Health Protection Legislative Renewal:

Analysis and Recommendations

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for the Canadian Environmental Network

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1. Summary of the Proposal

In the fall of 2003, Health Canada entered the second major phase of consultation on its review of health protection legislation. Four laws are up for review and proposed to be consolidated into a new Canada Health Protection Act. These laws include the *Hazardous Products Act (1969)*, the *Food and Drugs Act (1953)*, the *Quarantine Act (1872)* and the *Radiation Emitting Devices Act* (1969). Laws like *Tobacco Act* and the *Pest Control Products Act* are not included "but [will] be integrated in the new framework.'

A "detailed legislative proposal" is the subject of numerous stakeholder meetings. Written comments are due by March 31st, 2004. The first phase of this consultation occurred in 1997 under the name of Health Protection Branch, or HPB, Transition and was widely condemned by public interest organizations as a deregulation juggernaut. The name "HPB Transition" has disappeared and some of the deregulation ideas have been toned down but the current consultation is the next stage in the same process.

The document under review covers a lot of ground but stops short of actual legislative language. This second phase of consultation seeks feedback on overall directions in many areas. Although there is a lot of detail to consider, much will depend on the actual legislative amendments and/or new legislation, anticipated for introduction to Parliament in mid- to late-2005.

Modern Legislation?

Noting that federal health protection laws are old and were developed piecemeal, Health Canada says this proposal will "modernize and strengthen the legislation so as to help better protect Canadians against health risks, and provide policy direction in the area of health protection." Health Canada also states: "all elements of the detailed legislative proposal are open for discussion."

Framework of the Proposed New Law:

The list on the following page summarizes Health Canada's statements about the key elements that would be in the proposed Canada Health Protection Act. It has been prepared by using Health Canada's own summary materials but any statements or commentary by Health Canada about whether these changes constitute improvements, have been removed. Nor is any other commentary noted here. The following is therefore a basic summary of what is proposed as either new or revised in the legislative proposal.

FUNDAMENTAL VALUES: health protection decision-making would be guided by the primacy of health and safety, openness, and accountability.
GUIDING PRINCIPLES FOR RISK DECISION MAKING: assessing risk based on science, weighing risk against potential advantages, the concept of precaution, allowing for informed choice by consumers, considering health determinants, and sustainable development.
GENERAL SAFETY REQUIREMENT: In addition to specific safety standards set in regulations, the Act would apply a General Safety Requirement to all products and describe the respective responsibilities of the various participants in the supply chain.
CATEGORIZATION OF PRODUCTS: Proposals to categorize products for regulatory purposes and definitions of "food," "health products," "natural health products" and "cosmetics."
REVIEW OF NOVEL PRODUCTS: New legislative authority to review new drugs, genetically modified food and other novel products. Includes authority to increase transparency in the process.
ADVERTISING OF HEALTH PRODUCTS: Proposals for series of options and tools to deal with advertising of health products.
HEALTH AND SAFETY-RELATED ACTIVITIES: In the absence of provincial legislation, the proposed Act would provide the authority to regulate activities arising from new technologies, such as gene therapies.
COMMUNICABLE DISEASES: Within the limits of federal jurisdiction, the Act would revise the legislative authority to prevent the spread of communicable diseases, as in the case of persons and cargo entering, leaving or moving within Canada, while ensuring protection for human rights.
PASSENGER CONVEYANCES: Proposals for health and safety standards on passenger conveyances with regard to water, food, ventilation systems and general sanitation.
HEALTH SURVEILLANCE AND RESEARCH: Clarification of Health Canada’s authority to conduct health surveillance and research activities in cooperation with other governments and organizations.
INFORMATION: Proposals regarding the collection, use and disclosure of health information and the safeguarding of privacy and commercial confidentiality.
REGULATORY AUTHORITY: Revisions to regulation-making powers of the government.
ENFORCEMENT: New legal tools, including increased maximum penalties, to enforce compliance with the law.
EMERGENCY RESPONSE: Flexibility to address urgent situations, such as allowing the Minister to issue emergency orders.

Additional proposals address product tampering, deceptive and fraudulent health claims, and products made or imported for personal use. The proposed law would also address the use, by Health Canada, of advisory committees, dispute resolution mechanisms, and set conditions for cooperative arrangements and cost recovery. It would address the government's international responsibilities in the area of health and safety and would provide for the periodic review of the Act by Parliament.

2. Context and Fundamental Public Interest Needs

Together with the *Canadian Environmental Protection Act* (CEPA) and the *Pest Control Products Act (PCPA),* this new act will provide the foundation for environmental health policy in Canada. Being a revision and modernization of four statutes, the Act needs to reflect and incorporate:

- **Canada's commitments to health protection** in human rights, health and environmental conventions, for both Canadians and people in other countries, being a commitment to the "right of everyone to the enjoyment of the **highest attainable standard of physical and mental health;"**

- compliance with the duty specified in the *Canadian Environmental Protection Act* to ensure that its treatment of health protection is complementary with other federal regulation for environmental protection and human health to provide "effective and comprehensive protection;" (S. 2m)

- recent **evolution** of domestic and international law regarding health and risk, including the precautionary principle, and critiques of methodologies of risk assessment and management;

- current **proactive strategies** for health and environmental protection in product assessment and regulation, including proactive regulation and a comprehensive materials use policy ;

- a clear **duty and mandate of Health Canada** to protect peoples' health.

