

Toxic Substances – Focus on Children

*Developing a Canadian List of Substances
of Concern to Children's Health*

EXECUTIVE SUMMARY

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- To increase public participation in environmental decision-making;
- To work with the public and public interest groups to foster long-term sustainable solutions to environmental concerns and resource use; and,
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Pollution Probe offers innovative and practical solutions to environmental issues pertaining to air and water pollution. In defining environmental problems and advocating practical solutions, we draw upon sound science and technology, mobilize scientists and other experts, and build partnerships with industry, governments and communities.

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Executive Summary

Background

We know that children are often more vulnerable and more exposed to environmental contaminants; but which ones? We can choose from a possible list, in Canada at least, of more than 33,000 substances, and groups of substances, not even including pesticides.

This project arose from a desire to make sense of these many thousands of substances and to set some child-focused priorities. It has been a scoping exercise, drawing upon a wide array of information sources, to devise a list of substances of concern to children. In fact, due to the limitations of the information sources, it was concluded that the results should include several lists. The work has provided some answers to the question: which substances are harmful or suspected of being harmful to children? The research focused on substances and associated health effects. The diverse circumstances of exposure to these substances was not a major focus of this work, and it became clear that data on exposure were very limited.

With a short list, or short lists, it is reasonable and necessary to ask how, where, and under what circumstances, are children exposed? Understanding the conditions of exposure to the substances in the lists generated by this research became the focus of many of this report's recommendations.

Scope of Work

In the past decade or so, the scientific literature has exploded with the results of investigations into the issue of child health and environmental contaminants. The greater vulnerability and exposure of children to lead, mercury, PCBs, radiation, environmental tobacco smoke, certain air pollutants, and many pesticides, have figured prominently in this literature. Throughout roughly the same time, regulatory agencies and others from around the world have devised various lists of substances, mainly for the purposes of regulating, or otherwise evaluating or controlling, environmental emissions. Both the scientific literature and these many lists of chemicals comprise two very large streams of information. The research for this report tapped into these two information streams to devise short-lists of substances of concern to children. As a scoping exercise for an extremely large topic, the research also resulted in numerous recommendations.

The regulation of contaminants applies the tools of Risk Assessment. Using these tools, the results of scientific inquiry are evaluated in order to set environmental standards for allowable or recommended levels of contaminants in air, water, soil, food, consumer products, waste, etc. An initial project objective was to conduct a comprehensive review of how Risk Assessment approaches account for child health during the regulation of chemical substances. It became clear that such a review was far too large within the boundaries of this project. Instead, a more scoped review was done to complement the findings of the rest of the project and

assist with the preparation of recommendations for further work.

Finally, the project was scoped to exclude pesticides since the focus was primarily on children's exposures to chemical substances in the context of the funder's risk assessment work under the *Canadian Environmental Protection Act, 1999*, which does not apply to pesticides. This requirement resulted in some challenges, which are explained in the report, and it created a significant gap in describing or listing substances of concern to children since there is a large body of literature investigating the greater vulnerability and exposure of children to a wide range of pesticides. This exclusion of pesticides is another reason for maintaining several lists in the results, rather than one final list.

Information Sources for Developing a List of Substances of Concern

Literature Reviews on Child Health and Environment

A scan was undertaken of nineteen recent publications by credible sources that reviewed various aspects of the literature on child health and environment. Several of these sources conducted comprehensive reviews of the entire subject area (e.g., WHO-EEA, 2002, Wigle, 2003, etc.); others focused on key areas, such as indoor air, persistent organic pollutants, or exposure factors, to highlight a few. These sources were used to summarize the level of scientific consensus that exists with respect to several aspects of this large topic.

