ENVIRONMENTAL STANDARD SETTING AND CHILDREN'S HEALTH IN CANADA: INJECTING PRECAUTION INTO RISK ASSESSMENT

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Environmental Standard Setting and [1]Children's Health in Canada: Injecting Precaution into Risk Assessment

[1] This article is based on an in-depth study, the Children's Health Project: *Environmental Standard Setting and Children's Health*, published by the Canadian Environmental Law Association and the Ontario College of Family Physicians, Environmental Health Committee, May 25, 2000. Project authors were Kathleen Cooper, Loren Vanderlinden, Ph.D, Theresa McClenaghan, LLM, Karyn Keenan, Kapil Khatter, MD, Paul Muldoon, LLM and Alan Abelsohn, MD. The original study was funded by the Laidlaw Foundation. Full study available at the Canadian Environmental Law Association web site, www.cela.ca or in print format from CELA.

I. INTRODUCTION

Although risk assessment is routinely described as an objective, fact-based scientific activity, it is not, and probably never will be. Risk assessment methods are fairly reliable in predicting acute effects from high dose exposures but fall far short in the most important area of environmental concern: chronic effects from long-term, low dose exposure. As for assessing the real-world situation of exposure to, and the interactive effects of multiple chemicals in the environment, it fails miserably. There is a basic lack of data, of analytical methods, and ongoing challenges in a highly complex field. Moreover, the presentation of results and their incorporation into policy decisions, the risk management extension of the exercise, is equally subject to the value judgements and guesswork that are central to the "science" of risk assessment.

This paper reviews one of the theoretical foundations of standard setting, namely the process of risk assessment and risk management. A summary of the findings[2] of the May 2000 Canadian Environmental Law Association and Ontario College of Family Physicians (CELA-OCFP) study is presented and some developments since the study's publication are reviewed. In particular, developments pertaining to regulation of pesticides and regulation of lead, both of which were the subject of detailed case studies in the May 2000 paper, are examined. The full study explores whether risk assessment is protective of children's health in the resulting standards and finds that such protection is generally not the case.

Standard setting processes in Canada, while gradually improving, are not generally protective of children's health. Canadian regulators need to improve standard-setting processes through better and more data collection and analysis, more research, particularly within government, and embracing policy innovations. More particularly, regulators should explicitly adopt and implement the precautionary approach within the context of risk assessment. Although this approach has implications apart from risk assessment, it holds the promise of improving the process to be more protective of vulnerable populations.

Some recent improvements exist for pesticide regulation in the revised *Pest Control Products Act*, not yet in force. Whether children's health risks are reduced as a result of the new legislation is a question to be reviewed over time based on how industry and the regulator respond to the new legislation. Promises to bring consumer products under regulation with respect to lead have been repeatedly delayed. So far children continue to be exposed to lead in consumer products in unacceptable circumstances. This article concludes with a discussion of the means of injecting a precautionary approach during risk-based standard setting.

[2] This paper concentrates on the findings contained in Chapter 4 of the full study which was titled, "Risk Assessment and the Precautionary Principle."

II. CHILDREN'S HEALTH AND RISK ASSESSMENT

(a) The Environmental Health Risks Children Face

There is increasing evidence of health effects from various pollutants occurring at very low levels of exposure.[3] In some areas there are clear lines of evidence linking environmental pollutants and adverse health in children. For example, though the relationship is complex, it is clear that current high rates of asthma and other respiratory problems are causally related to air pollution. In many other areas, for literally thousands of substances, the evidence is less clear, there is a great deal of uncertainty and controversy but the stakes are very high. The number of children potentially affected is, in some instances very large, including asthma, as noted, and for some neurological effects as well as potential effects on the immune and/or endocrine system. Even where fewer children may be affected, the potential health effects are extremely serious or even fatal, including for example, increases in, again, neurological effects, reproductive effects, birth defects and cancer.

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 the intervention level for lead exposure.

The regulatory framework has not routinely considered prenatal (in the womb) or postnatal (via breast milk, foods or consumer products) exposures. Nor have other sensitive life stages during childhood and adolescence been factored into exposure calculations. These time periods can involve significant exposure when qualitative and quantitative differences from adults affect both how much exposure a child experiences and impacts upon highly vulnerable, developing systems.

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, [4] childhood exposure to air pollution may predispose to respiratory disease in adults and,

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[3] For a full discussion of these risks, see Canadian Environmental Law Association and Ontario College of Family Physicians, Children's Health Project: *Environmental Standard Setting and Children's Health*, May, 2000, chapter two. For more recent resources see: U.S. Environmental Protection Agency. Office of Children's Health Protection. Overview of the Special Vulnerability and Health Problems of Children. Paper Series on Children's Health and the Environment. Paper 2003-1. February, 2003. Online. Available: http://yosemite.epa.gov/ochp/ochpweb.nsf/content/2003_1.htm/$File/2003_1.pdf . 3/2003; U.S. Environmental Protection Agency. Office of Children's Health Protection. Critical Periods in Development. Paper Series on Children's Health and the Environment. Paper 2003-2. February, 2003. Online. Available: http://yosemite.epa.gov/ochp/ochpweb.nsf/content/2003_22.htm/File$/2003_2.pdf. 3/2003; and U.S. Environmental Protection Agency. Office of Children's Health Protection. Children's Environmental Exposures. Paper Series on Children's Health and the Environment. Paper 2003-3. March, 2003. Online. Available: http://yosemite.epa.gov/ochp/ochpweb.nsf/content/2003_33.htm/$File/2003_3.pdf . 3/2003.

[4] Cancer incidence in young Canadian adults (20-44 years) increased slightly from 1987 to 1996 with significant increases in several types of cancer (non-Hodgkin's lymphoma and thyroid cancer in both sexes, lung and brain

exposure to lead prior to age two is associated with permanent effects on growth, cognition 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 and contaminants in breast milk are but a few examples of recent, notable research results.

(b) A Short History of Risk Assessment

Techniques for evaluating hazards and measuring risks pre-date the environmental and health concerns that became the subject of policy and legislation in the late 1960s and early 1970s. Early techniques were developed often for engineering and/or insurance purposes (risk of death, chance of floods, etc.) and were subsequently borrowed and adapted to assess environmental risks.

The history of standard setting approaches is one of increasing complexity of techniques mostly preoccupied with the establishment of "safe" or "acceptable" levels of contaminants. In some early cases, evidence of environmental persistence and/or harm in humans or wildlife was used in many industrialized countries as justification for banning outright some chemicals (e.g., the pesticides DDT and mirex and the entire class of chemicals known as PCBs). These early decisions to ban substances were examples of standards that recognized the "inherent toxicity" of the substances in question. More often however, evidence of harm was only suspected, difficult or impossible to prove, and hotly contested by the industries responsible for the contamination.

Early approaches to environmental standard setting took a variety of forms. In many cases, health effects from toxic substances were more or less understood due to their use and control in occupational settings. These occupational standards were derived from animal testing as well as knowledge of health effects among occupationally exposed workers. Somewhat arbitrarily, standards for environmental exposure might have been set at 10 times or 100 times lower than the level considered safe in an occupational setting. This notion of using multipliers or "safety factors" in order to set standards for chemical exposures at levels 10 times, 100 times, etc., lower than the level where health effects are known or detected continues to be a key aspect of ever-more refined risk-based standard setting approaches to this day.

The application of safety factors, implying that safe levels of exposure are achievable, is a key foundation from which risk assessment has grown. Indeed, the practice of setting standards based on a scientific determination of an "acceptable" level of risk developed since the 1970s largely as a substitute for bans or phase-outs of chemicals. However, with greater understanding of the mechanisms of toxicity of certain classes of chemicals, the notion of "inherent toxicity" has arisen, or has perhaps been revived, whereby substances are identified as toxic without the need

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cancer in women, and testis cancer in men). Cancer in this young age group is rare and unexplained. Given the latency periods for most carcinogens, contributing factors could well have occurred during childhood. Statistics available from the National Cancer Institute of Canada: Canadian Cancer Statistics 2002, Toronto, Canada, 2002. Available at: www.cancer.ca and www.ncic.cancer.ca

for scientific determinations of harm. Substances that are considered inherently toxic are those that, by virtue of their molecular structure, are persistent and bioaccumulative and for which risk-based standards cannot establish "safe" levels of exposure.

Standard setting in both occupational and environmental settings also has often included making a distinction between chemicals for which a threshold is or is not apparent. In other words, in the case of chemicals with a threshold, the evaluation (using animal studies or the results of occupational exposure, accidents, etc.) determines the lowest point, or threshold, at which a health effect is detected. These threshold levels are called the Lowest Observed Adverse Effect Level (LOAEL). Lower limits are also calculated where no health effects are discernable. Also called the No Observed Adverse Effect Level (NOAEL), regulatory limits for human exposure to chemicals with threshold effects are often set by applying safety factors (typically between 10 and 1000) to NOAELs derived from animal studies.

