NB: This document was developed by Legislative Renewal staff as a working document for internal purposes, with a focus on content rather than presentation. However, it is being made available to the public to provide background information.

TABLE OF CONTENTS

1. A GENERAL SAFETY REQUIREMENT

Should a new Canada Health Protection Act contain a General Safety Requirement?

1.1 What is a General Safety Requirement?

A General Safety Requirement is bundle of legal obligations imposed on the maker[1] of a product and the other participants in the chain of supply. Firstly and most importantly, a General Safety Requirement prohibits the manufacture, promotion and marketing of any product that could present an undue risk of harm to the health of a person during its manufacture, its foreseeable use or its disposal.

Secondly, a General Safety Requirement requires the maker of a product to determine the risks that the product poses and to take reasonable steps to eliminate those risks *before* the product is put on the market.

Thirdly, it compels the maker to monitor the product for risks throughout the lifetime of the product and, if a significant risk is identified, to take appropriate corrective action.

Finally a General Safety Requirement requires others in the chain of supply to cooperate with the maker by transmitting safety information to the end user and cooperating with the maker's corrective actions.

1.2 What should the public like about a General Safety Requirement?

The health and safety of the public would be better protected because, among other things:

- As a general rule, all products would be subject to the safety standard established by the General Safety Requirement, thus eliminating gaps and inconsistencies.
- A General Safety Requirement imposes on the maker of a product, a clear obligation to ensure the safety of its products.
- A General Safety Requirement authorizes Health Canada to take preventive measures whenever a product presents an undue risk of adverse health effects.
- Contravening the General Safety Requirement could result in criminal prosecutions.
- The proposed General Safety Requirement incorporates the concept of precaution;

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[1] This term includes an importer.

that is, erring on the side of caution.

- The risk the product may present must be considered, not only at the point of sale but throughout its life cycle, from manufacturing right through to disposal.

- With the proposed General Safety Requirement, one must consider the reasonably foreseeable use of the product and the reasonable expectations of the consumer.

- The maker of a product must take measures, commensurate with the risk that the product presents, to monitor adverse health incidents and to take corrective action, if necessary.

- A General Safety Requirement does not in any way preclude government from adopting by way of regulations a specific standard for a particular product or class of products.

1.3 How would a General Safety Requirement affect the industry?

- Responsible makers of products are already exercising due diligence and addressing the health or safety risks in their products, thus conforming with the General Safety Requirement.

- A General Safety Requirement is outcome oriented. Provided that a product is safe and effective (from a health perspective), it meets the requirement.

- A General Safety Requirement offers more flexibility by widening the range of options available to set standards and ensure compliance. This can help eliminate barriers to innovation and facilitate harmonization with other developed countries, but the objective of protecting health and safety must never be compromised: See Section 1.5.

- The proposed General Safety Requirement would help to establish a more equitable marketplace. A person bringing a product to Canada for a commercial purpose would be subject to the same requirements regarding health and safety as the Canadian manufacturer of an equivalent product and no one could use the excuse of no mandatory safety standards to undercut the market by producing dangerously substandard products.

- Important segments of Canadian industry have been subject to a General Safety Requirement in one form or another for decades with continuing profitability and success. For example, there are General Safety Requirements of limited scope in the *Food and Drugs Act*.: See Section 2.1.2.

- Most developed countries to which Canadian products are exported and from which many products are imported into Canada have already adopted a General Safety Requirement in one form or the other: See Section 2.4.

1.4 Under a General Safety Requirement, when can Health Canada act against an unsafe product?

Under a General Safety Requirement, Health Canada can act against an unsafe product as soon as Health Canada believes on reasonable ground that the product contains a risk that could cause reasonably foreseeable injury. That evidence does not necessarily have to be evidence of actual injury. It can be evidence of close calls or near misses or it can be a theoretical expert opinion based on a scientific analysis. A General Safety Requirement, therefore, can permit Health Canada to take preventive action *before* injury or death occurs.

Once the General Safety Requirement has been activated by the discovery of the risk, Health Canada can use the full enforcement powers of the Act. Those powers include prosecution, seizing the product, ordering a halt to its manufacture or sale or requiring appropriate corrective action like recalling the product, sending a warning or providing a protective part.