The literature reviews were scanned to confirm consensus points about the greater vulnerability and greater exposure of children to environmental contaminants. The literature reviews reveal convergence of scientific opinion about six categories

of health effects of concern in children. The six categories are respiratory system effects, reproductive system effects, developmental effects, neurodevelopmental effects, cancer and endocrine system effects. Environmental contaminants are suspected in (and, more rarely, directly associated with) these six categories of health effects in children, or health effects for which childhood exposures are a concern. The reviews often emphasize that these effects are, in almost all cases, complex conditions with multiple causes and the relative contribution of environmental factors is poorly understood and very difficult to isolate.

The literature reviews also reveal convergence of scientific opinion about substances, or groups of substances, that are known or suspected to be associated with these six health effect categories. A first list of substances, and groups of substances, is drawn from this review (Table Four). Great care was taken to only include on the list those substances for which the literature reviews consistently and repeatedly report on the scientific evidence demonstrating associations, or suspected associations, with health effects in children. The list is sub-divided into lists of substances for which there is evidence in support of known or suspected associations, and those for which evidence is emerging. This list includes pesticides since it would not be an accurate reflection of this scan of the literature to exclude them.

Finally, most of the literature reviews took care to place the issue of child health and the environment in the context of child health in general. Fortunately, children in Canada are generally quite healthy. The health effects of concern with respect to environmental contaminants can be roughly divided into those for which incidence is quite rare, but seems to be increasing, and those for which

increasingly large numbers of children are affected.

Health effects in the first category would include those for which the incidence of rare events (cancer, birth defects and other complications of pregnancy, immune system problems, etc.) is increasing in ways that are still rare, but seem to be beyond the realm of chance.

For the second category, large numbers of children are affected by respiratory and neurodevelopmental effects. Cancer might reasonably be included in both categories. Fortunately, large numbers of children are not affected, but there are unexplained increases of certain cancers among young adults, and there are high rates of cancer in the adult population generally, raising the concern that exposures to substances with latent effects could have occurred during childhood, particularly during sensitive life stages.

Drawing direct relationships between environmental contaminants and any of these health effects in children is exceptionally difficult. Tragically, the only way that clear, causal relationships have yet been drawn has been where effects are clearly obvious or dramatic (e.g., thalidomide) or where large numbers of children have been exposed for extended periods of time and the scientific evidence has been collected to demonstrate the causal relationship. For example, this causal relationship was drawn with the evidence of harm from lead in gasoline, but only after millions of children were affected. Similarly, strong evidence is emerging about the contribution of air pollution to childhood asthma. This “wait and see” approach is what has prompted pediatrician and lead expert, Dr. Herbert Needleman to conclude, “we are conducting a vast toxicological experiment in which our children and our children’s children are the experimental subjects.”

Recurring themes and recommendations across all of the literature reviews that were scanned for this project included the need for precaution and the need to learn from past mistakes. Strong recommendations were made for increased research and monitoring, including the need for indicators, biomonitoring and a longitudinal study of the effects on children of large numbers of contaminants. In particular, recommendations were made for vastly enlarged epidemiologic research on child health, beginning before conception and following through adolescence, supported by major initiatives to monitor and track population exposures. Substantial international collaborative effort was considered valuable. All reviews noted that childhood poverty is associated with worse conditions for exposure and health outcomes, that boys seem to be more affected by neurodevelopmental effects than girls (for reasons unknown), and that more research must be directed towards understanding multiple effects and multiple exposures.

Database of Lists

The second major information stream used in this project was the creation of a database that combined more than 80 lists of substances obtained from all over the world. A great deal of care was taken to avoid comparing “apples to oranges” by ensuring that lists were cleaned up to remove, or correct, inconsistent or incomplete identifying information about individual substances, or groups of substances. Care was also taken to avoid making unreasonable comparisons among lists prepared for a variety of purposes. Most of the lists were created by regulatory agencies. The availability of a credible source of lists assigning known or suspected health effects to substances, and groups of substances, (e.g., see www.scorecard.org), was enormously valuable. To refine the

exercise to one that addressed only Canadian content, three key lists were used. These included the Domestic Substances List (the DSL, ~23,000 substances) and the non-Domestic Substances List (the nDSL, ~10,000 substances), as well as a list based on a preliminary attempt by Health Canada to determine substances having the greatest potential for exposure (the GPE list, which currently contains 849 substances).

