



Shared
Responsibilities,
Shared
Vision

**RENEWING
THE FEDERAL
HEALTH PROTECTION
LEGISLATION**

A Discussion Paper
Health Canada
July 1998

**Our mission is to help the people of Canada
maintain and improve their health.**

Health Canada

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An Invitation to a Discussion . . . from the Minister of Health

The Government of Canada is committed to modernizing our health system to meet the needs of Canadians in the 21st century. As part of that effort, it is preparing to improve and update its health protection legislation.

By working together, Canadians, their governments and the health community have made Canada one of the healthiest and safest places in the world to live. However, many of the laws that govern the activities of Health Canada in the area of health protection were written decades ago. Since then, changes in society, medicine, science, technology and people's lifestyles have created new risks to health—and new ways to address them—that were not foreseen when the laws were drafted. Over the years the laws were amended in piecemeal fashion in response to problems as they arose, creating a potential for gaps in the protection Canadians enjoy. Some of the provisions overlap, impeding governments' attempts to develop coherent policies.

As well, we've made a lot of progress in recent years in our understanding of health and the best ways to promote and safeguard it. We've recognized the importance of working with our partners in government and the private sector to effectively manage health risks. This new understanding is not well reflected in our laws.

It's time to reassess, integrate and update the laws that safeguard our health.

But what should the new federal legislation look like? What needs to be changed and what is worth keeping? What are the problems that need to be addressed? What are the core values that need to be preserved and strengthened as we debate possible solutions and work together to bring Canada's health protection legislation into the 21st century?

Health protection is everybody's business. All Canadians share responsibility for safeguarding and improving health, just as all Canadians share the benefits of having a healthy population and work force. So it is fitting that everyone has the opportunity to help develop a shared vision of how Canada's health protection laws should evolve.

To this end, Health Canada is launching a public consultation as a first step in the process of legislative renewal.

This discussion paper provides a starting point for this dialogue. It raises some questions and invites you, the reader, to raise others. It provides background information to this initiative, and explains some of the key terms and principles people will need to know in order to better understand one another. Finally, it sets out how you can participate at this stage of the process, and where you can get more information.

When drafted, Canada's new health protection legislation will touch all our lives. So we all have a stake in making sure that the laws are as relevant, fair and complete as they can be. Now is the time to make your contribution to this important initiative. I urge you to get involved.

Allan Rock
Minister of Health

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1 — What Is Health Protection?

Canada’s health system has three components, or aspects: health care, health protection and health promotion.

Health care is the part of the system with which Canadians are most familiar. It consists of the medical and hospital services that provide active treatment and care to people who suffer an accident or contract a disease.

Health protection involves interventions to prevent illness and injury in the first place, and to help people lead healthier, happier lives.

Health promotion involves, enabling people to increase control over, and to improve their health. Health promotion is not only the responsibility of the health sector, but goes beyond healthy lifestyles to well-being.

Together, these three aspects comprise a single, integrated health system that provides Canadians with a continuum of health services.

Evidence suggests that preventive measures are generally more cost-effective than traditional health care. Since the *Hazardous Products Act* was introduced in 1969, for example, product-related accidents involving children have decreased about 80 percent.

What Is Health Canada’s Role in Health Protection?

At the federal level, Health Canada has primary responsibility for helping Canadians to maintain and improve their health. At Health Canada, health protection means:

- helping Canadians to protect their health with programs and regulatory measures concerning the quality, safety and effectiveness of drugs, medical devices and pesticides; the safety of consumer products and workplace substances; the safety and nutritional quality of food; and the quality of air and water. Health Canada also helps prevent deception and fraud with respect to health claims attached to these products;
- helping Canadians to prevent the onset of disease, injury and disability. Prevention and control programs usually focus on specific diseases (such as HIV, cancer or cardiovascular disease) and groups or individuals who are especially at risk; and
- helping Canadians to understand the health risks they face, and developing appropriate interventions by collecting, analyzing and disseminating health-related information.

Of course, Health Canada doesn't do the job alone. It shares its health protection responsibility with other federal departments and agencies, including Agriculture and Agri-Food Canada, the Canadian Food Inspection Agency, Fisheries and Oceans Canada, Environment Canada and Indian and Northern Affairs Canada, to name a few. As well, it cooperates with the provinces, supporting their work and that of health care professionals by exchanging information and advice, promoting collaboration and consensus building, and by developing national guidelines. It works with industry and members of the health community, including educators, professional and community groups and associations, and with international health agencies. Health Canada also recognizes that individual citizens must play an active role in protecting their own health.

Within Health Canada, the work of health protection is carried out primarily by the men and women of the Health Protection Branch (HPB). HPB helps Canadians protect themselves against health risks by:

- reviewing the quality, safety and effectiveness of drugs and medical devices; the safety of radiation-emitting devices and select consumer products; and the labelling of chemicals;
- restricting tobacco promotion and sales targeted to young people;
- developing health and safety standards for food;
- helping prevent the entry into Canada of people and cargo carrying infectious disease;
- identifying, evaluating and managing environmental hazards;
- monitoring patterns of disease and injury; and
- developing policy options for public health action.

Health Canada also plays an important role in the federal government's Emergency Preparedness Program, and provides specialized laboratory services.

Health Canada works closely with its provincial/territorial partners and all stakeholders. Together, they have helped make Canada one of the healthiest and safest places in the world to live.

Health Protection in a Changing World (HPB Transition)

In recent decades, sweeping changes in society, science and technology have had an enormous impact on public health and the work of health protection. Health Canada recognizes the need to modernize the health protection system to deal effectively with these new challenges.

To this end, Health Canada has launched a fundamental review of its health protection operations. This effort, known as “HPB Transition,” will help Health Canada and its partners to better manage risks to the health of Canadians into the next century.

HPB Transition has the following objectives:

1. to update and integrate the federal health protection legislation;
2. to strengthen the science that underlies decision making, ensuring its capacity to meet current and emerging public health risks;
3. to improve the management of health risks, while explicitly recognizing the roles and responsibilities of all partners and participants in the process;
4. to improve and modernize the Canada-wide health surveillance network; and
5. to review and improve the delivery of health protection programs.

This discussion paper focuses on the first of these objectives.

2 – What Is Health Protection Legislation?

Health protection legislation gives the federal government the authority it needs to act, and sets out what the government can do to help make the lives of citizens safer, reduce health risks and preserve health benefits.

Canadians are usually more familiar with the *Canada Health Act* which governs contributions by the federal government to insured health care services provided by the provinces and territories (“Medicare”), according to five fundamental principles (public administration, comprehensiveness, universality, portability and accessibility).