Unfortunately, as proposed, the Act does not accomplish these goals. Rather, it reflects a minimalist view of the role and responsibilities of Health Canada in the protection of peoples' health. It also includes aspects, which downgrade current and future health protection, both for Canadians and for people in other countries, which import Canadian products.

In this analysis, we focus on those parts of the proposal which concern principles and products related to environmental protection and environmental health, and make recommendations which draw on language and concepts in more forward-looking and protective laws, treaties and policies including: the *International Covenant on Economic, Social and Cultural Rights, Pest Control Products Act, CEPA*, and the legal and scientific literature regarding risk assessment and management.

3. CHPA Purpose, values and guiding principles

The Proposal:
The purpose of the proposed Act is "to protect the health of the people," and underlying values include the primacy of health and safety, openness and encouragement of public engagement, and accountability of the Minister to Parliament.

Risk decisions will be based on risk assessment, cost-benefit analysis, and minimizing adverse impacts on the environment. Regulations and guidelines may be used in "various situations." (Legislative proposal 11-13)

Analysis:

As Canada has signed and ratified numerous international agreements relating to health, this Act needs to implement the values of those commitments as they have been elaborated by appropriate international institutions.

The *International Covenant on Economic, Social and Cultural Rights was ratified by Canada on August 1976,* committing Canada to " recognize the right of everyone to the enjoyment of "**the highest attainable standard of physical and mental health**" and obliging the Government of Canada to take steps to "achieve the full realization of this right" including providing for " the **healthy development of the child**; …improvement of all aspects of environmental and industrial hygiene; and …the prevention, treatment and control of epidemic, endemic, occupational and other diseases… (Article 12)

The UN Committee on Economic, Social and Cultural Rights elaborated on states' obligations in its *General comment 14 The right to the highest attainable standard of health, UN Doc. E/C.12/2000/4 (2000).* The Committee described the obligations of state parties regarding health under the Covenant as an obligation to "**progressive realization**" of the *Convention* rights, using "deliberate, concrete and targeted" steps forward…States parties have a **specific and continuing obligation** to move as expeditiously and effectively as possible towards the full realization of 'article 12." (paras 30 & 31)

The *Covenant* includes the obligations to "respect, protect and fulfill human rights," and the UN Committee commented that:

- Violations of the right to health can occur through the **direct action of States** or **other entities insufficiently regulated** by States." (paragraph 48)

- A violation of the obligation to *respect* can occur through the failure of the State to take into account its legal obligations regarding the right to health when

entering into agreements with countries and "other entities, such as multinational corporations." (paragraph 50)

- Violations of the obligation to *protect* follow from the failure of a State to take all necessary measures to safeguard persons within their jurisdiction from infringements of the right to health by third parties. This category includes such omissions as the **failure to regulate** the activities of individuals, groups or corporations so as to prevent them from violating the right of health of others; the **failure to protect consumers and workers** from practices detrimental to health…and the **failure to enact or enforce laws to prevent the pollution** of water, air and soil by extractive and manufacturing industries. (paragraph 51)

- The incorporation in the domestic legal order of international instruments recognizing the right to health can significantly enhance the scope and effectiveness of remedial measures and should be encouraged in all cases. (paragraph 60)

These legal obligations curtail the government's option to limit regulation and leave health protection to manufacturers and suppliers of products as is proposed in the CHPA. Ottawa has a positive duty to use its regulatory powers to continuously advance product safety, consumer health, and environmental health protections.

The *Government of Canada Regulatory Policy,* which governs all departments, lists the international and intergovernmental agreements, which departments must apply. Only trade agreements are listed. (NAFTA, WTO and the Agreement on Internal Trade) but no international health, human rights or environmental agreements are listed.

However, since Canada has ratified these UN covenants, Ottawa must implement them and move continuously to improve health for Canadians and to respect the right to health of people in other countries.

While the stated purpose of the CHPA is positive and useful, the underlying principles need to demonstrate a commitment to proactive law and policy to protect health and include both a departmental duty and mandate to do so.

Like the *Pest Control Products Act*, the CPHA should provide an explicit mandate to HC to achieve the highest attainable standard of health for Canadians and a duty on the Minister to take the necessary steps to achieve that standard, including continuous improvement, as the *Covenant on Economic, Social and Cultural Rights* requires.

The Act must directly address the particular health needs of vulnerable populations, including children and people with environmental sensitivities, and implement Canada's international commitments on their behalf.

Each element of the Act should explicitly recognize the particular health vulnerabilities of children and include strategies to address those vulnerabilities.

The Act needs to not only "encourage" public involvement, but also facilitate it.

Mechanisms for public involvement, including access to information, should be included in the Act.

(Deficiencies in the federal policies of risk assessment and precaution are addressed in subsequent chapters of this analysis.)

Recommendations:

The purpose of the CHPA should be to foster the highest attainable standard of health for Canadians;

The CHPA should incorporate the obligations of the Government of Canada in international human rights and health covenants, and include specific duties of the Minister and department to implement the treaties and meet those obligations.

