

Children and the Health Risk Assessment of Existing Substances under the *Canadian Environmental Protection Act, 1999*

Background

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) requires the federal Ministers of Health and of the Environment to identify and determine which existing substances pose a potential risk to human health and/or the environment. CEPA 1999 is the primary authority for the assessment and management of environmental contaminants in Canada, also making it the main source for policy direction. It is intended to protect the health and well-being, and the environment, of all Canadians, including children, from pollution and toxic substances.

The Act provides the framework¹ for the identification and control of existing substances and management of those considered to pose a risk to human health and/or the environment. This framework is broad, transparent and evidence-based, taking into account aspects (i.e., exposure and effects) of a substance in relation to the potential risk it may pose.

The identification of existing substances that may pose a risk to human health² and subsequent assessment of those risks are undertaken within the Existing Substances Division (ExSD) of the Environmental Contaminants Bureau of the Healthy Environments and Consumer Safety Branch of Health Canada.

This document highlights those aspects of assessment under the existing substances provisions of CEPA 1999 that address children's health.

Existing Substances under CEPA 1999

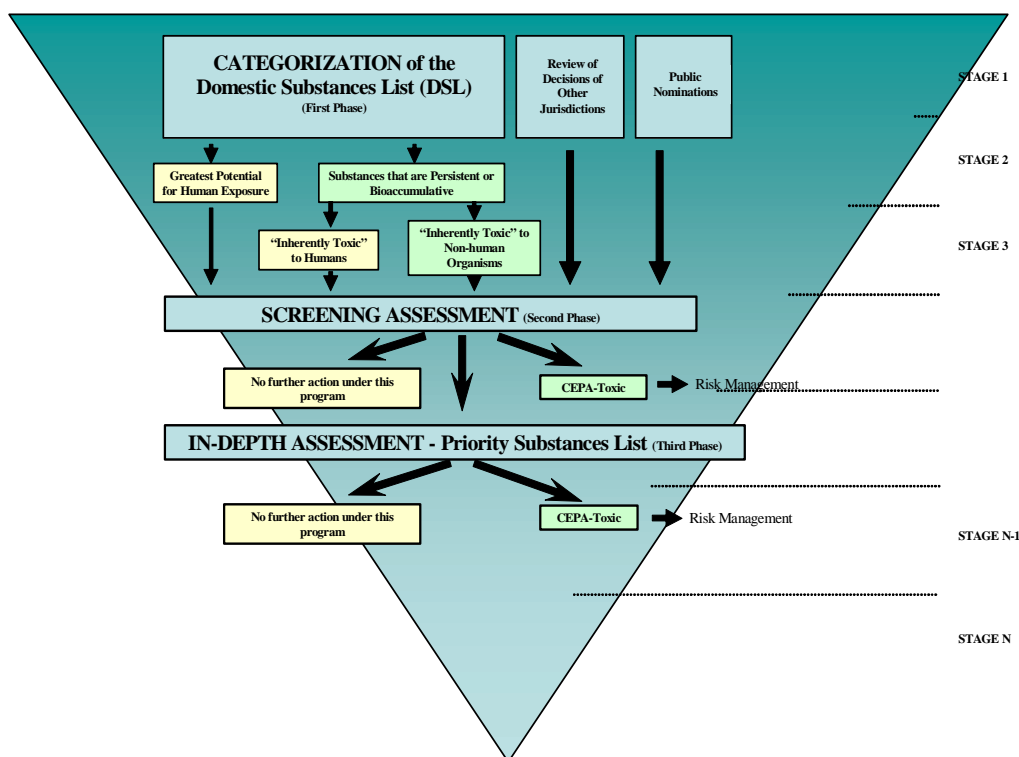
Existing substances are those included in an inventory known as the Domestic Substances List (DSL), published in 1994. The DSL is a compilation of about 23 000 substances used, imported or manufactured in Canada for commercial purposes between January 1, 1984, and December 31, 1986, at a quantity of greater than 100 kg per year; substances that are not listed on the DSL are considered to be new to Canada.³ The DSL is periodically amended to add substances that have met the listing requirements under the New Substances Notification Regulations of CEPA 1999.

¹ The approach and associated processes of issue identification, risk assessment and risk management are in line with the principles outlined in the Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks (http://www.hc-sc.gc.ca/hpfb-dgpsa/hcrisk_tc_e.html).

² Screening environmental assessments under CEPA 1999 are conducted by Environment Canada.

³ Substances new to Canada after December 31, 1986, are assessed under the new substances provisions of CEPA 1999.