Just as important are the collection of health protection laws which are aimed at preventing health hazards, before they lead to injury or disease. Acts administered in whole or in part by Health Canada in the area of health protection include the following:

Department of Health Act
Food and Drugs Act
Quarantine Act
Radiation Emitting Devices Act
Hazardous Products Act
Tobacco Act
Controlled Drugs and Substances Act
Pest Control Products Act
Canadian Food Inspection Agency Act
Canadian Environmental Protection Act
Patent Act

Here is a brief description of these legal tools (the dates shown are those in which the original legislation was passed):

Department of Health Act (1996)

The *Department of Health Act* sets out the duties, powers and functions of the Minister of Health. It empowers the Minister to promote and preserve the health of Canadians in all areas not otherwise assigned by law to another federal department or agency.

Health is not just the absence of disease or infirmity; it is the total “physical, mental and social well-being of the people of Canada.”

(Department of Health Act)

Food and Drugs Act (1953)

This statute enables the government to regulate the manufacture, importation and sale of food, drugs, cosmetics and medical devices to ensure their quality, safety and effectiveness. It also prohibits misleading advertising of these products.

Quarantine Act (1970 but most provisions date back to 1872)

This Act controls the entry into Canada of persons, vehicles or cargo suspected of carrying infection or communicable disease.

Radiation Emitting Devices Act (1970)

This Act sets standards for the sale, lease and importation of radiation-emitting devices, including cellular phones, televisions, tanning lamps, microwave ovens, ultrasound machines, x-ray machines and lasers.

Hazardous Products Act (1969)

This Act governs the sale, advertising and importation of products and materials that, because of their content, design or function, could pose a health risk to Canadians. Included in this category are poisonous, flammable, explosive, corrosive or infectious products, as well as a variety of consumer products such as children's sleepwear, hockey helmets, lighters and matches. The Act also controls the labelling and documentation that must accompany hazardous products and materials intended for use in the workplace.

Tobacco Act (1997)

This Act focuses on reducing tobacco consumption, especially among young people, by prohibiting sale to minors and by restricting the promotion of tobacco products through advertising and corporate sponsorships. It requires that tobacco products carry explicit warnings about the health risks associated with tobacco use.

Controlled Drugs and Substances Act (1996)

This Act controls the importation, traffic and use of narcotics and other illicit substances (such as heroin, cocaine and marijuana), while allowing for their medicinal use, where appropriate.

Pest Control Products Act (1969)

Any pesticide imported, manufactured, sold or used in Canada must first be approved under this Act. The law regulates, among other things, the composition and packaging of registered products and restricts their use to the specific purposes for which they are approved. Within Health Canada, the Pest Management Regulatory Agency administers this Act.

Canadian Food Inspection Agency Act (1997)

The Act establishes the Canadian Food Inspection Agency and assigns it responsibility for the administration and enforcement of a number of Acts relating to food and agricultural products. However, the Act provides that the Minister of Health is

responsible for establishing policies and standards relating to the safety and nutritional quality of food sold in Canada, and assessing the effectiveness of the Agency's activities related to the enforcement of food safety. The enforcement of these standards is the responsibility of the Agency.

Canadian Environmental Protection Act (1988)

This Act controls the distribution and use of substances in Canada that pose a danger to human health or the environment on which human life depends. It also contains provisions to restrict the flow of cross-border air pollution. The Act is administered by Environment Canada but Health Canada is responsible for assessing the impact of substances on human health.

Patent Act (Relevant provisions passed in 1993)

Although administered by Industry Canada, regulations adopted under the Act stipulate that Health Canada must withhold the approval of a new generic drug until the expiry of the patent protection for the corresponding innovator drug. The Act also establishes the Patented Medicine Prices Review Board, which monitors and controls the price of patented medicines.

What Is the Federal Authority in the Area of Health Protection?

“Health” is not specifically mentioned in the *Constitution Act* of 1867 and is therefore not within the exclusive domain of the federal Parliament or the provincial legislatures. Instead, both orders of government are given authority in matters related to health.

The *Constitutional Act* gives the provinces responsibilities over hospitals, property, civil rights and generally over matters of a local nature. For example, provinces and territories oversee the delivery of health care services and the health insurance plans for the general population. They regulate the practice of medicine and also play an important role in health protection within their respective territories through various statutes such as their public health legislation.

The courts have recognized that federal authority in matters of health protection derives largely from its constitutionally conferred power over Criminal Law. Criminal Law empowers Parliament to prohibit a public evil. The federal government can then formulate and enforce regulations that establish the parameters of the prohibition.

This, in a nutshell, is how the federal government's health protection legislation works. With the *Food and Drugs Act*, for example, Parliament prohibits the distribution of food or therapeutic products that may endanger people's health or involve public deception. The government then adopts regulations to this end: it might, for example, set standards for the manufacture and labeling of these products.

Most of Canada’s health protection legislation is framed in terms of Criminal Law. Legislation based on Criminal Law can apply anywhere in the country and at all levels of distribution.

The *Constitution Act* also gives the federal government power to regulate “trade and commerce”, but only when it crosses provincial/territorial or national borders. This power could also be invoked in certain circumstances related to public health (to control the importation of medical devices, for example).

Another potential authority is Parliament’s duty to ensure “peace, order and good government”. This power could be invoked in cases of national emergency or in matters of national interest that the provinces or territories could not effectively address themselves (for example, in the event of a nuclear catastrophe).

In addition, the federal power over quarantine (*Constitution Act* subsection 91(11)) gives Parliament power to detain individuals or cargo suspected of harbouring infectious disease.

This is not intended as an exhaustive description of federal powers in health protection. It is included here to demonstrate that the federal government, along with its provincial and territorial partners, has an important role to play in preserving the health of Canadians, and that cooperation among governments is essential to achieve this goal.

As we shall see, one of the goals of the legislative renewal exercise is to articulate more clearly the role of the federal government in health protection in order to facilitate cooperation — particularly with the provinces and territories, but also with other groups that are working to reduce risks to the health and well-being of Canadians.

3 — Why Do the Federal Health Protection Laws Need to Be Renewed?

Some laws are obsolete and no longer reflect real world conditions.