The CHPA should explicitly recognize the particular health vulnerabilities of children and include strategies to address those vulnerabilities

4. Risk assessment and precaution

The proposal:
HC proposes that in making decisions regarding risk, it will rely on risk assessment "based solely on science and objective observation." Actions to be taken regarding health risks would entail:

- weighing potential negative effects against "advantages"(cost-benefit analysis)
- applying the "concept of precaution;"
- considering individual Canadians' desires; recognizing measures can have differential impacts on various elements of the population;
- "minimizing adverse environmental impacts"
- allowing for sustainable development. (LP pp.12-16)

Analysis:

Health Canada's proposed approach to Risk assessment and treatment of precaution is outdated and will not protect health.
This proposed standard for risk assessment (RA) echoes an outdated theory which does not reflect the current literature of critiques of risk assessment. Nor does it accord with current methodologies, even as mandated by international trade agreements. It does not reflect the development of the precautionary principle in

Canadian and international law. It presumes a separation between assessment of risks and precautionary management of them, rather than the need to integrate precaution into assessment.

Conventional risk assessment is not "objective"

It is well established that RA, even as conventionally practiced, includes multiple assumptions and subjective judgments regarding many factors considered in the process so that "assessment based solely on science and objective observation" is impossible. As CELA has written:

> The notion that risk assessment is an objective, scientific phase that precedes the broader policy-making step of risk management, is an artificial and misleading distinction. There are too many uncertainties, assumptions, and judgments made during risk assessment to deny the reality of subjective interpretation within the risk assessment exercise…The denial by risk assessment practitioners of the subjective nature of risk assessment remains a problem[1].

Specifically, some examples of problematic assumptions in traditional risk assessment include:

- It tends to deal with simple and direct cause-and-effect relationships, often ignoring cumulative and synergistic effects of multiple activities or events.
- It does not adapt well to more complex situations (such as persistent, toxic, bioaccumulative substances, or endocrine disrupting chemicals) where simple dose-response effects are inapplicable.
- Those doing the calculation may not know of all hazards posed by the activity; for example, only possible "cancer risks" but not possible developmental or neurological risks, are studied in relation to the substance at issue.
- Assumptions about levels of exposure may be completely erroneous; expected behaviour or interaction with the product or activity in question may not be the same as actual behaviour or interaction.
- The range of consequences being considered may be very narrow (e.g. only human health but not biodiversity impacts; tendency to focus on direct impacts, with less attention to indirect or systemic impacts).
- The level of anticipated consequences may be completely erroneous.
- Traditional risk assessment often excuses involuntary public exposure to harm, and exposure of vulnerable populations to harm, by assuming or substituting manufactured or implied consent for true consent, and calculated risks for true protection. It achieves this in part by setting assumptions for what damage (e.g. number of cancer deaths) is "acceptable".

Even international trade agreements prescribe more factors for consideration in decisions regarding risk assessment, precaution and risk management actions than are proposed in the CHPA.

The WTO and NAFTA trade agreements are less restrictive for decision-makers than the proposed HC criteria. They propose criteria that are not based "solely on science and objective observations."

The *WTO Sanitary and Phytosanitary Standards Agreement (SPS*) provides that at a minimum, government assessments consider available evidence, relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest-or disease-free areas; relevant ecological and environmental conditions; and quarantine of other treatment. The corresponding NAFTA wording provides that SPS measures be "based on scientific principles" and account for other factors different geographic conditions…. " and factors similar to those in the WTO agreement. (*NAFTA 712)*

Both agreements refer to the right of countries to establish an "**appropriate level of protection**," recognizing that a governmental policy decision (regarding the level of protection for risk) is necessary and is a **policy choice**, not dictated by scientific findings.

The proposal to weigh potential "negative effects" of risks against "advantages" presumes an unsophisticated approach with undue privilege for economic benefits.

As the European Commission's precautionary principle statement[2] asserts:

> Examining costs and benefits entails comparing the overall cost to the Community of action and lack of action, in both the short and long term. This is not simply an economic cost-benefit analysis: its scope is much broader, and includes non-economic considerations, such as the efficacy of possible options and their acceptability to the public. In the conduct of such an examination, account should be taken of the general principle and the case law of the Court that the protection of health takes precedence over economic considerations.

The HC proposal fails to incorporate the precautionary principle and a concrete strategy for its implementation.

The proposal states that "the concept of precaution will be applied" and refers to several statements of the principle in Canadian and international law. (*the PCPA, CEPA,* and the *Rio Declaration*). However, the proposal does not state how the principle will be implemented, nor does it integrate a precautionary approach into its risk assessment proposals.

The specific precautionary wording included in the proposal is

> where there are threats of serious or irreversible damage, lack of full certainty shall not be used as a reason for postponing cost-effective measures to prevent adverse health impact or environmental degradation.

However, more protective application of the principle has been elaborated in law and scholarly writings. For example, the *Bergen Ministerial Statement* for the ECE Region, cited by the Supreme Court of Canada, provides:

> In order to achieve sustainable development, policies must be based on the precautionary principle. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation[3].

In addition, a more comprehensive and effective approach has been articulated in the *Wingspread Statement on the Precautionary Principle* of 1998:

> When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context, the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the precautionary principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action.

