

**SUBMISSION TO THE STANDING COMMITTEE ON ENVIRONMENT AND
SUSTAINABLE DEVELOPMENT**

**REVIEW OF THE CANADIAN ENVIRONMENTAL PROTECTION ACT
(CEPA 99)**

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1. Background

I have represented the Learning Disabilities Association of Canada (LDAC) on environmental health issues with government Departments, NGOS and industry for more than twenty years, and have prepared four submissions to committees studying CEPA since 1988. Currently I am a volunteer member of the Professional Advisory Committee of the Learning Disabilities Association of Canada (LDAC), which is a national voluntary organization with affiliates in all ten provinces and two of three Territories. LDAC is a member organization of the Canadian Partnership on Children's Health and the Environment. This presentation will focus on CEPA as it relates to the protection of human health - and particularly children's health and development that are the foremost concerns for our organization.

Few activities of government are more important than those devoted to ensuring that the water we drink, and the air we breathe, and the products we use, are safe, and do not cause adverse effects on human health and development, or a degraded environment. CEPA is the most important cornerstone in that regard, its provisions deserve strengthening, and the barriers to the regulatory system in Canada deserve close scrutiny if CEPA is going to work for Canadians and their health and environment. .

2. Costs of illness in children attributable to environmental exposures

Designating a substance toxic under CEPA is pivotal to most actions under the Act. Therefore this presentation will concentrate on Part 5 – Controlling Toxic Substances. To underline the importance to human health of preventing environmental exposures, the following is a quote from the executive summary of a report from the Global Development and Environment Institute of Tufts University: The costs of preventable childhood illness: The price we pay for Pollution¹.

A growing body of scientific literature implicates toxic exposures in childhood illnesses and developmental disorders. When these illnesses and disabilities result from environmental factors under human control, they can and should be prevented. This is not only a moral issue, concerning our responsibility to avoid doing harm. As important as the moral dimension may be, it is reinforced by the hard facts of economics. Preventable childhood illnesses and disabilities attributable to environmental factors impose staggering costs on society; plausible estimates for just a subset of these costs range up to \$1.6 billion annually in the state of Massachusetts.

A similar economic analysis was conducted in Washington State – finding that the costs of childhood illnesses and developmental disorders attributable to environmental exposures conservatively at 1.6 - 2.2 billion US dollars a year for that state alone². Other health economists have estimated the total national costs of the attributable fraction of four health and developmental conditions in children at \$ 55 billion a year to the US economy³. These costs could

¹ Massey R. & Ackerman F. (2002) Costs of environmental illness: The price we pay for pollution. The Global Development and Environment Institute, Tufts University.

² Davies Kate (2005) How much do environmental diseases and disabilities cost? Monograph, Northwest Public Health, Fall/Winter.

³ Landrigan P, Schechter C, Lipton J. et al, (2002) Environmental pollutants and disease in American children: Estimates of morbidity and mortality and costs for lead poisoning, asthma, cancer and developmental disabilities. Environmental Health Perspectives 110; 721-728.

be extrapolated to account for the smaller Canadian population to around \$ 5.5 billion in increased child health and special education costs to the Canadian economy each year. Muir and Zegarac⁴ estimated the annual costs to Canada of a loss of 5 IQ points to total income at \$30 billion annually – this is not counting other costs associated with neurodevelopmental effects that have been linked to environmental exposures, such as attentional disorders...

However apart from the economic costs of failing to deal with environmental chemicals that affect health and development, there is a moral and ethical issue around health protection that calls for action. It is unacceptable that there exists an environmental trespass of environmental chemicals in human tissues - found in all Canadians tested to date, and that we know so little about their potential to affect development, or the immune system. The research that is building up showing effects on the reproductive and endocrine systems at very low levels of exposure seems to be dismissed too easily.