Of course, considerable debate has occurred over whether or not health effects in fact do occur below these thresholds. The example of lead is one where the threshold for adverse effects has been progressively lowered from occupationally derived standards steadily downward to a point where there is increasing agreement that, for some health effects, there is probably no safe level of lead in young children.[5]

In the case of non-threshold chemicals, investigations are not able to discern any level or threshold below which certain effects (often called the most sensitive effect or the critical effect) do not occur. Such health effects are often various forms of cancer. The long history of the study of asbestos provides one of the best examples of a chemical for which no threshold is apparent. Regardless of a historical progression towards lower and lower levels of asbestos exposure, occupationally exposed individuals consistently experience excess rates of cancer.[6] For non-threshold effect chemicals, the safety factor applied has often been higher such as 1000 times the lowest dose at which cancer was detected. Or, more typically for carcinogens, the safety factor approach is replaced by the use of mathematical models that assume a linear dose-response relationship. Using these models, a standard is set with the intention of ensuring that there is only a one-in-a-million chance for the cancer to occur across an exposed population often assuming a 70-year or "lifetime" exposure period.

Risk assessment, although still a very new field, has the longest history in the area of assessing cancer risk. A multi-agency effort in the United States in the late 1970s proposed a "cancer policy" to coordinate risk analysis and risk management across their respective agencies and within the constraints of the statutes each administered.[7] The agreement reached among these agencies included a consistent approach for cancer risk assessment procedures. In particular, the proposed policy included a consistent approach to the choice of "inference options" or "default assumptions" that need to be applied throughout risk assessment in order to compensate for gaps

[5] See Canfield, R.L., et.al., Intellectual Impairment in Children with Blood Lead Concentrations below 10 μg per Deciliter, *New England Journal of Medicine*, 348(16)(2003):1517-1526.
[6] See review in Epstein, S. *The Politics of Cancer, Revisited*. East Ridge Press, 1998, pp. 54-68.
[7] Historical account summarized from: CRS Report 98-618, *Environmental Risk Analysis: A Review of Public Policy Issues.* 40 p., Appendix. July 15, 1998. (Hereinafter: CRS Report 98-618.) Part I and Part VII (available at http://www.ncseonline.org/NLE/CRSreports/Risk/rsk-11.cfm).

in data and scientific theory and methodology. The proposed policy was a first step towards addressing the problem of inter-agency differences in risk assessment procedures, as well as getting a grip on the many assumptions inherent in the process but many problems remained.

In 1981 the U.S. Congress turned to the National Academy of Sciences to address both the substance of risk assessment procedures and the issue of interagency coordination. The result was a pivotal study that had a far-reaching influence on risk assessment practices. *Risk Assessment in the Federal Government: Managing the Process*[8] reviewed the various agencies' practices and found the institutional arrangements to be basically sound. It recommended a framework for cancer risk assessment that has continued to be refined to the present day. Additional key recommendations included the need to separate risk assessment from risk management and to develop risk assessment guidelines for the federal government as a whole.

The report also identified the many gaps in both data and theory that exist in risk assessment. It identified at least 50 "inference choices" that are necessary during cancer risk assessment that cannot be made on a scientific basis. Herein lies the central criticism of risk assessment that has been part of an extensive and vocal critique, mostly championed by environmental organizations at least since the NAS report was published. The list in Figure 1 provides some examples of the inference choices or subjective judgements that are necessary during risk assessment. Despite the many inherent and fundamental limitations of risk assessment identified, the NAS report nevertheless concluded that risk assessment required refinement, (through the development of detailed guidance documents), not replacement.

Figure1 : Some Subjective Judgements in Risk Assessment[9]

- What kinds of evidence are needed to demonstrate carcinogenicity?
- How important are toxicity studies that show an effect relative to studies that show no effect?
- How are benign and malignant tumours in animals counted?
- What are the appropriate dose levels for experiments?
- How should animal doses be compared to human doses?
- How should animal effects be compared to human effects?
- Are the effects observed at high doses expected to occur at low doses?
- Should different chemical carcinogens be treated differently?
- How should carcinogenicity be compared to mutagenicity? To birth defects?

Among all the agencies, the US Environmental Protection Agency (EPA) has consistently taken the lead in developing and revising risk assessment guidelines. EPA was the first to propose an interim guideline for its cancer risk assessments in 1977. Using the framework proposed in the 1983 NAS report, EPA finalized its guideline for cancer risk assessment in 1986.[10] This guideline also included early consideration of developmental risks (from chemicals that can cause mutations or damage to human development) and guidance on assessing exposure (to both

[8] National Academy of Sciences, *Risk Assessment in the Federal Government: Managing the Process*. Washington, D.C., National Academy Press. 1983.
[9] Source: Adapted from Rushefsky, M. *Making Cancer Policy*. Albany, N.Y. State University of New York Press, 1986, p.40, as cited in CRS Report 98-618, Part VII (op cit, Note 7)http:///.
[10] *51 Federal Register* 33992-34054, Sept.24, 1986.

individual chemicals and chemical mixtures). Subsequently, a revised guideline for developmental risks was published in 1991[11] and for exposure in 1992.[12] During the late 1990s and to the present, these guidelines have been further refined, in particular, numerous additional guidance documents have been developed in response to new requirements flowing from the *Food Quality Protection Act* of 1996.

Coincident with this evolution in risk assessment techniques, the 1990s saw an explosion of publishing, mostly in the U.S., about the health effects in children of environmental contaminants, particularly pesticides. Another highly influential report from the U.S. National Research Council (NRC), *Pesticides in the Diets of Infants and Children*,[13] set the stage for the ensuing debate over whether and how pesticides and other contaminants could be regulated to protect children's health.

The policy conclusions drawn by the NRC significantly influenced subsequent changes to U.S. law and policy concerning pesticides and other environmental contaminants. Legal reforms included the passage in 1996 of the *Food Quality Protection Act* and amendments to the *Safe Drinking Water Quality Act*. Risk assessment has been central to the legal and many other policy initiatives addressing children's environmental health in the United States and increasingly in Canada.[14]

The NRC reviewed in detail the shortcomings in exposure assessment and toxicity testing for pesticides as these relate to the special circumstances of children (in all life stages including prenatal, neonatal, and adolescence). Key gaps were identified in terms of both data and methodologies for assessing exposure to, and metabolism and toxicity of, pesticides during children's developmental stages. For the two key areas of risk assessment uncertainty – exposure assessment, and dose-response assessment – the NRC made numerous recommendations.

Perhaps most significantly, the NRC report made two recommendations that attempted to address central criticisms of risk assessment – i.e. the large gaps in data and lack of methodology. For the latter, it is especially difficult to assess real-world combinations of chemical exposures. To compensate for the "data gap," particularly as it relates to children, the NRC recommended the use of an additional 10-fold margin of safety. While many other recommendations were made to fill the data gap, this additional margin of safety was intended for situations where information is incomplete. To address real-world combinations of chemicals, the NRC found that exposure estimates and dose-response assessments should not be restricted to the impact of a single pesticide but should be required to assess aggregated exposures to pesticides with a common toxic effects.

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[11] *56 Federal Register* 63798-63826, Dec.5, 1991.
[12] *57 Federal Register* 22888-22938, May 29, 1992.
[13] National Research Council. *Pesticides in the Diets of Infants and Children*. (Washington: National Academy Press, 1993).
[14] The federal and provincial government departments in Canada 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.

Formidable efforts continue, in the United States, and worldwide, to refine and strengthen the ability of regulatory agencies to set risk-based standards for environmental contaminants.[15]

III. CRITIQUE OF THE STANDARD SETTING REGIME

(a) Is it Science? What does that mean?

From its inception, risk assessment has had its critics. This section provides a brief review of some of the criticisms of the approach. It explores some of the scientific shortcomings of the approach, questions the strength of the epidemiological foundations, and then explores issues dealing with ethics, and the implications for policy setting.

As noted, although risk assessment is routinely described by its proponents as an objective, fact-based scientific activity, it is not, and probably never will be.[16] While it can provide a generally reliable means of predicting acute effects from high dose exposures, it falls far short in the most important area of environmental concern: chronic effects from long-term, low dose exposure. It is incapable of assessing the real-world situation of exposure to and the interactive effects of multiple chemicals in the environment. There are simply too many uncertainties inherent in the process in terms of 1) basic insufficiency of data; 2) lack of methodologies for key steps in the process; and 3) the difficulty of reproducing or ensuring consistency and equal levels of professionalism and expertise across highly complex analyses.[17] Moreover, the presentation of results and their incorporation into policy decisions, the risk management extension of the exercise, is equally subject to the value judgements and guesswork that are central to the "science" of risk assessment.

