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National Consultations

Summary Report

RENEWAL OF THE FEDERAL HEALTH PROTECTION LEGISLATION

Canada

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Health Canada

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INTRODUCTION

Background to the Legislative Review Initiative

As part of its efforts to modernize the health protection system to meet the needs of Canadians in the 21st century, Health Canada has undertaken to update and improve the laws that guide its work in health protection. To lay the groundwork for this initiative, the Department prepared and distributed two discussion papers, *Health Protection for the 21st Century— Renewing the Federal Health Protection Program* and *Shared Responsibilities, Shared Vision— Renewing the Federal Health Protection Legislation*. These documents were designed to stimulate discussion among the groups, agencies and individuals involved in helping to safeguard the health of Canadians. They provided background information, explained some key concepts and principles, and proposed topics for discussion.

Following the release of these documents in July of 1998, Health Canada initiated an initial round of public consultations. The aim was to give all interested parties a chance to express their views about what is working well in health protection and what needs to be changed, and to develop a shared vision among Canadians of what a revised legislative framework for health protection might look like. The results of this dialogue will be used to draft a legislative proposal. Later this year, Canadians will be invited to comment on the proposal during a second round of consultations. Drawing on these discussions, Health Canada will draft new health protection legislation for consideration by Cabinet.

The National Consultations, First Round

In September and October of 1998, Health Canada held a series of public meetings in Halifax (September 9, 10), Winnipeg (September 24, 25), Vancouver (September 29, 30), Ottawa (October 14,15), Montreal (October 22, 23) and Toronto (October 28, 29). About 500 people took part, including representatives of the public and public interest groups, provincial public health agencies, the medical and medical research communities, and industry, including those representing complementary health products.

The Department also provided funding for a series of five public meetings held in October in Saskatoon, Charlottetown, St. John's, Edmonton and Milton, Ontario. Hosted by the Consumers' Association of Canada (CAC), the meetings attracted 110 participants who brought the consumer's perspective to the process of legislative renewal.

Both series of meetings dealt with the Health Protection Branch's risk management framework and public involvement in the Health Protection Program. The question of public involvement was also addressed in three workshops on the topic. Held in Ottawa (May 27), Scarborough (June 25) and Burnaby (June 10, 11), the workshops attracted about 60 participants.

In addition, the Health Protection Branch's office in the Western Region held six town hall meetings in Courtney, Nanaimo, Kelowna, Prince George, Salmon Arm and Kamloops during November 1998. Approximately 150 people attended these meetings.

Health Canada also obtained the views of numerous stakeholder groups, including public interest groups, health professionals, and industry, through a series of bilateral meetings held mostly in August and September.

Finally, the Department received written submissions in the form of letters and briefs from individuals, industry and health-related organizations, and Consultation workbooks, which were completed by participants in the consultation sessions.

The Summary Report

This report summarizes the salient opinions expressed by participants in the initial round of consultations. For the sake of brevity, not every comment voiced by participants is recorded here. Instead, the report attempts a representative yet balanced account, using the following conventions:

- Opinions that were often repeated in one form or another, suggesting widespread agreement among participants on an issue, are expressed directly. Readers will have the impression that they are listening to a spokesperson representing the majority of participants.

- Important dissenting opinions and minority views are shown in italic type.

- Conflicting opinions, suggesting little agreement by participants on a given topic, are also shown in italics.

Submissions received after November 15, 1998 are being analysed, but are not included in this report.

Readers should be aware that the opinions expressed herein do not necessarily represent the views or policies of Health Canada or the Minister of Health.

EXECUTIVE SUMMARY

Some participants expressed scepticism about the government's motives in undertaking a review of the federal health protection legislation and its ability to significantly improve the operations of the Health Protection Branch. There was widespread agreement that the consultations were long overdue and represented a first step toward greater transparency in the management of the federal Health Protection Program.

The dominant messages to emerge from the consultations were as follows:

1. Health and safety must take precedence over economic and other considerations. Many people fear that health and safety standards are being lowered and that Health Canada has abandoned its responsibility to protect Canadians from hazards to their health.

2. Health Canada should be more accountable to Canadians. Health Canada and its Health Protection Branch have only one client—the people of Canada.

3. The Health Protection Program's activities and decision-making processes need to be made more transparent to the public and various stakeholders.

4. Health Canada has a responsibility to better inform and educate Canadians regarding risks to their health.

5. Health Canada needs to better explain the methods it uses to manage health risks.

6. People are concerned that the Department's reliance on fees from the industries it regulates to help fund core activities makes it vulnerable to a conflict of interest.

7. Contrary to popular perception, industry's goal is generally not deregulation but the updating of existing regulations to better reflect contemporary conditions, and increased fairness and consistency in how those regulations are enforced.

8. Canada's health protection legislation (and their regulations) need to be more attuned to the realities of contemporary society and science, particularly in the areas of product categorization, definition and advertising.

9. Health Canada's health protection legislation, and the laws that govern it, need to be thoroughly reviewed. The renewed legislation should embody a set of moral principles that would guide the Minister of Health in the area of health protection.

These points were reiterated during the consultations, suggesting consensus on these issues. Other topics elicited a greater divergence of opinions, which are grouped under 20 major subject headings, and summarized in the following pages.

1. GUIDING PRINCIPLES

Strong support was expressed for including in renewed health protection legislation a set of fundamental principles that would guide the government's policies and actions in this area, just as the five principles of medicare, as set out in the *Canada Health Act*, guide and define the delivery of health services in Canada. This statement of principles should:

1. articulate Health Canada's primary mission: to improve and safeguard the health of Canadians.

2. clearly define the federal government's role and responsibilities in the area of health protection.

3. recognize the importance of transparency and accountability to the public and to Parliament.

4. inscribe in law the principle that Health Canada should take remedial action in cases where there is evidence of a potential health risk to Canadians, even though the risk cannot be proven or measured with certainty. (There was significant differences, however, as to how this principle should be applied.)

5. ensure that the Department's health protection standards and practices are applied fairly and consistently across Canada, and that its decisions are made expeditiously.

6. balance the Department's mandate to protect the health and safety of Canadians and individual freedom of choice.

7. ensure that Health Canada remains responsive to new developments in science and technology.

8. recognize the importance of partnerships with other jurisdictions.

9. facilitate the acceptance of internationally recognized standards.

10. recognize the importance of an effective and efficient health protection system.

11. ensure that decisions are based on a systematic and comprehensive risk assessment that draws on scientific evidence and that the methods of assessing risk are applied consistently among all sectors while recognizing that "0" risk is unattainable.

12. scale regulations to the relative risk of the product or service being regulated.

13. clearly separate the Department's enforcement and approval functions.

