Executive Summary

Human behaviour has resulted in the introduction of many tens of thousands of different chemicals to the environment over the last half-century. The rate of production of new chemicals has overtaken the capacity to fully characterize their potential to cause harm to people. The state of the environment plays a critical role in causing or augmenting ill effects to human health and well being. Today's children are growing up in an environment that is radically different from that of their parents and grandparents, one that has an incomparable potential to impact on health throughout their lives.

The surface has only been scratched in our understanding of just how detrimental toxic environmental exposures during childhood can be to lifelong health. However, there are clear indications that children's health is being measurably compromised by environmental factors.

The challenge to protect children's health is enormous; society is contending with an environment in which there is both ample opportunity for exposure and limited information on the risks from those exposures.

The primary and immediate goals in response to these concerns are to prevent, or at the very least, reduce exposure to environmental contaminants in children and to better identify the risks to children from toxic environmental exposures. These, then, are the ultimate challenges of the standard setting processes. The question remains, however, how effective have the standard setting regimes been in responding to these challenges?

The following document is the initial product of the *Children's Health Project* that represents a 20-month collaboration between the Canadian Environmental Law Association and the Ontario College of Family Physicians' Environmental Health Committee. This report summarizes the findings of a lengthy investigation into the adequacy of the standard setting process for protecting the health of children in Canada and specifically, in the province of Ontario. The report also provides a detailed review of research into the greater susceptibility and exposure of children to environmental contaminants.

CHAPTER SUMMARIES AND CONCLUSIONS

Introduction

Chapter One lays out the overview, structure, rationale, methods and bounds for the study. The study defines "childhood" according to current practice in environmental health research as all stages prior to maturity, from *in utero* up to and including adolescence. The project team determined that the contaminants chosen for consideration would be primarily chemical and metal pollutants. This admittedly leaves out several significant types of environmental toxins that may or do affect children,[1] however, it was felt that focus on a smaller number of equally important environmental contaminants would realize greater gains without duplicating the efforts of others. In addition, the study focuses on reviewing specific areas of standard setting, again for chemical and metal pollutants, and addresses air, pesticides, consumer products and toxic substances. These areas reflect standards that have greatest relevance to the chemical exposures of children, in terms of known or suspected avenues of increased risk and, as well, they represent areas of standard setting most directly determined by evaluations of human health effects. We recognize that a key component of analyzing the adequacy of standard setting regimes

[1] For example, environmental tobacco smoke and other indoor air pollutants, physical contaminants like radiation and EMFs, and biological agents such as moulds, fungi and bacteria.

was to provide a thorough review of the scientific risk assessment process that is embedded in most regulatory frameworks.

The review of standard setting includes coverage of some areas in depth (air, pesticides, lead) and overviews of others. Since Phase I of the *Children's Health Project* provides a foundation for further work, opportunities for additional legal and policy analysis are identified. Two case studies, one concerned with lead, and the other with pesticides, allow for more extensive review and analysis of the information on exposure and health effects and the standard setting regimes in two areas that continue to be significant to children's environmental health in this country. Finally, **the central questions for the study were to decipher whether the regulatory framework as it exists in Canada is *intentionally* protective of children and where this is so, whether children's health is indeed protected.**

Exposure and Health Effects

In its summary of the extensive scientific literature characterizing children's greater exposure and susceptibility to environmental contaminants, Chapter 2 highlights some of the key trends in recent scientific understanding of children's environmental health. The conclusion is that this information must inform both scientific assessment of risks and regulatory decision-making.

There is increasing evidence of health effects from various pollutants occurring at very low levels of exposure. In some cases, it is speculated that there is no threshold below which children are safe from the effects of these contaminants. Examples include lead, ozone and particulate matter, all three of which have clear effects on children's health in particular. With most environmental contaminants we can characterize the outcome of exposure in terms of a pyramid of effects. At the apex of the pyramid, thankfully, few children suffer from fatal effects, but, toward the base there are increasing numbers exhibiting subclinical, yet often very important compromises to their health and well-being.

