Using the *Canadian Environmental Protection Act* to Regulate Toxic Substances in Products
Lessons learned from two case studies – lead and phthalates

March 30, 2007

Prepared for Health Canada (Contract Reference Number: 4500155747)

Prepared by:

Kathleen Cooper, Senior Researcher
Canadian Environmental Law Association

Kapil Khatter, M.D.

Joseph Castrilli, Counsel
Canadian Environmental Law Association

Please direct inquiries to:
Kathleen Cooper
kcooper@cela.ca
416-960-2284 ext. 221
or 705-324-1608

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Introduction: Toxic Substances in Products

Much recent attention focuses on consumer products as a significant and inadequately addressed source of exposure to toxic substances, particularly in the indoor environment.

Chemical exposures reach humans via many pathways, with some pathways of greater significance than others depending upon the chemicals in question. For chemicals that originate in consumer products, increasing evidence points to indoor air, surfaces, including surfaces of food or water containers, and 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 include (but are not limited to) perfluorinated chemicals, phthalates, brominated flame retardants, nonylphenol ethoxylates, parabens, organotins and numerous additional metals including lead and mercury, along with pesticides.

Biomonitoring of environmental chemicals provides a means of measuring human exposure to chemicals. Many recent biomonitoring studies reveal widespread human exposure to multiple chemicals, including many originating in consumer products, though sample size is often very small. However, results from smaller studies tend to confirm the more scientifically robust and multi-year studies done for the U.S. Centers for Disease Control which provide suggestive evidence that consumer products are a source of exposure to toxic substances.[1]

As is the case with many toxic exposures, children, especially the developing fetus, are identified as particularly vulnerable. Products intended specifically for children are of special concern. The release of chemicals from any products into the indoor environment raises concern due to behavioural and other vulnerabilities of children and the risk of fetal exposures via maternal exposure.

A wide array of products on the Canadian market has been identified as containing potentially harmful chemicals. They include baby and children's products, toys, cosmetics and personal care products, cookware and packaging materials, household cleaners, building materials, home maintenance products, furniture and fabrics, art materials and electronic equipment.

The extent of exposures from consumer products, pathways and health effects are only beginning to be recognized and they are poorly evaluated. Risk assessments for individual chemicals should account for exposures to chemicals in various media. They commonly address exposures in food, drinking water, soil or air. Such assessments may not necessarily account for exposures resulting from use in consumer products.

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

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

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.

The potential toxicity of chemicals in these products can extend beyond product use to disposal, especially if they are persistent or bioaccumulative. 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.

Structure of this report

This report looks at the manner in which federal legal and policy tools address toxic substances in products. It focuses on the *Canadian Environmental Protection Act, 1999,*[2] (CEPA)[3] as the primary tool in Canada to comprehensively address toxic substances, including therefore in products.

Chapter One reviews relevant federal statutes (existing and proposed) that address products. Also reviewed are overarching government policies that influence the implementation of CEPA and other federal statutes. Issues and analyses with respect to the effectiveness of these legal and policy tools continues in reserved for the next three chapters.

A case study approach is used – looking at lead (Chapter Two) and phthalates (Chapter Three).

The lead case study briefly reviews the well-established scientific understanding about the hazards and exposure circumstances for lead, particularly for children. It provides a historical review of federal government regulatory and/or policy actions for lead since the early 1970s. The phthalates case study focuses on scientific evidence about exposure and toxicity for four phthalates. It considers the manner in which that evidence was reviewed and interpreted during the federal government's risk assessment and risk management decisions made under CEPA during the 1990s and by Health Canada in a more limited review of one phthalate (DINP) in children's products.

Chapter Four draws conclusions about the federal law and policy reviewed in the first chapter and further illustrated in terms of lessons learned within the specific circumstances explored in the two case studies. Recommendations are provided for using and/or amending CEPA (via specific amendments noted in Appendix Two) to address identified shortcomings in the regulation of toxic substances in consumer products.

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[2] *Canadian Environmental Protection Act, 1999* (R.S.C. 1999, c. 33)

[3] Throughout this report, multiple references are made to the same statutes and regulations. A choice was made to provide the citation only when either a law or regulation is first mentioned.

Federal Legal and Policy Tools

Three key statutes in Canada play a role in controlling toxic chemicals in consumer products. They are the *Hazardous Products Act*[4] (HPA), the *Food and Drugs Act*[5] (F&DA), and the *Canadian Environmental Protection Act, 1999* (CEPA). The federal government has proposed new powers to address consumer products, including a "general safety requirement," under the proposed Canada Health Protection Act.[6]

In addition, several over-arching policy directives originating in Cabinet, the Treasury Board Secretariat or the Privy Council Office, further govern the implementation of federal activities concerning products. These policies would include the Government of Canada Regulatory Policy,[7] the Smart Regulation initiative and proposed Government Directive on Regulation,[8] the Guide to the Regulatory Process for Treasury Board Secretariat Program Analysts,[9] the Toxic Substances Management Policy,[10] and the Framework for the Application of Precaution in Science-Based Decision Making about Risk.[11]

An additional policy relevant to chemicals management is Pollution Prevention – A Federal Strategy for Action,[12] described as "the Government of Canada's policy framework for advancing pollution prevention,"[13] and with a goal "to eliminate the causes of pollution rather than be required to manage the waste after it has been generated."[14]

Several other statutes are relevant to certain consumer products including the *Pest Control Products Act*[15] (PCPA), *Radiation Emitting Devices Act*[16] and *Tobacco Act*.[17] Only the PCPA is considered in this review in terms of pointing out positive aspects of recent revisions.

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[4] *Hazardous Products Act* (R.S., 1985, c. H-3)
[5] *Food and Drugs Act* (R.S., 1985, c. F-27)
[6] Health Canada, 2003: *Health and Safety First! A Proposal to Renew Federal Health Protection Legislation*; *Health Protection Legislative Renewal – Detailed Legislative Proposal*; and *Health Protection Legislative Renewal - Issue Paper. General Safety Requirement.*
[7] 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
[8] Consultation and associated documents on-line at: http://www.regulation.gc.ca/default.asp@language=e&page=thegovernmentdirectiveon.htm .
[9] 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.
[10] Policy and associated documents on-line at: http://www.ec.gc.ca/toxics/en/index.cfm
[11] 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
[12] Pollution Prevention: A Federal Strategy for Action. On-line at: http://www.ec.gc.ca/pollution/strategy/en/index.cfm
[13] Progress on Pollution Prevention, Annual Report of the Pollution Prevention Coordinating Committee 1997-1998. On-line at: http://www.ec.gc.ca/p2progress/1997-1998/en/index.cfm
[14] Progress in Pollution Prevention, Annual Report of the Pollution Prevention Coordinating Committee 2002-2003. On-line at: http://www.ec.gc.ca/p2progress/2002-2003/en/index.cfm
[15] *Pest Control Products Act* (2002, c. 28)
[16] *Radiation Emitting Devices Act* (R.S., 1985, c. R-1)
[17] *Tobacco Act* (1997, c. 13)

Food and Drugs Act

The *Food and Drugs Act* (F&DA) governs the advertisement and sale of food, drugs, cosmetics and therapeutic devices. It was adopted to prevent public deception regarding these products and to prevent injury to the health of the purchaser or user. This law contains no provisions to govern the life cycle of products beyond this specific focus on advertisement and the intended use of the product.

Four sections of the F&DA and two associated regulations are relevant to a consideration of products that have the potential to create exposure to potentially harmful chemicals. These include prohibitions in the Act for adding harmful substances to food (Section 4), to Cosmetics (Section 16), to devices (Section 19) as well as the definition in Section 23(2)(b) of articles to which the Act applies (e.g., food packaging). Two regulations are also relevant, the *Food and Drug Regulations*[18] and the *Cosmetic Regulations*.[19]

Section 4 of the F&DA prohibits the sale of any food that has in or upon it any poisonous or harmful substance, is unfit for human consumption or is adulterated. Two areas within the *Food and Drug Regulations* are relevant to chemical exposures in food, those dealing with "adulteration" and those dealing with "food packaging."

The reference to packaging in Section 4 prohibits the sale of food that has been "manufactured, prepared, preserved, packaged or stored under unsanitary conditions." Section 23(2)(b) notes packaging as part of the definition of articles to which the Act and its Regulations apply, and includes "anything used for the manufacture, preparation, preservation, packaging or storing thereof." Section 30 provides for extensive regulation-making powers, including with respect to food packaging.

The *Food and Drug Regulations* stipulate that food may not be sold in packaging that may yield to its contents any substance that may be injurious to the health of a consumer of the food. This prohibition is activated only where specific substances are named in the regulation. A very small number of substances is specifically named. Likewise, with respect to the adulteration of food, the regulations provide for a very limited number of substances that could potentially adulterate food as a result of packaging. With the exception of detailed direction concerning agricultural chemicals on food, Division 15 in this regulation, concerning the Adulteration of Food, provides very limited coverage of only four substances: arsenic, fluoride, lead and tin.

Section 16 prohibits the sale of a cosmetic product containing any substance that may injure the health of the user. Recent changes to the *Cosmetic Regulations*, in effect as of November 2006, require manufacturers to provide information about ingredients in cosmetics and personal care products. Ingredients are to be identified through the use of symbols rather than by name, in contrast to requirements under U.S. law.

Some key products are excluded from the new labeling requirements due to the definition of cosmetic (a product which cleanses, improves or alters the complexion, skin, hair or teeth). Hence, the regulations exclude toothpaste, considered a natural health product, and sunscreens,

[18] *Food and Drug Regulations* (C.R.C., c. 870)
[19] *Cosmetic Regulations* (C.R.C., c. 869)

considered a drug product. Fragrances may not be identified as individual ingredients since manufacturers are allowed to use "parfum" or "aroma" to represent a wide range of different fragrance ingredients.

Health Canada has also developed the *List of Prohibited and Restricted Cosmetic Ingredients*,[20] called the Cosmetic Ingredient "Hot List". This list contains substances that should not be used or for which use is allowed under very specific conditions. For example, chemicals in this inventory can be prohibited, or can have concentration limits, labeling requirements or other measures applied. The majority of the substances are prohibited in cosmetics and the list is heavily populated with pharmaceuticals and also contains some CEPA-toxic substances (i.e., substances evaluated under CEPA and found to be toxic according to this law). it derives largely from the list of banned chemicals in Annex II of the European Union Cosmetics Directive.[21]

Finally, Section 19 prohibits the sale of medical devices that may cause injury to health. Details of application are spelled out in the *Medical Devices Regulation*[22] including a requirement noted in Section 16 of the Regulation, to "minimize any risk" from "reasonably foreseeable hazards" including "presence of a contaminant or chemical..." The regulation does not specify individual chemicals to which this provision could apply.

Hazardous Products Act

The *Hazardous Products Act,* (HPA), as the name implies, is a key statute for the regulation of consumer products in Canada. It is used mainly to address product safety issues such as the flammability of pyjamas, the safety of cribs and the breakability of glass. For chemicals, even those designated toxic under CEPA, the HPA is rarely used. Where it is applied, to chemicals and other situations, this law, and its associated regulations, tends to be focused on extremely high hazard or lethal situations resulting from products. It addresses hazardous situations by means of product-specific, sometimes category-wide, regulations.

Under the HPA, Health Canada can control the sale, importation, advertisement and labeling of dangerous or potentially dangerous consumer and industrial products. Two schedules in the Act are used to denote regulated products – prohibited products (Schedule I, Part I) and restricted products (Schedule I, Part II).

Prohibited products under Schedule I, Part I, may not be advertised, imported or sold in Canada. Restricted products under Schedule I, Part II, may be subject to further product-specific or category-wide regulations. Restrictions on products or classes of products may be further spelled out in regulations. To date, about 25 regulations have been established for products or product categories. As well, the *Consumer Chemicals and Containers Regulations, 2001,*[23] provides specific direction for labeling requirements for consumer products with very high hazard ingredients.

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[20] *List of Prohibited and Restricted Cosmetic Ingredients. On-line at:* http://www.hc-sc.gc.ca/cps-spc/person/cosmet/prohibited_e.html.

[21] European Union Cosmetics Directive. On-line at: http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1976/L/01976L0768-20060809-en.pdf

[22] *Medical Devices Regulations* (SOR/98-282)

[23] *Consumer Chemicals and Containers Regulations, 2001* (SOR/2001-269)

In addition, the HPA establishes a third category called Controlled Products, within which Schedule II of the Act specifies six classes of products, (exclusive of the Restricted Products on Schedule 1, Part 2 of the Act). The *Controlled Products Regulations*[24] focus on these six classes of products and set out requirements for Material Safety Data Sheets (MSDS) and labeling and information disclosure requirements. The MSDS' are of significant importance to workplaces but are often unavailable to the public. Or, if MSDS' are available, they are rarely in an accessible format providing information about products that can be understood by the general public. This regulation also specifies testing requirements for toxicity and other matters. Again, across these six classes, the focus of testing requirements is almost exclusively on addressing high hazard and/or acute toxicity although there are provisions for evaluations of chronic toxicity for "very toxic materials" and "toxic materials" (including tested and untested mixtures).

Advisories, Warnings and Recalls

Health Canada may issue an advisory or warning to the public about a particular product, or negotiate a voluntary industry recall, although there is no specific legislative authority to do so under the HPA. Advisories are used for classes of products, warnings are product-specific and voluntary action by industry can result in the manufacturer or importer removing a product from sale.

Health Canada rarely uses advisories to address toxic chemicals in products. Where they have been used, they often apply to items already prohibited or regulated. The HPA provides no authority to force a product recall. Health Canada may seize the products in storage. They cannot force removal from store shelves.

Canadian Environmental Protection Act (CEPA)

The *Canadian Environmental Protection Act, 1999* (CEPA) is Canada's principle tool for preventing and managing risks posed by toxic substances. Part 5 of CEPA provides for the assessment and management of both new and existing substances, including regulation-making powers.

Part 5 gives Health Canada and Environment Canada jointly held authority to identify, screen and assess substances to determine if they are toxic under this law (the risk assessment step). Once substances are found to be "CEPA-toxic" the risk management stage can follow a regulatory or non-regulatory course.

Regulation-making powers in Part 5 can be used to create substance-specific or sector-specific regulations. Further provisions, including some flowing from Part 3 and Part 4 of CEPA, provide direction on voluntary arrangements for risk management including environmental performance agreements or memoranda of understanding, pollution prevention plans, administrative agreements, codes of practice, environmental quality objectives or guidelines, or letters of agreement.

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[24] *Controlled Products Regulations* (SOR/88-66)

Across these regulatory powers and voluntary options, tools exist to control toxic substances in products. However, CEPA has been used primarily to address environmental emissions to air and water and much less on eliminating or reducing exposures from toxic substances contained in products.

CEPA-Toxic Substances

CEPA-toxicity is established for chemicals that are persistent, bioaccumulative and toxic and for which there is potential for human exposure. The assessment process is slow: only 80 substances (in some cases, classes of substances) have been designated CEPA-toxic. The pace may pick up now that the categorization exercise is complete for the vast majority of the 23,000 as-yet un-assessed substances on the Domestic Substances List (DSL). The categorization exercise enabled the generation of "short-lists" of these so-called legacy chemicals. The resulting short-lists are chemicals thought most likely to satisfy CEPA-toxic criteria, on the basis of currently available information, and for which priority should be given to further assessment. Results of categorization and plans for next steps towards assessment and management of several hundred substances was announced in December, 2006.[25] Many chemicals identified, via categorization, as priorities for action are in commonly-used consumer products that can contribute to human exposure.

Throughout the categorization effort, additional work continued on State of the Science reports and screening assessments on chemicals on the DSL already identified as being of concern. Many of these chemicals are also in commonly-used consumer products, such as PBDEs, perfluorinated chemicals, ethylbenzene, dichloroethene, quinoline, etc.

Once found to be CEPA-toxic, substances are added to Schedule 1 of the Act, also referred to as the Toxic Substances List (TSL). Once on the list, the subsequent risk management stage is guided by the Toxic Substances Management Policy[26] (TSMP), developed in 1995. The TSMP establishes two categories or "Tracks" for CEPA-toxic substances – those that are predominantly anthropogenic and that are persistent and bioaccumulative (Track 1) and those that are the subject of life cycle management to prevent or minimize their release into the environment (Track 2). Releases of Track 1 substances are intended to be virtually eliminated. Most CEPA-toxic chemicals are Track 2.

Regulations Under CEPA

Section 93 of CEPA, provides extensive regulation-making authority with respect to CEPA-toxic/TSL substances. In addition to Section 93, Sections 140 and 160 of CEPA provide regulation-making powers with respect to fuels and vehicle engine and equipment emissions, both of which can be relevant to a review of the tools available in CEPA to control toxic substances that may also be used, and released from, consumer products.

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[25] *Canada Gazette*, Part I, Vol. 140, No. 49 – December 9, 2006 - Notice of intent to develop and implement measures to assess and manage the risks posed by certain substances to the health of Canadians and their environment.

[26] *Op. cit.*

It is Section 93 however where CEPA provides for the primary regulation-making power for CEPA-toxic substances. While Section 93 reaches well beyond issues concerning chemicals in products, multiple sub-sections refer to regulation-making authority concerning: *the [CEPA-toxic] substance or a product containing it...*

Section 93 is reproduced below with those sections relevant to the regulation of products highlighted. This section, alongside Section 2 of CEPA, also excerpted below, provide the authority to regulate or ban products, including on a preventative basis.