Just looking at cancer risk assessment, which is, arguably the most well developed and reliable of any form of risk assessment addressing chronic health effects, several important points can be made that challenge the notion that risk assessment is objective, fact-based and "sound science." As noted, the National Academy of Sciences report in 1983[18] identified at least 50 "inference

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[15] Note that there are many areas where risk assessment and risk management are applied including the setting of standards, environmental assessment and planning decisions, remediation of contaminated lands or hazardous waste sites, and many non-environmental settings as well. Approaches and frameworks differ in each of these areas and this discussion is focused on risk assessment and management with respect to the setting of standards. For an overview of a variety of risk assessment and management frameworks, see: Dyck, W, et.al., *Current Directions in Environmental Risk Assessment and Management*, Network for Environmental Risk Assessment and Management (NERAM), February, 1999. Available at: www.neram.ca .

[16] CRS Report 98-618, Part II, *op.cit*., note 7. See also: Congressional Research Service Issue Brief for Congress No. 94036: *The Role of Risk Analysis and Risk Management in Environmental Protection*. September 6, 2001. Available at: http://www.ncseonline.org/NLE/CRSreports/Risk/rsk-1.cfm (Hereinafter: CRS Issue Brief No. 94036.)

[17] See for example, the discussion of Health Canada's risk assessment of plastic mini-blinds in the first Case Study to *Environmental Standard Setting and Children's Health*, Chapter 8, Standard Setting for Lead – The Cautionary Tale. The risk assessment calculations incorrectly used the *average* level of lead in the dust on the blinds as being representative of the 90th percentile. In so doing, the entire risk assessment greatly underestimates the potential exposure to lead from the most significant pathway - lead in dust. The dust-lead information originated from the analyses done by the U.S. Consumer Product Safety Commission and reported in: Health Sciences Laboratory Mini-Blind Study Surface Lead Determination (May 30, 1996), obtained from the US CPSC Office of Compliance, Division of Regulatory Management (June 7, 1996).

[18] *op. cit*. note 8

choices" that are necessary during a cancer risk assessment that cannot be made on a scientific basis, many of which directly influence the policy choices made about the chemical under investigation.

The conclusion of the NAS study was that there is a need to develop better risk assessment guidance documents and to continually improve the database upon which risk assessment depends. The result over time has been a steady increase in the sophistication of risk assessment procedures, particularly with respect to cancer. However, the amount and significance of inference choices has not changed very much. Rather, because of a long-term focus on cancer as the most serious of a variety of possible chronic health effects, a great deal of research has been conducted on whether and at what dose, chemicals contaminants can cause cancer. There also have been many cancer risk assessments conducted and revised in light of new and emerging information as well as increasing agreement about key areas where judgement is exercised.

The result of all of this work in cancer risk assessment has been a reduction in the range and variability of risk estimates but not necessarily a reduction in cancer risk. On the contrary, cancer risks have very likely increased as this chemical by chemical approach has proceeded and devised one-in-a-million cancer risk estimates for hundreds of different chemicals.

The result in terms of cancer risk is 100s-in-a-million and perhaps even thousands-in-a-million. The actual risk level is not one-in-a-million since each chemical is assessed separately and considered in isolation from any other cancer risks that may exist from either similar or dissimilar cancer-causing or potentially cancer-causing chemicals in the environment. Nor has cancer risk assessment been conducted on more than a mere handful of chemicals by comparison to the many tens of thousands of chemicals in commercial use for which almost no toxicological information exists at all.

This numbers game is particularly abhorrent to those who criticize the ethics of risk assessment (discussed further below). Another way of describing the risk result of this chemical by chemical assessment and generation of "negligible" risk estimates, is to think in terms of even just ten substances with a one-in-a-million excess cancer risk (two very conservative assumptions). This situation would work out to a risk level of ten in a million or one-in-one-hundred-thousand (10/1000000 = 1/100000). For risk assessments conducted at the one-in-one hundred thousand risk level (and there are many; even at a one-in-ten thousand level), the numbers get even worse, i.e., one in ten thousand to one in one thousand levels. Risk assessment practitioners would rightly point out that these simple calculations incorrectly assume that all exposures are additive. Although each person could be exposed to each and every one of the ten chemicals at the exposure levels assumed, such additive exposure may not be the case. Nevertheless, risk assessment proponents would never advocate that one-in-a-thousand is an "acceptable" risk of cancer from environmental exposure to contaminants. Taking these calculations further, if the number of carcinogens released is more than 10, (an entirely reasonable assumption), the risk level continues to increase. If excess deaths due to other mechanisms (non-cancer) from these chemicals are added, the risk number is worse yet. And such calculations still have not accounted for synergistic effects or inter-generational effects. In other words, no matter how much the individual risk assessment process is refined, it is still counting trees and missing the forest in terms of real risks to people.

The long period of time during which cancer research and risk assessment has occurred also contributed to a situation where carcinogenicity was, and to a considerable extent still is, heavily relied upon as a surrogate measure for any chronic health effects. This situation resulted in the near total exclusion in risk assessments of other less understood and less studied effects such as reproductive, neurological or neurodevelopmental effects, or immunological and endocrine effects. Notably, these other potential effects are particularly relevant to children's health.[19]

Other central criticisms of the scientific shortcomings of risk assessment include the fact that uncertainties and errors can result from:

- *small population generalizations* – i.e., when extrapolations are made from high concentrations of chemical exposures in small populations to predict health effects in large populations exposed to lower concentrations of the same chemical.
- *generalizations from animal studies to human health* – i.e., when extrapolations are derived from animal studies (both high dose, short term exposure and low dose, long term exposure) to predict human health effects.
- *ignoring background sources* – i.e., the tendency to ignore or be unaware of background sources of exposure to chemicals affecting people or ecosystems leading to exceedances of threshold values established through risk assessment.
- *ignoring multiple chemical exposure* – i.e., the inability of risk assessment to accommodate real world situations of multiple chemical exposures of varying dose and duration or to assess the possible cumulative or synergistic effects of such multiple exposures.
- *the "healthy white male" as the norm* – i.e., the tendency to exclude the most sensitive segments of the population from calculations of risk by not including a wide enough margin of safety (and even assuming safe levels are known or knowable).
- *major limitations in animal testing* – i.e., the fact that animal bioassays do not always extend over entire lifetimes, dosing generally begins after weaning, thereby skipping *in utero* and neonatal periods comparable to the first 3-6 years of human life, the complication of the "wasted dose" which is the difference between the lifetime dose and the dose that actually causes disease, and the inappropriate assumption that negative results in animal bioassays indicate safety for humans.

The above list is drawn from analyses published mostly during the early 1990s.[20] It is important to note the difference between the first two points and the final four. For the first two, there is no

[19] Note however that considerable work has continued in the development of additional risk assessment guidance documents for these other health effects. However, despite the existence or evolution of guidance for the evaluation of these other effects, they may not necessarily inform the risk assessment process if they are not part of "core testing" requirements.

[20] See for example: Benbrook, C.M., *et.al.*, Consumers Union, *Pest Management at the Crossroads.* (Consumers Union of the United States, New York, 1996) Chapters 3 and 4; Chess, C. and D. Wartenberg, The Risk Wars: Assessing Risk Assessment, *New Solutions* 3(2) (1993), pp.16-25; Chociolko,C., The Experts Disagree: A Simple Matter of Facts Versus Values?, *Alternatives* 21(3) (1995); Costanza, R. and L. Cornwell, The 4P Approach to Dealing with Scientific Uncertainty, *Environment* 34(9) (1992); Ginsberg, R., Quantitative Risk Assessment and the Illusion of Safety, *New Solutions* 3(2) (1993), pp. 8-15; Gregory, M., Pesticide Reform in Arizona: Moving Beyond Risk Assessment and Clean-up to Exposure Prevention, *Arizona Toxics Information*, (1991); Gregory, M., Some Unacceptable Risks of Risk Assessment, *Pesticides and You*, Spring (1995), p.14-16; Gutin, J., At Our Peril: The False Promise of Risk Assessment, *Greenpeace Magazine*, 16(2) (1991); Highland, J., *Risk-Benefit Analysis in*

way around the need to make such generalizations and extrapolations. Problems of uncertainty, variability, error, and gaps in data will exist but inferences have to be drawn from the information that such studies can provide. The final four points however are shortcomings of a different kind. They represent problems of fundamental gaps in information and methodology to assess both real-world exposure and actual risks to sensitive populations or life stages. While refinements in risk assessment continue and have begun to address some of these shortcomings, many fundamental limitations remain.