In contrast to the "sole science" risk assessment criterion proposed, a true implementation of a forward-looking precautionary approach would entail:

- A presumption in favour of **health and environmental values** with an accompanied strategy to **anticipate, prevent and attack** risks to health;
- a broad-based **goal of precaution** in the face of scientific uncertainty accompanied by a general **duty to use precaution**;
- dynamic, proactive goals should be set, for example in preventing, eliminating or reducing a specific hazard, acc
- **shifting the burden of proof** to those undertaking hazardous activities so that the proponent should demonstrate that no harm would occur and that there were no safer alternatives to an activity
- instructions on how to weigh scientific and other evidence regarding likelihood of harm
- Approaches to “acceptability” of hazards based on distributional issues, vulnerable populations, potential loss of social and ecological capital, and other non-monetary values.
- **prevention-based tools** (bans, phase-outs, clean production, pollution prevention)
- **assessment of alternatives** to the proposed product, activity, technology
- ongoing **monitoring** of products**, investigation and information** dissemination
- greater **transparency,** external review, participation and **democratic decision-making** with strong enforcement.

Recommendation:
Health Canada should adopt a comprehensive precautionary approach to risk prevention and assessment by including clear precautionary goals,
proactive risk prevention,
a shift in the burden of proof in assessment,
assessment of alternatives,
ongoing monitoring of products, and
greater transparency and public participation in decision making regarding risk.

5. General Safety Requirement
As described in the Legislative Proposal (LP) and the Background Paper (BP)

Elements of a General Safety Requirement: (BP p.1-2)

The proposed "General Safety Requirement" (GSR) is described as **a "bundle of obligations**" on manufacturers/ importers/ suppliers including:

- a prohibition of the manufacture, promotion or marketing of products presenting "**adverse effects to the health of a person**" (or **undue risk of harm** to the health of a person – both wordings are used given the specifications of what constitutes undue risk) during manufacture, "foreseeable use" or disposal;
- taking steps to identify and eliminate risks before marketing the product
- monitoring and correcting problems with the product
- requiring suppliers to transmit safety information and cooperate with manufacturer in corrective actions.

Undue risk: Ten factors would govern whether the risk from a product is an undue risk:
risk assessment; the nature and function of the product;
reasonable level of safety that can be expected; state of science knowledge;
likelihood and seriousness of risk of adverse health effects;
applicable regulations and "generally accepted standards that apply to it or similar products; vulnerability of individual; consent to the risk; product life cycle.

Failure to meet the GSR could arise from: design or manufacturing defect; lack of information about safe use and disposal; dysfunction of the product; adulteration; harmful emissions "in excess of what is necessary to achieve its purpose;" dangerous properties (corrosion, etc) w/o safeguards; lack of evaluation of hazards prior to marketing and failure to address health risks. (LP p.26)

Relationship to Health Canada responsibilities
The GSR would address gaps in the current regime, in which HC has limited powers to address product safety, flowing mainly from its' constitutional jurisdiction over criminal law to address a "public evil" such as injury to the health of the user of a product. (BP 5-6)

Health Canada could still set health and safety standards for some products, but the GSR would provide a “safety net” when they don’t adequately address a hazard.

HC would accept as product safety standards not only Canadian regulations but also "generally accepted health and safety standards applicable to the product or to similar products" (LP p.31) including foreign standards, industry voluntary standards ("a standard established by an accredited standard-writing body) or "a standard generally accepted by the responsible participants in an industry."
(BP p3, para 1.5)

HC would have the power to take preventive measures if a product provides an undue risk to health, and could prosecute producers/sellers/suppliers, seize the product, halt manufacture or sale or require corrective actions by companies.(warnings, recalls)

Once HC shows reasonable a foreseeable adverse health effect of a product in a prosecution, the burden of proof will switch to the producer to defend it. (p3 BP)

HC's description of the relationship of the GSR to industry
HC argues that the GSR “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.” (p2 BP)

"It is fair to assume that responsible manufacturers already take all the precautions necessary, so no new burden would be imposed on them." (p32,LP)

Analysis:

These General Safety Requirement proposals are unlikely to be effective in increasing product safety.
A General Safety Requirement could be a useful addition to law, providing greater jurisdiction to HC and supplementing civil liability for unsafe products, but it will not provide an effective substitute for proactive, regulatory action. The Requirement does not provide a substantive "modernization" of product safety law in Canada, and as proposed, is unlikely to contribute to a higher level of product safety.

Unclear fundamental standard
The fundamental standard to be met is unclear, since the proposal speaks of both "adverse effect on health" and the weaker, vaguer standard of "**undue** adverse effect on health." By incorporating ten factors which determine whether the risk of a product is "undue," the proposal introduces uncertainty and lowers the level of protection.

Too many shields for industry
The various factors that government intends to apply to decide whether the product risk is "undue" are broad, numerous, incorporate the deficiencies of HC's risk assessment, and include vague language and concepts (such as reasonable level of safety to be expected, "generally accepted standards that apply" to a product "or similar products," and consent of the consumer to the risk.") which will make enforcement difficult.

Broad endorsement of current industry practice
The perspective of HC, as quoted above, is that most manufacturers are sufficiently responsible now, and their products are safe, so that government oversight is only required for "irresponsible" producers. The LP speaks of providing industry with flexibility and helping to remove "barriers to innovation" but does not demonstrate that any such barriers exist, or how these proposals will remove them.

No commitment to enhanced protection
There is no recognition of broader problems of product safety, the deficiencies of the four Acts being replaced, and no intention to move to a higher level of safety. or enhanced protection for Canadians, such as would be achieved through a strategy of Clean Production and a Materials Use policy (discussed below).

HC proposes to rely on foreign or corporate "standards" for most products, rather than legislating regulations for product safety, thus eroding and downgrading safety standards

The proposed GSR incorporates the limitations of the Health Canada approach to risk assessment and ineffective references to precaution. (discussed above).

