HEALTH AND SAFETY FIRST!

A PROPOSAL TO RENEW FEDERAL HEALTH PROTECTION LEGISLATION

The Minister of Health Seeks Your Opinion

One of the most important responsibilities of government is to ensure that an effective and responsive health protection system is in place to protect its citizens.

Our increased awareness of the importance of health protection results, in part, from the lessons learned from the Commission of Inquiry on the Blood System in Canada (Krever Inquiry). The SARS outbreak provides a more recent reminder. This awareness is also shaped by our understanding that scientific and technological developments offer not only opportunities, but also new and more complex risks to our health and well-being. Strengthening and improving existing health protection legislation is one of the key steps government can take to ensure that our health protection system is able to respond effectively to new pressures.

It is with both the past and the future in mind that a few years ago Health Canada launched a comprehensive review of the federal health protection program. Since then, a number of important changes have taken place at the organizational and funding level to strengthen current health protection activities.

Reviewing the health protection legislative framework also requires us to answer a number of fundamental policy questions, such as how health authorities should respond to scientific uncertainty regarding risks to human health. Governments, health professionals, industry, communities and individual Canadians all play an important role in health protection and injury prevention. This is why our first step in renewing the legislative framework was to consult Canadians from across the country.

The most important message to emerge from those consultations was that in Health Canada's discharge of its regulatory functions on health protection matters, health and safety must take precedence over other considerations. Acceptance of this message will form the core of our work as we move forward with this initiative.

We must ensure that federal health protection programs deserve public confidence. This is a unique opportunity to develop legislative instruments that are modern and adaptable to changing circumstances, can be understood by Canadians and reflect a commitment to the highest standards of health protection.

Following the first consultations, Health Canada officials developed a proposal for a new Canada Health Protection Act. Its goal is to modernize, strengthen and integrate the current federal health protection laws into a comprehensive system that is more responsive to present and future realities, and that reflects a commitment to the highest standards of quality. Now, as requested at the first consultations, we submit this proposal to you for your views.

I want to provide all Canadians with the health protection legislation they require. Please comment on what you believe is sound in the proposal, and what you think needs further improvement.

I look forward to hearing from you.

A. Anne McLellan
Minister of Health

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Note: A detailed description of the legislative proposal and background documents are available separately.

SUMMARY

Canadians are invited to voice their opinions regarding a proposal to strengthen and improve federal health protection legislation; that is, the laws aimed at addressing risks to health before they lead to injury or disease.

A legislative framework centered on a new Canada Health Protection Act (the Act) is proposed. It would replace the *Food and Drugs Act*, the *Hazardous Products Act*, the *Quarantine Act* and the *Radiation Emitting Devices Act*. Existing laws remaining in force, such as the *Tobacco Act*, would be amended to be compatible with the new legislative framework without changing their substantive provisions.

The legislative proposal draws considerably on the results of the first round of consultations held across Canada in the summer and fall of 1998. It also takes into account the recommendations of several independent reviews of Health Canada's health protection program, such as the Commission of Inquiry on the Blood System in Canada (Krever Inquiry) into tainted blood.

All elements of the legislative proposal are open for discussion. The proposal is intended to focus discussion during a second round of consultations. Only after the results of these consultations have been analyzed will an actual Bill be drafted and presented to Parliament.

Among other provisions, the proposed Canada Health Protection Act would include the following:

- FUNDAMENTAL VALUES: The core values that would guide health protection decision making are primacy of health and safety, openness, and accountability.

- GUIDING PRINCIPLES FOR RISK DECISION MAKING: The proposed Act could also identify key guiding principles in addressing health risks—assessing risk based on science, weighing risk against potential advantages, the concept of precaution, allowing for informed choice by consumers, considering health determinants, and sustainable development.

- GENERAL SAFETY REQUIREMENT: In addition to specific safety standards set in regulations, the Act would establish a General Safety Requirement that would apply to all products. The respective responsibilities of the various participants in the supply chain would be described.

- CATEGORIZATION OF PRODUCTS: Ways of categorizing products for regulatory purposes and definitions of "food," "health products," "natural health products" and "cosmetics" are presented for discussion.

- ♦ REVIEW OF NOVEL PRODUCTS: Improved legislative authority is proposed regarding the review process for new drugs, genetically modified food and other novel products. This would include authority to make the process more transparent.

- ♦ ADVERTISING OF HEALTH PRODUCTS: A series of options and tools to deal with the issue of advertising of health products is proposed for discussion.

- ♦ HEALTH AND SAFETY-RELATED ACTIVITIES: In the absence of provincial legislation, the proposed Act would provide the authority to regulate activities arising from new technologies, such as gene therapies.

- ♦ COMMUNICABLE DISEASES: Within the limits of federal jurisdiction, the Act would strengthen and modernize the legislative authority to prevent the spread of communicable diseases, as in the case of persons and cargo entering, leaving or moving within Canada, while ensuring adequate protection for human rights.

- ♦ PASSENGER CONVEYANCES: The Act would help ensure that proper health and safety standards are maintained on passenger conveyances with regard to water, food, ventilation systems and general sanitation.

- ♦ HEALTH SURVEILLANCE AND RESEARCH: The Act would clarify the authority of Health Canada to conduct health surveillance and research activities in cooperation with other governments and organizations.

- ♦ INFORMATION: The Act would strike a balance between the need to collect, use and disclose health information to protect the health of Canadians, and the need to safeguard privacy and commercial confidentiality.

- ♦ REGULATORY AUTHORITY: The Act would clarify and improve the regulation-making powers of the government.

- ♦ ENFORCEMENT: More efficient legal tools, including increased maximum penalties, would be provided to ensure compliance with the law.

- ♦ EMERGENCY RESPONSE: The Act would provide more flexibility to address urgent situations, for example, by allowing the Minister to issue emergency orders.