Uncertainty, variability, error and large gaps in basic data and methodology occur in two of the four risk assessment steps. Procedures and/or definitions vary but the four basic steps include: hazard identification, *dose-response assessment, exposure assessment*, and risk characterization.[21] The second two (in italic) are especially difficult due to a basic lack of both critically important scientific and/or empirical data and assessment methodologies. Even when risk assessors are considering a single chemical at a time, basic scientific and/or empirical data and methodologies are lacking to calculate exposure and a dose-response relationship. Of course, this problem is greatly magnified when considering multiple exposures and the chance of cumulative or synergistic effects.

To illustrate,[22] risk assessors simply do not know exactly (or in some cases even remotely) how much of a pesticide (or a group of pesticides) makes up a child's exposure. They do not know whether the adverse effect levels detected in laboratory experiments on rats or dogs are comparable, or even approach the range of possible adverse effects in a human fetus, infant, child or adolescent. To be able to carry through to the risk characterization step and assign exposure and dose-response numbers for incorporation into a risk management strategy such as setting a standard for exposure or permitting the use of a pesticide, gaps are filled by the "inference choices" noted above. Also called "science policy choices" or "default assumptions," these gaps in critically important scientific and empirical data and methodologies are filled by what is essentially guesswork. It may be the product of modeling including "informed guesses" or "the informed judgement of experts" but it is still largely guesswork, not science.

It is true that more research can and does eliminate data gaps and uncertainty. Improvements in methodology can also reduce the broad range in risk estimates that risk assessments can generate. However, the enormity of the data collection task is formidable. According to one risk assessment expert and advocate, "toxicologists know a great deal about a few chemicals, a little about many, and next to nothing about most."[23] For key methodological gaps, such as modeling

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Regulatory Decision-Making, Toxic Chemicals Program, Environmental Defense Fund, undated; O'Brien, M., Alternatives to Risk Assessment, New Solutions 3(2) (1993), pp.39-42; Smith, C., K. Kelsey, and D. Christiani, Risk Assessment and Occupational Health: Overview and Recommendations, *New Solutions* 3(2) (1993), pp.26-38; Thornton, J., Getting Burned: Risk Assessment is the Real Threat to the People Who Live Near Toxic Waste Incinerators, and Risking Democracy, *Greenpeace Magazine* 16(2) (1991), p.15 and p.17.

[21] Nomenclature drawn from summary in CRS Report 98-618, *op.cit*., note 7.

[22] Adapted from example in: Risk Assessment –Part 2, Judge Breyer's Prescription for Risk, *Rachel's Hazardous Waste News*, #394, June 16, 1994. See also: *Rachel's Hazardous Waste News* Part 1, The Emperor's Scientific New Clothes, #393, June 9, 1994; Part 3, Which Problems Shall We Ignore?, #395, June 23, 1994; and The Ethical Hazards of Risk Assessment, #519, November 7, 1996.

[23] Rodricks, J., *Calculated Risks*. Cambridge University Press, New York (1992), p. 192.

multiple exposures or assessing toxic effects from multiple chemicals, new methods are only barely developed and largely untested.

Finally, and perhaps most fundamentally, the assigning of individual risk levels for each chemical is essentially a game of odds that cannot address two of the most serious issues of toxic chemical pollution. These are inherent toxicity and population-wide effects such as may be occurring with endocrine disrupting chemicals. Risk assessment enables risk calculations that allow for "acceptable" levels of one-in-a-million or one-in-ten-thousand risks (of cancer, birth defects, etc.) across a population. However, the odds game 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.[24] 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 no doubt affect some people more seriously than others depending on the flow of persistent chemicals through the environment.

(b) How strong is the epidemiological foundation of risk assessment?

Accurate identification of health effects is important. Direct human evidence is often not available or may be of limited use to risk assessments for a variety of reasons.[25] Some key issues that limit use of human data for the purposes of assessing environmental health risks include methodological or analytical weaknesses of epidemiological studies, identification of health effects, exposure assessment, sample size and representativeness. Different types of cancer represent distinct disease processes and so must be specifically defined. Many health effects of concern (including cancer, respiratory problems and neurological effects) may not appear for long periods following the causal exposure or they may occur as a result of progressive accumulation of damage that doesn't produce identifiable effects. These types of effects are difficult to associate with a specific exposure with any degree of certainty (because of the time lag) and they are also not easily detected. With "rare" health effects such as cancer, it is also difficult to collect data on a large enough sample. Larger sample size increases the ability (statistical power) to detect real associations between exposure and outcome.

Where those conducting a risk assessment are interested in quantifying dose-response relationships, epidemiological studies are often only able to address the exposure-response relationship. That is, there is no way of accurately determining what proportion of the amount to which people were exposed actually reached the body tissues. Even so, risk assessors are also frequently unable to accurately determine the degree of exposure to a contaminant of interest. They can often only infer exposure from job description in occupational studies, or by place of residence or subject recall in exposures of the population at large. In many instances, exposure can only be characterized as a dichotomous variable with subjects designated as either "exposed" or "not exposed." Biological exposure data (for example, measures of contaminants from urine

[24] Colborn, T, D. Dumanoski, and J. Peterson Myers, *Our Stolen Future* (Dutton, New York, 1996), see in particular, Chapter 11 (Beyond Cancer) and Chapter 11 (Flying Blind).

[25] For recent critical discussions of the role of epidemiology in risk assessments see sources such as Samet, J.M., R. Schnatter and H. Gibb, Invited commentary: Epidemiology and Risk Assessment. *Am. J. Epid*. 148(1998):929-936.; and Herz-Picciotto I., Epidemiology and quantitative risk assessment: A bridge from science to policy. *Am.J.Pub.Health* 85(1995): 484-491.

or blood samples) improves accuracy in assigning the dose-response relationship. However, such measurement adds extra expense and logistical problems, especially in large epidemiological studies and is often not an option in retrospective studies.

Another problem of exposure assessment is the reality of multiple exposures from multiple sources. For example, children can be exposed to many different pesticides via contamination of food, drinking water, and home, school and playground surroundings. Children experience exposure to other contaminants as well and via various pathways. Multiple exposures are especially the case for those who are exposed to contaminants in both occupational and environmental settings. For instance, pesticide workers are routinely exposed to several pesticides, and other toxicants such as solvents, emulsifiers and "inert" ingredients.[26] This multiple exposure makes it very difficult to attribute observed health effects to exposure to a specific toxin. A similarly complex picture exists for the children of these workers since they may be additionally exposed to pesticides on their parents' clothing and shoes, or due to living very near to where their parents work. This exposure is in addition to the range of pesticide residues and contamination to which all children are exposed.

Factors other than the exposure of interest may also confound the observations. For example, poor nutrition will enhance the uptake of lead and hence, the lead-based health effects in children. Lastly, the choice of human population samples for epidemiological studies is often opportunistic. As a result there may be inadequate representation of the effects in all population subgroups especially particularly sensitive ones, such as children or the elderly. This has sometimes been referred to as the healthy worker effect.[27]

As a consequence of these weaknesses in epidemiological data, risk assessors rely on models and other types of evidence (such as animal experiments and wildlife studies) which may provide only a prediction of the nature and magnitude of the health effects in humans. However, reliance on wildlife and animal studies alone would also have limitations.[28] It is insufficient for public policy and public protection to focus solely on cancer testing or bio-accumulation. Effects may be produced at extremely low levels, but at extremely sensitive times in the development of embryos. Rather than "the dose is the poison," the timing may be the poison. Extremely small amounts of dioxins exposed to the mother at day 15 in a rat's gestation or at day 56 in a human's gestation may irreversibly affect sexual differentiation in the offspring.[29]

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[26] Roberts, J.R., P.B. Curry, R.F. Willes, M.F. Mitchell, S.Narod and L.C. Neri, Epidemiological evidence of the effects of pesticides on human health in Canada. Monograph II. In: *Strengths and Limitations of the Benefit-Cost Analyses Applied to the Assessment of Industrial Organic Chemicals Including Pesticides*. Associate Committee on Scientific Criteria for Environmental Quality. National Research Council of Canada. NRCC No. 22852 (1985: 1).

[27] In occupational epidemiology if non-exposed workers are the control sample, they are less representative of the general population, since employed people are on the whole, in better health compared to the general population which includes people with a broader range of states of health from poor to good (Roberts, J.R., et al, 1985, *op.cit.*, note 26).

[28] Colborn, T.E., A.Davidson, S.N.Green, R.A. Hodge, C.I.Jackson, and R.A.Liroff, Human Health, Chapter 7 in *Great Lakes Great Legacy?* (Washington, Ottawa: The Conservation Foundation and the Institute for Research on Public Policy, 1990).

[29] Colborn, T, Listening to the Lakes, *Pesticides and You*, June, 1992: 4-8.