93. (1) Subject to subsections (3) and (4), the Governor in Council may, on the recommendation of the Ministers, make regulations with respect to a substance specified on the List of Toxic Substances in Schedule 1, including regulations providing for, or imposing requirements respecting,

(a) the quantity or concentration of the substance that may be released into the environment either alone or in combination with any other substance **from any source or type of source;**

(b) the places or areas where the substance may be released;

(c) the commercial, manufacturing or processing activity in the course of which the substance may be released;

(d) the manner in which and conditions under which the substance may be released into the environment, either alone or in combination with any other substance;

(e) the quantity of the substance that may be manufactured, processed, used, offered for sale or sold in Canada;

(f) the purposes for which the substance or a product containing it may be imported, manufactured, processed, used, offered for sale or sold;

(g) the manner in which and conditions under which the substance or a product containing it may be imported, manufactured, processed or used;

(h) the quantities or concentrations in which the substance may be used;

(i) the quantities or concentrations of the substance that may be imported;

(j) the countries from or to which the substance may be imported or exported;

(k) the conditions under which, the manner in which and the purposes for which the substance may be imported or exported;

(l) the total, partial or conditional prohibition of the manufacture, use, processing, sale, offering for sale, import or export of the substance or a product containing it;

(m) the total, partial or conditional prohibition of the import or export of a product that is intended to contain the substance;

(n) the quantity or concentration of the substance that may be contained in any product manufactured, imported, exported, offered for sale or sold in Canada;

(o) the manner in which, conditions under which and the purposes for which the substance or a product containing it may be advertised or offered for sale;

(p) the manner in which and conditions under which the substance or a product containing it may be stored, displayed, handled, transported or offered for transport;

(q) the packaging and labelling of the substance or a product containing it;

(r) the manner, conditions, places and method of disposal of the substance or a product containing it, including standards for the construction, maintenance and inspection of disposal sites;

(s) the submission to the Minister, on request or at any prescribed times, of information relating to the substance;

(t) the maintenance of books and records for the administration of any regulation made under this section;

(u) the conduct of sampling, analyses, tests, measurements or monitoring of the substance and the submission of the results to the Minister;

(v) the submission of samples of the substance to the Minister;

(w) the conditions, test procedures and laboratory practices to be followed for conducting sampling, analyses, tests, measurements or monitoring of the substance;

(x) the circumstances or conditions under which the Minister may, for the proper administration of this Act, modify

(i) any requirement for sampling, analyses, tests, measurements or monitoring, or

(ii) the conditions, test procedures and laboratory practices for conducting any required sampling, analyses, tests, measurements or monitoring; and

(y) any other matter that by this Part is to be defined or prescribed or that is necessary to carry out the purposes of this Part.

The powers in Section 93 are to be used in accordance with principles set out in Section 2 of CEPA that include reference to the importance of preventative measures to protect human health and the environment. Relevant sections are excerpted here:

2 (1) In the administration of this Act, the Government of Canada shall…

(a) exercise its powers in a manner that protects the environment and human health, applies the precautionary principle that, where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation, and promotes and reinforces enforceable pollution prevention approaches;

(a.1) take preventive and remedial measures to protect, enhance and restore the environment;

(b) take the necessity of protecting the environment into account in making social and economic decisions;

(j) protect the environment, including its biological diversity, and human health, from the risk of any adverse effects of the use and release of toxic substances, pollutants and wastes;

(1.1) The Government of Canada shall consider the following before taking any measure under paragraph (1)(a.1):

(a) the short- and long-term human and ecological benefits arising from the environmental protection measure;

(b) the positive economic impacts arising from the measure, including those cost-savings arising from health, environmental and technological advances and innovation, among others; and

(c) any other benefits accruing from the measure.

A final note about Section 93 is the qualifier provided in section 93(4) concerning substances regulated under other Acts of Parliament:

(4) The Governor in Council shall not make a regulation under subsection (1) in respect of a substance if, in the opinion of the Governor in Council, the regulation regulates an aspect of the substance that is regulated by or under any other Act of Parliament in a manner that provides, in the opinion of the Governor in Council, sufficient protection to the environment and human health.

The Prohibition of Certain Toxic Substances Regulations

Similar to the approach used in the HPA, Section 93 of CEPA allows for both full prohibition of toxic substances in products or for the establishment of prohibitions with exemptions. This approach is also provided for in CEPA's *Prohibition of Certain Toxic Substances Regulations, 2005*. Schedules 1 and 2 in these regulations make a distinction between chemicals subject to total prohibition in Canada (prohibiting their manufacture, use, sale, offer for sale and import) and those subject to prohibition with exemptions that are specifically noted in the regulation.

Schedule 1 substances, subject to total prohibition, include: Mirex, polybrominated biphenyls and terphenyls, bis (chloromethyl)ether and chloromethyl methyl ether, DDT, hexachlorobutadiene, nitrosodimethylamine (NDMA), and (4-chlorophenyl) cyclopropylmethanone.

Schedule 2 includes five additional substances – hexachlorobenzene and benzidine, 2-Methoxyethanol, Pentachlorobenzene and Tetrachlorobenzene – and prohibits all but specific applications identified in the Regulation.

Substance-specific or Sector-specific Regulations

The regulation-making powers provided for in Section 93 are more commonly applied towards substance-specific or sector-specific regulations. Over twenty regulations have been created to address substances (e.g., 2-Butoxyethanol, chlorobiphenyls, halocarbons, etc.) or, more commonly, activities or sectors (e.g., asbestos mines and mills releases, secondary lead smelters, pulp and paper mill effluent, solvent degreasing, off-road engine emissions, etc.).

Pollution Prevention Plans and other Voluntary Agreements

Part 4 of CEPA provides authority to require the preparation and implementation of pollution prevention plans for CEPA-toxic substances. Such requirements do not include public disclosure of such plans, only that the Minister of Environment be notified Minister that the plan has been done (Part 4, Sect. 58 (1)).

The Proposed CHPA – General Safety Requirement

In an ongoing attempt to review and consolidate several pieces of health protection legislation, including the HPA and F&DA, Health Canada[27] has proposed a new Canada Health Protection Act and therein a General Safety Requirement (GSR), 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 manufacturers in corrective actions.

The stated intention of the GSR is to provide a "safety net" when health and safety standards do not adequately address a hazard. It is described as additional to specific safety standards; the GSR would apply to all products and describe the respective responsibilities of the various participants in the supply chain.

The GSR proposal includes the notion of accepting as product safety standards not only Canadian regulations but also "generally accepted health and safety standards applicable to the product or to similar products" 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." These options for standards are seen as offering flexibility to industry, eliminating barriers to innovation and facilitating harmonization, while not compromising objectives for health and safety.

The onus of proof would be on Health Canada to show a reasonably foreseeable adverse health effect of a product. Then, in a prosecution, the burden of proof would switch to the producer to defend it. The proposal also notes, with perhaps considerable optimism, "It is fair to assume that responsible manufacturers already take all the precautions necessary, so no new burden would be imposed on them." The proposed GSR is discussed further in Chapter Four.

Over-Arching Policy Direction

As noted above, across the federal government, and across the statutes noted above in particular, the policy approach to evaluating and managing chemicals follows traditional Risk Assessment and Risk Management approaches. As well, several policy directives originate in Cabinet, the Treasury Board Secretariat or the Privy Council Office that further govern the implementation of federal activities concerning products, including, and perhaps not limited to, the following:

- Government of Canada Regulatory Policy[28]

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[27] Health Canada, 2003 – three documents. *Op. cit.*
[28] *Op. cit.*

- Smart Regulation initiative and proposed Government Directive on Regulation[29]
- Guide to the Regulatory Process for Treasury Board Secretariat Program Analysts[30]
- Toxic Substances Management Policy[31]
- Framework for the Application of Precaution in Science-Based Decision Making about Risk.[32]

The Government of Canada Regulatory Policy governs all departments. Despite Canada being a signatory to numerous international agreements such as the International Covenant on Economic, Social and Cultural Rights, the International Declaration of Human Rights, the Stockholm Convention on Persistent Organic Pollutants, and other agreements concerning health, human rights or the environment, only international trade agreements are named in this Regulatory Policy.

Similarly, in its next iteration, within the Smart Regulation initiative and the proposed Government Directive on Regulation (GDR), priority is given to economic considerations and voluntary over regulatory approaches. These initiatives recommend that agencies like Health Canada and Environment Canada evaluate toxic substances by giving priority, over regulatory approaches, to the promotion of innovation, competitiveness and efficiency. This direction is already in place in the Guide to the Regulatory Process for Treasury Board Secretariat Program Analysts, a document that states:

> Departments must review their regulatory proposals to ensure that they are necessary and that non-regulatory means or instruments are not better suited to address the issue identified.

Finally, in the Framework for the Application of Precaution in Science-Based Decision Making about Risk, primacy is further given to economic considerations with the direction that, where more than one option achieves a precautionary measure, the least trade restrictive measure is to be applied.

In the "implementation and accountability" section of the Toxic Substances Management Policy, trade and economic considerations are not given primacy over regulatory approaches though they are mentioned as needing due consideration.

This policy direction, and the three statutes and associated regulations noted above, are discussed further in Chapter Four.

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[29] *Op. cit.*
[30] *Op. cit.*
[31] *Op. cit.*
[32] *Op. cit.*

Chapter 2: Case Study – Lead

Introduction

Extensive scientific evidence exists about the health concerns and multiple sources of exposure sources for lead in Canada. This evidence is briefly summarized here relying upon more detailed work done elsewhere. It supports a conclusion that global lead contamination due to human activity creates a situation of little to no safety margin for further exposure to lead. Exposure sources have changed. Since the early 1990s, a broad array of unregulated consumer products, in many cases containing dangerously high levels of lead, have come into the Canadian market, mostly in the form of inexpensive, imported products.

The Canadian regulation of lead is reviewed in terms of the three statutes described above. The focus is on federal regulation, or lack thereof, of lead in consumer products.

Health Concerns

Medical and scientific understanding of the health effects in children of exposure to lead is extraordinarily detailed. This knowledge arises from a large number of studies investigating health effects in children exposed to environmental lead contamination in industrialized countries. A causal relationship has been demonstrated between low level lead exposure and adverse neuropsychological effects in children. Effects are asymptomatic or sub-clinical and are both cognitive and behavioural.[33]

Numerous studies have revealed a wide variety of measured and observed effects at blood-lead levels of 10 to 15 μg/dL.[34] Some effects appear below 10 μg/dL, appear to be irreversible, and there is no apparent threshold.[35] Effects include:

- deficits in IQ or deficits in comparable/age appropriate tests of intellectual functioning;
- deficits in speech and language processing;
- deficits in perceptual-motor function and integration;
- deficits in reaction time;
- reduced attention span;
- non-adaptive classroom behaviour;
- deficits in reading, spelling and mathematics scores;
- poorer handwriting;
- significant increase in the risk for learning disabilities, as measured by the need for remedial education in reading, speech and math;

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[33] Many summaries of this literature have been published. See e.g., Canfield RL et al, 2003. Intellectual Impairment in Children with Blood Lead Concentrations below 10 μg per Deciliter. *N Engl J Med*, 348(16) 1517-26; Standard Setting for Lead – The Cautionary Tale in Cooper, K et al, *Environmental Standard Setting and Children's Health*. Report of the Children's Health Project, Canadian Environmental Law Association and Ontario College of Family Physicians, May, 2000. Chapter 8.

[34] A deliberate choice is made in this case study to avoid metric nomenclature in describing blood-lead levels. Since the majority of scientific literature on lead reports blood lead measures in micrograms per decilitre, stepping away from Canadian metric conventions has been done for convenience in making easy comparisons.

[35] Canfield RL et al, 2003. *Op. cit.*

- sevenfold increased risk of failure to complete high school;
- sixfold increased risk for reading disability;
- poorer vocabulary and grammatical reasoning scores;
- poorer hand-eye coordination; and
- increased risk for antisocial and deliquent behaviour with the effects following a developmental course.[36]

Numerous risk factors predispose children to both higher exposure and greater vulnerability to the hazards of lead. These include differences, compared to adults, in terms of proportional body size and weight, and many aspects of behaviour, physiology and metabolism.[37] The effects of lead also seem to be more serious in boys than in girls for reasons that have not been explained. Finally, children living in poverty are at greatest risk from lead exposure due to circumstances that can contribute to both higher exposure and greater uptake of lead than generally exist for children of higher socio-economic status.[38]

Exposure Sources

Human activity, primarily during the 20th Century, has created global contamination with this persistent neurotoxin. A historical gradient exists of lead contamination following traffic patterns; contamination is highest in urban areas and along motor ways decreasing with distance away from traffic concentration. Alongside lead in gasoline, lead exposure has occurred from numerous sources, including via food and water, but especially from lead in paint. In some communities, child lead burdens have been greatly increased by point sources of industrial lead contamination.[39]

After 60 years of leaded gasoline use, this legacy creates a large reservoir of lead in urban and roadside soil and dust. Similarly, the widespread use of lead in paint, not adequately regulated until the mid-1970s, creates a legacy of potential contamination of soil and indoor dust and surfaces.

Since the beginning of the 1990s, new and unexpected sources of lead in mostly imported consumer products have arisen frequently such as lead in imported crayons, plastic mini-blinds, some candle wicks, inexpensive jewellery and a wide range of children's toys and clothing/accessories. These product lines routinely run into the millions contributing enormous amounts of lead to the municipal waste stream.

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[36] Summarized from Needleman, H.L. and D. Bellinger. The Health Effects of Low Level Exposure to Lead, *Annu. Rev. Publ. Health.* 12 (1991), pp. 111-140.

[37] Canadian Partnership for Children's Health and Environment, 2005. *Child Health and the Environment – A Primer*. Chapter 2: Why Focus on Children? On-line at: **www.healthyenvironmentforkids.ca**

[38] See, e.g., Mushak, P. and A.F. Crocetti. Lead and Nutrition: Part II. Some Potential Impacts of Lead-Nutrient Interactions in U.S. Populations at Risk *Nutrition Today*. 31 (1996), pp. 115-122.

[39] Documented in multiple sources, e.g., ATSDR (Agency for Toxic Substances and Disease Registry), (1988). *The nature and extent of lead poisoning in the United States: a report to Congress*. Atlanta; Centers for Disease Control. *Preventing Lead Poisoning in Young Children*. United States Department of Health and Human Services. (1991); Millstone E, 1997. *Lead and Public Health* (Earthscan Publ. Ltd. London); Royal Society of Canada Commission on Lead in the Environment, 1985, Final Report; etc.

No Safety Margin

It took a long time, an enormous amount of money and a lot of acute and chronic lead poisoning of children to confirm the greater vulnerability, exposure circumstances and health impacts of lead in children, including impacts of fetal exposure. Although early animal studies and preliminary studies of lead-exposed children raised concern about the neuropsychological toxicity of low-level lead exposure,[40] the response from industry and echoed in regulatory responses was to insist upon proof of harm before taking action. Global lead contamination via automobile emissions, industrial point source emissions, poisonings from lead in paint (and many other sources) enabled the above conclusions as to health impacts to be verified by assessing actual effects in huge numbers of children.[41]

However, the control of lead is, on one hand, a success story. Through a combination of both regulation and voluntary action by industry, children's lead exposure dropped steadily since the 1970s as measured in children's blood-lead levels. Across the population, this decline was evident in a close correlation between dropping blood-lead levels and the partial[42] and ultimately the full removal of lead from gasoline.

On the other hand, appropriate action was delayed until health-effect levels of exposure could be verified in huge numbers of children. With the legacy of contamination created by historical uses, there remains a very small safety margin for all children. While average blood-lead levels in Canadian children have dropped to below the "intervention level" of 10 µg/dL, the lack of an appreciable safety margin for all children means that any new or unexpected sources of lead are a significant concern.

Regulation of Lead in Canada

The regulation of lead in Canada has been, and continues to be, a protracted and reactive approach.[43] Canada has followed and consistently lagged behind or been less stringent than regulatory action taken in the United States.

The initial round of regulatory actions began in the 1960s and 70s and followed the typical chemical-by-chemical approach. For most chemicals, including lead, the subdivision went further and regulatory controls were placed on lead in occupational settings, paint, gasoline, air, soil, drinking water, food, consumer products and other areas. All of these limits became

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[40] See detailed review of the biological effects of lead exposure from animal studies in: United States Environmental Protection Agency. *Air Quality Criteria for Lead.* Vol. IV of IV, Section 12. Pp. 12-1 - 12-370. (1986) EPA-600/8-83/028dF.

[41] See e.g., ATSDR (Agency for Toxic Substances and Disease Registry), (1988). *The nature and extent of lead poisoning in the United States: a report to Congress*. Atlanta.

[42] Centers for Disease Control. Blood-Lead Levels in the U.S. Population, *Morbidity and Mortality Weekly Report 31, No.10* (March 19, 1982), pp. 132-134; and eventually reported in: U.S. Department of Health and Human Services/Public Health Service (1984). National Health and Nutrition Examination Survey Series II, No. 233, Blood Lead Levels for Persons Ages 6 Months - 74 Years: United States, (1976-1980). DHHS Publication No. (PHS), pp. 84-1683.

[43] See detailed review in Standard Setting for Lead – The Cautionary Tale in Cooper, K et al, *Environmental Standard Setting and Children's Health*. Report of the Children's Health Project, Canadian Environmental Law Association and Ontario College of Family Physicians, May, 2000. Chapter 8.

obsolete, and were revised, in some but not all cases, as the information base about low level impacts on children continued to grow during the 1980s and 1990s up to the present.

The three statutes described in Chapter One above have all been used to regulate lead in diverse sources, media or products. The table in Appendix One summarizes the current situation with respect to existing and proposed guidance, regulatory and risk management action by the federal government.[44]

Canadian Environmental Protection Act

Throughout the 1970s and 1980s, extensive scientific evidence confirmed that lead in gasoline was the primary contributor to both widespread environmental lead contamination and the lead measured in children's blood. Fully 60 to 80% of environmental lead contamination, world-wide could be attributed to its use in gasoline.[45] Lead in gasoline was regulated under the *Clean Air Act*, a law that was repealed and subsumed within the *Canadian Environmental Protection Act, 1988*. The decision to phase-out lead from gasoline as of January 1, 1990 is enshrined in the *Gasoline Regulations*[46] (see Appendix One). The limit of 5 parts per million in the gasoline used by most vehicles allows for a small amount of lead that reflects the reality of environmental contamination. The slightly higher level of lead allowed for certain boats and heavy equipment is in place to prevent valve seat recession in some older engines.

Lead was also deemed "CEPA-toxic" under CEPA, 1988 by automatic inclusion in the Toxic Substances List on Schedule 1. An assessment report (typically prepared for substances on the CEPA Priority Substances List) was not considered necessary.

Food and Drugs Act

The detailed investigations into lead in gasoline conducted during the early 1980s[47] confirmed that lead in gasoline contributed at least 50% of the lead contamination of food. It was also clear that alongside dust/soil, food was one of the most significant sources of human lead exposure. Lead-soldering of food cans was found to increase the lead contamination of food by as much as 5 to 10 times.

A regulation was enacted in 1968[48] setting maximum lead levels for a range of foodstuffs. The list of foods was not particularly representative of the foods consumed in Canada. The regulated levels were based on then-current health effect information[49] and these levels were extremely high (generally one to three orders of magnitude higher than actual lead levels found in food).

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[44] Provincial governments also have guidance and regulatory measures in place for lead in drinking water, soil, and various industrial emissions. These are not included in this analysis. Also omitted from consideration here are the federal regulations concerning emissions from secondary lead smelters.