Many of the federal laws that govern health protection were developed decades ago. Since then, travel, trade, technology, immigration patterns, manufacturing, medical science, social values and communicable diseases have all evolved substantially. Some laws have become irrelevant or outdated. Consider:

- When the *Food and Drugs Act* was adopted in 1953, Members of Parliament never envisaged that human organs could some day be transplanted. To regulate these practices today, the government is forced to treat human organs as “medical devices.” This is an awkward fit and complicates the development of standards in this area.
- The science of genetic engineering is yielding new products that were unimaginable a few decades ago. Some bioengineering products and practices carry potential health risks and raise difficult ethical questions that the current legislation may not be fully equipped to address.
- Existing laws were not designed to regulate newly emerging pathogens, such as prions — nonliving proteins suspected of causing “mad cow” (Creutzfeldt-Jakob) disease in humans.
- Penalties for violating the drug provisions of the *Food and Drugs Act* are capped at \$5,000 — an amount that may have made sense in 1953 when the Act was adopted, but today affords little deterrent. By comparison, penalties under the *Health of Animals Act* can reach \$200,000.
- The Free Trade Agreement and the *Canadian Charter of Rights and Freedoms* have opened up challenging new dimensions for those who must interpret and apply the laws.

The legislation has become fragmented and inconsistent.

In the past, health protection laws were drafted in response to problems and issues as they arose. The result is a patchwork of laws that cover some products and services while overlooking others. In some instances, similar products are treated differently in different statutes, creating confusion for consumers, manufacturers and the people who enforce the legislation. Consider:

- Contrary to other statutes which clearly state as a general principle that the responsibility for ensuring the safety of commercially available products falls squarely on the manufacturer, the *Hazardous Products Act* puts the onus on government to identify hazards and establish safety standards for each type of consumer product, on a case-by-case basis. This raises questions as to where the primary responsibility should lie? This piecemeal approach has also resulted in incongruities. For example, why are ice hockey helmets covered by the regulations while other sport helmets are not?
- X-ray machines are subject to two different sets of rules. They are regulated under the *Radiation Emitting Devices Act*, but are also covered as a medical device under the *Food and Drugs Act*.
- The *Food and Drugs Act* distinguishes between drugs and medical devices. But is a viscous fluid injected into a knee joint to help with articulation a drug or a device? It looks like a substance (a drug) yet acts like a device. Perhaps drugs and medical devices should be treated alike as therapeutic goods and dealt with according to the level of risk they represent, rather than according to their physical characteristics.
- Enforcement provisions vary. Inspectors, for example, have different powers, depending on which statute they are enforcing.

Governments need to be able to respond faster to new and emerging hazards.

Our rapidly changing world generates many new risks to health. Today, air travel can spread a contagious disease around the globe in a matter of hours. The organism responsible for tuberculosis is becoming resistant to traditional antimicrobial therapies. The arrival of new pathogens, like the Ebola virus, creates unprecedented challenges to the public health system. Yet, current health protection laws force government to deal with unexpected risks on a case-by-case basis. By the time government identifies a health hazard, assesses its risks and drafts the legislation needed to deal with it, it may be too late.

In short, the legislation does not allow for a flexible and innovative response to new and emerging issues. Governments are further constrained by the ambiguities that exist concerning their respective roles in such cases.

The present patchwork of laws provides a poor basis for policy making.

Lacking coherence, the federal health protection legislation provides government with, at times, confusing policy directions. The result is an uneven administration of the law as it applies to different products and activities, and a lack of consistency and predictability for consumers and manufacturers.

The legislation does not reflect current thinking about health and health protection.

The legislation needs to better reflect and support key ideas — such as risk management, population health and sustainable development — that are fundamental to modern-day approaches to health protection. (These core concepts are discussed in Section 6.)

4 — What Are the Goals of this Initiative?

Health Canada’s legislative renewal exercise has three main objectives:

- to update and integrate the federal health protection legislation into a coherent, comprehensive and flexible system that is more responsive to present-day global, technological, social and cultural realities, and that provides the necessary tools to address the challenges of the future;
- to better articulate the role of the federal government in health protection in order to facilitate cooperation with other governments and stakeholders; and
- to create a clearer, more relevant and more coherent legal base for federal policy in the area of health protection.

What Is the Scope of this Discussion?

To be productive, a discussion must have clearly defined limits. It is important that all participants agree in advance about what is, and what is not, on the table.

The subject of this consultation is the federal health protection legislation, especially the *Food and Drugs Act*, the *Hazardous Products Act*, the *Radiation Emitting Devices Act*, and the *Quarantine Act*. These four statutes are the ones most in need of modernization and, consequently, bear most directly on this discussion. They are the ones most likely to be replaced as a result of this exercise; however, other Acts may be amended to some extent. As well, numerous issues that are not currently addressed in any statute will likely be raised.

Our discussion will also respect the following guidelines:

- Issues relating to transfer payments for the delivery of health care services, as legislated under the *Canada Health Act*, are not part of this discussion.
- Our focus is the substance of the health protection legislation, not the governmental structure chosen to administer it. It follows that this discussion is not about how the Health Protection Branch of Health Canada should be organized, or whether some of its current responsibilities should be exercised by independent agencies.
- Fundamental policy decisions made by Parliament in recent years and reflected in legislation such as the *Tobacco Act*, the *Controlled Drugs and Substances Act* and the *Canadian Food Inspection Agency Act* — are outside the scope of this review.

- Bills currently pending before Parliament, such as the *Drinking Water Materials Safety Act*, are outside the scope of this review. If required, these Acts will be adjusted at a later stage.
- This exercise is not meant to replace other reviews already in progress — specifically, those dealing with new reproductive technologies, the environment and patent medicines. In the same vein, proposals to amend the *Pest Control Products Act* have already been developed as a result of extensive consultations and are therefore outside the scope of this consultation.

5 — A First Step Toward Renewal: a National Consultation

Why a Public Consultation?

Safeguarding and promoting health is a formidable undertaking. No single government, agency or organization has all the expertise, wisdom or resources needed to do the job. We did not arrive at the juncture we are at today by working in isolation, or by unloading responsibility for our health on any one individual, office, agency or order of government. We did it by owning and exercising our personal and collective responsibility for health, and by working together.

A renewed federal legislative framework for health protection will have far-reaching consequences. It will affect our health and how we work together to protect and promote it. So it's important that all Canadians have an opportunity to suggest how that framework evolves. At Health Canada, we are determined that what emerges from these deliberations should not be merely the product of bureaucrats, but the joint creation of all those who care deeply about the health of Canadians.

In the months ahead, Health Canada will be inviting partners and other stakeholders to join in this discussion. We will draw on the vast pool of knowledge and expertise that exists in the health community, industry, professional associations, Aboriginal organizations, universities and laboratories. We will reach out to consumer, environmental, religious, ethnic and other public interest groups, as well as to other federal departments. Most important of all, we will consult with provincial and territorial governments and their agencies — our principal partners in health protection.

The purpose of this consultation is to identify the strengths and weaknesses of Canada's current health protection legislation, and to develop a shared vision of a more coherent, flexible and comprehensive legal framework with which to address the challenges of the next century. But we also want to build a consensus about the functions of the federal government in health protection. To this end, we will be encouraging all our partners and other stakeholders to talk not only to us, but to each other.

