

Regulating Toxic Substances in Consumer Products

Response to the Discussion Paper on Canada's Food and Consumer Safety Action Plan

Submitted to:

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Background on CELA

The Canadian Environmental Law Association (CELA) is a non-profit, public interest organization founded in 1970. CELA is an environmental law clinic – within Legal Aid Ontario - dedicated to providing legal services to low income people and disadvantaged communities, and advancing the cause of strong environmental protection through advocacy, education and law reform.

In addition to providing direct legal representation and summary advice, CELA's law reform and public educational mandates include advocacy on ensuring access to environmental justice and protecting public environmental rights. This work occurs at the local, regional, provincial, national and international level.

Scope of CELA's Comments in Response to the proposed Action Plan

We provide general comments here on the proposed Action Plan. However, in the three areas included (Food Products, Health Products and Consumer Products) we focus most of our comments in the area of consumer products. For the reasons noted herein, we also include discussion of complementary product-focused reforms to the *Canadian Environmental Protection Act*.

Background – Toxic Chemicals Originating in Consumer Products

Members of our staff have worked on issues of consumer product safety for many years, particularly with respect to investigating the risks to prenatal and child health from chronic exposures to low levels of lead, phthalates, flame retardants, bisphenol A and fluorinated chemicals. We are also extensively involved in efforts to reduce exposure risks to known and suspected carcinogens in the environment and consumer products and to progressively eliminate persistent organic pollutants.

In 2000, a report by CELA and the Ontario College of Family Physicians included a detailed analysis of the shortcomings of the *Hazardous Products Act* in general, and the regulation of lead in consumer products and pesticides, in particular.¹ Since that time, we have been at the forefront of Canadian activity summarizing the research about the greater exposure and vulnerability of children to toxic chemicals.²

For chemicals that originate in consumer products, increasing evidence points to indoor

¹ CELA-OCFP, 2000. *Environmental Standard-Setting and Children's Health*. Joint Project of the Canadian Environmental Law Association and the Ontario College of Family Physicians Environmental Health Committee. On-line at: <u>www.cela.ca</u>

² See e.g., Cooper et al, for Toronto Public Health, *Environmental Threats to Children: Understanding the Risks; Enabling Prevention*, 2005; and Canadian Partnership for Children's Health and Environment, Child Health and the Environment – A Primer, 2005. www.healthyenvironmentforkids.ca

air, surfaces, including surfaces of food or water containers, and especially household dust as important exposure media. Releases occur during normal use, and can often increase over time as products age. Chemicals found in house dust and indoor air can include (but are not limited to) fluorinated chemicals, phthalates, brominated flame retardants, nonylphenol ethoxylates, parabens, volatile organic compounds, organotins, and numerous additional metals including lead and mercury, along with pesticides. The sources of many of these chemicals include a wide array of products on the Canadian market including baby and children's products, toys, cosmetics and personal care products, cookware, food containers and packaging materials, household cleaners, building materials, home maintenance products, furniture and fabrics, art materials and many different kinds of electronic equipment.³

Many recent biomonitoring studies, including robust population-based surveys conducted by the US Centers for Disease Control, reveal widespread human exposure to multiple chemicals.⁴ There is also increasing understanding that consumer products are a significant source of exposure to the toxic burden of all Canadians, a burden that biomonitoring results show is disproportionately higher in children than adults. These studies reveal body burdens of phthalates, flame retardants, fluorinated chemicals, metals and pesticides. Biomonitoring also reveals body burdens of banned or severely restricted chemicals including PCBs, dioxins and organochlorine pesticides. A common feature of most of these chemicals is their presence in consumer products.

In addition to a longstanding focus on the impact on children of chemicals in consumer products, CELA has been closely involved in the implementation and ongoing parliamentary review of the *Canadian Environmental Protection Act, 1999* (CEPA).⁵ That work has consistently revealed inadequate regulation of chemicals that are deemed toxic under CEPA and also found in consumer products, particularly in imported products. While some regulatory action has occurred within product-specific regulations established under CEPA, and under the *Hazardous Products Act*, large gaps remain in terms of adequate regulation of toxic chemicals in products and between these two federal statutes. Further, it is necessary to address gaps and improve coordination with the *Food and Drugs Act* as the example of phthalates, discussed below, illustrates.

To address persistent organic pollutants in consumer products, we have been closely involved in the six-year effort to categorize substances on the Domestic Substances List

³ Cooper, K, K Khatter and J Catrilli, 2007. Using the *Canadian Environmental Protection Act* to Regulate Toxic Substances in Products. Lessons learned from two cases studies – lead and phthalates. Report prepared for Health Canada.

⁴ The 1st, 2nd and 3rd reports of the National Biomonitoring Program are posted on-line by the Centers for Disease Control at: <u>http://www.cdc.gov/biomonitoring/</u>

⁵ CELA and Environmental Defence (Pollution Watch): Perfluorinated Substances and the Canadian Environmental Protection Act (CEPA). Submission to the Senate Standing Committee for Energy, the Environment and Natural Resources, February 20, 2007; Legislative Overlap and Interdepartmental Jurisdiction with respect to Consumer Products and the In Commerce List, Remarks for a presentation to the Parliamentary Review of the *Canadian Environmental Protection Act, 1999*, December 11, 2006; Reforming the *Canadian Environmental Protection Act*

Submission to the Parliamentary Review of CEPA, 1999, June, 2006. On-line in "Reviewing CEPA" collection at: <u>http://www.cela.ca/coreprograms/detail.shtml?x=2139</u>

as well as working closely with colleagues in the International POPs Elimination Network in efforts to implement, and expand the chemicals covered by, the Stockholm Convention on POPs. We are very supportive of current efforts to expand the POPs Treaty via nomination of nine chemicals, or chemical groups, by the European Commission⁶ most of which are in consumer products including several flame retardants, polychlorinated naphthalenes, used for cable insulation, and short-chained chlorinated paraffins used in metal working and leather finishing.