[45] United States Environmental Protection Agency. *Air Quality Criteria for Lead.* (1986) EPA-600/8-83/028dF.

[46] *Gasoline Regulations* (SOR/90-247)

[47] United States Environmental Protection Agency. *Air Quality Criteria for Lead.* (1986) EPA-600/8-83/028dF.

[48] *Food and Drug Regulations*, C. R. C., c. 870, B. 15.001.

[49] The information about health effects of lead exposure in the 1960s included a blood-lead concern level of 80 µg/dL, 8 times higher than the current "intervention level" of 10 µg/dL.

Where the regulated levels were closer to lead levels that would actually have been found in food, they were established to address two contamination sources: the use of lead arsenate as a pesticide on apples (phased-out during the 1970s) and lead soldering of cans. In these cases, the regulated levels were generally not much different than the levels that could be found in apple products or lead-soldered canned food. As noted above, it was well established that lead-soldering could increase the lead content of food by 5 to 10 times and represented a significant contribution to dietary sources of lead.

In 1979, the regulations for lead in food were minimally revised[50] by revoking some limits on a range of irrelevant foodstuffs and re-publishing slightly revised regulations for a more representative range of foods. The new list of foods was intended to address foods that are generally found in cans, and, at the time, often in lead-soldered cans. For those foods that had been on the 1968 list, the 1979 regulated levels were unchanged from those set in 1968. Hence, they were still based on exceptionally outdated information about the health impacts of lead.

Additional foodstuffs on the 1979 list included evaporated milk, condensed milk and concentrated infant formula, all of which were more likely or exclusively to be fed to children and which were often packaged in lead-soldered cans. Still another addition was made in 1986[51] when lead limits were placed on tomato paste and sauce and whole tomatoes, and it was unstated but implied that these were canned products.

The regulatory limit for all of these products was, again, not much different than the lead level that was typically found in these foods if they were in lead-soldered cans. Indeed, testing by Health Canada in 1988 confirmed that infant formula in lead-soldered cans was routinely at or significantly above the regulatory limit.[52]

With increased publicity throughout the 1980s about the health effects of lead and the significant contribution of lead-soldered cans to dietary intake, food manufacturers responded to negative publicity and public pressure and took the initiative to gradually phase out lead-soldering of cans. Regulatory action by the federal government had little to nothing to do with this change and F&DA regulatory standards for lead in food were never, and still are not, protective of children's health.

The above conclusion is reached by comparing the regulated levels, noted in Appendix One, to actual levels of lead found in foods. The regulatory levels provided in Appendix One are converted to parts per billion. They range from 80 ppb in ready-to-use infant formula to 1500 ppb in some tomato products to 10,000 ppb in edible bone meal. In measurements done in the early 1980s, actual levels of lead in food ranged from 20 ppb to as much as 600 ppb. At that time, lead in gasoline was still in widespread use and known to be a significant contributor to lead levels in food.

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[50] SOR/79-249.

[51] SOR 86/258.

[52] Dabeka, R.W., Food Research Division, Bureau of Chemical Safety, Health and Welfare Canada. Graphite Furnace Atomic Absorption Spectrometric Determination of Lead and Cadmium in Canadian Infant Formulas and Calculation of Dietary Intakes of Lead and Cadmium by Infants. Presentation made at the Third Chemical Congress of North America. (June 8, 1988) and for Release at Press Conference.

It is fair to assume that current lead contamination of food would be much lower. Hence, regulatory limits that are two to ten orders of magnitude higher than actual levels will do nothing to protect children from lead exposure. Assurances that such regulatory levels are not being exceeded are virtually meaningless in terms of these regulations providing adequate protection from lead exposure in food.

The OECD Declaration of Risk Reduction for Lead

Increasing recognition of the hazards to children of low level lead exposure resulted in the phase-out of lead from gasoline, the primary source of contamination, in most industrialized countries. Additional controls were placed on lead in other areas. For example, the Canadian Drinking Water Quality Objective (noted in Appendix One) was revised in the early 1990s, down from a prior limit of 50 μg/L to 10 μg/L.[53]

Despite the clear evidence of harm and the acceptance, at least in most industrialized countries, of the need for gasoline lead phase-out, a large number of new and unexpected sources of lead continued to arise, throughout the 1990s, almost entirely in imported consumer products.

Before discussing the Canadian regulatory response, via the *Hazardous Products Act*, it is instructive to review how governments and regulatory agencies in various countries, including Canada, responded at an international level.

Efforts aimed at controlling the risks associated with lead exposure included a 1995 Organisation for Economic Co-operation and Development (OECD) agreement. Proposed by the U.S. and the European Commission and backed by a majority of OECD members, it called for a truly international phase-out of lead from gasoline, the virtual elimination of lead in products intended for children, an end to the use of lead solder in food and drink cans and reduced exposure to lead in paint, ceramics and crystalware.

The agreement, which would have done much to reduce lead exposure, was blocked by Canada and Australia, which favoured voluntary industry actions.[54] The following year the OECD Declaration of Risk Reduction for Lead was adopted by the 26 OECD Environment Ministers, as well as the Environment Commissioner of the European Community. It commits signatory countries to strengthen their efforts to reduce the risks associated with exposure to all major sources of lead. The apparent difference between this agreement and its doomed predecessor is the new qualifier that states ...reduce lead exposure when they deem it to be *appropriate* (emphasis added) to do so through:

1. phasing down the use of lead in gasoline;
2. eliminating exposure of children to lead in toys and other products with which they may come in contact;
3. phasing down the use of lead in paint and rust proofing agents;
4. eliminating human exposure to lead from food and beverage containers;

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[53] On-line at: http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/doc_sup-appui/sum_guide-res_recom/index_e.html

[54] Pearce, F. Lead trickles through European loophole...while industry blocks international ban, *New Scientist*. (July 15, 1995)

5. restricting use of lead shot in wetlands; and
6. other actions which address risk of exposure for water, air and the workplace.[55]

The inclusion of the subjective test of "appropriateness" greatly diminishes the force of the agreement, permitting signatories to follow a lead reduction path and timetable of their own choosing.

Hazardous Products Act

Modern lead usage in a wide variety of consumer products continues to occur for the same reasons lead has been used for centuries: it is cheap, plentiful, malleable, strong, and it can produce bright colours and durable surfaces. Regulatory controls in Canada and other developed countries have been placed on the lead content of consumer products alongside the controls discussed thus far.

The earliest regulations for lead in consumer products in Canada were established for lead in glazed ceramics (in 1971),[56] revised and expanded in 1998[57] to include glazed ceramics and glassware. Regulations for kettles were put in place in 1974,[58] followed by regulations for lead in paint in 1976,[59] revised in 2005.[60] A regulation on children's jewellery, enacted in 2005,[61] is one of various activities included within Health Canada's Lead Risk Reduction Strategy.[62] Each of these is summarized in Appendix One and discussed in turn below.

Lead in Ceramics, Glassware and Kettles

The original regulations governing the amount of lead that can leach from glazed ceramics, or from kettles with lead-soldered seams, were based on health information current at that time (the early 1970s). Throughout the 1980s and 1990s, these regulatory limits were as scientifically out of date, and inadequately protective of health, as the lead in food regulations, and for the same reasons. While the 1998 revisions to the regulation for glazed ceramics and glassware partially address this concern, the limit on the amount of lead that can leach from lead-soldered seams in kettles (0.05 ppm or 50 parts per billion) is not health protective. For comparison, it is five times higher than the lead in drinking water standard in Ontario and the Canadian Drinking Water Quality Objective (10 µg/L or 10 parts per billion).

When ceramics, mostly imported from Latin America or China, contain lead, significant leaching is possible and can even cause serious cases of acute lead poisoning. Revisions in 1998 brought the *Hazardous Products Act* regulations in line with rules in the U.S. and broadened the regulations to apply to a range of ceramic and glassware products. The amount of lead allowed

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[55] Intergovernmental Forum on Chemical Safety. [Proceedings] of Forum II: Second Session of the Intergovernmental Forum on Chemical Safety. Thematic Session on Partnership: Lead Risk Reduction. (February, 1997).
[56] *Hazardous Products (Glazed Ceramics) Regulations*, C.R.C., c. 925.
[57] SOR/98-176.
[58] *Hazardous Products (Kettles) Regulations*, C.R.C., c. 927.
[59] *Hazardous Products (Liquid Coating Materials) Regulations*, C.R.C., c. 928.
[60] *Surface Coating Materials Regulations* - SOR/2005-109.
[61] *Children's Jewellery Regulations* - SOR/2005-132.
[62] On-line at: http://www.hc-sc.gc.ca/cps-spc/legislation/consultation/leadrisk_e.html

to leach from these products varies depending on the use. For example, permitted levels are lower for containers like pitchers and cups that would be used to hold or store liquids than for plates or small bowls. The test for lead involves determining how much lead can leach from the surface after it has been in contact with a 4% acetic acid solution (comparable to the acidity of vinegar) for 24 hours at room temperature. The higher the acidity of the food and the longer the storage time, the greater is the amount of lead that could leach into the food.

The new regulations place similar leachability requirements on lead contained in decorative patterns on the exterior surface of cups or glasses and require that such patterns be located a minimum of 20 millimetres below the rim.

While the harmonization with U.S. standards is of assistance to the industries producing and importing ceramics and glassware, the revised lead levels can potentially permit significant dietary lead intake. For example, the regulation stipulates that a glazed pitcher cannot leach more than 0.5 mg/L of lead into a 4% acetic acid solution if left for a 24 hour period. This regulatory level is equivalent to 500 parts per billion. If a child were regularly exposed to acidic foods (such as orange juice) contained, and especially stored in lead-glazed ceramics that approached this regulatory limit, dietary lead intake would be extremely high. While the likelihood of this kind of routine exposure is low, these revised standards are not health-protective for young children.

Lead in Paint

Canadian regulations for lead in paint were first enacted in 1970 at 5000 parts per million for paint used on furniture, toys and other articles intended for children. In 1973 this limit was also applied to paint or decorative coatings on pencils and artists' brushes. In 1978, the 5000 ppm limit was extended again to cover interior paints, and furniture or household products used in non-commercial/industrial buildings.[63] Paint with a higher lead content could continue to be used on the exterior surfaces of all buildings, and on the interiors and contained furniture of industrial/commercial premises, as well as all other buildings that children do not, or are unlikely to frequent, provided that the paint is labelled appropriately as containing lead. The Canadian limit of 5000 ppm was extended again, in 1985, to carriages and strollers[64] and in 1988, to cribs and cradles.[65]

Canadian regulatory levels for paint were revised to 600 ppm in 2005, the regulatory limit for both interior and exterior paint that had been established in the US in 1976, *28 years previously*.[66] Fortunately, the paint industry voluntarily moved to the U.S. regulation throughout North America.

In consultations during the 1990s about whether and how to reduce the Canadian limit from 5000 ppm to the US level of 600 ppm, proposed revisions languished in the "proposal" stage for over six years. Since at least the mid-1980s, children's health advocacy groups in Canada urged an updated regulation to match the U.S. standard and in particular, an end to the distinction between

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[63] *Hazardous Products (Liquid Coating Materials) Regulations*, C.R.C., c. 928.
[64] *Carriages and Strollers Regulations*, SOR/85 - 379.
[65] *Cribs and Cradles Regulations*, SOR/86-962.
[66] 16 C.F.R. s.1303 (1998) (Cornell Law, http://www.law.cornell.edu/cfr/16p1303.htm

paint used in buildings that may or may not be "frequented by children." This dubiously useful, or enforceable, distinction was finally dropped with the revised regulations in 2005. Instead, the regulation notes a series of exemptions where paint with a higher lead content is allowed, specific to a variety of industrial settings.

Lead in Multiple Consumer Products

Since 1994, in both Canada and the US, dangerously high lead levels have been discovered in crayons imported from China, plastic mini-blinds, jewellery, children's toys, clothing and accessories and numerous other products. Some of these problems were discovered as a result of elevated blood-lead levels in US children during blood-lead screening and/or reporting programs.

Crayons

The discovery of high lead levels in crayons in 1994 (imported from China, and labeled "non-toxic") occurred due to routine screening for blood-lead levels in U.S. children. An eleven month old child was found to have a blood lead level of 43 µg/dL. Follow-up investigations revealed high levels of lead (800 ppm) in orange crayons. The discovery led to additional testing, findings of other crayons from China with high lead levels, and subsequent US port seizures and a federal recall of over a dozen brands of crayons.[67] In Canada, products were not recalled. As previously noted, no authority exists under the *Hazardous Products Act* to recall products. Health Canada issued the first of many advisories to parents and caregivers of children about lead in consumer products.

Plastic Mini-Blinds

In 1996, a much larger problem emerged with the discovery of lead in plastic mini-blinds imported from China, Taiwan, Mexico and Indonesia. The Arizona Department of Health Services (ADHS), the same agency that discovered the lead-bearing crayons, investigated a case in 1995 of a one-year-old boy with a blood lead level of 37 µg/dL. The investigation eventually isolated the source to a plastic mini-blind within reach of the child's crib. The ADHS issued a lead warning about the blinds.[68] Soon after, similar findings arose in North Carolina of high lead levels on mini-blinds, associated with elevated blood lead levels in a child in a daycare centre. The Window Covering Safety Council in the United States denied any association between the blinds and elevated blood lead levels.[69]

Further testing by the U.S. Consumer Products Safety Commission confirmed that the blinds deteriorated in sunlight causing a layer of lead-bearing dust to form on the surface of the blinds. A national advisory was issued recommending that the blinds be removed from homes with children under six years of age. Over 25 million blinds had been sold in the U.S. and over 8 million had been sold in Canada.

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[67] Arreola, P., *et.al.* Lead-Tainted Crayons From China Part I: Secondary Prevention in Arizona. *Environmental Health.* (March, 1996), pp.6-15.

[68] Arizona Department of Health Services. *Miniblind Lead Warning Issued*, News Release. (December 7, 1995)

[69] Window Covering Safety Council. Mini Blinds Pose No Lead Poisoning Danger to Children: North Carolina Health Officials may have relied on discredited study. News Release. (date illegible, likely March or April of 1996)

The response in Canada was to issue a similar consumer advisory based on a risk assessment[70] that contained a significant error. In calculating the likely exposure in house dust, the risk assessment calculations incorrectly used the *average*[71] level of lead in the dust on the blinds as being representative of the 90th percentile. In so doing, the entire risk assessment greatly underestimated the potential exposure to lead from the most significant pathway - lead in dust. Nor did the risk assessment consider the likelihood of redistribution of lead dust from the blinds into house dust via cleaning activities, especially dry dusting. Even with these significant limitations, it concluded that the blinds posed a hazard to young children.

Authorities in both countries did not evaluate or, at least initially, warn about the risks of these blinds to pregnant women. By issuing only an advisory, instead of a product recall, and limiting it to homes with young children, it is very likely that some of these mini-blinds were not removed and continue, perhaps to this day, to represent a lead source to interior spaces.

Follow-up investigations undertaken by the North Carolina Department of Health indicated that despite the U.S. Consumer Product Safety Commission's (CPSC) 1996 hazard warning, mini-blinds remained a significant source of lead exposure for young children. 1998 investigations revealed that in the homes of children suffering from lead poisoning, dust lead levels from mini-blinds were as high as 77,213 $\mu g/ft^2$. Routine samples by the North Carolina Department of Health indicated that young children were being exposed to levels of ingested lead that on average exceeded the U.S. windowsill standards (for old lead-bearing paint) by more than two orders of magnitude.[72]

Multiple Advisories, Warnings and Recalls

Within the advisories, warnings or product recalls between 1995 and 2007 (available on the Health Canada website) having to do with chemical hazards in products, the majority are about products that pose a risk of lead poisoning to children. They have included warnings about lead in:

- plastic mini-blinds[73] (1996)
- children's pendant necklaces[74] (1998)
- candles and jewellery[75] (2001)
- again in pendant necklaces[76] (2003)

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[70] Wood, G., Bureau of Chemical Hazards, Environmental Health Directorate, Health Canada. *Risk Assessment for Lead in Dust from PVC Mini-Blinds*. (July 5, 1996)

[71] The dust-lead information originated from the analyses done by the U.S. Consumer Product Safety Commission and reported in: Health Sciences Laboratory Mini-Blind Study Surface Lead Determination (May 30, 1996), obtained from the US CPSC Office of Compliance, Division of Regulatory Management (June 7, 1996).

[72] Letter from Ed Norman, Children's Environmental Health Branch, North Carolina Department of Environment and Natural Resources, to the Honourable Ann Brown, U.S. Consumer Product Safety Commission. (October 15, 1997); memorandum from Kenneth Rudd, North Carolina Department of Health and Human Services, to Ed Norman, North Carolina Department of Health and Human Services. (June 15, 1998); and letter from A. Dennis McBride, State Health Director, North Carolina Department of Health and Human Services, to the Honourable Ann Brown, U.S. Consumer Product Safety Commission. (July 15, 1998)

[73] Lead hazard posed by PVC mini-blinds. On-line at: http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/1996/1996_48_e.html

[74] Potential lead exposure from Kids Klub Necklace with Pendant. On-line at: http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/1998/1998_23_e.html

[75] Health Canada advises Canadians about potential lead exposure from inexpensive jewellery and candles with lead core wicks. On-line at: http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2001/2001_02_e.html

- vending machine trinkets[77] (2004)
- necklaces and zipper pulls,[78] and jewellery charms[79] (2005)
- jewellery charms[80] (2006)
- lead in children's jewellery[81] (2007).

In addition to the above warnings from Health Canada, there were multiple instances of voluntary industry recalls for products containing lead, including: floating bath toys (in 2003), game pieces (in 2004), fishing kits for children with lead paint on the rods, paint on abacus balls (in 2005), and two additional instances of jewellery charms (in 2005).[82]

These are rarely trivial warnings in terms of volume of products. As noted above, across North America, 32 million mini-blinds were sold. For most of the jewellery warnings, tens of thousands and even millions of items were put on the market, or included with other products as promotional items, prior to the warnings being issued. A warning during the fall of 2004 about lead in vending machine trinkets in the US resulted in the single largest product recall in US history. Several months later, in March of 2006, a lead charm included with Reebok running shoes resulted in a child's death in the US.[83]

More warnings have come from the US about many of the same products noted above as well as additional products for which warnings have not been issued in Canada. Concerns about lead and cadmium in soft vinyl products arose in the late 1990s with Greenpeace[84] tests, later confirmed by the US Consumer Product Safety Commission, revealing lead and cadmium in plastic backpacks, rain clothes, assorted toys and toy cables (on headphones, toy phones, etc.). Soft vinyl lunch boxes with high lead levels were discovered in 2005 in the US.[85] Although multiple brand names were involved, an advisory about these products was not issued in Canada.