How Will the Consultation Work?

The plan is to hold an initial round of consultations, using this paper as a starting point and stimulus to discussion, during the spring, summer and fall of 1998. The purpose of this initial round of consultations is to identify and bring a focus to the issues the new health protection legislation should address. To a lesser extent at this stage, we are looking for possible solutions to the problems identified in this paper and in the subsequent discussions.

The dialogue will take many forms, including workshops, focus groups, meetings, interviews, electronic exchanges and written submissions. All interested stakeholders will have the opportunity to contribute their views as part of the consultation process. Multi-stakeholders workshops are planned in the five regions of Canada for the fall of 1998. The specific opportunities for dialogue will be made known shortly.

Step two will be to analyse the results of this consultation and to draft a legislative proposal. The draft legislative proposal will be a flexible framework that includes recommendations and options.

Step three will be to invite our partners and stakeholders to comment on the legislative proposal.

In step four, we will incorporate the comments received in the second round of consultations into draft legislation for consideration by Cabinet.

The final step will be to prepare a bill and initiate the parliamentary process.

6 — A Few Concepts and Definitions

This section explains some of the key concepts that bear on our discussion, namely:

- risk management,
- population health, and
- sustainable development.

Risk Management

Although the concept of health protection is fairly straightforward, the practice of it is extremely complex. Which products or substances present a health hazard? At what concentration or duration of exposure? What types of exposure are dangerous (contact, inhalation, ingestion, absorption)? Is everyone affected in the same way (for example, children and the elderly)? What about combinations of substances: are their effects cumulative, or do they cancel each other? What is a sufficient degree of protection, and how can it be achieved?

To help researchers and decision makers find their way through the maze of questions and uncertainties, a structured approach to identifying, assessing and dealing with health risks was developed.¹ The method is called risk management. Risk management is a sophisticated and convenient tool for determining — in a systematic and rational way — the nature and extent of a real or potential health hazard, and arriving at a reasonable decision as to what to do about it.² The method applies equally well to a wide range of products, processes and substances.

Risk management is a scientific process for identifying health hazards and deciding what to do about them.

In 1993, Health Canada adopted a formal framework for assessing and managing risks. Using such a framework offers many advantages. It helps ensure consistency and thoroughness in the way risks are assessed and decisions are made; results in a more understandable and transparent process; promotes consistency and use of the best available scientific and technical

¹ Risk is a measure of both the harm that can result from exposure to a health hazard and the likelihood that the harm will occur.

² Numerous risk management frameworks have been developed. For the purpose of this discussion, we refer to the entire process as one of risk management.

information; clearly identifies the roles and responsibilities of all participants; ensures that those who are affected by risk management decisions are properly consulted; and encourages the efficient use of resources by government.

Risk management involves several steps:

- identifying the public health issue (an issue can be a disease, agent, product, process or behaviour);
- gathering information about the risk by studying, among other things, the size and nature of the potentially affected population, the specific nature of the risk and the conditions of exposure;
- identifying options for dealing with the risk;
- deciding on a risk management strategy³;
- putting the risk management strategy to work; and
- evaluating the effectiveness of the risk management strategy.

Risk management strategies might include any or all of the following:

- alerting the public or specific population subgroups to unsafe products or practices;
- informing communities, health professionals and policy makers about identified risks and how to manage them (for example, how best to prevent disease or injury);
- implementing preventive measures and health care interventions, as required;
- developing and promoting codes of practice and safe-use guidelines;
- developing and disseminating national health and safety standards;
- regulating the importation, distribution, sale, labelling or use of a product through inspection, licensing and various forms of enforcement;
- prohibiting or restricting a hazardous product or practice; and
- responding promptly to emergencies with good science and good advice.

Underlying the theory and practice of risk management is the recognition that few things in life are entirely risk free. Driving a car provides convenient, swift transportation, but entails a risk of injury or death. Medicines can cure or ease a health problem, but often carry a risk of side effects. Many consumer products make our lives easier or more comfortable, but can be dangerous if used incorrectly or to excess. Virtually every activity and product — from using artists' paints to working at a computer terminal to operating heavy machinery — involve some degree of risk.

³ The choice of strategies takes into account factors such as the severity of the risk, researchers' degree of confidence in their data, legal requirements, public perceptions and socio-economic considerations (for example, the costs and benefits of a risk management strategy to people's health and the economy).

Risk management also recognizes that risks and benefits go hand in hand. They are a fact of life and — like the two sides of a coin — inseparable. You can't have one without the other. Reducing the health risks associated with products and processes to zero, even if it were possible, would in most cases eliminate their potential health benefits as well.

That's why Health Canada uses a risk management approach to health protection. It works to protect the health of Canadians by finding a reasonable balance between health risks and health benefits. Whenever possible, it tries to give citizens the tools they need to make an informed decision about where the point of balance lies for them.

Population Health

Population health is an approach to building a truly healthy citizenry by taking into account the full sweep of factors — or determinants — that bear on human health. It is a holistic approach that addresses all the determinants of health, including the provision of good health care and health protection.

What are the broader determinants of health? In addition to the two already mentioned — access to good health care and protection from dangerous products, processes and diseases — there are others:

- productive and satisfying work;
- loving personal relationships;
- a support network of family and friends;
- membership in a vibrant and safe community;
- a safe and healthy environment (including the urban, work and natural environments);
- a measure of financial security;
- gender - the array of social, behavioural, and attitudinal differences between men and women;
- good coping skills for dealing with life's stresses and challenges;
- a healthy lifestyle that includes exercise and a nutritious diet;
- education, to help people make informed life choices and lead productive lives; and
- healthy child development.

All the determinants of health must be kept in mind in developing health protection legislation, policies and programs because the same measures can affect different people in very different ways, depending on their particular circumstances.

The health of individuals is also influenced by broad societal factors. These factors refer to the entire array of socially determined roles, personality traits, attitudes, behaviours, values, relative power and influence that characterize the lives of women and men in Canadian society.

Some of the best-kept secrets of longevity and good health are to be found in one's social, economic and cultural circumstances.

New legislation needs to address fundamental issues such as gender, which have been overlooked in the past. Experience has demonstrated that health protection measures may have a different impact on women and men, thus the consultation process on legislative renewal should promote a gender analysis process.

The determinants of health are interrelated and work together to influence the health of individuals and whole populations in complex and subtle ways.

Basically, the theory of population health says that you can improve the health of individuals by improving the overall health of the population to which they belong, and that this is best achieved by attending to the entire array of interrelated determinants that impinge on human health.