(c) Politics, Ethics and Equity in conducting Risk Assessments

The political and ethical hazards of risk assessment stem directly from the combination of guesswork and science described above. Despite its gaps in basic information and methodologies to implement key steps, risk assessment is enormously complex and the domain of specialized experts. This complexity makes several things possible. Value judgements and questionable assumptions can be concealed. Policy-makers can be manipulated or misled during the political decision-making or risk management phase. An intellectual elite and those wealthy enough to hire them can dominate discussions, the political process and the outcome.

It is not surprising that a methodology that requires the making of frequent "inference choices," or "science policy choices," or what many consider to be significant and influential value judgements, will raise important issues of ethics and social equity. Commentators frequently note that risk assessment tends to impose risk on those that are often most susceptible to harm, and the least able to confront or resolve the source of harm, including the poor, the elderly, children (including fetuses) and minority groups. Moreover, risks can be imposed on these groups without their consent and under circumstances where those being placed under the highest risk receive little to none of the benefits that result from whatever activity the risk assessment sanctions. As noted above, the political malleability of the process provides the opportunity for those with money and power to influence the outcome.[30]

Two additional ethical issues arise directly from the shaky scientific foundation of risk assessment. First, the vast ignorance about the toxic effects of chemicals leads to each chemical being treated as "innocent until proven guilty." However, the human population does not have the right to avoid the cumulative risk of real-world exposure circumstances. In addition, some people are more exposed than others. For example, a one-in-a-million risk level may be established for chemicals emitted for particular air emissions or water effluents or leachate from landfills. The risks however can be borne disproportionately by the population living nearby, not the hypothetical population that informed the risk assessment calculation. Even if, as some do, the risk calculations account for the localized circumstances of the exposed population, these are still groups of people disproportionately exposed to toxic chemicals, and this is often the case because they are poor or otherwise disenfranchised from the political decisions flowing from risk calculations.

The second ethical problem with this approach of granting a risk level to each chemical is that risk assessment has only recently begun to consider health end-points other than cancer. There may in fact be other end-points such as endocrine disruption and neurodevelopmental effects, which may occur at even lower exposure levels or under different circumstances than the cancer risk assessment considered. These other unknown or poorly understood effects have to be assumed to be non-existent. Alternatively, they require the application of default assumptions and there is great uncertainty as to whether these assumptions adequately inform the risk assessment calculations. Further, those chemicals that are unidentified, untested, or otherwise not part of the analysis, (including the real-world situation of complex mixtures of small amounts of

[30] See multiple sources *supra* notes 20 and 22, in particular, O'Brien, M. and J. Thornton, *Rachel's Hazardous Waste News*, #519; and see also: Silbergeld, E., The Risks of Risk Assessment, *New Solutions* 3(2) (1993), pp.43-44.

chemicals) are simply not part of the risk assessment exercise. Again, the chemicals are dealt with based on an inherently incomplete risk level calculation and as a result the exposed human population does not have the right to be exposed to no more than a specific level of risk.

Risk assessment practitioners often react to the critique of risk assessment by ignoring it. For many, this non-self-critical approach is one of essentially pretending that the gaps in data and methodology are insignificant in terms of presenting barriers to continued application of what is, again, seen and described as an objective, fact-based scientific exercise. Such an approach is evident in the document prepared by the Canadian-based Network for Environmental Risk Assessment and Management (NERAM) entitled "*Current Directions in Environmental Risk Assessment and Management.*"[31]

Alternatively, for those risk assessment practitioners and advocates who recognize the scientific limitations of the process, the approach is to accept the level and degree of default assumptions as inevitable and a valid part of the exercise and something that ever more effort at refining techniques will ultimately overcome. In the meantime, they consider the solution to the problem to be a matter of improvements in risk characterization and communication.[32]

(d) Implications for Decision Making and Policy Setting

The fact that efforts to determine causation and interpretation of epidemiological and other scientific studies involves considerable judgement has important implications for decision making and policy setting based on those studies. Commentators have noted,[33] "science" is different from "policy." Policy is informed by many disciplines, including science, but also ethics, values, opinion, conflicting interests and perspectives. The foregoing review of the way in which the "science" is conducted illustrates that it is an impossible demand of science to provide the policy answers. Furthermore, the judgements and conclusions based on "science" may be far from certain even in terms of the limited questions that science attempts to answer. Accordingly, decisions must be made, based on all of the best available information. While the results of "science" (epidemiological studies; assessments as to contributors to the questions of "causation", etc.) are important contributors to the decisions, science is incapable of playing the role of the sole determinant of these questions.

Standard setting is primarily a policy-making exercise. Decisions on policy entail a review of the science, together with many other judgements. A "weight of the evidence" approach is appropriate for policy making as to standards, i.e., in the risk management process itself, not solely at the hazard identification stage. An important question in that context is what "burden of proof" to demand; where to place the "burden of proof"; and what elements of "proof" to consider in making standard setting decisions.

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[31] Dyck, W, *et.al.*, 1999, as cited in note 15.

[32] See for example, Stern, P. and H. Fineberg, (eds) *Understanding Risk: Informing Decisions in a Democratic Society*, Committee on Risk Characterization, Commission on Behavioral and Social Sciences and Education, National Research Council, (1996) 264 p.

[33] Weinberg, J. and J. Thornton, Scientific Inference and the Precautionary Principle. In: Weight of Evidence: Issues and Practice, A Report on a Workshop held October 24, 1993. (International Joint Commission, June 1994), pp 20-6.

There is a history of considering differences in required burdens of proof in legal decision making. Two commonly applied standards are the usual civil "balance of probabilities" (which means "is the contested fact more likely than not?") and the criminal law standard of proof of the contested facts as being "beyond a reasonable doubt." The reasons for the differences vary with the reasons behind the court proceedings that apply these different burdens. In criminal proceedings, the legal system has institutionalized an approach that, ideally, makes it extremely unlikely that an innocent person would be wrongly convicted. It is understood and accepted in that approach that sometimes, "guilty persons" will not be convicted. This is because the value of freedom for innocent persons is strongly protected by our legal system. On the other hand, for civil disputes – that is, disputes between two parties over contracts, tort claims and other such matters – the value is on expeditious resolution of disputes based on defendable and reasonable evidence. The burden is slightly higher on the party claiming a legal wrong has been committed, but they need not satisfy the decision maker "beyond a reasonable doubt" – it is only necessary to show that their claim is more likely than not "true" based on the evidence.

Because standard setting is intended to protect human health and welfare, ecosystems and other very high values, the "burden of proof" that is required in standard setting should be one that is more likely to be protective of those desired values. Too often, however, a protective approach has not been the case due in part, to a mis-application of the ideas of causation and the statistical significance testing that is applied to epidemiological studies.

In epidemiological studies, statistical tests that estimate the likelihood that the study has produced the correct answer (e.g. a causal link is present) have been set, usually at 95% or 99% "confidence" levels. It is important to remember that these confidence levels are arbitrary cut-off points chosen for convenience and consistency; they have "no sound logical basis and [remain] unjustified."[34] They indicate the statistical likelihood that an association shown in a study is purely due to chance. The value that the scientific method is protecting in this approach is a value to base hypotheses and further work on studies that meet this extremely rigorous test.[35] These tests do *not* mean that when the confidence level is less than 95% or less than 99% that the association is not present. They just mean that as the confidence level decreases, it becomes more and more possible that the association that was found is an artifact of chance.

However, to base standard setting decisions on the same approach *before* establishing protective measures or refusing to allow additional exposures raises the likelihood that too much exposure is allowed. One noted legal text on evidence discussed the possibility in some circumstances of a third standard of proof. It was described as that of "clear, strong and cogent" evidence.[36] There are also legal evidentiary tools that assist decision makers, such as the establishment of common inferences and presumptions. The "presumption of innocence" is an example. In deciding who should bear the risk from environmental contaminants, the burden should be shifted once there is

[34] Cornfield, J., Recent methodological contributions to clinical trials, *Am.J.Epidemiol*. 104(1974):553-58, as discussed in Needleman, H. and D. Bellinger, The Health Effects of Low Level Lead Exposure, *Annu. Rev. Publ. Health*, 12 (1991): 111-40.

[35] The intention is to avoid Type I errors (i.e., accepting spurious associations as causal). Notably, one of the six flaws found by Needleman and Bellinger, 1991 (*op.cit*. note 34) in the literature on lead and children's IQ, was a tendency to overvalue the status of the P value (or confidence level) as a criterion for inferring causality. The result was an increased tendency to overlook causal connections, i.e., an increase in Type II errors.

