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CANADIAN APPROACH TO A MORE RESPONSIVE FOOD SAFETY CONTROL SYSTEM

(Prepared by Canada)

As in many other countries, Canada's food safety control system is being challenged by sweeping changes in society and the marketplace, including the accelerating globalization of trade, new and emerging health risks, scientific and technological innovations, and evolving public expectations and attitudes. Consequently, Canada's food safety legislation needs to be updated, modernized and strengthened to keep pace with these developments.

1.0 Canada's Current Control on Food Safety

While an effective food safety system relies on a variety of elements, one of the fundamental cornerstones is its legislative base. In Canada, the *Food and Drugs Act*, adopted in 1953, is the core of the food safety system that aims at protecting the health of consumers. This Act prohibits the manufacture and sale of unsafe or adulterated food products anywhere in Canada. The Act, which derives its authority from criminal law, is supplemented by a large body of regulations that lay down specific requirements for the safety and nutritional quality of foods.

While the current Act provides a broad basis for control of the safety of the Canadian food supply, it has a number of limitations concerning the means to address the emerging challenges in the food marketplace and consumer expectations. For example:

- The provisions of the Act do not always provide the tools that are necessary for effective public participation in carrying out the objective of the Act.

- The Act does not spell out the philosophy or values that should guide decision-making regarding risks to health.

- New products regularly enter the marketplace and current legislation is silent about the responsibility of the various players in the supply chain and lacks flexibility as to the means to address health risks.

- The Act does not provide sufficient tools to allow the Minister of Health to take immediate action to deal with matters that may present a significant risk to human health.

- An increasing number of products coming into the market do not fall precisely within the existing definitions for a food or a drug, which are the basis for the applicable regulatory regime. This can result in inconsistencies and lack of clarity in the application of control measures in the marketplace. For example, a Anutraceutical product@Csuch as garlic pills that are generally sold in medicinal formsCcan

be regulated either as a drug or a food, each triggering very different regulatory requirements and enforcement options.

- With its focus on products, the Act may not provide flexible legal tools to address novel products, for example those resulting from the use of new technologies.

2.0 A New Canada Health Protection Act

To address these limitations, Health Canada has undertaken a legislative renewal initiative. In addition to the *Food and Drugs Act*, Health Canada administers a number of other statutes to protect the Canadian public from health risks, such as the *Hazardous Products Act* and the *Radiation Emitting Devices Act*. Adopted over a period of years to meet specific objectives, it is considered in the public interest at this time to replace the current piecemeal accumulation of statutes with a new legislative regime, a new Canada Health Protection Act (CHPA), to provide Canadians with the level of protection they expect and require from health risks associated with a wide variety of products, including food.

2.1 Goals, Values and Guiding Principles

The fundamental goals of the proposed legislative renewal are the following:

- update, strengthen and integrate 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 that is based on the highest standards of health protection.

When making decisions, health officials are often confronted with practical questions regarding, *inter alia*, the point at which preventive measures should be taken in the absence of scientific certainty; the balance between freedom of choice and protecting public interest; and the extent to which the public should be involved in the decision-making process.

The proposed CHPA would enunciate key values that would guide all actions taken under its authority, and guiding principles for risk decision-making. In this regard, the Act would:

- incorporate the concepts of transparency and of public involvement in the decision-making process which are viewed as important principles of governance today; and
- affirm key principles including the concept of precaution; the importance of science and objective observation as the basis for the assessment of risk; the requirement to weigh potential negative effects against potential benefits; and the consideration of the desire of individual Canadians to make decisions on matters which concern their own health.

2.2 General Safety Requirement in the CHPA

Under the current legal regime, Health Canada generally has the responsibility to identify hazards, assess the risk presented by the hazard on a case by case basis, and establish appropriate standards, by way of regulations, to indicate to the industry how to address the risk. While the *Food and Drugs Act* contains general provisions that recognize the responsibility of the manufacturer for marketing safe food products, Health Canada is proposing to make more explicit in the CHPA the obligation of a manufacturer to evaluate the safety of a product before putting it on the market. In addition, Health Canada proposes to establish, in general terms,

the responsibilities of the various participants in the chain of supply, e.g. manufacturer versus retailer, with regard to health and safety.