In addition, the proposed legislation would address product tampering, deceptive and fraudulent health claims, and products made or imported for personal use. The proposed legislation would provide guidance to Health Canada officials regarding the use of advisory committees and dispute resolution mechanisms, as well as set conditions for cooperative arrangements and cost recovery. It would also

address the government's international responsibilities in the area of health and safety. Finally, it would provide for the periodic review of the Act by Parliament.

1. INTRODUCTION

Canadians rightly expect an effective and responsive health protection regime from Health Canada.

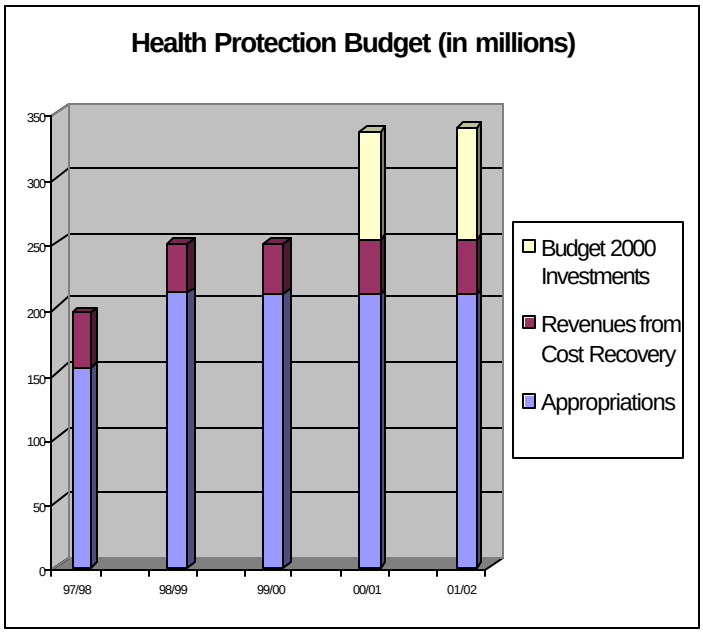
Working together with other partners in the federal, provincial and territorial governments, and working with individual Canadians, Health Canada carries out its responsibilities in this field in a number of ways, including:

- striving to ensure that the food we eat and the products we use are safe, and the medications we take are effective;
- helping to make our environment healthier because it is a key determinant of human health;
- monitoring diseases and injury patterns to intervene more quickly and effectively to prevent or reduce their incidence;
- ensuring that Canadians are properly informed so they can make the best decisions to increase control over their health and improve their well-being; and
- sharing knowledge and expertise with other health protection organizations across the country and around the world.

Over the last few years, a number of changes have been made to strengthen and renew the health protection program. These changes have included reinforcing the controls that ensure the safety of blood products, investing significant efforts and resources to improve our national health surveillance network, and enhancing the Department's scientific capacity. The Office of the Chief Scientist was established and Health Canada's risk decision-making framework was revised. The Natural Health Products Directorate, the Office of Consumer and Public Involvement, and the Marketed Health Products Directorate were created. The Canadian Institutes for Health Research was established and substantial new funding for research is now available.

Health Canada has undergone fundamental organizational changes that include the integration of its health protection and health promotion activities, the creation of three new branches and the strengthening of its regional capacity. These changes, which came into effect July 1, 2000, were designed to realign the Department to better serve Canadians through increased scientific capacities, better focused programs, increased management attention, and clearer accountability and reporting relationships.

The budget for the health protection program was also increased over the last few years. From $196 million in 1997/98, the budget was increased to $336 million in 2000/01.



Strengthening and improving the framework of federal laws that gives Health Canada the legal authority to take appropriate action to protect the health and well-being of Canadians is another fundamental component of the Department's actions to increase its health protection capacity.

Health Canada can act to provide that protection only within the powers entrusted to it by legislation. And that legislation needs to be updated, modernized and strengthened to keep pace with sweeping changes in society—changes that include new and emerging health risks, environmental changes, new scientific and technological discoveries, and changing public expectations and attitudes.

Every independent review of the health protection program since 1992, including the Krever Inquiry into tainted blood, has recommended changes to the legislation under which Health Canada operates.[1]

Moreover, Health Canada's own nation-wide consultations in 1998 concluded that current health protection legislation needs to be thoroughly reviewed, improved and updated.

Accordingly, Health Canada has developed a proposal for legislative renewal that takes into account the recommendations of the external reviews and draws heavily on the results of those consultations.

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[1]These reviews include: *Working in Partnership: Drug Review for the Future* (Gagnon Report), 1992; *Direction for Change: Report of the Medical Devices Review Committee* (Hearn Report), 1992; *A Strategic Direction for Change: A Review of the Regulations Under the Food and Drugs Act*, 1993; *Commission of Inquiry on the Blood System in Canada* (Krever Report), 1997; *Natural Health Products: A New Vision*, House of Commons Standing Committee on Health, 1998; *1999 Report of the Auditor General*; *Report of the Drug Review Process*, Science Advisory Board, 2000; *2002 Report of the Auditor General*.

A new legislative framework is proposed. At its centre would be a new Act, called the Canada Health Protection Act. This Act would consolidate, modernize and strengthen the existing patchwork of federal laws dealing with health protection, and provide clear policy direction by articulating key guiding principles.

Health Canada seeks to develop legislation that is adaptable to changing circumstances, that can be well understood by Canadians and that reflects a commitment to the highest standards of health protection.

The legislative proposal presented in this document is an important step along the path to accomplishing this, but it is not meant to be the final word. Rather, the proposal outlines the thrust of the provisions envisaged for the eventual legislation and the reasoning behind them. It is intended to focus the discussion and provide the basis for a second round of consultations with Canadians.

2. WHY REFORM NOW?

2.1 What We Have Heard from Canadians

At the start of the project to renew federal health protection legislation, Health Canada conducted extensive consultations across Canada. Nearly 1,000 individuals and organizations took part in the different consultation activities during that first round of consultations.