Health Canada has adopted a population health approach in carrying out its mandate to maintain and improve the health of Canadians. It tries to find ways to favourably influence the determinants of health and to reduce disparities in health and well-being among subgroups in the population. Specifically, Health Canada helps to promote population health by (among other things):

“Interventions aimed at preventing or mitigating the factors that contribute to ill health are key to the population health approach.”

Sustaining Our Health: Health Canada's Sustainable Development Strategy, 1997.

- promoting the health and safety of children, youth and the elderly;
- supporting parents in their efforts to create safe, nurturing environments for their children, both inside and outside the home;
- delivering programs that address specific issues such as AIDS, breast cancer, tobacco, drug and alcohol abuse, and family violence;
- identifying and addressing the unique health problems and needs of Canada's Inuit and First Nations people;
- anticipating and preventing new and emerging health risks;

In 1993, the total cost of illness, disability and premature death in Canada was an estimated \$156.9 billion. This works out to \$5,450 per person per year, or 22 percent of gross domestic product. Hospital care alone cost \$26.1 billion. Population health measures, which can ultimately reduce the need for health care, are a wise investment.

- helping to reduce the incidence of disease, injury, premature death and disability in the population by seeking out their root causes and working to prevent their occurrence;
- working to improve the safety and nutritional value of food;
- promoting healthier lifestyles and practices for all Canadians;
- working with other departments, provincial and territorial governments, health groups and professions to develop thoroughly integrated, multi sectoral interventions, policies and programs; and
- conducting further research into health and the interplay of physical, social, cultural and environmental health determinants.

Health protection programs and activities, which strive to reduce the health hazards present in our daily lives, are a vital part of Health Canada’s population health strategy.

Sustainable Development

The theory of population health recognizes that the environment is one of the factors that affects the health of people. But it works the other way, too: people and their activities have an enormous impact on the health of the environment. When the environment is sick, human health suffers.

Clearly, human and environmental health are related and interdependent. To put it another way, you can’t have a healthy population living in an unhealthy environment.

Which means that human activities must be environmentally sustainable.

Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs. The concept of sustainability stems from the recognition that the health and well-being of all living things on Earth are interdependent. To be healthy, people need a healthy environment, a healthy economy and healthy communities.

“The maintenance and improvement of health should be at the centre of concern about environment and development.”

Report of the World Health Organization’s Commission on Health and the Environment, 1992.

For Health Canada, sustainable development means integrating and balancing environmental, economic and social considerations to achieve health for the present generation, without sacrificing the health and well-being of future generations.

Sustainable development has become a cornerstone of Health Canada’s approach to building a healthier population. But, while many opportunities exist to practise a sustainable development approach in the context of health protection, in only a few cases does government have the

mandate and legal authority to pursue them. For example, current health protection legislation provides for intervention by government where a product's use poses a health risk to consumers. In contrast, legislation based on principles of sustainable development would support intervention if a product posed a risk to either human health or the environment at any point in its life cycle, including its manufacture, distribution, use and disposal.

Among the questions to be addressed in this discussion is, “Should our health protection legislation better reflect our understanding of health and its influences, and the means for achieving it? More specifically, how can the legislation embody and support the principles of population health and sustainable development?”

7 – A Matter of Principles

Before beginning the work of legislative renewal, we need to establish the values and principles that the new legislation should embody. Here, in no particular order, is a partial list of such principles. Again, treat this list as raw material, a work in progress, to be shaped and transformed by your experience, knowledge and insight.

Health Canada proposes that a new legislative framework for health protection should:

- recognize the role of the federal government in health protection and public health surveillance;
- respect the responsibilities of the federal, provincial and territorial governments in matters of public health and risk management, and promote collaboration among them;
- adhere to sound principles of risk management and risk communication;
- favour cooperation among all stakeholders;
- promote the use of sound science-based information in decision making;
- be fair, equitable and transparent;
- address the issues of accountability and liability;
- take into account ethical considerations;
- acknowledge socioeconomic and cultural factors;
- recognize that gender must receive appropriate attention in assessing health concerns;
- meet Canada's international obligations including free trade agreements;
- be sensitive to the importance of economic development;
- address issues within Health Canada's mandate;
- reflect Health Canada's commitment to the principles of population health;
- reflect Health Canada's commitment to the principles of sustainable development; and
- encourage creativity and advances in design and technology.

8 — Rethinking the Health Protection Legislation: Questions and Issues

Health Canada is seeking the views of Canadians about what should go into a new legislative framework on health protection. This section presents a preliminary list of questions for your consideration. The list is by no means exhaustive. You are invited to add and subtract from it, expand and elaborate on it as you see fit.

(The questions are numbered to facilitate future discussion.)

Risk Management

As explained earlier, risk management is the scientific method Health Canada and other provincial, national and international organizations use to identify, assess and deal with health risks. Managing risks does not mean that Health Canada or any other group or industry can totally protect Canadians against health hazards. Zero risk is impossible. However, risk management allows government to balance risks and benefits while setting priorities and allocating resources efficiently.

- 1) Should the legislation better express the risk management principles under which Health Canada operates?
- 2) What are the roles of various stakeholders in managing health risks? What role should industry play? Health professionals? Public interest groups? Individual consumers?
- 3) Should the legislation ensure greater involvement of stakeholders and the general public in the decision-making process? How can this be done without imposing too heavy a burden on the system? How can Health Canada ensure the confidentiality of information submitted by applicants?
- 4) What is the role of science in managing health risks? Should decisions be based on science only? How can government ensure that there is no undue interference with the scientific assessment of health hazards?
- 5) What measures are needed to ensure a proper analysis of costs and benefits in assessing health risks?

- 6) Should any other factors be considered in the process of risk management, apart from safety and efficacy? For example:
 - ▶ the impact on overall public health outcomes?
 - ▶ environmental considerations?
 - ▶ the social conditions of the individuals concerned?
 - ▶ economic impacts?
 - ▶ gender?
 - ▶ cultural diversity?
 - ▶ historical factors?
 - ▶ public perception?
- 7) How should questions of ethics be taken into account?
- 8) How to ensure that the unique needs of Aboriginal peoples are properly addressed?
- 9) How can Health Canada's risk management framework best include the principles of population health?
- 10) How can Health Canada's risk management framework best include the principles of sustainable development?
- 11) How can Health Canada and its partners shift from a curative to a preventive approach in addressing health risks?

Surveillance

Public health surveillance is the process of collecting and distributing information on health. The information is used to inform Canadians about health risks and to develop appropriate interventions.