The revised legislation might be called The Consumer Health and Safety Act. *This title would serve as a reminder that the Act's prime beneficiary is the Canadian consumer.*

2. THE FEDERAL ROLE IN HEALTH PROTECTION

Health Canada was consistently told that it must play an important and accountable role in protecting the health and safety of Canadians at the national level. Decisions affecting health and safety are too important to leave to the discretion of industry. This fact, in no way, reduces industry's responsibility to ensure that its products and services are safe to use.

At the same time, Health Canada must recognize that it is but one component of a complex system of health protection, which includes, among others, the various orders of government; the health care and medical professions; the academic and health sciences research and development communities; the manufacturers and importers of therapeutic products; the people and industries that produce, process and import our food; the manufacturers and importers of industrial and consumer products; and, of course, individual Canadians who every day make choices that affect their health and safety, and that of their families.

It is important to identify all those who play a role in protecting the health and safety of Canadians, to clearly define their respective roles and responsibilities, and to clarify Health Canada's relationship with each of them. A good place to begin is to delineate the roles and responsibilities of the federal, provincial and municipal governments.

Organizational Independence and Health Canada's Science Capacity

Some participants believe that Health Canada has, in recent years, been cutting back its Health Protection Program. They said this cannot continue. A strong central authority is considered necessary to regulate industry effectively and to maintain national health and safety standards.

Health Canada must ensure that it has the necessary in-house science capability to carry out its work effectively. A strong in-house science capacity is needed to support policy making; to set standards and regulations; to approve therapeutic products; and to respond to emerging health issues. These functions should be supported with public funds, not with money obtained through cost recovery from the industries that the Department regulates.

As science is an expensive endeavour and as there is not enough money in the public domain to duplicate the scientific capabilities to be found outside government, Health Canada should also recognize and make use of the excellent scientific resources belonging to other organizations involved in health protection. This is more important than ever now that the Department has lost some of its former in-house expertise. To ensure that its decisions are based on good science and good data, Health Canada should cultivate partnerships and exchanges with industry and academia.

The federal government's current view of partnership, whereby government provides the steering function while others foot the bill, is no longer acceptable.

3. ADDRESSING RISK

There must be a clear separation between risk assessment and risk management. Risk assessment, which determines the nature and degree of risk, must be objective and based on scientific evidence; non-scientific information should receive secondary consideration. Risk management, on the other hand, which develops and implements appropriate interventions, needs to take account of other things besides science, including gender, social, economic, cultural, political and policy considerations.

Risk management strategies should not be determined simply by balancing costs against benefits. The health of Canadians must remain the primary consideration.

Health Canada needs to recognize that there is no universally acceptable level of risk, since what is acceptable to one group or individual may be unacceptable to another. In assessing and managing risk, Health Canada should take into account the different needs, values and perspectives of women, cultural minorities, seniors, children and other groups, each of which may be affected differently.

Where Lies the Burden of Proof?

Different positions were presented concerning this issue:

The people who make, sell or supply products and services must be accountable for their safety. Manufacturers should be required to provide scientific evidence that their products are safe.

Industry cannot be relied on to ensure the safety of its products and services. Government needs to be involved to ensure that assessments are objective and accurate, and that decisions are made in the public interest.

Assessing the safety of products and services should be the work of an independent panel of experts that functions at arm's length from industry and government. This would effectively avoid the problem of conflict of interest.

Transferring responsibility for product assessment to a third party would be an abdication of responsibility by Health Canada. It would not avoid the problem of conflict of interest, since many academic researchers have connections with industry.

Scientific Assessment Should Be Free of Interference

Health Canada's scientists must be free to carry out the work of risk assessment without interference. At the same time, scientists must recognize that, once their work is done, they must stand aside and let the decision makers take over.

The integrity of scientific assessment could be protected by establishing a committee of respected Canadian and international scientists to oversee the work of Health Canada's scientists and shield them from interference.

The freedom of scientific assessment could best be ensured by employing scientists recognized by their peers to manage Health Canada's laboratories.

To ensure an independent assessment process, the government should enact legislation that spells out exactly who will conduct the assessments, together with their rights, powers and obligations.

When Scientific Information Is Incomplete

Many participants expressed the view that Health Canada should not await scientific certainty that a health risk exists before acting. In other words, it should act, whenever there is good reason to believe that public health is at risk. There was no consensus, however, on how this principle should be applied.

Caution was advised in applying this principle. The precautionary principle, as it is often called, should not replace risk management, but should be included in the Department's risk management toolkit. Deciding when the available evidence is sufficient to warrant action is a difficult task that requires judgment .

Where Health Canada's own scientific assessments are inconclusive or incomplete, the Department has an obligation to make every effort to obtain the information it needs from other experts.

Gender Analysis

Health Canada's risk assessment and risk management practices must become more sensitive to gender issues. The Department should adopt a firm policy of including gender analysis in the process of assessing and managing risk, wherever relevant. Under such a policy, departmental researchers and decision-makers would be required, among other things, to take stock of how a given risk or risk management strategy might affect elderly, pregnant or immigrant women.

Individual Rights versus Societal Rights

In carrying out the work of risk assessment and risk management, Health Canada has the difficult but vital responsibility of balancing the rights of individuals and groups against the needs and interests of society. For example, risk assessment needs to consider not only how a product or service will affect the users, but also how the use of the product or service will affect other people and Canadian society as a whole. At the same time, it is important to ensure that societal and group rights do not override unnecessarily the rights of the individual.

Should Health Canada Be Concerned with Ethical Issues?

While participants recognized the importance of ethical issues, there was no consensus as to whether or not Health Canada was responsible for addressing these issues.

In view of the rapid pace of technological change, Health Canada should consider moral issues as part of its work of dealing with risks to public health.

Moral issues are outside the mandate of Health Canada.

Health Canada should refer moral issues to appropriate decision-makers.

Risk Communication

Health Canada must be considerably more active in the area of risk communication. Many Canadians want more information concerning the nature and extent of a health risk, the methods used to assess it, the results of the assessment, the level of confidence in the assessment, the factors that are taken into account in developing a risk management strategy, and the margin of safety afforded by these measures.

Participants want Health Canada to be their first recourse when seeking information about health risks. Detailed product information should be readily available. All information released to the public should be timely, relevant, understandable and useful. Special care must be taken when communicating to groups whose first language is neither English nor French. Effective communication is especially important in cases where the public perceives a risk to be high, although scientific assessment might show a moderate or low level of risk.

Health Canada also has a responsibility to educate Canadians about risks to health. Canadians need to understand that every choice brings with it some degree of risk and that certain risks are shared by society as a whole. They need to be shown how to make wise personal choices by balancing the risk of using a product or service against its benefits.