In order to pare down the DSL and nDSL (together comprising about 33,000 substances) to a list of substances of concern to children, these lists were queried against a list created from ten health effect-based lists. The ten lists included nine lists obtained from the www.scorecard.org website and a tenth list of thyroid hormone disruptors. These health effect-based lists, the nine Scorecard lists in particular, were created from comprehensive and credible reviews of the scientific literature.

As in the literature reviews described above, the Scorecard lists identify substances suspected or associated with health effects. However, the Scorecard lists are particularly useful in that they identify substances using the internationally accepted Chemical Abstract Service numbering system, or CAS# system, which uniquely identifies chemical substances. Since most regulatory lists in the database (including the DSL and nDSL) also use the CAS numbering system, the health effect lists could be queried against the regulatory lists.

Another key advantage of the Scorecard lists is that they include groups of substances. Throughout this work, deciding how to accurately deal with the issue of groups of substances was very challenging. Approaches were inconsistent across the source lists. The DSL and nDSL do not include group entries. In order to accurately compare group entries across lists, the

choice was made to follow, and expand upon, the "NA" numbering system used in Environment Canada's National Pollutant Release Inventory (NPRI) — an approach that is also followed in the list of the Canadian Chemical Producers Association (CCPA) and the two Accelerated Reduction and Elimination of Toxics (ARET) lists. To apply this system consistently, all lists had to be scanned for group entries and the NA system applied to them. It was crucial to include, and be able to compare across lists, the group entries since these included some of the most toxic substances, such as dioxins and furans, lead compounds, mercury compounds, inorganic arsenic compounds, polybrominated biphenyls and phthalates. Moreover, the NA system could be used to assign consistent numbering to individual substances that do not have a CAS#, but which are very important to include in lists of concern for children, such as PM_{2.5} and PM₁₀.

The Scorecard lists of health effects contained both individual substances uniquely identified by CAS#, as well as group entries. These lists could then be directly compared to regulatory lists in a way that the results of the literature review could not. An important qualifier on the Scorecard health effect lists is that only four of the nine lists were prepared with a focus specifically on effects in children. These were lists of recognized and suspected developmental toxins, and recognized and suspected reproductive toxins. The additional five lists included suspected carcinogens, suspected neurotoxins, suspected respiratory toxins, suspected endocrine toxins, and suspected immunotoxins. The implication here is that the list of suspected neurotoxins, for example, could be different from a list of suspected developmental neurotoxins.

Using the database to winnow down to short-lists of concern, two lists were created, called Canadian List #1 and Canadian List #2. Due to limitations in the data used to create these lists, both were retained in the results. Further combining of these results would have meant the loss of useful information, as well as undue reliance on Health Canada's preliminary, and significantly qualified, data on greatest potential for exposure (the GPE list).

Canadian List #1 includes just over 1,400 substances and 29 groups of substances. The list includes substances, and groups of substances, that are suspected or associated with one or more of the ten health effects in the health effect lists. Within the 1,400 substances, just over 1,000 are on the DSL and 318 are on the nDSL.

Canadian List #2 was created by screening Canadian List #1 against Health Canada's GPE list, a list of 849 substances on the DSL for which Health Canada has made a preliminary determination that there is the greatest potential for (human) exposure. With this screen against the GPE data, the number of substances on the DSL dropped to 250. Hence, Canadian List #2 includes these 250 DSL substances, the 318 substances on the nDSL and the 29 groups of substances. Further querying was then undertaken on the two Canadian Lists.