3. Lack of action under CEPA to date

As you have heard from others, Canada had the worst, or second worst , rating of all 29 OECD countries in controlling environmental releases of key toxicants and pollutants. Few regulatory actions have been taken under CEPA since its enactment in 1988. CEPA does not seem to be working as it should. This may be due to deficiencies in the legislation itself, the devolution of powers under CEPA via harmonization and equivalency agreements with the provinces, or to a lack of political or regulatory will, or due to a lack of adequate financing of Health Canada and Environment Canada responsible for monitoring substances in the environment and assessing and managing the risks to human health and the environment , or to the mixed jurisdictional authority between the federal and provincial governments, and between government departments wherein no one seems to be able to take a decision in less than five years, or too many requirements for consultation and opportunities for political interference; the need under CEPA for cost/benefit and other analyses and/or a combination of all of these and other factors. The fact remains that very few effective regulations on toxicants have resulted since CEPA 1988 – nearly twenty years ago. .

A concerted effort needs to be made by Parliament to review these cumbersome processes, and to understand the reasons why Canada has fallen so far behind other countries in the regulation and control of toxicants.

The assessment and management of substances needs mandatory timelines under new provisions of CEPA where they are missing (for example between proposing a listing as toxic and finalizing it into control actions and/or regulations).

4. Need for direction and resources for the second phase of the DSL categorization – risk management

CEPA 99 requires systematic consideration of all 23,000 substances on the Domestic Substances List (DSL). Environment Canada (EC) and Health Canada (HC) are fulfilling the daunting mandate under Section 73 , it remains to be seen if sufficient political, technical and other support will allow timely and adequate health risk assessments for the 4000 substances that have been identified as needing further assessment. In addition, of major importance the Departments must make decisions on standards for daily intakes by Canadians from all sources of the substances reviewed, plan and undertake risk management, and regulate necessary control actions to protect the health of Canadians and their environment. HC and EC will need new research and scientific capacity similar to the Health Effects Research Laboratories at

⁴ Muir T. & Zegarac M. (2001) Societal costs of exposure to toxic substances: Environmental and health costs of four case studies that are candidates for environmental causation. *Environmental Health Perspectives*, 109(suppl. 6):885-903.

USEPA. Currently important decisions on priority chemicals seem to stay in limbo for decades. For example, Health Canada's review of the tolerable daily intake for dioxin, tritium, and radon - which in most cases are the highest limits permitted in any country, have been "under review" for many years. It is perhaps telling that what used to be the Health Protection Branch of Health Canada now has been given the innocuous title of "Safe Environments".

5. The need for new toxicity data

The revisions to CEPA must address the second phase of this program and must include some timelines and strategies to allow HC and EC to carry out the next and most important stage of the DSL program for large numbers of substances. This will require the generation of new toxicity data under section 71 (1) (c) because the great majority of these substances lack even minimal data on toxicity and persistence and bioaccumulation in the environment.

6. Enabling legislation: authority to obtain data.

We would agree with the final Report of the Multistakeholder Consultation on the CEPA New Substances Notification Regulations (2001) that: "***The next revision of CEPA should clarify the authority of regulators to require additional information when the prescribed information {and academic research} suggests a suspicion of toxicity but is insufficient to characterize the risk". "In the meantime EC and HC should adopt the interpretation of section 84 [and 71] and should develop a guidance document that describes how authorities under section 84 [and 71] can be accessedthe intent is that these criteria enable health , ecotoxicity hazards or exposure concerns to be addressed."***

Several Sections give regulators authority to obtain data on chemicals. These Sections need to be strengthened with timelines and penalties for non-compliance. . For example, Environment Canada reported in June 2005 that under authority of Section 71 (1) b a S71 Notice had been issued in the Canada Gazette in January with a compliance deadline of April 28, 2005 that required 170 Canadian companies and 110 industry associations to report on PFA/FA substances. In June fewer than 20 companies had replied – a very poor response. This section, like others, has no teeth, no enforcement and no penalties for not responding.

Section 71 (1) (c) also provides authority to the Minister to require any person engaged in the manufacture of importation of a substance or any product containing the substance, to conduct toxicological and other tests that the Minister may specify and submit the results of the tests to the Minister.

This authority to require new data when necessary is most important to protect public health and the environment. If risk is to be assessed scientifically and appropriately, especially risks to pregnant women and children. However it has been underutilized and we know of no instance when these provisions have been used to obtain necessary data. Again there are no penalties for not carrying out this requirement.