Surveillance involves collecting, analysing and interpreting data on health events (i.e. injuries and diseases) or determinants (a person's age, occupation, socioeconomic background and so on), integrating it with other information, and informing organizations involved in public health about the findings and their implications. Information gathered locally may be combined with regional, national and even international information. Surveillance also involves monitoring the outcomes of risk management strategies to assess their effectiveness.

Canada's national surveillance network comprises several thousand health professionals and institutions across the country, including public health officers, epidemiologists, hospital and university laboratories, and academics. The network builds on provincial and territorial surveillance efforts to create a national picture of health events and health risks. Canada also works with other countries to collect and interpret health information at the international level.

Modern information technology enhances surveillance opportunities but presents challenges as well. It demands close cooperation among all partners in the surveillance network; skilful management and collating of data; and greater vigilance to ensure that the confidentiality of individuals' health information is respected.

- 12) What measures are needed to protect the confidentiality of health information related to individuals while allowing for the collection and collation of data for health surveillance purposes?
- 13) Does Health Canada need additional authority to collect, analyse, interpret and disseminate information related to public health?
- 14) How can the legislation be recast to better support networking within the national health system?
- 15) To what extent should industry be required to report incidents or product defects that might affect public health?
- 16) Should Health Canada monitor the long-term health effects of products after they have been approved for sale?
- 17) How does all of this relate to provincial and territorial responsibilities? Are there unnecessary overlaps or gaps in the system? How can the synergy among orders of government be improved?
- 18) Should the legislation better recognize Health Canada's role in monitoring the health impacts of environmental substances?
- 19) Is legislation needed to provide a basis for the National Radioactivity Monitoring Network, which is essential to the Federal Nuclear Response Plan?
- 20) What measures are needed to ensure that data collection captures the effect of gender and other health determinants?

Communicable Diseases

Provincial and territorial health care and health promotion programs play an important role in preventing the spread of disease. However, some issues — containing an outbreak of a contagious disease, for example, or identifying a new strain of influenza — are better handled through collaboration on a regional, national or international level.

At the federal level, government officials can legally prevent the entry into Canada of any person or cargo suspected of carrying a communicable disease. Quarantine officers can board and inspect aircraft, ships and other vehicles arriving in or leaving Canada, impound suspected cargo, or require the cleansing of conveyances and their cargo. They may also detain in quarantine anyone found to be infected with a disease that could pose a significant health risk to Canadians.

The Human Pathogens Regulations of the Department of Health Act make it illegal to import human pathogens into Canada without a permit. But the laws offer few safeguards with respect to pathogens produced in Canadian laboratories. For the most part, Canadian laboratories are trusted to abide by voluntarily accepted safety standards.

- 21) What powers should the federal government have to control the entry into Canada of people and products that might be carrying communicable disease? In particular,
 - ▶ should the quarantine legislation be made more flexible while ensuring proper protection of human rights?
 - ▶ what are the proper links with immigration programs?
 - ▶ what are the proper links with provincial or territorial Public Health Acts?
 - ▶ do international regulations meet our needs?
- 22) Does Health Canada have a responsibility to prevent the export of diseases from Canada to other countries?
- 23) Is there a need to complement provincial and territorial legislation to prevent the spread of disease across the country?
- 24) Should existing controls on the importation of human pathogens be tightened?
- 25) Should the legislation establish additional requirements for laboratories that manipulate human pathogens?
- 26) Does the federal government have the necessary legal tools to deal with emergency situations at the national level, such as the major outbreak of a communicable disease or the threat of chemical or biological terrorism?

Commercial Products Generally

Canadians are exposed to thousands of different products. Health and safety issues associated with different categories of products are dealt with in different legislation. For example, food, drugs, cosmetics and medical devices fall under the Food and Drugs Act, while potentially hazardous consumer and workplace products are dealt with under the Hazardous Products Act. Products that emit radiation are dealt with as a special case under the Radiation Emitting Devices Act. This section contains general questions that are relevant to all categories of products.

- 27) Should the legislation establish more clearly that manufacturers have primary responsibility for ensuring the safety of their products? What are the responsibilities of distributors? What are the responsibilities of users?
- 28) Should Health Canada intervene only when individuals do not have the means to protect themselves? If so,
 - ▶ should Health Canada's priority be to ensure that consumers are provided with adequate information about the risks associated with products? How should this information be provided?
 - ▶ what, if anything, should Health Canada do for people who do not have the ability, time or inclination to use the information provided?
 - ▶ are special provisions needed to protect the very young, who cannot easily protect themselves? What about the elderly? People with low literacy skills?
 - ▶ what should Health Canada do if misuse or abuse of a product has an impact on people other than the user?
- 29) Where and how should the line be drawn between protecting public health and interfering with personal tastes and freedom of choice?
- 30) At what levels of distribution should Health Canada control products to ensure their safety and efficacy? Manufacturing? Importing? Wholesale/sub-distribution? Retail? Use? Disposal?
- 31) Should Health Canada be concerned with preventing public deception with regard to products only when the deception affects health (and assume that other federal or provincial/territorial legislation will address the rest)? How should the legislation address health and safety issues associated with new technologies?
- 32) Whenever feasible, should manufacturers establish their own standards for product design and manufacturing, with Health Canada playing a monitoring role to ensure that the standards result in safe products? Should these standards also cover product disposal?

- 33) Should the legislation encourage harmonization with national and international standards? Should it facilitate the incorporation of such standards into the regulations?
- 34) How should services and practices be dealt with? Is there a federal role in this area, or is it strictly a provincial or territorial responsibility?
- 35) What degree of certainty that a product is hazardous does Health Canada need to achieve before withdrawing a product from the market?
- 36) Should the legislation create an offence for product tampering? What penalties should be attached to such an offence?
- 37) Should Health Canada make use of third-party certification schemes, where someone other than the manufacturer or Health Canada certifies that a product meets appropriate requirements?

Consumer Products and Radiation-emitting Devices

Health and safety issues associated with consumer products are dealt with by the Hazardous Products Act on a case-by-case basis. Currently, products to which the Act applies include: carriages and strollers, cribs and cradles, booster cushions, nipples for feeding bottles, pacifiers, playpens, toys, child restraint systems (car seats), children's sleepwear, carpets, cellulose insulation, charcoal, asbestos, glass bottles for carbonated beverages, expansion gates and expandable enclosures, glazed ceramics, safety glass, ice hockey helmets, kettles, lighters, liquid coating materials (e.g. paints), matches, mattresses, tents and science education sets.

Regulations under the Radiation Emitting Devices Act help protect people from the hazards of exposure to products that emit acoustical or electromagnetic radiation, including medical and industrial x-ray and ultrasound equipment, suntanning lamps and booths, microwave ovens, cellular phones and lasers used in light shows at concerts.