Within the Parliamentary Review of CEPA, we have called for the use of CEPA to address toxic substances in consumer products since this law provides a comprehensive legal tool to address this growing problem insofar as it has an overarching mandate for the prevention of harm and the protection of environment and human health. CEPA provides for tools that can influence and/or regulate the use of substances across their entire life cycle, including in products. Application of both the *Hazardous Products Act* and the *Food and Drugs Act* end with product use and are thus far more limited in comparison. The potential toxicity of chemicals in consumer products exists prior to their use in products and can extend beyond product use to disposal, especially if they are persistent or bioaccumulative. Occupational exposures, environmental emissions and waste management options, whether during reuse or recycling, incineration or landfill, present continued opportunities for these substances to exert toxic effects on humans or the environment including as metabolites or products of physical/chemical breakdown or combustion.

In its report on public hearings into CEPA, the Standing Committee on Environment and Sustainable Development recommended that CEPA be used to regulate products containing toxic substances. The Committee also recommended a review of the *Hazardous Products Act* in order to better coordinate it with CEPA.⁷

The Example of Phthalates

Phthalates are a large group of chemicals, some in high volume use, with many applications in consumer products. These chemicals can variously fall under the purview of four federal statutes: the *Canadian Environmental Protection Act* (for chemical risk assessment and risk management), the *Hazardous Products Act* (children's products and toys and many additional product applications), the *Food and Drugs Act* (cosmetics, food packaging and medical devices) and the *Pest Control Products Act* (pesticide formulants).

Assessments of exposure and toxicity of several phthalates done during the 1990s by the federal government illustrate an approach to toxic substances in products that too easily allows for gaps, inconsistencies and lack of coordination.

⁶ EC - European Commission (2004) Chemical pollution: Commission wants to rid the world of more nasty substances. Press release, August 11, 2004. On-line at: <u>http://europa.eu.int/comm/environment/press/index.htm</u>

⁷ The *Canadian Environmental Protection Act, 1999* – Five-Year Review: Closing The Gaps, Report of the Standing Committee on Environment and Sustainable Development, on-line at: http://cmte.parl.gc.ca/emte/CommitteePublication.aspx?SourceId=204099

The need to include consumer products in exposure assessments is increasingly recognized. While exposure assessments routinely address food, drinking water, soil or air they have often not accounted for exposures resulting from use in consumer products, or where they do, can exclude important media such as house dust.⁸ For example, CEPA assessments of the phthalates DEHP,⁹ DBP¹⁰ and BBP¹¹ (conducted in the 1990s) did not consider exposure from all sources. Exposure assessments:

- for DEHP, did not consider medical devices, indoor air or house dust, or breast milk.
- for DBP, did not include breast milk or formula, direct contact with children's products or other household products nor house dust or cosmetics.
- for BBP, did not consider cosmetics, consumer products, house dust, breast milk or infant formula.

In general, across all media, exposure data are typically weak or missing. Modeling is often used in exposure assessments to estimate the aggregate exposure from all pathways. When exposures from products are unknown, ignored or under-estimated, exposures assessments will be inaccurate.

Nor are the additive or synergistic effects of multiple chemical exposures adequately assessed or even assessed at all. Methods are not available to assess the combined effect of dissimilar chemicals. For groups of substances with a common mechanism of toxicity, the aggregate exposure of chemicals in these groups should be factored into an assessment of overall toxicity for the entire group. Such an approach is only beginning to be applied in the assessment of pesticides.¹² As well, in the case of phthalates, (and other chemicals such as brominated flame retardants), the scientific evidence reveals that breakdown products, or metabolites, have similar toxicity concerns to the parent substance. This evidence underscores the need to include these metabolites as part of group assessments of chemicals with common mechanisms of toxicity.¹³

⁸ House dust is increasingly recognized as an important and overlooked exposure medium for indoor contaminants, especially for children. For evidence on phthalates, see e.g.: Bornehag, C-G et al. The Association between Asthma and Allergic Symptoms in Children and Phthalates in House Dust: A Nested Case–Control Study. *Environ.Health Perspect*. October 2004. 112(14): 1393–1397.

⁹ Government of Canada. *Canadian Environmental Protection Act* Priority Substances List Assessment Report: Bis(2-ethylhexyl) phthalate. 1994.

¹⁰ Government of Canada. *Canadian Environmental Protection Act* Priority Substances List Assessment Report: Bis(2-ethylhexyl) phthalate. 1994.

¹¹ Government of Canada. *Canadian Environmental Protection Act* Priority Substances List Assessment Report: Dibutyl phthalate. 1994.

¹² As of January, 2001, the Pest Management Regulatory Agency has published guidance on identifying pesticide with common mechanisms of toxicity. See: PMRA Science Policy Note: Guidance for Identifying Pesticides that have a Common Mechanism of Toxicity for Human Health Risk Assessment (SPN2001-01) January 25, 2001. This document notes that "the cumulative risk assessment process that the PMRA will use will be described in a forthcoming PMRA science policy guidance document once appropriate methods are developed." The agency has yet to publish this policy guidance.

¹³ See e.g., Gray L.E. Jr et al. Perinatal exposure to the phthalates DEHP, BBP, and DINP, but not DEP, DMP, or DOTP, alters sexual differentiation of the male rat. 2000. *Toxicological Science* 58: 350-365; Swan, S.H. et al. Decrease in Anogenital Distance among Male Infants with Prenatal Phthalate Exposure. *Environmental Health Perspectives*. August 2005; 113(8): 1056–1061; and Blount, B.C. et al. Levels of

Again, such problems are illustrated in the CEPA assessments of phthalates. Multiple shortcomings are apparent in the toxicity assessments under CEPA, in most cases because they were conducted over ten years ago.