Section 71 (1) a-c and (2) should include reference to penalties for non-compliance with the notice, and non-compliance within the timelines specified in the notice.

In addition there should be some reference in the Act that independent and industry test laboratories that provide toxicity data on substances under review must be certified, and use positive control data – showing their ability to find an effect when one exists. In a study reported by Crofton et al.⁵, only 3 out of 16 laboratories submitted positive control data adequate for proficiency purposes for all of the major endpoints in the Developmental Neurotoxicity (DNT)

⁵ Crofton KM, Makris SL, Sette WF, et al, Neurotoxicol Teratol. 2004 May-Jun;26 (3) :345-52.

study. Adequate positive control data are very useful in a weight-of-evidence approach to help determine the biological significance of results, and also to increase the confidence in negative results from DNT and other toxicity and environmental test data.

Under Sub-section 73 (1) substances must be categorized on the basis of **available** information on P and B. For most substances, there is little or no available evidence on persistence and bioaccumulation. There is no authority to require companies to develop these data within any timeframe..

Under Sub-section 73 (2) when available information is insufficient to identify substances that are P or B or inherently toxic, this section does not require industry to develop or provide new data, but authorizes its collection from other governments or persons, again with no timelines.

7. Hormonally-active substances

Three high-volume production chemicals are under scrutiny at present, PBDEs, PFOS and bisphenol-A have all been shown in research studies to affect hormonal systems and development in hazard/toxicity studies, in the case of BPA at very low environmentally-relevant doses. The actions of hormones are particularly important during development.

Section 44 (4) of CEPA imposes a legal obligation on the Minister of Health and the Minister of Environment to *“conduct research or studies relating to hormone disrupting substances, methods related to their detection, methods to determine their actual or likely short-term or long-term effect on the environment and human health, and preventive, control and abatement measures to deal with those substances to protect the environment and human health.”*

It would be important to have annual reports to parliament on the Ministers’ progress in fulfilling this mandated responsibility under CEPA 99. Also this report should outline HC and EC’s approach to incorporating endocrine disrupting considerations, e.g. weight of evidence approaches using data from academic and government-financed published research, in the course of conducting risk assessments and proposed risk management outcomes.

CEPA should mandate a database of substances shown to disrupt hormonal systems, e.g. thyroid, androgen and estrogen, and updates on validated screening methods to identify them.

8. The interpretation of toxic under provisions of CEPA

Primarily the narrow interpretation of when a substance can be considered “toxic” under Section 64 of CEPA is based on releases to the environment, which is contrary to traditional and current usage of the term.

Recommendation: The definition of a toxic substance as contained in the Health Canada PSL assessment program “Background” should be provided in CEPA as follows: *“A substance is toxic if it has an inherent potential to cause acute or chronic adverse effects in living organisms, including humans, via ingestion, inhalation, or skin contact.”*

Designating a substance not toxic under CEPA is misleading and results in confusion, because it has the effect of misrepresenting the inherent toxicity of substances that have been recognized as toxic by international bodies, but that have been assessed by Health Canada as not toxic under the interpretation of a toxic substance in CEPA Section 64. These include many high-volume toxic substances, such as toluene.

In addition the CEPA interpretation puts the emphasis on smokestack and end of pipe releases into the environment, but does not directly include the presence of toxic substances in products which are of concern because infants and children are exposed to these in their homes. In addition, the CEPA interpretation of a toxic substance, because first it requires a substance to be entering the environment in a quantity that may have an immediate or long-term harmful effect on the environment or its biological diversity, gives lesser weight to human health, and must constitute a DANGER – (not “a risk” which is usual in toxicology) to human health. .

The interpretation of when a “substance is toxic” under Section 64 might be clearer if it referred to a “substance for control” or “hazardous substance”.