- 38) Should Health Canada continue to establish regulations for consumer products on a product-by-product basis (a time-consuming process that puts the burden on government to identify hazards and set standards, and that results in unavoidable gaps in protection)? Or should it pursue legislation that is more general in nature — that is, legislation containing a general provision requiring products to be designed, manufactured and sold so as to enable consumers to use them safely?
- 39) In the case of radiation-emitting devices, should Health Canada be concerned with radiation-related risks only, or with all risks posed by these products (for example, mechanical hazards)?

40) Should cosmetics continue to be controlled under the *Food and Drugs Act*, or should they be treated as a potentially hazardous consumer product and be regulated under the relevant statute?

Therapeutic Products

The Food and Drugs Act distinguishes between drugs and medical devices, and regulates them differently. A drug is any substance or mixture of substances that has, or is said to have, a therapeutic benefit. Included in this category are pharmaceuticals, radio pharmaceuticals (drugs with a radioactive component), vaccines, blood and blood products, some hormones and some products of biotechnology. A medical device is characterized as an instrument or article having a health benefit. The category includes a wide range of products, from condoms to pacemakers to surgical lasers.

- 41) Should drugs and medical devices be treated as “therapeutic products” and regulated alike, according to the level of risk they represent rather than according to their physical characteristics?
- 42) What limits should be placed on the advertising of therapeutic products? The most important current restrictions are:
1. No therapeutic product may be advertised to the general public for the treatment, prevention or cure of any of the conditions listed in Schedule A to the *Food and Drugs Act*;
 2. Prescription drugs (those listed in Schedule F of the Food and Drugs Regulations) may not be advertised to the general public except with respect to name, price and quantity.
- 43) In addition to evaluating the safety and efficacy of new drugs, should Health Canada make a cost-benefit (pharmacoeconomic) analysis of overall health outcomes (in other words, should it weigh a product’s relative risks and benefits for the health care system)? Should Health Canada conduct the analysis, or should it act as an information broker to enable/facilitate analysis by others — the provinces, for example?
- 44) In special circumstances, should the Minister of Health encourage drug manufacturers to develop and market products that may have a positive effect on public health (as opposed to waiting for manufacturers to submit a new drug for approval)?
- 45) To what extent should practitioners be allowed to prescribe drugs for uses other than those for which they have been approved?
- 46) To what extent should Health Canada respect the personal choices of individuals where therapeutic products are concerned? To what extent should Health Canada allow the sale of products whose safety or efficacy has not been demonstrated? Should some types of drugs (for example, herbal remedies) be subject to less stringent requirements? What would be the rationale for such an exception?

- 47) Under certain conditions, the *Food and Drugs Act* exempts products for export: is this appropriate?

Food

Because food is the most widely consumed product and diet is one of the most important determinants of health, the Food and Drugs Act establishes standards to ensure that the food we eat is safe and nutritious.

The Act creating the Canadian Food Inspection Agency makes it very clear that standards relating to the safety and nutritional quality of food are established by the Minister of Health while the Agency's role is to enforce these standards. It should be noted that a review of all the legislation administered or enforced by the Canadian Food Inspection Agency has already been initiated and should result in the consolidation and modernization of the various Acts dealing with food. However, issues which have implications on commodities other than food (eg. the definition of food as it relates to the definition of drug) will be addressed as part of this current exercise. Officials of the Agency and Health Canada are working in close cooperation to ensure coordination between the two reviews.

- 48) To what extent should manufacturers be allowed to attach health claims to food products?
- 49) Does a food become a drug because a health claim is attached to it?
- 50) What measures should Health Canada use to ensure the nutritional value of food?
- 51) What role should Health Canada play in making information concerning the safety and nutritional value of food available to the public and health care professionals?

Diet is a critical factor in many diseases, including diabetes, heart disease and some forms of cancer.

New Technologies and Emerging Hazards

Current laws do not provide a sound basis for dealing with new and unforeseen health hazards — for example, the appearance of a potentially dangerous product, process or service that does not exist today, and may even be unimagined. Governments find it increasingly difficult to respond to situations on a case-by-case basis when the environment (technology, trade practices, etc.) is changing so rapidly. Nor is current health protection legislation clear about what government could do in the event of a national health emergency.

- 52) Should the new health protection legislation contain provisions that would allow government to deal with emerging and unforeseen hazards? If so,
- ▶ should these provisions apply only when no other statute, federal or provincial/territorial, could adequately address the situation?
 - ▶ what conditions should the use of such powers be subject to?
 - ▶ should the legislation establish the general principle prohibiting products that, when properly used, represent an unreasonable public health risk? Should the principle apply to services and practices as well? What criteria should be used to determine an unreasonable risk?
- 53) Should health risks associated with products of new technologies be treated differently from other health risks? In particular,
- ▶ with respect to products whose risk potential may be higher, should their manufacturing be monitored more closely than that of other products?
 - ▶ should manufacturers of such products be subject to special conditions before their products are allowed to enter the marketplace?
 - ▶ how should Health Canada deal with questions of ethics raised by the products it regulates?
- 54) Should the legislation define the responsibilities of Health Canada in emergency situations?

Compliance

At times, Health Canada must go beyond educating and informing to achieve health protection goals. It may regulate industry and establish binding standards. Where standards and guidelines are voluntary, Health Canada relies on persuasion and the honour system to secure industry's cooperation; where they are mandatory, the Department may adopt stronger measures, including inspection and court action.

The current health protection statutes provide government with limited options for enforcing compliance. For example, if a manufacturer chooses to disregard the advertising restrictions that apply to drugs under the Food and Drugs Act, the Department has only two options: it can either try to talk the company into abandoning the publicity or lay criminal charges and engage in a long and costly court battle. In any event, the fine imposed by the court will most likely be minimal.

- 55) In case of disagreement between Health Canada and a manufacturer, should the legislation expressly allow alternative modes of dispute resolution (for example, mediation involving all interested parties)?
- 56) Should the legislation provide for civil remedies, such as a court injunction (in which case a court, rather than Health Canada, would order the company to cease its activity)?
- 57) Should the Minister have the power to order mandatory recalls of faulty or dangerous products? If so, under what conditions?
- 58) Should Health Canada be able to confiscate profits resulting from illegal activities?
- 59) Do Health Canada's inspection practices need to be better defined and standardized?
- 60) Should the penalty provisions of the legislation be reviewed to ensure that they provide sufficient deterrence and are consistent (that is, that violations of equal magnitude receive equal penalties, irrespective of the products involved)?
- 61) Should the legislation empower the courts to hold administrators of corporations liable in cases of blatant negligence?
- 62) Should Health Canada be able to recover from violators the cost of seizing and destroying their illegal products?
- 63) Should aggrieved consumers be able to use a manufacturer's failure to meet the requirements of the health protection legislation as grounds for a civil suit in damages?
- 64) Should the legislation allow for enforcement actions, such as seeking injunctive relief, to be undertaken by third parties (for example, by a private individual or group)?
- 65) Should Health Canada pursue equivalency and mutual recognition agreements with other governments?
- 66) Should the legislation facilitate the coordination of functions between governments (for example, the creation of federal-provincial/territorial corporations to carry out enforcement duties)?

