaviour and the decisions people make about controlling risks.

Risk perception is influenced by many factors, including age, gender, level of education, geographic region, values, experience with the hazard or similar hazards and previous exposure to information on the hazard through the media or other sources.[59] Key influences include the degree to which people understand or experience the hazard through their senses; the degree to which the hazard elicits feelings of dread (e.g. fear of dying); their sense of control over the hazard; and the size and type of the population at risk, especially if children are affected.[60] 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.[57] Perceptions can change over time, as new information becomes available.

In a 1992 survey by Health Canada, 1500 Canadians were asked for their attitudes and opinions regarding 33 health hazards. The results showed significant differences in the perceptions of a number of subgroups. Older individuals, women, individuals with less education and those with lower incomes tended to perceive a higher degree of risk for the hazards. For some hazards, there were also regional differences. The study also found that the news media was the main source of information about health risks and that physicians and Health Canada were perceived to have a high degree of responsibility for protecting the public against health risks.[59,61,62]

Risk management decisions should take into account public perceptions of risk, as they may differ from the perceptions of technical experts. Differences in perceptions appear to result from differences in assumptions, conceptions and values regarding the hazard or activity of interest.[63]

A 1994 Health Canada survey illustrates how public perceptions differ from those of the scientific community. About 150 Canadian toxicologists were asked for their perceptions of the risk associated with 33 hazards—the same list that was used in the 1992 public risk perception survey. In general, toxicologists had a lower perception of risk and more favourable attitudes towards chemicals than the general public (see Figure 6).[63]

## Health Risk Perception in Canada[59,61,62]

In 1992, Health Canada surveyed 1500 Canadians to obtain information on risk perception, attitudes and opinions about health risks, ratings of perceived risk, sources of information on health risks and responsibility for risk management. The study found that:

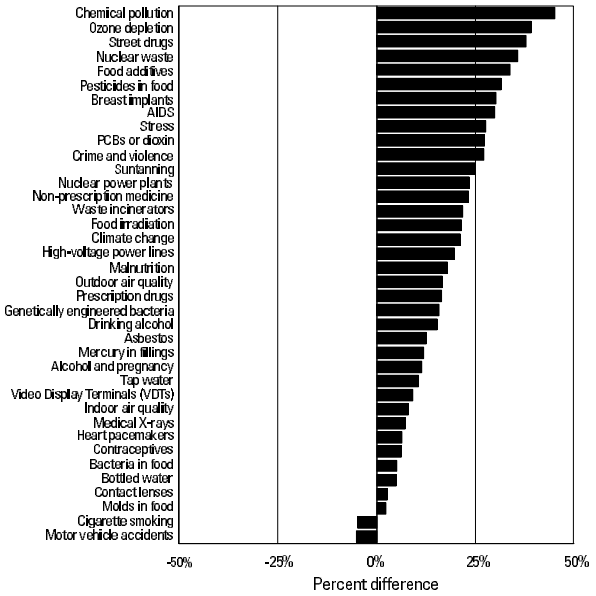
- Canadians perceived a high degree of risk for many hazards;
- AIDS, drugs and alcohol were perceived as posing a much higher risk to society in general than to oneself and one's family;
- there was much concern about the risks associated with industrial pollution (e.g. ozone depletion, chemical pollution, nuclear waste);
- perceptions of risk from nuclear power and nuclear waste were particularly high with respect to oneself and one's family and were not related to one's distance from nuclear power plants;
- persons concerned about one hazard were more likely to be concerned about other hazards, whereas those unconcerned about one hazard were more likely to be unconcerned about others;
- there was a high degree of concern over chemical products (except for medicines) and chemical pollution and a widespread belief (93.4%) that our land, air and water are more contaminated now than ever before;
- there was a widespread belief that a risk-free environment is achievable in Canada and an unwillingness to accept some health risks to aid the economy; however, most respondents would accept some risks in order to benefit personally from medicines or medical devices; and
- gender, age, education and region of residence had significant effects on risk perception.

## Risk Communication

*Risk communication* involves any exchange of information between interested parties about the existence, nature, form, severity or acceptability of health or environmental risks.[40,64] Interested parties may include government agencies, professional organizations, public interest groups, individual citizens, corporations, industry groups, unions and the media.[64]

Regulatory agencies practise many forms of risk communication. For example, they may provide risk-related information to the public to assist in decision making, alert the public to a significant risk or calm concerns about a risk that the public perceives as serious but that has been scientifically assessed as small. Risk communication may also involve obtaining information on public perceptions, attitudes, beliefs and experiences with a particular hazard, as well as public opinions on specific risk assessment and management issues.