In addition, by proposing to treat non-standards and even non-standard industry practices as substitutes for regulation, HC is seriously down-grading safety and the rule of law. HC proposes:

> 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 HC could acquire the necessary authority to take enforcement actions. When an appropriate standard...like a recognized American or European standard or a standard established by an accredited standard-writing body is generally accepted) by the responsible participants in an industry, HC can use the GSR 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 accepted standard and could cause undue adverse health effects. ((BP p.3)

Although this strategy is presented as increasing product safety, it is evidence of a de-regulatory direction in HC, and a retreat from protective law-making. The

proposal to simply accept standards and industry practices from anywhere in the world raises many questions.

What constitutes an "appropriate standard" and "general acceptance" of a European and American standard, and by whom should they be "recognized?"
It would be difficult to find product standards anywhere that are generally accepted by industry here and globally and consistently applied.

Further, there are different international bodies setting differing standards in the same or similar areas and many voluntary codes of conduct that aren't standards, can't be monitored, and aren't enforceable.

It is unclear how HC expects to establish the "responsible participants" in an industry and use whatever standards they utilize privately as enforceable industry standards on which to base a prosecution of another company,

The retreat from law-making deprives Canadian citizens of the opportunity to participate in standard-setting and hold government accountable for standards, since citizens have no opportunity to participate in the formation of standards from other countries or industry associations. Nor can they even know what "standard" applies to a product if it is not legislated and published.

It is very doubtful that a successful prosecution for failure to meet a GSR can be based on dubious, unclear, non-Canadian, un-legislated standards or industry practices. Criminal prosecutions require proof beyond reasonable doubt (a more difficult standard for evidence than the civil "balance of probabilities") and courts require great clarity in criminal law before convicting accused persons or companies. **These proposals are too vague to be enforceable**.

The best and only reliable measure of "general acceptance" of a standard is its incorporation into regulation. These proposals echo the governmental strategy in the failed, government-wide de-regulatory *Regulatory Efficiency Act.*

In contrast to these proposals, the GSR in the EU provides that producers must produce only safe products ie. ones that, under reasonably foreseeable conditions of use, present 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. The standard applies to the entire chain of supply and to any risk in a professional product not adequately regulated by specific legislation. It also requires mandatory reporting of unsafe products and stronger corrective actions.

Health Canada suggests that officials could issue a notice saying a given standard is not sufficient, or have an administrative list of those considered sufficient, which could be incorporated by reference. (LP 29--30) This suggestion also raises many questions.

Are they planning to do this for all the jurisdictions and international standard setters in the world? If they decide some standard is insufficient, will they then investigate, find and prosecute all those acting to that standard? This seems unlikely, nor would they easily be successful in the courts if they didn't have a regulatory standard in effect for comparison. This is an unworkable approach, and would only divert resources from more effective law-making in Canada.

The GSR will not provide the effectiveness for enforcement that HC claims without clear standards for enforceability.

HC claims that the GSR will give the department power to act if it "believes on reasonable ground that the product contains a risk that could cause reasonable foreseeable injury" and that it can then take actions including prosecution, product seizure, ordering a halt to manufacture or sale, ordering corrective action (recall), warning, protective parts.(BP p3)

These actions would be useful, but would require clear standards to be successful.

There is no indication of additional resources, commitment to enforcement including prosecutions, or higher safety standards within HC.

The absence of the other state-of-the-art thinking on product safety, including product substitution and materials use policies, indicate that this is not a health-protective statute, moving forward for health protection. Rather, HC is proposing the GSR, inappropriately, to substitute theoretical private liability and after-the-harm criminal prosecutions instead of proactive preventive policies to prevent harm.

Recommendations:

The General Safety Requirement should incorporate a clear, high standard general duty (like the European standard), to complement a precautionary approach to product safety, encompassed in precautionary risk assessment, a materials use policy, and the additional recommendations in this proposal.

The CHPA should not include the planned de-regulatory reliance on foreign standards, non-standards, and occasional industry practices.

The CHPA should mandate HC, during the setting of health protection standards, to account for the unique and often greater exposure and physiological vulnerability of children, from pre-conception to the end of adolescence, to environmental contaminants and substances used in consumer products.

The CHPA should mandate HC to set standards that will prevent harm from multiple exposures to substances with multiple effects.

6. Supply Chain

The Proposal: (LP p.34-5)

HC proposes that all participants in the supply chain shall have the following duties:

- to exercise reasonable care,
- not promote of sell a product which the person knows or ought to have known "does not meet safety requirements"
- to co-operate in monitoring and corrective actions (product recalls.)
- manufacturers and importers shall be responsible for all matters directly or indirectly under their control that may affect product safety; including monitoring health incidents and taking corrective action

Analysis:

The proposal includes no increased authority or intention of Health Canada to step up product safety regulation.

The proposal is a minimalist approach to issues of supply chain responsibility, reflects no real change or stepped up authority for HC to control or regulate consumer products for safety, and reflects no increased intention to regulate. Only the unreliable General Safety Requirement would appear to apply. The proposed Act, which would replace the *Hazardous Products Act,* does not correct the deficiencies of that Act.

The *Hazardous Products Act* only regulates those individual products for which problems have indicated the need for control measures, resulting in the drafting of a regulation. As a product-centred approach, it is time and labour intensive. The application of the few general provisions of the Act are not always clear, so that it is uncertain which products are required to satisfy safety stipulations, and which are not.