First, the two lists were summarized in terms of the number of substances on each list associated with the health effect categories. In both lists, more than 50 per cent of the substances were suspected neurotoxins. Similarly high percentages (45 per cent in Canadian List #1 and 54 per cent in Canadian List #2) of the substances on the lists were suspected respiratory toxins. This finding is striking and provocative since these are the two health effects that are affecting very large, and increasing, numbers of Canadian

children. While it is not possible to draw an association between these results and the incidence levels of these effects in the child population, this finding should inform further research and regulatory action.

Second, Canadian List #2 was short-listed further to those substances, and groups of substances, that are suspected or associated with four or more of the health effects. The resulting list contains 73 entries and could be considered a "dirty six dozen" of substances for which significant concern exists and to which high priority should be given for further research and regulatory action. Additional queries were done to determine sub-sets of substances associated with a variety of health effect combinations. These latter results are an indication of the wide range of options that exist for further querying of the database.

The two Canadian lists were also compared to the bulk of regulatory lists in the database to see how many substances, and groups of substances, matched. The results provide information that flows in two directions. First, the two Canadian lists provide an interesting perspective on the large preponderance of these contaminants on certain lists, such as the NPRI lists, the two ARET lists, the CCPA list, the Voluntary Children's Chemical Evaluation Program (VCCEP) list and the DSL Pilot (123 substances on the DSL for which Environment Canada sought, via regulation, detailed data from the chemical industry). As well, the regulatory lists provide interesting information about the nature of substances on the two Canadian lists. For example, large numbers of substances on the two Canadian lists appear on the Organization for Economic Cooperation and Development (OECD) high production volume list of chemicals, many are hazardous air pollutants and many appear on lists of hazardous waste. Very large numbers of substances on the

two Canadian lists are in the Nordic Countries database of substances in products and on European Economic Community (EEC) lists of hazardous substances.

Choosing a Final List

To accomplish the project objective of paring down the roughly 33,000 substances in commercial use in Canada to a list of substances of concern to children, several “short-lists” have resulted that are, in many ways, very similar. The literature review results (Table Four) contain many of the same individual and, in particular, groups of substances in Canadian Lists #1 and #2. These latter two lists provide specific information as to which of the individual substances are on either the DSL or the nDSL. Likewise, Canadian List #2A, prepared by focusing even more closely on substances associated with four or more of the health effects, closely mirrors the results of the literature review scan.

It was assumed during the research and database querying that further aggregation of these “short-lists” into a single list could be done to choose a final list. However, given the many qualifications noted above with respect to the data sources, it seems counter-productive to do so. Information would be lost that instead should prompt further investigation. The results of each exercise provide interesting and varied information that raises many questions.

For example, the list in Table Four resulting from the scan of literature reviews provides broad coverage of existing information and emerging issues. But, it lacks specificity about individual chemicals. The database exercise provides much the same information and fills in some useful details about specific substances that can be keyed directly into lists generated by regulatory agencies. But, when it is pared

down with the use of the GPE data, it appears that important data are lost. For example, the GPE data do not include some important emerging areas in which exposure is known to be high and increasing, such as flame retardants (polybrominated diphenyl ethers or PBDEs). Also, many questions arise with respect to the substances on the nDSL for which there are no exposure data.

The “final list” is therefore a series of lists: Table Four, Canadian List #1 (Appendix Four), Canadian List #2 (Appendix Five) and Canadian List #2A (Table Six). The results include many individual substances, but also retain the contextual information provided by describing substances as members of groups. Such groups often have common mechanisms of toxicity, and there is value in addressing the group as a whole, both in a regulatory sense, as well as in choosing individual substances on which to either focus further attention, or to illustrate characteristics about the group as a whole.

In summary, the results of the literature review lack specificity with respect to individual chemicals (via the unique CAS# identifier), but the review is entirely child-specific with respect to noting concerns about health effects and the substances, and groups of substances, surveyed. It also, appropriately, includes pesticides. The database exercise is almost entirely CAS#-specific, with additional useful information about groups of substances, but it relies upon lists of health effects, half of which were not developed solely with children in mind. The results also rely upon a foundation of exposure data (Health Canada's GPE list), that is still a very preliminary work in progress, and a complete lack of exposure data for the nDSL substances. It is therefore appropriate to retain separate results from both exercises, use the information together where it is complementary, seek the lessons that can be

learned from this work, and tease out the many research questions that it presents.