There is great concern among scientists because of the universality of some of these exposures. Air pollution and persistent organic pollutants (POPs) that appear in the food chain can potentially reach virtually all children. The latter is of exceptional concern because of the biologically plausible hypotheses surrounding their role as endocrine disruptors.

It is critical for the protection of all children that the variability inherent in human exposure or response to environmental contaminants is brought to the fore. Both exposure and susceptibility to health effects are mediated by genetic, social, economic and cultural factors. In particular, poor children and aboriginal children are generally more often at greater risk of environmentally related health problems. In Ontario for example, while the most recent data on blood lead levels indicate an *average* that is below the intervention level, the *distribution* of those values demonstrates that some portion of those children is close to or above the level for health effects from lead. Children living in poverty are at greater risk of reaching or surpassing that intervention level of exposure.

When determining the potential for exposure to a given contaminant, exposure assessments must account for the complexity and great variety of exposure pathways and media through which children may become exposed. In particular, we underscore the fact that the regulatory framework has not routinely considered exposures during the prenatal (when the child was in the womb) and early postnatal (via breast milk, foods or consumer products) periods. These represent significant exposure routes for children and ones that can have important impact because of the characteristic developmental windows of vulnerability during these times.

Similarly, it is increasingly recognized that exposures to contaminants that occur early in life may have long lasting or delayed consequences that may translate to more serious health problems later in life. For example, exposure to carcinogens may not result in cancer until later years, childhood exposure to air pollution may predispose to respiratory disease in adults and, exposure to lead prior to age two is associated with permanent effects on growth and neurocognition and behaviour.

Newer data that are gaining wider acknowledgement suggest we must be ever vigilant in expanding knowledge of the health effects from children's exposure to environmental contaminants. Delayed neurotoxic effects and acceleration of aging from early lead exposure, damage to DNA of immune cells after exposure to air pollution and the effects on the thyroid and immune systems from persistent organic pollutants are but a few examples of recent, notable research results.

Lastly, in Canada, it is clear that for most types of environmental exposures there is relatively much greater exposure in the Great Lakes basin compared to elsewhere. The Great Lakes Health Effects Program (GLHEP) found that measures of contaminants in human tissues were often consistently greater for populations living in this region. Of note, because contaminants such as PCBs and dioxin are present in breast milk in concentrations that approach or even far exceed the current guidelines of Health Canada, breastfed infants are being exposed and we are not certain what the effects of that exposure will be. Breast feeding continues to be the recommended method of infant feeding, however, greater attention must be paid to preventing further breast milk contamination and therefore exposure of children to toxins at a vulnerable age.

The Standard Setting Framework

Chapter 3 aims to make sense of how the legal and policy system operates. It is solely descriptive and lays out the basic regulatory framework and division of responsibilities between the federal and provincial governments. Two overarching policies of direct relevance to children's health are introduced: the *Toxic Substances Management Policy* and the *1997 Declaration of the Environment Leaders of the Eight on Children's Environmental Health*. The effectiveness and implementation of both of these policies are central to this study.

The federal and provincial government departments responsible for standard setting affecting children are Health Canada, the Pest Management Regulatory Agency (PMRA), Environment Canada and in Ontario, the Ministry of the Environment. Federal, provincial and territorial cooperation and partnership is sought through the Canadian Council of Ministers of the Environment (CCME). Under the CCME, a multi-lateral agreement, the Canada-Wide Accord on Environmental Harmonization, has been established that has far-reaching implications for standard setting across Canada.

Chapter 3 provides, for each of these agencies, summaries of their self-described authority, responsibilities and coordination with other departments. A brief description of recent trends in funding for each agency is also provided.