Under the Act it would be an offence to fail to carry out any of the legal obligations that make up the General Safety Requirement; that is,

- to make or sell a product that causes undue adverse health effects;
- to fail to monitor a product after sale in a manner commensurate with the risks that it poses; or
- where serious risks are discovered, to fail to report those risks to Health Canada or to fail to take appropriate corrective actions.

1.5 How does a General Safety Requirement relate to generally accepted standards?

With a General Safety Requirement, a standard can be enforced even if it is not incorporated in the regulations. Adopting specific norms by way of regulations would no longer be the only way by which Health Canada could acquire the necessary authority to take enforcement actions. When an appropriate standard[2] is generally accepted by the responsible participants in an industry, Health Canada can use the General Safety Requirement to enforce the accepted standard. Health Canada can take preventive or corrective action when an unprincipled maker supplies a product that does not meet the

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[2] Like a recognized American or European standard or a standard established by an accredited standard-writing body.

accepted standard and failure to meet the standard could cause undue adverse health effects. By comparison, under the current *Hazardous Products Act*, unless specific regulations are adopted, Health Canada has no jurisdiction to act against the substandard product, other than to try to persuade the maker to remove the product from the market on moral grounds.

1.6 Who has the burden of proof?

In a prosecution under the existing legislation the onus is on the government to prove beyond a reasonable doubt that the product is unsafe using Health Canada's own tests and any evidence that it can gather from the maker of the product. Yet the person in the best position to know whether the product is safe is the maker. It is the maker who sets the specifications for the product, who controls its production, who receives the complaints about the product and who profits from the sale of the product.

By contrast, in a prosecution under the proposed Canada Health Protection Act, once the government proves that the product is capable of causing a reasonably foreseeable adverse health effect, the onus switches to the maker of the product to prove its defence. Possible defences include showing that

- the product is not the source of the injury;
- the product does not contain the risk;
- the maker took all reasonable steps to eliminate the risk;
- the product meets an appropriate standard; or
- the risk is minimal or within the reasonable expectations of the user and other affected persons.

The easiest way for a maker to prove it took all reasonable steps to eliminate the risk is by establishing that the product meets the relevant regulatory standard.

In the absence of a regulatory standard, the maker could rely on other technical sources. It could demonstrate that the product complies with a National Standard, an international standard or with an official standard of another country that appropriately addresses the risks in the product. The maker could also use a standard for another product that manifests risks that are analogous to those in the product. In short, the maker must show that it has addressed the risks in the product in light of such factors as:

- the level of safety that the person at risk reasonably expects,
- the scientific knowledge and the state of the art and technology available about the product and
- generally accepted health and safety standards applicable to the product or to similar products.

1.7 How does a General Safety Requirement relate to the rest of the Act?

A General Safety Requirement works in tandem with several other provisions in the proposed Canada Health Protection Act. It interacts with the regulations, regulatory and approved standards, surveillance requirements and data collection processes, adverse incident reporting requirements, inspection powers, corrective actions and enforcement powers. Together these measures enable Health Canada and the regulated industries to identify and deal with risks in products.

For example, both Health Canada and the makers of products can use regulatory or non-regulatory standards to assess whether the risks in a product have been appropriately addressed. They can both use surveillance data and adverse incidents to identify risks that may need correction. In addition, Health Canada's enforcement powers enable it to do inspections, test samples and monitor the efforts of other national, provincial and international health protection agencies. The proposed Canada Health Protection Act would also give the Minister of Health powers to compel corrective actions – such as stopping the sale of a product that is causing undue adverse health effects. And makers are helped to put their corrective actions into effect because the Act would compel the other participants in the chain of supply to cooperate with their efforts.

2. BACKGROUND AND ISSUE ANALYSIS

2.1 Existing General Safety Requirement principles

Both the *Food and Drugs Act* and the *Radiation Emitting Devices Act* contain General Safety Requirements with a limited application. For example, section 4 of the *Food and Drugs Act* prohibits the sale of a food that:

- contains a poisonous or harmful substance;
- is unfit for human consumption;
- consists of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
- is adulterated; or
- was manufactured, prepared, preserved, packaged or stored under unsanitary conditions[3].