The brief review of Risk Assessment undertaken for this report reinforces this conclusion.

Risk Assessment and Children's Health

This part of the report provides a brief commentary on Risk Assessment, first in its broader context of Risk Assessment and Risk Management, and then in terms of a longstanding and well-developed critique. The critique of Risk Assessment relates largely to the scientific "data gap" that exists with respect to toxic substances, particularly the knowledge gap related to the effects on children.

The comments on Risk Assessment complement the more detailed reviews in this report about environmental contaminants and children's health. Both lead to common conclusions and recommendations about closing the data gap. There is an urgent need for more research and better monitoring, including biomonitoring, of chemical exposures, with a child health focus. The overwhelming lack of monitoring that occurs following what is widely considered to be the inexact "science" of Risk Assessment, is a major omission. It is an understatement to say that Risk Assessment lacks accuracy. The corresponding lack of basic data collection is a serious gap in the knowledge-development chain. Problems exist not only with basic data collection, but also with the lack of methods to assess multiple exposures to substances with multiple effects.

To illustrate some of the scientific frontiers and challenges in Risk Assessment, a summary is provided of a recent report on developmental toxicology and Risk

Assessment, with related commentary drawn from a recent and comprehensive international review of Risk Assessment of chemicals in products that was prepared by a UK Royal Commission.

In an effort to continue to scope a very large topic, an overview is provided on how a variety of national and multi-lateral agencies are converging in their application of Risk Assessment techniques, including the increasing ways in which children are taken into account. This convergence in Risk Assessment approaches is contrasted with the observation that there is an overall lack of integration across regulatory approaches. Instead, regulatory approaches are largely one-sided, focusing on individual chemical releases and emissions, and largely ignoring the full life-cycle and environmental fate of harmful substances, a point also illustrated by the regulatory lists gathered to construct the database of lists for this project.

Many calls have been made for a paradigm shift towards precaution and away from the "analysis paralysis" of Risk Assessment; that is, towards pollution prevention, chemical and product substitution, finding safer alternatives, removing entire classes of substances on the basis of their inherent toxicity, etc. These latter issues were beyond the scope of this review.

What should be noted from the results of this review of Risk Assessment, and the rest of the project results, is the recurring challenge of dealing with individual substances versus groups of substances. Part of the criticism of Risk Assessment is the ponderously slow evaluation of one chemical at a time. In the comprehensive review of Risk Assessment and children's health envisioned within upcoming research to be done for Health Canada's Applied Research and Analysis Directorate (ARAD), it would be valuable for this

work to include focused reviews of the results of the combined package of Risk Assessment and Risk Management so that an evaluation is conducted of the actual final results of this regulatory tool. Criteria to measure success should include an evaluation of whether or not the regulatory responses accomplish measurable reductions in exposure and prevention of harm, including whether or not health concerns associated with entire groups of substances are being efficiently, or even adequately, addressed.

The brief survey of Risk Assessment done for this project highlights a clear role for government in information generation and collection. Within the constraints of limited government resources, priorities and clear roles should be set. There is a logical, if not ethical, imperative that those wanting to use (and profit from) chemicals should be responsible for demonstrating their safety. While the chemical industry may not agree with such an imperative, it is increasingly accepted, and it is impossible for government to muster the resources to conduct the required evaluations. What government can and should do is monitor results and demand via legislative tools, if necessary, the data demonstrating chemical safety, assist with the coordination and some of the funding of research, and facilitate pollution prevention and chemical and product substitution.