Other Issues

Included here are some questions that do not fit well under any of the previous headings.

- 67) Could the health protection legislation be adjusted to support the uniform and fair administration of Health Canada's cost recovery programs and funding mechanisms? For example:
- ▶ could the legislation facilitate partnering arrangements?
 - ▶ should the Minister of Health have the authority to remit fees when charging the full amount due would be unfair to the user?
 - ▶ should the Minister of Health refuse to issue a regulatory authorization (that is, refuse a manufacturer permission to sell a product in Canada) for failure to pay the prescribed fees?
 - ▶ in establishing fee schedules, should the Department be allowed to charge enough to compensate the government for the cost of providing the regulatory process?
- 68) As far as health is concerned, what are the international responsibilities of the federal government?
- ▶ from the point of view of free trade?
 - ▶ from a public health perspective?
 - ▶ from the point of view of liaising with outside agencies?
 - ▶ with regard to international health organizations (such as the World Health Organization)?
- 69) Does Health Canada have a responsibility to promote economic development? Does it have a responsibility to create a suitable regulatory climate for business?
- 70) Should the Minister of Health be required to table regularly before Parliament reports on the nation's health in Canada?
- 71) Should there be federal legislation to ensure that animals used for research are not mistreated?
- 72) Should the federal legislation be concerned with Canadians who go abroad to obtain an organ transplant?
- 73) Should the legislation be reviewed by Parliament on a regular basis (every five years? ten years?) to ensure that it does not become outdated?

9 – A Proposal: The Health Protection Act

A renewed legislative framework for health protection might include a statute of a general nature that sets out the fundamental principles to be observed in all matters pertaining to health protection. This umbrella legislation — let's call it the Health Protection Act — would be complemented by commodity-based legislation that addresses specific issues related to products. The overall legislative scheme would need to be carefully coordinated to ensure consistency and coherence.

Among other things, the Health Protection Act could:

- Spell out more clearly the federal government's roles and responsibilities in health protection.
- State the federal government's overall policy in matters of health protection, and outline the risk management framework.
- Promote exchanges with other levels of government and stakeholders. For example, the Act could:
 - formalize the creation of advisory boards by Health Canada;
 - facilitate the inter-delegation of powers between federal and provincial/territorial government bodies;
 - allow for the creation of federal-provincial/territorial corporations to carry on certain activities, provide services or enforce regulations; and/or
 - facilitate federal-provincial/territorial agreements for the joint provision of services.
- Provide safeguards to protect the confidentiality of health information related to individuals, while allowing for the effective gathering and analysis of information for surveillance purposes.
- Sanction the principle of public involvement in certain aspects of the decision-making process in matters of public health. The Act could detail the means by which this can be achieved while safeguarding the integrity and freedom of scientific investigation and ensuring the confidentiality of personal or commercial information.
- Specify when and how social, cultural, gender, economic and ethical considerations could be incorporated into decision making.
- Review the definitions of food, drug, medical device and radiation-emitting device.
- Prohibit in principle the manufacture, importation, distribution and/or sale of any product, and the conduct of any activity, that might represent an unreasonable health hazard to people or other living things. (Such a provision would have to be carefully worded to restrict its application.)

- Empower the federal government to adopt interim orders to control new and emerging risks to public health. Such a provision would apply only in cases of extreme risk and in the absence of any other statute, federal or provincial/territorial, to adequately address the risk.
- Repeal the *Quarantine Act* and replace it with legislation that provides Health Canada with better tools to control the entry and movement of persons or products capable of spreading diseases. The new Act could also empower Health Canada to prevent the exportation of communicable disease to other countries.
- Complement existing federal and provincial/territorial laws designed to control the creation, importation, transportation and use of human pathogens. The Act could also formally recognize and endorse the voluntary standards observed by research laboratories in this regard.
- Articulate the philosophy, policies and functions of Health Canada with respect to health hazards posed by new technologies.
- Articulate Health Canada's mandate and responsibilities in the event of a health crisis.
- Articulate the federal government's international responsibilities in matters of health.
- Support the harmonization of health and safety standards. The Act could, for example, formally recognize the use of national and international norms as standards of reference for the purpose of risk management, and encourage governments to harmonize inspection, enforcement and other practices.
- Include provisions that deal with product tampering or the threat of tampering.
- Provide Health Canada with the means to monitor industry's activities and enforce regulations. For example, the Act could authorize the use of alternative forms of dispute resolution (including mediation), civil remedies (such as injunction and mandatory recalls), administrative penalties and the confiscation of profits from illegal activities. The Act could also define more clearly the inspection practices to be used by government.
- Improve fairness in the administration of cost recovery by, among other things,
 - allowing Health Canada to reduce or defer fees in cases where charging the full fee imposes an undue burden, or is otherwise inappropriate in the circumstances; and
 - empowering Health Canada to compel the payment of fees by, for example, refusing to issue a licence until outstanding accounts had been settled.
- Oblige the Minister of Health to submit to Parliament periodic reports on the nation's health.
- Mandate a Parliamentary review of existing health protection legislation at regular intervals to ensure that the laws remain applicable and up to date.

10 – What You Can Do

We've made a start. We've asked questions, raised issues — at least enough to get us all thinking about the health protection legislation Canadians really want and need, the kind that will serve them well into the 21st century.

Now it's your turn. As a valued partner in health protection, you have much to contribute to this discussion. You bring to it your expertise, your years of experience and your personal understanding of what makes for good health and the best ways to protect and promote it. You probably know a great deal about what is working well in the field of health protection, and what isn't, and how matters can be improved.

We at Health Canada invite you to share your knowledge and ideas with us. No doubt there are issues and questions we haven't considered. Now is the time to raise them. You may want to make a suggestion or propose a possible solution to a problem; by all means, do so.

Most of all, we need to hear about the issues you think a new health protection legislative framework should address.

Let's work together to revitalize our health protection legislation to make it better serve the needs of all Canadians in the decades ahead.

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All comments received will be handled in accordance with the provisions of the *Access to Information* and *Privacy* Acts.