The three principal phases of identification and assessment of priorities for risk management of existing substances specified under CEPA 1999 are presented here. These are categorization, screening assessment and in-depth (Priority Substances List, or PSL) assessment. One objective of the latter two phases, namely screening and full assessment, is to determine whether a substance is “CEPA-toxic” as defined in Section 64 of the Act, which may then set the stage for addition of the substance to Schedule 1 (the List of Toxic Substances) of the Act and for reviewing options for controlling risks to human health and/or the environment. In each of these three principal phases, there are a number of levels of complexity of identification and assessment, indicated here as stages within the overall scheme.



Key Elements of Children’s Health Protection with Respect to Existing Substances in Canada

Activities conducted by ExSD under the existing substances provisions of CEPA 1999 that contribute to the protection of children’s health encompass principally:

- the identification of substances that may pose a risk to the health of any age group;
- the assessment of the potential risks of substances to any age group; and
- continuing development of methodology for assessing risks to all life stages, including children.

Identification of Substances in Canada That May Pose a Risk to Children

The protection of children's health begins with identifying which of the approximately 23 000 existing substances in Canada are the highest priorities for further consideration of potential risk to health. Under CEPA 1999, the Minister of Health must identify such substances by categorizing all of the substances on the DSL with respect to the greatest potential for human exposure. The Minister must also identify which persistent and/or bioaccumulative substances are inherently toxic to humans. Importantly, the Act mandates that this categorization must be completed before September 14, 2006. Canada is the first jurisdiction to introduce a requirement to systematically examine all existing substances in this manner, based on consideration of both exposure and toxicity relevant to all life stages, including children.

The proposed first stage to delineate priorities for further consideration in categorization for greatest potential for human exposure involves looking at the use patterns of all existing substances — that is, how much of the substance is manufactured, imported or used in Canada, by how many companies and for what purposes. This will help determine, for example, whether the substance is present in household products or foodstuffs that children (and adults) eat or with which they might come into contact.

The proposed first stage to delineate priorities for further consideration for categorization of substances on the DSL for inherent toxicity to humans looks at effects that might adversely impact children's health. These include cancer and, importantly, reproductive/developmental effects, including those that result from disruption of the endocrine system.

The simple, predictive tools being developed in these two categorization streams enable identification, within a legislatively mandated timeframe, of those of the many thousands of existing substances in Canada that may pose a risk to children's health, either through their potential exposure to the substance or from the adverse health effects associated with exposure to the substance.

Substances that may pose a risk to any age group, including children, may also be identified under:

- Section 75 of CEPA 1999, where decisions taken in other jurisdictions to prohibit or restrict substances for environmental or health reasons are reviewed by the Ministers of Health and of the Environment to determine whether the substance in question is a danger to human health or the environment in Canada.
- Section 76(3) of CEPA 1999, where any person can write to the Minister of the Environment and request that a substance be added to the PSL for an in-depth assessment of risks to human health and/or the environment.

Health Risk Assessment of Existing Substances under CEPA 1999

Potential risks to human health posed by existing substances in Canada are evaluated through screening-level and in-depth assessments. Screening assessments represent a critical initial assessment of whether a substance poses a risk to human health. In-depth assessments are a critical, more comprehensive analysis of the risks to human health, undertaken for substances on the PSL.

Both screening and in-depth assessments of risks to human health address exposure and health-related effects important for protecting children.

Exposure Assessment

The exposure analyses for both screening and in-depth assessments have adopted a multimedia approach, typically estimating (where data permit) the intake of a substance from air, drinking water, foodstuffs, soil (dust) and consumer products. The daily intake of a substance is estimated for six age categories: 0–6 months, 0.5–4 years, 5–11 years, 12–19 years, 20–59 years and 60+ years. The 0–6 months age category is additionally subdivided into infants fed formula and infants fed breast milk during this period. The daily intake for these groups is estimated using monitoring data⁴ on the concentration of a substance in air, foods, drinking water, etc. and corresponding age-specific intakes (for a description of the approach to the exposure assessment for existing substances, see <http://www.hc-sc.gc.ca/exsd-dse>). Depending upon the source(s) of exposure, the highest estimated daily intakes for some Priority Substances are somewhat higher in infants or young children 0.5–4 years of age than in adults, due to higher intake of air, water and food relative to body size.

Hazard Characterization

The hazard characterization for both screening and in-depth health assessments examines effects critical to adults' and children's health, such as potential organ-specific effects or more specialized hazards such as immunotoxicity, neurological/behavioural toxicity, reproductive toxicity, genotoxicity, cancer and developmental effects.