Main Conclusions

Children are clearly at greater risk than adults to environmental contaminants. There is international scientific consensus, even among high profile scientists whose research is frequently funded by the chemical and/or pesticides industry, that the developing fetus and infants up to the age of six months are more vulnerable than adults to environmental contaminants. This vulnerability arises from higher exposure to contaminants that can then affect highly sensitive developing systems.

For children older than six months of age, the industry-funded literature no longer concurs with the still very large scientific consensus that the vulnerability of children continues, in various ways, through the rest of childhood and adolescence. This field of inquiry is enormous and encompasses every single aspect of human development, and multiple health effects that are complex, not fully understood, and multi-factorial in origin. It also includes the exposure circumstances and health effects of tens of thousands of different chemical substances routinely released to the environment or incorporated into consumer products. The level of scientific ignorance across this vast field, in the opinion of many health and environmental professionals and organizations, is frighteningly high. Yet, what is known about the toxic effects of a relatively small number of environmental contaminants and the constituents of consumer products is deeply troubling. While scientific inquiry continues, exposure also continues, and data collection about chemical exposure is inadequate.

Some children's health trends are troubling. Fortunately, most Canadian children are quite healthy. However, there are very high levels of respiratory illness and neurodevelopmental or neurobehavioural effects among Canadian children. The findings in this project demonstrate that the vast majority of substances of concern are associated with these two health effects. While a direct causal relationship cannot be drawn between these health effect trends and this report's findings about substances of concern, this result should inform future detailed investigation. Rare, but serious, health effects, such as cancer, birth defects and other complications of pregnancy, are suspected or associated with environmental contaminants. Their occurrence and trends in children and young adult populations are also of concern.

The strength of the evidence linking contaminants and health effects varies. There is fairly solid evidence of associations between environmental contaminants and respiratory effects, developmental and reproductive effects, neurodevelopmental effects and cancer. However, the evidence is strong for only a few substances. A great deal of evidence is emerging for many more substances, but links are still tenuous. The evidence is also tenuous, but increasing, about effects in the immune system and endocrine system. In looking at this evidence, an overall impression arises of chemical substances interfering with the integrating systems of the body; those that contribute to development and good health by using naturally-occurring chemicals to "communicate" messages within and across bodily systems. The investigation of the effects of chemical exposures is often about interference by synthetic chemicals, or excess levels of natural substances (such as metals), with the chemical messages that continuously occur across these integrating systems. Beyond some of the

very thoroughly studied substances, such as lead and PCBs, some of the strongest evidence of associations exists for air pollution links to respiratory effects. It also seems clear that exposures from indoor air (including substances released from consumer products) appear to be strongly implicated. However, the relative importance of biological factors (pet dander, moulds, dust mites) versus other indoor exposures (environmental tobacco smoke — ETS, consumer products, etc.) must be carefully examined.

While a detailed review was not included here about exposure sources and pathways, this is an obvious next step. Air pollution appears to be the most significant source of environmental contamination, outweighing water emissions by a considerable margin. It also seems generally true from this review that areas, or substances, of emerging concern are often related to consumer products and others for which exposure is occurring via food, or exposures indoors, in house dust, air or dermal exposure. This general conclusion requires further investigation to be verified. Examples include flame retardants, perfluorochemicals (PFCs) used in non-stick and non-stain surfaces on products, phthalates, etc.

The results of the literature review and queries of the database of lists for this report reveal a very large number of substances, and groups of substances, of concern for children. These include:

- metal groups (lead, mercury, arsenic, cadmium, Chromium VI) and numerous compounds within each group;
- dozens of pesticides and, therein, several key groups of pesticides;
- all the persistent organic pollutants identified in the recent Persistent Organic Pollutants (POPs) Treaty and several additional POPs;

- dozens, and more likely hundreds, of indoor and outdoor air pollutants, including those associated with vehicular emissions and other sources of combustion, as well as many additional hazardous air pollutants;
- phthalates;
- various sources of radiation;
- a range of additional substances, mostly in consumer products, including flame retardants, specifically PBDEs, nonylphenol and its ethoxylates, perfluorochemicals, as well as (drinking water) disinfection by-products.