The purpose of the first round of discussions was to give all interested parties a chance to express their views about the issues that a new legislative framework should address and the values that it should reflect.

The key messages that emerged from these consultations include the following:

- Health and safety must take precedence over economic and other considerations. Many people fear that health and safety standards are being lowered, and think that Health Canada should be more committed to protecting Canadians.

- Health Canada should be more accountable to Canadians. In carrying out its health protection activities, Health Canada has only one client—the people of Canada.

- The health protection program's activities and decision-making processes need to be made more transparent to the general public and other interested parties.

- Health Canada has a responsibility to better inform Canadians about risks to their health.

- Health Canada needs to better explain the methods it uses to address health risks.

- People are concerned that the Department is vulnerable to conflicts of interest because it relies on fees from the industries it regulates to help fund core activities.

- There is a need to update current regulations, and to have greater fairness and consistency in the way these regulations are enforced.

- Canada's health protection legislation and regulations need to be thoroughly reviewed to better reflect the realities of contemporary society and science, particularly in the areas of product categorization and advertising.

- The new legislation should embody a set of principles that would guide the Minister of Health and the Department in the area of health protection.

The initial discussion paper, entitled *Shared Responsibilities, Shared Vision* (1998), as well as the *National Consultations Summary Report* (1999) can be viewed on Health Canada's Legislative Renewal Website at http://renewal.hc-sc.gc.ca or obtained from Health Canada at the toll-free number: **1-888-288-2098**.

2.2 Why Do We Need New Legislation?

Looking for ways to improve the existing regime should not make us lose perspective. Historically, the health protection system has served Canadians well. It has probably been a contributing factor in explaining why the Canadian population's life expectancy has been improving constantly over the years.

However, there have also been some well-known and tragic failures that have highlighted important weaknesses in the system. The 1997 Final Report of the Commission of Inquiry on the Blood System in Canada (Krever Report) documented some of these shortcomings.

Just as important, rapid changes in science, technology, our environment and in society itself are creating new and more complex risks and challenges to our health and well-being. It is difficult to meet the challenges of the future with approaches designed in the distant past.

Under the *Food and Drugs Act*, Health Canada regulates the manufacturing and distribution of drugs. However, emerging gene therapies can involve the exchange of information and the manipulation of human cells rather than the manufacturing and sale of a tangible product. Such therapies may, eventually, replace many conventional drugs. With its narrow focus on products, the *Food and Drugs Act* may not provide adequate legal tools to address these and other emerging technologies.

Broadly speaking, the shortcomings of the current legislation include the following:

A. There are gaps in what is covered by existing health protection legislation.

B. There are inconsistencies in how current legislation addresses health risks.

C. Enforcement and compliance mechanisms are inadequate.

D. There are no expressly stated guiding principles, philosophy or values.

Here are just a few examples of these shortcomings:

A. Gaps in the Legislation

Most of the current health protection legislation was adopted prior to most of the recent technological breakthroughs.

With respect to the *Food and Drugs Act*, adopted in 1953, consider the following:

- When this Act was adopted, no one envisaged that human organs would one day be transplanted. To regulate the safety of organs used in transplantation under current law, Health Canada must resort to treating human organs as "medical devices." This ill-suited approach complicates the development of comprehensive standards.

- Similarly, Health Canada does not have clear jurisdiction to control chemical products—not currently considered as drugs—which could be administered to farm animals that are later consumed by humans.

- The concepts of transparency and of public involvement in the decision-making process were not viewed as important principles of governance. Consequently, the provisions of the *Food and Drugs Act* do not always provide the tools that are necessary for effective public participation in the work of Health Canada in carrying out its responsibilities under the Act.

Under the *Hazardous Products Act*, Health Canada must address newly identified risks found in consumer and industrial products on a case-by-case basis by adopting standards through either regulations or new legislation. This presents several problems.

- First, the process of establishing standards through regulations inevitably takes time. Meanwhile, products already identified as potentially dangerous can remain on the market.

- Second, the accelerating pace of innovation means that new types of products come onto the market so quickly and in such numbers that Health Canada cannot possibly keep up with developing new product-specific standards to govern them all.

- Third, the Department currently has no regulations for a variety of consumer products, including children's products, such as playground equipment and baby walkers that are associated with injuries and fatalities; a variety of home products, such as ozone generators, particle board cabinetry and furniture that can negatively affect indoor air quality; sports and recreational equipment; upholstered furniture and other products that may present a fire hazard; carbon

monoxide detectors, whose reliability is critical for public safety; and chemical products associated with long-term negative health effects. In the absence of specific regulations, Health Canada is limited to issuing a public warning about the dangers of a particular product and trying to persuade a manufacturer to take corrective actions.

Another gap is found in the *Quarantine Act*, which needs to be strengthened to better address the risks posed by new and re-emerging dangerous diseases. For example, under the *Quarantine Act*, for a disease to be classified as "infectious or contagious", and thus be subject to not only entry restrictions but also to exit restrictions at our borders, it must be listed individually by way of regulations, a very time-consuming process. In addition, the provisions concerning the responsibilities and procedures for detention must be clarified, taking into account how they can meet the spirit and intent of the *Canadian Charter of Rights and Freedom*s.

Another crucial gap is in the field of health surveillance. To acquire the information necessary to make informed decisions regarding risk management, Canadian and international health authorities collect, analyze and exchange data to identify and predict risks to public health. However, the current legislation provides only limited and ambiguous authority and direction to this vital surveillance function. The 1999 and 2002 Auditor General's Reports highlighted the essential importance of Health Canada's health surveillance activities for protecting Canadians against threats to public health within the context of cooperation with the provinces and territories. They pointed out serious deficiencies in Health Canada's ability to fulfill its responsibilities in this area. The Auditor General strongly recommended that Health Canada strengthen and clarify its role and responsibility in public health surveillance.