- DEHP was deemed CEPA-toxic on the basis of a developmental study in mice that showed increased resorptions, dead fetuses and potential teratogenic effects. More recent data point to additional impacts on the male reproductive system.
- The DBP assessment is nearly fifteen years old. Determination that DBP was not CEPA-toxic arose in an information vacuum. The assessment focused entirely on the parent substance, did not account for large gaps in knowledge about developmental and reproductive toxicity (and, as noted above, excluded known and potential exposure sources).
- The BBP assessment (that concluded BBP was not CEPA-toxic) did not accept evidence about toxicity to the testes or estrogenic activity in breast cancer cells. The result was a Tolerable Daily Intake (TDI) that, like the TDI for DBP, did not include an extra safety factor for children. Nor did the assessment consider evidence about the developmental toxicity of BBP metabolites.

Similar shortcomings are apparent in the application of the more limited, non-regulatory review of DINP by Health Canada's Consumer Products Division (published in 1998).¹⁴ The assessment looked only at liver and kidney toxicity and not the anti-androgenic effects similar to those seen with DEHP, DBP and BBP.

A recent study of DINP metabolites found that monoisononyl phthalate (MINP), historically thought to be the main breakdown product of DINP, is only a minor metabolite. Three of the major ones are mono(carboxyisooctyl) phthalate (MCIOP), mono(oxoisononyl) phthalate (MOINP), and mono(hydroxyisononyl) phthalate (MHINP). The authors suggest that DINP biomonitoring has underestimated the population exposure to the chemical by using urinary MINP levels as a biomarker.¹⁵

Despite concluding that DINP exposure in soft vinyl teethers and rattles created risks to children, no Canadian regulation was written to limit or prohibit DINP in children's products. Instead, in 1998 Health Canada warned physicians, parents and other caregivers to dispose of these items, published a list of those they knew were DINP-free (though not a list of those containing DINP) and relied on industry voluntarily withdrawing the toys. Greenpeace International tests in 2001¹⁶ found that phthalates made up to 40% of the weight of popular brands of soft PVC toys, and found excessive DINP levels in two teether products; toys that at the time would have been legal in the US and Canada but banned in the European Union.

Seven Urinary Phthalate Metabolite Levels in a Human Reference Population . *Environmental Health Perspectives*. October 2000. 108(10): 979-982.

¹⁴ Health Canada. Risk Assessment on diisononyl phthalate in vinyl children's products. Nov 14, 1998. On-line at: <u>http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/1998/1998_85bk7_e.html</u>

¹⁵ Silva, M.J. et al. Oxidative Metabolites of Diisononyl Phthalate as Biomarkers for Human Exposure Assessment. *Environ Health Perspect* Aug 2006, 114(8): 1158-1161.

¹⁶ Greenpeace International. Toxic Chemicals in a Child's World: An Investigation into PVC Plastic Products. June 2001. <u>http://www.greenpeace.eu/downloads/chem/childworldpvcproducts.pdf</u>

Canada has done nothing further about DINP but has proposed a regulation¹⁷ under the *Hazardous Products Act* that would ban DEHP in children's products imposing a limit of less than 0.1%, in accord with limits already in place in the European Union. In contrast, EU legislation bans 3 phthalates (DEHP, DBP and BBP) from all toys and child care articles and 3 other phthalates (DINP, DIDP, and DNOP) in toys for children under 3 years that could be placed in their mouths.¹⁸

Under the *Food and Drugs Act*, recent Canadian regulation publishes a "Hot List" of ingredients not allowed in cosmetics as well as requirements for labelling of cosmetic ingredients.¹⁹ While this regulation represented a progressive move for Canada, neither the list nor the labelling requirements, includes any phthalates, including DEHP, classified as CEPA-toxic. Likewise, BBP and DBP, both classified by European and California authorities as developmental and reproductive toxins, are not on the Hot List. DBP and DEHP have both been banned from cosmetics in Europe since 2003.²⁰

For phthalates in food packaging, Health Canada provides a list of polymers²¹ approved for use in food packaging, including poly vinyl chloride (PVC). This list provides no indication that specific phthalates, or the amounts used in the PVC, are restricted for food packaging. Rather, this approach to regulating food packaging appears to simply ignore the potential for phthalates to absorb into food. Nor, therefore, is there any attempt to address the fact that all three of these phthalates are lipophilic so absorption is likely to increase with higher fat foods. A Canadian survey of butter and margarine wrapped in aluminum foil found BBP, DBP and DEHP in these products.²² Packaged foods can therefore add to the overall body burden of phthalate exposure and no action has been taken under the F&DA to reduce this contribution.

On medical devices, the *Food and Drugs Act* is equally silent. The use of DEHP in medical devices is widespread. Clear evidence shows that patients receive large doses, particularly during intensive procedures, and infants and children are more highly exposed. With the primary toxicity of DEHP on the developing male reproductive

¹⁷ See: Consultation regarding the proposed prohibition of di (2-ethylhexyl) phthalate (DEHP) under the *Hazardous Products Act* (HPA), on-line at: <u>http://www.hc-sc.gc.ca/ahc-asc/public-</u>consult/consultations/col/phtalate/index_e_html

¹⁸ Directive 2005/84/EC of the European Parliament and of the Council of 14 December 2005 amending Council Directive 76/769/EEC on the approximation of the laws of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles. *Official Journal of the European Union*, 27.12.2005. L/344-40 -L/344/43. On-line at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:344:0040:0043:EN:PDF

 ¹⁹ See: Health Canada, on-line information about Cosmetics and Personal Care at: <u>http://www.hc-sc.gc.ca/cps-spc/person/cosmet/index_e.html</u>; and *Cosmetic Regulations* (C.R.C., c. 869)
²⁰ Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003

²⁰ Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products. Official Journal of the European Union, 11.3.2003. L/66-26 - L/66/35. Online at: <u>http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/1_066/1_06620030311en00260035.pdf</u>

 ²¹ Lists of acceptable polymers for use in food packaging applications. On-line at: <u>http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/polymers_tc-polymere_tm_e.html</u>.
²² Page B.D. & Lacroix G.M. Studies into the transfer and migration of phthalate esters from aluminium

²² Page B.D. & Lacroix G.M. Studies into the transfer and migration of phthalate esters from aluminium foil-paper laminates to butter and margarine. *Food Addit Contam* 9:197-212 (1992).

system, DEHP-containing devices put young boys and male fetuses at proportionally higher risk.