A list of substances of concern to children would be incomplete without also including environmental tobacco smoke (ETS). The database of lists presented in this report assists with identifying specific substances within these groups. This specificity is useful for further tracking of regulatory action since regulatory lists are routinely characterized by uniquely identified, individual substances. Reasons for placing substances into groups varies, but it is often useful contextual information that can be used to inform decisions about policy and/or regulatory responses.

The Risk Assessment of toxic substances has too often involved a “wait and see” approach in which exposure continues until enough evidence of harm exists before regulatory action is taken. The history of lead in gasoline is a case in point. After sixty years of exposure and nearly thirty years of research, amid repeated calls for the precautionary step of eliminating a developmental neurotoxin from the environment, regulatory action to eliminate lead from gasoline did not occur until compelling evidence existed that millions of children were affected. History is repeating itself with mercury. As with lead, the neurological effects of high-level mercury poisoning were learned unexpectedly, via

the tragedies of Minimata, Japan, and other situations of unintended but widespread poisoning. Debate about low-level effects continues in the scientific literature. The recommended levels for mercury in food, particularly in fish, continue to drop as new evidence emerges. Meanwhile, widespread exposure continues.

Risk Assessment continues to use a ponderously slow process of evaluating one chemical at a time. Even though steps have been taken in the past to ban entire groups of substances because of their inherent problems (toxicity, persistence, etc.), such as the banning of PCBs in the 1970s, we tend not to repeat the efficiency of this approach. PCBs are much like flame retardants, specifically the polybrominated diphenyl ethers (PBDEs). This group of substances demonstrates the same kinds of properties as PCBs, that is, persistence, bioaccumulation, and various kinds of serious toxicity, including cancer and neurotoxicity. Yet, ponderously slow evaluations continue for each substance within this group. Similarly, there are entire groups of pesticides that are strongly implicated as developmental neurotoxins. Attempts to evaluate entire groups of substances continue, slowly, but the individual assessments also continue. Across all of these examples, it can be said that regulatory action, derived from Risk Assessment, is only beginning to partially address these concerns. The usual response is selected product or emission controls, such that exposures will drop slowly over a long time. The result, for example, is that rates of asthma among children might rise slightly less quickly than would otherwise occur without emission controls.

It seems clear that an overall paradigm shift is necessary. There is an urgent need to consider the use and emissions of toxic substances much more broadly than simply as end-of-pipe environmental

contaminants. Consideration of environmental and human health impacts is necessary across the entire life-cycle of substances, from their extraction from natural sources, their synthesis in the lab, and through all manner of manufacture, use, reuse, recycling and disposal. Risk Assessment involves a “science-based” regulatory response at a narrow point in this cycle, and demands a high degree of scientific proof of harm at the same time as the information base upon which it relies is extremely limited.

Some progress is occurring and Canada appears to be at the forefront of using efficiency measures, such as Quantitative Structure Activity Relationships (QSARs), to categorize groups of substances for their dangerous properties. Regulatory agencies around the world face a backlog of tens of thousands of substances that require evaluation, many that will require regulatory control. It is essential that the tools of Risk Assessment are not used to address this enormous challenge in a way in which mistakes of the past are repeated.

Recommendations

The following recommendations are grouped within eight categories of activity. They are accompanied by additional brief discussion in the Recommendations section of this report.

Monitoring, Longitudinal Study and International Coordination

1. The federal government should be directly involved in research into monitoring (including exposure and body burdens) of chemical substances and longitudinal study of child health. This work should be coordinated with international efforts already under development.

Further Database Queries — Including Pesticides and Further DSL Categorization Results

2. The database constructed for this project and the short-listing exercise should be expanded to include pesticides and further results of DSL categorization.
3. The ongoing results of efforts by Health Canada and Environment Canada to categorize the DSL should be compared to the results of this project. How are the results comparable? What is different and why?