[36] Cross, Sir Rupert and C. Tapper, *Cross on Evidence*, 6th edition, (London (UK) Butterworths, 1985).

epidemiological evidence showing an increase in incidence of the harm under study.[37] Normally the legal concepts of duty of care, the failure of which may lead to legal liability, are based on a "balance of probabilities" or "50% plus one" likelihood standard. Standard setting policy decisions should follow a paradigm in which it is *at least* "more likely than not" that the appropriate protective decision has been made – that is, that a standard is set that is protective of children's health. An approach that requires human epidemiological evidence demonstrated at a 95% or 99% confidence interval *before* taking protective action would not meet this requirement.[38] On the other hand, an approach that truly weighs all of the available evidence and arrives at a prudent protective judgement based on all of that "weight of the evidence" would be more likely to meet this standard.

In considering this issue, "precautionary inference" was proposed as a method to make scientific judgements when data are incomplete or inconclusive, and where significant harm may follow from a false negative judgement.[39] This approach would be a reversal of the current scientific and policy framework. For instance, since data are lacking for most chemicals, if a given chemical belongs to a class for which it is plausible to presume that members of that chemical class may be persistent toxic substances, the onus, under this approach, should be reversed. Hence, using a reverse onus approach, specific exceptions could be made upon proof that a particular chemical is not a persistent toxic substance. Similarly, for those engaging in processes that mix chemicals and release the products of those mixtures, the onus should be on them to demonstrate that the processes do not result in the release of persistent toxic substances. These recommendations are specifically directed to the area of environmental contamination and health damage. Rather than the traditional epidemiological approach, in which all confounding variables cannot be controlled and the "webs of cause and effect ... are too complex to be fully illuminated by the tools and models currently available...", a precautionary inference approach would rely on "an integrated body of evidence from laboratory experiments, wildlife studies and epidemiological investigations... to consider [not] whether causal relationships have been definitively proven, but whether the body of evidence suggests a plausible hypothesis that harm has occurred."[40]

Herein lies the central difference between standard setting approaches that apply risk assessment versus a precautionary approach. In both the U.S. and Canada, the application of risk assessment has predominated and contaminants largely have been considered "innocent until proven guilty." We will discuss later weight of evidence, burden of proof, and precautionary inference with respect to the implications of a precautionary approach to standard setting that is protective of children's health.

In light of the foregoing discussion of science and policy, and for the purposes of critically evaluating the application of risk assessment, it is worthwhile asking a central question.

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[37] Harris, O.F., Toxic Tort Litigation and the Causation Element: Is there any hope of reconciliation? *Southwestern Law Journal* I 40(Sept.1986): 909-965.
[38] Jenicek, M., Rules of Evidence: Criminality and Causality. In: *Epidemiology: The Logic of Modern Medicine.* (Montreal: Epimed, 1995), pp 192-4.
[39] Weinberg and Thornton, 1993, *op.cit.*, note 33.
[40] Ibid.

For a given standard or proposed standard, is the best hypothesis, based on all of the evidence, that harm is *not* likely to occur to children? If not, the standard should be improved (made more strict) until the best hypothesis on all of the evidence is that at that standard, harm to children is *not* likely to occur. For areas of uncertainty that make it difficult to assess this question, the approach should be modified by a precautionary approach. In that case, the standard should be made appropriately more rigorous unless and until the uncertainty is resolved to demonstrate on "clear, strong and cogent evidence" that at the permitted exposure level, no harm to children will result. To this point, a precautionary approach has not been followed for the majority of standards affecting children's health.

IV. IMPROVING THE REGIME

(a) The Precautionary Approach: Dealing with the unknown and the uncertain in the face of possible severe harm

Earlier we described the nature, scope and the limits of risk assessment. We commented on the scientific limits, (such as attempting to generalize animal studies to human health, ignoring background sources, ignoring multiple chemical exposure, among many others), the gaps and deficiencies in data and methodologies and those limits pertaining to epidemiological and causation issues.

Two responses have emerged to respond to these criticisms of risk assessment. Predominantly, as mentioned, the response has been to find risk assessment basically sound and in need of ever more complex refinement. To a certain extent, this refinement has included incorporation of the weight-of-evidence approach.

The other response is to provide a new "overlay" on risk assessment that instills in effect a new approach. This new approach incorporates the precautionary approach.

Simply put, the precautionary approach provides a policy framework to make decisions to protect human health and the environment in the face of scientific uncertainty. As summarized by one commentator, the principle has a "dual trigger," namely, "If there is a potential for harm from an activity and if there is uncertainty about the magnitude of impacts or causality, then anticipatory action should be taken to avoid harm."[41]

Although simply put, the definition of the approach, the legal basis, the scope of its application, its core elements and how to implement it, are but a few issues raised by the concept and which are now being debated both within the context of international law and domestic legislation and policy.

One of the key issues raised by the precautionary approach is how it relates to risk assessment. While the precautionary approach is not usually viewed as an alternative to risk assessment, it is at times regarded as a threat to the "sound science" and the rigour that is supposedly inherent within risk assessment. We attempt to provide some context regarding the precautionary

[41] Raffensperger, C. and J. Tickner (eds.), *Protecting Public Health and the Environment: Implementing the Precautionary Principle* (Washington, D.C.: Island Press, 1999), Introduction, p. 1.

approach in terms of its origins, definition and application. We also further discuss ideas like "weight of evidence", "burden of proof" and "precautionary inference". The components of the precautionary approach are reviewed again here in terms of their relevance to children's health followed by a review of the present status of the precautionary approach in Canada.

(b) What is the Precautionary Approach?

There is no consensus on how to define the "precautionary approach." The definition is important since it either expands or constrains the scope of the concept. A comparison of two definitions illustrates the point. The *Rio Declaration on Environment and Development*[42] states the definition as follows:

> In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

While this definition speaks to "serious or irreversible damage" and "cost-effective" measures, other definitions do not have such qualifications. For example, the *Wingspread Statement on the Precautionary Principle*[43] 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.

The Lowell Statement on Science and the Precautionary Principle[44] built upon the 1998 Wingspread Statement. It emphasized the need to "change the ways in which environmental protection decisions are made and the ways that scientific knowledge informs those decisions."

(c) Components of the Precautionary Approach and their Relevance to Children's Health

Some of the policy implications arising from application of the precautionary principle most germane to the context of standard setting and children's health pertain to: onus of proof; the weight of evidence approach; prevention-based tools and standards; and public participation. [45]

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[42] June 14, *International Legal Material* 31(1992) p.849.

[43] The Wingspread Statement is reproduced in: Raffensperger and Tickner, Appendix A, *op.cit.*, note 41.

[44] Statement from the International Summit on Science and the Precuationary Principle, hosted by the Lowell Center for sustainable Production, University of Massachusetts Lowell, 20-22 September 2001.

[45] The criteria identified are derived from a review of the literature, and in particular, see: Castrilli, J.F., The Precautionary Principle and Canadian Environmental Law: From Principle to Practice. A Report Prepared for Pollution Probe, 1999, pp.11-13; and Raffensperger and Tickner, 1999, A Map Toward Precautionary Decision Making, pp. 166-177, *op.cit.*, note 41. Other components identified include use of the "polluter pays" principle, evaluating alternative activities, technologies and chemicals, ongoing monitoring, investigation and information dissemination, strong enforcement, among others. See also Nancy Myers, "Debating the Precautionary Principle", March 2000, Science and Environmental Health Network at page 3 of 9, no publication data, and for a more complete bibliography of recent discussions of the precautionary principle, see Benevides, H. and McClenaghan, T., "Implementing Precaution: An NGO Response to the Government of Canada's Discussion Document, 'A Canadian Perspective on the Precautionary Approach/Principle'", Canadian Environmental Law Association Report No. 419, Toronto, April 2002.

(i) Burden/ Onus of Proof

One of the commonly noted elements of the precautionary principle is that, where there is a threat of harm, the onus should be on those threatening such harm to establish the activity will not cause harm to the environment or human health. Standard setting is primarily a policy-making exercise and decisions on policy entail a review of the science, together with many other judgements. While there is increasing agreement and application by regulatory agencies of the need to apply a "weight of evidence" approach in standard setting, in most contexts, disagreement remains concerning the "burden of proof." In particular, the questions include: what "burden of proof" should be demanded; where should the "burden of proof" be placed; and what elements of "proof" should be considered in making standard setting decisions.

If environmental standards are to protect human health and welfare, ecosystems and other very high values, the "burden of proof" that will be protective of those desired values cannot rely strictly upon the statistical significance testing that is applied to epidemiological studies or animal test data. To base standard setting decisions on scientifically derived inferences of causation *before* establishing protective measures or refusing to allow additional exposures will result in potentially hazardous exposure to contaminants. The twenty year saga of efforts to phase-down and phase-out lead from gasoline is a case in point. Lead exposure continued and millions of children were poisoned while regulatory agencies awaited proof of harm. The lead case provides a cautionary tale of the perils of this rigid approach.[46]

The legal concepts of duty of care based on a "balance of probabilities" or "50% plus one" likelihood standard are valid here and can reasonably be applied. Standard setting approaches that would truly weigh all of the available evidence and arrive at a prudent protective judgement based on all of that "weight of the evidence" would be the most likely to create standards that are protective of children's health.