The following is an proposed **revised Interpretation: “A substance for control is a substance that is toxic, or that is entering, or may enter the environment - including the built environment, in a quantity or concentration or under conditions that constitute, or may constitute, a hazard to human life or health or the environment.”**

“Danger” should require that the precautionary principle be invoked

Sections 64 and 73 of CEPA should be revised to allow decisions on chemicals based on hazard to human health alone, this is the stated primary concern in the European Union’s chemical program REACH, and should be primary in CEPA. Currently provisions for categorizing DSL substances under Section 73 there is a need for them to have the greatest potential for exposure, or to be persistent (P) or bioaccumulative (B) in the environment **and** to be inherently toxic to humans or biota before they can be categorized a possibly hazardous. If this requirement remains, then the numerous substances that have been found in human tissues via biomonitoring data, the most accurate evidence of exposure, should be an additional consideration re chemicals that may not be P or B eco, but are ubiquitous, if not persistent, in the environment and are producing chronic exposures that show bioaccumulation in human tissues.

As I have urged in previous submissions, the language of the Act should bring public, scientific and regulatory attention to health endpoints of concern for toxicity e.g. carcinogenesis, immunotoxicity, neurotoxicity, developmental and neurodevelopmental toxicity, reproductive toxicity, and endocrine disruption.

9. Including specific reference to infants and children - Vulnerable populations and risk assessment

Explicit recognition of children as a sensitive group should be included in the language of the revised CEPA as in the revised Pest Control Products Act (given Royal Assent in 2002), as follows: “In assessing risks to humans, consideration be given to aggregate exposure to pest control products [from a range of exposure sources], cumulative effects of pest control products [from several PCPs with similar modes of action in one medium], **and the different sensitivities to [toxic substances] of major identifiable subgroups, including pregnant women, infants, children, women and seniors”**.

The importance of requiring tests to protect prenatal development, infants and children from the potential of chemicals to affect development and neurodevelopment has been demonstrated in reports and research worldwide. . Presently under provisions of CEPA 99, there is no requirement for developmental data for even the highest production volume chemicals under the New Substances Notification (Chemicals and Polymers) Regulations (October 2004).

In 1993 the US Congress mandated the Food Quality Protection Act as precautionary legislation to protect children. It requires **an additional** 10-fold safety factor to be applied in the risk assessment process for pesticides lacking toxicity or exposure data relevant to children.

CEPA should mandate the requirement of developmental and reproductive toxicity test data and exposure data particular to children, for substances reviewed on the NDSL and the DSL. If these data are not available, an additional safety factor of 10 should be mandated in health risk assessments to protect the health and development of children.

USEPA scientists have recently faulted the Agency for approving pesticides without using the additional 10X safety factor when developmental neurotoxicity data are missing for classes of pesticides known to be neurotoxic⁶. The letter reads “The prevailing belief among [risk] managers in the pesticides and toxics program is that regulatory decisions should only be made after reaching full consensus with the regulated pesticide and chemicals industry” and “Risk assessments cannot state with confidence the degree to which any exposure of a fetus, infant or child to a pesticide will or will not adversely affect their neurological development” the same could be said for the many chemicals that have a potential to affect the nervous system.

Under Section 74 the health endpoints being considered in screening assessment of substances being categorized for hazard under the DSL program should be listed, and expanded to capture substances that are inherently neurotoxic (e.g. as identified in Material Data Safety (MDS) information for occupational exposure) and/or immunotoxic, or that have known effects on hormonal systems that guide development. OECD or USEPA test guidelines exist for both DNT and immunotoxicity endpoints.

10. The Precautionary Principle: Implies a Duty to Act.

There should be a defined process in the Act whereby the duty to take timely action under the precautionary principle could be realized. There is a most serious concern regarding the implementation of the precautionary principle: That in order to achieve regulation, government policies require a number of strict justifications for the use of regulations that are proposed to protect human health and control environmental risks. These include several lengthy consultations, cost/benefit analysis, regulatory impact analyses, comment periods, opportunity for objections, and so on – the process itself severely restricts timely action, or action itself, on toxic substances. At best risk management takes three years – unacceptable for example when the presence of a substance like PBDEs is doubling in breast milk every three years. These policies, hurdles and barriers set in regulatory policy militate against ever taking a precautionary approach, or responding in a timely fashion to the duty to act that is implied in the principle.