4. SURVEILLANCE

The renewed federal health protection legislation must give Health Canada full authority to collect health-related information across Canada. It should also provide a mandate for the Department to work closely with the provincial and territorial governments to build a co-ordinated national health surveillance system. Such a system would include improved co-ordination between public laboratories and other public health surveillance bodies as well as a requirement to report the incidence of communicable disease. It is vitally important that health data be shared across all jurisdictions to create a national picture of health risks and health outcomes.

In addition, attention should be paid to monitoring the environment upon which human health depends.

Safeguarding Privacy and the Security of Health Information

While it is important for researchers and members of the health community to have timely access to health surveillance data compiled by Health Canada, it is also important that every precaution be taken to safeguard the privacy of individuals.

First, Health Canada needs to develop, in consultation with its private- and public-sector partners in health protection, clear guidelines for the collection, storage, use and sharing of health-related data. At the very least, the guidelines should:

- stipulate how health data are to be collected and stored to ensure their security and the privacy of individuals;
- preclude the sharing of health data with other governments or agencies, unless reciprocal and enforceable privacy agreements are in place;
- prohibit the sale of health data; and
- define suitable penalties for infractions.

Access to health data should be under the control of a central authority that operates according to a strict protocol. The protocol should spell out, among other things:

- who is authorized to release information and under what conditions;
- who is authorized to receive information;
- different levels of access for different users;
- the types of information that can or cannot be released;
- how the information can be used; and
- cases where additional patient consent is required, before information can be released.

In general, health information should be released only to persons who can demonstrate a legitimate need for specific information. Applicants should be required to demonstrate their

willingness and ability to ensure the security of the data and to use them in ways that do not compromise confidentiality.

Inevitably, conflicts will arise between the government's need to collect and use health information, and the individual's right to privacy. After consulting with other stakeholders in health protection, Health Canada should develop clear guidelines for balancing these conflicting interests. Among other things, the guidelines should clearly define the conditions under which the public interest can supersede individual rights.

Where health information can be linked to particular individuals, Health Canada must obtain the informed consent of the individuals concerned before releasing the information to anyone. This conditions should be waived only when:

- it is impossible or impractical (because of the urgency of the situation, for instance) to obtain prior consent;
- no other responsible agency has access to the required information and the ability to deal with the threat;
- the threat involves death or serious bodily harm; or
- the information is essential to a departmental initiative, and there are no alternatives.

Post-market Surveillance

A post-market surveillance system that reports on product defects, the long-term effects of therapeutic products, and any unforseen side-effects of using products or services would be a desirable feature of a national health surveillance system. The renewed federal legislation should oblige manufacturers, consumers, health professionals and others to report such information to regulatory authorities, when it is known.

A post-market surveillance system would be too costly. Instead, greater focus should be on the communication of known hazards.

5. IMPORTING PRODUCTS

Products imported for sale in Canada should meet either Canadian health and safety standards or international standards that have been recognized in Canada.

People should be allowed to import products for their own personal use, provided they do not infringe on the rights or safety of the community. Although the principle of caveat emptor (buyer

beware) should prevail in such cases, Health Canada should nevertheless inform Canadians about any known hazards associated with such products.

The importation of medicines for personal use should be limited to a 60-days' supply. Health care products imported for personal use should not be used in public health care institutions.

6. EXPORTING PRODUCTS

The discussion concerning whether or not Canadian exports should meet Canadian health and safety standards brought out opposing views.

Health care and consumer products manufactured in Canada for export to other countries should be required to meet the same health and safety standards as products sold in Canada; to do otherwise would be unethical and irresponsible.

Health care and consumer products manufactured or packaged in Canada and designated for export should not be required to meet Canadian health and safety standards, provided that they do not contravene any laws of the country to which they are consigned.

Therapeutic Products

The current exemptions in the Food and Drugs Act *that permit Canadian manufacturers of pharmaceutical and biological products and medical devices to export products which are not approved for sale in Canada should be revoked.*

In regulating the export of therapeutic products, Health Canada should take into account the conditions that exist in the importing country, including the state of the market in that country, the need for the product, the availability of alternatives, and so on. Such a flexible approach would allow, among other things, the export of non-standard products to respond to a health emergency in the importing country. The Department should also bear in mind that some exported therapeutic products are designed to address conditions that do not exist in Canada.

The World Health Organization should be encouraged to develop a convention on the safety and efficacy of therapeutic products sold abroad.

7. CONTROLLING COMMUNICABLE DISEASE

The federal government must be given, either through legislation or through memoranda of understanding among provincial and territorial governments, the authority it needs to effectively address any outbreak of a communicable disease, where the health risk extends beyond provincial borders.

Health Canada has a responsibility to prevent the export of diseases from Canada to other countries, just as it has a responsibility to guard against the importation of diseases. The Department should develop comprehensive surveillance and control measures to prevent the exportation of communicable diseases, despite the obvious difficulties of putting such a scheme into practice.

8. DEFINITIONS

The definitions included in the *Food and Drugs Act* are deemed inadequate, incomplete and outdated by those who took part in the substantial discussion. A new scheme is needed, at once comprehensive and flexible, to categorize the countless health-related products and services available to consumers. The new scheme would need to be compatible with the Codex Alimentarius Commission's definition of food.

Essentially, participants outlined two options that received support for redefining health-related products and services:

Option 1:
Three-part Classification System

Food	Natural Products and Nutraceuticals (Complementary Health Products[1])	Drugs and Medical Devices
the major part of a diet	a supplement to a diet	a substance used to treat disease
whole food form (includes functional foods)	non-food form	non-food form
health claims are supported by some evidence	health claims are supported by a significant or moderate amount of evidence	health claims are supported by rigorous and verifiable scientific evidence

All products, regardless of how they are classified, should be subject to the same rules regarding the need for scientific evidence to support a health claim.

Health claims should certainly be supported by evidence; but the kind, quality and amount of evidence required should be proportional to the identified risk associated with use of the product.

Option 2:
Regulate Health Products According to the Degree of Risk They Pose, Rather Than According to Their Form or Usage.

This approach would ignore product distinctions and definitions altogether, focussing instead on the risks involved in using the products. Product assessment, safety standards and regulatory controls would be scaled to the perceived or actual degree of risk associated with a given product: the greater the risk, the higher the applicable standards of safety, efficacy and quality. The kind, quality and quantity of evidence needed to support a health claim would be scaled to the

[1]A complementary health product (CHP) may be defined as any substance or combination of substances derived from plant, animal or other sources, containing minerals, herbs, botanicals or amino acids, and which is consumed as a dietary supplement or as an aid to maintaining or improving health.

specific health claim being made.

Many participants voiced considerable enthusiasm for this approach while acknowledging that it would be difficult to put into practice. For one thing, it would require a very different type of administration from the one currently in place. Then there would be the problem of determining in advance the standards and degree of regulatory control that would be appropriate to each level of risk. Making the whole scheme rational and consistent would present additional challenges. However, most people felt that the concept deserved further consideration, because it goes directly to the heart of the issue—addressing risks to health—while avoiding the quagmire of product categories and definitions.