As mentioned earlier, "precautionary inference" is a preferred method for making scientific judgements when data are incomplete or inconclusive, and where significant harm may follow from a false negative judgement, i.e., in matters typical of environmental contamination and health damage. With precautionary inference, the risk assessment approach of contaminants largely being considered "innocent until proven guilty" is reversed and the burden of proof is on demonstrating lack of harm. Standards would be set at rigorous levels of safety and not lowered unless and until the relevant uncertainty is resolved to demonstrate on "clear, strong and cogent evidence" that at the permitted exposure level, no harm to children will result.

(ii) Weight of Evidence Approach

Although, as noted above, regulatory agencies are increasingly applying a weight-of-evidence approach, another question implicit within the precautionary principle is the determination of how much evidence is required that harm may occur before precautionary action will be taken. Is it necessary that there will be absolute proof of harm or only a mere suspicion?

[46] See detailed discussion in Canadian Environmental Law Association and Ontario College of Family Physicians, Children's Health Project: *Environmental Standard Setting and Children's Health*, May, 2000, Chapter 8, Standard Setting for Lead – The Cautionary Tale.

One commentator summarized the preferred approach this way:

> Decision –making about associations or likelihood of harm under the Precautionary Principle should be based on a "weight-of-evidence" approach, rather than on some quantitative probability of harm (as is the case with risk assessment approaches). The weight-of-evidence approach to decision-making takes into account the cumulative weight of information from numerous sources that address the question of injury or the likelihood of injury to living organisms."[footnotes omitted][47]

A wide array of evidence is at issue when identifying potential human health hazards, especially when appropriate human data are lacking and inferences have to be made about the degree of proof that is provided by existing toxicological data.

(iii) Prevention-Based Tools and Standards

Another element of the precautionary principle calls for the use of prevention-based tools and standards aimed at avoiding or preventing harm from some activity. In other words, rather than focusing on the proof of harm, a focus would be on designing products and activities such that the threat of harm would be avoided. Examples of such measures in this context would include recognition of inherent toxicity as the basis for phasing out of dangerous substances, the establishing of pollution prevention standards, the development and encouragement of clean technologies and methodologies to promote alternatives, to name but a few.[48] It is important that principles of Just Transition be applied so that workers affected by the phase-down and phase-out of toxic chemicals are able to at the very least obtain alternative training and employment. Ideally, the expertise of these affected workers can assist with the process of workplace transition and transformation.

(iv) Public Participation

One of the implementing mechanisms for the precautionary principle relates to greater public participation in environmental decision-making. This mechanism is important since the implementation of the principle requires "the need to balance value judgements before decision-makers when health and environmental risks of activities are being evaluated."[49]

(d) Precautionary Approach in Canada

Initiatives to embrace the precautionary approach in Canada have been described as "hesitant hugs." The approach has been accepted in principle in various legislative enactments, but neither federal or provincial governments in Canada have provided any specific roadmap with respect to its practical implementation in those contexts.[50]

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[47] Tickner, J., A Map Toward Precautionary Decision Making, in: Raffensperger and Tickner, p. 169, *op.cit.,* note 41.
[48] Castrilli, J.,F., 1999, p. 11, *op.cit*., note 45; and Raffensperger and Tickner, 1999, p. 171, *op.cit*. note 41.
[49] Castrilli, J.,F., 1999, p. 13, *op.cit*., note 45; and Raffensperger and Tickner, 1999, pp. 175-6, *op.cit*. note 41.
[50] VanderZwaag, D., The Precautionary Principle in Environmental Law and Policy: Elusive Rhetoric and Embraces , *Journal of Environmental Law and Practice* 8(355)(1999), p. 369. See also: Moffet, J., Legislative Options for Implementing the Precautionary Principle *Journal of Environmental Law and Policy* 7(1997), p. 157.

In 2001, the Supreme Court of Canada quoted Cameron and Abouchar in stating that there may already be "currently sufficient state practice to allow a good argument that the precautionary principle is a principle of customary international law." In that context, the Court noted that municipal action to pass a pesticides by-law controlling use of pesticides on private property "fit well under the rubric of [the precautionary principle's tenets] of preventive action."[51]

In 2002, the Canadian federal government solicited feedback and comment from the public on a discussion document[52] entitled, "A Canadian Perspective on the Precautionary Approach/Principle." The document proposed to outline "broad, guiding principles to support consistent, credible and predictable policy and regulatory decision making when applying the precautionary approach/principle."

However, the Canadian Environmental Law Association and other NGO's objected[53] to the discussion document in that it subsumed the precautionary approach in "risk" frameworks for standard setting. The federal government discussion paper did not include any discussion regarding better protection of vulnerable populations such as children. No final position paper has yet been issued as of the date of this article.

The precautionary approach has also been recognized in federal legislation such as the *Oceans Act*,[54] the Canadian Environmental Protection Act[55] and lately in the *Pest Control Products Act.* It has also been recognized in the Canada-Wide Accord on Environmental Harmonization. [56]

In the fall of 1999, the House of Commons Standing Committee on Environment and Sustainable Development held hearings for its review of the then 29 year old *Pest Control Products Act.* The Committee's report, issued in the Spring of 2000[57] recommended comprehensive overhaul to the law and its administration including inclusion of the precautionary approach for all decisions made under the act. In October, 2002, Bill C-8, amending the *Pest Control Products Act*, was passed by the House of Commons, subsequently passed by the Senate, and given Royal Assent in December. However, promulgation will likely occur in mid-2004 after several implementing regulations are developed. Bill C-8, an "Act to protect human health and safety and the environment by regulating products used for the control of pests" replaces the prior *Pest Control Products Act* and introduces some significant reforms to the process of pesticide registration in

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[51] *114957 Canada Ltee (Spraytech) v. Hudson (Town)* [2001] 2 S.C.R. 241 at para. 32 per L'Heureux-Dube, J. referring to J. Cameron and J. Abouchar, "The Status of the Precautionary Principle in International Law", in D. Freestone and E. Hey, eds., *The Precautionary Principle and International Law*, (1996), at p. 41

[52] Government of Canada "A Canadian Perspective on the Precautionary Approach/Principle", September, 2001, http://www.pco-bcp.gc.ca/raoics-srdc/docs/Precaution/Discussion/discussion_e.pdf , accessed January 12, 2003

[53] Benevides, H. and McClenaghan, T., "Implementing Precaution: An NGO Response to the Government of Canada's Discussion Document, 'A Canadian Perspective on the Precautionary Approach/Principle'", Canadian Environmental Law Association Report No. 419, Toronto, April 2002.

[54] *Oceans Act*, S.C. 1996, c. 31, Preamble and section 30.

[55] *Canadian Environmental Protection Act*, 1st Sess. 36th Parl. 1997-98-99, section 2(1)(a) and section 76.1.

[56] For example, see: Canadian Environmental Law Association and the Canadian Institute for Environmental Law and Policy, Brief to House of Commons Standing Committee on Environment and Sustainable Development Regarding the Canadian Council of Ministers of the Environment (CCME) Environmental "Harmonization" Initiative, CELA Brief No. 332; CIELAP Brief No. 97/4 (October 1997).

[57] Standing Committee on Environment and Sustainable Development, House of Commons Canada, Report: *Pesticides - Making the Right Choices For the Protection of Health and the Environment.* May, 2000.

Canadian law. While not going as far as the Standing Committee recommended, one of the most significant amendments is the introduction of a definition of acceptable risk. The new section 2(2) provides:

> "For the purposes of this Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration."

Under section 7(6) of the Act, the applicant has the burden of persuading the Minister that the health and environmental risks are acceptable. Accordingly, the Minister cannot register or re-register a pest control product unless the applicant has proven to the Minister and the Minister has determined that there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product. "Environmental risk" and "Health risk" are both defined in the legislation. Accordingly, for new registrations and for re-evaluations in the normal course, these amendments represent a significant, more precautionary shift in decision making.

With respect to some pesticide re-evaluations, the Rio formulation of the precautionary approach was explicitly included in Bill C-8 as authority to cut short the re-evaluation or special review and suspend the pesticide registration straight away. This power would apply in cases where "in the course of a re-evaluation or special review, the Minister has reasonable grounds to believe that the cancellation or amendment is necessary to deal with a situation that endangers human health or safety or the environment, taking into account the precautionary principle set out in subsection (2)."[58]

In summary, Bill C-8 incorporates the basic premises of the precautionary approach for new pesticide registration and for re-evaluations and special reviews. It shifts the burden of proof to applicants and precludes the Minister from registering or re-registering unless a relatively stringent standard of proof has been met, i.e. reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.