One of the barriers to action on toxicants may be the requirement in Section 65 (3) to proceed to virtual elimination itself, which requires considerable time for the development of levels of quantification for the substance in various media.

Section 77 subsection 2 of CEPA should include a provision that allows the Ministers to act in a precautionary manner and to prescribe some mitigating actions to control exposures while proceeding to virtual elimination under Section 65 (3) or when the substance is listed on Schedule 1, and while regulations are being developed.

Under Section 70: If a determination cannot be made whether a substances on the Priority Substances List is toxic or capable of becoming toxic, then as a precautionary measure, the substance should be considered toxic and no new uses or increased production is permitted until new data are obtained to allow a decision on toxicity.

⁶ Public Employees for Environmental Responsibility (May 25 2006). USEPA Scientists protest pending pesticide approvals.

11. Environmental Fate legislation

International monitoring has established that certain substances contained in products are present in detectable levels in the environment – most particularly in wastewater and surface waters. It is important that the environmental fate of products regulated under the Foods and Drugs Act, such as pharmaceuticals, biologics, veterinary drugs, personal care products, biotech products and cosmetics come under provisions of CEPA. CEPA requires existing Acts to demonstrate that they meet CEPA's requirements for environment assessments. Currently the Food and Drugs Act, which is administered by Health Canada does not meet CEPA requirements. The Notice of Intent to develop regulations for the environmental fate of products was Gazetted in September 2001 by Health Canada but no draft regulations have been released to date.

CEPA must include environmental fate regulations regarding current and new products regulated under the Food and Drugs Act.

12 Consumer Products

CEPA can impose control measures and/or regulate substances that are manufactured or released into the environment in Canada, or if they are imported as chemicals. However the same substances are not regulated as they appear in consumer products. PFOS/PFOAs, and PBDEs are examples of substances undergoing review, ubiquitous in the environment and in human tissues, but that cannot be controlled as they occur in imported products such as sofas and carpets, on non-stick, or stain resistant coatings. Cleaning products containing substances on the PSL or on Schedule 1, or regarded as pesticides by PMRA, are not labelled and they are used in the home environment. These have been shown to produce releases into the home environment which is of concern for exposures to children and pregnant women via house dust and air contaminants.

There must be some connection between action on substances under CEPA with coordinated action concerning their use and importation in products. The Hazardous Products Act requires decades to finalize a new regulation, (e.g. the lead content in paint) – again there has to be authority in CEPA for timely action.

12. Summary of recommendations:

Parliament needs to make a concerted effort to investigate the many lengthy procedural requirements that militate against regulation under CEPA; and to understand the reasons why Canada has fallen so far behind other countries in the regulation and control of toxicants.

The assessment and management of substances needs mandatory timelines where they are missing (for example between proposing a listing as toxic and finalizing it into control actions and/or regulations).

“The next revision of CEPA should clarify the authority of regulators to require additional information when the prescribed information [and academic research] suggests a suspicion of toxicity but is insufficient to characterize the risk”. “In the meantime EC and HC should adopt the interpretation of section 84 [and 71] and should develop a guidance document that describes how authorities under section 84 [and 71] can be accessed to . . . enable health, ecotoxicity hazards or exposure concerns to be addressed.”

The revisions to CEPA must address timelines and scientific, managerial and support resources for the second phase of the DSL categorization and assessment program – risk management.

Re Hormonally active substances section 44 (4)

It would be important to have annual reports to Parliament on the Ministers' progress in fulfilling this legal obligation under section 44 (4) of CEPA 99, and on other obligations under CEPA. Also the report should outline HC and EC's approach to incorporating endocrine disrupting considerations in the course of conducting risk assessments and proposed risk management outcomes, e.g. weight of evidence approaches using data from academic and government-financed published research.

CEPA should also mandate a database of substances shown to disrupt hormonal systems, e.g. thyroid, androgen and estrogen, and updates on validated screening methods to identify them.