An entirely reasonable and precautionary assumption is that lead could still be in many of these and similar soft vinyl products on the market and especially those circulating for re-use or re-sale in thrift stores or in garage sales. All told, these products represent vast quantities of lead ultimately going into the municipal waste stream.

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[76] Health Canada warns Canadians about potential child's lead exposure. On-line at: **http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2003/2003_82_e.html**

[77] Health Canada warns Canadians to discard children's metal toy jewellery obtained from vending machines. On-line at: **http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2004/2004_39_e.html**

[78] High lead levels in children's necklaces and zipper pulls. On-line at: **http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2005/2005_136_e.html**

[79] Health Canada advises Canadians to remove "Charming Thoughts" metal charms from children's reach. On-line at: **http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2005/2005_23_e.html**

[80] Health Canada advises Canadians of high lead levels in children's Reebok charm bracelet. On-line at: **http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2006/2006_13_e.html**

[81] Health Canada advises Canadians of high lead levels in children's pendant necklaces and key chains. On-line at: **http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2007/2007_01_e.html**

[82] Wordsworth, A. 2006. Toxic Substances in Consumer Products and the Potential for Children's Exposure. Paper prepared for Health Canada, August 16, 2006.

[83] Centers for Disease Control (2006) Death of a child after ingestion of a metallic charm – Minnesota, 2006, *MMWR* 55(12): 340-341

[84] Di Gangi, J. Lead and Cadmium in Vinyl Children's Products: A Greenpeace Exposé; Greenpeace Canada Briefing. (Oct. 9, 1997) Vinyl Children's Products Pose Lead and Cadmium Hazard.

[85] Center for Environmental Health, Lead in Children's Lunch Boxes. On-line results of investigation at: **http://www.cehca.org/lunchboxes.htm**

The proposed "Lead Reduction Strategy"

Health Canada began, in 1997, to develop a national strategy on lead reduction. An early statement of the overall rationale for the strategy was a desire to correct the historical approach of reducing lead exposure on a product-by-product basis which had resulted in an ongoing situation of products being available containing excessive amounts of lead.[86] Instead, preventive measures that avoid crisis situations were noted as necessary. Other stated goals of the strategy were to enable industry to phase out the use of lead in non-essential applications and to provide industry with guidance to set quality control, purchase raw materials, etc. As well, the strategy was intended to create public confidence in the products and the marketplace.

A range of guidelines for achieving these objectives was outlined when the strategy was launched for consultation in 1997. These included:

1. The elimination of lead from all non-essential production applications.
2. Lead should not be added during production to any product subject to this strategy
3. The total lead content should not exceed 15 ppm which will be used to determine compliance with the strategy and the above two guidelines.
4. Use of children's and other consumer products by children should not increase the overall body lead burden of the user.
5. Industry (manufacturers, importers, retailers, and distributors) is responsible for voluntary compliance with the strategy.
6. All products subject to the Health Canada strategy and guidelines will be in compliance by the year 2001.

None of these objectives were met.

The Lead Risk Reduction Strategy

The Lead Reduction Strategy became the Lead Risk Reduction Strategy.[87] The initial rationale of getting beyond the reactive, product-by-product approach was clearly abandoned. Nor has the problem been approached with the efficiency implied in the first objective (eliminating lead from non-essential lead product applications).

After ten years, Health Canada has accomplished three regulations. First, the glazed ceramics and glassware regulations, described above, were revised. Second, the regulation on lead in paint[88] was brought in line with the US limit (established 28 years previously in 1976). The third is a regulation on children's jewellery that, arguably, avoids over 90% of the problem of lead in costume jewellery and related items.

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[86] Subramanian, M., Acting Director, Product Safety Bureau, Health Canada. Undated speech apparently delivered in February, 1999.

[87] Current version available on-line at: http://www.hc-sc.gc.ca/cps-spc/legislation/consultation/leadrisk_e.html

[88] *Surface Coating Materials Regulations* - SOR/2005-109.

The Children's Jewellery Regulation

The *Children's Jewellery Regulation*[89] was promulgated in June of 2005, after multiple product warnings and eight years after Health Canada identified lead in jewellery as a hazard. Lead levels in inexpensive costume jewellery, promotional key chain fobs, zipper pulls, and other decorative metal objects runs as high as 50% pure lead (500,000 ppm).[90] It is a conservative estimate that millions of these items have been available for over ten years in stores selling inexpensive notions and accessories as well as from street vendors, temporary booths at fairs and expositions, shopping malls, and from marketing-support companies that provide promotional key chain fobs, conference pins, etc.

However, the regulation applies only to jewellery that is marketed to children. This choice was made, according to the Regulatory Impact Analysis Statement (RIAS) published in the *Canada Gazette*, to avoid economic hardship to the costume jewellery industry. In providing a rationale for not banning all lead-containing jewellery, the RIAS prepared by Health Canada presents the interests of the costume jewellery industry:

> Such a ban would be extremely disruptive to the costume jewellery trade, since much of the costume jewellery currently on the Canadian market does contain lead. This action would likely result in significant reduction in consumer choice, since many manufacturers would not be willing to produce lead-free adult jewellery for the relatively small Canadian market.[91]

In further disputing the need for warning labels, in support of the economic interests of the costume jewellery industry, the RIAS states:

> ...this recommendation would require that the majority of adult costume jewellery be labelled, since most of it contains lead. Warning labels posted next to jewellery displays would be of limited effectiveness since they would be separated from the product at point-of-sale. Retailers believe that such labels would be a considerable disincentive to the customer. If the jewellery itself were labelled, the labels would have to be so small and inconspicuous that they would be ineffective for the purpose of ensuring that children do not interact with the jewellery.[92]

The distinction between adult and children's jewellery is an artificial one that is impossible to enforce. Even where the regulation legitimately applies, more advisories about lead in children's jewellery have been issued (as noted above, in March of 2006 and in January of 2007) and there were three voluntary industry recalls of lead in children's jewellery during 2006.

As a demonstration of how this problem remains unresolved, after taking eight years to write a regulation that only addressed a tiny fraction of the problem, Health Canada issued an advisory during the 2006 Christmas season warning parents to exercise caution in holiday purchases of

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[89] *Children's Jewellery Regulations* - SOR/2005-132.

[90] Analyses, (done by a metallurgical laboratory at the University of Toronto for the Canadian Environmental Law Association), of several pieces of commonly available jewellery, conference lapel pins and key chain fobs, found lead concentrations ranging between 13% (130,000 ppm) to 50% (500,000 ppm) lead with a single item containing 95% (950,000 ppm) lead.

[91] Regulatory Impact Analysis Statement for the Children's Jewellery Regulations. *Canada Gazette*, Part 1, Vol. 137, No. 47 — November 22, 2003.

[92] *Ibid.*

children's jewellery.[93] Such a warning is clearly necessary since the regulation does nothing to remove many thousands, probably millions of these items from stores and other vendors. Moreover, the artificial and unenforceable distinction between regular jewellery and "jewellery intended for children" would not address the ability of women to purchase and wear necklaces containing this kind of jewellery that their small children could handle and put in their mouths.

Proposed Actions for Five Product Groupings

As summarized in Appendix One, further actions under the Lead Risk Reduction Strategy extend the product-by-product approach to a broad array of consumer items. Long gone from this approach are the objectives proposed in 1997 of getting beyond product-by-product crisis management, seeking the elimination of lead from non-essential production applications, avoidance of adding lead during production and the objective of keeping total lead content below 15 ppm.

If these original objectives remained, the allowable level of 15 ppm would provide for a contamination level, in recognition of the reality of global lead contamination and the fact that lead is a naturally occurring substance. Instead, the Lead Risk Reduction Strategy states that:

> A total prohibition on lead in a consumer product would be unrealistic because trace amounts of lead are found everywhere in the natural and human environments.

This statement sets up the proverbial "straw man" to knock down. Rather than banning non-essential uses of lead and setting regulatory limits that account for the reality of contamination, as was done with lead in gasoline, these proposals for regulations across five product groupings will essentially sanction the use of lead in dozens of consumer products. It is a highly inefficient, labour-intensive exercise to both create and enforce multiple regulations applicable to myriad products. It also sends a signal that continued use of lead across broad categories of products is acceptable.

Of particular note are the exemptions for Group 3. The applications noted in the first category of exemptions would include the use of lead and other heavy metals in electrical and electronic equipment, just the sort of e-waste that more progressive jurisdictions are attempting, via technology-forcing, regulatory action to bring under control. For example, the Waste Electric and Electronic Equipment (WEEE) Directives of the European Union focus on restricting the use of certain hazardous substances in electrical and electronic equipment[94] and reducing the resulting waste stream.[95] Measures that require recycling and producer take-back provide incentives for both redesign (to facilitate recycling) as well as elimination of toxic components to

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[93] Parents and caregivers advised to exercise caution in holiday purchases of children's jewellery. On-line at: http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2006/2006_128_e.html

[94] 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: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0095:EN:HTML

[95] 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

reduce the toxicity of the entire production chain, through to waste management. The WEEE Directive also includes electric toys such as electric trains (as listed in Annex 1A to the Directive).

The second exemption for Group 3 would allow for exposure to potentially toxic levels of lead to children "over 36 months" or just three years old. The hazards of lead are of concern to children up to at least six years of age. More important, like the children's jewellery regulations, such distinctions ignore the reality of homes and other child care settings with multiple children of many ages as well as the need for women of child-bearing age and particularly pregnant women to avoid lead exposure throughout the child-bearing years.

Lessons learned from the case of lead and phthalates (discussed in the next chapter) are noted in Chapter Four alongside conclusions and recommendations for improved regulation of toxic substances in consumer products.

Chapter 3: Case Study – Phthalates

Introduction

Phthalate esters are oily liquid plastic softeners that look similar to vegetable oils and dissolve poorly in water. They are generally added to polyvinyl chloride (PVC) to make it more flexible by allowing the long polyvinyl molecules to slide against one another. First produced in the 1920s, they have been used in large quantities since the 1950s when PVC was introduced. Because phthalates are not chemically bound to the plastic, they may be released during use and after disposal. In addition to PVC plastic, phthalates are in cosmetics, pharmaceuticals and insecticides, among other uses.

As of 1996, global production exceeded 3.5 million tonnes per year. According to the recent categorization, the Canadian Domestic Substances List counts 65 phthalates, four of them having been evaluated under the Priority Substances Program:

- di(2-ethylhexyl) phthalate (DEHP);
- di-*n*-butyl phthalate (DBP);
- di-*n*-octyl phthalate (DOP); and
- *n*-butyl benzyl phthalate (BBP).

Of the four phthalates evaluated under the Priority Substances Program, only DEHP was found to be Toxic under the *Canadian Environmental Protection Act* (CEPA). The Consumer Products Division of Health Canada also did a human health assessment of diisononyl phthalate (DINP) in children's products.

DEHP is the most frequently used phthalate in the world accounting for half of global production. Roughly 95% of it is used to soften PVC, the plasticizer making up on average 30% of the weight of the plastic. Other heavily used phthalates include di-*n*-butyl phthalate (DBP) and *n*-butyl benzyl phthalate (BBP), the worldwide consumption of each surpassing 100,000 tonnes in 1996.[96] As of 1994, over 107,000 tonnes of DINP were produced annually in the European Union alone and production was expected to increase further.

In looking at the regulation of phthalates in consumer products this case study focuses on the four major phthalates used in household consumer products that have had some sort of assessment in Canada. Risk assessments under CEPA have been conducted for DEHP, DBP and BBP; DINP has had a more limited evaluation concentrating on the risk to children from exposure through children's products. Regulatory action in Canada is briefly summarized but conclusions drawn from this review and related recommendations are included in the analysis of both case studies, in Chapter Four.

[96] Bornehag, C-G et al. The Association between Asthma and Allergic Symptoms in Children and Phthalates in House Dust: A Nested Case–Control Study. *Environmental Health Perspectives*. October 2004. 112(14): 1393–1397.

DEHP

Use and exposure

The Priority Substances Program evaluation of DEHP was completed in 1994 under the synonym bis(2-ethylhexyl) phthalate. According to the 1991 numbers available at that time, 5,000 tonnes of DEHP were produced in Canada at two domestic facilities. Another 5,000 tonnes was imported, almost entirely from the United States. It is difficult to estimate how much additional DEHP was imported into the country in products, but at that time, over 1,000 tonnes was estimated to be entering Canada already added to products made of PVC plastic.[97] While the earliest National Pollutant Resource Inventory (NPRI) report of DEHP emissions showed 24 tonnes in 1994, the reported releases under the program had decreased to just over 9 tonnes by 2005.[98]

Of Canadian-produced DEHP, at the time of the assessment, over 50% went into vinyl products such as coated fibres and 35% was used for PVC films and sheets. The amount of DEHP contained in each generally ranged from 10 to 40% by weight.[99] In 1994, DEHP was still routinely used in children's products sold in Canada. Of a preliminary survey of pacifiers, teethers, baby bottle nipples and flexible toys, seven out of 24 had DEHP levels above the limit of detection with three of them containing between 20 and 23% plasticizer.[100]

DEHP breaks down into:

- mono(2-ethylhexyl) phthalate (MEHP);
- mono-2-ethyl-5-oxohexyl phthalate (MEOHP); and
- mono-2-ethyl-5-hydroxyhexyl phthalate (MEHHP).

The 1999-2000 U.S. National Health and Nutrition Examination Survey (NHANES) tested for the MEHP metabolite in the urine of 2541 people. Detectable levels were found in 78% of the 2541 samples. This result likely underestimates the exposure of DEHP in the American population as MEOHP and MEHHP were not included in these tests.[101] Silva et al. have since reported that these two metabolites occur in higher concentrations in human urine than MEHP.[102]

While DEHP has largely been phased out of children's products intended for mouthing, exposure still occurs through consumer products intended for both children and adults. The substance has also been widely incorporated into cosmetics, another usage that is being phased out. DEHP can contaminate food through materials used to process and package food. Some pharmaceuticals, such as those with special coatings, may also contain significant levels of DEHP. Other important sources of DEHP include indoor air and levels of the chemical found in house dust.

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

[98] National Pollutant Release Inventory. On-line at: http://www.ec.gc.ca/pdb/npri/npri_home_e.cfm..

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

[100] *Ibid.*

[101] National Toxicology Program Centre for the Evaluation of Risks to Human Reproduction. Draft NTP Brief on the Potential Human Reproductive and Developmental Effects of Di(2-ethylhexyl) Phthalate. May 2006.

[102] Silva M.J. et al. Urinary levels of seven phthalate metabolites in the U.S. population from the National Health and Nutrition Examination Survey (NHANES) 1999-2000. *Environmental Health Perspectives* 2004; 112:331-338.

One of the most significant sources of DEHP exposure is via its presence in medical products made from PVC. Blood bags, intravenous bags, tubing, catheters, and other medical devices often contain high levels of DEHP, and the DEHP has been shown to leach from these products so that the phthalate enters directly into the bodies of patients with use.

The DEHP Priority Substances evaluation took into account the presence of DEHP in products meant for children's mouths when calculating the average exposure. Lacking reliable information about the rate at which DEHP leached, an estimate of 30 µg per hour was used. Besides these exposures, food, air and water were considered, with food thought to be the largest source of DEHP contact. The greatest exposure was therefore thought to be for children six months of age to four years, determined to be 18.9 to 23.1 µg/[kg (b.w.)·d].[103]

The DEHP assessment left out important sources of contact with the chemical. Though not universal in the population, the use of DEHP-containing medical devices would have greatly elevated the total estimated exposure for those receiving medical care. The lack of discussion of the presence of DEHP in medical devices suggests that risk assessors were unaware of this use and exposure at the time.

More relevant to other phthalate assessments, the evaluation left out exposures from consumer products not meant for young children. Direct contact with household products containing significant quantities of DEHP and with personal care products having DEHP in them was omitted. Although there were estimates of indoor air exposure which would be related to use in flooring, products and cosmetics, there was also no attempt to estimate the exposure through house dust.

House dust has since been recognized as an important reservoir for chemicals shed from consumer products and building materials. Ingesting dust may be an important route of exposure for the general population but even more so for children who put more things in their mouths and crawl or play more on the floor. A 2004 study looking at the association of allergies and asthma with phthalates found that asthma rates were associated with the level of DEHP found in house dust, and that having PVC flooring increased those DEHP levels.[104] Finally, breast milk exposure was also not included in the calculation of DEHP food intake for infants.