Finally, some pesticide formulants contain phthalates, bringing a fourth statute, the *Pest Control Products Act*, into the regulatory picture.²³ Pesticide formulants are another area where the Chemicals Management Plan (discussed further below) is prompting the need to update the evaluation and classification of pesticide formulants for their potential toxicity.

Four Federal Laws Affecting Products – Gaps, Uncoordinated and Inconsistent Approaches

Phthalates are but one example of situations where hazardous chemicals have come to be used in many different consumer products and normal use and disposal creates unanticipated health risks, particularly to the fetus or young child. Three and sometimes four federal laws can come into play and there are clear indications of gaps as well as uncoordinated and inconsistent approaches being applied with none of these laws doing an adequate job of controlling potentially hazardous and certainly cumulative exposures.

The *Hazardous Products Act* and the *Food and Drugs Act* are similar in terms of focusing almost exclusively on end-use of products or commodities and often in a reactive, or after-the-fact, manner. For example, in situations of exposure to small amounts of substances where chronic toxicity is a concern, such as lead in children's products, responses to complaints or problems have tended to occur, if at all, only after they have been identified, often long after they have been repeatedly identified, and after harm may have already occurred.²⁴ Their legislative provisions and associated regulations are also structured to come into play only for products or commodities that are specifically identified or itemized in these laws or their regulations, within which very few chemicals are included.²⁵

Neither of these two laws has been applied to phthalates at all with the recent exception of the proposed ban on DEHP in children's items, a fairly hollow move that regulates the status quo since voluntary phase-out is occurring due to regulatory action already well in place elsewhere.

The *Canadian Environmental Protection Act* provides broad authority to regulate CEPAtoxic substances in products across their production chain, from import through to disposal – but designation of DEHP as CEPA-toxic has little impact on its continued use in consumer products. The same can be said for lead (designated CEPA-toxic in 1988) in consumer products. The decision to ban the flame retardants penta-BDE and octa-BDE

²³ Pest Management Regulatory Agency, 2007. PMRA List of Formulants. Regulatory Note 2007-04. 28-June, 2007. On-line at: <u>http://www.pmra-arla.gc.ca/english/pdf/reg/reg2007-04-e.pdf</u>

²⁴ Cooper et al, 2007, *op. cit.* Chapter 2, Lead Case Study; and CELA-OCFP, 2000, Chapter 8, Standard Setting for Lead – The Cautionary Tale. *op. cit.*

²⁵ *Ibid*, and see, e.g., Section 23 in the following excerpt from the *Food and Drugs Regulations*: http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/legislation/e_d-text-2.pdf

but not deca-BDE is a similarly hollow move. This ban applies to chemicals voluntarily withdrawn in 2004 and allows continued (and increasing) use of deca-BDE while ignoring compelling scientific evidence about the toxicity and bioaccumulation of deca-BDE.²⁶

Regulation of Products; Regulation of Trade

In a global market, any domestic consideration of the regulation of products will be influenced by international trade agreements. The Canadian economy is one of the most trade-dependent in the world. Several government policies mention this reality. Of particular note are the Government of Canada Regulatory Policy,²⁷ the Cabinet Directive on Streamlining Regulation,²⁸ the Guide to the Regulatory Process for Treasury Board Secretariat Program Analysts,²⁹ the Toxic Substances Management Policy,³⁰ and the Framework for the Application of Precaution in Science-Based Decision Making about Risk.³¹

These policies include either a requirement to consider trade agreements when setting environmental policy or, in some cases, direct that economic and trade considerations, including voluntary over regulatory measures, be considered paramount. As a result, we are very concerned that consistently weak regulatory action on toxic substances in consumer products reflects an overall approach where trade trumps health.

This implied paramountcy of trade and non-regulatory approaches is evident in the OECD regulatory reform program³² which focuses particularly on strengthening "market openness and competition, and [reducing] regulatory burdens." With a focus on "horizontal" and "whole-of-government" aspects of regulatory systems, specific regulatory contexts can be lost. The OECD program notes that:

Isolated efforts cannot take the place of a coherent, whole-of-government approach to create a regulatory environment favourable to the creation and growth of firms, productivity gains, competition, investment and international trade.

However, such approaches will tend to weaken the influence of regulatory departments, such as Health Canada or Environment Canada. These departments, in contrast to central

²⁸ Cabinet Directive on Streamlining Regulation, on-line at: <u>http://www.regulation.gc.ca/directive/directive01-eng.asp</u>

²⁶ See: Notice of Objection Re: Proposed Polybrominated Diphenyl Ethers Regulation, Filed by Sierra Legal Defence Fund on behalf of the David Suzuki Foundation, Environmental Defence and Canadian Environmental Law Association, February 14, 2007; and Supplement to Notice of Objection Re: Proposed Polybrominated Diphenyl Ethers Regulation, November, 2007. On-line in collection "PBDEs - Flame Retardants as problematic as PCBs" at: http://www.cela.ca/coreprograms/detail.shtml?x=2310

²⁷ Government of Canada, Privy Council Office, 1999. Government of Canada Regulatory Policy. On-line at: http://www.tbs-sct.gc.ca/ri-qr/ra-ar/default.asp@language=e&page=publications&sub=governmentofcanadaregula.htm

²⁹ Treasury Board Secretariat, A Guide to the Regulatory Process for TBS Program Analysts. On-line at:

http://www.tbs-sct.gc.ca/ri-qr/processguideprocessus_e.asp Last modifed, Dec. 9, 2002. ³⁰ Policy and associated documents on-line at: http://www.ec.gc.ca/toxics/en/index.cfm