No pre-market assessment occurs for either regulated or non-regulated products; only some case-by-case inspection is done in response to complaints or irregularities or potential dangers that are perceived by inspectors. When risks are identified, Health Canada has few options. It has no power to mandate product recalls and only limited power to seize products. In both cases it must rely on voluntary action by industry to remove dangerous products from retail shelves.

As HC has written in this proposal, the department's primary tool in the control of hazardous products, including both regulated and unregulated products, is the release of public advisories and warnings or adopting a regulation under the *Hazardous Products Act.* However, the regulation-making authority under the act is limited and problematic, since it is unclear which products can be included. The toxicity tests that underlie regulatory action are unclear and based on complicated laboratory data that are not readily available.

The proposal does not recognize or respond to the particular needs for protection of children's health, and does not correct the deficiencies of the *Hazardous Products Act* regarding products for children.

Under the *Hazardous Products Ac*t, it is difficult to determine whether a particular children's product is regulated, and if so, whether it is in compliance with the regulatory stipulations. For example, it appears that children's products made of or containing plastics are nearly unregulated by Health Canada. Further, despite the fact that the phthalate plasticizer in children's plastic products was determined more than 9 years ago to be "*CEPA*-toxic" (as defined by the *Canadian Environmental Protection Act)*, to our knowledge, this determination has not resulted in regulatory action to control or eliminate this chemical in children's products.

Recent studies demonstrate that the failings of conventional risk assessment are particularly evident in assessment of the safety of children's products, and that the need to move to a truly precautionary approach to regulation of these products is acute.

> The answer to the question as to whether standards for consumer products are intentionally protective of children is a very qualified yes and limited to only those products for which regulations have been established in reaction to identified problems. But, for children's products containing plastic the answer is unclear and probably no. For lead in consumer products the answer is decidedly no.. Only once problems or poisonings have been identified have regulations been established, after the fact, to be intentionally protective of children[4].

Recommendations:

1. The Health Protection Act product supply provisions should be based on a Materials Use Policy, a proactive precautionary and preventive public policy which would require that consumer products be manufactured with materials that are inherently safe utilizing safer productions methods. (The elements of a Material Use policy are summarized in Annex A.)

2. The CPHA should provide Health Canada with the power to issue mandatory consumer product recalls.

3. HC should conduct a review of the child-specific *Hazardous Products Act* regulations to determine whether they were developed in a precautionary manner or in reaction to identified hazardous or lethal situations.

7. Novel Food

The proposal:

Strangely, the legislative proposal does not actually make any proposals regarding the regulation of novel foods, which includes genetically-modified foods. It merely records a number of recommendations of the Royal Society Expert Panel on the Future of Food Biotechnology without indicating any proposals for change in policy. (LP p.59)

Analysis:

The proposal fails to cite the most important recommendations of the Royal Society, namely, that the regulatory regime for GM foods be fundamentally changed by the implementation of the precautionary principle.

The panel spelled out how to implement precaution regarding these products, specifying that the use of the concept of "substantial equivalence" to exempt GM foods from full safety assessment is an inappropriate use of the concept. Rather, what is required in order to use substantial equivalence as a regulatory tool, is a "rigorous demonstration" that the novel trait in the GM organism is harmless in the tested genetic and environmental context, before one can conclude that the food is as safe as the original variety from which it was derived.

The Society recommended testing for harmful effects on health (short and long term testing for human toxicity, allergenicity or other health effects) and on the environment. The testing regimes should be designed and executed in consultation with scientific experts, with results monitored by "arms-length" experts from all sectors, and decisions and rationale reported to the public[5].

The Royal Society concluded that if the standard of substantial equivalence were applied to GMOs to involve appropriate tests to **show** (not assume) that the GMOs' types and magnitudes of environment and health risks were "substantially equivalent" to those of its conventional alternative, the concept of substantial equivalence would be a "fairly rigorous precautionary safety standard.[6]"

Noting that "The claim that the assessment of biotechnology risks is “science based” is only as valid as the independence, objectivity and quality of the science employed," [7] the panel recommended the involvement of independent scientists in assessment, public access to the assessment data, and requirements that the tests be of peer-review quality.

Recommendation:

HC should fully implement the recommendations of the Royal Society Expert Panel regarding the regulatory regime for genetically modified foods.

In particular, HC should not use the assumption of "substantial equivalence" as a rationale to exempt GM foods from full assessment.

Rather, HC should institute appropriate testing of gm food crops, using independent scientific advisors to establish peer-review quality testing protocols with public access to the test data, to establish **whether** the risk/safety of the foods are substantially equivalent to the safety of the plants from which they are derived.

The protocols for testing, as the Royal Society recommended, should address risks of allergenicity and toxicity.

8. Water

Proposal:

HC proposes that the CHPA will confirm the Minister's authority to develop guidelines for drinking water quality with provincial governments and other ministries.

The General Safety Requirement would apply to manufacture, promotion and marketing of bottled water, and to the components of drinking water systems. Specific standards could be set in regulations.

The Act would also confirm HC's mandate to conduct health surveillance and research. (LP p.101-103)

Analysis:

HC does not propose to increase its current level of oversight over bottled water, which is regulated as a food product under the *Food and Drug Regulations* under the *Food and Drugs Act*.