Risk Assessment and Implications

The health risk assessment takes into account both the exposure assessment and hazard characterization in determining whether an existing substance is “toxic” to human

⁴ In some cases, modelling is used to predict the concentration of a substance in environmental media.

health under the Act.⁵ For existing substances, the assessment of “CEPA-toxic” involves identification of the critical effect — that is, the relevant health-related effect occurring at the lowest level of exposure. For most Priority Substances, the critical effect identified in the risk assessment was one that occurred at a dose (exposure) that was *less* than that causing any potential adverse effects on fetal or neonatal survival or development. Consequently, for those compounds, the development of a tolerable intake based upon that critical effect or any action taken to reduce exposure to that substance would be protective for any adverse effects upon the young. However, for three substances on PSL1⁶ — dibutyl phthalate, bis(2-ethylhexyl)phthalate and styrene — the critical effects upon which the risk assessments were based were possible developmental effects, maternal toxicity and fetal deaths, and neurobehavioural effects, respectively. For 2-methoxyethanol, a substance on PSL2,⁷ the critical study upon which the risk assessment was based addressed developmental toxicity.

The assessment of “CEPA-toxic” also considers the highest estimated exposure, and, as noted above, this often means that such determinations are made based upon the estimated intakes of the substances by infants or young children.

For substances considered “CEPA-toxic,” where identified in the assessments, risk management measures are developed to protect the most susceptible life stages, including children.

Development of Risk Assessment Methodology for the Protection of Children’s Health under CEPA 1999

ExSD leads and contributes to, often with international partners, the improvement of methodology for risk assessment to ensure efficient and effective identification of potential hazards and risks to human health associated with exposure to environmental contaminants. This is essential to meeting the progressive mandate of CEPA 1999 and includes development of frameworks for increasing transparency in decision-making in risk assessment as a basis, in part, for establishing priorities for research.

Specifically, to ensure that the best scientific information can be applied to the assessment of the risks to children’s health under CEPA 1999, ExSD is developing, with partners in the United States, a framework for assessing children’s risks from exposure to environmental contaminants, based upon the most up-to-date scientific information available. ExSD also supports research both within and outside Health Canada to better address life stage analysis in risk assessment and development of internationally accepted test methods to address endocrine disruption.

⁵ Under Paragraph 64(c) of CEPA 1999, a substance is “toxic” to human health if it is entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

⁶ Substances on the first Priority Substances List.

⁷ Substances on the second Priority Substances List.

Children's Environmental Health

Certainly, factors other than exposure to environmental contaminants impact upon the overall health of children in Canada. These interdependent elements include physical safety, nutrition and socioeconomic factors. Although environmental contaminants have been highlighted as dangers to children's health, children spend more than 80% of their time indoors, and therefore elements such as second-hand smoke are likely to make a greater contribution to the detriment of their health.

There are successes. Recent studies and environmental scans indicate a significant reduction in chemical contaminants in the general environment. Air quality continues to improve, with a 49% decrease in average levels of the six primary air pollutants in Canada since 1980. In 1992, environmental lead concentrations in Canada had been reduced by 97% compared with 1974; Canadian children's average blood lead levels were reduced by 70% between 1984 and 1992. The levels of benzene in air and emissions of mercury to air both decreased by 35% from 1995 to 2000. The levels of contaminants in breast milk show similar downward trends, with the levels of polychlorinated biphenyls (PCBs) decreasing 73% between 1982 and 1992 and the levels of the pesticide DDT decreasing 94% between 1967 and 1992.

The progressive mandate under CEPA 1999 to systematically set priorities for risk management among the thousands of existing substances in Canada will undoubtedly lead to additional gains in this area.

Children's Health Protection and Existing Substances under CEPA 1999

Although the existing substances provisions of CEPA 1999 refer to human health with no explicit reference specifically to "children" *per se*, the protection of children's health has been, is and will continue to be a vital component of those activities related to the identification and assessment of existing substances that may pose a risk to the health and well-being of children and of Canadians of all ages. The categorization and screening assessment provisions of CEPA 1999 enable rapid progress in identifying substances that may pose a risk to children, assessing those risks and, where indicated, initiating the necessary actions for management of the risks. Assessments transparently delineate considerations related to life stage analysis, including those relevant to children, and methodology continues to evolve to reflect latest developments in these areas.

Additional Information

Additional information on the health-related aspects of the Existing Substances Program under CEPA 1999 is available at <http://www.hc-sc.gc.ca/exsd-dse>.