Participants in the first round of consultations generally agreed on the importance of timely access to health surveillance data. However, they also pointed to the sensitive nature of health information—and emphasized the importance of protecting its confidentiality in the current technological environment that allows for the rapid circulation and matching of information. The Privacy Commissioner has also voiced similar concerns. Yet, the current federal health protection laws provide no guidance as to how to balance the need for an effective health surveillance system with the need to safeguard privacy.

B. Inconsistencies

An increasing number of products do not fall squarely within the existing definitions that determine which regulatory regime should apply (e.g. food, drug, medical device, radiation-emitting device). This results in inconsistencies, such as some products not being covered at all while others are subject to several different regulations. Some examples include the following:

- 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 medical devices under the *Food and Drugs Act*.

- Depending on how it is sold, the same disinfectant can be subject to the *Pest Control Products Act*, the *Food and Drugs Act* or the *Hazardous Products Act*.

- Acetone as a consumer chemical has to meet safety standards; acetone as a cosmetic (nail polish remover) does not.

- Nutraceutical products—such as garlic pills that are isolated or purified from foods and generally sold in medicinal forms—can be treated either as a drug or a food, with very different regulatory requirements in each instance. The level of regulatory control does not depend on the level of risk that the products actually present, but on whether the health claim appears on the product label itself or is presented in separate material.

Beyond the obvious problems of these inconsistencies, the inadequate categorization of products under current laws leads to an even more fundamental problem that was raised repeatedly by participants in the public consultations. It significantly limits Health Canada's ability to establish a regulatory framework in which the stringency and type of regulations are proportional to the actual level of risk to health and safety that various categories of products present.

C. Deficient Enforcement Tools

Because the various health protection laws were adopted piecemeal over several decades, there are significant deficiencies in the powers at Health Canada's disposal to enforce health protection measures.

The maximum fine that can be imposed on a drug manufacturer for violating provisions of the *Food and Drugs Act* is $5,000. This was a significant penalty in 1953 when this Act was adopted, but scarcely a deterrent today. In comparison, penalties under the *Health of Animals Act* can go as high as $200,000.

Health Canada has the power to demand satisfactory evidence of safety before it issues a Notice of Compliance for a new drug and allows it to be sold. If, however, concerns about the drug's safety arise after it has entered the marketplace, although Health Canada can revoke the Notice of Compliance, it does not have the authority to force a company to recall the drug or to take other remedial measures to have the product removed from the marketplace. If the company refuses to comply voluntarily, Health Canada can seize the product. However, Health Canada often has no means of knowing the retailers to which the product was distributed. There is also no provision under which Health Canada can be reimbursed for the often considerable expenses incurred in storing or destroying dangerous products, seized because a manufacturer refused to withdraw them voluntarily.

Conversely, while these and other deficiencies exist in Health Canada's powers to protect public health, industry has complained that there is no recognized mechanism other than the courts to resolve disagreements with Health Canada officials over regulatory issues.

D. Lack of Guiding Principles

Current federal health protection statutes do not spell out the philosophy or values that should guide decision making regarding risks to health.

This is not a theoretical concern. In making decisions, health officials are often confronted with practical questions such as at which point the government should take preventive measures in the absence of scientific certainty; how to balance freedom of choice with public interest; and the extent to which the public should be involved in making decisions.

Through legislation, Parliament could provide clear, expressly stated policy direction for health protection.

2.3 Why a Comprehensive Legislative Review?

Even with all these examples of deficiencies, it is still pertinent to ask why Health Canada is contemplating such a comprehensive revision in the form of a whole new Canada Health Protection Act to take the place of four existing statutes.

Why not simply adopt specific amendments to deal with the identified deficiencies in the existing legislation one by one?

The attempt to find patchwork solutions over the years has left us with serious flaws, gaps and inconsistencies in existing health protection legislation. Trying to address shortcomings piecemeal or selectively has proven to be far more difficult, and far less likely to produce good results, than a comprehensive revision. Among other things, it would require going to Parliament several times with a series of amendments to numerous laws.

One Act would help ensure greater coherence and consistency among all the pieces that make up the health protection regime, and thus help avoid gaps and overlap. For the most part, the rules generally applicable whenever addressing health risk would all be found in one Act, and would be much easier to keep up-to-date.

As well, some fundamental assumptions made in the past and upon which current legislation is based need to be reviewed. Today, our changing world and society have new issues to consider. For example:

- In today's more educated and informed society, people want greater participation in decisions concerning their own health.

- A more multicultural society has new expectations in areas such as traditional medicines.

- The free flow of products around the world, coupled with the rapid growth of new information vehicles such as the Internet, requires greater international coordination among regulatory agencies.

These fundamental policy issues cannot be addressed through piecemeal amendments to existing laws. A patchwork or piecemeal approach cannot satisfactorily address such large issues, along with the number and nature of the deficiencies in current legislation.

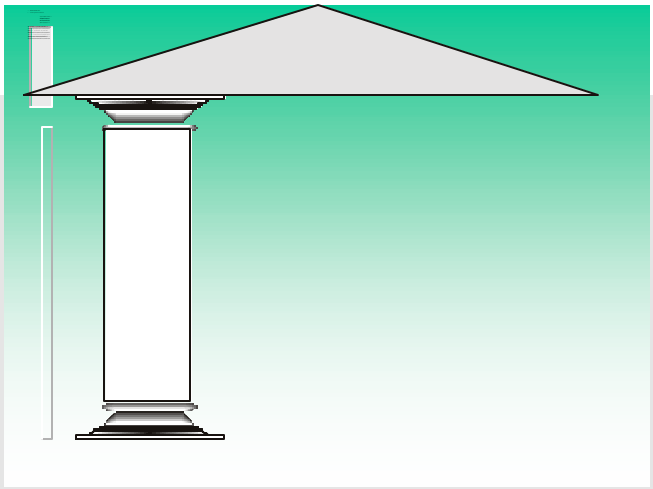
Canadians are entitled to expect that Health Canada will earn their continued confidence by putting into place the legal instruments to meet the challenges of the new century and setting out clear principles to guide the health protection program. That is what underlies this initiative.