Interpretation of toxic under CEPA

A revision of the misleading Interpretation of toxic under CEPA : Section 64

A more accurate interpretation would be a "substance for control" e.g. "A substance for control is a substance that is toxic, or that is entering, or may enter the environment - including the built environment, in a quantity or concentration or under conditions that constitute, or may constitute, a hazard to human life or health or the environment ."

Assessing risks to children

Explicit recognition of children as a sensitive group should be included in the language of the revised CEPA as in the revised Pest Control Products Act (given Royal Assent in 2002).

To protect the health and development of children, CEPA should mandate the provision of developmental toxicity test data and exposure data for all substances reviewed on the NDSL and the DSL, and if these data are not available, an additional safety factor of 10 should be mandated in health risk assessments. Developmental neurotoxicity test data should be required for substances that have been shown to produce developmental toxicity, or are known or suspected neurotoxicants.

Under Section 74 the health screening assessment of substances being categorized for hazard under the DSL program should be expanded to capture substances that are inherently neurotoxic (e.g. as identified in Material Data Safety (MDS) information for occupational exposure) and/or immunotoxic. OECD or USEPA test guidelines exist for both endpoints.

When assessing risks to humans, CEPA should give attention to the need to consider aggregate exposure to substances [from a range of exposure sources], and cumulative effects of substances [from those with similar modes of action/effects on health endpoints]
We are not exposed to chemicals one by one.

Under Section 70: If a determination cannot be made whether a substances on the Priority Substances List is toxic or capable of becoming toxic, then as a precautionary measure, the substance should be considered toxic and no new uses or increased production is permitted until new data are obtained to allow a decision on toxicity.

RE Enabling legislation Sections 71 - 73

"The next revision of CEPA should clarify the authority of regulators to require additional information when the prescribed information {and academic research} suggests a suspicion of toxicity but is insufficient to characterize the risk". "In the meantime EC and HC should adopt the interpretation of section 84 [and 71] and should develop a guidance document that describes

how authorities under section 84 [and 71] can be accessedthe intent is that these criteria enable health , ecotoxicity hazards or exposure concerns to be addressed.”

The authority to require new data when necessary is most important to protect public health and the environment. If risk is to be assessed scientifically and appropriately, especially risks to pregnant women and children. To be effective, Section 71 (1) a-c and (2) must include reference to penalties for non-compliance with the Notice, and penalties for non-compliance within the timelines specified in the Notice.

Under Sub-section 73 (1) substances must be categorized on the basis of available information on P and B. For most substances on the DSL , there is little or no available evidence on persistence and bioaccumulation, or developmental toxicity . There is no authority to require companies to develop these data within any timeframe or face penalties.

Section 77 subsection 2 of CEPA should include a provision that allows the Ministers to act in a precautionary manner and to prescribe some mitigating actions to control exposures when the substance is listed on Schedule 1,

Actions under these voluntary agreements must be monitored.

A generic Guidance Document must be prepared for voluntary agreements, providing information on expectations, reporting, independent monitoring, timelines and penalties for non-compliance. Regulations toward the elimination of PBiT substances should be carried out.

Re Environmental Fate Legislation:

International monitoring has established that certain substances contained in products are present in detectable levels in the environment – most particularly in wastewater and surface waters. Currently the Food and Drugs Act , which is administered by Health Canada does not meet CEPA requirements. The Notice of Intent to develop regulations for the environmental fate of products was Gazetted in September 2001 by Health Canada but no draft regulations have been released to date.

Environmental Fate Regulations for substances regulated under the Food and Drugs Act must be included under CEPA, and must include substances used in products currently, as well as new substances or products.

Environmental Releases from Products: Exposures to children and pregnant women

Re toxic substances in products : Under provisions of CEPA, substances on the PSL or on Schedule 1 that are manufactured in Canada or imported as chemicals can be controlled, but they cannot be controlled as they occur in imported products such as sofas and carpets, non-stick coatings, food containers, and in cleaning products used in the home environment. These substances have been shown to produce releases into the home environment as they degrade into house dust or volatilize into air. This near-field route of exposure is a major concern for children and pregnant women . There needs to be a new automatic connection between actions on hazardous substances under CEPA and action on their presence in products under the Hazardous Products Act or some other legislation.

Thank you.