Drilling into Canadian Lists #1, #2 and #2A

4. The lists of substances of concern generated from the database exercise in this project should be scanned to determine whether list entries are inappropriately or needlessly on the list.

5. The 834 substances in Canadian List #1 that were not included in Health Canada's Greatest Potential for Exposure (GPE) list should be investigated to determine whether emissions or exposure warrant further concern. This review should inform an assessment of the reliability of the GPE data.
 6. Particular emphasis in further research should be placed on the "dirty six dozen" results (Canadian List #2A, Table Six) of substances suspected or associated with four or more of the health effects noted.
 7. For the fourteen substances from the nDSL in Canadian List #2A, further research should include detailed review of these individual substances for data on the amount and circumstances of emissions, exposure and biomonitoring data (if any), and a determination of why and how substances suspected or associated with so many health effects have been approved for use in Canada during the time that (supposedly) stringent evaluation criteria have been in place.
 8. For the 318 substances on the nDSL in Canadian Lists #1 and #2, similar questions should be asked about emissions, exposure, monitoring and the child health aspects of the evaluation procedure that approved the use of these substances in Canada.
 9. Research questions for subsequent evaluation of the substances of concern identified from this research should include: where are these substances used; how are emissions and/or exposures occurring; can specific facilities and/or consumer products be identified; are some exposures of greater significance to children than others; and for the latter, which ones and why? What kind of child-specific data and methodologies have been, or are being, employed in the setting of regulatory limits? Have precautionary measures to prevent exposure or harm, or both, been incorporated in the setting of regulatory limits. If so, how, and if not, why not?
- Respiratory Toxins and Neurotoxins***
10. Priority should be placed on respiratory toxins and developmental neurotoxins, including ensuring that substances suspected or associated with developmental neurotoxicity are caught during DSL categorization for inherent toxicity and evaluation of nDSL substances.
 11. The findings of high levels of respiratory effects and neurodevelopmental effects in the child population and the parallel findings, in this research, of very large numbers of substances of concern associated with or suspected of contributing to respiratory and neurotoxic effects, should prompt routine evaluation of these effects during Risk Assessments of toxic substances.
- Seeking Efficiencies — Dealing with Groups of Substances***
12. Evaluations of substances contained in consumer products and in environmental emissions must include the efficiency of making decisions about entire groups of substances, particularly when entire groups of substances are suspected or associated with health effects of concern.

13. Given that the results of this exercise include many groups of substances of concern, as well as substances on the non-Domestic Substances List, it should be investigated whether and how the evidence of harm about entire groups of substances is being incorporated into the DSL categorization efforts? Alongside the DSL work, how are Health Canada and Environment Canada addressing groups of substances of concern on the non-Domestic Substances List?

Informing the CEPA Review and the Proposed Canada Health Protection Act

14. The many research questions raised in this report and its recommendations should be focused on various ways to assist with an evaluation of the effectiveness of the *Canadian Environmental Protection Act* (CEPA) and to formulate recommendations for the proposed Canada Health Protection Act (CHPA).
15. Given the recent changes to the *Pest Control Products Act*, (to be proclaimed during 2004), with respect to ensuring the evaluation of exposure and toxicity to children, as well as reversing the onus of proof about pesticide safety, an evaluation should include whether and how these measures could or should be incorporated into CEPA and the proposed CHPA.

Comparing Substances of Concern with Exposure Data

16. A longer-term research goal should include aggregating information about substances of concern to be able to compare exposure data (from environmental levels, biomonitoring, etc.) with health-based reference levels.

Health Canada ARAD's Child Health Policy Review — Risk Assessment Research Priorities

17. The research scheduled to begin in the fall of 2004 for Health Canada's Applied Research and Analysis Directorate to analyze domestic and international governance tools that address the protection of children's health from exposure to environmental contaminants should include a comprehensive review of Risk Assessment approaches as they address the vulnerability of children.