³¹ Privy Council Office, Government of Canada, 2003. A Framework for the Application of Precaution in Science-Based Decision Making about Risk. On-line at: http://www.pco-

bcp.gc.ca/default.asp?Language=E&page=publications&doc=precaution/precaution_e.htm ³² OECD OECD OF CONTRACT TO THE ACCEPTER OF THE ACCEPTER

OECD, OECD Guiding Principles for Regulatory Quality and Performance (OECD, 2005), p. 1.

agencies, or over-arching government policies, are more likely to have the scientific expertise and the legislative obligations to implement regulatory objectives. In its very different cross-governmental role, the Auditor General commented in the Annual Report for 2000³³ on the Government of Canada Regulatory Policy, noting that the government:

... should explain to Canadians and the government's regulatory and inspection community its priorities for health and safety regulatory programs, particularly the balance that the government has reached to protect Canadians and address budget, social, economic and trade objectives. The government should revise its regulatory policy and other policies to reflect this emphasis.

The Auditor General further recognized that citizens support health and safety over economic considerations in the areas of health and the environment and noted how government regulatory policy failed to indicate clearly the relative priorities of health, environmental and economic factors:

Health Canada's 1999 National Consultations Summary Report found that Canadians believe that 'health and safety must take precedence over economic and other considerations.' However, the government's regulatory policy contains potentially conflicting requirements. The policy requires that costs and economic objectives be considered when developing and implementing regulatory programs. In our view, there is a need for the government to clarify the priorities of the regulatory policy for health and safety regulatory programs and clarify the balance it has reached to protect Canadians[,] and address costs and other objectives. *Our concern for priorities of these programs stems from the emphasis on economic considerations in the regulatory policy* ... (emphasis added)

Eight years later it is probably fair to say that this belief among Canadians is stronger than it has ever been.

Finally, the existence of these over-arching policies and guidelines, and the paramountcy they give, or attempt to give, to economic and non-regulatory considerations, creates a lack of public transparency about regulatory objectives but also creates confusion about whether they are mandatory or merely advisory. The OECD³⁴ has also noted the lack of clarity:

[O]ne criticism of the Canadian approach may indeed be that it is too comprehensive, in the sense that drafters are subject to a larger number of quality criteria and procedural requirements than can reasonably be understood and implemented. For example, the Privy Council Office Web site lists a total of 16 publications, with seven relating to different requirements of the *Regulatory Policy* such as cost benefit analysis, compliance strategies, [and] writing a RIA statement. The question of whether regulators can be expected to assimilate all of this material effectively necessarily arises. Moreover, there may be issues in terms of the ability of the centre of government itself to keep up to date with this range of material.

We have additional concerns about an approach that favours non-regulatory options over regulatory ones in the context of the proposed "general safety requirement" as discussed

³³ Chapter 24, 2000 Report of the Auditor General of Canada, "Federal Health and Safety Regulatory Programs."

³⁴ Organisation for Economic Co-Operation and Development, OECD Reviews of Regulatory Reform: Regulatory Reform in Canada: Government Capacity to Assure High Quality Regulation (OECD, 2002), pp. 21-22.

further below.

The Proposed General Prohibition

The Action Plan for Consumer Products notes that it will prevent problems through the creation of a "new general prohibition that would allow Health Canada to address any consumer product in Canada that poses a danger to the health or safety of the public" (Action Plan, p. 18).

We cannot comment on this proposal without seeing actual legislative language. However, we are concerned if this proposal is substantially the same as the General Safety Requirement (GSR) proposed during previous consultations held in 2004, to address shortcomings in the regulation of risks posed by consumer products. In analyzing this previous proposal, we investigated the GSR approach in the European Union which provides that producers must produce only safe products, that is, products 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.³⁵

In contrast, the analysis by non-governmental organizations, and prepared by the Canadian Environmental Law Association, finds the Canadian GSR proposal to be very different.³⁶ We found that although the notion of a GSR proposal could be a useful addition to law, providing greater jurisdiction to Health Canada and supplementing civil liability for unsafe products, as proposed, it would not provide an effective substitute for proactive, regulatory action for several reasons.

It proposed a weak and vague approach to first defining and then verifying "undue risk." This vagueness extended to provisions removing undefined "barriers to innovation," and allowing industry the flexibility to meet unclear "standards." The GSR was described as allowing for a "standard" (e.g., from another country or practices followed within a particular industry) to be enforced even if it was not incorporated in Canadian regulations. This approach raised many questions about how 'standards" would be developed, generally accepted, recognized, monitored, and in particular, enforced.

CELA found instead that the GSR, as proposed, would constitute a retreat from lawmaking and would deprive Canadian citizens of the opportunity to participate in standardsetting and hold government accountable for standards. Citizens would have no opportunity to participate in the formation of standards from other countries or industry associations. Nor could they even know what "standard" applies to a product if it is not legislated and published.

³⁵ Direct 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. *Official Journal of the European Communities* 15.1.2002. L 11/4 – L 11/17.

³⁶ Canadian Environmental Law Association, 2004. Health Protection Legislative Renewal: Analysis and Recommendations. On-line at: <u>http://62.44.8.131/publications/cardfile.shtml?x=1441</u>

We also found it very doubtful that a successful prosecution for failure to meet a GSR could be based on 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.

We further noted that the best and only reliable measure of "general acceptance" of a standard is its incorporation into regulation. As proposed in 2004, the GSR would substitute theoretical private liability and after-the-harm criminal prosecutions for proactive policies intended to prevent harm. As such, it also would not extend the reach of Canadian law or regulations further beyond what the F&DA and the HPA accomplish now in terms of preventing harm rather than just responding afterwards.

Hence, we are supportive of general product safety requirements to make manufacturers and importers responsible for the safety of their products. However, we will review the new proposal for a "general prohibition" in light of this prior analysis.