2.4 Goals of the Renewal Initiative

Against this background, the fundamental goals of the proposed legislative renewal are the following:

- update, strengthen and integrate federal health protection legislation into a coherent, comprehensive and flexible system that is more responsive to present and future social and technological realities, and that provides the necessary tools to better protect the health of Canadians; and

- provide overall policy direction in the area of health protection that is based on the highest standards of health protection.



hazardous materials and to provide safety information. The *Canada Labour Code* requires employers in federal workplaces to provide WHMIS information to their employees and to train them in the safe use of hazardous substances. Provincial and territorial legislation imposes similar requirements as the *Canada Labour Code* on employers in all other workplaces. Another component of WHMIS, the *Hazardous Materials Information Review Act*, establishes a commission to review claims for exemptions from disclosing trade secret information, and to review the material safety data and the labels to which such claims relate.

Pest Control Products Act, 1969 (revised in 2002). 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.

Radiation Emitting Devices Act, 1970. This Act sets standards for the sale, lease and importation of radiation-emitting devices, including televisions, tanning lamps, microwave ovens, ultrasound machines and X-ray machines.

Quarantine Act, 1872. This Act controls the entry into Canada of persons, vehicles or cargo suspected of being carriers of infectious or communicable diseases.

Controlled Drugs and Substances Act, 1996. This Act controls the importation, traffic and use of narcotics and other illicit substances (e.g. heroin, cocaine, marijuana) while allowing for their medicinal use, where appropriate.

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 allows for regulations that require that tobacco products carry explicit warnings about the health risks associated with tobacco use.

Canadian Environmental Protection Act, 1999. This Act controls the distribution and use of substances in Canada that pose a danger to human health or the environment. It also contains provisions to restrict the flow of cross-border air pollution. It 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). Regulations adopted under this 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. It also establishes the Patented Medicine Prices Review Board, which monitors and controls the price of patented medicines.

Canadian Food Inspection Agency Act, 1997. This 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. It 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 for assessing the effectiveness of the Agency's activities related to the enforcement of food safety.

3.2 Scope of the Legislative Renewal

The parameters to keep the discussion focused on proposed legislative changes are listed below:

- 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. These issues were the recent focus of attention of both the Commission on the Future of Health Care in Canada (led by Commissioner Roy Romanow) and the Standing Senate Committee on Social Affairs, Science and Technology (chaired by Senator Michael Kirby), and were a key feature of the 2003 federal budget.

- The focus should be on the substance of the health protection legislation, not on the governmental structure chosen to administer it. For instance, in his final report, Commissioner Roy Romanow recommended the creation of a National Drug Agency that would assume many of the responsibilities over drugs now assigned to Health Canada. Irrespective of which governmental structure is charged with the administration of the Act, the current legislation needs to be strengthened and modernized.

- Legislation adopted in recent years by Parliament—specifically, the *Tobacco Act*, the *Controlled Drugs and Substances Act*, *the Pest Control Products Act* and the *Canadian Food Inspection Agency Act*—is outside the scope of this review.

- This review does not cover the *Patent Act* and its regulations.

- Bills currently pending before Parliament are outside the scope of this review. If required, these Acts, together with those recently passed, will be adjusted at a later stage to ensure consistency with the overall system.

- Unless WHMIS partners take the opportunity to amend and update the system, the WHMIS provisions now in Part II of the *Hazardous Products Act* and in the *Hazardous Materials Information Review Act* would be consolidated without substantive change in the new Act.

4. THE PROPOSED LEGISLATION

4.1 Open for Debate

In response to the need for a comprehensive overhaul of the federal health protection legislation described in the preceding section, Health Canada officials have developed a proposal, the key element of which is a new Canada Health Protection Act.

In developing the proposal, they have drawn heavily on input received during the first round of nation-wide consultations.

This section provides an overview of what is being proposed. A more detailed description of the legislative proposal is available separately (see last page for details on how to reach us).

EVERYTHING IN THIS PROPOSAL IS OPEN FOR DEBATE. What follows is just one possible scenario for eventual legislation. It is based on: the shortcomings and the needs that have been identified; the directions received from Canadians in the first round of consultations; and the health protection objectives that appear appropriate.

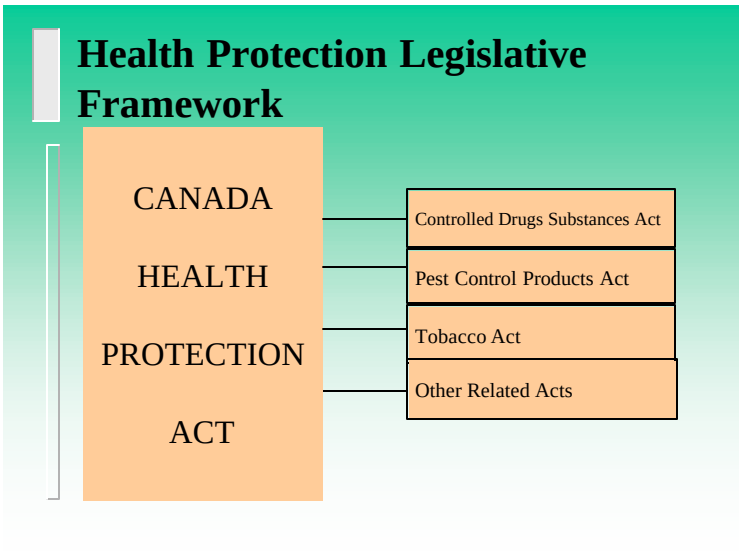
The goal of this renewal initiative is to provide Canada with health protection legislation and programs that will serve Canadians well into this new century. The way to achieve this—the way to get it right—is through the broadest possible public input. This detailed proposal is intended to facilitate that consultation.

