Chapter 1 - Introduction

1.1 OVERVIEW AND STUDY BOUNDARIES	21 22 23
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1.1 Overview and Study Boundaries

This study represents Phase I of the *Children's Health Project*, a collaboration of the Canadian Environmental Law Association and the Ontario College of Family Physicians Environmental Health Committee. It addresses the risks to children's health from environmental contaminants and the adequacy of regulatory responses. It explores whether the rules or standards in place and the manner in which those standards are set ensure that children's health is protected.

Several very large areas of inquiry are at issue here: the amount and availability of toxins in a child's environment; the effects of toxins on a child's health; and the control of those toxins by regulatory agencies. In each of these areas there are thousands of different types and sources of toxic substances, all with varying degrees of usage and ability to create environmental or consumer product contamination. Equally as diverse are the potential health effects from toxic substances. There are also numerous regulatory agencies at the federal and provincial levels of government often with overlapping, conflicting or confusing mandates. The passage of time is also an important consideration in this investigation. Regulatory responses in recent years have increasingly recognized children as a sensitive sub-population. A review of regulatory action must therefore make a distinction between current and past approaches or techniques to the evaluation of environmental contaminants.

Over all of these areas of inquiry hangs a cloud of uncertainty and controversy due to the enormous complexities involved, incomplete information, constraints on both resources and research capabilities, differences in scientific opinion, and vested or competing interests of different stakeholders.

The study focus is children in Ontario. A wide net is cast across the internationally reported and peerreviewed literature concerning the exposure to and effects of environmental contaminants in children. However, exposure data from Ontario, where these are known, are provided to be able to talk about children in Ontario

Similarly, the review of standard-setting addresses the Ontario and federal governments. Hence, although more information is provided with respect to Ontario, for those standards set by the federal government, the study provides a review and analysis that is applicable to standards affecting children across Canada. Central to the analysis is a review of the history, ongoing evolution and appropriate role for risk assessment in standard-setting.

The focus is also primarily on chemical and metal pollutants. Time and budget constraints did not permit a more comprehensive review. Not included are physical contaminants (including electromagnetic frequency, radiation, radon or radionuclides), biological agents (such as mould, fungi, bacteria) or environmental tobacco smoke and other indoor air pollutants. Although these are important areas for children's health, the focus on chemicals and metals provided some bounds on a very large field of inquiry.

The study is further bounded by the exclusion of some areas of standard-setting. Included are detailed reviews of standard-setting for air, pesticides, consumer products and toxic substances. These areas were chosen since they represent the most significant areas of chemical exposure for children and are also the areas where standard-setting is primarily focused on evaluations of human health effects. Categories that are not included in detail are water, food (other than pesticides, i.e., there is no review of standards for genetically-modified foods, food additives or food irradiation), soil, or *new substances* as these are defined

under federal environmental law. The reviews of standard-setting are mainly descriptive and provide either preliminary analysis and in some cases recommendations for further detailed analysis and/or action. A very detailed review and analysis of standard-setting is provided in two case studies: the first on the "cautionary tale" of lead and the second on the regulation of pesticides by the federal government. The review of risk assessment in Chapter 4 is relevant to all categories where human health effects are assessed and standards established.

A central question for this study is whether the rules in place concerning environmental contamination are *intentionally protective* of children's health. Further, where standards are or are increasingly established to be *intentionally protective* of children, the question remains whether children's health is indeed protected. This study provides a foundation for answering these questions and a detailed set of recommendations for further research and action steps, including educational activities. Phase II of the *Children's Health Project* is now underway with the translation and summary of this large study into a variety of academic and popular educational media and the preparation of further educational materials on standard-setting.

1.2 TOXIC SUBSTANCES AND CHILDREN'S HEALTH: A GROWING CONCERN

There is growing world-wide concern that toxic substances in the environment and consumer products are, or may be, particularly harmful to the health of children. We know that children's health has been harmed and continues to be harmed by certain environmental contaminants. Historically, lead is perhaps the most well known example. By the 1980s, environmental lead contamination, primarily from the use of lead in gasoline, was high enough to affect the health of literally millions of children in most industrialized countries, including Canada. Average blood-lead levels were at or above the range where lead can lower IQ, reduce attention span, and create behavioural problems. This situation has improved dramatically with the removal of the primary exposure source via the decision to ban gasoline lead additives.