Toxicity

The critical study used to determine the Tolerable Daily Intake (TDI) was a developmental study in mice that showed increased resorptions and dead fetuses. The NOEL for both mothers and offspring was 44 mg/[kg(b.w.)·d]. In deciding that DEHP was Toxic under CEPA due to its risk to human health, the risk assessors used a 1000-fold uncertainty factor giving a TDI of 44 µg/[kg (b.w.)·d]. This 1000-fold factor included the usual 10-fold factor for interspecies variation and a 10-fold for intraspecies variation. In addition, it included an extra 10-fold factor due to the

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

[104] Bornehag, C-G et al. The Association between Asthma and Allergic Symptoms in Children and Phthalates in House Dust: A Nested Case–Control Study. *Environmental Health Perspectives*. October 2004. 112(14): 1393–1397.

potential teratogenic effects seen in the critical study.[105] The authors discussed the likelihood that the food intake used in the assessment was an underestimate and that if a worse case scenario was used that the estimated exposure would approach or exceed the TDI.[106]

Since the Priority Substances Program evaluation of DEHP, evidence of reproductive impacts has emerged as the most worrisome characteristic. DEHP has been shown to be an anti-androgen that blocks testosterone synthesis in animals and affects masculinization. Gray et al. found that the male offspring of rats dosed with DEHP had a reduced anogenital distance (a marker for degree of masculinizaion), had smaller testis, and 87% had nipples, a trait reserved for females.[107]

In Shanna Swan's seminal 2005 study on anogenital distance (AGD) in human infant boys, she and her colleagues studied DEHP through its metabolites. The researchers found that though MEHP was not related to a decreased AGD, MEHHP and MEOHP were both significantly associated.[108] MEHP itself has nonetheless been shown in other studies to be toxic to the testicle and a teratogen in animals.[109]

DPB

Use and Exposure

The Priority Substances Program evaluation of DBP was also completed and published in 1994. There was no production of DBP in Canada at that time but 540 tonnes were imported into the country, almost 85% of that from the United States.[110] The first NPRI reporting of DBP releases in Canada totaled 0.83 tonnes; by 2005 that had greatly increased to 4.26 tonnes.[111]

Dibutyl phthalate is used widely as a plasticizer in polyvinyl chloride; PVC tubing can contain as much as 23% DBP. In 1991, 54% of the Canadian supply of DBP was used in adhesives and 31% in miscellaneous applications, including paper coating. DBP has also been used as a perfume solvent and fixative, in aerosols, as a skin softener and in nail polish and fingernail elongators.[112] A Canadian market basket survey from 1986 found the highest levels of DBP in butter. Other foods containing greater than average amounts of the plasticizer were margarine, freshwater fish and baked potatoes.[113]

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[105] Government of Canada. *Canadian Environmental Protection Act* Priority Substances List Assessment Report: Bis(2-ethylhexyl) phthalate. 1994.
[106] *Ibid.*
[107] 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.
[108] 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.
[109] Blount, B.C. et al. Levels of Seven Urinary Phthalate Metabolite Levels in a Human Reference Population . *Environmental Health Perspectives*. October 2000. 108(10): 979-982.
[110] Government of Canada. *Canadian Environmental Protection Act* Priority Substances List Assessment Report: Dibutyl phthalate. 1994.
[111] National Pollutant Release Inventory. On-line at: http://www.ec.gc.ca/pdb/npri/npri_home_e.cfm.
[112] Government of Canada. *Canadian Environmental Protection Act* Priority Substances List Assessment Report: Dibutyl phthalate. 1994.
[113] *Ibid.*

The average daily intake of DBP was estimated to be 1.9 to 5.0 μg/[kg (b.w.)·d]. This estimate, however, left out many potential routes of exposure. It did not account for exposures through breast milk or formula, through direct contact with children's products or other household consumer products and did not attempt to estimate the well-known exposures from cosmetics. The exposure assessment also left out any ingestion of DBP through house dust.

Toxicity

The Priority Substances Program assessment of DBP acknowledged insufficient data at that time on the chronic toxicity or carcinogenicity of the substance. Neurotoxicity and immunotoxicity data were also not available. It did find that DBP had fetotoxic effects at levels that were not toxic to the mother and the report stated that DBP might be teratogenic.[114]

The risk assessment of DBP focused entirely on the parent substance and found it to be not Toxic. It did not investigate the potential toxic effects of its breakdown product, Mono-butyl phthalate (MBP). The TDI for DBP was calculated based on a NOEL for fetotoxicity and teratogenicity in mice.[115] The 10-fold uncertainty factors for inter- and intra species differences were used but there was no additional safety factor for teratogenic effects as with the DEHP evaluation. Nor were there additional factors included to account for the large gaps in information both due to the absence of scientific studies and the exclusion of known and potential sources of exposure.

Since the DBP Priority Substances evaluation, the National Toxicology Program's expert panel confirmed in 2000 that DBP is developmentally toxic to both mice and rats.[116] In 2005, DBP was listed in California under Proposition 65[117] as a developmental and reproductive toxin based on the growing body of evidence for DBP's effects. The European Union as well has classified DBP as a reproductive toxin. Like the breakdown products for DEHP, MBP has also been associated with increased anogenital distance in both animal and human studies.[118]

BBP

Use and Exposure

The BBP assessment was done as part of the second batch of the Priority Substances Program (PSL 2) and was completed and published in 2000. The assessment found that, as of 1996, 4,000 tonnes of BBP were being imported into Canada.[119] As of 1999, 10.8 tonnes of BBP was reported being released by Canadian industry under NPRI. This amount had risen to 25.5 tonnes by 2005, with 22.6 of those 25.5 tonnes released by one facility: an Armstrong World Industries plant in Montreal.[120]

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[114] *Ibid.*

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

[116] National Toxicology Program. NTP-CERHR Expert Panel Report on Di-n-butyl Phthalate, October 2000.

[117] *Safe Drinking Water and Toxic Enforcement Act, 1986.* California Code of Regulations.

[118] 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.

[119] Government of Canada. *Canadian Environmental Protection Act* Priority Substances List Assessment Report: Benzylbutylphthalate. 2000.

[120] National Pollutant Release Inventory. On-line at: http://www.ec.gc.ca/pdb/npri/npri_home_e.cfm.

According to Canadian surveys done at that time, BBP was found in PVC flooring and other PVC products. It was noted to be in paints and coatings, in adhesive formulations and in printing inks. Research on food levels found BBP in a number of products, with dairy, and in particular butter, having the highest levels. No Canadian data for breast milk or infant formula was found at the time; likewise, no information on the levels of BBP in consumer products was available.[121]

The average daily intake and worst-case scenario were estimated to be 5.0 and 145 µg/kg-bw per day respectively. This, however, left out any exposure through cosmetics, consumer products, house dust, breast milk or infant formula.[122]

Toxicity

Some of the major effects noted for BBP were related to toxicity to the testes and to *in vitro* screening which showed BBP to be estrogenic in breast cancer cells. There was some evidence of carcinogenicity, but the risk assessors did not find the case convincing. The TDI calculated was based on the 95% percentile for pancreatic lesions found to be 132 mg/kg-bw per day. Using the conventional 100-fold uncertainty factors, the TDI was determined to be 1300 µg/kg-bw per day. As with DBP, no extra safety factor was used for children.[123]

An expert panel of the National Toxicology Program concluded in 2000 that "oral exposure to BBP can cause reproductive toxicity in adult rats and developmental toxicity in rats and mice. These data are assumed to be relevant to humans."[124] As with DEHP and DBP, BBP has been listed under California Proposition 65, though only as a developmental toxin. Earl Gray's 2000 study also found BBP to be a male reproductive hazard. Seventy percent of male offspring whose mothers were given BBP had female nipples. Their average testes weight was reduced, as was the anogenital distance.[125]

BBP breaks down into monobenzyl phthalate (MBzP), but also into monobutyl pththalate (MBP) akin to DBP. The MBP breakdown product is actually generally found in higher amounts than MBzP at a 5:3 ratio.[126] These metabolites themselves have been shown to induce effects on the testes and other problems similar to their parent compounds, with MBP having the greater potency.[127] Other studies have confirmed this effect of MBP on the male reproductive system, including anti-androgenic effects in a multi-generational study.[128] Shanna Swan's human study

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[121] Government of Canada. *Canadian Environmental Protection Act* Priority Substances List Assessment Report: Benzylbutylphthalate. 2000.
[122] *Ibid.*
[123] *Ibid.*
[124] National Toxicology Program. NTP-CERHR Expert Panel Report on Butyl Benzyl Phthalate, October 2000.
[125] 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.
[126] Government of Canada. *Canadian Environmental Protection Act* Priority Substances List Assessment Report: Benzylbutylphthalate. 2000.
[127] Mikuriya, H.I. et al. Urinary metabolites contributing to testicular damage induced by butylbenzyl phthalate. 1988. *Jikeikai Medical Journal.* 35: 403–409, quoted in Government of Canada. *Canadian Environmental Protection Act* Priority Substances List Assessment Report: Benzylbutylphthalate. 2000.
[128] Foster P. M. et al. Effects of phthalate esters on the developing reproductive tract of male rats. Human Reproductive Update 2001; 7: 231-235.

of phthalate levels and anogenital distance (AGD) found that MBP and MBzP were associated with AGD along with MEOHP and MEHHP.[129]

Evidence for the reproductive effects with both of BBP's metabolites, MBzP and MBP suggest that BBP is indeed a reproductive toxin. These metabolites, and those of DEHP, are certainly part of the toxicity of their parent compounds, and may even be the sole source of harm. This finding suggests the importance of taking a class-based look at these chemicals. More importantly, the fact that DBP and BBP share a common metabolite builds a strong case for considering the effects of these phthalates jointly.

DINP

Use and Exposure

The Consumer Products Division assessment of DINP was published on November 14, 1998. As noted above, over 107 000 tonnes of DINP were produced annually in the European Union in 1994 and production was expected to increase further. No information on DINP release in Canada is available through the NPRI.

The 1998 assessment looked at the presence of DINP in 42 children's PVC products.[130] Twenty-seven of those tested contained measurable DINP, the range being from 3.9% to 44%. The assessment used Dutch research on adult volunteers which found the rate of migration of DINP into saliva to range from 18 to 534 µg per 10 square centimeters per hour (10 cm^2 estimated to be the contact area with a child's mouth).[131]

Interestingly, the amount of DINP in the product had little relation to the rate at which it leached, smaller amounts having the same exposure potential. Health Canada's estimated exposure from a teether was 4 – 320 µg/kg b.w./day with18 – 640 µg/kg b.w./day from a pacifier.

Pacifiers were not considered a risk since the division's survey of the Canadian marketplace did not find DINP in any pacifier. Almost all the pacifier nipples were made of latex or silicone. Overall, Health Canada's probabilistic analysis found the 95th percentile for exposure to be 73.9 µg/kg bw/day including dietary and other sources for children aged 3-6 months who mouthed teethers. The 99th percentile for this group was at 173.5 µg/kg.

Silva et al.'s 2006 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

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[129] 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.

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

[131] Könemann, W. H., ed., Phthalate Release from Soft PVC Baby Toys. National Institute of Public Health and the Environment (RIVM), September, 1998.

DINP biomonitoring has underestimated the population exposure to the chemical by using urinary MINP levels as a biomarker.[132]

Toxicity

The calculated Tolerable Daily Intake (TDI) was based on an unpublished study submitted near the end of the assessment. The study results were used to establish an NOAEL of 29.2 mg/kg/day for the rat population. Until that study was submitted, Health Canada was working with a NOAEL of 15 mg/kg/day. The original intention was to use an additional safety factor of 2 (giving 200 in factors overall) due the weakness of the evidence. With the new study, the 2-fold safety factor was eliminated and the TDI was set at 292 µg/kg/day for children.

The assessment of DINP was based on evidence for liver and kidney toxicity. Since then however, DINP has been shown to have anti-androgenic effects similar to DEHP, DBP and BBP. Gray et al.'s study of phthalates and reproductive toxicity found that 7.7% of male offspring had female nipples when their mothers were exposed to DINP. This was statistically significant though three to four times fewer pups were affected than with DEHP and BBP.[133]

Nevertheless, Health Canada determined that "the quantity of DINP released from soft PVC products designed specifically to be mouthed by young children may pose a risk to the health and safety of children between the ages of 3 months and 1 year."[134] Though the estimated exposure was less than the TDI, the risk assessors remained concerned because DINP is composed of many different isomers. Some grades of DINP could be more potent than others. In addition, because release rates had more to do with the type of product than the amount of DINP in a product, household products beyond the three tested in the Dutch study could create higher exposures.

The assessors also asserted the need to be cautious in the use of DINP in children's products as children did not have the capacity to make their own informed choices about using the products. And finally, the authors noted that "since there are readily available alternatives in the marketplace which do not contain DINP, the potential risk, though small, is judged to be unnecessary and therefore unacceptable."[135]

Health Canada's approach was to warn physicians, parents and other caregivers that soft vinyl products designed to be mouthed were a potential risk from DINP and should be disposed of. The department posted a list of products known to be DINP-free though they did not list those they knew contained the chemical. In addition, in cooperation with the Canadian Retail Council, Health Canada advised manufacturers to remove soft vinyl rattlers and teethers that contained DINP from the shelves. No regulation prohibiting the use of DINP in these products was written, the department relying on voluntary withdrawals.

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[132] Silva, M.J. et al. Oxidative Metabolites of Diisononyl Phthalate as Biomarkers for Human Exposure Assessment. Environmental Health Perspectives. Aug 2006, 114(8): 1158-1161.

[133] 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.

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

[135] *Ibid*

At the same time, in December of 1998, the U.S. Consumer Products Safety Commission made a similar request of manufacturers, asking them to remove phthalates from rattles and teethers while more scientific study was being done.[136] In a press release, they stated that 90 percent of manufacturers had agreed to remove phthalates by early 1999.

However, Greenpeace International's 2001 testing of children's products for of phthalates suggested that the voluntary withdrawal was not effective. Two of the products tested were teethers sold in the United States, and both of them were over 20% DINP.[137] While these teethers were still legal for sale in the United States and in Canada, they would not have been in Europe. By 1999, the European Commission had stipulated that products intended for mouthing by children under age 3 could not contain more than 0.1% PVC containing DINP.

Despite more recent evidence of reproductive toxicity, the U.S. Consumer Products Safety Commission made a further announcement in 2003, this time allowing the continued use of DINP in toys made for children under five. This effectively removed the voluntary ban on DINP use in teethers and rattles.[138]

Additional Regulatory Options

In addition to the above shortcomings in the application of CEPA to phthalates and the limited and non-regulatory review of DINP, neither the F&DA or the HPA have been effectively applied to phthalates.

Food and Drugs Act

The F&DA has, in theory, the ability to regulate the presence of chemicals in products in three relevant areas: food packaging, cosmetics and medical devices. In all three of these areas, phthalates like DEHP, DBP and BBP have been used and by and large are still being used.

For food packaging, Health Canada provides a list polymers approved for use that includes polyvinyl chlorides, i.e., PVC plastic. There is no indication that the specific phthalates used in the PVC, or the amount of the phthalate, is restricted for food packaging.[139] Rather, the inclusion of polyvinyl chlorides on the list of acceptable polymers for use in 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.[140] Packaged foods can therefore add to the

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[136] US Consumer Product Safety Commission, Media Release Dec. 2, 1998. CPSC Releases Study on Phthalates in Teethers, Rattles and Other Children's Products. On-line at: http://www.cpsc.gov/cpscpub/prerel/prhtml99/99031.html

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

[138] Hileman, B. U.S. Consumer Products Safety Commission allows the Continued Use of Phthalates in Toys While EU Seeks Ban. *Chemical and Engineering New.* March 3, 2003.

[139] Lists of acceptable polymers for use in food packaging applications. On-line at: http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/polymers_tc-polymere_tm_e.html.

[140] 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).

overall body burden of phthalate exposure and no action has been taken under the F&DA to reduce this contribution.

As noted in Chapter One, the F&DA, like the HPA applies regulatory limits on specific chemicals only where these are noted in the regulations, within which very few chemicals are included.[141] Indeed, the opposite is the case for phthalates given the fact that Health Canada's F&DA guidance offers a long list of polyethylene terephthalates[142] (with only Trade names provided) as acceptable for food packaging alongside the blanket approval for the use of polyvinyl chlorides.

Nor has the F&DA been applied to phthalates in cosmetics. Despite its designation as CEPA-toxic, DEHP is not included in Health Canada's "Cosmetics Hot List," (described in Chapter One). In contrast, DBP and DEHP have both been banned from cosmetics in Europe since 2003.[143] In 2001, they were both declared to be reproductive toxins and the 2003 European directive declared that no reproductive toxins could be used in cosmetic products. This restriction and some consumer pressure has led to the reduction of DBP and DEHP in products in Canada and the United States as well. The major cosmetics companies have committed to not using these phthalates as ingredients. Nevertheless, Health Canada officials state that they believe DBP is still used in nail polish. As well, the 2007 *Shop Smart Guide* from Consumer Reports in the United States includes the testing of eight fragrances from major companies and all still had detectable levels of DEHP.

There does not appear to be a statutory requirement for a risk assessment under the F&DA or CEPA for such exposures. As a CEPA-Toxic substance, DEHP is an obvious choice for the hot list. BBP and DBP, as developmental and reproductive toxins, should also be restricted in cosmetics given the direct exposure that such products cause.

Finally, with respect to the regulation of medical devices, the F&DA is equally silent. The amount of DBP and BBP used in medical devices is unclear but the use of DEHP is widespread. This DEHP use includes those devices which expose patients through inhalation via masks and tubing or directly into a vein. DEHP can often make up a large percentage of the weight of the PVC product, usually to give the device flexibility. The DEHP is not bound to the plastic however, so it leaches into the fluids and gases running through the devices.

There is much evidence that patients can receive large doses of DEHP, particularly during intensive procedures, and infants and children are more at risk because of their lower body weight relative to the amount of fluid they might receive. Because the primary toxicity of DEHP appears to be to the developing male reproductive system, DEHP-containing devices put young boys and male fetuses at proportionally higher risk. Both the Food and Drug Administration in

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[141] 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

[142] See Health Canada, Food and Nutrition Guidelines, Lists of acceptable polymers for use in food packaging applications, Table 7 – Polyethylene terephthalates On-line at: http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/pet-tpe_e.html

[143] 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. On-line at: http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_066/l_06620030311en00260035.pdf

the United States and Health Canada have studied this situation and recommended the use of non-DEHP containing products in high risk situations for this population.[144] [145]

No regulatory action has been taken in either jurisdiction or in the European Union to protect young males, and there is little evidence that the recommended changes have happened voluntarily. In Canada, arguably, the level of health care provider awareness of the risks remains quite low. In addition, a more precautionary approach would go beyond substitution in only the most high risk situations. As DEHP is a CEPA-Toxic substance, it is important to protect the population from as much exposure as possible. Reducing the use of DEHP-containing PVC would also decrease environmental emissions from manufacturing that contaminate food and contributing to the population body burden of DEHP found in biomonitoring studies.

Interestingly, one study of neonates in an intensive care unit found that their levels of MBzP were higher than those of the average American as seen in biomonitoring studies.[146] More study is needed to determine the sources of BBP in the neonatal intensive care environment and whether they are from medical devices or other sources in the unit. The additional phthalate load also raises the question of combined exposure and the need to look at BBP and DEHP exposure together in neonatal intensive care.

Hazardous Products Act

The HPA has not been applied to the issue of phthalates in consumer products at all. While the European Union was taking health-protective action on the major phthalates in children's toys, BBP, DBP, DEHP and DINP, Canada did not use the HPA to do the same. Canadian children have benefited from actions taken in other jurisdictions like Europe as reformulations for that market have prompted companies to do the same for others. It is questionable whether that protection would have occurred if Canadians were left to protect their own.

For DINP, Health Canada chose to go with a voluntary approach similar to that used in the United States. Greenpeace's 2001 research, however, showed that the U.S. approach had not worked. Only two American teethers were tested in the study but both had considerable amounts of DINP. It is likely, given the close relationship between the Canadian and American markets that Canadian teethers also contained DINP. The United States has since loosened its restrictions on DINP while Canada has not. It would be important to determine what kind of an impact this has had on DINP levels in children's products. Greenpeace's work suggests that products meant to mouthed still contain DINP in Canada.