**Figure 6**
**Differences Between Public Perceptions and Those of Scientists**




*Source: Adapted from data reported in "Intuitive Toxicology. II. Expert and Lay Judgements of Chemical Risks in Canada" in* **Risk Analysis,** *1995, 15 (6), Slovic P et al. Reproduced with permission from the authors, 1997.*

*Note: Figure includes 33 environmental hazards and 5 medical devices.*

Risk-related information may be communicated in a number of ways, such as through advisory bodies, booklets, computer bulletin boards, conferences, discussion papers, discussion groups, displays, drop-in centres, focus groups, information letters, general interest publications, magazine inserts, newsletters, pamphlets, posters, public hearings, public service announcements, referenda, reports, stakeholder meetings, television commercials, toll-free telephone lines and the Internet.[60,65] Health Canada uses a variety of publications to inform people about health hazards. Contact the Health Canada Publications Office for more details.

Visit Health Canada on the World Wide Web! Our address is:
**http://www.hc-sc.gc.ca**

### Do Smog Advisories Work?[67]

In 1993, the Canadian Smog Advisory Program was introduced by Environment Canada and other partners to provide information to the public on smog episodes. The advisories include environmental information, such as a description of the pollution sources that contribute to smog and information on the possible health risks associated with smog exposure. Smog advisories are issued when ozone levels are expected to exceed a specified level, generally 82 ppb.

A Health Canada/Environment Canada study was completed in 1994 to evaluate the effectiveness of smog advisories in increasing public awareness of the environmental and health effects of smog and encouraging people to take actions that protect the environment and human health. The results showed that residents of some areas surveyed were generally aware of smog advisories when they were in effect. Although only a minority of those surveyed took any action during smog episodes (e.g. reducing the use of cars or reducing strenuous outdoor exercise during peak ozone periods), individuals with health problems were about twice as likely to act on the information. The study concluded that although advisories are successful in generating awareness, additional tools are needed to convince people to change their behaviour and show them that individual action can make a difference.

Risk communication is an integral part of the risk assessment and risk management process. Regulatory agencies and other decision makers have an obligation to ensure that the scientific and technical analyses underlying risk management decisions are effectively communicated to the public. They also have an obligation to understand public concerns about health risks and to ensure that risk management decisions respond to these concerns appropriately. These obligations must be met for government risk management decisions to appear credible and reflect the public's informed consent.[40,65] Proper risk communication ensures that policy decisions and public discussions are based on the best information available.[66]

## Some Risk Management Strategies

Government departments use a variety of strategies to manage environment-related risks to human health. Examples of some of the strategies that involve Health Canada follow.

### The Action Plan on Health and the Environment

Concerns about the relationship between health, the economy and the environment have grown in recent decades. In 1987, a report to the United Nations by the World Commission on Environment and Development (also known as the Brundtland Commission) introduced the concept of sustainable development, which integrates environmental and social concerns into economic decision making. A series of government-sponsored consultations in 1990 noted Canadians' increasing concerns about the effects of the environment on their health and that of future generations.[68]

In December 1990, the federal government announced Canada's Green Plan, which provided a framework to help Canadians move towards sustainable development.[68] *Sustainable*

*development* is the integration of social, economic and environmental goals, taking into account their effects on human health. The concept reflects the fact that development is essential to satisfy human needs and to improve the quality of human life and that development must be based on the efficient and environmentally responsible use of all of society's limited resources: natural, human and economic.[69]

The Action Plan on Health and the Environment (APHE) was Health Canada's contribution to the Green Plan and addressed the critical link between health and the environment. APHE was initiated in April 1992 and lasted for five years. The APHE strategy consisted of a series of initiatives to identify environmental contaminants, investigate their effects on the health of Canadians and reduce and prevent health risks associated with the contaminants. APHE provided funding to monitor air, water and food; ensure that safety standards were met; enhance existing regulations; and help develop new regulatory measures to prevent or reduce pollution. It also fostered individual, community and international health protection and health promotion initiatives.

APHE focussed on areas of Canada that are especially vulnerable to pollution (e.g. the North and Arctic, the St. Lawrence River region and the Great Lakes basin), as well as particularly vulnerable groups, such as children, pregnant women, the elderly and First Nations communities. Several initiatives received funding through APHE.[70] For information on these initiatives, see the Appendix.

## The Health and Environment Program

Health Canada continues to build upon the work achieved by APHE largely through Health and Environment, a program being undertaken by the Department's Health Protection Branch and Health Promotion and Programs Branch. The Health and Environment program focusses on reducing health impacts of environmental origin and identifying and managing emerging environmental health issues. It uses a variety of approaches to fully address risk management objectives, including science, legislation, community action and social marketing.

As major environmental health risk management decisions can have great economic impacts, the program places a particular focus on cost–benefit analyses of different risk management options. Economic analyses help to ensure that pollution management strategies are cost-effective and promote competitiveness and sustainability.[71]

The Health and Environment Program is working with other federal and provincial government departments and agencies, such as Environment Canada, and with international organizations, such as the World Health Organization.