Risk Assessment and the Precautionary Principle

The focus of Chapter 4 is a lengthy, critical review of the theoretical foundations of standard setting, namely the processes of risk assessment and risk management. The focus is on the use of risk assessment for deriving health-referenced standards. By the late 1970s, risk assessment became the regulatory tool of choice that increasingly replaced early decision-making that, in some cases, banned very hazardous substances (such as DDT and PCBs) due to their inherent toxicity. Instead, risk assessment enabled continued use of toxic chemicals at scientifically sanctioned "acceptable" levels. During the process of bringing risk assessment in greater synchrony with the increased knowledge of environmental health issues, attention has focused on continually refining rather than replacing risk assessment. Criticisms and some fundamental limitations of the system have been identified for well over 10 years and have yet to be adequately addressed. One of the first problems identified was the disproportionate focus in risk assessment towards managing cancer risks. It was not until the mid-1980s that the U.S. Environmental Protection Agency (EPA) began to add some consideration of developmental risks into its risk assessment protocol. More fundamental limitations concern the numerous stages wherein inference and judgement are applied to compensate for large gaps in data and methodologies rendering risk assessment anything but a wholly objective scientific exercise.

Critical problems with risk assessment surround the characterization of exposure and dose-response. For the vast majority of chemicals, we do not know exactly how much of a particular substance, or combination of substances, to which people will be exposed in the course of its/their use, emission and path through the environment. It is also exceedingly difficult to determine what the relationship is between the amount that reaches the tissues and the response of the body to that dose.

More fundamentally, risk assessment enables risk calculations that allow for "acceptable" levels of chemical exposure that may cause one-in-a-million or one-in-ten-thousand risks (of cancer, birth defects, etc.) across a population. However, this game of odds becomes useless if further research confirms the suspicion that chemicals such as endocrine disruptors are capable of exerting population-wide effects at current levels of exposure. Nor is it appropriate to make such calculations for chemicals that are persistent and bioaccumulative. Risks will continue to increase for chemicals that do not break down and which accumulate in animal fat, breast milk, etc. Such risks will affect some people more seriously than others depending on the flow of persistent chemicals through the environment. The predicted avenues of exposure and the health endpoints that are used to assess risk clearly have implications for the ability of ensuing policy decisions to protect children's health.

The ever-increasing complexity of risk assessment methodologies has been matched and consistently overcome by the greater complexity of the problems they attempt to address including accounting for the special exposure circumstances and vulnerabilities of children. For those risk assessment advocates or practitioners who recognize the significance of the data gap, and many do not, the problem is considered inevitable and insignificant and a key solution is seen as the need to improve techniques of risk characterization and communication.

Issues of ethics and equity are also highlighted. Risk assessment is a complex, opaque system and that complexity and lack of transparency afford the opportunity for obscuring the value judgements it includes as well as the manipulation of policy-makers. Chemicals are assessed in isolation and each is treated in essence as "innocent until proven guilty." Risk assessment demands that decisions as to the harmfulness of toxic chemicals be determined according to the very high standard of proof demanded of scientific inquiry. This standard is nearly impossible to achieve given the arguably problematic scientific foundation of risk assessment. Yet, when action is taken only in the face of rigorous proof of harm, the chemicals ostensibly have greater rights than the human population. Each chemical, assessed in isolation is allotted an "acceptable" risk level whereas the human population does not have the same right to avoid the cumulative risk of real-world exposure circumstances to many different chemicals in the environment.

The critique of risk assessment, its assumptions and practice, is supported by a summary of the science behind the assessment, namely the relevant principles of epidemiology and determination of causation. The summary highlights the fact that scientific inquiry is extremely cautious and demands a rigorous degree of certainty in order to make definitive statements about causation**. We conclude that the scientific standard of proof is an inordinate, unbalanced and unfair burden to demand prior to the establishment of protective standards**. This standard of proof is particularly inappropriate when at issue is the prevention of harm to children's health. We conclude that the demand for such a standard of proof will very likely contribute to undue exposure and possibly irreversible health effects before protective action is taken. Such exposure occurred for millions of children exposed to lead from gasoline. As the Lead Case Study illustrates, the lessons of that cautionary tale need to be applied to the regulation of pesticides and other toxic substances.