Bill C-8 also includes specific provisions relative to risks to children, including a preamble paragraph noting that in assessing risks to humans, consideration be given to aggregate exposure to pest control products, cumulative effects of pest control products and the different sensitivities to pest control products of major identifiable subgroups, including pregnant women, infants, children, women and seniors.[59] Likewise, in the body of the Bill is a specific provision requiring that in evaluating the health and environmental risks of a pest control product and in determining whether those risks are acceptable, in deciding whether to grant or deny a registration or whether to continue a registration on a special review or re-evaluation, the Minister shall,

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[58] Bill C-8, *Pest Control Products Act*, section 20 (1). Section 20(2) provides, "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent adverse health impact or environmental degradation."

[59] Bill C-8, Second Session, Thirty-seventh Parliament, 51 Elizabeth II, 2002, preamble.

(b)(i) among other relevant factors, consider available information on aggregate exposure to the pest control product, . . . including drinking water and use in and around homes and schools, and cumulative effects of the pest control product and other pest control products that have a common mechanism of toxicity,

(ii) apply appropriate margins of safety to take into account . . . the use of animal experimentation data and the different sensitivities to pest control products of major identifiable subgroups, including pregnant women, infants, children, women and seniors, and

(iii) in the case of a threshold effect, if the product is proposed for use in or around homes or schools, apply a margin of safety that is ten times greater that the margin of safety that would otherwise be applicable . . . to take into account potential pre- and post-natal toxicity and completeness of the data with respect to the exposure of, and toxicity to, infants and children.[60]

Similar provisions are included for determining maximum residue limits of pesticides.[61]

Whether or not the federal government will now implement a more precautionary approach to standard setting for pesticides remains to be seen. Health Canada's record on the regulation of lead is a cautionary tale of regulatory inaction in the face of clear evidence of harm. The risk assessment approach to the regulation of lead in gasoline resulted in extensive exposure and the poisoning of millions of children before effective regulatory action was taken. Moreover, more than a decade later, after a steady stream of imported consumer products have been discovered to contain hazardous levels of lead, regulatory action, begun with discussions in 1997, remains delayed until at least mid-2003. The Canadian Environmental Law Association –Ontario College of Family Physicians report discussed in detail the problems associated with the reactive nature of the *Hazardous Products Act* which provides one of the worst examples of a regulatory tool that can only react, and then very slowly, after serious problems have been identified. More promising are statements made by a Health Canada official that the solution to the problem of hazardous consumer products is a revised *Hazardous Products Act* containing a "product safety requirement." Such a precautionary measure could accomplish both movement towards the use of safer materials in manufacturing and would shift the burden of proof – to demonstrate safety - to manufacturers.

V. CONCLUSIONS

This paper provides a foundation for answering the question as to whether environmental standard setting, via the predominant approaches of risk assessment and risk management, is or can be, *intentionally* protective of children. It is clear from this historical review that risk assessment approaches to standard setting have evolved over time and continue to do so. These changes have attempted to resolve gaps in data and methodology including better accounting for children's health effects. However, the ever-increasing complexity of risk assessment

[60] Bill C-8, section 7(7)(b)
[61] Bill C-8, section 11

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.

Advances in risk assessment guidance and methodologies continue to be undermined by central problems that have been with risk assessment from the start. Even when risk assessment approaches have been modified to specifically account for children's health, as is occurring under the *Food Quality Protection Act* in the United States, with Canada following suit, the outcome in terms of actual reduction in risk is acrimonious and slow, while progress in Canada remains to be evaluated once the new law is fully in place. Methodologies to overcome key barriers (aggregate exposure, cumulative effects) are only just being developed and have yet to be employed to any significant extent.

These problems frequently stem from the incorrect assertion that risk assessment is an objective science-based activity. However, two of the four key steps in risk assessment suffer from large gaps in data and methodology providing many opportunities for uncertainty, variability and error. When gaps have to be filled with informed guesswork, the risk assessment exercise can no longer claim to be objective and scientific. This paper's review of the "science behind the assessment" explores many of the reasons for the high degree of difficulty and scientific uncertainty in drawing inferences of causation in environmental health matters. A key issue for standard setting is a mis-application of the standard of proof demanded by scientific inquiry. While there are important reasons for maintaining this standard, not the least of which is ensuring the integrity of scientific inquiry, problems arise when the scientific standard of proof is applied to the only-partially scientific process of setting standards to limit exposure to contaminants.

The insistence on risk assessment to provide objective science-based standards has resulted in a demanding, time and resource intensive chemical-by-chemical approach. With so many chemicals to assess, so many gaps and uncertainties in data and a lack of methodologies to assess both exposure and health effects, it is distinctly unfair and illogical to insist on "scientific" standards of proof (of exposure and harm) before taking preventative action. Such an approach is doomed to failure in terms of being truly protective of children. Given these fundamental constraints, it is debatable whether individual techniques can be added to make risk assessment *intentionally* protective of children. Although standard setting agencies can and do increasingly apply a weight-of-evidence approach, the political forces brought to bear on the risk management side of the exercise can be formidable and can serve to remove any safety margins or precautionary influence on the final choices as to standards.

The assigning of individual risk levels for each chemical is also a game of odds that cannot address two of the most serious issues of toxic chemical pollution: inherent toxicity and population-wide effects such as may be occurring with endocrine disrupting chemicals. Risk assessment enables risk calculations that allow for "acceptable" levels of one-in-a-million or one-in-ten-thousand risks (of cancer, birth defects, etc.) across a population. However, the odds game becomes useless if further research confirms the suspicion that chemicals such as endocrine disruptors are capable of exerting population-wide effects. 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. These risks will of course be highest for children and other vulnerable populations than for the adult population at large.

Important issues of ethics and equity arise during risk assessment and risk management. Within the domain of specialized experts and those wealthy enough to hire them, the combination of science and guesswork provides numerous opportunities for value judgements and bias to enter risk calculations. Again, the chemical by chemical supposedly scientific process is a central part of the problem. Assessed one at a time, in isolation from other chemicals, risk levels are assigned to new chemicals regardless of risk levels that already exist or that are yet to be calculated for new chemicals. Such assessments also underestimate risk since they rarely account for all relevant health effects or for the cumulative or synergistic effects of chemicals acting in combination. As more and more chemicals continue to be assigned a risk level (alongside the many thousands of chemicals that have never been adequately assessed), the human population does not have an enforceable right to be exposed to no more than a specified level of risk.

Many implications arise when applying judgement and non-scientific values to the process of weighing a body of evidence and setting policy or standards for exposure to contaminants. Key among them is the choice made as to the "burden of proof" demanded. Because standard setting is intended to protect human health and welfare, ecosystems and other very high values, the "burden of proof" that is required in standard setting should be one that is more likely to be protective of those desired values. However, standard setting rarely applies such a protective approach. Instead, protective standards generally are not set until rigorous scientific inquiry has been applied to the available (and always incomplete) information in order to verify proof of harm. The result is delay in setting protective standards and the greater likelihood of too much exposure before protective action is taken. A more appropriate standard of proof would incorporate the legal concepts of duty of care, based on a "balance of probabilities" or "50% plus one" likelihood standard. Standard setting policy decisions should follow a paradigm in which it is *at least* "more likely than not" that standards have been set that will be protective of children's health. Where data are incomplete or inconclusive, the approach of "precautionary inference" is a more prudent and appropriate means of making scientific judgements particularly since significant harm may flow from incorrectly assuming that no harm is possible from the environmental contamination being regulated. This approach reverses the current scientific and policy framework, recognizes the inherent shortcomings of information and methodologies, and would set protective standards first. Such standards would be made less stringent only when the uncertainty as to the toxicity of the chemical hazard is resolved via "clear, strong and cogent evidence" that, at the permitted exposure level, no harm to children will result. Such a "reverse onus" approach would place the scientific burden of proof on those wishing to create environmental contamination while regulatory agencies could apply precautionary inference to the setting of protective standards.

In contrast to risk assessment, the precautionary principle provides a policy framework to make decisions to protect human health and the environment in the face of scientific uncertainty. While the precautionary approach is not usually viewed as an alternative to risk assessment, it is at times regarded as a threat to the "sound science" and the rigour that is supposedly inherent within risk assessment. The components of the precautionary principle, if implemented, would

profoundly recast how environmental standard setting takes place. These components are essentially direct responses to the limits of risk assessment. The onus of proof, weight of evidence and pollution prevention are a number of the key elements that are required to ensure that real progress can be made towards more protective standards. In Canada we will now have a test as to the difference some of these changes might make as a result of revisions to the *Pest Control Products Act*.