The *Food and Drugs Act* also prohibits the sale of a cosmetic or medical device with

[3] See Sections 4, 7, 8, 11 and Paragraph 16(d).

characteristics that "cause injury to the health of the user"[4]. Similarly, subsection 4(b) of the *Radiation Emitting Devices Act* prohibits the sale, lease or importation of a radiation emitting device that "creates a risk to any person of genetic or personal injury, impairment of health or death from radiation".

These examples show that obliging the maker of the product to consider the safety of its product is not a new principle in health protection law. The proposed Canada Health Protection Act would extend the principles in the *Food and Drugs Act* and the *Radiation Emitting Devices Act* to all products and all risks that cause undue adverse health effects.

2.2 Problems of the current regime

2.2.1 Limited powers

The legal authority for federal health protection legislation lies primarily in the federal constitutional responsibility for criminal law[5]. Essentially, this means that health protection legislation must describe the "public evil" that it is prohibiting, such as the sale of a product that could cause "injury to the health of the purchaser or user"[6]. Health Canada can then set regulatory standards to define the parameters of the prohibition and to take action against persons who violate the prohibition.

Because Health Canada is exercising a criminal law power, its enforcement powers are interpreted restrictively. For example, the powers in the *Radiation Emitting Devices Act* can be used only against risk of injury from radiation. That Act does not permit Health Canada to act when the injury is caused by another hazard. When older legislation addresses only injury to the "purchaser or user"[7], Health Canada may not be able to act against indirect injuries that affect only someone other than a purchaser or user. Similarly, legislation that refers to "customary or usual" use may limit action against adverse health effects that result from foreseeable use that is not "customary or usual".

By contrast, more recent legislation addresses risks to the public in general and uses a test of foreseeable use. For example, young children will drink almost anything, including hazardous chemicals. Drinking a chemical is not a customary use of

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4 See Sections 16 and 19.

5 Set out in Subsection 91(27) of the *Constitution Act, 1867*.

6 See Section 19 of the *Food and Drugs Act*.

7 See Sections 16 and 19 of the *Food and Drugs Act*.

chemicals but it is *reasonably foreseeable* that young children might do so. As a consequence, the *Consumer Chemical and Containers Regulations, 2001*[8], requires all toxic and corrosive chemical products to be sold in child-resistant containers.

Several of Canada's health protection Acts, while containing limited General Safety Requirements, are too narrow and do not capture all the persons who could be injured by a product, all the ways in which injury can foreseeably occur or all the hazards that could cause the injuries.

2.2.2 Civil Law or Criminal Law

In civil law, it is a well-established legal principle that the makers of products are responsible for adverse health effects caused by their products. In every province and territory of Canada – through the product liability law of common law provinces and Articles 1468, 1469 and 1726 of the *Civil Code of Quebec* – every victim injured by a product can sue the maker of the product in a *civil* action *after* they have been injured. Civil actions for compensation for injury, also called "tort" actions, are expensive and take a long time to reach a verdict. If, at the end of the process, the maker of the product is found to have been negligent about the safety of its product, the court will order the maker to pay monetary compensation to the injured person. But the judge in a tort action has no authority to order the maker to remove the unsafe product from the market or to warn other possible victims. Tort actions, therefore, do not directly prevent the sale of unsafe products or safeguard others from injury.

It has been argued that tort actions can, without further legal constraints, prevent the sale of unsafe products by detering their marketing. The premise is that the makers of products want to avoid the costs and bad publicity associated with tort actions. To do so they pay close attention to the safety of their products so that their customers will not be injured. Unfortunately, there is evidence[9] that such deterrence only works where the injuries are grievous. Tort actions do not work as a deterrent where the injuries are difficult to link to their cause or are minor injuries experienced by many people. While minor injuries result in considerable lost productivity and substantial health care costs[10], often the victims cannot afford to individually seek compensation from the maker of the products that injured them.

In a civil law context, injured individuals must often do battle with large

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8 Made under Section 5 of the *Hazardous Products Act.*

9 Donald N. Dewees and Michael J. Trebilcock, *Study of the Effectiveness of Tort as a Deterrent to the Production and Supply of Hazardous Consumer Products*, January 25, 1994.