The objective of child-protective standards would be better served by standard setting that weighed more in favour of the legal concepts of "duty of care", "the balance of probabilities" and the medical dictum of, "do no harm." Our review of the "science behind the assessment" highlights the observation that science and policy are, and should be, separate entities because of the incorporation of a broader range of values and considerations in the latter. However, given the often shaky scientific foundations that exist when

standards must be set, a "weight-of-evidence" approach needs to be applied throughout both the scientific and policy stages of the standard setting exercise.

We conclude that a new paradigm is necessary to supplement and in some instances to replace the current risk assessment framework in science and policy. The paradigm, borrowing concepts from the legal context, centres on shifting the burden of proof that is required in regulatory decision-making on to the parties wishing to create environmental contamination, a reverse onus approach. The paradigm must also incorporate the notions of making decisions that reflect prudent, protective judgement and precautionary inference, including consideration of the weight of evidence. While weight of evidence is increasingly used in standard setting, it is applied in too limited a manner revealing that only minor first steps are being taken towards a more precautionary paradigm.

The review of risk assessment includes a close look at recent steps taken by the Environmental Protection Agency to implement the *Food Quality Protection Act* in the United States since 1996. The review focuses on the practical challenges of implementing this regulatory device that was intended to enhance protection for children from exposure to pesticides through their diet, but has yet to achieve those original goals to any significant degree. At every step of the risk assessment process there has been ongoing fine-tuning and generation of ever more complex, voluminous and numerous guidelines. These efforts have served to effectively place increasing constraints on application of the key progressive elements of the FQPA, in an endless quest for definitive scientific evidence. In particular, with respect to the extra 10-fold safety factor, decisions as to when it is applied (rarely, as it turns out) appear to fall into the black box known as "scientific judgement." The renewed practice of human testing by pesticide companies has been a perverse, unintended result of attempts by the pesticide industry to avoid the 10-fold safety factor. This phenomenon is currently under scrutiny and further highlights the ethical and equity issues enmeshed in the current risk paradigm.

It is important however to recognize that valuable and progressive elements exist in the FQPA including at least the *concept* of, the 10-fold child-protective safety factor as well as requirements to aggregate chemical exposures and to assess groups of chemicals with common mechanisms of toxicity. The latter two are extremely important attempts to assess real-world exposure circumstances and to move beyond the ponderously slow chemical-by-chemical assessment approach. Unfortunately, the long-standing, central limitations in the science within risk assessment are brought into stark relief in trying to implement these progressive ideas. Ideally, however, Canadian regulatory agencies can and should learn from the FQPA experience, avoid the pitfalls and adopt its strengths.

Chapter 4 also reviews the precautionary principle, a contrasting as well as complementary paradigm whose acceptance has gained international approval, at least on paper. It mandates that in the policy arena, where potential for harm exists together with a great degree of scientific uncertainty, measures to avoid such harm should be adopted without delay. Considerable debate exists as to the appropriate definition and ways of implementing a precautionary approach. In Canada, it is acknowledged as having informed the *Oceans Act*, the revised *Canadian Environmental Protection Act*, the Canada-Wide Accord on Environmental Harmonization and legislation in two maritime provinces, although in none of these instances is it explicitly stated how the precautionary principle is to be applied and implemented, nor is implementation occurring. Canadian regulators also appear to be adopting the Rio Declaration definition which qualifies that "cost-effective" measures be taken to avoid harm. A preferable alternative is the *Wingspread Statement on the Precautionary Principle* which states:

When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically.

Air

Chapter 5 examines whether the regulation of contaminants in air, which involves both federal and provincial governments, has been intentionally protective of children. The approaches differ depending

on the jurisdiction, however there are some commonalties. In terms of recent policy on air pollutants, both jurisdictions have focused largely on reviewing standards for so-called "priority" substances as defined by the "risk" paradigm, while there has been continued reliance on out-dated standards for other substances. For each of these reviews the documentation states that there is regard for balancing cost-effectiveness with considerations of human health. **The attention to cost-effective measures has led to examples where industry's concerns have taken precedence over those of protecting the most sensitive receptor.**

The Ontario Ministry of Environment's recently revised Standard Setting Plan holds promise of improvements as it states that it will consider the most sensitive receptor in hazard analysis. This may be children, or presumably children will also be protected if a more sensitive receptor, such as an ecosystem effect, is chosen. Another positive feature of this plan is that it applies a multi-media, pathways approach when determining the most sensitive receptor. It remains to be seen, however, whether the risk management phase of the standards reviews will in fact carry forth the progressive aims of this plan that might protect children.