It should be noted that neither the description in this section nor the detailed legislative proposal are legal text. Each clause is intended to indicate what the **content** of a corresponding clause in eventual legislation might be, rather than the precise wording that might be employed.

The most helpful comments, consequently, will be those that focus on the content and intent of what is being proposed—that is, on the ideas rather than the wording. Where you disagree with this proposal, your specific alternatives together with explanations of your reasons for proposed changes will also be most helpful.

4.2 Overview of the Proposed Legislation

The proposal is to replace the current piecemeal accumulation of statutes that has occurred over time, with a new legislative regime. At its centre would be a new Canada Health Protection Act.



Existing laws that would remain in force (e.g. *Tobacco Act*) could be amended to integrate them into the new legislative framework without modifying their substantive provisions. For example, the existing inspection powers under those laws would be replaced by more effective authorities established in the new Canada Health Protection Act. These amendments would be of a technical nature and would be addressed at the time of drafting the actual Bill.

It should be noted that the proposed legislation would not constitute an extension of the jurisdiction of Health Canada. What would change is that Health Canada would obtain the legal instruments it needs to exercise its responsibilities more effectively in areas over which it already has a mandate. It is also important to remember that the courts have clearly recognized federal jurisdiction in matters of health protection.

The principal provisions of the proposed Canada Health Protection Act would include the following:

POLICY DIRECTION

PURPOSE: The Act would state its purpose—to protect the health of the people of Canada.

FUNDAMENTAL VALUES: It would then enunciate three key values that would underlie and inform all actions taken under its authority.

- **Primacy of Health and Safety:** The health and safety of Canadians shall be the primary consideration in actions taken under the proposed Act.

- **Openness:** Public scrutiny of government actions relating to health and safety and public engagement in the decision-making process shall be encouraged.

- **Accountability:** As a member of the Government of Canada, the Minister of Health is ultimately accountable for the administration of the Act to the people of Canada through Parliament.

GUIDING PRINCIPLES FOR RISK DECISION MAKING: The Act would also affirm key principles that would guide decisions about risks to health. The first principle pertains to the **assessment** of risks while the others pertain to ways of **addressing** risks.

- The assessment of risk shall be based solely on science and objective observation.

- Potential negative effects shall be weighed against potential advantages for the people of Canada.

- The concept of precaution will be applied.

- The desire of individual Canadians on matters which concern their own health shall be considered, when they are in a reasonable position to make an informed choice and the public interest is not threatened.

- It shall be recognized that the same measures can impact different people in different ways, depending on factors such as gender, age, social situation, economic conditions, education, culture, or personal convictions and values.

- Decisions will be made with a view to minimizing adverse impacts on the environment on which human health depends, and allowing for development that meets the needs of the present without compromising the ability of future generations to meet their own needs.

INTERPRETATION: A lexicon of terms used throughout the proposed legislation would be included. To assist in future deliberation, the following terms are discussed in the detailed description of the legislative proposal: "health," "manufacture," "market," "product," "promote," "qualified health practitioner," "reasonably foreseeable conditions" and "supplier."

APPLICATION TO PRODUCTS: The Act would apply to all products that are not already covered by other federal laws. All products within the scope of the current *Food and Drugs Act*, Part I of the *Hazardous Products Act* and the *Radiation Emitting Devices Act* would be covered. These include consumer products, food, therapeutic products, natural health products, cosmetics, radiation-emitting devices and products used in the treatment of drinking water.

GENERAL SAFETY REQUIREMENT: In addition to specific safety standards set out in regulations, the Act would establish a General Safety Requirement that would apply to all products. It

would establish the general rule that any product which represents an undue risk for the public, at any stage in its life cycle (from production to final disposal), would be prohibited. The General Safety Requirement would be articulated as follows:

- The Act would prohibit the manufacture, promotion or marketing of any product which can reasonably be foreseen to cause injury to the health of a person for any of the reasons listed in the Act (e.g. the product is defective or it fails to accomplish what it is supposed to do).

- The factors to be considered in determining whether the supplier has exercised reasonable care would include the guiding principles on risk decision making described above, the nature and function of the product, the vulnerability of users, etc.

SUPPLY CHAIN: The Act would describe the respective responsibilities of the various participants in the supply chain, including the responsibility of the manufacturer to monitor adverse health effects after a product has been sold and to take corrective action when necessary.

PERSONAL USE: The Act would not apply to products made, possessed or imported strictly for one's personal use, provided these products pose no risk to other people. Exceptions to this provision, designed to prevent an intolerable risk to the health of the person using the product (for example, prescription health products), would be specified in the regulations.

TAMPERING: It would be an offence to tamper with a product to render it unsafe or to make it appear to be unsafe, to threaten to do so, or to allege to have done so.

DECEPTION: The Act would make it an offence to deceive consumers regarding the health and safety benefits of a product. The burden of proving the validity of a health claim would be on the person making the claim.

CATEGORIZATION OF PRODUCTS: As new products are introduced onto the market, it becomes increasingly difficult to divide products into neat categories (e.g. food, drug, consumer product) in order to determine which regulations to apply. Regulations could establish lists of products considered to fall in any given class or category. The Act would provide a binding mechanism to rule on the classification of products.

Definitions of "food," "health products," "natural health products" and "cosmetics" are presented in the detailed proposal for discussion.

REVIEW OF NOVEL PRODUCTS: A number of provisions would have implications for the evaluation of novel products, such as new drugs or genetically modified food. For example, the proposed Act would reinforce Health Canada's authority to collect, use and disclose information related to the safety and effectiveness of these products; facilitate cooperation with other governments; and provide additional regulation-making authority where necessary.