Definition of Food

With regard to food in particular, some participants recommended using the definition of the Codex Alimentarius Commission (Codex), which provides the following definition of food: any substance, processed or raw, intended for human consumption, including beverages, chewing gum and any substance used in the manufacture, preparation or treatment of food, but excluding cosmetics, tobacco and substances used only as drugs.

9. DISINFECTANTS AND SANITISERS

Concern was expressed regarding the methods used to regulate a special class of products that includes disinfectants, sanitisers, moldicides and mildewcides. Presently, these products are regulated as "pesticides" under the *Pest Control Products Act (PCP),* and as "drugs" under the *Food and Drugs Act,* if used in a hospital or in food-processing. Those that have multiple uses may be subject to both sets of regulations.

Attempts by Health Canada to resolve the confusion by regulating all such products as drugs under the Food and Drugs Act *are inappropriate because:*

- *these substances are not drugs, as that term is commonly understood. To treat them as such is misleading;*
- *the regulation of drugs involves various standards for GMP [good manufacturing practices], which are inappropriate for products that are clearly not drugs; and*
- *the approach is inconsistent with that of Canada's major trading partners.*

Revised regulations should reflect the low level of risk that these products present while ensuring their effectiveness and safety. This might be done by creating a new product category of "antimicrobials" for low-risk sanitisers and disinfectants. Revised regulations should establish, for a single jurisdiction, a set of regulations that would be harmonized as much as possible with those found in other key jurisdictions, or NAFTA.

10. COMMERCIAL AND CONSUMER PRODUCTS

Participants in the consultations recognized that few products are risk-free and that consumers are responsible for using and disposing of products in accordance with manufacturers' instructions. These facts should be spelled out in the federal health protection legislation. For their part, manufacturers have a responsibility to disclose all known risks associated with the use of their products; to provide consumers with clear, comprehensive instructions for the safe use and disposal of their products; and to report to Health Canada any previously undetected product defects and any previously unforseen health risks associated with the use of their products, whenever such defects and risks are discovered subsequent to the sale of the products. These obligations should also be spelled out in the legislation.

Consumer information should be provided through careful labelling and, where a product is particularly hazardous, through product inserts. The available information should list all ingredients, provide instructions for the safe use and disposal of the product, detail all known risks associated with the product's use and prescribe first-aid treatments, where appropriate. This information must be clear, precise, easily understood and expressed in ways that are sensitive to cultural differences. Essential information, such as hazard symbols and allergy alerts, should be prominently displayed.

The revised health protection legislation should include a general prohibition against manufacturing, importing, distributing and/or selling any product, and the conduct of any activity, that is demonstrably unsafe under normal conditions, or that threatens the health of people or other living things.

Primary responsibility for ensuring the safety of new products and technologies properly rests with their makers. Canada's health protection legislation should spell out this obligation and should require manufacturers to meet standards of safety commensurate with the risks associated with their products.

Who Should Develop Standards for Products?

Divergent views emerged concerning the development of standards.

As far as possible, industry should be left to establish its own standards for product design and manufacturing, with Health Canada monitoring overall compliance.

Voluntary standards would not provide adequate protection for consumers. Standards for product performance should be set by Health Canada, perhaps with input from consumers.

Industry should be allowed to set its own standards subject to government approval, within broad parameters established by Health Canada.

Health Canada's active involvement in standards setting is especially important to ensure the

safety of products aimed at particular market segments, such as very young children.

The following views regarding product standards were also expressed:

- *Where public health and safety are involved, standards should be made mandatory in the legislation as opposed to voluntary industry standards.*
- *The health protection legislation should provide clear direction for the disposal of used, obsolete and unsafe products, and it should clearly spell out the responsibilities of the government and manufacturers in this area.*
- *Health Canada should be actively involved in the development of international product standards to ensure that the best possible standards are adopted.*
- *Health Canada should examine the* General Safety Requirement *found in European statutes with the goal of adopting a similar rule in Canada.* (The *General Safety Requirement* places an onus on manufacturers and distributors to ensure that all products sold to the public are safe.)

11. THERAPEUTIC PRODUCTS

In addition to comments on specific topics outlined below, participants made the following general observations:

- *Drugs and medical devices should not be treated as "therapeutic products." Drugs are inherently more potent and dangerous than medical devices and should be regulated separately.*
- *In reviewing therapeutic products, Health Canada should take into account the clinical need for the product, as well as its safety, efficacy and quality.*
- *The Bureau of Veterinary Drugs should be part of the Therapeutic Products Program.*

Advertising and Labelling of Over-the-counter Therapeutic Products

A range of divergent views were expressed.

Government should exert only minimal control over the advertising of therapeutic products sold over the counter. More and more people are now self-diagnosing and need access to product information, so that they can make informed decisions.

Government should allow manufacturers to supply consumer information freely, provided the information is accurate and truthful.

Government should exercise a reasonable amount of control over the advertising of over-the-counter therapeutic products. The control and monitoring of over-the-counter therapeutic products could be delegated to an independent third-party.

Government should exert total control over the advertising of over-the-counter therapeutic products.

National controls on the advertising of over-the-counter therapeutic products would be pointless, since information would be readily available via print and electronic media originating outside Canada.

Manufacturers should not be permitted to make health claims for over-the-counter therapeutic products.

Manufacturers should be allowed to make health claims for their over-the-counter therapeutic products, provided they can support the claims with suitable evidence. The required amount of evidence should be proportional to the degree of risk associated with the product.

Manufacturers should be required by law to disclose all known side-effects associated with the use of over-the-counter therapeutic products.

Information supplied by manufacturers should be tailored to consumers' level of literacy and linguistic profiles.

Schedule A of the *Food and Drugs Act*

Schedule A of the *Food and Drugs Act* lists a number of disorders and diseases. The Act forbids the advertising to the general public of any product used to treat, prevent or cure any of the conditions on the list. The original purpose of this restriction was to encourage individuals to seek medical attention for serious conditions and to prevent fraudulent health claims.

The consultations indicated support for both maintaining and eliminating the schedule.

Schedule A should be retained but updated and revised to include new categories of products (including natural health products) and to eliminate inconsistencies. This should be done with the help of medical experts.

Schedule A has outlived its usefulness. Information concerning drugs is readily available from references such as the CPS [Compendium of Pharmaceutical Specialties] and the Internet.

Schedule A should be eliminated because, given the pace of change, it quickly becomes obsolete. As well, there are better ways to prevent false claims.