The Health and Environment program has four priorities:

- *Control of Toxic Substances in the Environment*
  This area is concerned with protecting Canadians from the health effects of environmental pollution and ensuring access to clean air, clean water and safe food. Most activities relate to regulatory initiatives based in legislation as well as the development of guidelines and other non-statutory instruments. Priorities include the assessment and management of health risks under the *Canadian Environmental Protection Act* (CEPA) and the *Canadian Environmental Assessment Act* and participation in international efforts to control and reduce the long-range transport of air pollutants.
- *Assessment and Management of Bioregional Health Effects*
  Complex environmental pollution issues usually require solutions that integrate health protection and health promotion perspectives. Such integrated solutions are based on risk assessment and risk management principles and require partnerships that incorporate common health and environmental objectives. Targeted geographic areas include the Arctic, the Great Lakes basin, the St. Lawrence River region and the Fraser River valley.
- *Environment-Related Disease Surveillance and Control*
  Epidemiological and toxicological studies indicate that cancer, poor reproductive health, problems in child development and asthma are the major human health effects that can be influenced to some extent by the environment. National surveillance programs for these problems strengthen national public health information infrastructure and produce timely, reliable analyses that assist in decision making. Such surveillance is being conducted by the Laboratory Centre for Disease Control as part of Health Canada's Public Health Intelligence Network (see Box: Monitoring Diseases Through the Public Health Intelligence Network).
- *Promoting and Supporting Population Health*
  The goal of this priority is to develop a strategy to promote and support population health objectives, in partnership with provincial, territorial and other federal government departments and agencies and the private sector. The strategy will encourage individual and collective actions to improve health by sustaining a healthy, diverse ecosystem and fostering healthy, active living and working conditions throughout Canada.[72]

For more information about initiatives being carried out under the Health and Environment program, see the Appendix.

## Initiatives of Specific Relevance to the Health of Aboriginal Peoples

The Medical Services Branch of Health Canada is continuing its work on three former APHE initiatives, in partnership with the Assembly of First Nations and the Inuit, Métis and Dene peoples. Although they are not formally part of the Health and Environment program, these initiatives share similar goals. They are as follows:

*Drinking Water Safety Program for Native People*
This initiative has become an ongoing part of the Branch's activities. Most of the program's funds are distributed to different regions of Canada to deal with drinking water issues at a Tribal Council or community level.

*Effects on Aboriginals from the Great Lakes Environment (EAGLE) Project*
This initiative has been extended to allow completion of existing projects and to address emerging issues.

*Northern and Arctic Pollution Initiative*
This initiative will continue in order to address health and environmental issues related to Aboriginal Peoples in the North and Arctic.

## The Toxic Substances Management Policy

The Toxic Substances Management Policy (TSMP) is a federal policy that provides direction on the management of toxic substances. Under the TSMP, any substance that results from human activity, takes a long time to break down in the environment, accumulates in biological tissues and is "CEPA-toxic"(1) or equivalent to CEPA-toxic will be designated as a "Track I" substance and targeted for virtual elimination. For substances that meet some but not all of these criteria ("Track II" substances), the objective is to prevent or minimize their release throughout their life cycles (during their manufacture, use, transport and disposal), using pollution prevention approaches.[73]

The TSMP is a key element of the federal government's Pollution Prevention Strategy, which was launched in July 1995. The goals of the Strategy include:

- institutionalizing pollution prevention across all federal government activities;
- fostering a national pollution prevention effort;
- achieving a climate in which pollution prevention becomes a major consideration in private sector activities;
- providing access for all Canadians to the information and tools necessary to implement pollution prevention practices; and
- participating in international pollution prevention initiatives.[74]

1. According to Section 11 of CEPA, "... a substance is *toxic* if it is entering or may enter the environment in a quantity or concentration or under conditions: a) having or that may have an immediate or long-term harmful effect on the environment; b) constituting or that may constitute a danger to the environment on which human life depends; or c) constituting or that may constitute a danger in Canada to human life or health."

## Bill C-83: An Amendment to the *Auditor General Act*

The federal government's commitment to sustainable development has recently been strengthened through changes to the *Auditor General Act*. Under the *Auditor General Act*, the Auditor General's office has the authority to conduct financial and value for money audits on federal government programs and must report the results of its audits to the House of Commons. On December 15, 1995, an amendment, called *Bill C-83*, came into effect, which recognizes the importance of promoting and supporting sustainable development by integrating social, economic and environmental concerns.

*Bill C-83* authorizes the Auditor General's reports to consider the environmental aspects of sustainable development. It also requires all federal government departments to prepare sustainable development strategies and table them in Parliament by December 1997. *Bill C-83* also established a federal Commissioner of the Environment and Sustainable Development.[75]

*A Guide to Green Government*, which was developed to help departments prepare their sustainable development strategies, lists these objectives: sustaining our natural resources through sustainable jobs, communities and industries; protecting the health of Canadians and of ecosystems; ensuring equity (between current and future generations and between the poor and the more affluent); maintaining our quality of life and well-being; and meeting international obligations (working effectively with other countries towards common goals).[69]

Sustainable development strategies must be part of all departmental policies, programs, legislation, regulations and operations and must be updated and tabled in Parliament every three years. These strategies must include goals, objectives and targets for achieving sustainable development within individual departments. Departmental strategies will provide benchmarks for measuring progress towards sustainable development. Progress will be assessed by the Commissioner of the Environment and Sustainable Development.[69]