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[144] Draft Position Statement on DEHP in Medical Devices for Stakeholder Consultation. On-line at: http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/sci-consult/dehp/dehp_position_draft_ebauche_e.html.

[145] US Food and Drug Administration. July 12, 2002. FDA Public Health Notification: PVC Devices Containing the Plasticizer DEHP. On-line at: http://www.fda.gov/cdrh/safety/dehp.html.

[146] Weuve, J. Exposure to Phthalates in Neonatal Intensive Care Unit Infants: Urinary Concentrations of Monoesters and Oxidative Metabolites. *Environmental Health Perspectives*. September 2006; 114(9): 1424–1431.

Chapter 4: Lessons Learned and Recommendations

Introduction

Of the three statutes in Canada that play a role in controlling toxic chemicals, all three contain provisions for regulating toxic substances in consumer products, including some of the same substances under all three laws.

The HPA and the F&DA 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. That is, these two laws tend to be applied to products or commodities after problems are identified or where harm may have already occurred. 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.

In comparison, CEPA allows, in theory, for a much more comprehensive approach to regulating the entire life cycle of products or commodities. However, there are limitations in terms of both the interpretation and scope of existing legislative provisions in CEPA for this law to be effectively used to regulate toxic substances in products.

Across these statutes the underlying policy for evaluating and managing chemicals follows traditional risk assessment and risk management approaches. These approaches are rarely integrated, despite the fact that the same substances may need to be assessed within two or even all three of these statutes. These traditional risk assessment approaches rarely include the more modern notion, increasingly embraced in the European Union, of prohibiting, in consumer products, the use of inherently toxic substances (such as carcinogens or reproductive toxins).

As the lead case study illustrates, these three federal statutes have been applied to the regulation of lead in diverse situations, including for consumer products. This situation creates confusion. Paradoxically, it also creates both overlap and gaps in regulation. The designation of CEPA-toxicity for both lead and at least one phthalate, DEHP, has had very little impact on continued use and exposure to these substances in consumer products. Nor are these substances effectively controlled under the HPA, despite the focus of that law on hazards in products. The F&DA has not been effectively applied to the control of either lead or phthalates.

Overall conclusions

An overall conclusion of this review is that toxic substances in products are not adequately regulated in Canada. Shortcomings exist across all three laws reviewed here. Nor are these shortcomings addressed by the proposed "general safety requirement."

A second overall conclusion is that the regulation of products involves the need to assert a domestic, national authority to regulate imported products for the sake of ensuring environmental protection and public health and safety. The manner in which government policies assert or imply the primacy of economic considerations, including international trade agreements, over other societal interests is highly problematic. Where these policies also assert or imply primacy of voluntary approaches over regulatory approaches, they can undermine the ability of federal

departments to implement federal laws intended to address environmental protection and public health and safety.

A third overall conclusion is the need for recognition of two related concepts that would improve the regulation of toxic substances in products. These include:

1. The need to modernize regulation such that the default position on chemicals with inherently toxic properties is that they are simply not allowed in consumer products; and
2. Recognition that certain "essential" uses of these same substances in products could be allowed but only under clearly specified circumstances such as those necessary for medical or safety reasons.

These conclusions are further explored below with respect to the three laws under review, related government policy, including the proposed GSR, and in light of the two case studies.

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. Of the five government policies noted in Chapter One, each mentions this reality. They provide for either a requirement to consider trade agreements when setting environmental policy or, more often, require that economic and trade considerations, including voluntary over regulatory measures, be considered paramount.

This paramountcy of trade and non-regulatory approaches is evident in the OECD regulatory reform program[147] 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 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 2000[148] 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.

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[147] OECD, OECD Guiding Principles for Regulatory Quality and Performance (OECD, 2005), p. 1.
[148] Chapter 24, 2000 Report of the Auditor General of Canada, "Federal Health and Safety Regulatory Programs."

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 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)

Seven 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 arguably 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 OECD[149] 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.

Proposed General Safety Requirement

The General Safety Requirement (GSR) has been proposed to address shortcomings in the regulation of risks posed by consumer products. The GSR approach in the European Union 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.[150]

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.[151] Although the notion of a GSR proposal could be a useful addition to law, providing greater

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[149] 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.

[150] 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.

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

jurisdiction to Health Canada and supplementing civil liability for unsafe products, as proposed, it will not provide an effective substitute for proactive, regulatory action for several reasons.

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

CELA found instead that the GSR, as proposed, would constitute a retreat from law-making and would deprive Canadian citizens of the opportunity to participate in standard-setting and hold government accountable for standards. 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 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.

The best and only reliable measure of "general acceptance" of a standard is its incorporation into regulation. The proposed 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.

Food and Drugs Act

Summarizing the descriptive review of the F&DA in Chapter One, this law can regulate poisonous or harmful substances, or "adulterants," in food, food packaging, in cosmetics or medical devices. Such substances can and do include CEPA-toxic substances. Control of such substances under the F&DA only occurs via direct reference in Regulations. The scope of which substances are included in F&DA regulations is narrow, covering only a very few substances for which hazardous properties are clearly established. The range is broader for cosmetics but again only addresses situations of relatively high hazard.

The F&DA contains no provisions to govern the life cycle of products beyond the specific focus on advertisement and the intended use of the product.

As described in Chapter Two, the regulation of lead in foodstuffs under the F&DA serves to prevent lead contamination from lead-soldered cans, a practice that has been phased out. The F&DA regulated levels are much higher, in some cases by several orders of magnitude, than lead levels actually measured in foods. Assurances that such levels are not being exceeded would be largely meaningless.

As described in Chapter 3, neither has the F&DA been effectively applied to phthalates. This law has, in theory, the ability to regulate the presence of phthalates in products in three relevant areas (food packaging, cosmetics and medical devices). Despite this fact, as well as clear evidence of human exposure, no action has been taken under the F&DA to regulate phthalate exposure from these multiple sources.

Although the Canadian "Hot List" of chemicals banned from cosmetics derives from European efforts, it is a shorter list than the European Cosmetics Directive. Like other efforts under the F&DA and the HPA, the Canadian cosmetics "Hot List" has a narrow focus only on high hazard circumstances. This narrow focus does not even include DEHP, despite its designation as CEPA-toxic. DBP and DEHP have both been banned from cosmetics in Europe since 2003,[152] and in 2001 were both declared to be reproductive toxins.

The progressive feature of the 2003 European directive is a declaration that no reproductive toxins could be used in cosmetic products. Similar provisions are applied to carcinogens. Although North American cosmetics companies have committed to voluntarily eliminate DBP and DEHP as ingredients, independent testing refutes this claim, at least for DEHP.

Hazardous Products Act

The HPA is focused mainly on mechanical problems associated with products and therein, it is primarily focused on acute risks. Where it addresses toxic substances in products, similar to the F&DA, in fact to an even greater degree, the HPA is almost exclusively focused on those that are known to have extremely toxic or lethal properties. Beyond addressing situations of well-known and high hazard, this law is reactive in nature. It can respond to new circumstances of previously unknown or poorly understood hazards only after harm, including death, has already occurred. Prevention of harm via this law is possible within a very narrow sphere.

The HPA and associated regulations do a relatively thorough job of responding to high hazard situations. They provide for a system for identifying, labeling, and warning the public about products that present extremely high hazards. Hazard symbols and associated mitigation information on labels help to prevent poisoning, fire, death, etc. But, the HPA establishes very little in the way of general requirements for products or product safety. Nor does the HPA spell out requirements for pre-market testing of products or ingredients to ensure or demonstrate safety, other than the product-specific requirements specified in regulations concerning restricted products or the measures to assess high hazard, acute toxicity, and chronic toxicity of "very toxic" or "toxic" materials within the six classes of chemicals in the *Controlled Products Regulations*.

Inspections are generally complaint-driven and tend to focus only on regulated products. A risk assessment of a product occurs only after a probable hazard is apparent and a risk assessment may result in restrictions or prohibition.

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[152] 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. On-line at: http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_066/l_06620030311en00260035.pdf

Although the HPA addresses some products containing substances that are designated CEPA-toxic, there is no requirement to do so. Nor does there appear to be any integration between these two laws in terms of controlling (or in some cases, even measuring) exposure to CEPA-toxic substances in products regulated under the HPA.

Health Canada's use of the HPA, historically and up to the present, has not been effective in regulating lead in consumer products. HPA regulations have been entirely reactive and do little more than regulate the status quo. Regulatory limits for ceramics, glassware, kettles and paints mirror either an industry standard or levels that have been established in other countries, in some cases decades earlier.

The HPA has not been applied to the issue of phthalates in consumer products at all. Health-protective action on the major phthalates in children's toys, BBP, DBP, DEHP and DINP has occurred, via regulation, in the European Union. While this regulatory action may have reduced some uses in North America, independent tests reveal DINP remains in children's products in North America.

With all that is known about lead, this understanding includes recognition that lead is essential in only a few product applications. These essential uses, or those for which there are no alternatives, include lead-acid batteries for vehicles and some solar power or other electrical applications, radiation shielding in medicine and nuclear technologies, and some additional electrical cable sheathing applications. Many other uses are unnecessary. It is very unlikely these other uses would be phased out unless forced by actual or threatened regulatory action.

It is also apparent that Canadian regulation of lead in consumer products, focused by necessity on products that are almost entirely imported, follows a pattern of avoiding regulation that significantly, or even minimally, impacts on international trade. During the 1990s, Canada and Australia, two of the leading lead-producing nations, collaborated to weaken the OECD Declaration of Risk Reduction for Lead. After absurd delay, the regulation of lead in jewellery avoided most of the problem with the stated reason being a desire to avoid economic hardship to the costume jewellery industry.

The response, via the HPA, to over ten years worth of findings of lead in myriad consumer products remains almost entirely in the proposal stage and it follows the cumbersome product-by-product, reactive approach that Health Canada stated ten years ago that it should be trying to get beyond. Where action has occurred it has been both tortuously slow and ultimately ineffective. The children's jewellery regulation and further proposed actions under the LRRS simply serve to sanction business as usual. Actions thus far, and those proposed, will provide little to no interference with international trade in millions of items containing lead, in some cases at very high levels, with no regard for the ultimate disposal of what will amount to huge volumes of toxic waste.

It is unlikely that the HPA can be the main source of protection for human health and the health of the environment for CEPA-toxic chemicals. Its product-by-product approach makes it inefficient. The case of lead demonstrates that even where it is applied, it applies a patchwork of

regulations rather than a comprehensive approach. The Act is also ill-equipped to consider the full life cycle of a product and include the risks due to pollution from manufacture or disposal.

Canadian Environmental Protection Act

CEPA provides for the most comprehensive tool set, across these three laws, to regulate chemical exposures from products, including the prevention of harm. CEPA includes an overarching mandate for pollution prevention and the protection of the environment and human health. It provides for regulatory and non-regulatory tools that can influence and/or regulate the use of substances across their entire life cycle, including in products. It also enables prohibitions that allow regulators to look at the full range of products at once, creating exceptions where reasonable alternatives are not available.

However, CEPA has been rarely used to address the use of CEPA-toxic substances in products. Said differently, the designation of substances as CEPA-toxic, rarely has an impact on their continued use in products. Within the 80 substances or classes of substances on the TSL, numerous of these "CEPA-toxic" substances have been the subject of regulations, comprehensive assessment reports or other risk management measures for many years. These measures have only rarely accounted for the presence or release of CEPA-toxic substances from consumer products. Rather, the focus is primarily on their use and release, mainly to air or water, from industrial or commercial settings.

For those substances that have not been deemed to be CEPA-toxic, the HPA might provide an opportunity to take action to prevent direct exposures that may be creating the greatest risks. As with the European Union directive to keep BBP, DBP and DEHP out of toys that children routinely put in the mouth, and the 2005 extension to childcare articles, the HPA could be used to establish precautionary regulations to help avoid these unnecessary exposures. However, the historical application of the HPA would need to change significantly for this to occur.

CEPA-Toxicity and Product Uses

For CEPA-toxic substances, the overlap, gaps and conflicting approaches between CEPA and the HPA are a serious problem and in need of correction in order to effectively address lead, and other CEPA-toxic substances, in consumer products.

Since its inception in 1988, CEPA has designated lead as "CEPA-toxic." Despite the fact that CEPA provides broad authority to regulate CEPA-toxic substances in products across their production chain, from import through to disposal, this reality has had no impact on the regulation of lead in consumer products.

DEHP was determined to be CEPA-Toxic to humans by risk assessment in 1994 but was not added to the schedule of toxic substances until 2000. Though deemed to be a danger to health, the risk management process that followed made no proposals for action.

Although it is not clear whether the risk managers knew of DEHP use in medical devices, or the risks that may create, it was apparent that DEHP was widely used in plastics that children might put in the mouth. The CEPA evaluation specifically refers to DEHP being found in pacifiers,

teethers, baby bottle nipples and flexible toys. Still, despite its CEPA-Toxic status, no action was taken to limit the DEHP exposure to children from these products.

Though CEPA gives the government the authority to control the use, importation and sale of CEPA-toxic chemicals in products, DEHP is a good example of how the government generally fails to use these powers to protect health. CEPA has been used to restrict chemicals in products, either as part of prohibition regulations or specifically, as with benzene in gasoline. But on the whole, these powers are little used and decisions regarding products appear to be left to those concerned with product safety and the use of the HPA.

In 1999, the European Union banned DEHP, along with BBP and DBP, from toys that that children put in their mouth - this without full risk assessments demonstrating significant risk. In Canada, DEHP was found to be a problem by risk assessment. Still, similar action was not taken under CEPA or the HPA. To date the HPA has never been used to restrict DEHP in products despite its listing in Canada on the Toxic Substances List.

The potential to use CEPA to restrict BBP and DBP was lost when the two phthalates were considered not toxic under the Act. Different conclusions may have been reached had children's safety factors and cumulative assessments been used (as discussed further below).

Looking at examples beyond the two case studies, the use of CEPA to control Schedule 1 substances in products has improved recently but has also been limited in scope as well as inconsistent.

For example, TSL substances in consumer products are addressed in proposed regulations for several flame retardant chemicals (PBDEs), [153] perfluorinated chemicals (PFOS)[154] and 2-butoxyethanol. [155] However, even with this recent attention to the presence of these chemicals in consumer products, the proposed regulations for these "legacy" chemicals generally regulate the status quo by either prohibiting chemicals that have already been voluntarily withdrawn by manufacturers (the PBDEs and PFOS) or setting limits that simply reflect current industry practice for amounts included in consumer products (2-butoxyethanol).

The PBDE regulations are also considered problematic[156] since they do not include restrictions or a ban on the ongoing and increasing use of deca-BDE. The 2-butoxyethanol regulation provides for numerous exemptions for common uses of this chemical in products.

The final proposal for the PFOS regulation improves upon earlier drafts. An initial choice to exempt imported consumer products was removed. Hence, even though the regulation bans those PFOS chemicals that have largely been voluntarily withdrawn by major manufacturers, it will serve to ban imports from countries where the chemical may still be in use. Further, the

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[153] *Canada Gazette*, Part I. Vol. 140, No. 50 — December 16, 2006. *Polybrominated Diphenyl Ethers Regulations*
[154] *Canada Gazette*, Part I. Vol. 140, No. 50 — December 16, 2006. *Perfluorooctane Sulfonate and its Salts and Certain Other Compounds Regulations*
[155] *Canada Gazette*, Part II. Vol. 140, No. 26 — December 27, 2006. *2-Butoxyethanol Regulations*.
[156] Notice of Objection Re: Proposed Polybrominated DiPhenyl Ethers Regulation. Filed February 14, 2007 by Sierra Legal Defence Fund, David Suzuki Foundation, Environmental Defence and the Canadian Environmental Law Association. On-line at: http://www.cela.ca/publications/cardfile.shtml?x=2933

regulation imposes a phase-down with time-limited exemptions that allow for continued use where reasonable alternatives are not available. A similar approach when DEHP was scheduled as Toxic would have initiated a thorough look at DEHP-containing products and started a process for determining where it should be removed and where exceptions should be made. Instead, there has been no move to get DEHP out of products despite the pollution and risks that its manufacture and use in products creates.

Despite the progress made in regulating the PFOS legacy chemicals, the approach to regulation of this larger group of chemicals in consumer products has been inconsistent. In the proposed regulation of four fluorotelomer-based substances under the *New Substances Notification Regulations,*[157] a similar prohibition on manufactured items did not occur. Despite the decision to propose the addition of these four fluorotelomer-based substances to the *Prohibition of Certain Toxic Substances Regulations,*[158] the proposed regulation exempts this prohibition where these chemicals are present in manufactured items,[159] thus avoiding regulation of key exposure sources.

The *Prohibition of Certain Toxic Substances Regulations* provides a powerful tool to restrict chemicals, including in products, but its use is, thus far, very limited. Notably, the chemicals to which Schedule 2 of the Regulation applies have had wider use in consumer products in past. These regulatory restrictions generally limit ongoing use to very specific, industrial applications.

Additional substance-specific or sector-specific regulations under CEPA, in most cases, are directed at reducing emissions rather than controlling use in products.

Formaldehyde is a good example. Despite evidence of cancer risk resulting from indoor exposures, such indoor air concentrations of formaldehyde (released by building materials or other wooden products) were not considered significant enough in the assessment of formaldehyde to warrant a risk management strategy. Instead, formaldehyde risk management in Canada has focused on limits on the emissions of off-road compression-ignition engines.[160]

For CEPA-toxic substances used in consumer products, pollution prevention planning has the potential to reduce use in products. However, without any requirements for public disclosure and no enforceability, key questions arise including whether the plans specifically address exposures from products, whether industries actually follow the plans, and whether reductions in CEPA-toxic substances occur via substitution of one hazard by another.

Like the regulatory options used under CEPA, within the various voluntary options for risk management of toxic chemicals, the focus tends to be on uses and releases of chemicals by manufacturers or other industrial emitters. For example, pollution prevention plans can be developed that can alter the entire production chain in order to reduce overall risk to the

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[157] *New Substances Notification Regulations (Chemicals and Polymers)* (SOR 2005/247)

[158] *Prohibition of Certain Toxic Substances Regulations, 2005* (SOR/2005-41)

[159] Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (Four New Fluorotelomer-based Substances). *Canada Gazette*, Part 1, June 17, 2006. 1593-94.