Schedule A should be moved from the Food and Drugs Act *to the Regulations so that it can be applied with greater flexibility.*

Schedule F of the *Food and Drugs Regulations*

Schedule F of the *Food and Drugs Regulations* lists drugs that can only be obtained by prescription. The *Regulation* permit only the advertising of product's name, price and quantity to the general public of any prescription drug on the list.

Support was expressed both for retaining and eliminating the provisions of Schedule F. The predominant view expressed supported retaining the provisions.

Advertising of prescription drugs would drive up their cost.

Advertising of prescription drugs should be allowed on the basis of people's right to know.

Consumers are sophisticated enough to benefit from advertised information without being unduly influenced by it.

Ionizing and Radiation-emitting Devices

Prescribing safety standards for human exposure to radio frequency electromagnetic fields should be one of the Minister of Health's responsibilities under a new health protection legislation. These standards would be used by other federal agencies in establishing regulations for the safe use of radio transmitting devices.

The **design** and **manufacture** of ionizing products and radiation-emitting devices are regulated. It was suggested that the federal government also set standards for the **use** of such products and devices.

Assessment and Approval of Therapeutic Products

While many people disagreed, the majority of participants consider that the health and safety of Canadians should be the sole criterion for assessing and approving therapeutic products. Therapeutic products should be evaluated solely on the basis of their safety, efficacy and quality; other factors, such as costs, social impacts and ethical considerations should not be included in the approval process. The approval process for therapeutic products should be based on scientific evidence, and be fully transparent and accountable to Canadians.

The assessment and approvals process for therapeutic products is deemed to be too much under the sway of special interests. Legal limits should be placed on the activities of industry lobbyists to ensure the integrity and independence of the process.

12. FOOD

Food Standards

To guide its decisions concerning the quality and safety of food, Health Canada should adopt the Codex Alimentarius Commission's[2] Statement of Principles. The Codex Statement of Principles specifies how science is to be used by decision makers concerned with food safety and the extent to which decision makers should take other factors into account.[3]

Health Canada should also consider adding a section to the new legislation that would establish the Codex as the "default" reference for decision makers concerned with food safety. In other words, the standards, guidelines and recommendations of the Codex would automatically apply in the absence of relevant Canadian statutes or regulations.

As well, Health Canada should establish advisory groups to set standards and regulations regarding the enrichment of food and food products.

Finally, the Department should develop standards against which claims about the nutritional benefits of food could be measured.

Labelling of Food

Food labelling and the health benefits attributed to food are important to Canadians, said participants in the consultations. Health Canada should take active measures to inform Canadians about food safety and nutrition. One way to do this would be to establish a clearing house that would provide health professionals and the general public with reliable, scientific information about nutritional and health claims, as well as adverse effects, such as allergic reactions.

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[2] An intergovernmental organization to which more than 150 countries are members, the Commission's mandate is the protection of consumer health and the promotion of fair trade practices regarding food.

[3] The Codex Statement of Principles reads as follows:

1.The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.

2.When elaborating and deciding upon food standards, Codex Alimentarius will have regard, where appropriate, for other legitimate factors relevant to the health protection of consumers, and for the promotion of fair practices in food trade. In this regard, it is noted that food labeling plays an important role in furthering both these objectives. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

Labels attached to food products are an important source of consumer information. However, labels alone can't do the job. Health Canada should use other tools to help educate Canadians about food and nutrition.

Consumers' right to know what is in the food they eat is more important than industry's need to keep secret "proprietary" information. Food processors should be required by law to list all the ingredients of their products, including nutrition enhancers (added vitamins and minerals) and other additives (preservatives, colouring, etc.). Labels should list ingredients by name rather than by using vague terms such as "artificial flavours" and "spices." Food labels should spell out the food's nutritional value and indicate whether it contains any genetically altered substances or has been subject to any special treatments (such as irradiation) during preparation. Food processors should also be required to provide, on request, information about how their products are produced, processed, stored and distributed.

Putting too much information on food labels could overwhelm and desensitize consumers, to the point where they might ignore important notices.

Health Claims for Food

Opposing views were expressed regarding health claims on food and food products.

Health claims for food and food products should not be permitted. But claims regarding the function of food—for example, the claim that a certain food can decrease cholesterol absorption—could be allowed.

Health claims for food should be permitted, provided they are based on scientific evidence. The supporting evidence should be evaluated by an independent panel.

Health claims for food should be permitted, provided they are backed by scientific evidence. The type, quantity and scientific rigour of the supporting evidence should be proportional to the degree of risk associated with the health claim. This arrangement, though desirable, might cause problems due to the difficulty of deciding what evidence was sufficient and appropriate in each case.

Food Handling

The federal health protection legislation should include standards of practice and hygiene for anyone engaged in food processing and preparation. Owners of restaurants and other food outlets should be required to provide employees with the facilities they need to meet the standards.

13. ALTERNATIVE OR COMPLEMENTARY MEDICINES AND THERAPIES

Participants noted that, in recent months, the Parliamentary Standing Committee on Health has examined the legislative and regulatory regime governing natural health products. Participants put forward the following definitions and opinions concerning complementary health products (CHPs):

A CHP is any substance or combination of substances derived from plant, animal or other sources, containing vitamins, minerals, herbs, botanicals or amino acids, which is consumed as a dietary supplement or as an aid to maintaining or improving health.

CHPs are safe to use. Most contain harmless, natural substances. Many have been used in traditional medicine for centuries. In some cases, the safety of these substances is substantiated by scientific evidence.

Nutraceuticals are over regulated, according to many participants, and they should not be classified or treated as drugs. Some felt that these products should not be regulated by the Therapeutic Products Program. However, there is a need to ensure that health claims attributed to these products are substantiated by suitable evidence.

Regulations regarding CHPs should:

- begin by recognizing the validity of alternative, traditional or culturally distinct therapies and models of health;
- recognize the uniqueness of these non-drug products;
- establish a regulatory body, composed of experts in the field of alternative medicines, to oversee the manufacture and sale of these products;
- establish an open and transparent appeal process and mechanisms for dispute resolution that would include consumers, practitioners of traditional medicine and other alternative therapies, as well as members of related trade and professional associations;
- provide an efficient and cost-effective method for ensuring compliance;
- not restrict consumers' access to these products or their freedom of choice;
- ensure that consumers have access to full and accurate information so they can make informed choices concerning these products;
- ensure equal and fair treatment of all competitors in the industry; and
- not impose undue costs or other regulatory burdens on manufacturers, importers, distributors or consumers of CHPs, thereby ensuring public access to a wide range of affordable products.

Health Canada should establish a formal review process, including mandatory consultations

with stakeholders, to evaluate the impact of each proposed regulation, before it is implemented.

Alternative or Complementary Therapies

There was support for recognizing the validity of complementary and alternative therapies. Our current understanding of health and medicine needs to be broadened to include these approaches. However, there was little agreement on the role that the Health Protection Branch should play in the development of such therapies, or on the question of government support for clinical trials and the training of practitioners.