The Need for Law Reform and Coordination

Across the three federal statutes discussed here, unlike the recently revised *Pest Control Products Act*, there is a no legal requirement to accurately assess real-world exposure circumstances by aggregating exposure from all sources, including sources unique to children. Nor do these three laws require the assessment, as a group, of multiple chemicals that have a common mechanism of toxicity.

Only the *Pest Control Products Act* imposes a legal duty to assess impacts on children and to include an additional child-focused uncertainty factors during risk assessment of chemicals. Further, only for pesticides is there a legal requirement to re-assess chemicals that have been previously assessed to take into account new scientific information. In the example of phthalates, the scientific evidence in support of regulatory action (and inaction) in Canada is woefully out of date. Nothing in CEPA or the *Hazardous Products Act* compels a re-assessment of this information. None of these four laws require assessments to consider metabolites when parent chemicals are assessed – an issue that the phthalate example illustrates as being necessary to accurately assess exposure to groups of chemicals with similar toxicity.

Beyond the need to improve the assessment of exposure and toxicity of chemicals, the problem of toxic substances in consumer products underscores the broader consequences of modern-day international trade. In response to the staggering volume of often over-packaged consumer goods in international commerce, where legislation addresses these products at all, it typically ends with the sale of the product. The environmental and human health consequences of international trade in consumer goods are increasingly apparent. The sheer volume of garbage created by the millions upon millions of product recalls of 2007 would likely fill a large landfill or keep an incinerator burning for weeks creating toxic emissions in the process. Also during 2007, much needed attention turned

to the world's excessive use and disposal of plastic with the identification of a floating mass of garbage in the Pacific Ocean.³⁷ Dubbed the 'eighth continent,' it is twice the size of Texas and 85% of it is made up of plastic.³⁸ The burgeoning problem of electronic waste generated world-wide but especially from industrialized countries is creating a toxic nightmare for developing countries³⁹ affected by either waste dumping or poorly regulated recycling operations or both with children most seriously affected.⁴⁰ Ironically, recent evidence indicates a new 'circle of poison'⁴¹ created by the recycling of lead in waste electronics in China and its reuse in inexpensive imported jewellery containing dangerous levels of lead.⁴²

In response to this waste management challenge and its origins in consumer products, a rich literature now exists about the concept and necessary implementation details of 'extended producer responsibility' (EPR).⁴³ EPR can play a major role in protecting public health and the environment via better management of products or packages after their use and through redesign of products to reduce their environmental impacts. For toxic substances in products, a central feature of EPR approaches is embodied in the Substitution Principle whereby efforts are made to constantly replace hazardous substances with less hazardous ones. Sweden has adopted this principle as necessary public policy and is developing policy guidance for its implementation. It requires that, where risks to the environment and human health and safety can be reduced by replacing a chemical substance or product either by another substance or by some non-chemical technology, then this replacement should take place.⁴⁴

Progress on EPR in Canada has focused mainly on keeping materials out of landfills and

³⁷ Casey, S. Plastic Ocean. Our oceans are turning to plastic, are we? *Best Life On-line*. 2007. http://www.bestlifeonline.com/cms/publish/health-fitness/Our_oceans_are_turning_into_plastic_are_we_2.shtml

⁸ Reid, D. Earth's Eighth Continent. It swirls, it grows, it's massive floating garbage patch. *The Tyee*. Nov. 21, 2007. On-line at: http://thetyee.ca/News/2007/11/21/PacificGarbagePatch/

³⁹ See e.g., Basel Action Network and Silicon Valley Toxics Coalition, 2002. Exporting Harm: The High Tech Trashing of Asia, on-line at: http://www.ban.org/E-waste/technotrashfinalcomp.pdf; and United Nations Environment Program, Environment Alert Bulletin. E-waste, the hidden side of IT equipment's manufacturing and use. January, 2005. On-line at:

http://www.grid.unep.ch/product/publication/download/ew_ewaste.en.pdf ⁴⁰ Huo et al, Elevated blood-lead levels of children in Guiyu, an electronic waste recycling town in China, Env Health Perspect. 115:1113-1117(2007).

⁴¹ The 'circle of poison' is a term that has been widely used since the 1970s to refer to the selling of products in international markets that are banned or restricted in the country where they were produced. Examples have included banned pesticides or food products containing banned additives. For example, if a pesticide banned for use in the US is used in a South American country on food crops intended for export, it can, (if not caught by border monitoring), return to the US as a residue on food, exposing US citizens whose government banned the use of the pesticide, (but not its export), often due to human health concerns.

⁴² Weidenhamer JD, Clement ML. Leaded electronic waste is a possible source material for leadcontaminated jewelry. Chemosphere. 2007 May 24; doi:10.1016/j.Chemosphere.2007.04.023 [Epub ahead of print]; Weidenhamer JD, Clement ML.Widespread lead contamination of imported low-cost jewelry in the US. Chemosphere. 2007 Mar;67(5):961-5. Epub 2006 Dec 12.