10 Abt Associates of Canada, *An Economic Assessment of Proposed Changes to the Hazardous Products Act*, March 31, 1994

manufacturers. The disparity of resources in such cases is often inherently unfair. In addition, safety can become a strictly economic decision. If it is cheaper to pay compensation than to redesign the product to make it safer, the maker of the product has no economic incentive to make it safer.

Criminal law, on the other hand, not only provides greater deterrence but it removes the inequities inherent in civil actions by individuals against corporations. A General Safety Requirement permits Health Canada to act preventatively against products that cause undue adverse health effects. A General Safety Requirement provides the means and the tools to act quickly and, in appropriate circumstances, permits Health Canada to compel the maker to take corrective action, like removing the product from the market and warning potential victims. Makers can also be prosecuted.

While the threat of prosecution is often an effective deterrent by itself, the proposed Act contains additional sentencing provisions that could eliminate the economic disincentive to making a product safer. Under the proposed Canada Health Protection Act, the court on conviction could, in addition to any fine or imprisonment, roll back the profits made from the non-complying product, prohibit the maker from selling similar products for a period of time or require the maker of the product to do research into making the product safer.

2.2.3 Gaps in health protection

There are hundreds of thousands of consumer products for sale in the Canadian marketplace. Only about 1,500 are captured by the existing health protection legislation administered by Health Canada. Under the current legislation for hazardous products, the *Hazardous Products Act*, Health Canada cannot act against a product until a regulation has been developed to deal with it. Only then can Health Canada prohibit it or require that it meet a standard set out in regulations.

It is not realistic to expect Health Canada to test every product before it is placed on the market or to develop and adopt regulatory standards for all of them. There are too many products and they evolve too quickly. The resources needed to carry out such a task would be immense. There is not a country in the world that could afford such a health protection regime.

It is much more realistic to demand that the person who proposes to market a product evaluate its safety before putting it on the market. The person marketing the product knows it best: how it is made, whether it contains hazardous substances, how it can be used, who will be using it, how long it will last and how it will likely be disposed of. The makers of products already have this obligation in civil law.

A General Safety Requirement closes the gaps in the current health protection legislation by making it an offence to manufacture, promote or market a product that

poses an undue risk to the health or safety of the public. A General Safety Requirement sets a health and safety standard for all products. It permits Health Canada to act against an unsafe product as soon as Health Canada believes on reasonable ground that the product contains a risk that could cause reasonably foreseeable adverse health effects.

It is important to understand that the presence of a General Safety Requirement in the proposed Act would not, in any way, preclude setting regulatory standards. Health Canada would continue to establish standards by way of regulations. The General Safety Requirement operates as a safety net where there are no applicable regulatory standards.

2.3 What we heard

During national consultations which took place in the fall of 1998 we were told that any revised health protection legislation should:

- include a general prohibition against manufacturing, importing, distributing or selling any product, and conducting of any activity that is demonstrably unsafe under normal conditions or that threatens the health of people or other living things;

- compel makers to recognize their responsibility for ensuring the safety of new products and technologies, and to meet standards of safety commensurate with the risks associated with their products;

- spell out the fact that few products are risk-free and that consumers are responsible for using and disposing of products in accordance with manufacturers' instructions; and

- state that manufacturers have a responsibility to:

    - disclose all known risks associated with the use of their products;
    - provide consumers with clear, comprehensive instructions for the safe use and disposal of their products; and
    - report to Health Canada any previously undetected product defects and any previously unforeseen health risks associated with the use of their products.

2.4 International Comparison

2.4.1 European Union

The European Union regulates commercially sold consumer products using a General Safety Requirement. Each member state has adopted legislation that legally obliges every producer of a consumer product to market only safe products. The European Union Directive[11] defines a "safe product" as one that, under reasonably foreseeable conditions of use, presents only a minimum risk compatible with the product's use and which is consistent with a high level of protection for the health and safety of persons. It sets out the responsibilities of persons in the supply chain to assist in identifying and correcting safety problems. It was recently amended to apply to any risk in a professional product that is not adequately regulated by the legislation that specifically applies to that product, and to require mandatory reporting of unsafe products and stronger corrective actions. These changes will be implemented in the national legislation of the member states by January 15, 2004.