Among other things, it was suggested that:

- Health Canada sponsor public consultation on alternative medicines; and
- the Government of Canada sponsor an international forum (involving the World Health Organization, perhaps) that would review studies from different countries and develop international standards of practice for complementary and alternative therapies.

14. EMERGING HAZARDS AND PUBLIC HEALTH EMERGENCIES

Emerging Hazards

The term "emerging hazard," though often used, needs to be better defined.

The Minister of Health has a duty to protect Canadians from products and services that present an unreasonable risk to people's health. This duty includes identifying new and emerging health hazards. Canadians are especially concerned about health risks associated with biotechnology.

The federal health protection statutes must enable Health Canada to act quickly and decisively, as soon as a new or unforseen public health hazard is identified. The Department must:

- carry out surveillance and monitoring activities to detect and assess emerging health risks;
- work with its partners in health protection to develop and implement strategies for dealing with such risks;
- enforce its decisions and regulations; and
- inform Canadians about new and emerging risks to health.

Such provisions would only apply in the absence of any other statute, either at the federal or provincial level, to adequately address the situation.

The current inspection powers, as defined in Section 23 of the Food & Drugs Act*, are sufficiently broad and powerful to serve as a model for a new or revised statute.*

Public Health Emergencies

The federal health protection legislation should be amended to:

- give Health Canada authority to act quickly and decisively in the event of a national health emergency;
- clearly define what constitutes an emergency situation;
- precisely delimit the government's powers and authorities in such situations; and
- ensure that these powers are exercised, only when the emergency involves more than one province or territory.

Among other things, the legislation should contain measures to protect individual rights in the face of government actions, and to make the government fully accountable for its actions, once the crisis is over.

A situation might be deemed a national emergency if it:

- poses a serious threat to public health;
- affects particularly vulnerable segments of the population;
- exceeds the capacity of local authorities to deal with the risk; and
- involves pathogens that could be rapidly transmitted across national and international borders.

To fulfil its responsibilities in this area, Health Canada must have the mandate and the necessary resources to monitor, assess and respond to health crises.

Health Canada's role in a public health emergency might include:

- co-ordinating a national response;
- acting as an information broker;
- keeping the public informed; and
- monitoring and enforcing public- and private-sector compliance with any emergency measures.

15. COMPLIANCE AND ENFORCEMENT

There was widespread support for defining the roles and responsibilities and overall powers of the Minister of Health in a new health protection legislation. The legislation would need to provide a framework for the development of regulations. The regulations must be clear and easily understood.

Specific suggestions included:

- an adequate inspection program must focus on prevention;
- regulations must not be too prescriptive and must be applied consistently throughout industry;
- risks and benefits need to be carefully analysed when preparing regulations;
- appeal mechanisms that do not compromise enforcement activities should be provided for in the regulations;
- the publication of alerts, recalls, prosecution and compliance actions (including pending and unresolved issues) would enhance enforcement and increase public confidence; and
- product tampering should be considered a serious offense subject to severe penalties.

A comprehensive compliance program should be established under the new legislation that does not increase costs to industry.

The fact that, under the present legislation, inspectors have different powers depending of which statutes they are enforcing is not necessarily a weakness in the system. In reality, it gives regulators a strategic advantage that is very much in the interest of health protection.

Alternative Dispute Resolution

The predominant view expressed was that Health Canada should have the legislative authority to use Alternative Dispute Resolution (ADR)[4] mechanisms.

[4] Alternative Dispute Resolution (ADR) are quasi-judicial processes that are compatible with criminal law and provide an effective alternative to costly and time-consuming court action. ADR methods can include third-party mediation, expert fact finding, and arbitration. ADR decisions can result in the dismissal of charges, voluntary compliance by the offending party, or enforced compliance as a result of a court order. In some cases penalties can be negotiated, as when a company agrees to rectify a violation in return for a reduced penalty.

ADR methods **should** be used if:

- the infraction is minor;
- no criminal intent is involved;
- the accused party has a good track record;
- they have proven successful in similar cases in the past;
- a flexible solution is sought;
- it is desirable that all affected parties be involved in crafting a solution; and
- the wrongdoer has demonstrated a willingness to take remedial action.

ADR methods should **not** be used if:

- the infraction is serious or life threatening;
- the accused is a repeat offender;
- the offense is willful and motivated by profit;
- they have proven ineffectual in other similar cases, or with the particular person or company;
- the offender is unwilling to co-operate; or
- traditional enforcement is difficult or impossible.

The following guidelines **should** be observed in employing ADR methods:

- The process must be transparent and thoroughly documented;
- The process should include an appeals procedure that is detailed in the legislation;
- Independent arbitrators or mediators should be used;
- All affected parties should be included;
- The penalty should fit the offence;
- The intervention should result in more good than harm.

Health Canada must always reserve the right to prosecute the offender in a court of law, if the ADR method fails.

Opponents to including ADR mechanisms in legislation consider that:

- *Use of ADR methods is inadvisable, because the details of the dispute and its resolution are not on the public record. This means there is little public accountability. Health Canada would do better to employ a process that "ensures public participation and fully discloses the details of the dispute."*

Mandatory Recall

Positions on this issue generally provided strong support for giving the Minister of Health the power to order and enforce a mandatory recall[5]. This authority would be subject to constitutional restraints and would be exercised only if:

- a product has been sold that poses a serious health risk to consumers;
- the manufacturer/distributor will not recall the product voluntarily; or
- warning consumers would not provide adequate protection.

The legislation should also ensure that Health Canada has the necessary resources to collect and distribute information on recalled products (lot numbers, for example) to pharmacists, physicians, other orders of government, food distributors, retailers and consumers.

It was noted that the *Canadian Food Inspection Agency Act* gives the Minister of Agriculture the power to order the mandatory recall of an agricultural product that poses an unacceptable risk to the health of animals or people.

Other positions were expressed.

The authority to order a mandatory recall properly belongs in the regulations, not in the legislation.

In exercising the power to order a mandatory recall, the Minister of Health should observe the "precautionary principle," by acting whenever there is reasonable cause to believe that public health is at risk.

A mandatory recall provision is cumbersome to administer and subject to political pressure.

Health Canada already has the power to order a mandatory recall by virtue of Section C.08.006 of the Food and Drugs Act.

Penalties

The penalties for violating the drug provisions of the *Food and Drugs Act,* currently capped at $5,000, are unanimously deemed to be inadequate. The federal health protection legislation should be amended to allow for more severe penalties, especially in cases where people's health and safety have been put at risk. Monetary penalties should be part of a graduated system of disincentives that includes the confiscation of profits resulting from illegal activities and the naming of repeat offenders.