Nor does it propose any increased specific standards for the components of water systems, for which only voluntary standards now apply and "compliance levels vary," merely stating that the General Safety Requirement would apply to them.

Currently, if bottled water is labeled as spring or mineral water, Division 12 of the *Food and Drug Regulations* requires that the water must come from an underground source. It cannot come from a public water supply. Mineral water is the same as spring water except that it contains a larger amount of dissolved mineral salts, usually more than 500 milligrams per litre of dissolved solids.

Under the regulations, chemicals cannot be used to change the composition of mineral and spring waters. However, carbon dioxide and ozone may be added to protect the freshness. In addition, the source of the spring or mineral water must be

identified. If bottled water is not labeled as spring or mineral water, it can come from any source, and be treated to make it fit for human consumption. This type of bottled water may come from a well or even a municipal water supply.

Bottled water that is not from a spring may be altered before it is presented for sale. It can be treated in different ways including carbonation, ozonation, ultraviolet radiation or filtration to remove harmful bacteria. It may be distilled or deionized to remove the minerals. The regulations require that these treatments be identified on the label as "carbonated", "demineralized", or "distilled", for example. Carbonated or sparkling water contains carbon dioxide.

The Canadian Food Inspection Agency periodically samples and analyses both imported and domestic bottled waters. This monitoring focuses primarily on testing bottled waters for bacterial contamination.
However, there are concerns that the monitoring and labelling requirements and enforcement are too limited to ensure the safety of this drinking water. Nor is it acceptable that lower standards apply to bottled drinking water than to the water in municipal systems.

Recommendation:

The CHPA should provide for the regulation and management of bottled water and its sources to a level equivalent to municipal water system standards, and improve standards for water quality, monitoring, and labelling.

Regulations should provide numerical limits on chemical, bacterial and radiological contaminants in bottled water, equivalent to those in Ontario Regulation 169/03.

Test data for water quality of bottled water should be available to the public.

Drinking water system components should be regulated to the same standards as municipal water systems.

9. Export of potentially unsafe products

HC is agreeing to endanger the health of non-Canadians by explicitly continuing to permit the export of products manufactured in Canada but not subject to Canadian standards. (LP p.183)

This practice is immoral and contravenes Canada's international human rights obligations. As the UN Committee on Social, Economic and Cultural Rights stated in its General Comment 14 *The Right to the Highest Attainable Standard of Health:*

- To comply with their international obligations in relation to article 12, States parties have to respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries, if they are

able to influence these third parties by way of legal or political means…" (Para.39)

Recommendation:

HC should release to the public a report of all products exported from Canada which are not produced in compliance with Canadian standards, consult with Canadians, and then review this policy to ensure Canada complies with its duty to protect the health of people in importing countries.

Annex A

Developing a materials use policy and promoting clean production in Canada requires the consideration and incorporation of the following components.

This information summarizes key ideas of Ken Geiser in, Material Matter and efforts of Clean Production Action promote development of material use policy based on clean production, available at http://www.cleanproduction.org/AAbase/default.htm.

Implementing the precautionary principle is a key component towards achieving sustainability.

A **materials use policy** is premised on a number of key concepts:

* **materials life cycle** - recognizes the interaction between different systems that exist in a society. To understand the materials life cycle, one must follow the flow of materials through the environment and through human economies in a continuous set of cycles. The material system would comprise of three cycling loops
    1) environmental system - closed cycling system
    2) economic/environment system - exchanges happens between the environment and economic system
    3) economic subsystem - closed system

For decades the economy promoted the production of products and services at affordable costs but it resulted in significant cost to the surrounding environment and human health. The goal to address this trend is to produce safer products that do not pose a risk of harm in the workplace, and at the same time do not degrade the environment. There are several key strategies that must be implemented to ensure that future society produces cleaner and safer products:

a) **product labelling** - to inform consumers (i.e., ecolabels). These labels work to inform the public of the hazards of the packaged contents.
b) **employee and consumer information** - for example, right to know laws in the US and Canada are effective in improving a workers' understanding on the chemicals being used or to support efforts for safe products.
c) **environmental procurement policy** - government departments have outlined procurement policies that avoid the use of products containing toxic substances.
d) **bans and phase out of toxic substances** - Due to environmental and health impacts, specific toxic substances are banned or phased out using laws or international agreements.
e) **Cleaner production** - based on pollution prevention strategies. Cleaner production promotes "**toxics use reduction**" through the various pollution prevention techniques.

Pollution prevention (PP) techniques include:
* material substitution in the product

* material substitution in the process
* improved production efficiencies
* improved process operations or maintenance and
* close-loop recycling process.
* development of environmentally appropriate material

All PP techniques are integral for promoting clean production regimes. Clean production looks at the complete system used for producing products and services (product life cycle). By reviewing every phase of the product life cycle, producers must take into consideration how materials and energy are used throughout the production system. Current production practices result in hazardous waste generation at various phases of the product life cycle. Clean production aims to improve products and processes to ensure that the hazardous waste generation is eliminated, thereby producing a product or process that does not threaten the integrity of the natural ecosystem.

Again, information on worker rights and community protection is a critical component in these efforts. Often there is limited information available to both the community and workers.