The federal process for setting air standards has moved to the Canada-Wide Standards approach which is a stakeholder, rather than a health-based approach. Unanimous consensus is required for adoption of new standards and this has resulted in some standards being driven to levels that are less protective of health and the environment under the influence of those jurisdictions with the greatest problems for a particular contaminant. Accordingly, **the Canada-Wide Standards stakeholder approach to setting standards is neither intentionally, nor actually protective of children, but is heavily shaped by the risk management phase of the process**.

Toxic Substances

Chapter 6 provides primarily an overview of the regulation of toxic substances. The chapter considers a broad variety of vehicles such as the: Great Lakes Water Quality Agreement, *Canadian Environmental Protection Act*, Toxic Substances Management Policy, *Pest Control Products Act*, Canada-Wide Standards, current negotiations towards an international treaty on Persistent Organic Pollutants (POPs) and Ontario's Municipal Industrial Strategy for Abatement (MISA). Similar themes recur in this chapter as in the previous one (i.e. that a risk framework is applied, that a small number of priority substances are targeted for review and that in most cases, there is a stated commitment to cost-effectiveness and reasonably achievable solutions). Another recurring theme is that the legislative framework does not incorporate in any meaningful way the precautionary principle or pollution prevention as outlined in Chapter 4.

However, chapter 6 also highlights the few instances in the Canadian regulatory scene where there is at least an attempt to regulate substances because they are deemed inherently toxic. (These attempts too, are not without their flaws.) **Under the Toxic Substances Management Policy, persistent bioaccumulative substances are slated for virtual elimination which is defined as a lack of measurable release, rather than the more protective action which would eliminate *use* of the substance.** In Ontario, the MISA regulations were not risk-based but intended to reduce pollution as much as possible while calling for the use of the best available technology economically achievable. The focus of the MISA regulations, passed in 1995 and 1996, is on persistent and bioaccumulative substances. This focus brought about a significant reduction in toxic pulp mill emissions. The Hazardous Contaminants and Water Resources Branches of the Ministry of the Environment also have focused, at least in past, on inherently hazardous substances that they state should ideally not be allowed to enter the environment. They cite that the focus on inherent toxicity is a direct result of the lack of exposure data that would be necessary in the formal risk assessment approach. Despite these progressive approaches in the past, regulatory action by the Province on toxic substances has been minimal in recent years.

Consumer Products

Stemming from the review in Chapter 7, it is apparent that both the *Hazardous Products Act*, the vehicle by which Health Canada controls the sale, importation and advertisement of consumer and industrial products, and Health Canada's role in its enforcement, are of limited value in protecting children's health. The Act does not define general product requirements and it is a product-centred approach that is reactive rather than preventive. In other words, **no mechanism is in place for formal pre-market assessment of consumer products such as toys or equipment and furniture that is intended for children's use.** Product inspection can only take place, for products regulated under the Act, when Health Canada receives a complaint, or if a Health Canada inspector believes there to be a potential risk from a product. In both instances this represents post-market assessment, once the goods have already been made available to unwitting consumers. If Health Canada's risk assessment determines that there is indeed a risk, it has no power to mandate product recalls. Instead, it relies upon voluntary industry action and may issue warnings and advisories to the public. Stronger action, such as the adoption of a regulation under the Act, will ensue only when Health Canada deems that the above strategies are insufficient to protect the public from risk.

The two case-studies provide greater depth for critical analysis of the standard setting regime in two specific contexts that have vast implications for children's health in Canada, namely regulation of lead and of pesticides.