2.4.2 United States

In the United States, commercial law[12] interacts with tort law to provide regulators with many of the same tools that are used in Europe. Firstly, the U.S. system relies in part on the identification of hazards by the U.S. civil courts. Tort law in the U.S. functions quite differently from its Canadian counterpart. Not only is American culture more litigious – in part because of the huge punitive damages that are often awarded to persons injured by hazardous products – but because of its huge population, injuries are more likely to occur in the U.S. sooner and more often than in Canada. As a consequence, the deterrent effect of tort law in the U.S. is greater and more quickly felt by producers than it is in Canada. U.S. producers, therefore, will "voluntarily" take actions equivalent to those that are legally required under the European General Safety Requirement.

Secondly, U.S. federal law contains a series of limited General Safety Requirements. The US *Federal Food, Drug, and Cosmetic Act* prohibits the manufacture of, and interstate commerce in, "adulterated" food, drugs, devices or cosmetics; that is, a food, drug, device or cosmetic that "contains any poisonous or deleterious substance which may render it injurious to health"[13]. Similarly, the

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11 See Article 2(b) of 2001/95/EC, December 3, 2001.

12 U.S. federal health protection law is made under the federal power to regulate commerce. In contrast to Canada, the US federal government cannot make criminal law. Only the states can make criminal law.

13 See s. 402.(a)(1); s. 501.(a)(2).

Consumer Product Safety Act (CPSA) makes it illegal for a manufacturer to fail to report the existence of a product that shows "unreasonable risks of injury"[14]. U.S. regulatory agencies, therefore, have automatic jurisdiction to act wherever they find products that cause undue adverse health effects. When such products are found, the U.S. authorities can order corrective actions.

The U.S. approach to product safety, therefore, is much stronger and more flexible than the Canadian regime. Like Canada, the U.S. has product-specific Acts that require manufacturers to address the safety of some products, with varying comprehensiveness of safety coverage. But, unlike Canada, the U.S. government has automatic jurisdiction over almost all consumer products. In contrast to the cumbersome regulatory process that cripples the *Hazardous Products Act,* the U.S. Consumer Product Safety Commission can take virtually immediate action to protect the public. The U.S. regime also includes impressive enforcement powers, including reporting requirements and an ability to order corrective actions.

While the U.S. does not have an express General Safety Requirement, the commercial-law based U.S. approach to product safety contains all the basic elements of a General Safety Requirement:

- prohibitions on unsafe products or on failing to report unsafe products;
- legal compulsion, albeit stimulated by fear of civil suits, for producers to review the safety of their products;
- legal authority for the U.S. government to take immediate enforcement actions to protect the public;
- powers to set standards for hazardous products;
- reporting requirements; and
- effective corrective actions.

3. PROPOSAL

A General Safety Requirement could be articulated as follows in Canadian law.

B2.1- As under the current regime, standards and requirements could be established in the proposed Act or the regulations and failure to meet these standards or requirements would constitute a contravention.

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[14] Section 8, 15 U.S.C 2057. A manufacturer must tell the Consumer Product Safety Commission when it fails to comply with a mandatory safety rule or a voluntary standard for its industry. A manufacturer must also report when it loses or settles three product liability actions with respect to the same product within a two year period: Section 15, 15 U.S.C. 2064; s. 37, 15 U.S.C. 2084.

In order to maintain at least the current level of safety, there would still be detailed regulatory standards applicable to various products. For example, new drugs and novel food would continue to be subject to the premarket review process.

B2.2- In addition, a General Safety Requirement would apply to all products, even in the absence of specific standards or requirements in the proposed Act or the regulations. More specifically, it would provide that:

B2.2.1- No supplier shall manufacture, promote or market any product that, when manufactured, marketed, promoted, used or disposed of under reasonably foreseeable conditions, could cause adverse effects to the health of a person because:

B2.2.1.1- the product could be defective or could become so prematurely in comparison with similar products;

The concept of holding the supplier responsible for a product which deteriorates prematurely in comparison with products of the same type exists in other legislation, such as section 1729 of the Civil Code of Quebec.