The Act would eliminate existing legal barriers to making the process of reviewing new products more transparent, while offering reasonable protection for confidential commercial information. A number of options to increase transparency and public involvement are proposed for discussion in the detailed proposal, which is available separately.

FOOD: The Minister of Health would continue to be responsible for establishing health and safety standards for food. The current requirements of the *Food and Drugs Act* would be retained.

A new definition of "food" is proposed, and the regulation-making authority with regard to veterinary drugs used in food-producing animals would be strengthened.

HEALTH PRODUCTS

PRESCRIPTION STATUS: Regulations would clearly specify the criteria for deciding which health products should be sold by prescription only. The process for making this determination would be simplified.

SCHEDULE A: Three options are being proposed with respect to the current prohibition against advertising to the general public of any product for the prevention, treatment or cure of conditions (e.g. cancer, obesity) that are listed in "Schedule A" of the *Food and Drugs Act*. These options are tailored to better reflect public health objectives.

ADVERTISING OF HEALTH PRODUCTS: Aside from "Schedule A," measures to control drug advertising are also proposed for discussion. They range from a prohibition on the promotion of prescription health products to the general public, to control mechanisms aimed at ensuring that the consumer is provided with objective information.

HEALTH PRACTITIONER-ORIENTED PROMOTION: The question is also raised whether restrictions should be imposed on the promotion of health products to health professionals.

DISTRIBUTION OF SAMPLES: The Act would establish regulation-making authority regarding the distribution of samples of health products.

NATURAL HEALTH PRODUCTS: The proposal addresses issues which are particularly relevant in the case of natural health products. For example, the proposed guiding principles on risk decision making provide that government shall consider the desire of individual Canadians on matters that concern their own health—when they are in a position to make an informed choice and the public interest is not threatened.

WATER: The proposed Act would confirm the authority of the Minister of Health, in cooperation with other orders of government, to develop guidelines on drinking water quality. The Act would apply to the production of bottled water and water served on common carriers. It would also cover drinking water materials, such as treatment devices and additives, and water system components.

VETERINARY DRUGS: The proposed Act would reinforce the authority of Health Canada to regulate veterinary drugs, particularly with regard to food-producing animals.

HEALTH AND SAFETY-RELATED ACTIVITIES: In addition to controlling the manufacture, promotion and marketing of products, the Act would authorize Health Canada to establish regulations regarding certain activities involving new technologies, such as gene therapies. Such regulations could be adopted after consultation with the provinces and territories and other interested parties. They would apply only where the risk is not addressed by provincial or territorial legislation.

COMMUNICABLE DISEASES

> **QUARANTINE:** The proposed Act would replace the *Quarantine Act* and would update measures for the detention, examination and treatment of persons and cargo arriving in or departing from Canada that may be carrying a dangerous communicable disease. Such measures would be consistent with the realities of rapid, modern travel and would conform with the rights guaranteed by the *Canadian Charter of Rights and Freedoms.*
>
> **MOVEMENT WITHIN CANADA:** As it relates directly or indirectly to the safety of transportation, the provisions regarding quarantine could also apply, with the necessary adjustments in the case of persons, conveyances, goods and cargos moving across provincial or territorial boundaries within Canada or on navigable waters flowing across provincial, territorial or national boundaries.
>
> **DOMESTIC AND INTERNATIONAL REGULATIONS:** The proposed Act would provide a new basis for the existing regulations concerning human pathogens used for research or manufacturing purposes. The Act would allow for the full implementation of Canada's international obligations under various treaties and charters both nationally and internationally.

PASSENGER CONVEYANCES: The Act would provide the necessary regulation-making authority to establish health and safety standards for passenger conveyances with regard to water, food,

ventilation systems and general sanitation. In addition, a General Safety Requirement with regard to these matters would apply to passenger conveyances designated in the regulations.

HEALTH SURVEILLANCE AND RESEARCH: The Act would recognize Health Canada's need to conduct health surveillance and research activities in cooperation with public authorities in Canada and abroad, as well as with individual Canadians and other interested parties. These activities would include gathering and disseminating health information, conducting national surveys, and establishing and maintaining laboratory facilities.

INFORMATION

> **AUTHORITY TO COLLECT, USE OR DISCLOSE INFORMATION:** Under the Act, Health Canada would be authorized to collect, use or disclose information, but only to the extent necessary to promote and preserve the health of the people. A person or an organization could be compelled to provide information to Health Canada in specified circumstances set out in the detailed version of the proposal.
>
> **IDENTIFYING PERSONAL INFORMATION:** Health Canada would be subject to a set of rules aimed at protecting the privacy of individuals while allowing the Department to fulfill its responsibilities toward the Canadian public. For example, Health Canada could only collect, use or disclose the least amount of identifying personal information required to promote and preserve public health, and only in circumstances specified in the proposal. To ensure that Health Canada acts responsibly in this very sensitive area, a number of oversight mechanisms are also proposed for discussion.
>
> **CONFIDENTIAL COMMERCIAL INFORMATION:** The Act would authorize the collection and use of commercial information, as required for the administration of the legislation. Information of a confidential nature could not be disclosed by the Minister except under certain conditions set out in the detailed version of the proposal.

REGULATORY AUTHORITY: The government could adopt regulations to fulfill the purposes of the Act. It would also set the conditions under which external standards could be incorporated by reference.

ENFORCEMENT: The Act would provide more effective legal tools to ensure compliance with the law. For example, maximum penalties would be increased to $1,000,000 and three years of imprisonment. Courts could issue additional remedial orders, such as prohibiting a person found guilty of contravening the law from engaging in similar activities for a period of time. The Minister could exercise

a broad range of preventive measures, such as ordering a supplier to take corrective measures to protect the public or suspending the sale of a product while seeking further information on its safety. Cooperative agreements on enforcement measures could be entered into with other governments or public authorities, on certain conditions.