[160] See more detailed review in: Wordsworth, A. 2006. Toxic Substances in Consumer Products and the Potential for Children's Exposure. Paper prepared for Health Canada, August 16, 2006.

environment or human health. This option is under-utilized and would benefit from specific provisions in CEPA that direct its use to controlling toxic substances in products.

The New PCPA "Benchmark"

Recent revisions to the *Pest Control Products Act* have included four important aspects of modern risk assessment approaches. These include the need to:

- assess toxic exposures by aggregating exposure;
- look at classes of substances with common mechanisms of toxicity; and
- incorporate additional safety factors for the sake of addressing the greater vulnerability of, (and often lack of knowledge about risks to), children; and
- assign the burden of proof for demonstrating safety on proponents rather than on government.

Aggregate Exposure and Cumulative Assessment

The issue of lead amply demonstrates the need to consider the aggregate exposure from all sources as well as the cumulative assessment of exposure to developmental neurotoxins, when chemicals are assessed.

For example, in looking at the regulated limits that exist under the HPA, and those proposed under the LRRS, these limits do not account for the aggregate exposure that could result from the combined exposure to products meeting all of the existing or proposed regulated limits. Nor would there be any further safety margin for other sources of lead such as in contaminated urban soil, or in homes built prior to the 1970s, and especially prior to the 1960s, with old, deteriorating paint or during renovations. Children could also continue to be exposed to lead from plastic mini-blinds purchased prior to 1997 and to lead in the millions of pieces of jewellery and similar items that are not included in the Children's Jewellery Regulations but which are readily available to children either in stores, given to them as gifts or hanging around their mother's necks or on a parent or caregiver's key chain.

Since the effects of low-level lead exposure are sub-clinical and since there is so little tracking of children's blood-lead levels, it is impossible to know whether lead in consumer products are adding an excessive lead burden to that already experienced by children in Canada, particularly those living in conditions of poverty.

We do know however, that modern risk assessment approaches require that the exposure assessment for toxic substances should aggregate exposures from all possible sources so that regulatory limits from individual sources do not contribute an excess risk under real-world exposure circumstances. Even more progressive approaches recognize the need to progressively eliminate exposure to substances that are inherently toxic, including carcinogens and reproductive toxins.

Where continued use of toxic substances is allowed, modern risk assessment approaches also consider the combined exposure to substances with common mechanisms of toxicity.

The case of phthalates illustrates the need to address these chemicals as a class of similar chemicals for which multiple exposures can occur from diverse sources.

There are many phthalates reported to be in use in Canada that have never had evaluations for their health and environment impacts and there are many gaps in our knowledge of their effects and the mechanisms of any toxicity. Some, like DEHP, DBP, BBP and DINP are more widely studied and there is more research into their mechanisms of action.

In particular, there is evidence that all of these phthalates can have reproductive impacts, particularly on the developing male. For all of them, there is thought to be interference with the synthesis of testosterone, essential to male development, either directly or through a breakdown product. This shared toxicity points to the need to aggregate their exposures and do cumulative risk assessments.

The 2000 Toxicological Sciences study looking at perinatal exposure to phthalates found that DEHP, BBP and DINP all had similar impacts though with varied potency. The authors wrote of the need for these phthalates to be evaluated as a group when looking at reproductive toxicity. "It appears," they stated, "that phthalates with monoester metabolites with an ester group 4-6 carbons long are reproductive toxicants."[161] Silva et al. also noted the similarities in structure among the metabolites of DINP and those of DEHP.

It is logical to assume that if these chemicals act in the same way that their effects will be additive. This may not always be true of course. They may be synergistic and increase one another's potency or they may be competitive with each other and sometimes inhibit each other's effects. In the absence of evidence for synergy or inhibition, a safe default is additive effect. A new study in Toxicological Sciences on rats has shown that administering both DBP and DEHP increased reproductive malformations by 150%. The authors concluded that the two phthalates were indeed dose additive despite having different metabolites.[162]

For BBP and DBP, the case for combined assessments is even stronger. DBP's major breakdown pathway is monobutyl phthalate MBP, which is itself likely toxic to the developing reproductive system. BBP, though it will partly metabolize into MBzP, will also break down into MBP. Therefore, BBP and DBP share a common toxic metabolite. An evaluation of the impact of MBP would by proxy then be an evaluation of its precursors, namely BBP and DBP.

In addition to the common mechanism of toxicity, there is good evidence that exposure to all three phthalates is common and that they are often found together. One study looking at population samples in Krakow and New York found that 100% of subjects had all three phthalates in their personal air samples and that all had the three breakdown products MBP, MBzP and MEHP (DINP and its metabolites were not measured).[163] A 2005 study of Finnish and

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[161] 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.

[162] Howdeshell KL et al. Cumulative effects of dibutyl phthalate and diethylhexyl phthalate on male rat reproductive tract development: Altered fetal steroid hormones and genes. *Toxicological Sciences*. Advance Access Published March 30, 2007, doi:10.1093/toxsci/kfm069

[163] Adipi JJ et al. Prenatal exposures to phthalates among women in New York City and Krakow, Poland.

Danish breast milk consistently found levels of MEHP, MBP,MBzP and MINP. The levels ranged widely from 0.07 to 1,410 µg/L but all three were frequently found in each subject.[164] These studies make a case for these phthalates to be treated together as a mixture.

None of the phthalates evaluated under CEPA used a cumulative assessment approach. Though the DBP and BBP assessments both refer to their common metabolite, there has been no attempt to combine their exposures and look at the most sensitive endpoint for MBP in determining whether they should be toxic under CEPA. This has left these two phthalates with a non-Toxic status under CEPA preventing risk management measures under this Act.

Children's Safety Factor

BBP and DBP are also non-Toxic under CEPA in part due to the deficiency of child safety factors in their evaluations. In addition to the conventional 10-fold uncertainty factors to account for differences within and between species, the *Pest Control Products Act* includes a provision for a safety factor of up to 10-fold to acknowledge the extra vulnerability of children and the fetus. None of CEPA, the F&DA, or the HPA, stipulate the use of such a factor.

The designation of DEHP as Toxic under CEPA, and DBP and BBP as not Toxic, was in part due to differences in the application of extra safety factors. The DEHP assessment applied an extra 10-fold factor due to the potential teratogenicity of the chemical. Though similar evidence existed for DBP there was no factor applied.

All three of these phthalates are potential hazards for developing males. As substances that interfere with testosterone production, their exposure at certain points in a male's development may enhance the risk they pose. There is a scientific consensus that timing can be as important as dose and that children and the fetus are particularly vulnerable due to the changes occurring. While a children's safety factor should be part of standard risk assessment practice, the importance of this is increased when the key effects are on child development. The CEPA risk assessments of BBP and DBP failed to fully protect children by not including such a factor.

The assessment of DINP also did not include a safety factor for children. The assessors did though, when coming to their conclusions, account for the vulnerability of children. While the estimated exposure was slightly below the Tolerable Daily Intake, Division scientists took a precautionary approach. They recognized that children do not get to make the choice to avoid exposures in teethers and rattles and therefore need extra protection. As well, they pointed out that where there were good alternatives, it was unreasonable to expose children to the risks even if they believed them to be small. Unfortunately, the risk management approach did not follow through and ensure that these unnecessary exposures did not continue.

Children's products are not the only important sources of exposure however. As evidence presented on vinyl flooring and phthalates demonstrates, the choice of building materials, upholstery, paint, etc. in the home will all affect a child's chemical exposure as will a parent's

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Environmental Health Perspectives. November 2003; 111(14): 1719–1722.

[164] Main K.M. et al. Human Breast Milk Contamination with Phthalates and Alterations of Endogenous Reproductive Hormones in Infants Three Months of Age. *Environmental Health Perspectives*. February 2006; 114(2): 270–276.

use of personal care products or use on the child. Household products containing phthalates can increase house dust contamination and indoor air levels. Because there may be multiple sources of exposure that are not specific to children, prohibitions of substances under CEPA can be the best way to tackle the larger problem. A comprehensive approach to products and the use of safety factors for children are essential in ensuring that the threshold of protection is at a level that will protect children's health.

Choosing to Apply CEPA

It is poor legislative practice for more than one law to apply to the same circumstances. Where this occurs, it should be made clear which law predominates if and when a conflict arises. CEPA is intended to provide for the comprehensive management of toxic substances in Canada. The amendments proposed in the concluding section of this report provide for the realization of this intention so that management of chemicals effectively includes the manufacture, import, sale, use and disposal of consumer products containing CEPA-toxic substances.

Recommendations for Amending CEPA

Summarized below is an outline of proposed amendments to several parts & sections of CEPA to address improved regulation of toxic substances in consumer products. This outline is expanded upon in detail in Appendix Two with each part and section of CEPA noted and specific amendments proposed. A rationale is provided for each amendment proposal drawn from the analysis in this report.

Amendments are proposed throughout to address key aspects of the assessment and management of substances. Highlights include:

- adding the new "benchmarks" recently attained within the revised PCPA to address vulnerable populations, and to require, during risk assessments, the calculation of aggregate exposure and the assessment of groups of chemicals with common mechanisms of toxicity;
- applying a new burden and standard of proof with respect to the assessment of substances; and
- multiple amendments to insert and/or clarify powers to control toxic substances in products, including during pollution prevention planning, during the assessment of substances, concerning the use of Schedule 1 substances in products, and by adding legislative powers to recall consumer products.

Outline of Parts and Sections of the Canadian Environmental Protection Act to be Amended Respecting Toxic Substances in Consumer Products (see Appendix 2 for detailed amemdment proposals)

- Preamble

Administrative Duties

- Duties of Government of Canada (section 2(1), new subsection (k.1))

Interpretation

- Definitions (section 3)

PART 1 - ADMINISTRATION

Advisory Committees

- Consumer product expert advisory committees (new section 7.1(1))
- Publication of report (new section 7.1(2))

PART 2 – PUBLIC PARTICIPATION

Environmental Registry

- Contents of Environmental Registry (section 13, new subsection (b.1)

PART 3 – INFORMATION GATHERING, OBJECTIVES, GUIDELINES AND CODES OF PRACTICE

Environmental Data and Research

- Monitoring, research, publication (section 44, new subsection (g))

Information Gathering

- Mandatory reporting on pollution prevention in consumer products (new section 46(1.1))
- Publication of report (new section 46(1.2))

PART 4 – POLLUTION PREVENTION

Pollution Prevention Plans

- Pollution prevention targets, goals, and measures for consumer products (new section 56.1(1))
- Comments or objections (new section 56.1(2))
- Publication by Minister of results (new section 56.1(3))
- Publication of final pollution prevention targets, goals, and measures for consumer products (new section 56.1(4))
- Mandatory pollution prevention action by persons (new section 56.1(5))
- Report to Parliament (new section 56.1(6))
- Consequential amendments (sections 57-60)

PART 5 – CONTROLLING TOXIC SUBSTANCES

General

- Research, investigation and evaluation (section 68, new subsection (a.1))
- Data collection and investigation of development and use of alternatives (new section 68.1)
- Report to Parliament on research, investigation and evaluation (new section 68.2)

Priority Substances and Other Substances

- Weight of evidence and precautionary principle (section 76.1)
- Burden and standard of proof (new section 77(8.1)(a))
- Where burden and standard of proof not met (new section 77(8.1)(b))

Regulation of Toxic Substances

- Priority (section 90(1.1))
- Regulations (new section 92.2)
- Regulations (section 93, new subsection (q.1))
- Priority of CEPA to regulate Schedule 1 substances in products (new section 93(4.1))

Consumer Products (new)

- Authority to prohibit or restrict toxic substances in consumer products (new section 103.1)
- Notice of objection (new section 103.1(2))
- Publication by Ministers of results (new section 103.1 (3))
- Report to Parliament (new section 103.1(4))

PART 10 – ENFORCEMENT

Consumer Product Recall

- Authority to recall consumer products containing toxic substances (new section 233.1(a))
- Obligation to comply (new section 233.1(b))

PART 11 – MISCELLANEOUS MATTERS

Board of Review Proceedings

- Establishment of Board of Review (section 333)
- Review for consumer products (section 333, new subsection (7))

Conflicts

- Conflict of laws with respect to toxic substances in consumer products (new section 343.1)

Appendix 1: Federal Regulations, Guidelines and Risk Management Actions/Proposals on Lead

Source/Media/Product	Limit	Date Enacted	Instrument
Lead in drinking water (in a flushed sample)	10 µg/L (10 ppb)	1992	Canadian Drinking Water Quality Objectives
Canadian Environmental Protection Act			
Lead "Grandfathered" from Clean Air Act to CEPA, 1988 (no assessment report required or prepared)	Included in Toxic Substances List, Schedule 1 ("CEPA-toxic")	1988	*CEPA, 1988*
Lead in Gasoline - range of levels for "unleaded" (to allow for contamination) for most vehicles and slightly higher levels for heavy farming equipment, boats and trucks	5 mg/L (5 ppm) and 26 mg/L (imported gasoline) or 30 mg/L (domestically produced gasoline)	1990	*Gasoline Regulations*
Food and Drugs Act			
- Edible bone meal	10 ppm (10,000 ppb)	1968	*Food and Drug Regulations*
- Tomato paste and tomato sauce	1.5 ppm (1500 ppb)	1986	*Food and Drug Regulations*
- Fish protein and whole tomatoes	0.5 ppm (500 ppb)	1986	*Food and Drug Regulations*
- Fruit juice, fruit nectar, beverages when ready-to-serve and water in sealed containers other than mineral water or spring water	0.2 ppm (200 ppb)	1968	*Food and Drug Regulations*
- Evaporated milk, condensed milk and concentrated infant formula	0.15 ppm (150 ppb)	1979	*Food and Drug Regulations*
- Infant formula when ready-to-serve	0.08 ppm (80 ppb)	1979	*Food and Drug Regulations*

Hazardous Products Act			
Kettles - amount of lead allowed to be released to water from kettles soldered with lead	0.05 ppm (50 ppb)	1974	*Kettles Regulations*
Glazed Ceramics and Glassware - regulated as releasable lead from flatware, small hollow-ware, other than cups or mugs, large hollow-ware, other than pitchers, cups and mugs, and pitchers - regulates drinking vessels with a distinctive exterior decorative pattern – if patter within 20 mm of the rim	Range of levels between 0.5 and 3.0 mg/L (0.5 to 3 ppm or 500 to 3000 ppb) Pattern contents cannot release lead in excess of 4 mg/L (4 ppm or 4000 ppb)	1998	*Glazed Ceramics and Glassware Regulations*
Surface Coating Materials - Consumer paints, enamels and other surface coating materials - Paints, enamels and other surface coating materials on furniture, household products, children's products, exterior and interior surfaces of any building frequented by children - Paints, enamels and other decorative coatings on pencils and artists' brushes, and on toys, children's furniture, and other articles intended for children - Paints and other surface coatings on toys, equipment, and other products for use by a child in learning or play	600 ppm (mg/kg)	2005	*Surface Coating Materials Regulation*
Children's Jewellery - permits the import, advertisement or sale of jewellery items intended primarily for children under 15 years of age only if the items do not contain more than specified lead limits	600 mg/kg total lead and 90 mg/kg migratable lead	2005	*Children's Jewellery Regulations*
(Corded Window Coverings) - will limit the lead content of any exterior component of blinds or other corded window coverings which can be touched or ingested by young children	Maximum of 200 mg/kg (200 ppm) total lead of the window covering	**Proposed** (in drafting stage)	Proposed regulations under the HPA (according to undated submissions from Health Canada to the Senate Committee Reviewing CEPA – received February 18/07)

Lead Risk Reduction Strategy Framework for further, phased actions. Lead content restrictions proposed for five groups of products.	
Group 1: **Products Likely to be Ingested in Significant Quantities** Examples: children's crayons, modelling clays, and paints	Proposed Lead Limit: total lead and migratable lead must not exceed 75 ppm. Exemptions: food, beverages, medicines or other products intended for human consumption.
Group 2: **Products Intended to be or Likely to be Placed in or near the Mouth** (excluding group 1 products) Examples: - toys labelled by the manufacturer as being suitable for children less than three years of age, or which by their nature are likely to be used by a child less than three years of age - mouthpieces used in sports equipment such as snorkels and breath deflectors - mouthpieces of musical instruments - pacifiers, teethers, rattles, baby bottle nipples, and crib toys - plastic beverage straws	Proposed Lead Limit: 90 mg/kg (ppm) total lead and migratable lead not to exceed 75 ppm.
Group 3: **Children's Equipment, Furniture, Toys and other Items intended for use by a child in Learning or Play** (excluding group 1 and group 2 products) Examples: - baby carriers, strollers, playpens, high chairs and cribs - children's clothing, footwear, and accessories - interior and exterior play equipment	Proposed Lead Limit: 600 mg/kg (ppm) total lead and 90 mg/kg migratable lead. Exemptions: 1. components of products that are required to store, generate, or conduct an electrical current, such as batteries, electrical solder and flux, and cables, provided that these components are not accessible to children. This exemption does not apply to toys, hobby kits, and similar products which are intended for children older than 36 months and which require assembly. 2. solder and flux used to fuse or connect components of jewellery, crafts, or artists' products 3. artistic paints and pigments will be exempt from the requirement for total lead not to exceed 600 ppm, but they will be subject to the migratable lead limit of 90 mg/kg.

Group 4: **Products intended for use in preparing, serving, or storing food or beverages.** (excluding products in groups 1,2, and 3) Examples: - cooking utensils such as beaters, spatulas, pots and pans - serving utensils such as spoons, forks and knives - tableware such as plates, bowls, drinking glasses and mugs - food storage materials and containers such as plastic and foil wrap, sandwich bags, and juice jugs - lead crystal decanters and other crystalware	Proposed Lead Limit: 600 mg/kg total lead Exemptions: 1. glazes, coatings, and decorations on ceramics and glassware (already regulated - *Hazardous Products Act*) 2. kettles, already regulated for migratable lead content - *Hazardous Products Act.* 3. pre-packaged food items, which are regulated under the *Food & Drugs Act*
Group 5: **Consumer Products intended to be or likely to be Melted or Burned in Enclosed Spaces** (groups 1,2,3 and 4 products excluded) Examples: - incense - candles - fire logs - metal moulding kits for craft making - chemical fire logs	Proposed Lead Limit: 600 mg/kg total lead. (Candles Regulation drafted; not enacted). Exemptions: 1. untreated firewood to which lead has not been intentionally added 2. products covered under the federal *Explosives Act*

APPENDIX 2 - PROPOSED AMENDMENTS TO THE CANADIAN ENVIRONMENTAL PROTECTION ACT RESPECTING TOXIC SUBSTANCES IN CONSUMER PRODUCTS

CEPA section #	Proposed Amendment	Rationale
Preamble (between current 11th & 12th Whereas)	Whereas the Government of Canada recognizes the risks posed by toxic substances to the well-being of Canadians in general, and to major subgroups of the population in particular, including pregnant women, infants, children, women, and the elderly; Whereas the Government of Canada recognizes that regulation must be designed to protect human health and environment by assessing risks posed by, considering aggregate exposure to, evaluating cumulative effects of, and controlling impacts arising from, toxic substances; Whereas the Government of Canada will endeavour to encourage development and implementation of innovative measures designed to facilitate the development and use of less hazardous and non-hazardous substances and technological processes as substitutes for toxic substances;	As the Report makes clear, there is a need to consider children and other sensitive populations during the assessment of potentially toxic substances. The Report also notes the need to substitute safe alternatives for such substances. The Preamble to the *Pest Control Products Act* is a precedent for the wording suggested in these proposed amendments.