Recent decades have seen substantial increases in childhood asthma, allergies and respiratory problems. Environmental contaminants such as ozone, sulphates and particulate matter aggravate symptoms associated with these conditions and may be causes. According to the Ontario Medical Association:

... the available evidence on the impact of air pollution on children shows that, when all the data are taken together, there is no doubt that relatively low levels of pollution are responsible for increased morbidity in children.¹

The concern extends far beyond cases for which clear, causal connections have been established. Increasing concern exists about a wide range of chemicals that, both animal studies and human clinical evidence suggests, are neurotoxic, suspected or known carcinogens, or that can impair immune system functioning. Childhood cancers, such as leukemia, bone and brain tumours are rising and may be related to immune suppressive effects, or, to the direct genotoxic effects of environmental toxins. More question marks surround the relationship between exposure to environmental contaminants and adverse pregnancy outcomes including spontaneous abortions, increased rates of stillbirth, and anatomical abnormalities in the newborn.

Endocrine disrupting chemicals are also of concern. Studies in wildlife and laboratory animals are showing effects of hormone disruption on reproductive development, behaviour and thyroid or immune system

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¹ Ontario Medical Association, 1998. *OMA Position Paper on The Health Effects of Ground-Level Ozone, Acid Aerosols and Particulate Matter*, p. 11. www.oma.org/phealth/ground.htm

functioning. Disturbing trends in human populations in industrialized countries include declining sperm counts, increasing prevalence of prostate, testicular, and breast cancers, reproductive organ abnormalities and fertility problems, all of which may be linked with the presence of endocrine disrupting chemicals in the environment. Further, there is increasing understanding as to the notion of "windows of vulnerability." These windows are highly sensitive stages during fetal, infant, child and adolescent development when chemical exposures that may be otherwise safe for adults or even during other periods of childhood, might cause or contribute to serious or fatal health effects in later life.

Chapter 2 provides a detailed review of the relationship between children's health and environmental contaminants by addressing the factors influencing children's exposure, uptake and susceptibility to contaminants and the issues of concern at each of the developmental stages of children. Note that this study defines "children" as including each of the developmental stages discussed in Chapter 2, from *in utero* to adolescence. Chapter 2 explores the diverse environmental media and exposure routes for contaminants and the many factors influencing contaminant exposure and susceptibility that are unique to children and that frequently place children at greater risk. The chapter goes on to describe a range of contaminants and their known effects focusing on classes of chemicals and metals for which the existing knowledge base reveals cause for significant concern. A detailed review is provided of the known, suspected and controversial nature of health problems in children related to environmental exposures and concludes with an assessment of trends in children's environmental health problems and the future of children's environmental health. Building upon Chapter 2, the two case studies provide greater detail in each of the areas noted above. The first addresses a single pollutant, lead, and all of its many exposure sources and well-known health effects. The second addresses pesticides as a class of pollutants and focuses on those for which the greatest amount of concern exists about possible health effects.

1.3 TOXIC SUBSTANCES: UNDERESTIMATED VOLUMES AND INFORMATION GAPS

Every year, more substances are introduced into the Canadian marketplace. These are added to the more than 23,000 substances in commercial use in Canada. In addition, there are over 500 active ingredients in pesticides registered for use in Canada, over 300 of which were approved for use before 1981 (and over 150 approved for use before 1960), under far less rigorous testing requirements than exist today.

Of the over 23,000 substances in commercial use in Canada, probably less than 15% of these has a full or comprehensive data set evaluating toxicological properties.² A preliminary first step towards addressing this problem has been taken by Health Canada with the creation of a detailed inventory of 72 activities within that agency on children's health and the environment.³ Further "gaps analysis" continues across the federal government.