B2.2.1.2- the product could fail to accomplish what it can reasonably be expected to do;

B2.2.1.3- the product could be more dangerous than the user would normally expect;

The "consumer expectations test" is used by American courts in product liability cases and is also found in the European Council Directive on General Product Safety 2001/95/EC at Article 3(f).

B2.2.1.4- adequate information is not provided to the user to ensure the safe use and disposal of the product;

B2.2.1.5- the product could be adulterated;

In other words, the product is falsified or made inferior, impure or not genuine by the addition of a harmful, less valuable or prohibited substance and does not conform to expected standards.

B2.2.1.6- the product is fabricated, packaged, preserved, transported or stored in conditions that could cause the product to become unsafe;

B2.2.1.7- the product could contain or emit potentially harmful substances or radiation, and there are not adequate safeguards to address the risk;

B2.2.1.8- the product could emit potentially harmful substances or radiation in excess of what is necessary to achieve its purpose;

B2.2.1.9- the product could be poisonous, corrosive, flammable, explosive, toxic, infectious or dangerously reactive, and there are not adequate safeguards to address the risk;

B2.2.1.10- the product could be expected to come in contact with other products thus creating a hazard, and there are not adequate safeguards to address the risk;

B2.2.1.11- the design, structure or characteristics of the product could create a hazard, and there are not adequate safeguards to address the risk;

B2.2.1.12- prior to being promoted or marketed the product was not evaluated objectively to assess and address potential negative health effects; or

B2.2.1.13- human or animal cells, tissues or organs are being collected, and there are not adequate safeguards to address the risk; or

E.g. failing to ensure the safety of the donors, recipients or other parties, through proper donor suitability assessment, retrieval, processing, record keeping, etc.

B2.2.1.14- such other cause as specified in the regulations.

B2.3- Factors such as the following would be considered in determining whether the supplier has exercised reasonable care in the circumstances:

B2.3.1- the guiding principles on risk decision-making;

See the section on Making Decisions Regarding Risk above. In summary: the assessment of risk should be based solely on science and objective observation; potential positive and negative effects for the people must be weighed; the concept of precaution

will be applied; the desire of individual Canadians to make informed decisions concerning their own health will be recognized; consideration will be given to the fact that the same measure may impact differently on various people; and the connection between human health and the environment must be acknowledged.

B2.3.2- the nature and function of the product;

B2.3.3- the life cycle of the product;

For example: a product which contains a hazardous substance could be designed so as to facilitate its safe dismantling and disposal and bear a label as to how to proceed to discard it. When selling a product likely to become dangerous if not properly maintained, the supplier might have to ensure that a system is in place in this regard (e.g. maintenance contract).

This also means that factors intervening prior or during manufacturing will also be considered if they can have a negative impact on health and safety (e.g. choice or raw material). How would this affect the chain of supply in areas such as food?

B2.3.4- the likelihood and seriousness of any potential adverse health effect;

B2.3.5- the level of safety that the person at risk may reasonably expect;

E.g. Has the person consented to the risk?

B2.3.6- the degree of vulnerability of the person at risk;

B2.3.7- the scientific knowledge and the state of the art and technology available about the product;

B2.3.8- federal, provincial or territorial laws applicable to the product or to similar products;

For example, one way of establishing a defence of due diligence would be for the supplier to show that the product complies with regulatory standards. However, the government could refute that defence by demonstrating that the supplier knew or should have known that the standard did not address a particular hazard or did not sufficiently protect health and safety in the circumstances. This is similar to section 39 of the British Consumer Protection Act 1987,

Article 3 of the European Directive on General Product Safety 2001/95/EC, and the relevant case law. In tort liability cases, American courts have often considered that merely complying with regulatory standards does not mean that the product is sufficiently safe.

B2.3.9- generally accepted health and safety standards applicable to the product or to similar products;

This is assuming of course that the standard addresses the particular hazard responsible for causing injury in the circumstances.