ADMINISTRATIVE DUTIES

CEPA section #	Proposed Amendment	Rationale
Section 2 - (add new subsection 2(1)(k.1) - Duties of the Government of Canada	protect human health from the risks posed by the presence of toxic substances in consumer products;	The Report indicates that the presence of toxic substances in consumer products poses risks to the well-being of Canadians generally, and to vulnerable populations such as women, children, and the elderly, in particular. Accordingly, this amendment adds as a further duty of the Government of Canada the obligation to take measures to protect the health of Canadians from the presence of toxic substances in such products.

INTERPRETATION

CEPA section #	Proposed Amendment	Rationale
Section 3 - Definitions	"carcinogen or reproductive toxin" means any substance listed in Group 1 or Group 2A of periodic reports issued by the International Agency for Research on Cancer or in the schedule of such substances established pursuant to the California Safe Drinking Water and Toxic Enforcement Act of 1986;	Establishes the scope of the expanded labelling authority for consumer products that contain substances that are carcinogenic or reproductive toxins as set out more fully under the revised Part 5 – Controlling Toxic Substances, below, and other Parts of *CEPA*. IARC Group 1 consists of substances known to be carcinogenic to humans. IARC Group 2A consists of substances probably carcinogenic to humans. As of January 2007, these two groups consisted of 168 substances or classes of substances. The California law (also known as Proposition 65) lists chemicals known to cause cancer or reproductive toxicity.
Section 3 - Definitions	"consumer product" means any controlled, prohibited, or restricted product as defined under the *Hazardous Products Act*, R.S.C. 1985, c. H-3 or any food, drug, cosmetic, or device as defined under the *Food and Drugs Act*, R.S.C. 1985, c. F-27; or any product that contains, by intentional addition during manufacturing, substances included on the List of Toxic Substances in Schedule 1 of this Act.	Establishes the scope of the term "consumer product" for the purposes of controlling toxic substances in such a product under *CEPA*.
Section 3 - Definitions	"essential" means necessary for medical or safety reasons;	Defines part of the scope of the test for when a person may continue to use a Schedule 1 substance in a consumer product, set out more fully below.

PART 1
ADMINISTRATION
Advisory Committees

CEPA section #	Proposed Amendment	Rationale
Section 7.1(1) (new) – Consumer product expert advisory committees	For the purpose of carrying out their duties under this Act, the Ministers or either Minister shall (a) establish one or more consumer product expert advisory committees; (b) direct the committee or committees established pursuant to subsection (a) to evaluate and report upon each year to the Parliament of Canada the adequacy of, and recommendations regarding, monitoring activities pertaining to toxic substances in consumer products; and (c) specify such other functions that each committee is to perform and the manner in which those functions are to be performed.	Oversight measure to ensure that monitoring efforts on toxic substances in consumer products are robust enough to achieve objectives of Act.
Section 7.1(2) (new) - Publication of report	The report of a committee established under subsection (1), including its recommendations and reasons, shall be made public.	Similar authority contained in existing section 7(2) of the Act.

PART 2
PUBLIC PARTICIPATION
Environmental Registry

CEPA section #	Proposed Amendment	Rationale
Section 13 (add new subsection (b.1) - Contents of environmental registry	copies of all investigations, orders, prosecutions, convictions, appeals and the results thereof, under this Act, the *Hazardous Products Act*, R.S.C. 1985, c. H-3, and the *Food and Drugs Act*, R.S.C. 1985, c. F-27, pertaining to toxic substances in consumer products; and	Improves the information base on the status of compliance and enforcement measures pertaining to controlling toxic substances in consumer products.

PART 3
INFORMATION GATHERING, OBJECTIVES, GUIDELINES AND CODES OF PRACTICE
Environmental Data and Research

CEPA section #	Proposed Amendment	Rationale
Section 44 (add new subsection (g) – Monitoring, research and publication	maintain and update on an annual basis an inventory of all monitoring activities of the Government of Canada pertaining to toxic substances in consumer products.	Improves the information base on the status of government measures pertaining to monitoring of substances in consumer products.

Information Gathering

CEPA section #	Proposed Amendment	Rationale
Section 46 (1.1) (new) – Mandatory reporting on pollution prevention in respect of toxic substances in consumer products	Notwithstanding subsection (1)(l), the Minister shall require that persons described in the notice referred to in that subsection report on pollution prevention measures undertaken in respect of toxic substances in consumer products.	Improves the information base on the level of pollution prevention efforts being undertaken in respect of toxic substances in consumer products.
Section 46 (1.2) (new) - Publication of report	The report referred to in subsection (1.1) shall be made public.	Similar authority contained in other existing sections of Act.

PART 4
POLLUTION PREVENTION
Pollution Prevention Plans

CEPA section #	Proposed Amendment	Rationale
Section 56.1(1) (new) – Pollution prevention targets, goals, and measures for consumer products	Notwithstanding section 56, the Minister shall publish in the *Canada Gazette*, not later than one year after the coming into force of these amendments, a notice identifying (a) pollution prevention targets for consumer products; (b) elimination goals for all carcinogens and reproductive toxins identified in consumer products; (c) elimination or reduction goals for all toxic substances appearing on the List of Toxic Substances in Schedule 1 of this Act identified in consumer products; (d) reduction goals for other substances identified in consumer products; and (e) measures to be implemented to achieve over a five and ten year period following the final publication of the targets and goals identified pursuant to subsection (4) for consumer products.	Improves pollution prevention planning and implementation initiatives in respect of consumer products.
Section 56.1(2) (new) – Comments or objections	Within 90 days after the publication of the notice referred to in subsection (1), any person may file with the Minister comments or a notice of objection.	Similar authority contained in other existing sections of Act.

Pollution Prevention Plans

CEPA section #	Proposed Amendment	Rationale
Section 56.1(3) (new) – Publication by Minister of results	After the end of the period of 90 days referred to in subsection (2), the Minister shall publish in the *Canada Gazette* and in any other manner that the Minister considers appropriate a report or notice of the availability of a report that summarizes how any comments or notices of objection were dealt with.	Same.
Section 56.1(4) (new) – Publication of final pollution prevention targets, goals, and measures for consumer products	The Minister shall publish in the *Canada Gazette*, not later than two years after the coming into force of these amendments, a notice identifying the final pollution prevention targets, goals and measures for consumer products.	Same.
Section 56.1(5) (new) – Mandatory pollution prevention action by persons	The Minister shall require all persons described in the notice referred to in section 46(1.1) to undertake planning and implementation measures in order to meet the pollution prevention targets and goals established for consumer products.	Improves likelihood that pollution prevention targets and goals established by Minister for consumer products will be achieved.
Section 56.1(6) (new) – Report to Parliament	The Minister shall include in the annual report required by section 342 a report on the administration and enforcement of this section.	Similar authority contained in other existing sections of Act.
Sections 57 - 60	Add section 56.1 wherever reference to section 56 appears.	Consequential amendments arising from addition of section 56.1.

PART 5
CONTROLLING TOXIC SUBSTANCES
General

CEPA section #	Proposed Amendment	Rationale
Section 68 (add new subsection (a.1)) – Research, investigation and evaluation	(i) consider available information on aggregate exposure to the substance for all potential exposures, (ii) consider the cumulative effects of the substance and other substances, where concurrent exposure is likely, which have a common mechanism of toxicity, (iii) apply appropriate margins of safety to take into account, among other relevant factors, the use of animal experimentation data and the different sensitivities to substances of major subgroups of the population, including pregnant women, infants, children, women, and the elderly; (iv) in the case of a threshold effect, if exposure to the substance is likely to occur in or around homes or schools, apply a margin of safety that is ten times greater than the margin of safety that would otherwise be applicable in respect of that threshold effect, to take into account potential pre-natal and post-natal toxicity and completeness of the data with respect to the exposure of, and toxicity to, infants and children unless, on the basis of reliable scientific data, the Minister has determined that a different margin of safety would be appropriate; and (v) consider the effectiveness of existing risk management approaches.	The assessment provisions in *CEPA* do not include explicit requirements for considering the protection of children and other vulnerable populations. By contrast, the *PCPA* now contains specific language (noted in the column, left) mandating the application of techniques with respect to aggregate exposure, consideration of substances with common mechanisms of toxicity, and the application of additional safety factors, in order to begin to ensure that risk assessments are protective of the most vulnerable populations. The assessment and management of toxic substances in Canada should be at least as protective as that provided for pesticides. Regardless of the fact that pesticides are formulated to be chemically active and to exert a toxic effect, albeit a controlled toxic effect, this amendment addresses the problem that some industrial chemicals are biologically active as well, even if they were not so intended. This amendment is part of a series of amendments that removes the presumption of innocence for industrial chemicals and ensures they are assessed for impacts on vulnerable populations and, as much as is possible, under real-world exposure circumstances.

General

CEPA section #	Proposed Amendment	Rationale
Section 68.1 (new) – Data collection and investigation of development and use of alternatives	Notwithstanding subsection (a)(xii), the Ministers shall collect data and conduct investigations respecting the development and use of alternatives to a substance.	As discretionary authority, section 68(a)(xii) has failed expectations as a measure to ensure that alternatives are developed and used where warranted.
Section 68.2 (new) – Report to Parliament on research, investigation and evaluation	The Minister shall include in the annual report required by section 342 a report on the administration of sections 68 and 68.1.	Similar authority contained in other existing sections of Act.

Priority Substances and Other Substances

CEPA section #	Proposed Amendment	Rationale
Section 76.1 – Weight of evidence and precautionary principle	Add to the end of the last sentence: , and shall, (d) consider the impact on subgroups of the population, including pregnant women, infants, children, women, and the elderly, (e) aggregate exposures to substances, (f) assess groups of substances with common mechanisms of toxicity, (g) apply an extra ten-fold child-protective safety factor in all risk assessment calculations, and (h) consider the development and use of less hazardous or non-hazardous substances or technological processes as substitutes for toxic substances.	These requirements can help ensure a more comprehensive and realistic approach to assessing multiple exposures to multiple chemicals. While some policies are in place to apply these modernized approaches, they need to be enshrined in *CEPA*. Section 68(a)(xii), regarding the consideration of alternatives, is discretionary and ineffectual. As a result, alternatives primarily are considered at the risk management phase, if at all. However, it is necessary for alternatives to be taken into account at the assessment phase as well.

Priority Substances and Other Substances

CEPA section #	Proposed Amendment	Rationale
Section 77 – (add new (8.1)(a)) – Burden and standard of proof	During an assessment or before a board of review, the person seeking to (a) import, manufacture, transport, process, or distribute a substance for commercial purposes, or (b) use a substance in a commercial manufacturing or processing activity, shall have the burden of proving by a preponderance of the evidence to the Minister or the board of review, as the case may be, that the substance does not pose a threat to human health or the environment.	Persons seeking to manufacture, process, or use substances should have the burden of demonstrating why the substance is not *CEPA*-toxic. Because of the potential threats to human health and environment posed by toxic substances there is a good argument for applying a criminal law standard of proof beyond a reasonable doubt. However, this amendment chooses a standard of proof more consistent with civil or administrative law.
Section 77 – (add new section 8.1(b)) – Where burden and standard of proof not met	Where the person referred to in subsection 8.1, fails to meet the burden and standard set out therein, the Minister or the board of review, as the case may be, shall propose the measure referred to in paragraph (2)(c).	Same.

Regulation of Toxic Substances

CEPA section #	Proposed Amendment	Rationale
Section 90(1.1) – Priority	Amend the end of the sentence to read: , the Ministers shall give priority to (a) pollution prevention actions; (b) consideration of the impact the substance may have on subgroups of the population, including pregnant women, infants, children, women, and the elderly; and (c) development and use of less hazardous or non-hazardous substances or technological processes as substitutes for toxic substances.	Risk management measures should consider vulnerable populations and safe alternatives.
Section 92.2 (new) – Regulations	For the purposes of subsection 103.1(1), the Ministers may make regulations prohibiting the use in a consumer product of a substance that has been added to the List of Toxic Substances in Schedule 1.	Derivative risk management authority arising from proposed section 103.1(1), below.
Section 93(1) (new subsection (q.1)) - Regulations	the labelling of consumer products where such products contain a substance that is carcinogen or reproductive toxin;	This labelling authority would apply to those substances on Schedule 1 for which exceptions are obtained for their continued use in consumer products. However, it would extend further to any substances not on Schedule 1, or not yet on Schedule 1, to allow for public notification of hazardous components in consumer products, and appropriate warnings. The definition for "carcinogen or reproductive toxin" has been provided in amendments to section 3, above.
Section 93(4.1) (new subsection)	Nothing in subsection (4) shall be interpreted to restrict the authority of the Governor in Council to regulate in consumer products substances identified in the List of Toxic Substances in Schedule 1.	To ensure the application of a regulatory regime that can address the full life-cycle of products rather than the end-use focus of other statutes that address consumer products.

Consumer Products (new)

CEPA section #	Proposed Amendment	Rationale
Section 103.1(1) (new) – Authority to prohibit toxic substances in consumer products	Where, pursuant to section 90, the Governor in Council has by order added a substance to the List of Toxic Substances in Schedule 1, the order shall authorize the Ministers, having regard to section 56.1 and subject to subsection (2), to prohibit or restrict the use of the substance in consumer products and deem such products as hazardous waste for the purposes of disposal, by the date specified in the order.	Establishes the authority to prohibit the use of toxic substances in consumer products and designate them for management as hazardous waste.
Section 103.1(2) (new) – Notice of objection	Within 60 days after the publication of the order referred to in subsection (1) in the *Canada Gazette*, any person may file a notice of objection with the Minister requesting that a board of review be established under section 333 and stating the reason for the objection.	Similar authority contained in other existing sections of Act.
Section 103.1(3) (new) – Publication by Ministers of results	After the end of the period of 60 days referred to in subsection (2), or such additional period as the Ministers require thereafter, the Ministers shall publish in the *Canada Gazette* and in any other manner that the Ministers consider appropriate a report or notice of the availability of a report that summarizes how any notices of objection were dealt with.	Same.
Section 103.1(4) (new) – Report to Parliament	The Ministers shall include in the annual report required by section 342 a report on the administration and enforcement of this section.	Similar authority contained in other existing sections of Act.

PART 10
ENFORCEMENT
Consumer Product Recall

CEPA section #	Proposed Amendment	Rationale
Section 233.1(a) (new) – Authority to recall consumer products containing toxic substances	The Ministers may issue a notice of recall regarding consumer products that contain substances that have been added to the List of Toxic Substances in Schedule 1 to any person who owns or operates a retail, or wholesale, operation where such products are present.	Authorizes Ministerial notices of recall in relation to consumer products that contain *CEPA*-toxic substances. Because the determination of whether a substance is toxic is authorized under *CEPA*, recall powers are necessary under this statute.
Section 233.1(b) (new) – Obligation to comply	Persons who receive the notice referred to in subsection (1) shall comply with the contents of the notice forthwith.	Imposes an obligation to comply with the notice of recall and, thereby, makes the obligation subject to the other enforcement authorities currently contained in *CEPA*.

PART 11
MISCELLANEOUS MATTERS
Board of Review Proceedings

CEPA section #	Proposed Amendment	Rationale
Section 333(1) – Establishment of board of review	Amend the first line to read: Where a person files a notice of objection under subsection 56.1(2), 77(8), 103.1(2), or 332(2) in respect of	Authorizes notices of objection in relation to new pollution prevention and consumer product authority proposed by these amendments.
Section 333(7) (new – Review for consumer products	Where a person files with the Ministers a notice of objection under section 103.1(2), the board of review shall inquire into (a) the reasonableness of the date specified in the order of the Governor in Council for prohibiting the substance in consumer products, (b) whether persons who import or manufacture a substance that has been added to the List of Toxic Substances in Schedule 1 may continue to use the substance in consumer products after the date specified in the order and the board of review shall only so recommend where such persons can demonstrate by a preponderance of the evidence that there is no reasonable, technically feasible, or prudent alternative to the use of the substance in consumer products at all, or at existing or lower quantities or concentrations, and that the use of the substance in consumer products is essential, and (c) whether to deem such products as hazardous waste for the purposes of disposal.	The effect of this proposed amendment is to prohibit and/or strictly limit the use and environmental release of Schedule 1 substances in consumer products. The deadline for the ban allows for orderly notice to suppliers, and phase-down and phase-out in favour of less toxic alternatives. The amendment addresses the gap between determination of toxicity under *CEPA* and continued, unregulated use of toxic substances in consumer products. The amendment also allows for continued and carefully controlled uses where necessary. For example, the amendment could allow for the continued use of lead in x-ray shielding but a ban on other non-essential uses of lead in consumer products like jewellery or toys. Such a policy, known as "materials use", is proactive, effective, and efficient in comparison to regulating substances in on consumer product at a time. The EU-REACH policy authorizes the use of certain hazardous substances for a specified time period to facilitate identification of alternatives. This is an opportunity to promote a similar approach in Canada, stimulate innovation, and manage such products as hazardous waste, where necessary. The amendment also promotes decision-making transparency.

Conflicts

CEPA section #	Proposed Amendment	Rationale
Section 343.1 (new) – Conflict of laws with respect to toxic substances in consumer products	Where there is a conflict between this Act and any other special or general Act regarding requirements in respect of consumer products containing substances on the List of Toxic Substances in Schedule 1, the requirements of this Act prevail to the extent of the conflict.	Amendment gives primacy to the requirements of *CEPA* in respect of toxic substances in consumer products