Additional gaps in information occur with respect to pollutant releases. Estimates are incomplete

The figures for south of the border are comparable. The U.S. Office of Technology Assessment (OTA) estimates that there are over 62,000 chemicals in commerce in the United States with 1500 new chemicals introduced each year. Concerning the approximately 15,000 chemicals that are deemed to be produced in high volume, the EPA recently reported that complete health and environmental effects data are available for only 7% of these. Source: Congressional Research Service, Issue Brief to Congress. No. 94036: *The Role of Risk Analysis and Risk Management in Environmental Protection*. November 5, 1999. By L. Schierow, pp. 8-9. Available at: www.cnie.org.nle.rsk-1.html

³ Inventory on Children's Health and the Environment – Activities at Health Canada. Fax memo to Loren Vanderlinden from Monica McAuley, Program Development Bureau, Health Protection Branch, Health Canada, April 9, 1999.

concerning the total volumes of toxic substances that are released to the environment. The Canadian pollution inventory, the *National Pollutant Release Inventory* (NPRI), reports that for 1997, over 160,000 tonnes of chemicals, (over 15,000 tonnes of which are toxic and carcinogenic), were either released into the Canadian environment or transferred from source facilities. Despite the huge volumes of chemicals these numbers suggest, the NPRI focuses only on large facilities, includes only a limited number of substances, does not include mobile sources and as a result reflects only a small fraction of total pollutant emissions to the environment. The total volume reported in the NPRI is derived from fewer than 2000 reporting facilities. Hence, similar to the Toxic Releases Inventory (TRI) in the United States, inventories like the NPRI and the TRI may only estimate some 5% of actual emissions to the environment.

According to annual reports released for three years in a row by the Commission for Environmental Cooperation, Ontario was, in 1994 and 1995, the third worst polluter in North America, behind Louisiana and Texas, and as of 1996 was ranked the second worst. Over 68 million kilograms of pollutants were released into the environment or transferred off-site in 1996 from reporting facilities in Ontario. The most recent reporting of NPRI data for 1997 reveals a continuation of a trend towards lower overall emissions in Ontario by reporting facilities during the 1994-1997 period. Whether or not this drop in 1997 data will affect Ontario's ranking as among the top polluters in North America will depend upon the annual comparisons of all North American data conducted by the CEC. That comparison will likely be reported, as in years past, in August of this year (2000).

1.4 ARE REGULATIONS KEEPING UP?

Regulatory responses have not, in past or currently, always adequately considered children's health. Children can be more vulnerable to environmental contaminants than adults for many reasons mostly related to immaturity and sensitivities associated with growth and development. Exposure can also be much greater, again due to numerous circumstances that are unique to children. Both exposure and uptake can be greater under conditions of poverty, an increasing reality for large numbers of children in Ontario.

The reality that children's exposure patterns and special vulnerabilities are not adequately accounted for in regulatory controls on toxic substances was recognized in 1997 when Canada signed the 1997 Declaration of the Environment Leaders of the Eight on Children's Environmental Health, which states:

We pledge to establish national policies that take into account the specific exposure pathways and dose-response characteristics of children when conducting environmental risk assessments and setting protective standards.⁷

This report is, in part, an assessment of whether this commitment is being achieved to protect children in

⁴ Environment Canada, 1999. National Pollutant Release Inventory - 1997.

⁵ United States General Accounting Office, *Toxic Chemicals: EPA's Toxic Release Inventory is Useful but Can be Improved.* GAO/RCED-91-121, June, 1991, p.3; see also: United States General Accounting Office, *Pollution Prevention: EPA Should Re-examine the Objectives and Sustainability of State Programs.* GAO/PEMD-94-8, January, 1994, p.54 and multiple additional cites therein.

⁶ See the three annual reports of the Commission for Environmental Cooperation, 1997, 1998 and 1999. All entitled *Taking Stock - North American Pollutant Releases and Transfers – 1995 (-1996)(-1997)*. Legal Deposit-Bibliotheque national du Quebec. Pages 21, 31 and 47, respectively.

⁷ 1997 Declaration of the Environment Leaders of the Eight on Children's Environmental Health, Environment Leaders' Summit of the G7 countries plus Russia (the "Eight"), Miami, Florida. May 6-7, 1997.