The Minister could issue a notice informing the industry and the public that a given standard is not considered sufficient to address a hazard. Conversely, The Minister could maintain an administrative list of the standards considered to be adequate to protect the public. Such standards could also be incorporated by reference in the regulations.

B2.3.10- the level of expertise one can reasonably expect from the various participants involved in the supply chain and their respective responsibilities (see hereunder); and

For example, the manufacturer will be expected to be more knowledgeable about its products than the retailer who sells a variety of products and may not have the same specialized knowledge.

B2.3.11- other factors as identified in the case law or in the regulations.

B2.4- Background:

While not in any way precluding the adoption of regulatory standards to address specific situations, a General Safety Requirement would act as a safety net in the absence of such regulations and ensure that Health Canada can take action regarding all products, regardless of their nature. It would also confirm that suppliers are responsible for ensuring that the products they put on the market do not present an undue risk.

In existing Canadian legislation, at least partial General Safety Requirements are contained in the Food and Drugs Act with regard to medical devices and cosmetics, and in the Radiation Emitting Devices Act.

It is also a well-established principle in both Canadian Common Law and in Articles 1468, 1469 and 1726 of Quebec's Civil Code that the manufacturer will be held responsible for damages caused by a faulty product. This is effectively an after-the-fact General Safety Requirement enabling victims to take civil action after they have been injured. The General Safety Requirement in the proposed Canada Health Protection Act would allow the government to take preventive action before injury or death occurs and also to undertake criminal prosecutions where appropriate.

We would also, in fact, be catching up with other developed countries. The European Union's Directive on consumer products (1992) imposes a general safety requirement on the entire chain of supply. The United Kingdom has had a General Safety Requirement in its Consumer Protection Act since 1987. The U.S. has long imposed an after-the-fact General Safety Requirement through its Tort law regarding product liability, which is probably the toughest in the world, with its use of jury trials and punitive damages.

It does not appear that the proposed framework would impose an undue burden on industry. It is fair to assume that responsible manufacturers already take all the precautions necessary, so no new burden would be imposed on them. Moreover, the proposed shift in burden of proof essentially reflects the already-existing jurisprudence in the case of regulatory prosecutions, particularly with regard to strict liability and due diligence. The supplier already has the obligation to demonstrate to the court that it has taken reasonable measures not to contravene legislative requirements.

A General Safety Requirement would therefore achieve two important objectives: It would clarify the responsibilities of the suppliers of products with regard to health and safety and it would ensure that the health protection system has the proper legal authority to consistently and effectively address risks to health.

The respective responsibilities of the various participants in the supply chain would be described as follows.

B3.1- The responsibilities of the manufacturer (other than a transporter or a person who stores a product):

N.B: manufacturer as defined above includes the person who brings the

product into Canada.

B3.1.1- would apply to all matters which may affect the safety of the product that are directly or indirectly within the manufacturer's control;

B3.1.2- would include taking measures commensurate with the risk presented by the product to monitor adverse health incidents after the product has been marketed and taking appropriate corrective action (including reporting to Health Canada). Appropriate corrective action could include, for example, measures to address off-label use by ensuring that cautionary labelling information is provided for a prescribed health product that was becoming the subject of growing off-label use.

> *In some circumstances (e.g. innovative new products such as some new drugs), should the manufacturer be required to pursue long term research to confirm the safety and effectiveness of the product?*

B3.2- Every person in the supply chain would be responsible for:

B3.2.1- exercising reasonable care in the conduct of the person's activities within the limits of the person's capacity to influence the safety of the product;

B3.2.2- not promoting or marketing a product which the person knows, or ought to know, does not meet safety requirements;

B3.2.3- in the case of a person who distributes products at the wholesale or retail level, transmitting information relating to the safety of the product between the manufacturer and the user and cooperating with the manufacturer in implementing corrective actions.

B3.3- The regulations could describe in more details the responsibilities of specific participants in the supply chain.

4. CONCLUSION

In summary, a General Safety Requirement would:

- offer better protection to Canadians by making all products to which the Act would apply subject to a comprehensive safety standard;
- establish a legal regime that is outcome oriented and offers more flexibility and consistency;
- provide Health Canada with the legal tools it needs to address health risks; and
- bring Canada up to speed with what already exists in other developed countries.