The concept of a general safety requirement (GSR), proposed in the new legislation would achieve two objectives. The GSR would be the basis to better define the industry's responsibilities, and would ensure that the food control system has the legal authority to consistently and effectively address risks to health. Under the GSR, the manufacture, promotion and marketing of any product would be prohibited if it could present an undue risk to the health of a person at any point during manufacturing, use or disposal. The GSR would be a collection of legal obligations imposed on the manufacturer (including importer) of a product and the other players in the chain of supply; and failure to carry out any of these obligations would constitute an offence.

A GSR would apply to all products. It would not preclude the establishment of standards for food safety and nutritional quality by way of regulations. The GSR would operate as a safety net where there are no applicable regulatory standards. With the GSR, a standard could be enforced even if it is not incorporated in the regulations. Therefore, adopting specific norms by way of regulations would no longer be the only way by which the government could take action when an appropriate standard, not specified in the law, is generally accepted as the practice by an industry sector.

The GSR would work in tandem with other provisions in the proposed CHPA, e.g., regulatory and approved standards, surveillance, inspection and enforcement powers. Together, these measures would assist the government and the regulated industries to take the necessary actions in the identification and management of risks related to the use or consumption of products.

3.0 Emergency Response

Canada has promulgated a new statute, the *Public Safety Act, 2002* which provides a new power to various Ministers, including the Minister of Health, to issue an emergency interim order (e.g. to prohibit the sale of a food) if the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to human life, health and safety. This interim order would only cover matters for which regulations would normally be made except that the imminency of the threat requires an immediate action. This new power would also be integrated in the CHPA.

4.0 Food Safety and the Proposed Canada Health Protection Act

Under the proposed CHPA, the Minister of Health would retain the authority to establish standards governing the safety and nutritional quality of food sold in Canada, throughout the food continuum; and the Canadian Food Inspection Agency continue to be responsible for the enforcement of these standards. The CHPA would integrate the current requirements of the *Food and Drugs Act*, as well as incorporating new concepts and provisions. In particular, the CHPA would provide the necessary flexibility to exercise appropriate controls in a marketplace where it is becoming increasingly difficult to divide products into categories (e.g. food, drugs) to ensure that products presenting a greater risk are subject to more stringent controls. For example, the following are being considered:

- A new definition of food would be proposed to better recognize the role of food on the physiological function or structure of the body beyond the generally recognized biological role of known nutrients.
- With respect to the safety assessment of novel foods, including genetically modified foods, the proposed Act would reinforce Health Canada's authority to collect, use and disclose information related to the safety of these products; facilitate cooperation with other governments; and provide additional

regulation-making authority where necessary, including the authority to require post-market surveillance for safety purposes.

- The Act would make the process of reviewing new products more transparent, while offering appropriate protection for confidential commercial information.

5.0 Challenges

The modernization of the Canadian health protection legislation to regulate better and more effectively in the 21st century is a complex exercise. Careful consideration must be given to establishing the appropriate framework in order to balance official and non-official controls, thus achieving efficiency in interventions in the marketplace commensurate with the level of risk.

Health Canada intends to provide flexibility in how it regulates products in the marketplace through provision for the establishment of non-official as well as official controls. For example, the GSR in the new legislation is outcome oriented. Provided that a product is safe and effective from a health perspective, it would meet the GSR. This would give industry more freedom and opportunities to market innovative products while maintaining high level consumer protection. The role of each player throughout the chain in ensuring the safety of the food supply should be defined accurately and well understood by all players. This would also permit timely government actions and interventions as may be necessary.

During the policy analysis and development of detailed provisions of the CHPA, a continued open and transparent dialogue with all parties must be maintained. In an increasingly multicultural society, Canadians have many and varied views on the protection of their health that must be taken into account.

More and more, the participation of citizens in the decisions that affect their lives is crucial. Careful consideration must be given to the determination of criteria to guide decisions on the consumer right to choose the level of risk versus the need for stricter controls and scrutiny to protect the public. The extent and means of participation of citizens representing different groups (e.g. consumers, special interest groups, industry) in the decision-making process must be well characterized and defined to ensure the efficient and effective carrying out of government responsibilities related to health protection and the safety of the food supply.

For additional information on the proposed CHPA, please consult the Internet site http://renewal.hc-sc.gc.ca.