[5]Although under current legislation the Minister of Health can issue a public warning regarding a hazardous product or seize the product from distributors or retailers - an arduous and costly affair - the Department does not have the legislative authority to force a company to recall a product..

16. REGULATORY MATTERS

Government regulation of industry needs to be made more efficient, but not at the expense of thoroughness and accountability**.**

Protecting the Public versus Freedom of Choice

As much as possible, the government's aim of safeguarding the health and safety of Canadians must be balanced against the freedom of individuals to make personal choices. However, where these two interests are at odds, Health Canada's actions, given the Department's mandate, must always favour the former over the latter.

Where should the line be drawn between protecting public health and safety versus preserving freedom of choice? There is no easy answer to this question. However, for Health Canada to achieve the desired balance, two things are needed: thorough and consistent application of risk benefit analysis to every regulatory question, and a comprehensive program of public education to give consumers the tools that they need to make safe, healthy choices.

Toward an Integrated National System for Health Protection

Canadians find that the present scheme, in which responsibility for health protection is scattered among several orders of government, confusing and frustrating. Health Canada should take the lead in working with the other orders of government to clarify the roles, responsibilities and authorities of each. The goal should be to sort out conflicting regulations and overlapping jurisdictions (as in the area of enforcement, for example), to eliminate gaps in the protection that Canadians enjoy, and to ensure that health protection programs are delivered seamlessly across the country.

A certain amount of flexibility will be needed to create a truly efficient national scheme for health protection. To this end, the federal health protection legislation should be amended to permit Health Canada, where appropriate, to delegate some of its duties, with the corresponding authority and accountability, to other orders of government. In doing so, however, the Department should also transfer sufficient resources to enable the designated authority to carry out its responsibilities.

Mutual Recognition Agreements and the Harmonization of Standards

In general, participants in the consultations support the goal of harmonizing global standards through intergovernmental co-operation. Countries can move toward this goal by recognizing and adopting each other's health and safety standards. Such agreements of mutual recognition could:

- complement and strengthen Canada's own science capacity;
- help reduce costs and duplication of effort;

- speed up the assessment and approvals process for new products and services; and
- allow Canada to align with international regulatory standards.

Health Canada should pursue mutual recognition agreements with other countries provided that:

- the standards in the other countries are based on sound science;
- the mutually recognized standards are at least as high as our own;
- the agreements do not limit Health Canada's capacity to regulate products within Canada;
- the agreements do not limit Health Canada's capacity to conduct its own risk assessment and risk management; and
- the legislation should favour our official partners in international accords such as NAFTA, when global harmonization is not yet achieved.

At the same time that it pursues these international accords, Health Canada should work to ensure a comparable harmonization of standards across Canada.

Third-party Certification

Should Health Canada be permitted to delegate to an independent third-party some of its responsibilities for assessing the safety and efficacy of products and services sold in Canada? Views on this issue are polarized.

Canadians might be willing to accept third-party certification provided that:

- *the designated third-party is deemed thoroughly competent to carry out its responsibilities;*
- *Health Canada retains the power to certify and decertify the third party;*
- *Health Canada establishes, publishes and enforces strict conflict-of-interest guidelines for third-party certifiers;*
- *third-party certifiers remain fully accountable, and accountable only to Health Canada;*
- *the standards enforced by the third party are clearly referenced in the health protection legislation or its regulations; and*
- *the use of a third-party certifier is demonstrably the most cost-effective and efficient way to enforce Canadian standards.*

The use of third-party certification would be an abdication by Health Canada of its responsibilities. Only Health Canada, working in partnership with other concerned governments and agencies, can adequately represent the interests of Canadians. Privatizing the risk management process exposes it to the biases of private interests.

However, both positions stressed that Health Canada has ultimate responsibility and

accountability for enforcing the federal health protection legislation and regulations.

Self-regulation of Industry

Canadians consulted are divided on the question of allowing industry to regulate itself.

Industry has a responsibility, as a good corporate citizen, to regulate itself. Indeed, self-regulation is in industry's interest, since harming the consumer is not good business.

Self-regulation does not mean that Health Canada should abdicate its responsibilities or surrender its decision-making authority or accountability.

Self-regulation by industry is not in the public interest. Government has an indispensable role to play in protecting the health and safety of consumers. In the final analysis, regulation by government works in industry's favour, because it supports good public relations.

The Canadian Food Inspection Agency

Concern was expressed that Health Canada's responsibility for food safety have been transferred to the Minister of Agriculture. Those who voiced these concerns consider that the Canadian Food Inspection Agency's priority is supporting food producers, not ensuring the safety and nutritional value of food. They also consider the Agency to be seriously understaffed and they say that responsibility for inspecting food should remain with the Minister of Health.

17. COST RECOVERY

Generally speaking, Canadians consulted are not opposed to the concept of cost recovery, but many criticized the manner in which it is applied. It seems fair that Health Canada should levy certain fees on the industries that it regulates to help offset the cost of providing the regulatory services. However, many are concerned that such practices will compromise the Department's integrity by exposing it to a conflict of interest. How, they ask, can the Department avoid favouring the very industries that supply at least some of its funding? If Health Canada becomes too reliant on fee collection to support its operations, how can people be confident that they, and not industry, will remain the Department's primary "client?"

On no account can the integrity of the assessment and review process be put at risk. If the practice of cost recovery is to be continued, the Department will need to put in place a system of checks and balances to ensure its continued independence from industry.

How is this to be done? For one thing, Health Canada must ensure that its regulatory functions are completely separate from those of revenue collection. For another, it must find and maintain an appropriate balance between public and private sources of funding. The Therapeutic Products Program, for one, appears to rely far too heavily on fee collection for its own good. Careful

consideration must be given to how the money collected through fees is spent. Health Canada must continue to support all its core regulatory activities only with public funds. Cost recovery must be either centralized or carefully co-ordinated to ensure that industry does not pay double or triple fees, as sometimes happens, when more than one bureau (or order of government) has approval authority over a given product or substance.

Perhaps what's needed is some form of ongoing review of the government's cost-recovery activities. Such a review would of necessity involve stakeholders participation.

Should the practice of cost recovery be enshrined in the legislation? Again, people are concerned about the consequences of diluting the relationship that now exists in law between the government and the Canadian public, with a new, tripartite relationship that would include industry as well.

18. TRANSPARENCY AND ACCOUNTABILITY

Transparency and accountability were important issues during the consultations. Many participants felt that the operations of the Health Protection Branch remain "invisible to the average consumer" and that the Branch was not accountable to the public for its decisions.