Lead: The Cautionary Tale

Case Study #1 deals with standard setting to protect children from lead. It represents the "cautionary tale" and illustrates central problems with risk assessment and risk management. For example, industry-controlled information and research limited and biased the understanding of low-level lead exposure in children for many years. Assumptions of safety were made in the absence of proof of harm despite early warnings of neurological effects in children and evidence from animal studies that raised concerns about the potential dangers to children from low-level lead exposure. The science was extremely complex. Validated testing protocols for measuring multiple sources and exposure pathways and then body burdens were expensive and, for blood-lead, intrusive. Complex and age-sensitive measurement tools were necessary to discern subtle effects in childhood neurodevelopment. Such tools have only recently been developed to discern and measure effects of lead on behaviour. Research results were hotly contested and findings of health effects were elusive and subtle requiring the application of complex meta-analyses to discern significant effects.

Regulatory agencies, particularly Health Canada in its reaction to lead in gasoline, waited while the debates continued and did not act in a precautionary manner until exposure was high enough for investigators to reveal incontrovertible evidence of harm. Lead is now one of the most extensively studied pollutants in the world. Clear causal associations are apparent between lead and adverse neurobehavioural effects in children. The data are extensive enough that two powerful meta-analyses have verified the realization that an increase in blood-lead levels from 10 µg/dL (micrograms per deciliter) to 20 µg/dL results in an IQ deficit of approximately 2 points. The Lead Case Study summarizes the variety of adverse neurological and neurobehavioural effects that have been revealed as associated with exposure to lower and lower levels of lead.

The regulation of lead did not keep step with the scientific evidence of risks to health. The use of lead in gasoline represented an effective way to expose literally millions of children around the globe to unsafe levels of lead. **Phase-out of lead in gas was a significant step in reducing the exposure of children to lead**.[2] However, significant problems remain in Canadian regulations for lead in paint and the process for

[2] It should be noted that leaded fuel is still commonly used in many developing nations.

dealing with lead in other unexpected sources, including products such as mini-blinds and toys. Proposals to regulate lead in consumer products promise to make Canada a world leader in the control of lead in children's products. However, this regulation is not likely to be in place until at least 2001 and may not survive opposition from the toy industry or the possibility of international trade obligations trumping attempts at domestic regulation.

Average blood lead levels in Canadian children have been on a steady decline since the move away from leaded gasoline, however, **1994 estimates suggest that over 66,000 children still had blood-lead levels in the range known to have health effects**. Since scientific research has determined that there likely is no threshold for health effects in children from lead exposure, it should remain an issue of concern and greater awareness.

The Lead Case Study makes five key conclusions that highlight aspects of the cautionary tale. First, regulatory action on dangerous, persistent substances must include a precautionary and preventative approach. Second, it is essential that research on pollutants be independent of the industries responsible for the contaminant emissions. Third, lack of proof of harm must not be considered proof of safety. Fourth, when the insistence on "sound science" serves to delay regulatory standards a dangerous "Catch-22" situation is created wherein once the scientific data are conclusive enough to prove harm there has already been extensive contamination and harm done. Fifth, Health Canada's regulation of current uses of lead is largely ineffectual, although their stated commitments hold considerable promise. In the meantime, consumers cannot assume that products for sale have undergone independent or legislatively required testing to ensure children's safety.

Pesticides

The regulation of pesticides to protect children's health is the focus of Case Study #2. The information on pesticides contrasts with that of lead, in that there is relatively more limited information on what represents a varied group of environmental contaminants. The comprehensive review of literature concerning exposure to and health effects from pesticides in children concludes that the potential for the health of children in Ontario to be affected by pesticides is undeniable. Studies point to a wide variety of possible health effects in children from pesticides, many of which are serious and in some cases, life-threatening. Although the body of evidence for pesticides is not as weighty as that for lead, the data do tend towards implicating pesticides as inducing damage to children's immune, endocrine, nervous and reproductive systems, as well as congenital anomalies and cancer. Both exposure and susceptibility to the effects from pesticides are documented as being greater in children as compared to adults based on current scientific research. It is likely that many Canadian children are enduring the negative effects of pesticides, including those that are: from poor homes that may be treated with pesticides; children living in agricultural areas and the children of agricultural workers; aboriginal children exposed through their traditional diet and mother's milk; and children with chemical sensitivities and immune deficiencies. **The cumulative effects of being exposed to many different pesticides over a lifetime represent an unquantified and unacceptable risk to all Canadian children.**