⁴³ See detailed review in: Jackson, J, 2007. Extended Producer Responsibility in Canada, Europe and the United States, in European and Canadian Environmental Law: Best Practices and Opportunities for Cooperation. Canadian Environmental Law Association, January 2007. Chapter 2. On-line at: http://www.cela.ca/coreprograms/detail.shtml?x=2916

⁴⁴ Swedish Chemicals Agency, The Substitution Principle, Report NR 0/07. Stockholm. November 2007. On-line at: http://www.kemi.se/upload/Trycksaker/Pdf/Rapporter/Report8_07_The_Substitution_Principle.pdf

incinerators. Europe began here and has continued on to also encourage design measures with the environment in mind. A central necessity in achieving these goals is to place full responsibility on the producer of a product rather than the seller or consumer.⁴⁵

In response to the e-waste problem, a progressive EPR policy response is occurring in the European Union via technology-forcing, regulatory action in the Waste Electric and Electronic Equipment (WEEE) Directives that restrict the use of certain hazardous substances in electrical and electronic equipment⁴⁶ and reduce toxic substances in the waste stream. ⁴⁷ Measures that require recycling and producer take-back provide incentives for both redesign (to facilitate recycling) as well as elimination of toxic components to reduce the toxicity of the entire production chain, through to waste management. While implementation by Member States is inconsistent,⁴⁸ these and other European Directives are influencing North American companies to eliminate toxic substances such as lead and mercury from their e-products to ensure eligibility of sales in the EU.⁴⁹

There is a clear need for better coordination across federal statutes that address chemicals in products. More fundamentally, there is a need to modernize these laws as is tentatively contemplated (at least for consumer products) in the Action Plan and as has been discussed at length during the ongoing CEPA review. However, we note that the Action Plan, in its review of Food Products and Health Products, identifies several areas where there are gaps or overlaps between related pieces of legislation. The section on Consumer Products however does not mention either the *Canadian Environmental Protection Act* or the Chemicals Management Plan.

Statements from Health Canada officials during 2007,⁵⁰ including the Minister of Health,⁵¹ repeatedly refer to the Chemicals Management Plan (CMP) as Canada's world-leading plan to address chemical risks. In particular, a key objective of the CMP is noted as providing an opportunity to integrate government activities: "The Chemicals Management Plan will strengthen CEPA's coordination with other federal statutes, including: *Hazardous Products Act, Food and Drugs Act* and *Pest Control Products*

⁴⁵ Jackson, 2007, *op. cit.*

⁴⁶ Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. *Official Journal L* 037, 13/02/2003 P. 0019 – 0023 On-line at: <u>http://eur-</u>

 ⁴⁷ Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE) - Joint declaration of the European Parliament, the Council and the Commission relating to Article 9. *Official Journal L 037*, *13/02/2003 P. 0024 – 0039*. On-line at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0096:EN:HTML

⁴⁸ van Rossem, Chris, Naoko Tojo & Thomas Lindhqvist, Lost in Transposition: A Study of the Implementation of Individual Producer Responsibility in the WEEE Directive, September 2006.

⁴⁹ Canadian Environmental Law Association, 2007. European and Canadian Environmental Law: Best Practices and Opportunities for Cooperation. On-line at: <u>http://www.cela.ca/topical/detail.shtml?x=2916</u>

⁵⁰ Children's Health and the Environment – The Canadian Tool Set. Address by Paul Glover, Director General, Safe Environments Program, Health Canada to the National Policy Consultation Series on Children's Health and the Environment, Ottawa, January 24, 2007. ON-line at: <u>www.pollutionprobe.org</u> ⁵¹ Speech for the Hon. Tony Clement, Minister of Health to National Policy Consultation Series on Children's Health and the Environment, Ottawa, January 24, 2007. ON-line at: <u>www.pollutionprobe.org</u>

*Act.*⁵² It is troubling therefore for the Action Plan discussion paper addressing reform of consumer product legislation to not even mention either CEPA or the CMP.

We recognize that the categorization effort under CEPA and the resulting CMP is a significant step forward in setting priorities for action on toxic substances, including in consumer products. We strongly recommend that the federal plan for law reform governing consumer products be closely integrated with CEPA and the CMP such that those aspects of the Action Plan having to do with consumer products can truly live up to its stated promise of a "renewed focus on active prevention."

Reactive Measures to Address Consumer Products

We respond to the Action Plan by addressing the claims made in the discussion paper, and at the consultation held on January 24th, that these proposals "make history" ⁵³ and "modernize Canadian law, as our international counterparts have done"⁵⁴ in terms of introducing measures to prevent problems and apply a precautionary approach.

For the consumer products proposals, we did not reach this conclusion. Rather, we find the proposed "Canadian Consumer Product Safety Act," as described at the January 24th consultation, to be primarily reactive. We were told that this proposed bill would replace the current Part 1 of the *Hazardous Products Act*. We accept that it would include important and useful reforms including product recall powers, product traceability and related improvements in record keeping and reporting, and updated provisions related to corrective measures, inspections, offences, fines and penalties. We generally support these proposals. For the general prohibition proposal, we will await the text of the bill to respond in detail.

Further details, and related discussion, beyond those included in the Action Plan discussion paper were provided at the January 24th consultation. Four areas are discussed further here. While we generally support each of these proposals, they are all reactive rather than proactive provisions.

First, on the issue of **traceability**, we support provisions that will require product suppliers to maintain accurate records to support tracing of products/components along the supply chain to facilitate tracking of products requiring recall or other corrective measures. We echo suggestions made on January 24th that this responsibility for tracing should include assurance that companies who must recall products must also ensure proper disposal so products are not sent to other countries. In addition, the requirement to disclose records should ensure provisions for public access to this information.

 ⁵² Consumer Products, Chemicals and Health. Remarks by Sue Milburn-Hopwood, Safe Environments Program, Health Canada and Robert Iannero, Consumer Product Safety, Health Canada to National Policy Consultation Series on Children's Health and the Environment, Montreal, September 26, 2007. ON-line at: www.pollutionprobe.org
⁵³ As described by Meena Ballantyne, ADM, Health Products and Food Branch, Health Canada in her

⁵³ As described by Meena Ballantyne, ADM, Health Products and Food Branch, Health Canada in her opening remarks to the 24 January 2008 Technical Consultation on the Food and Consumer Safety Action Plan.

⁵⁴ *Ibid*.

Second, regarding **mandatory reporting,** we support the establishment of new requirements for manufacturers or importers to report details of significant product health or safety incidents or product defects. We are interested in reviewing the language of regulations that would specify these requirements noting that clear criteria are necessary to define a significant or serious incident or a product defect. Like the provisions for traceability, it is in the public interest to provide for public access to this information.