Here are their suggestions for making the operations of the Health Protection Branch more transparent and accountable:

- Ensure that the new health protection legislation prescribes transparent consultation and management practices that include meaningful opportunities for public input.
- Initiate a thorough public review of the Health Protection Program.
- Establish, through legislation, a Health Protection Advisory Committee. comprising consumers and recognized experts in the various fields related to the mandate of the Health Protection Program and reporting to the Minister of Health, the Committee would oversee the operations of the Health Protection Branch.
- Ensure not only the Branch's accountability but also that of its advisors, contractors, employees, partners in health protection, and the industries that it regulates.
- Explain the structure, functions, operations and regulatory processes of the Health Protection Branch to the public. The entire concept of risk and the methods used by the Department to address risk need to be better explained.
- Make information about the Branch's operations and decisions available to public scrutiny. The Branch must find ways to do this without revealing essential proprietary information entrusted to it by industry, and without exposing itself to frivolous inquiries or suits.

- Publish on a dedicated Internet web site:
  - summaries of all risk management decisions, including the results of product assessments, approvals and investigations;
  - an organizational chart of the Health Protection Branch, together with the names and phone numbers of key staff members;
  - a flow chart showing the course of a typical review process;
  - copies of all important internal documents pertaining to Branch operations; and
  - updates on any regulatory changes or procedures.

19. PUBLIC INVOLVEMENT

Participants would like to see a Health Protection Program that:

- demonstrates its commitment above all to protecting the health and safety of Canadians;
- is transparent to public scrutiny;
- is fully accountable for its actions and decisions;
- welcomes new suggestions and new partnerships;
- invites and values public participation; and
- is flexible and readily adapts to new situations.

To create an environment that is more receptive to public participation, the Health Protection Branch needs to transform its corporate culture and rechart its direction. It needs to rethink its priorities, values and objectives.

Here are some specific suggestions for how Health Canada and the Health Protection Branch might improve the level of public participation:

- Develop a set of guidelines that outline when it is appropriate and inappropriate to consult the public, how consultations should be carried out, and how much public input is appropriate under different circumstances.
- Establish an office within the Health Protection Branch to advise on, encourage and support public involvement.
- Develop an infrastructure that supports and promotes public involvement. Some possibilities: toll-free phone lines, an Internet web site, a regularly published newsletter that features a section for reader feedback, and provisions for participant funding.
- Create a Health Protection Ombudsman and/or an independent health protection advisory

board, with public representation, to give Canadians a direct voice in the work of the Health Protection Branch.

- Involve the public as early as possible in the decision-making process.
- Ensure an equal and balanced participation of all segments of the Canadian public concerned by an issue.
- Provide enough lead time to allow participants to adequately prepare for their discussions with Health Canada.
- Ensure that all parties being consulted have equal access to relevant information.
- Maintain ongoing contact with external partners, even when there are disagreements.
- Better publicize the work of the Health Protection Advisory committees, and encourage them to consult with the public.
- Create a women's bureau within the Health Protection Branch to ensure that women's interests are reflected in health policy.
- Provide grassroots community groups with financial assistance to undertake health protection and public awareness projects.

Public Education

An informed citizenry is a crucial element of an effective health protection system and a prerequisite to effective public participation in health protection.

Here are some suggested public education initiatives for the Health Protection Branch:

- Publish and distribute relevant documents and briefings.
- Develop partnerships with private-sector groups, non-governmental organizations, other orders of government, business aimed at keeping the public informed.
- Develop educational materials for use in schools and other forums. Such materials should be sensitive to differences of culture and gender.
- Conduct annual health protection forums for the public on key issues.
- Sponsor community-based public education initiatives.

Public Participation in Decision Making

Public participation means that the public should have access to relevant information, and that individuals and groups have an opportunity to express their views and influence policy decisions. It does not mean that unelected and unaccountable members of the public should make decisions. Ultimately, somebody has to make decisions, and that individual or group should be accountable through the parliamentary system.

Public involvement in decision making might take the form of public representation on advisory panels, and regular consultations with consumer associations and other groups. Health Canada should ensure that the groups that will be most affected by a given decision are adequately represented in these consultations.

20. OTHER ISSUES

Aboriginal Health

- Health Canada must ensure that all Native Canadians, whether they live on or off reserves, in an urban or rural community, have equal access to health services and health products.
- Health Canada needs to clarify its roles and responsibilities in the area of Aboriginal health.

National Standards for Medical Procedures

There is a lack of national standards for certain medical procedures. For example, methods of diagnostic testing vary across the country. The new health protection legislation should mandate Health Canada to establish, in co-operation with the provinces and territories, guidelines and standards for all medical procedures.

Determinants of Health

- *It is important that Health Canada acknowledge the influence of social and economic factors on health, even if it ultimately decides that such factors are best addressed by other departments.*

Economic Development

- *True, economic development is one of the determinants of health, but this in no way, obliges Health Canada to promote it.*
- *Some federal departments are more concerned with marketing food and drugs than with ensuring their safety and efficacy. Health Canada must act to buffer their influence.*
- *Health Canada must ensure that public health is duly considered whenever trade treaties are negotiated.*

Environmental Protection and Sustainable Development

- *Health Canada should work to replace the current guidelines for air and drinking- water quality with national, enforceable standards.*
- *The Environmental Health Directorate should be given the scientific and research capacity it needs to properly assess chemical hazards, and to respond to new and emerging health hazards, particularly in the area of children's health.*
- *Health Canada's areas of responsibility need to be clearly distinguished from those of Environment Canada.*
- *Health Canada should ensure that no product is sold or imported into Canada, which releases, at any point during its life cycle (including manufacturing, distribution, use and disposal), harmful substances in amounts greater than what is found in clean, healthy soil.*

Moral Issues Related to Health Protection

- *Health Canada should be involved "at a macro ethics level, not a micro level," which would be an invasion of people's lives.*
- *Moral questions related to health protection should be addressed by an independent body, not by the regulating authority.*

Screening Immigrants

New immigrants to Canada should be more carefully screened for their health.

Reporting on the Nation's Health

- *The Minister of Health should be required to regularly table before Parliament a report on the nation's health.*
- *Requiring the Minister of Health to produce a periodic report on the nation's health would distract too much from the essential work of health protection, regulation and prosecution. The exercise would quickly become political window dressing of little value to individual Canadians.*
- *Canada needs a Chief Health Officer for Canada, a position similar to that of the Surgeon General in the United States.*

Pesticides

- *The health protection legislation should give people the right to refuse involuntary exposures to pesticides, as often happens during urban spraying programs. People have a right to be protected from avoidable risks that they do not wish to assume.*
- *The regulation of pesticides needs to be reexamined. Existing databases need to be updated to list not only active ingredients but also inert ingredients found in pesticides.*

Reviewing the Legislation

- *The health protection legislation should be reviewed by Parliament at least every ten years (more often, if circumstances warrant).*
- *The health protection legislation should be reviewed as often as necessary, not according to a predetermined schedule.*
- *The health protection legislation should be subject to permanent ongoing review and renewal.*