The role of the producer is significant in the clean production regime. The **Extended Producer Responsibility (EPR**), is a concept that aims to achieve the clean production goals. It promotes:

* Overall waste prevention
* Precautionary approach
* The use of non-toxic materials and processes
* The development of closed materials cycles
* The development of more durable products
* The development of more re-usable and recyclable products
* Increased re-use, recycling and composting
* Regionalization of production, consumption and materials management

Extended Producers Responsibility (EPR) programs are being implemented in Europe and in the US with varying degrees of success, including in Switzerland, Norway and the Netherlands. Each program outlines some level of government involvement (i.e, developing legislation, part of the collection process, etc.) There are other EPR programs that are based on voluntary participation.[1] The EPR programs enforced by government action demonstrate a level of effectiveness. Programs that have government support through regulations create incentives for clean product design.

[1] In the US, a voluntary approach to EPR is being undertaken. The voluntary take back programs require consumers to pay an end-of-life fee. For example, Dell, Hewlett Packard, and IBM have set up voluntary programs whereby they charge consumers a $20-30 fee for taking back the product. These programs have not resulted in high return rates and in some cases have led to illegal dumping of products. Due the voluntary aspect of these programs, there are no incentives for the producers to improve design of products.

While EPR program considers waste generation at every point of the production cycle, many EPR programs currently underway focus on managing waste generated at the end of a product's lifecycle. Clearly, a shift in the EPR program will be required to make clean production a reality.

Elements of an EPR program include:

* **Recovery, Reuse, and Recycling Requirements** - Minimum recovery, reuse and material recycling targets need to be established. Incentives to achieve full recovery, re-use and recycling must be built in. Incineration or combustion of end of life products should not be considered 'recycling' as incineration transforms materials into hazardous air and water emissions and generates toxic ash which presents an ongoing toxic waste problem.

* **Environmental Standards for Recycling Facilities** - End-of-life facilities should ensure safe, clean recycling processes for workers and nearby communities.

* **Material Restrictions** - aimed at replacing hazardous materials (i.e, metals and carcinogenic substances) with safer ones.

* **Labelling, Consumer Notification and Free Take Back** - manufacturers and retailers must provide consumers with specific information outlining hazardous material content, EPR responsibility for disposal, contact information for proper disposal by consumer.

* **Landfill and Incinerator Bans** for products

* **Export Bans** - EPR programs should prohibit export of end of life product waste to other countries. Importers of products must bear responsibility for their part of the product chain and original equipment managers must be liable for the final fate of their products.

* **Defined Government Oversight** - EPR programs should be administered by designated government agency to ensure full participation by producers. Penalties should be levied if producers fail to meet the established requirements. Full public access to this information is important.

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International Covenant on Economic, Social and Cultural Rights, G.A. res. 2200A (XXI), 21 U.N.GAOR Supp. (No. 16) at 49, U.N. Doc. A/6316 (1966), 993 U.N.T.S. 3

Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology of Food Biotechnology in Canada*, An Expert Panel Report on the Future of Food Biotechnology prepared by the Royal Society of Canada, (Ottawa: January, 2001).

Endorsements

Canadian Environmental Law Association
Sierra Club of Canada
Canadian Institute for Environmental Law and Policy (CIELAP)
Pollution Probe
Protect Our Water and Environmental Resources (POWER)
The Allergy & Environmental Illness Group
Citizens Environment Alliance of southwestern Ontario
Univeristy of Manitoba Recycling and Environmental Group
Bert Riggall Environmental Foundation
Sierra Youth Coalition
Environmental Defense Canada
Citizens' Stewardship Coalition
Poetical Asylum
New Brunswick Partners in Agriculture
Nova Scotia Allergy and Environmental Health Association
Canadian EarthCare Society
Saint John Citizens Coalition
One Sky - Canadian Institute of Sustainable Living
Le goupe environmental Calhoun/Memramcook
The Regional Environmental Action Committee
Friends of the Oldman River
Parksville Streamkeepers Society
Inter-church Uranium Committee/Educational Cooperative Saskatoon
Tantramar Environmental Alliance (TEA)
The Gaia Group
STORM Coalition
PEI Eco-Net
PEI Climate Change Hub
Stop the Hogs Coalition, Saskatchewan
Community Recycling Committee
Healthy Food Choices Group
People Against Nuclear Energy
Qualicum Beach Streamkeepers
Hog Watch Manitoba, Inc
Conservation Council of New Brunswick

Endnotes

[1] CELA and Pollution Probe, Toxic Substances - Focus on Children - Developing a List of Substances of Concern to Children, forthcoming.

[2] Communication from the European Commission on the Precautionary Principle" to the Committee on Trade and Environment, World Trade Organization. WT/CTE/W/147; G/TBT/W/137, 27 June 2000.

[3] Bergen Ministerial Declaration on Sustainable Development in the ECE Region (Economic Commission for Europe, paragraph 7) May 1990; prepared for the preparatory process for the UN Conference on Environment and Development, and endorsed by the Supreme Court of Canada in the Hudson decision (*114957 Canada Ltée (Spraytech, Société d'arrosage) and Services des espaces verts Ltée/Chemlawn* v. *Town of Hudson*, 2001 SCC 40 at paras. 31 and 32.

[4] CELA and Ontario College of Family Physicians, Children's Health Project: *Environmental Standard Setting and Children's Health*, CELA, 2000 at p. 223.

[5] Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology of Food Biotechnology in Canada*, An Expert Panel Report on the Future of Food Biotechnology prepared by the Royal Society of Canada, (Ottawa: January, 2001). p.191

[6] Ibid. p 205
[7] Ibid. p.212