Moreover, this investigation revealed that children's health is at risk because of inherent weaknesses in the Canadian regulatory system that governs pesticides. The analysis focuses on the many unfulfilled promises that are part of federal government commitments, some dating as far back as 1994, to improve the regulation of pesticides. The most serious shortcomings highlighted in the critique centre on aspects of the work by the Pest Management Regulatory Agency (PMRA), in particular, the inaccessibility, lack of clarity and contradictory nature of its risk assessment and risk management process. **The review concludes that rather than Canadians having a regulator for pesticides, the pesticide industry has a "customer service department" in the Pest Management Regulatory Agency**. In order to honour existing commitments as well as prevent harm to children from pesticides, the Case Study also concludes

that the PMRA is in need of both significant expansion and, more important, re-orientation towards a mind-set that gives first priority to health promotion and prevention of harm.[3]

OVERALL STUDY CONCLUSIONS

Several recurring observations have been made throughout this study that bear highlighting separately.

In terms of the state of knowledge regarding pediatric environmental health, much has been achieved in terms of an enhanced awareness of children's environmental health issues among health scientists. However, researchers acknowledge that the issues are complex, there remain significant gaps in information and measurement tools to discern exposure and effects, and that generally research has progressed slowly.

Regarding the regulatory realm, a fundamental conclusion is that the disconnect between the twin processes of risk assessment and risk management as they are applied in standard setting regimes perpetuates a questionable notion that risk assessment is the "objective," science-based part of this dual exercise. This report concludes that the gaps in information and methodologies are too profound for risk assessment to be considered an entirely objective activity. Rather, risk assessment is a combination of science and conjecture and like the risk management phase, it is replete with opportunities for value judgements and bias to influence decisions.

The many judgement calls throughout risk assessment and risk management are recognized as a necessary part of exercises that seek to set standards in the face of large areas of uncertainty. However, the insistence on "risk assessment as science" sets up regulatory agencies for failure in terms of setting protective standards. This failure results from the insistence on scientific standards of proof *before* protective action is taken. When science is unequal to this task, i.e., in the majority of cases, regulatory agencies wait and see or bow to industry pressure for an unreasonably high standard of proof of harm. This situation becomes even more complicated when industry pays for or controls the generation of scientific information about its own pollutants.

The cautionary tale in the Lead Case Study illustrates both a public health success story and the failure of risk assessment. The Pesticides Case Study and Chapter 4 reveal that the lessons have not been learned. The decision to follow the U.S. Environmental Protection Agency "science-based" risk assessment approach to revising standards for questionably safe pesticides perpetuates existing problems. The regulation of air pollution, toxic substances, and consumer products applies the same approach. Under the risk assessment paradigm, children are being exposed and will continue to be exposed unduly to environmental and consumer product contaminants as governments wait for definitive proof of harm and delay decision-making that would better protect them.

Another overall conclusion is that even where risk assessment exercises may provide for protective standards, the risk management phase or policy-making step is not transparent, is highly malleable and often results in weakening of the initially proposed standards such that they are no longer particularly protective of human health.

[3] It is important to note that, since the Pesticides Case Study was published earlier than the main study it is current to December 1, 1999. More recent announcements by the PMRA state that it will follow the lead of the United States Environmental Protection Agency with respect to pesticide re-evaluation. Hence the conclusions and recommendations of the Case Study regarding the conduct and transparency of the PMRA's risk assessment process for both new and currently registered pesticides need to be considered in light of when they were made. The reader is also reminded that the U.S. EPA's re-evaluation strategy is the subject of a detailed up-to-date review in Chapter 4 of this study.