Ontario. With a focus on Ontario, the scope of this report is both provincial and federal insofar as laws, regulations and policies exist at both jurisdictional levels that will affect the health of children in Ontario. Chapter 3 provides an introduction and overview to this constitutional context whereby roles and responsibilities are shared and/or divided between the two levels of government. For each of the federal and provincial departments, or joint federal-provincial organizations, relevant to this inquiry, Chapter 3 describes the relevant mandates, specific regulatory or policy tools that are applied to standard-setting as well as a sense of how these players relate to each other to accomplish their particular standard-setting functions.

The central scientific, legal and policy analysis of this report is the review in Chapter 4 of *risk analysis* or *risk assessment*. Chapter 4 looks at how standard-setting to assess human health impacts has been a roughly 30 year process of refining *risk analysis* or *risk assessment* methods. A detailed look at trends and recent activity in the United States is included due to the significant impact on Canada of approaches taken in the United States. The "science behind the assessment" takes a detailed look at how inferences of causation can be drawn from epidemiological evidence. The Chapter also contrasts the standard or burden of proof in scientific versus legal settings and looks at how "weight-of-evidence" and "precautionary inference" approaches offer useful input to alternative models for setting environmental standards. To conclude, the Chapter addresses the role of the *precautionary principle* or a *precautionary approach* to standard setting.

Chapters 5 through 7 then provide detailed reviews and/or overviews of actual standard-setting processes and techniques with a focus on health-based standards and the predominance of risk assessment in their derivation. Again, the choice was made to focus on those human-health based standard-setting areas which are also of increasing concern for children's health, i.e., air, consumer products, and toxic substances. In addition, more detailed regulatory analyses and recommendations contained in the two case studies provide illustrations and lessons for the study as a whole.

1.5 RESEARCH METHODS

This review of children's health issues and environmental standard setting was assembled by a team of environmental, legal and medical researchers.

The summary of the relationship between children's health and environmental contaminants (in Chapter 2 and in the two case studies) was founded on an extensive review of the most current literature available. Researchers accessed a variety of sources including research publications (both primary and secondary sources), unpublished documents (conference proceedings, reports and data from research agencies, government ministries and public interest groups, among others) and electronic sources (web pages for a variety of agencies). Data gathering was both systematic and exploratory. Medline was the primary tool used to search published sources, and Internet search engines such as Lycos, were used to search the web. Data were gathered for a number of different subject areas, reflecting the fact that Chapter 2 examines children's environmental health issues from several perspectives. Among the topics researched were: growth and development patterns in the young, developmental toxicology, physiological and behavioural features of children affecting exposure, environmental contaminants of concern (as defined in Chapter 2, for the purposes of this study) and their health effects, children's health problems related to environmental exposures, and environmental exposure monitoring data relevant to children in Ontario.

The review of standard setting in this report included an extensive review of the available literature using research methods and information sources similar to those noted above. Extensive use was made of the websites of regulatory agencies and non-governmental organizations in Canada and the United States. Particularly useful for the US research was the availability of Congressional Research Service Reports on

the website of the Committee for the National Institute for the Environment, based in Washington.

The involvement throughout the project of the librarian with the *Resource Library for the Environment* and the Law (located in the offices of the Canadian Environmental Law Association) provided valuable research assistance and cataloguing expertise. Since Phase I of the *Children's Health Project* is intended to provide a foundation for further work, the extensive collection of research materials for both the health and legal sides of this project have been exhaustively referenced. This detailed referencing has been done to facilitate print and internet access to source materials during Phase II as well as for use by other researchers working in this field.

The literature reviews for both the health and legal areas of research were supplemented by interviews of key informants in medicine, pediatrics, public health, research agencies, government departments, non-governmental organizations, public interest groups and community associations. Key informants were an invaluable resource providing important theoretical perspective and contextual information that allowed the research team to more adequately characterize environmental health and standard-setting issues for Ontario's children. They were also helpful in directing team members to additional key informants and current literature on children's environmental health and standard-setting.

1.6 REFERENCES CITED

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