Third, we strongly support new requirements for **record keeping** of health and safety information that suppliers would be expected to collect, maintain and make available or report to the Minister.

Across each of the above three areas, we suggest that the bill should provide for a corresponding government duty to act to regulate products when receipt of such information indicates a risk to public health or safety.

Fourth, among the **corrective measures** to be provided for in the bill, these were listed at the January 24th meeting as including: stop orders (manufacture, importation, distribution, advertising ,sale); product recalls, issuing of public warnings/advisories; product labelling requirements; establishing conditions around product returns. While these are all useful additions to legislation that can more effectively react to problems with products, we note that labelling can be far a more proactive tool than is contemplated in this consultation, as discussed further below.

Of the five additional areas planned for the proposed bill and discussed on January 24th, all but the general prohibition and perhaps some elements of regulation-making authority, are also reactive in nature, including new testing requirements and provisions for offences and fines and penalties.

Proactive Measures to Address Consumer Products

Truly precautionary provisions that would proactively prevent problems from occurring as a result of the use and disposal of consumer products could include the following:

- Across all federal statutes, including the *Canadian Environmental Protection Act*, the *Hazardous Products Act* and the *Food and Drugs Act*, the legal provisions governing the assessment of exposure and toxicity for chemicals should be updated to provide at least as much protection from chemicals as is provided for pesticides under the *Pest Control Products Act*, including explicit recognition of children, including the fetus, as more vulnerable than adults.
- An Action Plan on Consumer Products that fully integrates the broader chemical assessment and full life cycle provisions of the *Canadian Environmental Protection Act* with the *Hazardous Products Act* and the *Food and Drugs Act*.
- An automatic trigger that bans or restricts, via comprehensive regulations, any

products containing CEPA-toxic substances, with an automatic prohibition of CEPA-toxic substances in toys, clothing or furniture or other products intended for children, and similarly automatic labeling requirements to warn pregnant women about CEPA-toxic substances in the workplace or in products used in the home, such as for cleaning or home renovations.

- Active support by Canada for efforts sponsored by the European Commission to expand the Stockholm Convention on Persistent Organic Pollutants to include brominated flame retardants, polychlorinated naphthalenes, short-chained chlorinated paraffins and other persistent organic pollutants used in consumer products.
- Adopt a list approach similar to California Proposition 65⁵⁵ and several European countries that publish chemicals that are undesirable, including for inclusion in consumer products. Include in a Canadian list all CEPA-toxic substances, known carcinogens and developmental and reproductive toxicants and the lists of high hazard substances identified through categorization of the Domestic Substances List (include substances that are produced in high volumes as well as those that are inherently toxicity, regardless of whether they are in high volume production).
- Expand upon the current Action Plan proposals for product labelling to require that products containing substances on the list noted above are labelled, akin to California Proposition 65 requirements, such that consumers have the right to know when such substances are in products, their toxicity concerns that placed them on the list, and precautionary advice to apply when using the product and how to properly dispose of it.
- Expand upon the current Action Plan proposals for traceability, record keeping and reporting by requiring public disclosure of chemicals of concern, (i.e., those on the above list), public disclosure of which products contain these chemicals, and information about safer alternative products; require that the information be available on a publicly accessible web-based database.
- Expand upon the current Action Plan proposals for testing requirements by placing the onus on manufacturers to evaluate impacts of products beyond their intended use, considering the life cycles of hazardous or persistent substances in their products.
- Expand the Action Plan to include, across the management of chemicals in all federal statutes, the Substitution Principle whereby active replacement occurs of hazardous with less hazardous substances where these alternatives are available.
- Establish a product registry such as that currently required in Canada for cosmetics under the Cosmetic Regulations and in keeping with the registry used

⁵⁵ Safe Drinking Water and Toxic Enforcement Act, 1986. California Code of Regulations.

in Sweden that has been helpful in that country in identifying problems.

- Establish national regulations requiring the reduction of packaging and substitution of renewable materials in packaging as well as elimination of packaging containing toxic substances.
- Establish national regulations for the progressive elimination of toxic substances in electronic waste akin to the WEEE Directive and similar initiatives in Europe.

Conclusion

We applaud the federal government's recognition that Canada does not have the legal basis for addressing the hazards and risks associated with consumer products. After the millions upon millions of products recalled world-wide during 2007, there is little public tolerance for the *status quo*, particularly where children are placed at risk. There is also strong public support for proactive, precautionary reform to protect the environment and public health. Unfortunately, the Action Plan for Consumer Products is mostly reactive and does not live up to the promise made by Health Canada officials or the Minister of Health, of modernizing Canadian law, as our international counterparts have done. It does not even mention how it will be integrated with the Chemicals Management Plan, arguably among the more progressive initiatives on chemicals policy in the world at present.

This submission uses the example of phthalates to illustrate how high production volume chemicals, especially groups of chemicals, can be used in myriad products. Despite the fact that phthalates are regulated under CEPA and are in products that are regulated, or potentially regulated, by multiple statutes, there are significant gaps in this regulation as well as an inconsistent and uncoordinated policy response.

As the statute that assesses chemicals for toxicity, considers their entire lifecycle and includes multiple powers to regulate products, the *Canadian Environmental Protection Act* should be considered an integral part of a federal Action Plan for addressing health and environmental concerns with consumer products, including those that are regulated under the *Hazardous Products Act* and the *Food and Drugs Act*. Moreover, the ongoing review of CEPA has provided an extensive canvassing of issues that are central to addressing the problem of inadequate regulation of toxic substances in consumer products. The Action Plan should include a coordinated package of revisions to CEPA alongside the ongoing implementation of the Chemicals Management Plan.

In addition to the largely reactive proposals for reform suggested in the Action Plan for Consumer Products, this submission recommends a series of proactive reforms to reduce or eliminate toxic substances in consumer products, increase public right-to-know about these chemicals, as well as other progressive aspects of Extended Producer Responsibility.