EMERGENCY RESPONSE: The Minister of Health could, under certain conditions, issue an interim order if immediate action is required to deal with a significant risk to human health or to the environment.

DISPUTE RESOLUTION: The proposed Act would provide the necessary authority to establish dispute resolution mechanisms.

ADVISORY COMMITTEES: The Act would provide guidance regarding the use of advisory committees involving experts from outside of government on matters such as transparency and conflict of interest.

INTERNATIONAL RESPONSIBILITIES: The Act would recognize the moral responsibility of the Government of Canada to promote public health and safety around the world, particularly in less developed countries, and the need to cooperate with other countries in this regard. The Act could apply to products meant for export—when prescribed in regulations, upon request from the receiving country or when the Minister believes that the product could re-enter Canada.

COOPERATIVE ARRANGEMENTS: The Minister of Health could enter into cooperative agreements with other organizations, provided that Health Canada does not abandon its authority to enforce the Act and that such agreements are made accessible to the public.

COST RECOVERY: The Act would state that any regulatory function for which fees are charged shall be conducted separately from the operations relating to the collection of such fees. It would also address technical questions concerning the administration of these programs. For example, the Minister of Health could reduce or defer fees in the case of an orphan drug.

REVIEW BY PARLIAMENT: Parliament would review the Act every seven years to ensure that it is kept up-to-date.

RELATED STATUTES: The provisions dealing with policy direction, categorization of products, information and administration would apply, with the necessary adjustments to the actions taken by the Minister of Health under other statutes or regulations related to health protection.

COMING INTO FORCE: The Act would come into force at a date determined by the Governor in Council (the Cabinet). The existing health protection regime, including the regulations, would remain in force until the new Act is put into place and fully established.

For more information on the preceding items, please consult the detailed version of the proposal.

5. HOW TO PROVIDE INPUT

This proposal concerns all Canadians. The government, through Health Canada, has a key role in health protection, particularly in the areas that have been described in this document. However, all of society has an interest and a responsibility to protect health and safety.

Would the proposed legislation serve the needs of Canadians in the decades ahead? How can it be improved?

Nothing has been decided yet. It is important to know what Canadians believe is sound in the legislative proposal and what appears to need further improvement. A Bill will be drafted and presented to Parliament only after the results of the consultation have been analyzed.

A public discussion will take place on these questions in the months to come. There will be opportunities to comment in writing and to participate in consultation sessions in different parts of the country.

We are seeking your views on the detailed proposal for a new federal health protection Act. You can access this detailed proposal (about 200 pages), as well as additional background information on our Website. You can also request a paper or CD copy.

There are several ways to participate in the consultation process:

1. Comment interactively, directly on our Website.

You can provide your comments on the detailed proposal by answering questions at the end of each section of the Web document. Your comments will be recorded automatically in our database.

2. Send your written comments or submissions by e-mail, mail or by fax.

To help us compile the information, identify the number of the clause in the detailed proposal that you are commenting on, whenever applicable.

If you send your comments electronically as an attachment to an e-mail, it is preferable that the text be saved as a Word Perfect or a Microsoft Word file.

If it is not possible for you to send your comments electronically, please mail or fax them. Avoid handwritten comments, if possible.

3. Participate in meetings to be scheduled in the coming months.

Fill out the registration form and mail or fax it to us as soon as possible. We will contact you a few weeks in advance of the meeting, which will likely be held in the fall.

Please note: Comments or submissions provided without the name and coordinates of the author or the organization (if applicable) will not be considered. The comments and identity of the author or the organization (but not the coordinates) will be considered public information. They may be displayed in a public database at some point during or following the consultation period.

Please tell us what you think.

Health Protection Legislative Renewal
Health Canada

Website: http://renewal.hc-sc.gc.ca
E-mail address: Renewal_Renouveau@hc-sc.gc.ca
Phone: 1-888-288-2098 (toll-free) Fax: (613) 954-0716
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TO REGISTER FOR FUTURE CONSULTATION MEETINGS AND/OR TO REQUEST THE DETAILED PROPOSAL:

Please complete this form and return it to us by **FAX (613-954-0716) or**
MAIL (Legislative Renewal, A.L. 0700A, Tunney's Pasture, Ottawa, Ontario, K1A 0L2).

Name:	Title:	
Organization:		
Complete Mailing Address:		
Phone:	Fax:	E-mail:

PREFERRED OFFICIAL LANGUAGE:

I wish to receive material(s) in: English ☐ French ☐

I wish to participate in activities in: English ☐ French ☐ Either ☐

TO REGISTER FOR FUTURE CONSULTATION MEETINGS: *Times and locations to be determined*

I identify myself for the purpose of consultation as being part of:

(more than one can be marked)

☐ Aboriginal Organization	☐ Academic Community	☐ Consumer Group
☐ General Public	☐ Government	☐ Health Professional
☐ Industry	☐ Patient Group	☐ Public Interest Group
☐ Voluntary Organization	☐ Other, please specify: _____	

I would like to discuss the following subjects:

☐ Advertising of Health Products	☐ Categorization of Products
☐ Communicable Diseases	☐ Confidential Commercial Information
☐ Deception	☐ Enforcement
☐ General Safety Requirement	☐ Health Surveillance and Research
☐ Overall Policy Direction	☐ Passenger Conveyances
☐ Privacy	☐ Review Process (Novel Products)
☐ Other, please specify:_____	

TO REQUEST MATERIALS:

Please mail me the detailed Proposal: ☐ Paper copy ☐ CD (includes all web documents)

The information provided in this form is subject to the *Access to Information Act* and the *Privacy Act*. For more information, consult the publication *Info Source* (Bank number: HCan PPU 051) from the Treasury Board Secretariat of Canada on their Website at http://www.tbs-sct.gc.ca/ by requesting it from the Information and Security Policy Division, Treasury Board of Canada Secretariat, Telephone (613) 957-2455, Fax (613) 952-7287.