A further (and related) conclusion is that preventive action in standard setting has rarely occurred. In the increasingly rare instances where toxic substances have been banned or severely restricted, action has only been triggered by clear evidence of harm in the environment and in human populations (or sub-populations) often from levels that were initially assumed to be safe. For many more substances, weak or non-existent regulation has continued, often for long periods of time, in the face of scientific complexity and uncertainty but with indications of serious risk. Even with increased awareness of the need to protect sensitive populations, including children, regulatory action has been minimal. The regulation of lead is a clear example of the lack of prevention within the risk assessment approach to standard setting. Scientists fear that regulation of pesticides and endocrine disruptors may not heed the advice of that cautionary tale. The complexity of scientific investigation into the single pollutant lead, pales in comparison to the effort necessary to understand the multiple exposure pathways and health effects of hundreds of pesticides (dozens of which are known or suspected to cause serious health effects), and tens of thousands of endocrine disruptors.

Many declarations and policy statements have been made at the international, national and provincial level espousing the need to act in a more precautionary manner to prevent harm from environmental contaminants for children or the environment in general. However, very limited progress has occurred to ensure their effective implementation.

Finally, the choice to focus the study on chemical and metal pollutants as areas of greatest concern for children's environmental health and those for which standards tend to be health-referenced, sent an Ontario-focused effort into large areas of federal jurisdiction. **A consistent finding was an extreme reluctance on the part of the federal government to effectively regulate chemical or metal pollutants in a timely manner or at all.**

MAIN STUDY RECOMMENDATIONS

Multiple recommendations stem from this report. They reflect the specific analyses conducted as outlined above and are contained in each of Chapters 2, 4, 5, 6, 7 and the two case studies.

The fundamental theme of the recommendations is that in order to significantly improve the current standard setting framework, there is need for a shift in paradigm to one that incorporates a precautionary approach at every stage in the process. In specific terms, a weight of evidence approach and the reverse onus burden of proof will ensure that prudent, timely decisions are made to provide standards that protect children's health.

A fundamental recommendation is the need to expand research, in both clinical and academic settings, on children's environmental health. In particular, research that improves our understanding of the how, why, when and what of children's environmental health is necessary. We need to better understand how contaminants travel through the environment, why children's unique behaviours expose them to contaminants, how much exposure and to which contaminants, when there are critical windows of developmental susceptibility, and what are the health effects from exposure. The focus of research should be on the health effects that potentially affect many children (e.g. asthma, neurodevelopmental and neurobehavioural effects) and as well, on characterizing the children at highest risk for environmental health problems.

We need to improve monitoring of the environment and population health. This includes monitoring of air, food and water quality, the potential health effects in wildlife, as well as population health surveys (along the lines of the National Health and Nutrition Examination Survey – NHANES - in the U.S.). This monitoring will allow for establishing a baseline of exposure and the ability to track trends in environmental health.

Health professionals of all sorts can play a role (alongside academic researchers) in expanding such information and understanding. Therefore, there is need to incorporate pediatric and general environmental health education modules into curricula, particularly in the training for family physicians, obstetricians, pediatricians, and midwives, nurse practitioners and social workers.

Recommendations for regulatory action are often but not exclusively focused on the federal government. However, changes to, and where necessary replacement of, risk assessment and risk management practices are relevant for all regulatory agencies involved in standard-setting. In addition to the problems associated with standards generated by risk assessment and risk management, the reluctance, inertia and slowness of the federal government to regulate toxic substances, consumer products or pesticides is a serious problem and unnecessarily puts children's health at risk. The situation is made worse by the removal of some areas of standard-setting to the Canada-Wide Standards process established under the Environmental Harmonization Accord; a process which this review finds is neither intentionally nor actually setting standards to protect children's health.

Political will and government funding is a final ingredient that is critical to achieving success in the realm of research and education in children's environmental health issues and in setting child-protective standards.